115061-CV

CAUSE NO. _____

LARRY MAXWELL, and SIMILARLY SITUTATED INDIVIDUALS (Jane and John Does 1-100,000,000),	§	**IN THE DISTRICT COURT**
Plaintiffs	§	
	§	**____ JUDICAL DISTRICT**
v.	§	
CVS PHARMACY, INC., H-E-B, LP, WAL-MART STORES TEXAS LLC, THE KROGER CO., WALGREEN CO., UTMB HEALTHCARE SYSTEMS, INC.,	§	**BRAZORIA COUNTY, TEXAS**
Defendants		

PLAINTIFF'S VERIFIED[1] ORIGINAL PETITION FOR DELCLARATORY JUDGMENT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER AND TEMPORARY AND PERMANENT INJUNCTION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, Plaintiff Larry Maxwell ("Maxwell") who files this Verified Original Petition in the interest of justice and fairness, the liberty right to remain alive and to not be coerced into injecting deadly poisonous chemicals to maintain employment, for fraudulent concealment, fraudulent inducement, deceptive trade practice, violation of Texas Informed Consent statutes, and for a Declaratory Judgment as stated herein, and asks this Honorable Court to grant the Application for Temporary Restraining Order and Temporary and Permanent Injunction ("the Petition"), against Defendants CVS

[1] Maxwell's VERIFICATION affidavit is attached hereto as Addendum 1.

PHARMACY, INC. ("CVS"), H-E-B, LP ("HEB"), WAL-MART STORES TEXAS LLC ("WALMART"), KROGER CO. ("KROGER"), collectively ("Defendants"). Maxwell would respectfully show the Court as follows:

I.

PARTIES

1. Plaintiff Larry Maxwell is an individual whose domiciliary address is 2122 Tower Bridge Rd., Pearland, Texas 77581.
2. Other similarly situated individuals (Jane and John Does 1 – 1,000,000) are Texas citizens whose names, addresses and defendants will be added hereto when they join the lawsuit. Maxwell reserves the right to amend his Petition to add more than one million Jane and John Does to ensure that all similarly situated individuals have a right to seek justice and have their day in court.
3. Defendant CVS PHARMACY, INC., Texas Registered Agent C T CORPORATION SYSTEM who can be served at 1999 Bryan St., STE 900, Dallas, Texas 75201.
4. Defendant H-E-B, LP, aka HEBCO GP, LLC, c/o Abel Martinez, Registered Agent, Arsenal N/2, who can be served at 646 S. Main, San Antonio, TX 78204.
5. Defendant WAL-MART STORES TEXAS LLC aka WALMART STORES TEXAS 2007, LLC, Texas Registered Agent C T CORPORATION SYSTEM who can be served at 1999 Bryan St., STE 900, Dallas, Texas 75201.
6. Defendant THE KROGER CO., Texas Registered Agent Corporation Service Company dba Csc-Lawyers Incorporating Service Company, who can be served at 211 E. 7th Street, Suite 620, Austin, Texas 78701-3218.

7. Defendant WALGREEN CO., Texas Registered Agent Prentice Hall Corporation System who can be served at 211 E. 7th Street, Suite 620, Austin, Texas 78701-3218.

8. Defendant UTMB HEALTHCARE SYSTEMS, INC., Texas Registered Agent Maria L. Gonzalez who can be served at 301 University Blvd. Rt 0985, Galveston, Texas 77555-0100.

II.

JURISDICTION AND VENUE

9. Maxwell's claims for declaratory and injunctive relief are brought pursuant to the laws of the State of Texas and are properly founded upon the subject matter jurisdiction of this Court.

10. Venue is proper in the State District Court because this suit contains actions, subject matter, and property located in Brazoria County. §15.001 TCPRC; §17.56 TBCC

III.

DISCOVERY CONTROL PLAN LEVEL

11. Maxwell moves the Court to order that discovery in this matter be conducted in accordance with a Level 2 discovery control plan tailored by the court to the circumstances of the suit. *See* TEX. R. Civ. P. 190.3

12. Maxwell formally requests that Defendants disclose, within fifty (50) days of service of this request, the information or material described in Rule 194.2(a) – (l). Copies of any documents produced in response to these requests must be

produced before the expiration of fifty days of the service hereof at the home of Maxwell or at a place otherwise agreed upon by counsel.

IV.

MAXWELL APPEARING PRO SE

13. Maxwell brings this cause of action in his individual capacity.

14. Maxwell has considerable experience in litigation.

15. Maxwell has retained stand-by counsel whose services are used to provide consultation, guidance, and, if deemed necessary by Maxwell, appearance on Maxwell's behalf before the Court.

16. Maxwell retains the full right to represent himself in this matter and does not waive that right, by and through relinquishment of said right to bar licensed legal counsel, either partially, or in full, unless/until knowingly, and intentionally, doing so through express notice to the Court and all parties.

17. All parties are to direct all communication directly to Maxwell unless given express written authorization to communicate with standby counsel or any other party to this suit.

18. To the extent Maxwell is drafting pleadings or acting in any manner regarding this litigation for any party other than himself, Maxwell's actions are, in that regard, only under the authority and direction of standby counsel as a legal assistant or legal consultant retained by counsel for that specific purpose. Maxwell's pro se actions are protected by law. Maxwell's right to work as a legal consultant and legal assistant are protected by law. Any and all baseless attacks on Maxwell for acting within his lawful rights will be met with countermeasures

seeking damages as warranted. Any and all slanderous, libelous acts against Maxwell with intent to defame Maxwell's character will be met with lawsuits seeking punitive damages in amounts to send the message that such acts are INTOLERABLE in a civilized society and must be ENJOINED to prevent those from who would knowingly and willfully promulgate lies, seeking only to cover up the heinous crimes of the defendants, and genocide that is occurring in our society at this moment, much of which is occurring because of media (in many forms) assaulting the character of any person who attempts to expose the truth. NOTICE HAS BEEN GIVEN.

19. If Maxwell receives death threats or for any reason feels he, his family or his property are being targeted by the deranged criminals who believe Maxwell's life is meaningless and that he should be erased to prevent enforcement of Texas laws, Maxwell will be seeking a PROTECTIVE ORDER asking the Court to order Brazoria County Sherriff Bo Stallman to provide protection for Maxwell, his family, and his property.

V.

STATEMENT OF CLAIM

20. This lawsuit is based on the knowing and willful omissions of Defendants in which they fail and/or refuse, through fraudulent concealment (for the purpose of enormous financial gain; unjust enrichment), §148.002 failure to warn patients of the unreasonable risk of substantial harm that can lead to death and/or

permanent disability proximately caused by experimental Covid-19 inoculations[2], fraudulent inducement, unjust enrichment, and violation of state statutes mandating informed consent for medical procedure, through a heinous scheme in which the Defendants circumvent, and therefore violate the spirit and intent of the TEXAS INFORMED CONSENT Statutes.

21. Maxwell and his soon-to-be-co-plaintiffs, similarly situated individuals, seek declaratory judgment for being subjected to Defendants' unconscionable fraudulent schemes that are the proximate cause of the damages described herein.

22. Because this action seeks award for actual and punitive damages, as well as immediate action for TEMPORARY INJUNCTION, the detail in this Statement of Claim and Summary of events will be far more extensive than a typical Petition, as it also serves as the basis for Maxwell's application for Temporary Injunction. The issues encompassed herein are massive. Texas has never seen the kind of brazen state-wide scheme to bring death and destruction to its citizens as will be described herein.

23. Maxwell must lay a foundation to promote understanding of how the harm he has faced — and that other similarly situated individuals have and will face — can and will continue without the immediate intervention of this Court. Maxwell is asking the court to immediately enjoin Defendants from continuing their

[2] Maxwell does *not* acquiesce to the fraudulent use of the term "vaccine" to describe the experimental Covid inoculations. The term "vaccine" is defined on both the CDC and FDA websites. The experimental mRNA gene therapy specifically is excluded from the pure definition of "vaccine", both in meaning and purpose. Hence, Maxwell will properly utilize the term "inoculation." Plaintiffs will show that Defendants' (and the FDA, CDC, Media, etc.) use of the term "vaccine" is to give the experimental gene therapy inoculations the appearance of *normalcy* associated with traditional, actual "vaccines."

fraudulent practices and unconscionable violation of the Texas Informed Consent laws that could have resulted in death or permanent disability to Maxwell and can and will result in death and permanent disability to other similarly situated individuals unless the Court steps in to stop Defendants' unconscionable and illegal acts.

24. Maxwell seeks an award for the damages proximately caused by Defendants' fraudulent actions.

25. Maxwell seeks punitive damages to send a message to Defendants that their fraudulent schemes that have resulted in wrongful death of, and permanent disability to, thousands of Texas citizens are intolerable in a civilized society and must never occur again.

UNDISPUTED FACTUAL PREMISES

26. The injection of a drug by a healthcare provider is a medical procedure.

27. Texas informed consent laws — on their face — are a *statutory injunction* to a medical procedure *mandate*.

28. The government is statutorily enjoined from practicing medicine without a license.

29. The government has no lawful authority to mandate that every citizen undergo a medical procedure, much less a potentially lethal and/or life-altering medical procedure.

30. No entity can mandate that a citizen undergo a medical procedure or lose their livelihood — quid pro quo, extortion — much less a procedure that can kill the citizen or disable them for the balance of their life.

31. The Defendants have knowingly and willing — pocketing massive financial gain — become the executioners to carry out the government's lethal injection sentence against Texas citizens.

32. The Defendants are guilty of lying by omission and failing to warn of unreasonable risk of substantial harm. Civil Practice and Remedies Code Title 6, CHAPTER 148. LIABILITY DURING PANDEMIC EMERGENCY Sec. 148.002. PRODUCTS LIABILITY ACTIONS RELATED TO PANDEMIC EMERGENCY requires Defendants warn a patient of the unreasonable risk of substantial harm of any medical procedure so that the patient has the *ability* and *opportunity* to weigh the risks vs. the benefit, and choose to say, "Yes" or "No" based on **their personal evaluation for what is in their best interest**.

33. Informed consent laws, on their face, provide 100% autonomy to Texas citizens that the individual citizen — and only the individual citizen — can decide whether it is in their best interest to undergo a medical procedure.

34. Neither the government nor an employer have authority to decide for a citizen whether a *medical procedure* is in his or her best interest.

35. Informed consent statutes, on their face, were enacted to PREVENT the very crimes against humanity — the complete annihilation of Texas citizen's medical liberty and medical freedom — that are occurring unchecked every day in the State of Texas.

VI.

FACTS AND HISTORY OF THE CASE

36. Before Maxwell shares *his personal experiences* . . . Maxwell asserts that in just the last few weeks he has learned that Defendants are fully informed and aware of the CDC database that monitors death and horrific adverse events that have occurred directly because of the CoVid-19 inoculations to Texas and U.S. citizens.

37. Indeed, Defendants even reference the **VAERS (Vaccine Adverse Event Reporting System)** in their working documents and know that they are REQUIRED BY LAW to report adverse events that occur from inoculating their patients with Covid-19 experimental and investigational drugs.

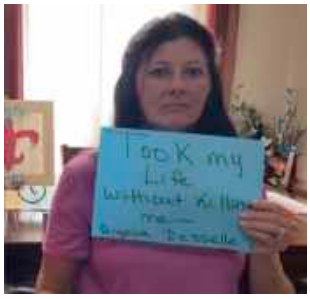
38. Defendants cannot plead ignorance of the VAERS reporting system. Its express purpose is to keep Defendants (and all health care providers) *aware* of the number of adverse events that are occurring due to the administration of inoculations, especially including COVID-19 inoculations.

39. Maxwell has learned from VAERS — information known to the Defendants — that as of September 24, 2021, Doctors and others have reported **16,310 deaths**[3] to the CDC as a direct result of the administration of the Emergency Use Authorization(s) ("EUA") of Covid inoculations, namely Pfizer ***BioNTech***, ***Moderna***, and Johnson and Johnson **Jannsen**.

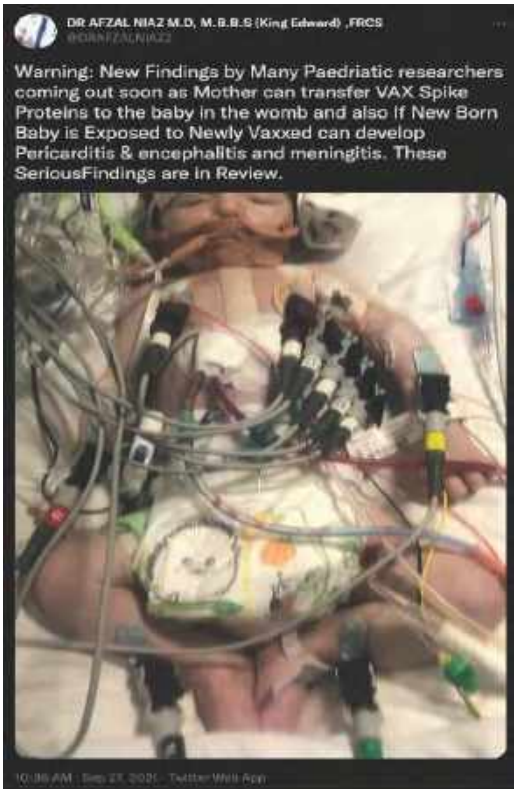
40. Maxwell shows the Court that his claims are real. Death is real. Pain and suffering are real.

[3] As Maxwell will show, the FDA's published study, Lazarus Report - 2011, shows that VAERS is severely "underreported" and states that these numbers are *less than 1%* of actual adverse events.

41. 

42. 

43. Over 555 birth defects have been reported to VAERS, caused by injecting soon-to-be mothers — not warned of the risks and substantial harm, to wit:



44. Breastfeeding mother takes inoculation and tiny baby receives poisonous chemicals through her milk and dies the next day (1st picture below). Five-month-old baby dies from breastfeeding (2nd picture below):

45. 

46. Maxwell has viewed thousands of these pictures.[4] Maxwell has watched hundreds of videos of people suffering from convulsions and seizures and describing their burning and itching and horrific joint pain from the onset of crippling arthritis. Thousands of lives destroyed by strokes. Tinnitus, ringing in your 24/7, with no possible relief, can be so horrific that the victim contemplates or commits suicide. Lives taken. Lives destroyed. Without one word of WARNING by the Defendants of the RISKS that the soon-to-be victims faced through the experimental medical procedure from which they could have been protected had the Defendants not violated Texas Informed Consent laws.

47. Maxwell prays that the Court can see, in just these few pictures, multiplied by hundreds of thousands, that lives that have been taken, that lives have been

[4] FB page of Holly Sinclair has over 2,350 pictures and 469 videos. There is no denying the massive genocide that is occurring because of the Covid-19 inoculations. https://www.facebook.com/search/top?q=holly%20sinclair

destroyed simply because the Defendants knowingly and willingly chose to fail to warn Texas citizens in violation of Texas Informed Consent laws and Texas Pandemic Protection §148.002.

48. Maxwell respectfully requests the Court take 5 minutes and watch this **DEATH AND DISABILITY VIDEO**,[5] compiled by Maxwell, that is representative of the hundreds of thousands of citizens whose lives have been destroyed by the toxic lethal injection being imposed on them by government, by employers — and by *healthcare provider* who are duty-bound to warn them of the "unreasonable risk of substantial harm." The court can also watch the video by scanning the QR code:

 or go to the LINK: https://vaersanalysis.info/vaxinjury/

TEXAS LAW

49. Civil Practice and Remedies Code Title 6, CHAPTER 148. LIABILITY DURING PANDEMIC EMERGENCY Sec. 148.002. PRODUCTS LIABILITY ACTIONS RELATED TO PANDEMIC EMERGENCY. (a) This section applies only to the following products: (3) drugs, medicines, or *vaccines* used to treat or prevent the spread of a pandemic disease, including drugs, medicines, or *vaccines* prescribed, dispensed, or administered for an unapproved use in an attempt to treat or prevent the spread of

[5] One of the grieving young ladies is very angry. Heart stricken. Broken. Crying. She just lost her sister the previous day to the *lethal injection*. She uses foul language a few times to express her anger. She shoots the finger. It might be offensive to some. Maxwell *informs the Court* of the *risk* of being offended, but suggests that the *benefit* of witnessing the hurt and grief far outweighs the *risk* of being temporarily offended and missing out on learning the TRUTH.

the disease or used outside of their normal use in an attempt to treat or prevent the spread of the disease; (b) A person who designs, manufactures, sells, or donates a product described by Subsection (a) during a pandemic emergency is not liable for personal injury, death, or property damage caused by the product unless: (2) *the product presents an unreasonable risk of substantial harm to an individual* using or exposed to the product. (c) A person who designs, manufactures, labels, sells, or donates a product described by Subsection (a) during a pandemic emergency is not liable for personal injury, death, or property damage caused by a *failure to warn* or provide adequate instructions regarding the use of a product unless: (2) *the failure to warn or provide adequate instructions regarding the use of the product presents an unreasonable risk of substantial harm to an individual using or exposed to the product.* (d) A person is not liable for personal injury, death, or property damage caused by or resulting from the person's selection, distribution, or use of a product described by Subsection (a) during a pandemic emergency unless: (2) *the product presents an unreasonable risk of substantial harm to an individual using or exposed to the product*.

50. Maxwell asserts and will show that Covid-19 inoculations "present an unreasonable risk of substantial harm to an individual." *Id.*

51. It was all Maxwell could do to get the Defendants to provide a Vaccine Information Fact Sheet, before Maxwell chose to *opt out* from taking the JAB that Defendants were more than ready to administer. With Maxwell waiting beside a loaded syringe, Defendants had to go search the internet, find, download and print the Vaccine Information Fact Sheet, often providing Maxwell a document that was wholly irrelevant to the drug that was in vial from which they had filled the syringe.

52. Only because Maxwell demanded that Defendants tell him the dangers and risks, did Defendants manage to find *something* to give to Maxwell. None of the Defendants' employees had READ the Vaccine Information Fact Sheet(s).

53. §148.002 is a statutory mandate that Defendants must *warn of unreasonable risk of substantial* harm.

54. Defendants are fully culpable and liable for their complete and utter failure to comply with the statutory injunction that is enjoins *failure to warn*. §148.002.

55. Hereinbelow Maxwell will discuss the actual *ingredients* of the BioNTech (Pfizer) and Moderna inoculations. The *primary ingredient* in each of these inoculations are listed by OSHA (U.S. Government Occupations and Safety Hazard Agency) as *hazardous chemicals*. The SDS (Safety Data Sheets) on these "lipids" in the inoculation — that make up 50% of the injection are the *"delivery system"* designed to get the mRNA Spike Protein into the blood stream of the recipient of the inoculation — are depicted with the GHS (Globally Harmonized System) PICTOGRAMS for these chemicals in the Pfizer BioNTech inoculation (ALC-0315) and the Moderna inoculation (SM-102) as:

 Dangerous and potentially deadly toxin (ALC-0315),

and

Signal word: DANGER  Deadly poison (SM-102).

56. Maxwell will show that the injection of these highly toxic and deadly chemicals into your blood stream could be one of the proximate causes of many of the adverse reactions to Covid-19 inoculations.

57. The Defendants did NOT tell Maxwell that they are about to inject him with chemicals that are listed by OSHA at 29 CFR 1900.1200 as Category 2 hazardous, toxic, deadly poisonous chemicals than can and do rise to the level of *unreasonable risk of substantial harm*, injury and/or death. §148.002

58. The Pfizer **BioNTech** inoculation is the only Pfizer inoculation that is being injected by the Defendants. Maxwell will show that the Pfizer Comirnaty inoculation has *not* been distributed for use in the United States. Defendants each confirmed to Maxwell they had never received any Comirnaty inoculations.

59. Maxwell provides the QR Code that, as of this writing at 3:10 PM, Wednesday, October 20, 2021, will take you (if opened with a QR reader on your phone) to the EUA (non-approved) Pfizer BioNTech inoculation page that states in the first paragraph, to wit: *"In countries where the vaccine has NOT been approved by the relevant regulatory authority, it is an investigational drug, and its safety and efficacy have NOT been determined."* (Uppercase and italics emphasis mine).  Feel free to SCAN the QR code to read it for yourself. Maxwell expects that language to instantly be removed or modified by Pfizer within hours of this suit being filed, but Maxwell has made a screenshot of the webpage, and has screen recorded the process. Maxwell also can show the Court what was on the Pfizer website at this moment in time and *when it was removed* should Pfizer attempt to destroy evidence.

60. You can also get to this webpage by typing in the URL: cvdvaccine.com and it will return the following:

61. 

See **Exhibit A** attached hereto.

62. Despite the lies that the Covid-19 inoculation has been "approved," the reality is that the FDA's auspicious approval was of the COMIRNATY Pfizer inoculation, that has NEVER been distributed to any healthcare provider in the United States, and specifically has NOT been distributed to the DEFENDANTS.

63. Maxwell has checked and re-checked that the Defendants ONLY inject with the Pfizer **BioNTech** inoculation that is specifically authorized *only* under the EUA which, in Pfizer's own words, "is an investigational drug, and its safety and efficacy have NOT been determined" *Id*. Even so, Pfizer's Vaccine Information Sheet claims that the undistributed Comirnaty inoculation contains the exact same deadly chemicals as the BioNTech inoculation, i.e. Pfizer claims the two deadly injections are "interchangeable." *Id.*

64. Before showing the staggering numbers of adverse events reported to the CDC in the last nine and one-half months, Maxwell asserts that it is accepted knowledge that only 1% of all adverse events are reported to VAERS, as established by an FDA study in 2011 (Maxwell will show the *Lazarus Report* and explain its basis hereinbelow). The "1% under reporting assessment" remains unchallenged by the

CDC (or any entity to Maxwell's knowledge) in the ten (10) years since its release by the Department of Health and Human Services ("DHHS").

65. So, to put the number of reported deaths into perspective, using the 1% model, to see the true picture we must add the 99% of *unreported* deaths caused by the Covid inoculations. As if 16,310 deaths is not enough to shake you to the depths of your soul, consider that if 16,310 is 1%, then 100% of deaths is **1,631,000** (both U.S. and non-US reported deaths), or **743,700 DEATHS** in the United States alone. See VAERS ANALYSIS summary below (VAERS data released by CDC through 10/1/2021), to wit:

66.

High-Level Summary	COVID19 vaccines (Dec'2020 - present)	All other vaccines 1990-present	US Data Only COVID19 vaccines (Dec'2020 - present)	US Data Only All other vaccines 1990-present
Number of Adverse Reactions	778,685	824,864	593,728	723,780
Number of Life-Threatening Events	17,618	13,634	9,011	9,725
Number of Hospitalizations	75,605	78,604	34,880	38,211
Number of Deaths	16,310*	9,155*	7,437	5,129
# of Permanent Disabilities after vaccination	23,712	19,638	8,628	12,467
Number of Office Visits	121,304	43,674	111,693	42,348
# of Emergency Room/Department Visits	87,758	209,950	74,464	200,967
# of Birth Defects after vaccination	528	141	330	90

67. *See* VARES ANALYSIS at: https://vaersanalysis.info/2021/10/15/vaers-summary-for-covid-19-vaccines-through-10-8-2021/[6]

[6] Maxwell has also obtained CDC data from openvaers.com and medalerts.org that provide extensive and superior searching capabilities over the data vs. the CDC's VAERS website.

68. Note that the total number of deaths associated with the Covid-19 inoculations is 1.78 times GREATER than the number of deaths associated with all other vaccines given in the past 32 years COMBINED! Since the year 1990!

69. Can anyone truly claim that an inoculation that has KILLED as many as 1.6 million people in the past nine months is "safe"?

70. Maxwell has read, been told, and also listened to doctors who report to VAERS that the reporting of an adverse event to VAERS is at best tedious and extremely time consuming (45 minutes to an hour for one report), and at worst, creates frustration that causes many doctors/health providers and consumers simply give up because the reporting process (18 pages of data) appears to be intentionally difficult and/or cannot be uploaded.

71. **Lazarus Report:** Commissioned by the Department of Health and Human Services ("DHHS") the *Lazarus Report* that studied VAERS data from 12/01/07 - 09/30/10 and was submitted to both the FDA and the CDC to wit:

72. "Adverse events from drugs and vaccines are common but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs." *See* Lazarus Report*:* Electronic Support for Public Health-Vaccine Adverse Event Reporting System

(ESP:VAERS) attached hereto as **Exhibit B**.

73. An important takeaway from this report and the extensive work of **Ross Lazarus** and his team is that the automated adverse event reporting system he proposed (that was plenty doable in 2011) was never implemented because the CDC turned a blind eye and refused to respond or move forward with implementing as system (like the Medicare CMS system) that would report ALL adverse events in real time, to wit:

74. "Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation." *Id*.

75. So, rather than Texas citizens and the American people having real-time data regarding administration of experimental Covid-19 inoculations rushed to market under an EUA, <u>full well knowing that Texas citizens are the guinea pigs testing the experimental drugs</u>, the CDC continues with a 32-year-old system that requires logging in and completing tedious, lengthy reports where the data — that already exists in the doctor's database — have to be re-typed and re-submitted via 18 pages of inputting data and answering questions. Hence, the (forced) *underreporting* that the CDC then claims is "unreliable" (and, of course, never speaks of it in press conferences and wishes it never saw the light of day!)

76. The irony of the CDC's (and Defendants') insidious claim that there are "very few" adverse events to the Covid-19 inoculation because "only 16,310 deaths have been reported" is that their claim of under reporting a FULL-ON

ADMISSION that there are *far more adverse events* than even the staggering 1% numbers that ARE being reported!

77. Remember the claim for the need for a "vaccine" to stop Covid? "If we could save just one life." Well, the illegal acts of the Defendants and their cohorts have KILLED far more people than could possibly have ever perished from SARS-CoV-2 (CoViD-19), a number that could have been world's lower if hospital protocols weren't designed to hasten death rather provide a cure. Maxwell asserts that wrongful death from *forced* hospital protocols that were as experimental and filled with substantial risk and harm as the Covid19 inoculations, is a whole other CAUSE OF ACTION that will come into this suit when SIMILARLY SITUATED INDIVIDUALS join this action with claims for WRONGFUL DEATH.

78. On October 9, 2021, at 11:45 AM, just before the nurse at Defendant UTMB was about to apply alcohol to Maxwell's arm and inject the ***Jannsen*** inoculation, Maxwell asked the nurse if she knew about the 16,310 deaths reported on VAERS? She responded that she was *not surprised* by that number but that it was "miniscule and insignificant when compared to how many people had been inoculated." Maxwell replied, "Well it is not miniscule or insignificant to the 16,310 people that died!" The nurse smiled and said, "No, I get that."

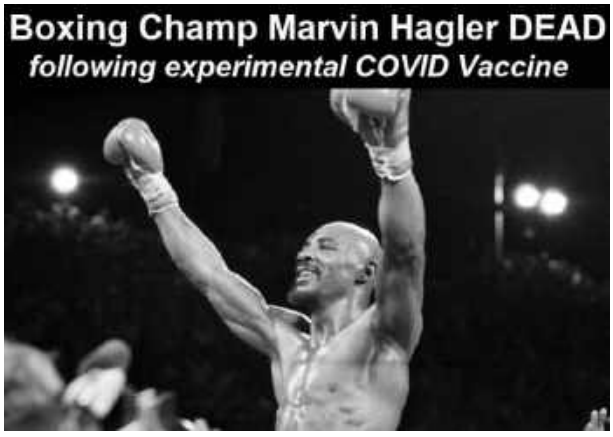
79. It was not miniscule or insignificant to Ernest Ramirez as he stood looking at the dead body of his son, Ernest Ramirez, Jr. who died just days after being inoculated with the "safe and effective" drug that was supposed to

protect this teenager who has virtually zero chance of dying from C-19.

80. One death . . . one "miniscule and insignificant death."

81.

82.



83. 

84. 

85. Was Ernest Ramirez told that HIS SON COULD DIE if he was injected? Was he *warned* that the RISK OF DEATH should be weighed against the possible "benefit" that 16-yr-old Ernest Jr. *might* have lesser symptoms when he got Covid? Did anyone even think warn this FATHER of the unreasonable risk of substantial harm that could come to his son, and get Ernest Sr. to obtain INFORMED CONSENT for his son to RISK DEATH? Or do they care that his heart will be forever broken because he . . . UNIFORMED . . . allowed his

SON to take a shot Ernest Jr. did NOT NEED, and it KILLED HIM? Does Ernest Jr. matter? Does Earnest Sr. matter? Do the INFORMED CONSENT laws matter?

86. What warning of *unreasonable risk of substantial harm* was given to the nearly 800,000 people whose adverse events have been reported to the CDC? How many deaths and permanent disabilities could have been prevented if, since December 2020, Defendants would have pre-warned inoculation recipients of the *unreasonable risk of substantial harm* of Covid-19 inoculations by showing them VAERS Reports (CDC data) and the Covid-19 Inoculation VIS that has warnings? What if Defendants had shown tens of thousands of Texas citizens that there was *unreasonable risk of substantial harm* that could occur if they chose to be injected? Do Texas citizen have the INALIENABLE RIGHT to DEFEND themselves against DEATH and/or PERMANENT DISABILITY? Wasn't the RIGHT OF SELF-DEFENSE stripped away from Maxwell and similarly situated individuals when Defendants, through fraudulent concealment, failed to warn Plaintiff(s).

87. Defendants' *failure to warn* ensured that Plaintiff(s) had no *opportunity* to make the personal decision as to whether they wanted to undergo or forego the medical procedure?

88. Maxwell will show that if the 16,310 is the FDA-projected underreported 1% of deaths, there are possibly 1,631,000 deaths (100%) from the Covid-19 inoculation. Are 16,310 deaths miniscule or insignificant? How about 1,631,000? Are autopsies being done to show the cause of death. Maxwell

will show that autopsies are NOT being done according to normal and traditional protocol on inoculated citizens alleged to have died from the Covid-19 inoculations.

89. Defendants' daily acts to fraudulently conceal the KNOWN RISKS of being injected with the Covid-19 inoculations . . . killing thousands of Texas citizens and/or causing tens of thousands to be disabled for life is being done in *violation of the laws and sanctity of the State of Texas.*

90. Can Defendants claim that they are unaware of the tragic deaths and massive permanent disability that is being caused by the inoculations they are selling? With hospitals having to close because so tens of thousands of nurses are REFUSING to be inoculated because they has SEEN WITH THEIR OWN EYES the horrible pain, suffering, disfigurement, permanent disabilities and DEATH caused by the C-19 inoculations, and they REFUSE to RISK losing their lives or be disabled and subjected to pain and suffering for life!

91. Is the insane irony lost on the Defendants? Frontline NURSES are saying, "HELL NO!" and Defendants are *marketing the inoculation* as if they are the Snow Cone Stand on a hot July day!

92. Maxwell did a browser search on "VACCINE DEATHS" and within just a few minutes was able to capture more articles than he could read in a week that described told of unsuspecting person after person who had been injected with a Covid-19 inoculation and DIED, to wit:

93. 

94. Maxwell requests that this Court find that Defendants are mandated to follow the LAW and that Defendants must ensure that Texas Citizens must are given a CHOICE to decide — knowingly and willingly — whether they want to RISK DEATH or BEING DISABLED FOR LIFE, or choose the so-called "benefit" of possibly having lessened symptoms when they get Covid.

95. **Medicare CMS Reporting System:** There does exist is a real time system for reporting (much like the Lazarus Commission sought to have implemented) within the MEDICARE system. That system is monitored by the Department of Defense and the JAIC (Joint Artificial Intelligence Center). A few days ago, Maxwell obtained from the HUMETRIX website — Worldwide Digital Health Innovations for Precision Public Health — that publishes data from the studies conducted under PROJECT SALUS that

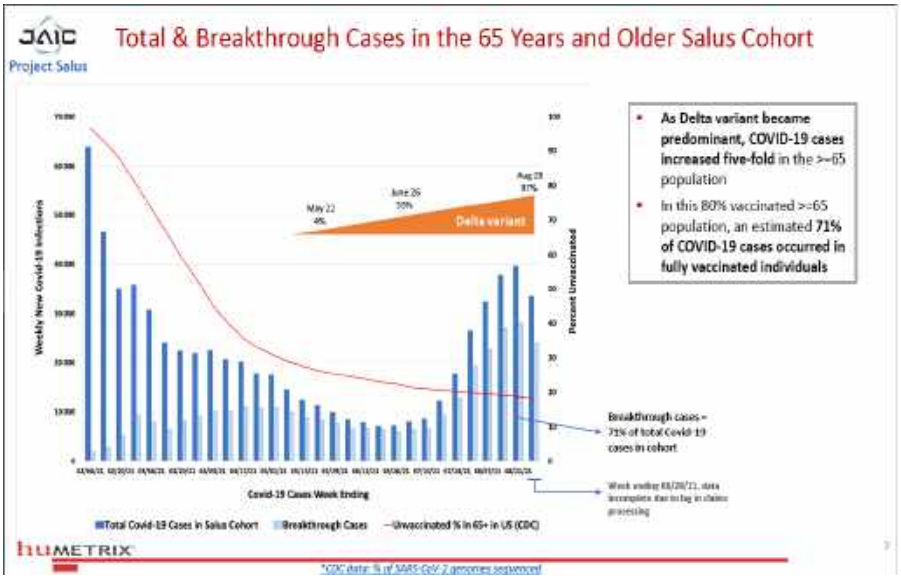
show that data collected from the MEDICARE *real time* database (much like what LAZARUS was proposing in 2011 that does exist for Medicare). Humetrix explains that it has a system of "Raw data acquisition", "Data processing and analytics (with decoding, aggregation, and normalization)", and Customized Data returns (to client software)", and further shows that there is a software application titled the **C**enters for **M**edicare and Medicaid **S**ervices ("CMS") Blue Button 2.0 to upload and access Medicare FFS & MA, Medicaid FFS & Plans and Commercial Plans in conjunction with the U.S. Department of Veteran Affairs, Department of Defense, direct to the Provider EHRs, to wit:

96. 

97. In a presentation that Maxwell downloaded from the Humetrix website a few weeks ago[7], Maxwell learned that from the Chart/Graph generated for the DOD from CDC data, that "In this 80% vaccinated >=65 population, an

[7] This REPORT was removed from the Humetrix website on October 7, 2021. Maxwell went back to the site Saturday, October 9th to review the report and it was gone. Maxwell, working with an IT expert, was able to discover the day that the report was removed from the website.

estimated 71% of the Covid-19 cases occurred in fully vaccinated individuals.", to wit:

98. 

99. So what is the BENEFIT of a Covid-19 inoculation if it does NOT prevent Maxwell, or similarly situated individuals from getting Covid-19 (as was the false claim from the beginning of the push to get the whole country vaccinated)?

100. As will be shown hereinbelow, in the "consultations", Maxwell, of his own accord asked each defendant, "What is the benefit of getting the Covid inoculation?" Each Defendant's response can be summarized in lockstep with the NEW NARRATIVE which is "The inoculation can *possibly* lessen the severity of the disease and *might* prevent hospitalization." None of the defendants even hinted to Maxwell that the inoculation could *prevent* Maxwell from getting Covid.

101. The *soon-to-be* NARRATIVE is that all citizens need to get a BOOSTER because the old inoculation is wearing off. Defendants plan, in violation of

§148.002, to administer Booster shots without *warning of the unreasonable risk of substantial harm*.

102. The DOD/CDC data, published by Humetrix, *Id.*, utilizes data taken directly from the CMS Medicare reporting system. The *Project Salus* chart shows that through August 21, 2021, fully 71% of vaccinated people are not just *getting* Covid but are being HOSPITALIZED because their symptoms are so severe.

103. Maxwell was told by Defendant Kroger's Pharmacist that she fully expects *everyone* who had received the inoculation to either get Covid and/or require a booster very soon. Her sole expectation was that the inoculated patients would hopefully have less severe symptoms *when* they get Covid. She, having had the Moderna inoculation early this year, said she knew her IgM (not IgG) had "waned" and she "needed a *booster shot* soon" to keep her protected.

104. Clearly no benefit of the Covid-19 injection exists to PREVENT Covid infection.[8] And no benefit exists to prevent transmission of Covid when the "vaccinated person" gets infected. Indeed, it is now fully acknowledged that when inoculated individuals become Covid-infected their "viral loads" are far greater than if that of person who was NOT inoculated, such that they are far more contagious.[9]

105. To exacerbate the big lie — that the inoculation could *prevent* infection —

[8] If and when necessary, Maxwell will provide documentation and put on expert testimony that will show the Covid-19 inoculations were <u>never even *designed*</u> to prevent infection from the CoViD-19 virus.

[9] Again, if and when this factual assertion is challenged, Maxwell will provide studies and expert testimony to back up this claim.

the party line has been to utilize the term "breakthrough cases" for people who are inoculated and get infected. Of course, since the inoculation was never even designed to prevent infection, it seemed unimaginable to the population (that have been bullied into swallowing the lies), that "breakthrough cases" were even real, much less far and away the *majority* of Covid infections in the last four to five months.

106. The chart above at ¶47 from the CMS Medicare data, shows that 71% of breakthrough cases were the majority of hospitalizations as far back as August 21, 2021. *Id.*

107. Maxwell can only conclude that there is no benefit whatsoever to receiving the inoculation.

108. From the chart shown at above at ¶25, in nine and one-half months, 778,685 adverse events from Covid inoculations have been reported (If 1% reporting, then 77,868,500 adverse events have occurred that the neither the FDA, the CDC nor the Media is reporting on any level!). SEVENTY-SEVEN MILLION EIGHT-HUNDRED SIXTY-EIGHT THOUSAND FIVE HUNDRED reported adverse events from being injected with the Covid-19 inoculaton! Total media blackout. Neither FDA or CDC ever mentions adverse events. That is one hell of a criminal *cover-up*!

109. From the ¶25 chart, through Ocotober 21, 2021, 23,712 permanent disabilities caused by Covid inoculations, If this is 1% FDA-projected under-reported, then 2,371,200 people – our parents, brothers, sisters, children — will be permanently disabled for the rest of their lives!

110. Maxwell will show hereinbelow exactly what these reported disabilities include and that the Defendants KNOW that these horrific illnesses are proximately caused by the Covid inoculation.

111. Reported hospitalizations are 75,605 (1%).

112. 87,758 reported having to go to the E.R. (1%).

113. If those numbers are 1%, then hospitalizations and E.R visits are **7,560,500 and 8,775,800**, respectively! The Defendants KNOW THIS, and they are *lying by OMISSION* when they *fail to warn of the unreasonable risk of substantial harm* associated with taking the inoculation.

114. Defendants' employees are Healthcare Providers who have taken the Hippocratic Oath to "DO NO HARM!". Lying by omission to allow uninformed and unsuspecting patients to take a lethal and/or life-altering injection is the very definition of "doing harm." Defendants are violating Texas Laws put into place to ensure that the patient is given a CHOICE to weigh the RISK vs. BENEFIT. Defendants have a carefully orchestrated schemes specifically designed to RIP THAT CHOICE away from the patient.

115. Defendants have 24/7 access to the VAERS data. They are trained to track this information and are knowingly and intentionally IGNORING this information, as they are *unjustly enriched* by the billions they are being paid to inoculate unsuspecting Texas citizens!

116. Possibly the most difficult to understand is why the Defendants are pushing the inoculation on pregnant women when they KNOW that the birth defects caused by the Covid inoculations are horrific, can cause miscarriages and/or cause a birth

defect that destroys the possibility of a normal life for a child. Pregnant women were *excluded* from the clinical trials. It is unprecedented to inject biologics into people groups that were never tested in the trial.

117. From the October 8, 2021, CDC VAERS data shown in the chart at ¶30, 555 babies were reported (FDA-projected 1% of under reported birth defects) to having been born with birth defects to mothers who were inoculated while pregnant. If 1% represents the under reported birth defects, that is 55,500 babies in the past 9.5 months whose lives are destroyed by the mother being injected with an experimental mRNA gene therapy drug the was engineered to modify her DNA and cause her to generate SPIKE PROTEINS that cause bleeding and horrific injury to the child in their womb. The DEFENDANTS KNEW THIS COULD HAPPEN AND THEY DID NOTHING TO WARN ANY OF THE PREGNANT MOTHERS OF THE UNREASONABLE RISK OF SUBSTANTIAL HARM ASSOCIATED WITH BEING INJECTED WITH THE EXPERIMENTAL COVID-19 INOCULATIONS!

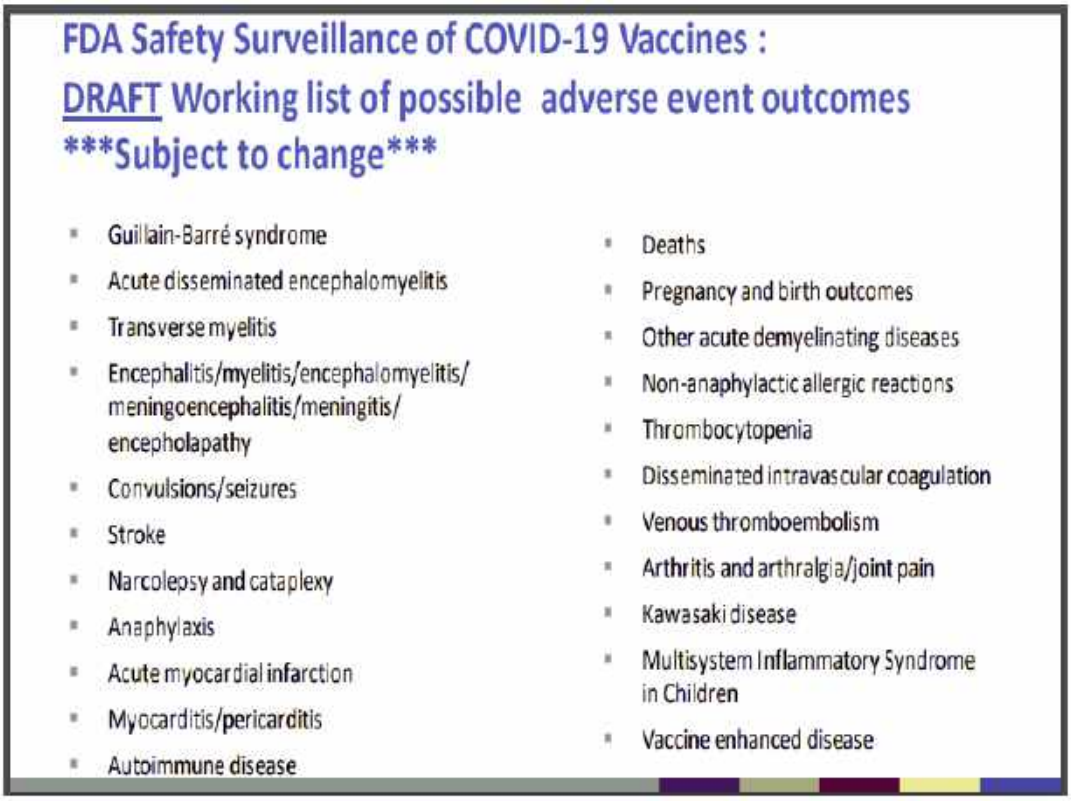
118. Parents will be burdened forever with tending to a child with horrific, preventable birth defects. They will also be burdened forever with the knowledge that their decision to be injected with the Covid-19 inoculation, while pregnant, did this to their child. Why are the Defendants' failing or refusing, in violation of Texas Law, to give pregnant mothers the VAERS data that shows tens of thousands of babies are being born with birth defects when the mother gets inoculated during pregnancy?

119. Maxwell is asking this Court to ENFORCE the LAW and stop this horrific tragedy that is destroying the lives of these babies and doing horrific harm to the hearts and souls of their unsuspecting parents, grand-parents, brothers and sisters.

120. These unconscionable actions that are the proximate cause of so much damage to so many people were 100% preventable. Yet, the Defendants have turned a blind eye, and are completely culpable and liable for the death and despair that is rocking our State and our Nation.

121. Did Defendants know that this would happen even BEFORE the inoculations were rolled out in December 2020? They *should have known* because the FDA published a REPORT telling them what to expect.

122. On October 22, 2020, just 12 days before the November 3rd 2020 election between President Donald Trump and challenger Joe Biden, the **V**ACCINES and **R**ELATED **B**IOLOGICAL **P**RODUCTS **A**DVISORY **C**OMMITTEE (VRBPAC) of the FDA held a meeting and provided a Power Point Presentation (PPT) to show their *findings* from the clinical studies of the previous months of Operation Warp Speed. One of the PPT slides show the "FDA Safety Surveillance of COVID-19 Vaccines" and lists the "possible adverse event outcomes" that had been observed to date (six weeks before the Covid inoculations began to be administered in the U.S. on December 11, 2020), to wit:

123. 

See VACCINES and RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE (VRBPAC) / FDA, October 22, 2020. https://www.fda.gov/media/143557/download attached hereto as **Exhibit C**, Slide 17.

124. Can the DEFENDANTS claim not to know that the FDA published known adverse events would occur when the Covid inoculations begin?

125. Can the FDA claim they did not know its own compilation of death and horrific life-threatening and/or permanent disabilities that they listed on Slide 17 their own presentation?

126. The entire reason for listing these ADVERSE EVENTS was to provide the information to the Defendants so they could WARN the patients of the dangers of death and destruction of life if they chose to be inoculated!

127. The FDA presentation shows that it knew the outcomes of the Covid inoculations would be:

a) *Death;*
b) *Myocarditis/pericarditis (irreparable damage to heart muscle);*
c) *Pregnancy and birth outcomes (birth defects);*
d) *Stroke;*
e) *Convulsion/seizures;*
f) *Narcolepsy/cataplexy;*
g) *Anaphylaxis (instant shock that can lead to death);*
h) *Acute demyelinating diseases;*
i) *Acute disseminated encephalomyelitis;*
j) *Encephalitis/ myelitis/ encephalomyelitis;*
k) *Meningoencephalitis/meningitis/encephopathy;*
l) *Thrombopenia;*
m) *Disseminated Intravascular Coagulation;*
n) *Venus Thromboembolism*
o) *Acute myocardial infarction (deadly heart attack);*
p) *Autoimmune disease;*
q) *Crippling arthritis and arthralgia/joint paint;*
r) *Multisystem Inflammatory Syndrome in Children;*
s) *Vaccine Enhanced Disease;*
Id.

128. Maxwell asserts to the Court that it should not for a second believe the FDA What-To-Expect list compiled before the INOCULATE AMERICA CAMPAIGN began December 11, 2020 is anywhere close to a comprehensive list of the actual illnesses and disabilities that have been reported to VAERS proximately caused by inoculating over 200 million Americans. Maxwell can and will show the entire list in the proper court-room setting, and give each Defendant the opportunity to explain WHY they chose to risk the lives of their patients rather than tell them

what they faced when the plunger was pushed to inject them with the dangerous chemicals that could end their lives.

129. Texas Informed Consent law requires the Defendants to have warned Maxwell, and similarly situated individuals that these KNOWN RISKS were associated with the Covid inoculations that they intended to INJECT into Maxwell's arm.

130. Maxwell should have, at the very minimum, been given a LIST OF THE KNOWN RISKS ASSOCIATED WITH TAKING THE INOCULATION. Defendant should have told Maxwell that ***"DEATH and/or any of these illnesses can befall you, LARRY MAXWELL, if you CHOSE to allow us to INJECT whatever ingredients are in this syringe into your arm, instead of trusting the IgG antibodies you already have in your body because you quickly recovered from Covid-19 when you got it last December."***

131. Was Maxwell given — by any of the six (6) Defendants — even a hint that something bad could happen to him if Maxwell had allowed them to plunge the deadly chemicals into his body, much less DEATH and PERMANENT DISABILITY? Not hardly. On SIX (6) occasions, Maxwell went to each of the Defendant's locations and was sitting in a chair waiting to see if the SYRINGE — that was loaded with the deadly poisons that have wreaked havoc on Texas and U.S. citizens — was going to be INJECTED into his arm without the Defendant(s) saying even ONE WORD to Maxwell to WARN HIM that the liquid in that syringe could KILL or disable MAXWELL for the balance of his life.

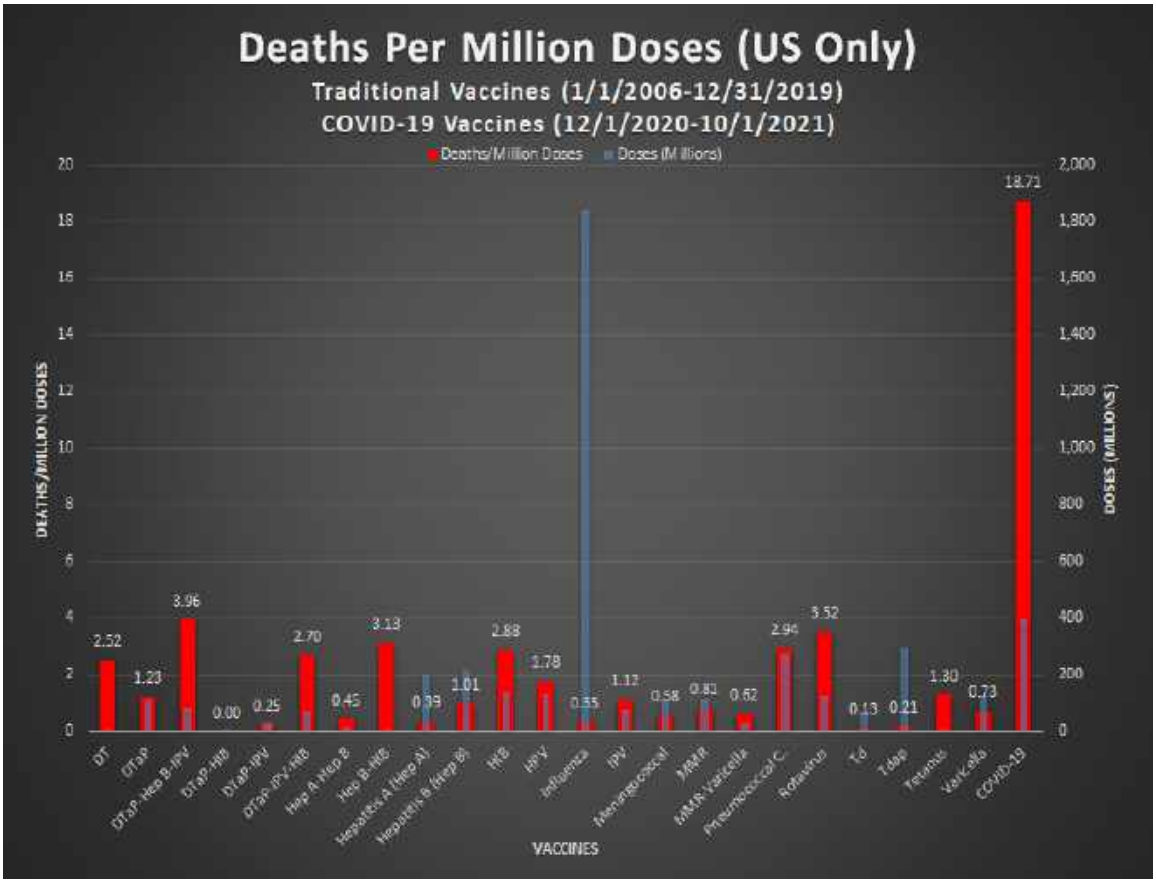
132. No, not one Defendant even hinted at warning Maxwell of the dangers he faced. Instead, the Defendants, in very similar fashion, engaged in FRAUDULENT

CONCEALMENT to ensure that Maxwell believed the exercise of being injected with an experimental drug that they KNOW has killed thousands (possibly millions) of people and had destroyed the lives by permanently disabling millions of people, would somehow benefit Maxwell who had IgG antibodies up to "900 times stronger"[10] against the Covid-19 virus than could possibly be received by Maxwell through an mRNA Spike Protein inoculation.

133. As will be shown below, Maxwell had much greater risk of having a severe adverse reaction because of his robust and durable NATURAL IMMUNITY from having recovered from Covid. Defendants know that someone with IgG antibodies to Covid-19 is at far greater risk of adverse reaction to the inoculation, and they demonstrate complete indifference to the life-threatening or life-taking (death) risks that faced Maxwell, had he succumbed to Defendants' fraudulent concealment and fraudulent inducement and allowed himself to be injected.

134. The chart below is a graph from VAERS data reported to the CDC through 10/1/2021 that shows that the deaths per million doses of Covid 19 inoculation is over 18 people *reported* dying from the injection as compared to all the other reported deaths from ALL vaccines from January 2006 to the present.

[10] Basis for this claim will be shown hereinbelow.

135. 

136. The most of any other vaccine reported death per million was 3 people per million over the space of 15 years. Given that we are told that over 200 million Americans have been inoculated, and the *reported deaths* are 1% of how many have died, the 100% figure is 1,800 deaths per million. Multiply the 1,800 deaths per million times 200 (millions of people inoculated in the U.S.), suggesting that up to 360,000 deaths can be attributed to the Covid-19 inoculation.

137. Do the Defendants believe it was ACCEPTABLE and LAWFUL to CONCEAL from this 45-year-old father of two that the inoculation could kill him? . . . to wit:

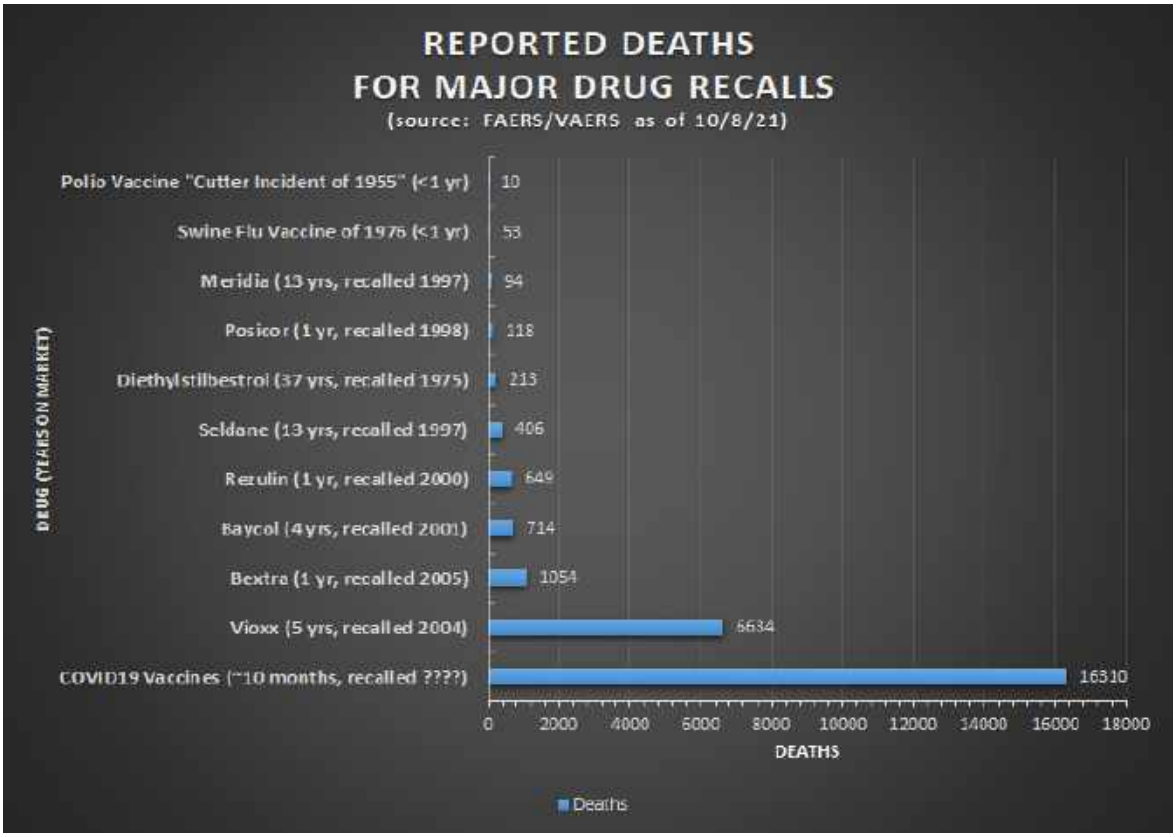
138. 

139. If the Defendants had obeyed the INFORMED CONSENT LAWS and the PANDEMIC LAWS, and cared in the least about this husband, father, son and brother, would he still be alive today to provide care and love to his family? Why has this senseless killing been allowed to happen? Why have Texas Laws been ignored? Laws specifically put in place to PROTECT TEXAS CITIZENS from making choices that could cause needless harm and injury . . . totally ignored by Defendants.

140. Maxwell shows the next chart, from VAERS and FAERS[11] data provided on Friday, October 8, 2021, that shows that the RECALLS for actual "vaccines" (as that term

[11] FARES is the FDA version of VARES (that is hosted by the CDC). FAERS = **F**DA **A**DVERSE **E**VENTS **R**EPORTING **S**YSTEM.

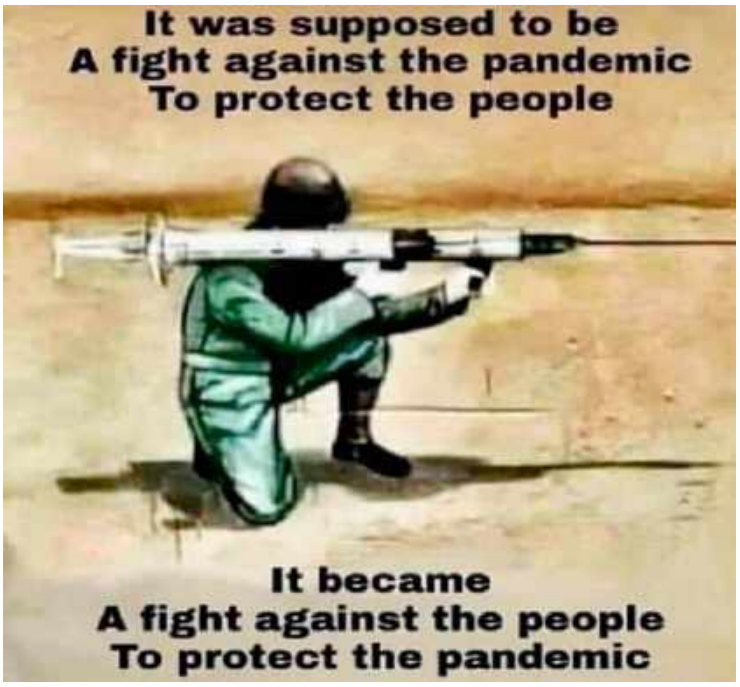
is defined by the FDA and CDC) and FDA approved drugs after a certain number of deaths occurred within a period of time, to wit:

141. 

142. Notice that the vaccine for Swine Flu of 1976 that was administered for less than 1 year, was RECALLED after 53 people died.

143. But COVID-19 inoculations? With 16,310 deaths *reported* in just NINE MONTHS, there is not only NOT a RECALL, but rather Texas citizens and Americans are being told that it is MANDATED that they take the deadly inoculation or be PUNISHED by losing their jobs, and everything they've ever worked for. For many, having lost all, they choose to end their lives by suicide.

144. THIS IS BEING DONE BY THE GOVERNMENT THAT WAS CREATED TO PROTECT THE LIVES OF THE CITIZEN, to wit:

145. 

146. The Defendants, by fraudulent concealment and fraudulent inducement are PROFITING to the tune of billions from these crimes against humanity.

147. Defendants' own documentation — that was utilized for ONLINE REGISTRATION by Maxwell to set an appointment for what Maxwell thought would be a CONSULATION regarding the risks versus the benefits of the inoculation — shows ON ITS FACE that Defendants know that they are required to obtain a *written verification* that Maxwell had been presented with documentation showing the RISKS of the inoculation and that Maxwell must DECLARE that he had been shown the risks in comparison to the *benefit*, and had, to his "satisfaction" made the INFORMED decision to take the injection because he (Maxwell) deemed the *benefit* to outweigh the risks associated therewith.

148. From VAERS data released by the CDC through October 8, 2021, obtained by Maxwell (by and through the data analyst who is assisting Maxwell), Maxwell provides the following spreadsheet to wit:

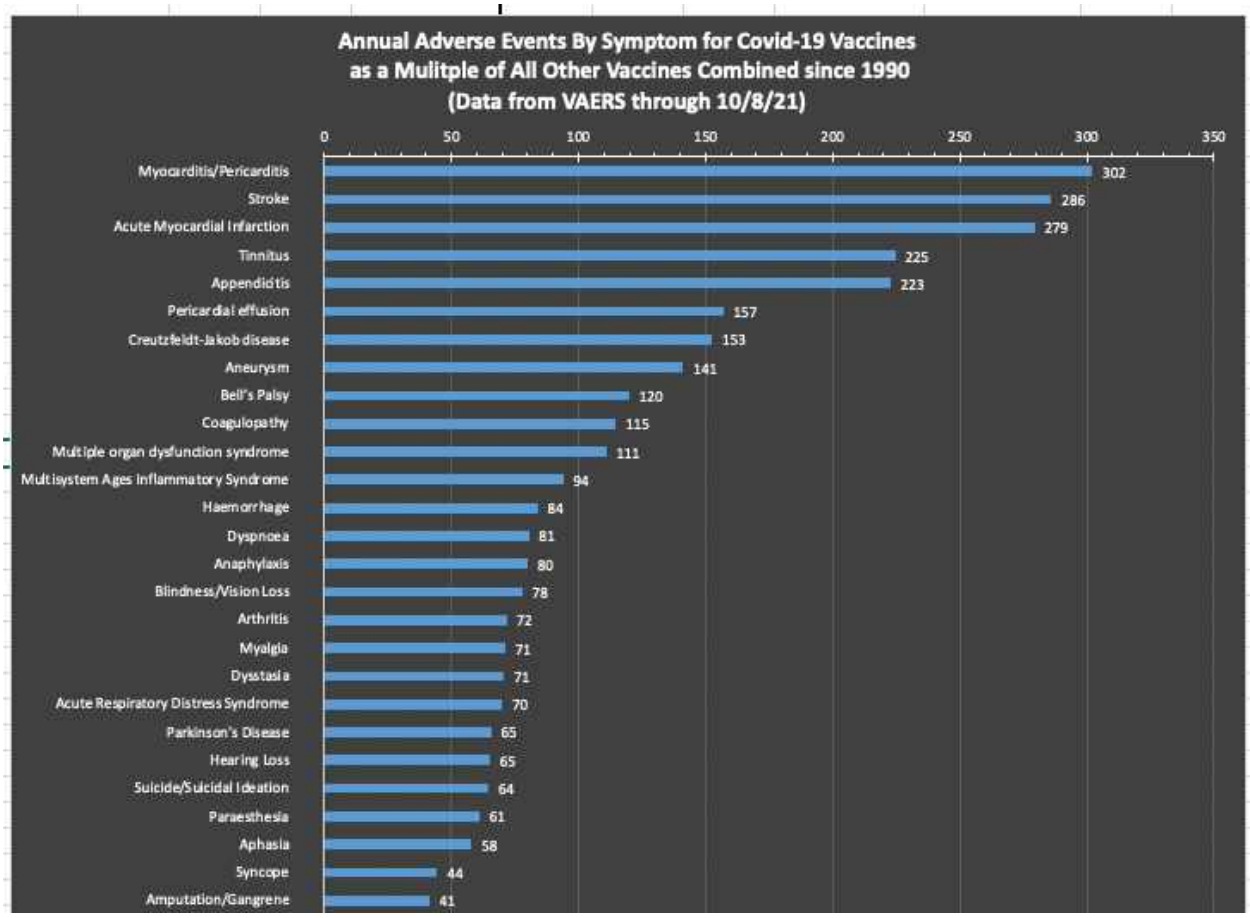
Location	Symptom	non-Covid19 jab				Covid19 jab				Multiplier
		AEs	Deaths	Total	Annualized Avg	AEs	Deaths	Total	Annualized Avg	
location	symptom	AEs	Deaths	Total	AnnualizedAvg	AEs	Deaths	Total	AnnualizedAvg	Multiplier
US+FR	Myocarditis/Pericarditis	956	103	1059	33.09375	8248	113	8361	10033.2	302.1750708
US+FR	Stroke	897	93	990	30.9375	6667	734	7401	8881.2	286.0690909
US+FR	Acute Myocardial Infarction	326	156	482	15.0625	2660	859	3519	4222.8	279.3518672
US+FR	Tinnitus	2323	3	2326	72.6875	13656	8	13664	16396.8	224.5793637
US+FR	Appendicitis	137	2	139	4.34375	808	2	810	972	222.7697842
US+FR	Pericardial effusion	212	18	230	7.1875	906	40	946	1135.2	156.9408696
US+FR	Creutzfeldt-Jakob disease	1	3	4	0.125	10	6	16	19.2	152.6
US+FR	Aneurysm	88	17	105	3.28125	287	102	389	466.8	141.2628571
US+FR	Bell's Palsy	3006	22	3028	94.625	9497	36	9533	11439.6	119.8940555
US+FR	Coagulopathy	7297	442	7739	241.84375	22056	1249	23305	27966	114.6366456
US+FR	Multiple organ dysfunction syndrome	25	56	81	2.53125	64	172	236	283.2	110.8814815
US+FR	Multisystem Ages Inflammatory Syndrome	105	1	106	3.3125	245	17	262	314.4	93.91320755
US+FR	Haemorrhage	4756	367	5123	160.09375	10525	800	11325	13590	83.88776108
US+FR	Dyspnoea	21380	500	21880	683.75	44573	1875	46448	55737.6	80.51751371
US+FR	Anaphylaxis	3407	68	3475	108.59375	7275	45	7320	8784	79.88863309
US+FR	Blindness/Vision Loss	4939	22	4961	155.03125	10149	30	10179	12214.8	77.78927636
US+FR	Arthritis	27816	74	27890	871.5625	52550	158	52708	63249.6	71.57035497
US+FR	Myalgia	29273	74	29347	917.09375	54916	198	55114	66136.8	71.11563703
US+FR	Dysstasia	1419	23	1442	45.0625	2655	35	2690	3228	70.63384189
US+FR	Acute Respiratory Distress Syndrome	99	33	132	4.125	123	121	244	292.8	69.98181818
US+FR	Parkinson's Disease	74	4	78	2.4375	123	12	135	162	65.46153846
US+FR	Hearing Loss	1348	7	1355	42.34375	2332	1	2333	2799.6	65.11601476
US+FR	Suicide/Suicidal Ideation	237	37	274	8.5625	425	42	467	560.4	64.44817518
US+FR	Paraesthesia	17125	78	17203	537.59375	27754	21	27775	33330	60.99848864
US+FR	Aphasia	1370	29	1399	43.71875	2047	100	2147	2576.4	57.9312366
US+FR	Syncope	17289	116	17405	543.90625	20325	281	20606	24727.2	44.46224648
US+FR	Amputation/Gangrene	58	10	68	2.125	62	13	75	90	41.35294118
US+FR	Non-anaphylactic allergic reactions	1340	9	1349	42.15625	1088	2	1090	1308	30.02742772
US+FR	Diabetes	1147	29	1176	36.75	842	57	899	1078.8	28.35510204
US+FR	Pregnancy-related (incl. Miscarriages)	8486	101	8587	268.34375	6252	104	6356	7627.2	27.42324444
US+FR	Sepsis	1444	377	1821	56.90625	766	328	1094	1312.8	22.06952224
US+FR	Autoimmune	12388	201	12589	393.40625	7329	122	7451	8941.2	21.72765112
US+FR	Paralysis	1946	101	2047	63.96875	1084	29	1113	1335.6	19.8789448
US+FR	Encephalopathy	821	134	955	29.84375	381	88	469	562.8	17.8582199
US+FR	Transverse Myelitis	609	7	616	19.25	254	0	254	304.8	14.83376623
US+FR	Multiple sclerosis	1511	24	1535	47.96875	575	3	578	693.6	13.45941368
US+FR	Optic neuritis (ON)	766	6	772	24.125	278	1	279	334.8	12.87772021
US+FR	Ataxia	789	13	802	25.0625	285	2	287	344.4	12.74164589
US+FR	Guillan-Barre	4361	136	4497	140.53125	1427	26	1453	1743.6	11.4072048
US+FR	Seizure/Convulsion	26934	428	27362	855.0625	8536	246	8782	10538.4	11.32471311
US+FR	Myelitis	538	8	546	17.0625	171	0	171	205.2	11.02637363
US+FR	Narcolepsy/Cateplexy	274	2	276	8.625	62	1	63	75.6	7.765217391
US+FR	Acute Disseminated Encephalomyelitis	406	30	436	13.625	94	3	97	116.4	7.543119266
US+FR	Encephalitis	1530	145	1675	52.34375	309	20	329	394.8	6.542447761
US+FR	Meningitis	1686	168	1854	57.9375	285	7	292	350.4	5.04789644
US+FR	Encephalomyelitis	118	3	121	3.78125	19	0	19	22.8	5.029752066
US+FR	Kawasaki disease	547	3	550	17.1875	8	0	8	9.6	-0.441454545

149.

150. This list shows that MYOCARDITIS/PERICARDITIS (irreparable damage to heart muscle) is the #1 highest occurring outcome from being inoculated with one of

the three FDA EUA drugs. STROKE is the second highest outcome. Acute Myocardial Infarction (heart attack) is third.

151. This is the CHART that illuminates the data in the spreadsheet, to wit:

152. 

153. This CHART compares the ADVERSE EVENTS (being reported daily to the CDC) with the same ADVERSE EVENTS for all other vaccinations, COMBINED, over the past 32 years.

154. For example, you see that "Myocarditis/Pericarditis" is at the top of the chart and out to the right is the number 302. This means that you are 302 times more likely to experience Myocarditis or Pericarditis after being inoculated with a Covid-19 inoculation than after being inoculated with any or all of the other vaccinations combined, over the past 32 years. The CDC has admitted that

Myocarditis/Pericarditis is especially prevalent in younger males. Damage to heart muscle is irreparable and permanent.

155. You are 286 times more likely to have a STROKE than all the people who have suffered a heart attack from vaccines administered, collectively, in the past 32 years!

156. *Acute Myocardial Infarction* (heart attack)? 279 times greater risk of heart attack over all other vaccines in the past 32 years!

157. Tinnitus? Ringing in your eats 24/7 until you feel like you are losing your mind?!? 225 times more likely to be debilitated with horrible life-suffering TINNITUS than from every other vaccine in the past 32 years!

158. And on and on and on. No evil has ever been visited on the human population like that which is being done right before our eyes . . . today . . . October 2021 . . . IN YOUR FACE!

159. Maxwell, and similarly situated Texas Citizens — *being bullied, fired, cancelled* — are in need of a lawful means and method to stop the killing and maiming of Texas citizens!

160. Three separate Covid-19 inoculations (masquerading as vaccines) were approved by the FDA by issuance under an Emergency Use Authorization. These inoculations are Pfizer ***BioNTech*** ("BioNTech"), **Moderna** ("Moderna"), and Johnson & Johnson's Jannsen ("Jannsen") inoculation. Defendants each offer all three (3) inoculations to their patients.

161. In Maxwell's experience, through their automated registration process, Defendants make the *choice* as to which inoculation will be administered, though

they will modify that decision if they learn that the patient has a different preference. Of course, how would the patient know what are the ingredients of the inoculation, or why one inoculation might be better or worse for them than the other? If Defendants were following the law and informing Maxwell of the risks associated with the severe adverse reactions to the inoculation, they would also know the ingredients of each CoviD-19 inoculation. Yet Maxwell learned, in registering and appearing at the location of each Defendant that they were completely clueless as to what was inside the vial from which they drew the liquid into a syringe and were simply going to inject Maxwell with an inoculation that had already, in 9.5 months, triggered reporting (1%) of 778,685 adverse reactions, 17,618 life-threatening events, 75,605 hospitalizations, 16,310 deaths, 23,712 permanent disabilities, 121,304 visits to their doctor, 87,758 emergency room visits and 528 birth defects from the mother taking the inoculation while she was pregnant. Yet, the Defendants, fully connected with the FDA and the CDC that provides this data every Friday, did not say one word to Maxwell, or to similarly situated individuals about these known risks associated with receiving the inoculation.

162. On October 4, 2021, Maxwell registered to receive an inoculation at Defendant HEB on Broadway Street, Pearland, Texas. Maxwell's appointment was confirmed for 2:45PM. Maxwell, upon arriving and checking in at the "Vaccine Desk" was told to sit in the waiting area and the person who would administer the injection would take him back into the room to be injected. Maxwell asked if there was any information available about the drug to be injected and after a while Maxwell was

handed a VACCINE FACT INFORMATION SHEET on the Pfizer BioNTech inoculation. Maxwell began reading the document and saw this warning in uppercase bold print, underline emphasis Pfizer's: **WHO SHOULD <u>NOT</u> GET THE VACCINE** *(Bold and underline emphasis Pfizer's): You should not get the vaccine if you: 1) had a severe allergic reaction after a previous dose of this vaccine; 2) had a severe allergic reaction to any ingredient of this vaccine." See* Pfizer Vaccine Information Fact Sheet attached hereto as **Exhibit D**, Pg. 3.

163. The HEB Pharmacist assistant, Chris, asked Maxwell to come back to the room where he asked Maxwell to have a seat in the chair to get the injection. Chris had the injection drawn in the syringe and was ready to swab Maxwell's arm and give Maxwell the injection. Maxwell waited to see if Chris would initiate a discussion regarding the risk vs. the benefit of taking the Covid-19 inoculation. When it was clear that Chris' intent was simply to inject Maxwell without any warning as to the risks, Maxwell spoke up and said, "I was reading the Vaccine Information Fact Sheet that I got from the guy at the counter." Chris acknowledged that he knew what the fact sheet was and said, "Yes, I have that to give you after I inject you." Maxwell said, "Well, wouldn't that be too late?" Chris was surprised, as Maxwell continued. "It says right here I should "<u>NOT</u>" take the vaccine if I am allergic to any of the ingredients in the vaccine." Chris looked at the paper and said, "Yes, I see that." Maxwell: "How do I know if I am allergic to any of the ingredients?" Chris: "Hmmm. That's a good question." Maxwell: "Well, it lists the ingredients right here. First ingredient is mRNA. Do you know what that is?" Chris: "No idea." Maxwell: "Well, I know what that from my college studies. Graduating with a

minor in Biology. That is **m**essenger **R**ibonucleic **A**cid." Chris: "Oh. Cool." Maxwell: "How would I know if I am allergic to whatever is included in mRNA?" Chris: "No idea." Maxwell: "Well this next one stumps me. It says "Lipids . . . which I know to be an oil of some kind . . . but then it says ((4-hydroxybutyl)azanediyl)bis(hexane-6), 1-diyl)bis(20hexyldecanoate). Any idea what that is?" Chris: "No idea. Wow!" Maxwell: "Well since you don't know what is in that syringe right there that you are intending to inject into my body, and I might be allergic to it such that it kills me or damages me for the rest of my life, I am going PASS." Chris: "Well, I will tell you that when I got the injection I had a horrible reaction . . ." and Chris went on to explain his horrific experience with his injection and that he had reported to VAERS, etc. etc. Maxwell could have pressed Chris as to why he neglected to tell Maxwell about his personal experience, but young Chris was shaken enough as it was. Maxwell politely excused himself and avoided the injection of *((4-hydroxybutyl)azanediyl)bis(hexane-6), 1-diyl)bis(20hexyldecanoate)*. Maxwell returned home and did a browser search for: ((4-hydroxybutyl)azanediyl)bis(hexane-6),1-diyl)bis(20hexyldecanoate).

The search returned the result that this LIPID was known to be one of the ingredients in the Pfizer BioNTech inoculation. It's CAS (Chemical Assessment System) No. is 2036272-55-4. Its Product name is **ALC-0315** and Maxwell was easily able to pull up the SAEFETY DATA SHEET FOR **ALC-0315** to learn that **ALC-0315** is a toxic deadly poison listed with the GHA Pictogram

Dangerous and potentially deadly toxin (ALC-0315). *See* MedChem SDS for ALC-0315 attached as **Exhibit E**.

1. The Safety Data Sheet instructs that if you get ALC-0315 on your skin you should immediately flush with water and *seek medical attention.*
2. The Safety Data Sheet instructs that if you get ALC-0315 in your eyes to immediately flush with water and *seek medical attention (also states that you can be blinded)*.
3. The Safety Data Sheet instructs that if ALC-0315 is *inhaled* that you should give the VICTIM cardio-pulmonary resuscitation and strictly says to **NOT** do mouth to mouth resuscitation or the person trying to resuscitate would ALSO be overcome by the toxic fumes.
4. Three guesses as to what it says about INGESTING ALC-0315?
5. Maxwell was seconds away from being INJECTED with a deadly poisonous chemical that was fraudulently concealed — hidden — as an inexplicable chemical formula in the VACCINE INFORMATION FACT SHEET.
6. Could Pfizer have put the actual PRODUCT NAME ALC-0315 in the list of ingredients? Of course, they could have! But then it might have been too easy for someone to locate and learn that their INOCULATION was 50%[12] deadly poison.

[12] Maxwell's determination that the ALC-0315 is 50% of the Pfizer BioNTech injection is published in The Tatty Journal, EXPERT EVIDENCE REGARDING COMIRNATY (PFIZER) COVID-19 MRNA VACCINE FOR CHILDREN, § 3.2.3 Genotoxicity, https://thetattyjournal.org/2021/07/17/expert-evidence-regarding-comirnaty-pfizer-covid-19-mrna-vaccine-for-children/. Pfizer claims in its VIS that the ingredients in Comirnaty and BioNTech inoculations are "identical and interchangeable."

7. Pfizer could have, as required by law, put a  beside the ALC-0315 ingredient so it immediatley could be recognized as the GHS (Globally Harmonized System) PICTOGRAM for a TOXIC and potentially deadly chemical. But that would have foiled their scheme to *hide* the toxic chemicals in the injection.

8. Could Defendant HEB (and all the Defendants) have done a ten-second browser search of ((4-hydroxybutyl)azanediyl)bis(hexane-6),1-diyl)bis(20hexyldecanoate) just like Maxwell did and connect the dots so THEY WOULD HAVE KNOWN that they would be injecting a deadly poison into Maxwell's body?

9. ALC-3015  . The SDS instructs that if get it on you, *seek medical attention!* If you inhale it, *seek medical attention!* If you ingest it, you are really in trouble! *Seek medical attention!* If you get it in your eyes, you may be blinded! But, what the heck, you might as well *seek medical attention!*

10. But, since the Defendants had the lethal inoculation drawn up in a syringe when Maxwell walked into the room, alcohols swab ready to *disinfect* the area where they were about to inject a  chemical, Defendants might as well inject the Category 2 Poisonous Lipid INTO Maxwell's BODY!

11. From the charted VAERS data shown above at ¶129 we see that had Maxwell been injected with the toxic poisonous chemicals he would have been 91 times more likely to be overcome with Multisystem Inflammatory Syndrome than if he

had taken all other 70+ vaccines administered in the past 32 years! Injecting toxic deadly chemicals just might be the cause. *Id.*

12. Blindness! Vision loss! 7500% greater chance than all other vaccines administered in the last 32 years! *Id.* What the hell? Why would Maxwell need to be able to SEE for the rest of his life?!?!? As long as he has lessened symptoms if he got Covid, right?

13. A very common result of the inoculation is Anaphylaxis? How could that possibly happen? Inject a toxic dose of ALC-0315 deep into the muscle so it can disseminate quickly into the BLOOD, HEART and LUNGS of the recipient . . . then stand back in awe and wonder as to why the patient goes into anaphylactic SHOCK! 75 times more likely to happen with a Covid-19 inoculation than all other vaccines combined that have administered in the past 32 years!

14. Defendants cannot be allowed to dupe Maxwell and similarly situated individuals into swapping a lifetime of being BLIND or risk ANAPHYLAXIS or STROKE or PERMANENT DAMAGE TO HIS HEARTH MUSCLE (Myocarditis) or DEATH . . . over the so-called "benefit" of having "lessened symptoms" of what begins like a head cold, and with proper treatment of Hydroxychloroquine (HCQ) and/or Ivermectin (IVM), that, in Maxwell's case (and his family) was knocked out faster than any cold or flu Maxwell ever had!

15. What is *now known* (and proven over and over by Maxwell, his extended family and friends) is that there does appear to be a what amounts to a *cure* for the common cold (a coronavirus) and/or the flu and even RSV (Respiratory Syncytial Virus) In the last 19 months Maxwell and many of his friends have utilized

perfectly safe and powerful medicines to stop the onset of viral infections in a matter of hours, symptoms completely gone in just a few days. And then Maxwell and friends have IgG antibodies to these illnesses — NATURAL IMMUNITY!

16. Because of the so-called Pandemic, Maxwell, his family and many friends were motivated to do more research on boosting their immune system and decided it was wise to have HCQ and IVM on hand, along with Budesonide[13] that can be used quickly in a NEBULIZER if any chest congestion occurs. As a result, Maxwell and friends have experienced the healthiest 18 months of their lives!

17. When Maxwell was questioning the risk of the inoculation with the NP at Defendant CVS's location in Pearland on September 29, 2021, she told Maxwell she had not heard of IVM until just recently. She then said that the Pharmacist had told her just a few days earlier that they were filling as many as 30 to 50 Ivermectin prescriptions a day!

18. Yesterday, October 19, 2020, the Attorney General of Nebraska announced that doctors could prescribe HCQ and IVM off-label. It took all this time — and pressure from CITIZENS demanding their rights to have access to perfectly safe medicines that can cure Covid-19 — for Nebraska to wake up.

19. Texas doctors have *always* been allowed to *practice medicine* and prescribe HCQ and IVM and Budesonide even though in March 2020 the State Board of

[13] Budesonide is marketed as Pulmicort. Millions of school children with Asthma pull out their Pulmicort (Budesonide)) inhaler and take a deep breath of the corticosteroid that instantly allows them to begin to breath freely. E.R. doctor, Dr. Richard Bartlett, Midland, Texas, came out in April 2020 calling Budesonide the SILVER BULLETT for preventing death when patients who *could not breathe* came into his ER. Dr. Bartlett reported (and still reports) 100% success with knocking out Covid using Budesonide. Maxwell got a prescription for Budesonide to have on hand and . . . it works like a charm! Amazing!

Pharmacy enacted a highly questionable and confusing "Emergency Rule" that was spuriously added to the Texas Administrative Code that *mislead* doctors to believe they could not prescribe HCQ. Maxwell began calling the State Board of Pharmacy, the Texas Medical Board, and the Secretary of State to find out how/why this could occur, and in the midst of his investigation the "RULE" was suddenly *removed* from the Texas Administrative Code. Maxwell was told by the Secretary of State's office that it "expired" by law because it not re-upped within 90 days. Yet it was still nearly a year before doctors lost their *fear* of prescribing HCQ. How many lives were lost because the medical community suddenly stopped practicing medicine and had NO TREATMENT for Covid-19? For the first time in modern history there was suddenly NO TREATMENT for an illness.

20. Defendants KNOW there is an incredibly effective treatment protocol that stops Covid-19 dead in its tracks. But the Defendants a are NOT being paid billions to sell treatment protocols.

21. Defendants knowingly and willingly are withholding evidence through their scheme of *failure to warn of unreasonable risk of substantial harm* so that they can be unjustly enriched by the billions of dollars being paid to them to inject Texas citizens and U.S. Citizens with a potentially lethal and/or life altering experimental drug that *might lessen* symptoms.

22. Proper treatment protocol CURED Maxwell of Covid-19 and helped him develop IgG antibodies to give him NATURAL IMMUNITY that is up to 900 times greater than IgM antibodies that he *might* get from the Covid-19 inoculation . . . IF IT DIDN'T KILL HIM!

23. As shown above, Pfizer's BioNTech has toxic, deadly ingredients. How about the Moderna inoculation than contains Product **SM-102**.

24. Moderna's Vaccine Information Fact Sheet (VIS) list the *primary* ingredient (lipid that is the delivery system for the mRna spike protein) as **SM-102.** *See Moderna* Vaccine Information Fact Sheet attached hereto as **Exhibit F**.

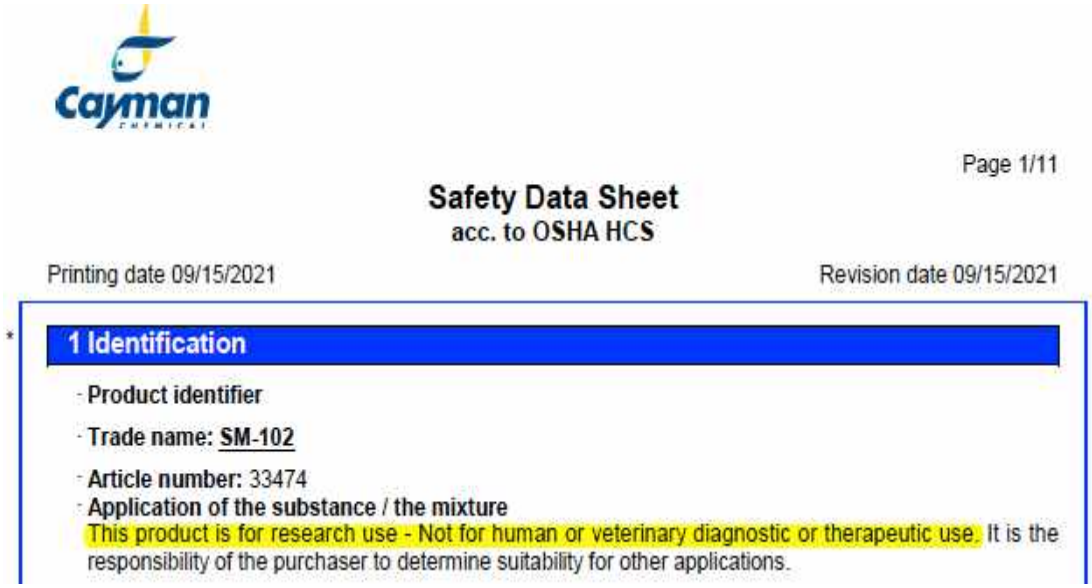
25. The Safety Data sheet for SM-102 shows:

Signal word: DANGER  Deadly poison (SM-102).

26. Moderna's "lipid delivery system" is SM-102 dipicted on the Safety Data Sheet with the GHS Pictogram: SKULL and CROSSBONES! *See* MedChem Safety Data Sheet attached hereto as **Exhibit G.**

27. The SDS for SM-102 — being the primary ingredient (lipid delivery system) in Moderna's inoculation — states clearly that SM-102 is for "research use" and is "Not for human or veterinary diagnostic or therapeutic use, to wit:

28.



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Safety Data Sheet
acc. to OSHA HCS

Printing date 09/15/2021 Revision date 09/15/2021

* **1 Identification**

· **Product identifier**

· **Trade name: SM-102**

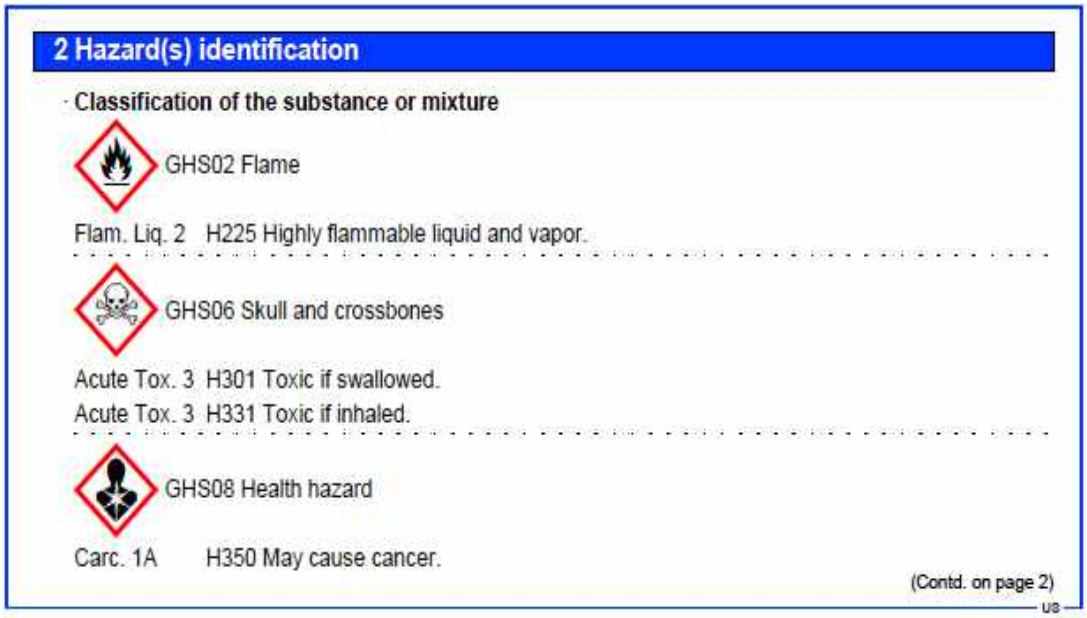
· **Article number:** 33474

· **Application of the substance / the mixture**

This product is for research use - Not for human or veterinary diagnostic or therapeutic use. It is the responsibility of the purchaser to determine suitability for other applications.

29. How about the DANGERS that are listed, to wit:

30.



2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.

GHS06 Skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 3 H331 Toxic if inhaled.

GHS08 Health hazard

Carc. 1A H350 May cause cancer.

(Contd. on page 2)

US

31. Next page . . . Page 2 . . . the SDS is meant to WARN so that there is NO MISTAKE that this is a deadly poisonous material, to wit:

32.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**

GHS02 GHS06 GHS07 GHS08

· **Signal word** Danger

33. "**Signal word** Danger". *Id.*

34. So, of course, On October 6, 2008, Defendant WALGREENS Pharmacist was ready for Maxwell to lift his shirt sleeve so they could INJECT HIM with the toxic, deadly poison, SIGNAL WORD: DANGER MODERNA SM-102  inoculation.

35. Walgreens did NOT warn of unreasonable risk of substantial harm, §148.002, that could result when the deadly SM-102 chemical was injected into his blood stream. Maxwell was NOT warned that the deadly chemical could KILL HIM or permanent disable him like it has already done to tens of thousands of unsuspecting citizens.

36. Walgreens Pharmacist Helen (last name withheld at this time) was stunned that Maxwell had questions about the safety of the inoculation. She searched and searched for a Vaccine Information Statement ("VIS"). When she handed a document to Maxwell, he quickly pointed out that what she had given him only had to do with "INFLUENZA (FLU) Vaccine" and had nothing to do with Moderna. She searched for another five minutes and couldn't find *anything* on the Moderna Covid-19 inoculation they were about to inject into Maxwell. She even showed Maxwell a box the inoculation vials to prove to Maxwell that there were *no package inserts* in the box(es).

37. Maxwell told her that he had learned that there was serious risk associated with the injection and since she didn't have any knowledge of the risks and could not assure him there was no risk that he was *not* going to take the injection.

38. Even so, the next day Maxwell received an email from WALGREENS congratulating him on getting his first dose of MODERNA and telling him that they had scheduled the date for his *second dose*. Maxwell just figured it was some kind of weird mistake.

39. Then, when Maxwell visited Defendant KROGER two days later October 8, 2020, Maxwell *learned* that a request for PAYMENT had submitted, and that Maxwell was in the State Database as having been injected with Moderna. Upon arriving for his appointment, the Kroger Pharmacist assistant pulled up Maxwell in her system and asked Maxwell why he wanted another injection so soon after his first injection. Maxwell assured her he had NOT been injected and she showed Maxwell where some entity had submitted Maxwell's injection for PAYMENT. Later that day Maxwell connected the dots. Maxwell created a Walgreens account, logged in and sure enough, there was proof that Walgreens had filed a prescription for Covid-19 inoculation and had submitted it for payment.

40. 

41. Maxwell then went to the Walgreens and had them DELETE the record that falsely showed he had been injected.

42. Maxwell returned to Kroger on Broadway in Pearland, Texas that same afternoon, checked in, and questioned the risk of the injection. Different from the other Defendants, the very gracious Kroger Pharmacist and other assistants were adamant that the shot was safe, "very safe" and, essentially conveyed that they thought Maxwell was nuts not to get the injection, even though he told them he had IgG antibodies.

43. Defendant Kroger viewed IgG antibodies much the same as CVS. Irrelevant. Multiple Kroger Pharmacists and assistants told Maxwell, "You need the shot to be protected." Maxwell attempted to explain that he was aware of serious risks, but the only response Maxwell got was that "everyone here had received the shot with no consequence so it must be perfectly safe."

44. Maxwell then moved on to Walmart on Main Street, Pearland. Same song, fifth verse. The Walmart Pharmacist did, *upon request*, provide Maxwell with the Pfizer BioNTech "Vaccine Information Fact Sheet" and she left that information with Maxwell to review. When she returned Maxwell, as he had done with Chris at HEB, pointed out that Pfizer specifically stated that no one should take the injection if they were allergic to the ingredients, and she could not have appeared more puzzled. Then Maxwell showed her the LIST of serious risks (Death is omitted on the Pfizer VIS) and the Pharmacist seemed quite surprised. She did, however, acknowledge that ANAPHYLAXIS was not uncommon (Shock that leads to unconscious) but assured Maxwell that she had EPINEPHRINE on hand to help

revive Maxwell and *hopefully* get him to a hospital before he died. Maxwell said, "No thanks."

45. Maxwell recently learned about and obtained the AFFIDAVIT of Lieutenant Colonel Teresa Long MD, MPH, FS, that was filed *IN SUPPORT THE MOTION FOR PRELIMINARY INJUNCTION* in the recently filed federal case *Robert v. Austin,* filed in United States District Court, District of Colorado on August 17, 2021. (Ironically this case was filed the same day that Maxwell made his first visit to Defendant CVS located on Broadway Street in Pearland, Texas.)

46. Plaintiff Dan Robert, SSCT U.S. Army filed suit against Secretary of Defense Lloyd Austin seeking an INJUNCTION to prevent U.S. Military members from being inoculated with Covid-19 injections. *See Docket Sheet attached hereto as* ***Exhibit H***.

47. In this lawsuit, ROBERT filed a Motion for Preliminary Injunction and attached the AFFIDAVIT of Lieutenant Colonel Teresa Long MD, MPH, FS in support thereof. *See* AFFIDAVIT of Lieutenant Colonel Teresa Long MD, MPH, FS attached hereto as ***Exhibit I***.

48. LTC Teresa Long's affidavit, given under penalty of perjury and under the PROTECTION of the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, states her qualifications, to wit:

"After receiving a bachelor's degree from the University of Texas Austin, completed my medical degree from the University of Texas Health Science Center at Houston Medical School in 2008. I served as a Field Surgeon for ten years and went on to complete a residency in Aerospace and Occupational Medicine at the United States Army School of Aviation Medicine, Fort Rucker, AL. I hold a Master's in Public Health, and I have been trained by the Combat Readiness Center at Ft. Rucker as an Aviation Safety Officer. Additionally, I have trained in the Medical Management of Chemical and Biological Causalities at Fort Detrick

and USAMIIRD. I am board certified in flight Aerospace Medicine and board eligible in Occupational Medicine. I am currently serving as the Brigade Surgeon for the 1st Aviation Brigade Ft. Rucker, Alabama and am responsible for certifying the health, mental and physical ability, and readiness for all nearly 4,000 individuals on flight status on this post. My appended curriculum vitae further demonstrates my academic and scientific achievements by me over the past thirteen years."

49. Maxwell can't imagine a more qualified Medical Expert to testify on behalf of Plaintiff SSGT Dan Robert. Maxwell relies on the Affidavit Testimony of LTC Long to help him in his understanding of the urgency of correcting the wrongs that are being perpetrated by the Defendants.

50. As will be shown hereinbelow, LTC Long states that she has GROUNDED at Fort Rucker, Alabama "all active flight personnel who received the vaccinations until such time as the causation of these serious systemic health risks can be more fully and adequately assessed."

51. Maxwell asks the Court (and anyone reading this Petition), "Have you heard on the NEWS that flight personnel at Ft. Rucker Alabama have been GROUNDED by the Brigade Surgeon for the 1st Aviation Brigade Ft.? Why is there a complete blackout of one of the most courageous actions of a Military Officer in modern history? Doesn't LTC Theresa Long's REASON for taking this incredibly aggressive action warrant scrutiny from ALL AMERICAN CITIZENS who are being subjected to forced inoculation of the experimental gene therapy?

52. Maxwell respectfully request that the Court to go to ***EXHIBIT I*** and read the entirety of LTC Long's stunning, sworn declaration. How severe are the adverse effects on America's most fit young men and women that forced LTC Long to *ground* an entire U.S. Army Aviation Brigade?

53. LTC Long MD, MPH, FS, just three weeks ago, declares to the U.S. District Court, District of Colorado, why she was forced to take drastic measures to ground thousands of the military flight personnel. At ¶¶ 35 – 41 LTC Long states, to wit:

¶35 I have reviewed the Motion for a Preliminary Injunction which discusses the issue of prior immunity benefits outweighing the risks of using experimental Covid 19 Vaccines, together with proposed exhibits and materials cited therein. In opinion on this subject matter, I am also drawing my own conclusions that will be put into practice in my current role as an Army flight surgeon knowing full well the horrific repercussions this decision may befall me in terms of my career, my relationships and life as an Army doctor.

¶36 I personally observed the most physically fit female Soldier I have seen in over 20 years in the Army, go from Collegiate level athlete training for Ranger School, to being physically debilitated with cardiac problems, newly diagnosed pituitary brain tumor, thyroid dysfunction within weeks of getting vaccinated. Several military physicians have shared with me their firsthand experience with a significant increase in the number of young Soldiers with migraines, menstrual irregularities, cancer, suspected myocarditis and reporting cardiac symptoms after vaccination. Numerous Soldiers and DOD civilians have told me of how they were sick, bed-ridden, debilitated, and unable to work for days to weeks after vaccination. I have also recently reviewed three flight crew members' medical records, all of which presented with both significant and aggressive systemic health issues. Today I received word of one fatality and two ICU cases on Fort Hood; the deceased was an Army pilot who could have been flying at the time. All three pulmonary embolism events happened within 48 hours of their vaccination. I cannot attribute this result to anything other than the Covid 19 vaccines as the within 2 days post vaccination. Correlation by itself does not equal causation, however, significant causal patterns do exist that raise correlation into a probable cause; and the burden to prove otherwise falls on the authorities such as the CDC, FDA, and pharmaceutical manufacturers. I find the illnesses, injuries and fatalities observed to be the proximate and causal effect of the Covid 19 vaccinations.

¶38 I can report of knowing over fifteen military physicians and healthcare providers who have shared experiences of having their safety concerns ignored and being

ostracized for expressing or reporting safety concerns as they relate to COVID vaccinations. The politicization of SARs-CoV-2, treatments and vaccination strategies have completely compromised long-standing safety mechanisms, open and honest dialogue, and the trust of our service members in their health system and healthcare providers.

¶39 The subject matter of this Motion for a Preliminary Injunction and its devastating effects on members of the military compel me to conclude and conduct accordingly as follows:

a) None of the ordered Emergency Use Covid 19 vaccines can or will provide better immunity than an infection-recovered person;

b) All three of the EUA Covid 19 vaccines (Comirnaty is not available), in the age group and fitness level of my patients, are more risky, harmful and dangerous than having no vaccine at all, whether a person is Covid recovered or facing a Covid 19 infection;

c) Direct evidence exists and suggests that all persons who have received a Covid 19 Vaccine are damaged in their cardiovascular system in an irreparable and irrevocable manner;

d) Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro clots in their cardiovascular system that present a danger to their health and safety;

e) That such micro clots over time will become bigger clots by the very nature of the shape and composition of the Spike proteins being produced and said proteins are found throughout the user's body, including the brain;

f) That at the initial stage of this damage the micro clots can only be discovered by a biopsy or Magnetic Resonance Image ("MRI") scan;

g) That due to the fact that there is no functional myocardial screening currently being conducted, it is my professional opinion that substantial foreseen risks currently exist, which require proper screening of all flight crews;

h) That, by virtue of their occupations, said flight crews present extraordinary risks to themselves and others given the equipment they operate, munitions carried thereon and areas of operation in close proximity to populated areas;

i) That, without any current screening procedures in place, including any Aero Message (flight surgeon notice) relating to this demonstrable and identifiable risk,

I must and will therefore ground all active flight personnel who received the vaccinations until such time as the causation of these serious systemic health risks can be more fully and adequately assessed;

j) That, based on the DOD's own protocols and studies, the only two valuable methodologies to adequately assess this risk are through MRI imaging or cardio biopsy which must be carried-out;

k) That, in accordance with the foregoing, I hereby recommend to the Secretary of Defense that all pilots, crew and flight personnel in the military service who required hospitalization from injection or received any Covid 19 vaccination be grounded similarly for further dispositive assessment;

l) That this Court should grant an immediate injunction to stop the further harm to all military personnel to protect the health and safety of our active duty, reservists, and National Guard troops.

¶40 I am competent to opine on the medical and flight readiness aspects of these allegations based upon my above-referenced education and professional medical, aviation and military experience and the basis of my opinions are formed as a result of my education, practice, training and experience.

¶41 As an Aerospace Medicine Specialist, and flight surgeon responsible for the lives of our Army pilots, I confirm and attest to the accuracy and truthfulness of my foregoing statements, analysis and attachments or references hereto:

/S/

LTC Theresa Long, MD, MPH, FS

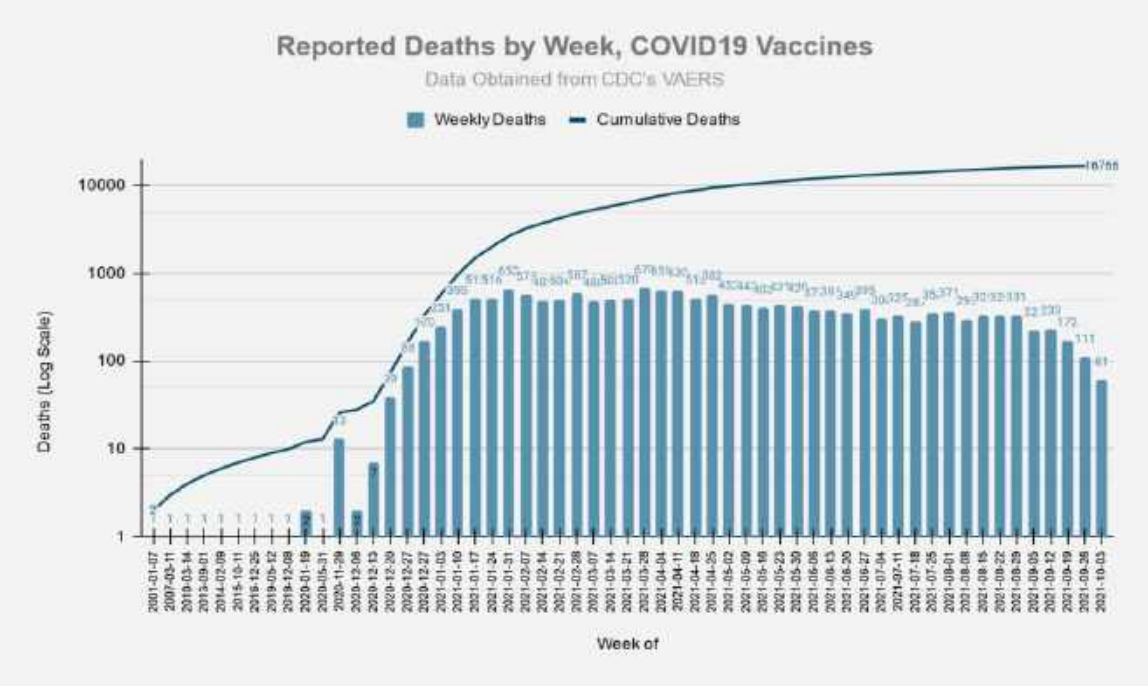
54. *Id.* Maxwell reads the entirety of LTC Long's testimony to mean that 800,000 of our 1.4 million military service personnel are *dead men walking*.

55. LTC Long has sworn under oath that most fit men and women in America are already "damaged in their cardiovascular system in an irreparable and irrevocable manner" . . . "Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro

clots in their cardiovascular system that present a danger to their health and safety;" *Id*. What does that say about the Defendants continuing to INJECT thousands of UNIFORMED Texas citizens every day to initiate, with the push of the plunger in the syringe, the ENDING CHAPTER of their lives?

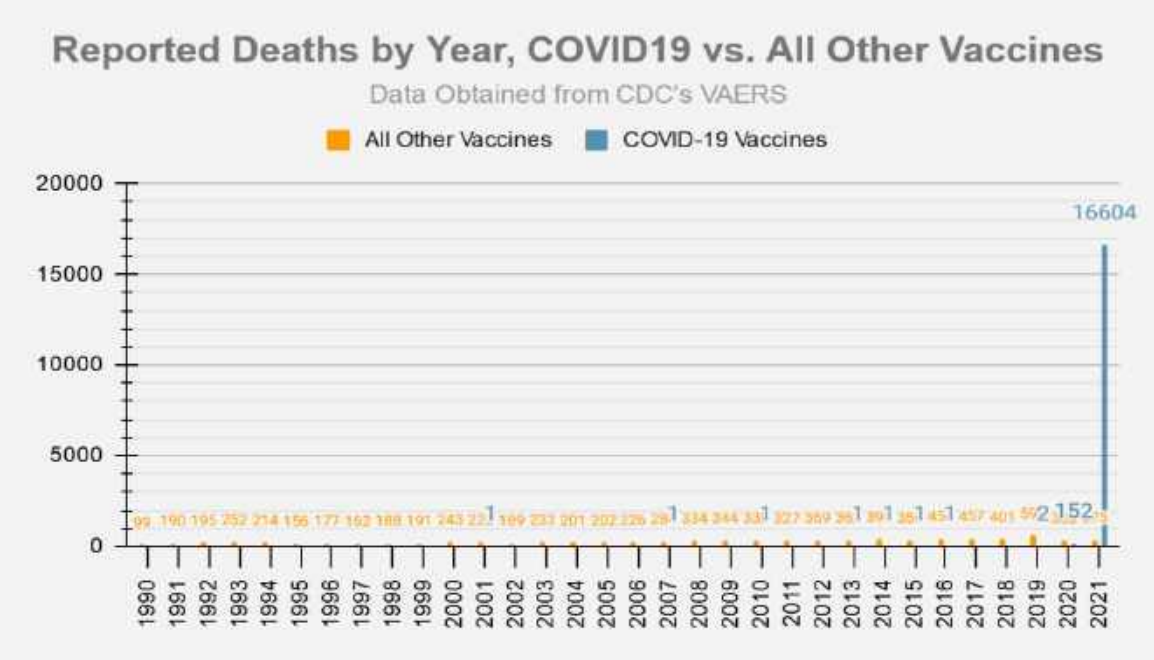
56. Does the LTC Theresa Long MD, MPH, FS declaration explain this chart of CDC VARES compiled data through last week, to wit:

57.



58. See VAERS ANALYSIS, "**VAERS Summary for COVID-19 Vaccines through 10/8/2021", https://vaersanalysis.info/2021/10/15/vaers-summary-for-covid-19-vaccines-through-10-8-2021/**

59. Or maybe this chart compiled from CDC VAERS data is even more compelling, showing that prior to 2021 the average annual vaccine deaths reported to CDC was 283. But this year, with two months to go, it is already 16,604! "SAFE"? This is the Defendants' definition of "SAFE"?!? . . . to wit:



60.

61. [Note that COVID19 counts for years before 2020 are due to incorrect date data in the VAERS system (including 1 not pictured due to date in 1921)]

62. *Id*.

HISTORY

63. August 17, 2021, Maxwell was administered a Covid antibodies test at CVS by NP (Nurse Practitioner) ____("NP"); (name withheld to protect CVS employee)[14] Following the antibodies test the NP called Maxwell into her office and informed Maxwell that the test was positive for Maxwell having mounted an IgG (Immunoglobulin G) response to the Covid virus. Maxwell has a solid understanding of the major types of antibodies produced by his immune system to help battle bacterial and viral infections. Maxwell also has a 17-yr-old son who

[14] Throughout this pleading Maxwell will assert that he met personally with the specific employees of the defendants at the locations so stated. Maxwell makes no allegations that the employees, individually, knowingly or intentionally participated in the fraudulent schemes of the defendants. Their names are withheld from the pleadings to protect them from harm and retribution by their respective employers, the Defendants.

was "born with no real immune system" and to whom Maxwell gave injections every Monday night (that lasted three hours each time) of IgG antibodies from the time Joshua was 6 until nearly 9 years old — 27 months, once each week. Through this process, Maxwell became quite educated on IgG antibodies, immunity to disease and everything in between.

64. Maxwell's intent in getting the test was to solidify his belief that because he was infection-recovered from Covid, that he had robust, durable and complete immunity — NATURAL IMMUNITY — to the Covid virus.

65. To Maxwell's dismay, he was handed a printout by NP ___ that confirmed the POSITIVE finding of the **IgG antibodies** against Covid-19, but contained a patently fraudulent statement, to wit: *"If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last."*

66. Maxwell questioned the NP as to the validity of that statement, and her answer was non-responsive, deflecting to that last part of the statement suggesting that it is not known *how long* that immunity to Covid-19 might last, but continuing to avoid acknowledging that IgG antibodies give immunity to Covid-19.

67. Maxwell was stunned that a *healthcare provider*, much less CVS Minute Clinic, would put such a brazenly false statement in writing and present it to him as if it was fact.

68. But the reason for such a fraudulent scheme is seen in the double-speak that follows, as CVS not only intentionally downplays the validity of the test they just

gave (and charged $38.00), but then fraudulent induces Maxwell to "proceed with standard vaccination recommendations", to wit:

69. *"If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last . . . Please note that no test is perfect, and this test can result in 'false positives' where the test says you have antibodies when in fact you do not. For all these reasons, regardless of your test result, you should continue to follow CDC COVID-19 guidelines to protect yourself and others from the COVID-19 virus and proceed with standard vaccination recommendations."* See **Exhibit J** attached hereto.

70. Maxwell expressly asked the NP if she truly believed he should get an inoculation because of his IgG antibodies providing him natural immunity and she said, "Absolutely!" Maxwell asked, "What are the risks of taking the Covid inoculation?" NP, "None that I know of."

71. Maxwell returned to CVS 42 days later on September 29, 2021 and again has his antibodies tested. Sure enough, Maxwell still had robust, durable and complete immunity to Covid, IgG rockin' the house! But, CVS, same document provided to Maxwell with same patently false claim that "it is not known if your IgG antibodies are a defense against Covid *at all*."

72. Maxwell began doing research on IgG antibodies to Covid-19, perplexed that CVS would make such a glaringly false claim. In short order Maxwell learned of a lawsuit filed in the Eastern District of Virginia by Professor Todd Zwicky, who sued the trustees of George Mason University for mandating that *Zwicky* get

injected with the experimental Covid inoculation or he would be fired from his position as law profession in the Antonin School of Law.

73. In support of his Complaint and Motion for Preliminary Injunction *Zwicky* filed the Declaration of Dr. Hooman Noorchashm, MD, PhD. *See* **Exhibit K** attached hereto.

74. According to his Declaration, Dr. Noorchashm graduated from Perelman School of Medicine at the University of Pennsylvania with a Doctorate Degree in immunology and has taught and practiced clinical medicine for nearly two decades. Dr. Noorchasm states that he reviewed Professor Zywicki's medical history, especially with regard to Zywicki's having had severe Covid illness and having recovered fully. Dr. Noorchasm states that he prescribed a "full COVID-19 serological screening which was conducted on June 1, 2021, at LabCorp. Dr. Noorchasm states that he "examined the results and as expected, the test confirmed Professor Zywicki had previously recovered from SARS-CoV-2 and had a positive IgG Spike Antibody assay and a positive SARS-COV-2 Nucleocapsid result." *Id*.

75. Here is where Maxwell was blown away! Dr. Noochasm states that "Zywicki's semiquantitative antibody reading measured 715.6 U/ml — approximately 900 times higher than the baseline level of <0.8." . . .which Dr. Noorchasm says, of the <0.8 level, "This level is comparable to that I have seen empirically in vaccinated persons who share his (Zywicki) age and health profile, including myself (Noorchasm)." *Id.*

76. The essence of Professor's Zywicki's complaint and request for injunctive relief was that since he was already protected from Covid, why would he be forced,

against his will, and without giving CONSENT, to take an injection that he was learning was very dangerous, was causing horrific, life-altering events, or death that were being reported to the CDC by the thousands every day?

77. Even further, Dr. Noorchasm stated that because Zywicki had robust, durable, and complete natural immunity to Covid that the likelihood of Zywicki having a SEVERE ADVERSE REACTION to a Covid inoculation increased exponentially. Dr. Noorchasm stated at ¶12 **"It Is Medically Unnecessary To Undergo Vaccination Against Sars-Cov-2, And Forcing Him To Do So Would Subject Him To An Elevated Risk Of Adverse Side Effects.** (Bold emphasis upper case words his) *Id*.

78. The essence of Dr. Noorchasm's finding and medical advice was that Zywicki avoid, at all costs, being injected because of the potentially deadly and/or permanent injury that could be inflicted on Zywicki, notwithstanding that Zywicki already had immunity 900 times greater than any immunity he could possibly receive from an experimental Covid inoculation.[15]

79. Maxwell found himself in a huge dilemma as he was hearing daily of "vaccine mandates" and had family and friends who he knew were Covid *infection-recovered persons* who were being forced to take the injection or have their lives destroyed by the loss of employment, benefits, pensions, etc.

[15] All Covid inoculations being administered by Defendants are under the EUA issued by the FDA in December 2020. A *bait and switch* was done by the FDA to claim that a Pfizer vaccine was "approved", but that inoculation was for Comirnaty not for BioNTech that is the inoculation administered by the Defendants. Comirnaty has NOT been provided to any of the Defendants for administration, or apparently to any providers in the U.S. The whole charade was to preempt a VACCINE MANDATE against the American people . . . demonstrating the continued FRAUDULENT SCHEMES that appear to drive virtually everything associated with the Covid delirium.

80. Maxwell was even more distraught over Defendant CVS's glaringly fraudulent claim that it was *"not known"* that his IgG antibodies gave him any protection from Covid "at all."

81. As stated in more detail hereinabove, Defendant HEB failed to warn Maxwell of any of the risks associated with the Pfizer BioNTech inoculation. HEB's policy and practice showed they never warn anyone of the risks of being injected with the toxic chemicals in the BioNTech inoculation.

82. Defendant Walgreens provides an online Registration Form that can also be obtained if Maxwell had walked into the clinic without an online appointment. The form is titled: **Vaccine Administration Record (VAR) — Informed Consent for Vaccination.** *See* Defendant Walgreens' Online Registration Form/Informed Consent, attached **hereto as Exhibit L**.

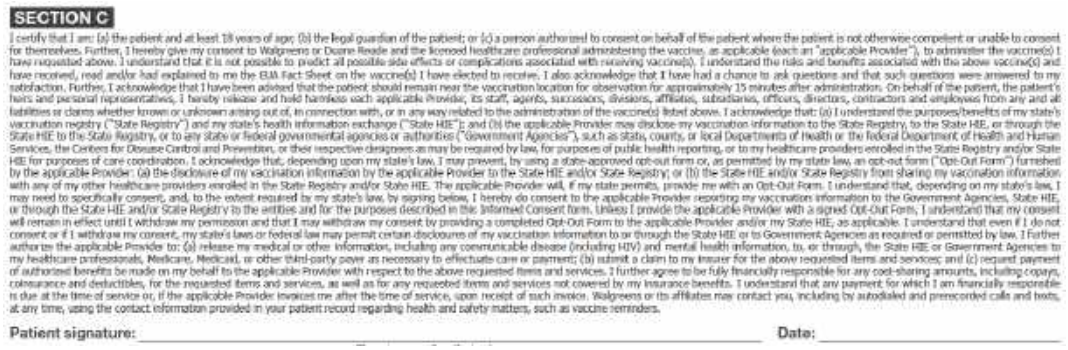
83. Within the tiny print of the Informed Consent portion of the form, Section C, Defendant Walgreens includes the following statement (to be acknowledged by Maxwell), to wit:

84. "I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the EUA Fact Sheet on the vaccine(s) I have elected to receive."

85. This small font is copy/pasted from the document and intentionally left at this size to show the Court how the "Informed Consent" portion of the registration document was less than one-half the size of the other portions of the registration form. What cannot be shown here is the manner in which the text was jammed together so tightly to have virtually NO SPACE between the lines making it very difficult for Maxwell (or anyone) to read. *See Section C, Id.*

86. This is the INFORMED CONSENT, Section C of the registration form, to wit:

87.



SECTION C

I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient; or (c) a person authorized to consent on behalf of the patient where the patient is not otherwise competent or unable to consent for themselves. Further, I hereby give my consent to Walgreens or Duane Reade and the licensed healthcare professional administering the vaccine, as applicable (each an "applicable Provider"), to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the EUA Fact Sheet on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should remain near the vaccination location for observation for approximately 15 minutes after administration. On behalf of the patient, the patient's heirs and personal representatives, I hereby release and hold harmless each applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) the applicable Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, or to any state or federal governmental agencies or authorities ("Government Agencies"), such as state, county, or local Departments of Health or the Federal Department of Health and Human Services, the Centers for Disease Control and Prevention, or their respective designees as may be required by law, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider: (a) the disclosure of my vaccination information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state's law, I may need to specifically consent, and, to the extent required by my state's law, by signing below, I hereby do consent to the applicable Provider reporting my vaccination information to the Government Agencies, State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent form. Unless I provide the applicable Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the applicable Provider and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws or federal law may permit certain disclosures of my vaccination information to or through the State HIE or to Government Agencies as required or permitted by law. I further authorize the applicable Provider to: (a) release my medical or other information, including any communicable disease (including HIV) and mental health information, to, or through, the State HIE or Government Agencies to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment; (b) submit a claim to my insurer for the above requested items and services; and (c) request payment of authorized benefits be made on my behalf to the applicable Provider with respect to the above requested items and services. I further agree to be fully financially responsible for any cost-sharing amounts, including copays, coinsurance and deductibles, for the requested items and services, as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if the applicable Provider invoices me after the time of service, upon receipt of such invoice. Walgreens or its affiliates may contact you, including by autodialed and prerecorded calls and texts, at any time, using the contact information provided in your patient record regarding health and safety matters, such as vaccine reminders.

Patient signature: _____ **Date:** _____

88. What is patently clear is that Defendant Walgreens (as did all the other five Defendants) KNEW that they must obtain a signed *Informed Consent* before they could/would administer the Covid-19 inoculation.

89. None of the Defendants require that an injection recipient have a Primary Care Provider (PCP) or discuss with them whether they have or have not discussed the *risk of substantial harm* that can come from being injected with the Covid19 inoculation. Maxwell specifically conveyed on the registration to each Defendant that he did NOT have a PCP so Defendants were fully informed that Maxwell had no one to guide him or warn him other than the shot-injecting Defendants.

90. WALGREENS (and the other five Defendants) each sought to obtain a hold harmless of the Walgreens Co., staff, etc. before they could/would administer the Covid inoculation, to wit:

91. "I hereby release and hold harmless each applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above." *Id. Section C.*

92. Maxwell was sitting at his kitchen table when he made this online appointment. How is it possible for Maxwell to truthfully sign an Informed Consent stating that

he had "received, read and/or had explained to me the EUA Fact Sheet on the vaccine(s) I have elected to receive."?

93. WALGREENS (same as all Defendants) had NOT provided Maxwell an EUA Fact Sheet (at that time Maxwell did not even know what that was!). How could Walgreens have provided Maxwell an "EUA Fact Sheet", much less provided Maxwell with an opportunity to read it, understand it, or have it explained to him? Explained to him by WHOM? Maxwell was sitting in front of his laptop at his kitchen table!

94. Then WALGREENS suborns another pejorative statement from Maxwell by asking Maxwell, to claim that: *"I also acknowledge that I have had a chance to ask questions and that my questions were answered to my satisfaction." Id.*

95. Both fraudulent concealment and fraudulent inducement acts by Defendant Walgreens apply fully to the other five (5) Defendants.

96. Each Defendant's policy and practice employs virtually the same *INFORMED CONSENT* registration form provided to Maxwell, both online and/or in person at each location where Defendants intended to inject Maxwell with the dangerous inoculation without providing Maxwell ANY documentation of ANY kind as to the known VAERS-REPORTED ADVERSE EVENTS — reported to the CDC — by thousands of doctors and recipients of the toxic, poisonous and deadly inoculations.

97. Maxwell has undertaken to do a screen recording of the registration and appointment he made online with each Defendant. Maxwell has all of the forms. Everything Maxwell has done to provide evidence of his process will expose any

effort by the Defendants to destroy the evidence of their unlawful policies and practices.

98. See CVS Informed Consent registration form attached as Exhibit M.

99. See HEB Informed Consent registration form attached as Exhibit N.

100. See Kroger Informed Consent registration form attached as Exhibit O.

101. See Walmart Informed Consent registration form attached as Exhibit P.

102. Defendant UTMB does not provide a physical registration form. Maxwell learned through the registration process that there was no "form" online or a PDF form that he could download.

103. Maxwell spoke with personnel at the UTMB registration office and specifically asked for the registration form and/or an Informed Consent form. Maxwell was told that no such form existed, and the entire process occurred between the patient and the person at the registration desk when Maxwell was registering for to be inoculated.

104. UTMB *markets* the Covid-19 inoculation. UTMB pushes the inoculation as if it is the only hope for saving the world. Maxwell did a screen recording of UTMB's website wherein UTMB has eight (8) scrolling images with nothing but positive images of people of all ages and ethnicity that state *their reasons* to get the Covid-19 inoculation, such as:

a) Dr. Matthew Dacso — "I am ready to return to enjoying live music and seeing friends, and gathering with my extended family" . . . implying that with the C-19 inoculation that a return to a normal life is not possible;

b) Dr. Cindy Chan: "I'd like to better serve the resistance against Covid-19."

c) “ 

105. and on and on and on. *See* UTMB marketing campaign at: https://www.utmb.edu/covid-19/vaccine .

106. Scroll to near the bottom of the webpage to see the scrolling images and statements of UTMB professionals. Maxwell made a screen recording as evidence of the marketing campaign than can be produced in court after UTMB removes it from its website proving that they realize that SELLING the inoculation is a conflict of interest of their lawful duty to *warn of unreasonable risk of substantial harm.* §148.002. UTMB's conflict of interest is unconscionable!

107. Beside every statement by a UTMP doctor or nurse promoting the inoculation is their smiling face and their *reason* for taking the inoculation.

108. Beside each scrolling advertisement is this statement to wit:

Have you thought about why you want to get the COVID-19 vaccine?

Everyone at UTMB, from doctors and nurses to technicians, scientists, educators, support staff and administrators, have been working hard to combat the COVID-19 pandemic. Now they have a new tool in their tool belt: a vaccine. We all have different reasons for getting the vaccine but we have the same goal - ending the pandemic.

109.

110. Can UTMB serve two masters? UTMB is a *proponent* of the Covid-19 inoculation. UTMB *sells the inoculation* that same way Ford sells trucks!

111. How can UTMB possibly comply with Texas law that requires that them — as healthcare providers — to warn patients of the substantial harm that may befall the patient if they get inoculated — if they are invested up to their necks to SELLING the Covid-19 inoculations and marketing it as the solution to "end the pandemic."? *Id.*

112. Should it be the *business* of Texas hospitals to *promote and sell* medical procedures that carry unreasonable risk of substantial harm?

113. UTMB only has wonderful, exciting propaganda to share with their unsuspecting patients wherein they portray the Covid-19 inoculations as the means of reaching their "*goal . . . to end the pandemic." Id.*

114. Of course, that fact that there are tens of millions of "breakthrough cases" seems to be lost on the so-call *healthcare providers*. Hence the NEWEST chant . . . on UTMB's website and on the menu recordings when you call into their switchboard, is "SCHEDULE YOUR COVID-19 BOOSTER TODAY!"

115. This also explains why the UTMB nurse scoffed at Maxwell's question as to the safety of the inoculation, and said to Maxwell, "If there was a VAERS to report adverse events from eating, it would show far more people die from eating than from a Covid-19 inoculation. More people die each year from eating PEANUTS than from taking the Covid-19 injection." [At the appropriate time, if contested by Defendant UTMB, Maxwell will play the recorded conversation in open court.]

116. Maxwell did a quit browser search and learned that "Somewhere around 150 to 200 people die in the U.S. each year because of food allergies. It's estimated that around 50 percent to 62 percent of those fatal cases of anaphylaxis were caused by peanut allergies. Meanwhile, around 10 people in the United Kingdom die each year because of food allergies." *See https://health.howstuffworks.com/diseases-conditions/allergies/allergy-basics/allergies-and-immune-system.htm*

117. What was the *motivation* of the UTMB nurse to say to Maxwell that 16,000+ deaths reported to VAERS in 2021 was "miniscule and insignificant"? Or that is is *less* than the 200 people who die in the U.S. each year of *food allergies?* Why would she fabricate such an absurd and false response to Maxwell? Had her *training* by Defendant UTMB taught her to deflect questions about the *unreasonable risk and substantial harm* of the Covid-19 inoculation so she could CLOSE THE SALE? If so, UTMB are knowingly and intentionally are thumbing their noses at the §148.002 statutory mandate that requires them to *warn of unreasonable risk of substantial harm of a vaccine,* said scheme devised so they can be unjustly enriched by the billions paid out for "Covid relief."

118. UTMB's actions rise to a level of GROSS NEGLIGENCE, WANTON ENDAGERMENT, and DERELICTION OF DUTY for its egregious violation §148.002.

119. Defendants, collectively, knowingly and intentionally create an ATMOSPHERE designed to discourage any kind of question about risk. Every part of their procedure is orchestrated to create the illusion that being injected is "safe and effective."

120. Because Defendants provided Maxwell NOTHING to show adverse reactions and failed or refused to TELL MAXWELL that it was possible that he could DIE from the injection or could be hospitalized, or have to go to the Emergency Room, or contract a illness that would disable him for the rest of his life. How could Maxwell even *suspect* the level of DANGER he was in had he allowed a NEEDLE to be jabbed into his arm and the potentially LETHAL INJECTION injected into his blood stream by the Defendants?

121. Maxwell has done NOTHING to deserve LETHAL INJECTION.

122. Maxwell, like all similarly situated individuals, Maxwell's fellow citizens, neighbors, cohorts, family, friends . . . actually . . . until a few weeks ago . . . believed that TEXAS LAWS protected him from these kinds of heinous actions that could have taken his life or left him disabled for the balance of his days.

123. Maxwell has a right to recover damages for being subjected to Defendants' scheme of fraudulent concealment and scheme of fraudulent inducement.

124. Defendants' carefully crafted and well-thought-out illegal schemes, all done in violation of Texas Informed Consent laws, are the proximate cause of Maxwell's damages, and the damages of other similarly situated individuals that, without intervention of the Court, will continue to allow unsuspecting Texans to be killed or permanently disabled for the rest of their lives.

125. Maxwell seeks Temporary and Permanent Injunction enjoining Defendants from violating the Texas Informed Consent Statutes.

VII. REMEDY AT LAW

126. Maxwell has no other remedy at law than to bring suit for recovery of his damages, and to provide opportunity for similarly situated individuals to be receive the statutory mandated protection provided them by Texas Informed Consent Statues, and/or to sue for damages, including but not limited to wrongful death and permanent disability caused by Defendants fraudulent concealment of the VAERS-REPORTED abhorrent risks of being injected with the experimental Covid-19 inoculations.

NON-REMOVAL TO FEDERAL COURT

127. Maxwell fully expects some or all the Defendants to attempt to remove this lawsuit to FEDERAL COURT. Each of the Defendants do business in Texas and have a registered agent in Texas who Maxwell has specified at Section I, PARTIES.

128. By choosing to do business in TEXAS, Defendants have subjected themselves to TEXAS LAW and cannot now attempt to run and hide from JUSTICE sought in TEXAS COURTS in an attempt to forum shop the case to a Court wherein they believe they would have a better outcome.

129. This Court can take and seal JURIDICTION of this Case by issuing the requested TRO.

130. Further, the Court can ORDER that Defendants are enjoined from filing any REMOVAL ACTION without first seeking LEAVE OF THE COURT and allowing for

a hearing and/or motions practice to specify what they believe would be the basis for removal.

131. In so doing, Maxwell would then be assured *due process* to file amended pleadings to CURE any portion of the Petition that could possibly warrant removal. Any other means or method of removal would be a violation of Maxwell's *due process* rights under the Texas Constitution.

132. Maxwell *only* cites Texas statutes. There is no basis for removal to federal court.

133. Maxwell requests that the Court include an injunction against any attempt to remove the case under the conditions listed hereinabove.

VIII.

CAUSES AND ACTION FOR DECLARTORY JUDGMENT

AND INJUNCTIVE RELIEF

COUNT 1: DECLARATORY JUDGMENT

134. Each and every allegation contained in the above Paragraphs is re-alleged as if fully stated herein.

135. **VIOLATION OF TEXAS INFORMED CONSENT STATUTES:** Defendants knowingly and willfully have orchestrated a scheme to fraudulently conceal from Maxwell and similarly situated individuals the known abhorrent risks of being injected with the Covid-19 inoculation, the entirety of their scheme being done in violation of Texas Informed Consent Statutes coded at Texas Administrative Code, Title 25, Health Services, Part 7, Texas Medical Disclosure Panel, Chapter 601, Informed Consent.

136. **Liability exists under Civil Practice and Remedies Code Title 6**, CHAPTER 148. LIABILITY DURING PANDEMIC EMERGENCY Sec. 148.002. PRODUCTS LIABILITY ACTIONS RELATED TO PANDEMIC EMERGENCY. Section (a) and (b)(2) and (3) which makes Defendants liable for selling "vaccines" knowing that "the product presents an unreasonable risk of substantial harm to an individual.

137. Maxwell seeks punitive damages for Defendants' fraudulent concealment of facts that were and are orchestrated to put blinders on Maxwell and similarly situated individuals knowing that inoculating Maxwell and similarly situated individuals could kill them, cause horrific suffering and permanently disability.

COUNT 2: TEMPORARY AND PERMANENT INJUNCTIVE RELIEF

138. Each and every allegation contained in the above Paragraphs is re-alleged as if fully stated herein.

139. In accordance with the declaratory judgment requested in Count I, Maxwell also petitions the Court for the permanent and final injunctive relief needed to effectuate this Court's binding judgment, Specifically, Maxwell seeks an order permanently enjoining Defendants from violating the Texas Informed Consent statues and willfully failing to warn Maxwell and similarly situated Texas citizens of the risks and dangers of the Covid-19 inoculation.

COUNT 3: APPLICATION FOR TEMPORARY RESTRAINING ORDER AND TEMPORARY INJUNCTION

140. Each and every allegation contained in the above Paragraphs is re-alleged as fully stated herein.

141. Maxwell is entitled to temporary injunction to restrain Defendants from continuing in the illegal scheme of fraudulent concealment of the abhorrent risks — as reported to the CDC and published in VAERS — so that Maxwell and Texas Citizens are given their statutory right of choice, the choice to say, "NO!" to being inoculated with a life-altering, potentially LETHAL injection.

142. Other similarly situated individuals, who will join Maxwell as co-plaintiffs when the suit is established, are entitled to a temporary injunction to preserve the status quo of the subject matter of the suit pending a judicial resolution of the merits. See Butnaru v. Ford Motor Co., 84 S.W.3d 198,204 (Tex. 2002). Other similarly situated individuals (Jane and John Does 1-100,000,000) may be facing harm of being terminated from employment by an employer who is practicing medicine without a license by mandating a medical procedure. Other similarly situated individuals, who will be known to the Court in the coming days enjoy the statutory injunction afforded them by the §601 Informed Consent Statutes and the Pandemic Laws codified at Title 6, §148.02 to be "warned" of the risks of the medical procedure so that they can DEFEND THEMSELVES from LETHAL INJECTION that can lead to DEATH or PERMANENT DISABILITY. *Self-defense* is an INALIENABLE RIGHT GIVEN BY GOD that cannot be taken away by an employer or by the State.

143. A plaintiff seeking a temporary injunction must plead and prove three elements: (1) a cause of action against the defendant and a probable right to the relief sought; (2) a probable and imminent injury, and (3) an irreparable injury or inadequate remedy at law. *Id*. As set forth below, Larry Maxwell seeks injunctive

relief to protect him from Defendants continued fraudulent concealment. Maxwell has the right to be properly warned of the dangers and abhorrent risks, and to be given the opportunity to REFUSE the medical procedure and **establish a RECORD of his having been shown the risks versus benefit of the injection and that he exercised his lawful right to refuse a medical procedure**. Maxwell can then, present this medical record, should he so choose, to anyone attempting to force an unlawful mandate on him (Maxwell), providing Maxwell even further grounds to seek protection from the next comer who seeks to practice medicine without a license or damage Maxwell through any other schemes conjured up to inoculate Maxwell against his will.

144. In conjunction therewith, Maxwell is entitled to a Temporary Restraining Order because he will suffer immediate and irreparable injury, loss, or damage before a hearing can be held on his request for a temporary injunction.

A Cause of Action against the Defendant and a Probable Right to the Relief Sought

145. The first prerequisite to immediate preliminary injunctive relief is a cause of action against the relevant Defendants, pursuant to which the plaintiff also has a probable right to the relief sought.

146. Maxwell has petitioned this Court for declaratory judgment to fully and finally adjudicate his rights to be warned of risks associated with a medical procedure. The legal principles that govern this dispute are both familiar and well settled. Just as the Court would do in any other dispute, allegation of fraud, fraudulent concealment, fraudulent inducement or deceptive trade practice, it must now use

these neutral principles of state law to determine the merits of Maxwell's factual allegations and the remedy necessary to make Maxwell as whole again as possible.

147. As established by the Texas Supreme Court, the factors relevant to this question include the necessity to determine the truthfulness of the factual allegations and to permanently enjoin such illegal behavior that is the causation of irreparable damage and harm to Maxwell.

148. After conducting a neutral and secular examination of the facts and documents, it is unimaginable that the court could make any finding other than that there is absolutely no legal basis on which Defendants can claim excuse or exemption for their unconscionable fraudulent concealment of the mountainous volume of nearly 800,000 adverse events, nearly 17,000 deaths and nearly 21,000 permanent disabilities reported to the CDC by doctors and individuals close to those who have suffered death, horrific pain, illness and disease because they were deceived by Defendants into believing the Covid-19 inoculation was "safe."

149. When Texas law is applied to these facts and instruments, there can be no doubt that Defendants committed fraudulent concealment, fraudulent inducement, and sought to INJECT Maxwell, for which they would have been PAID a soon-to-be-discovered sum of MONEY from the U.S. government, which, had Maxwell DIED from the injection, would have been the EXECUTIONER'S FEE.

150. Conspiracy to commit MURDER carries the same penalty as the MURDER.

151. Because Maxwell will almost certainly succeed on the merits of its case. Maxwell has shown his probable right to the relief sought herein.

Probable and Imminent Injury

152. The second prerequisite to immediate preliminary injunctive relief is proof of a probable and imminent injury.

153. The infliction of a real and immediate injury is not only possible, but clearly is the daily policy and practice of Defendants. Their illegal acts must be enjoined for the safety and sanctity of Maxwell and all Texas citizens.

154. The threat of the Defendants are imminent in that they will, up until the moment they are ENJOINED BY COURT ORDER, continue to fraudulently conceal the abhorrent risks associated with the Covid-19 inoculation and allow multiple other Texas citizens to risk death and/or life-long disability so they can continue to be UNJUSTLY ENRICHED BY POCKETING MORE MONEY FROM THE FEDERAL GOVERNMENT . . . the lives and health of Texas citizens be dammed!

Irreparable Injury and Inadequate Remedy at Law

155. The third and final prerequisite to preliminary injunctive relief is proof of an irreparable injury and inadequate remedy at law. Ordinarily, "[a]n injury is irreparable if the injured party cannot be adequately compensated in damages or if the damages cannot be measured by any certain pecuniary standard." Butnaru, 84 S.W.3d at 204. See also Texas Indus, Gas v. Phoenix Metallurgical Corp., 828S.W.2d 529, 588 (Tex. App - Houston [lst Dist.] 1992) (finding no adequate remedy at law when potential damages cannot be calculated).

156. Because the requested restraining order and injunction is intended to protect

Maxwell's right NOT to be deceived into taking a lethal injection, and Maxwell right to be warned about risks of medical procedure so he can defend himself against death and destruction of his life, the inadequacy of any legal remedy is presumed. Tx. Civ. Prac. & Rem. Code $ 65.011(a).

157. The concerns expressed above easily exceed the type of irreparable injury needed to justify preliminary injunctive relief.

158. In light of the foregoing concerns, likelihood of success, and probability of harm, a temporary restraining order and injunction while this suit is pending is necessary to enjoin the Defendants from continuing their illegal actions, fraudulent concealment that will cause more death and destroyed lives, to protect Maxwell and similarly situated individuals whatever additional scheme can and will likely be executed by Defendants seeking more MONETARY GAIN at the expense of the lives and health of Texas citizens who are completely unaware and previously trusted the Defendants to have their best interest at heart.

159. Compared to the immeasurable, irreparable, and irrevocable damage that might be experienced by Maxwell and similarly situated individuals if this Court does not issue an injunction, the harm that Defendants might suffer because of the requested injunction is wholly immaterial.

160. A temporary restraining order and temporary injunction are needed to enjoin Defendants from continuing to violate Texas law, to force them to warn Texas citizens of the dangers and risks of the Covid-19 inoculations, and, for those similarly situated individuals who are facing the destruction of their livelihood, preserve the status quo until such time as the merits can be adjudicated and be

determined by the civil courts.

161. Maxwell understands that under the rules the Court may direct him to post a reasonable bond. However, Maxwell requests that the Court take into consideration the illegal, fraudulent, criminal and heinous nature of Defendants' actions that have forced Maxwell to the last resort of seeking this lawful remedy, that Maxwell has already expended enormous time, energy and cost to seek sanctuary from Defendants' fraudulent practices, Maxwell's cost and expense to bring this legal action to protect both himself and similarly situated individuals across Texas, weighed against the unlikeliness that any actual harm could possibly come to Defendants.

162. Maxwell respectfully requests a hearing on his Petition for Temporary Injunction immediately.

IX.

PRAYER FOR RELIEF

For the reasons stated above, plaintiff, Larry Maxwell, prays for a declaratory judgment in his favor and injunctive relief as follows:

1) Declaratory Judgment finding that Defendants CVS PHARMACY, INC., H-E-B, LP, WAL-MART STORES TEXAS LLC, THE KROGER CO., WALGREEN CO., UTMB HEALTHCARE SYSTEMS, INC., knowingly and willfully engaged in fraudulent concealment, fraudulent inducement and have been unjustly enriched by failing to warn Maxwell and Texas citizens of the known abhorrent dangers of the Covid-19 inoculation, or provide Maxwell or any Texas citizen with the INFORMED CONSENT opportunity to say "NO" to the dangerous inoculation;
2) Injunctive relief both temporary and permanent as listed, defined and set forth hereinabove;

3) Award of actual damages for harm and injury to Maxwell through the knowing, intentional, willful and purposeful act to seek unjust enrichment at the expense of Maxwell's life and/or permanent damages and suffering of Maxwell for the balance of his days in the amount of not less than $100,000.00 per Defendant;
4) Award of exemplary damages in an amount of no less than $1,000,000.00 per Defendant to Maxwell, and damages as appropriate for all similarly situated individuals that will be based on their specific harm and damage as to each Plaintiff, to send a message to Defendants that their unconscionable acts to fraudulently conceal information and refuse to warn Maxwell and similarly situated Texas citizens, seeking to be unjustly enriched through what could be and will be death and destruction of the lives of Texas citizens is intolerable in a civilized society and must be eliminated from the marketplace and from Texas soil to ensure Texans can live free, can *defend their right to life and health*, to make their own choices as they see fit, to do what they deem to be in their own best interest;
5) All reasonable attorney's fees;
6) All costs of suit; and
7) For all such other further general and equitable relief to which Plaintiff Maxwell may be entitled.

Respectfully submitted,

10/20/2021

Larry Maxwell
2122 Tower Bridge Rd.
Pearland, Texas 77581
Mobile: 713-816-2942
Email: larry@earthloc.com

ADDENDUM 1

VERIFICATION

THE STATE OF TEXAS §
§
BRAZORIA COUNTY §

Before me, the undersigned Notary Public, on this day personally appeared ***Larry Maxwell,*** a person who identity is known to me. After I administered the oath to affiant, affiant testified:

1. My name is Larry Maxwell. I am over the age of 18, of sound mind, a citizen of the United States, and fully capable of making this verification.
2. I have read the **PLAINTIFF'S VERIFIED ORIGINAL PETITION FOR DELCLARATORY JUDGMENT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER AND TEMPORARY AND PERMANENT INJUNCTION** to be filed on behalf of Larry Maxwell. I am familiar with the facts alleged therein.
3. Based upon a reasonable review of the Petition together with my familiarity with the general subject matter, I attest to the truthfulness of the statements and factual allegations in the Petition made regarding Larry Maxwell and his direct interaction with Defendants CVS PHARMACY, INC., H-E-B, LP, WAL-MART STORES TEXAS LLC, THE KROGER CO., WALGREEN CO., UTMB HEALTHCARE SYSTEMS, INC.

Further affiant sayeth not.

Larry Maxwell
~~LARRY MAXWELL~~
for LAWRENCE S. MAXWELL

Sworn to and subscribed before me this 18 day of October ~~18~~, 2021.

A. MEDELLIN
NOTARY PUBLIC
ID# 133055557
State of Texas
Comm. Exp. 04-22-2025

A Medellin
Notary Public for the State of Texas
My Commission Expires: 04/22/2025

Pfizer-BioNTech COVID-19 Vaccine

En

Global Information About Pfizer-BioNTech COVID-19 Vaccine (also known as BNT162b2)

The approval status of the Pfizer-BioNTech COVID-19 Vaccine varies worldwide. In countries where the vaccine has not been approved by the relevant regulatory authority, it is an investigational drug, and its safety and efficacy have not been established.

As country information may vary, please choose the country below in which you are a licensed healthcare professional for more information on the Pfizer-BioNTech COVID-19 Vaccine.

This site is intended for Healthcare Professionals only.

I am a Healthcare Professional in:

Select

I am **NOT** a Healthcare Professional

Select

Report an Adverse Event

Information about the Pfizer-BioNTech COVID-19 Vaccine is only available for certain countries. This site will be updated as more information becomes available.

Terms of Use | Privacy Policy | Contact Us

Manufactured by
Pfizer Inc.
New York, NY
10017

Manufactured for
BioNTech Manufacturing
GmbH
An der Goldgrube 12
55131 Mainz, Germany

PP-CVV-USA-0259

EXHIBIT B
Maxwell v CVS, et al.

Grant Final Report
Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator:
Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

Team members:
Michael Klompas, MD, MPH

Performing Organization:
Harvard Pilgrim Health Care, Inc.

Project Officer:
Steve Bernstein

Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

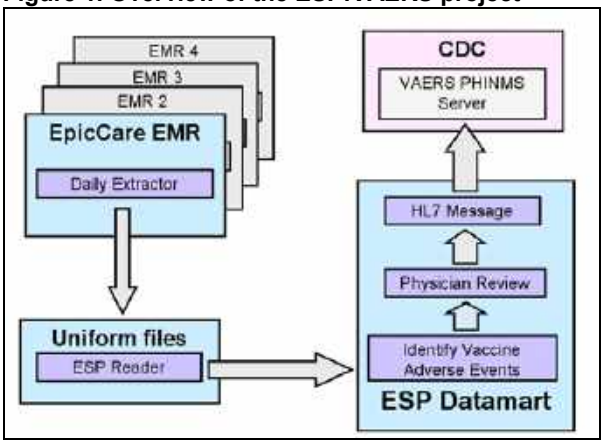
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration*, and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS)*, was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at:
http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

EXHIBIT C
Maxwell v CVS, et al.

U.S. FOOD & DRUG ADMINISTRATION

CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting
October 22, 2020

FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

"Safety throughout the lifecycle" approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities
  - Submitted for BLA and for EUA
  - Post-licensure commitment (PMC) – studies, registries for general safety concern
  - Post-licensure requirement (PMR) – clinical study, epidemiological study, registries, etc. to verify a specific safety signal
  - Routine pharmacovigilance – Passive surveillance (VAERS), review of safety literature, available studies, etc.

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - FDA BEST
   - FDA-CMS partnership

FDA Vaccine Surveillance Programs: Post-Licensure

1. **Passive Surveillance of Vaccines**
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     - **Management shared by CDC and FDA**

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   - FDA BEST
   - FDA-CMS partnership

VAERS

Vaccine Adverse Event Reporting System

Co-managed by CDC and FDA

CDC + FDA

http://vaers.hhs.gov

VAERS – FDA CBER Efforts

- CDC presentation covered VAERS so will provide summary of FDA efforts
- **FDA and CDC have weekly and bi-weekly coordination meetings** on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- **CBER DE Physicians will be reviewing the serious adverse event reports** from VAERS for COVID-19 vaccines – review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- **FDA will utilize statistical data-mining methods** to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

FDA Vaccine Surveillance Programs: Post-Licensure

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   - Vaccine Adverse Event Reporting System (VAERS)
     - Management shared by CDC and FDA

2. **Active Surveillance Monitoring Program**
   - **FDA BEST**
   - **FDA-CMS partnership**

FDA Vaccine– Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

FDA Amendments Act of 2007:

- Directed FDA to develop an active risk identification and analysis system – such as Sentinel, and later BEST, and others and covers ≥100 million persons

Prescription Drug User Fee Act VI (2017)

- Discussion between FDA and Industry on Priority Areas - Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc

FDA Vaccine– Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

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Prescription Drug User Fee Act VI (2017)

- Discussion between FDA and Industry on Priority Areas - Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc

1. FDA Biologics Effectiveness and Safety (BEST) System

- Several partners – Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, Academic organizations
- Represents variety of healthcare settings – inpatient, emergency department, outpatient, etc.

BEST Initiative Expansion

CLAIMS Data Sources

Data Sources	Type	Patients (millions)
MarketScan	Claims	254
Blue Health Intelligence	Claims	33.6
Optum	Claims	70
HealthCore	Claims	56
Healthagen	Claims	26
OneFlorida Clinical Research Consortium (Medicaid)	Claims	6.7

BEST Initiative Expansion
EHR Data Sources

Data Sources	Type	Patients (millions)
MedStar Health	EHR	6
IBM Explorys	EHR	90
Regenstrief Institute	Claims and EHR	20.2
Columbia University	EHR	6.6
University of Colorado	EHR	17
University of California San Francisco	EHR	3.2
PEDSnet Clinical Research Consortium	EHR	6.2
Optum EHR	EHR	105
OneFlorida Clinical Research Consortium	EHR	5.6
OneFlorida Clinical Research Consortium	Linked EHR-Claims	1.5
MarketScan Explorys Claims-EHR (CED)	Linked EHR-Claims	5.5
Optum	Linked EHR-Claims	50

2. CMS (Center for Medicare & Medicaid Services)

- **Federal Partners**
  - Ongoing FDA-CMS partnership on vaccine safety since 2002
  - Data cover very large population of approximately 55 million elderly US beneficiaries ≥65yrs of age
  - >92% of US elderly use Medicare so database represents the elderly population and not a sample
  - Represents variety of healthcare settings – inpatient, outpatient, etc.
  - Consists of claims data with access to medical charts

Limitations of Data Systems

- Not all claims and EHR data systems can be used to address a vaccine safety or effectiveness regulatory question

- Each data system has its limitations
  - Populations, healthcare settings, clinical detail, necessary parameters, data lag, exposures and outcomes that are captured

FDA COVID-19 vaccine safety surveillance planning

"Near real-time surveillance" or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using CMS data for COVID-19 vaccine RCA – near real time with efforts

FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

FDA Experience with Near Real Time Surveillance / RCA

FDA and CMS - RCA

- Conduct "near real-time" surveillance for annual influenza vaccine and Guillain-Barre Syndrome(GBS) since 2007
- Support confirmation of CDC rapid-cycle analyses of safety for seasonal influenza vaccine, Shingrix, and others

FDA Sentinel – Rapid Surveillance

- Near real-time, rapid surveillance in 2017-2018 seasonal influenza vaccine – evaluation of 6 health outcomes of interest

FDA COVID-19 vaccine safety surveillance Plans

- **Epidemiological analyses**
  - Need capability to resolve potential safety signals identified from near real-time surveillance, TreeScan and other sources
  - Rapid queries and small epidemiological studies
  - Larger self-controlled, cohort, comprehensive protocol-based studies

COVID-19 Vaccine Effectiveness Surveillance Plans

- COVID-19 vaccine(s) – there may be limited information available at licensure on level and duration of effectiveness
- Manufacturers may conduct certain COVID-19 vaccine effectiveness post-licensure studies
- FDA may conduct COVID-19 vaccine effectiveness studies
  - General effectiveness studies – including subpopulations of interest
  - Duration of protection studies
  - Others
- FDA coordinating COVID-19 Vaccine Effectiveness efforts with the CDC NCIRD through monthly, bi-monthly meetings

FDA-CMS-CDC Vaccine Effectiveness Experience

- Extensive experience with the data and methods needed to conduct vaccine effectiveness studies
- Produced several vaccine effectiveness and relative vaccine effectiveness studies for influenza and zoster vaccines
- Conducted duration of effectiveness analysis of Zostavax vaccine

CBER COVID-19 Vaccine Monitoring Transparency Considerations

- Master Protocols for Safety and Effectiveness outcomes
- Posting of draft protocols for public comment
- Posting of final protocols and final study reports on the BESTinitiative.org website

FDA-CMS Vaccine Effectiveness Experience

- Actively studying risk factors for COVID-19 and preparing to study safety and effectiveness of vaccines and biologics therapies
- More than 30 publications since 2012
- Results included in Congressional testimony

US Government-wide Efforts
COVID-19 Vaccine Monitoring

Large US Government Effort

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

US Government-wide Efforts
COVID-19 Vaccine Monitoring (2)

Large US Government Effort

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD

Acknowledgments

- Richard Forshee
- Azadeh Shoaibi
- Hui-Lee Wong
- CBER Surveillance Team
- Manette Niu
- CBER OBE Colleagues
- CDC Colleagues
- CMS Colleagues
- VA Colleagues
- FDA Partners: Acumen, IBM Watson – and new partners in FY2021

Thank you!

Questions?

EXHIBIT D
Maxwell v CVS, et al.

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

You are being offered either COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and also includes information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under Emergency Use Authorization (EUA) have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for prevention of COVID-19 in individuals 16 years of age and older. It is also authorized under EUA to provide:

- **a two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide:

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose for individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- **18 through 64 years of age at high risk of severe COVID-19**
- **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS COMIRNATY (COVID-19 VACCINE, mRNA) AND HOW IS IT RELATED TO THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever

[1] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?
The vaccine will be given to you as an injection into the muscle.

Primary Series: The vaccine is administered as a 2-dose series, 3 weeks apart. A third dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

Booster Dose: A single booster dose of the vaccine may be administered to individuals:
- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?
You should not get the vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE VACCINE?
The vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HAS THE VACCINE BEEN USED BEFORE?
Yes. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. Data from these clinical trials supported the Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine and the approval of COMIRNATY (COVID-19 Vaccine, mRNA). Millions of individuals have received the vaccine under EUA since December 11, 2020.

WHAT ARE THE BENEFITS OF THE VACCINE?
The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea

- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include either "COMIRNATY (COVID-19 Vaccine, mRNA)" or "Pfizer-BioNTech COVID-19 Vaccine EUA", as appropriate, in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

You may also be given an option to enroll in v-safe. V-safe is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, it is your choice to receive or not receive the vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COMIRNATY (COVID-19 VACCINE, mRNA) OR PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering receiving COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the vaccine. The third dose may still not provide full immunity to COVID-19 in people who are immunocompromised, and you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE VACCINE GIVE ME COVID-19?
No. The vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your next dose(s) of the vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?
No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?
Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer

exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-9.3

Revised: 22 September 2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 08/2021

Safety Data Sheet

Revision Date: Mar.-23-2021
Print Date: Sep.-9-2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name : ALC-0315

Catalog No. : HY-138170

CAS No. : 2036272-55-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company: MedChemExpress USA

Tel: 609-228-6898

Fax: 609-228-5909

E-mail: sales@medchemexpress.com

1.4 Emergency telephone number

Emergency Phone #: 609-228-6898

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin corrosion/irritation (Category 2),H315

Serious eye damage/eye irritation (Category 2A),H319

2.2 GHS Label elements, including precautionary statements

Pictogram 

Signal word Warning

Hazard statement(s)

H315 Causes skin irritation

H319 Causes serious eye irritation

Precautionary statement(s)

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/attention.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula:	$C_{48}H_{95}NO_5$
Molecular Weight:	766.27
CAS No. :	2036272-55-4

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; Do NOT induce vomiting; call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.2 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate

personnel to safe areas.

Refer to protective measures listed in sections 8.

6.2 Environmental precautions

Try to prevent further leakage or spillage. Keep the product away from drains or water courses.

6.3 Methods and materials for containment and cleaning up

Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol; Dispose of contaminated material according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

Recommended storage temperature: 4°C, protect from light

* In solvent : -80°C, 6 months; -20°C, 1 month (protect from light)

Shipping at room temperature if less than 2 weeks.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

This product contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering controls

Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

Personal protective equipment

Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Viscous liquid
Odor	No data available
Odor threshold	No data available

pH	No data available
Melting/freezing point	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids/alkalis, strong oxidising/reducing agents.

10.6 Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

Other decomposition products - no data available.

11.TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Classified based on available data. For more details, see section 2

Skin corrosion/irritation

Classified based on available data. For more details, see section 2

Serious eye damage/irritation

Classified based on available data. For more details, see section 2

Respiratory or skin sensitization

Classified based on available data. For more details, see section 2

Germ cell mutagenicity

Classified based on available data. For more details, see section 2

Carcinogenicity

IARC: No component of this product present at a level equal to or greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by ACGIH.

NTP: No component of this product present at a level equal to or greater than 0.1% is identified as a anticipated or confirmed carcinogen by NTP.

OSHA: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by OSHA.

Reproductive toxicity

Classified based on available data. For more details, see section 2

Specific target organ toxicity - single exposure

Classified based on available data. For more details, see section 2

Specific target organ toxicity - repeated exposure

Classified based on available data. For more details, see section 2

Aspiration hazard

Classified based on available data. For more details, see section 2

Additional information

This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumlative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose substance in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging

Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT (US)

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IMDG

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IATA

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

15. REGULATORY INFORMATION

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.

16. OTHER INFORMATION

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, **MODERNA COVID-19 VACCINE**, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each) 1 month apart.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

For information on clinical trials that are testing the use of the Moderna COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19
Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle and body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

Storage and Handling
The information in this Fact Sheet supersedes the information on the vial and carton labels.

During storage, minimize exposure to room light.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2° to 8°C (35° to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Dose Preparation
- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

CONTRAINDICATION

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *(see Full EUA Prescribing Information)*.

WARNINGS

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Moderna COVID-19 Vaccine.

Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. *(See Full EUA Prescribing Information)*

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 Vaccine.

USE WITH OTHER VACCINES
There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

- FDA has authorized the emergency use of the Moderna COVID-19 Vaccine, which is not an FDA-approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are evaluating the use of the Moderna COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION
In order to mitigate the risks of using this unapproved product under EUA and to optimize the

potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events* (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
    - cases of COVID-19 that result in hospitalization or death.

    Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

    *Serious adverse events are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect;
    - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be

reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM
This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

Although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization, visit FDA at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM
The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA)
PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial (range: 10-11 doses)	Thaw in refrigerated conditions between 2° to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour.
Maximum 15-Dose Vial (range: 13-15 doses)	Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
    - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
    - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
    - Each dose must contain 0.5 mL of vaccine.
    - If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
    - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with

conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence
Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.5 Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

Myocarditis and pericarditis have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination outside of clinical trials.

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=15,179) and participants receiving placebo (n=15,163) with at least 1 documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Local Adverse Reactions				
Pain	9,908 (86.9)	9,873 (89.9)	2,177 (19.1)	2,040 (18.7)
Pain, Grade 3[b]	366 (3.2)	506 (4.6)	23 (0.2)	22 (0.2)
Axillary swelling/tenderness	1,322 (11.6)	1,775 (16.2)	567 (5.0)	470 (4.3)
Axillary swelling/tenderness, Grade 3[b]	37 (0.3)	46 (0.4)	13 (0.1)	11 (0.1)
Swelling (hardness) ≥25 mm	767 (6.7)	1,389 (12.6)	34 (0.3)	36 (0.3)
Swelling (hardness), Grade 3[c]	62 (0.5)	182 (1.7)	3 (<0.1)	4 (<0.1)
Erythema (redness) ≥25 mm	344 (3.0)	982 (8.9)	47 (0.4)	43 (0.4)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=11,406) n (%)	**Dose 2** (N=10,985) n (%)	**Dose 1** (N=11,407) n (%)	**Dose 2** (N=10,918) n (%)
Erythema (redness), Grade 3[c]	34 (0.3)	210 (1.9)	11 (<0.1)	12 (0.1)
Systemic Adverse Reactions				
Fatigue	4,384 (38.4)	7,430 (67.6)	3,282 (28.8)	2,687 (24.6)
Fatigue, Grade 3[d]	120 (1.1)	1,174 (10.7)	83 (0.7)	86 (0.8)
Fatigue, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Headache	4,030 (35.3)	6,898 (62.8)	3,304 (29.0)	2,760 (25.3)
Headache, Grade 3[f]	219 (1.9)	553 (5.0)	162 (1.4)	129 (1.2)
Myalgia	2,699 (23.7)	6,769 (61.6)	1,628 (14.3)	1,411 (12.9)
Myalgia, Grade 3[d]	73 (0.6)	1,113 (10.1)	38 (0.3)	42 (0.4)
Arthralgia	1,893 (16.6)	4,993 (45.5)	1,327 (11.6)	1,172 (10.7)
Arthralgia, Grade 3[d]	47 (0.4)	647 (5.9)	29 (0.3)	37 (0.3)
Arthralgia, Grade 4[e]	1 (<0.1)	0 (0)	0 (0)	0 (0)
Chills	1,051 (9.2)	5,341 (48.6)	730 (6.4)	658 (6.0)
Chills, Grade 3[g]	17 (0.1)	164 (1.5)	8 (<0.1)	15 (0.1)
Nausea/vomiting	1,068 (9.4)	2,348 (21.4)	908 (8.0)	801 (7.3)
Nausea/vomiting, Grade 3[h]	6 (<0.1)	10 (<0.1)	8 (<0.1)	8 (<0.1)
Fever	105 (0.9)	1,908 (17.4)	37 (0.3)	39 (0.4)
Fever, Grade 3[i]	10 (<0.1)	184 (1.7)	1 (<0.1)	2 (<0.1)
Fever, Grade 4[j]	4 (<0.1)	12 (0.1)	4 (<0.1)	2 (<0.1)
Use of antipyretic or pain medication	2,656 (23.3)	6,292 (57.3)	1,523 (13.4)	1,248 (11.4)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.

[f] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
[g] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
[h] Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)

	Moderna COVID-19 Vaccine		**Placebo[a]**	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Local Adverse Reactions				
Pain	2,782 (74.0)	3,070 (83.2)	481 (12.8)	437 (12.0)
Pain, Grade 3[b]	50 (1.3)	98 (2.7)	32 (0.9)	18 (0.5)
Axillary swelling/tenderness	231 (6.1)	315 (8.5)	155 (4.1)	97 (2.7)
Axillary swelling/tenderness, Grade 3[b]	12 (0.3)	21 (0.6)	14 (0.4)	8 (0.2)
Swelling (hardness) ≥25 mm	165 (4.4)	400 (10.8)	18 (0.5)	13 (0.4)
Swelling (hardness), Grade 3[c]	20 (0.5)	72 (2.0)	3 (<0.1)	7 (0.2)
Erythema (redness) ≥25 mm	86 (2.3)	275 (7.5)	20 (0.5)	13 (0.4)
Erythema (redness), Grade 3[c]	8 (0.2)	77 (2.1)	2 (<0.1)	3 (<0.1)
Systemic Adverse Reactions				
Fatigue	1,251 (33.3)	2,152 (58.3)	851 (22.7)	716 (19.6)
Fatigue, Grade 3[d]	30 (0.8)	254 (6.9)	22 (0.6)	20 (0.5)
Headache	921 (24.5)	1,704 (46.2)	723 (19.3)	650 (17.8)
Headache, Grade 3[e]	52 (1.4)	106 (2.9)	34 (0.9)	33 (0.9)
Myalgia	742 (19.7)	1,739 (47.1)	443 (11.8)	398 (10.9)
Myalgia, Grade 3[d]	17 (0.5)	205 (5.6)	9 (0.2)	10 (0.3)
Arthralgia	618 (16.4)	1,291 (35.0)	456 (12.2)	397 (10.9)
Arthralgia, Grade 3[d]	13 (0.3)	123 (3.3)	8 (0.2)	7 (0.2)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,762) n (%)	**Dose 2** (N=3,692) n (%)	**Dose 1** (N=3,748) n (%)	**Dose 2** (N=3,648) n (%)
Chills	202 (5.4)	1,141 (30.9)	148 (4.0)	151 (4.1)
Chills, Grade 3[f]	7 (0.2)	27 (0.7)	6 (0.2)	2 (<0.1)
Nausea/vomiting	194 (5.2)	437 (11.8)	166 (4.4)	133 (3.6)
Nausea/vomiting, Grade 3[g]	4 (0.1)	10 (0.3)	4 (0.1)	3 (<0.1)
Nausea/vomiting, Grade 4[h]	0 (0)	1 (<0.1)	0 (0)	0 (0)
Fever	10 (0.3)	370 (10.0)	7 (0.2)	4 (0.1)
Fever, Grade 3[i]	1 (<0.1)	18 (0.5)	1 (<0.1)	0 (0)
Fever, Grade 4[j]	0 (0)	1 (<0.1)	2 (<0.1)	1 (<0.1)
Use of antipyretic or pain medication	673 (17.9)	1,546 (41.9)	477 (12.7)	329 (9.0)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).

[a] Placebo was a saline solution.

[b] Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.

[c] Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.

[d] Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.

[e] Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.

[f] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

[g] Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.

[h] Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.

[i] Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.

[j] Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported

by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell's palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell's palsy is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

In 60 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no Grade 3 or Grade 4 events were reported.

Serious Adverse Events

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell's palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history
- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Moderna COVID-19 Vaccine EUA" as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be

reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single human dose of Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed

infant or on milk production/excretion.

11.3 Pediatric Use

Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age *[see Clinical Trial Results and Supporting Data for EUA (18)]*. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants *[*see *Overall Safety Summary (6.1)]*.

11.5 Use in Immunocompromised

Safety and effectiveness of a third dose of the Moderna COVID-19 Vaccine have been tested in persons that received solid organ transplants. The administration of third vaccine doses appears to be only moderately effective in increasing antibody titers, so patients should be counselled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated as appropriate for their health status.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

A Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older is ongoing in the United States (NCT04470427). Randomization was stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one

NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per- Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)*
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room

air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

A separate randomized-controlled study has been conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years). A third dose of the Moderna COVID-19 Vaccine was administered to 60 individuals approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 Vaccine group and 10/57 (17.5%) of the placebo group.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials are supplied as follows:

NDC 80777-273-99	Carton of 10 multiple-dose vials, each vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL)
NDC 80777-273-98	Carton of 10 multiple-dose vials, each vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL)

During storage, minimize exposure to room light.

Store frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50°C (-58°F).

Vials may be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2°C to 8°C (35°F to 46°F)

If transport at -50° to -15°C (-58° to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2° to 8°C (35° to 46°F) when shipped using shipping containers which have been qualified to maintain 2° to 8°C (35° to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C (35° to 46°F), vials should not be refrozen and should be stored at 2° to 8°C (35° to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: Aug/27/2021

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/15/2021 Revision date 09/15/2021

*
1 Identification

· **Product identifier**

· **Trade name: SM-102**

· **Article number:** 33474
· **Application of the substance / the mixture**
This product is for research use - Not for human or veterinary diagnostic or therapeutic use. It is the responsibility of the purchaser to determine suitability for other applications.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Cayman Chemical Co.
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
USA

· **Information department:** Product safety department
· **Emergency telephone number:**
During normal opening times: +1 (734) 971-3335
US/CANADA: 800-424-9300
Outside US/CANADA: 703-741-5970

*
2 Hazard(s) identification

· **Classification of the substance or mixture**


GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.


GHS06 Skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.
Acute Tox. 3 H331 Toxic if inhaled.


GHS08 Health hazard

Carc. 1A H350 May cause cancer.

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GHS07

Eye Irrit. 2A H319 Causes serious eye irritation.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**

GHS02 GHS06 GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**
ethanol
· **Hazard statements**
H225 Highly flammable liquid and vapor.
H301+H331 Toxic if swallowed or if inhaled.
H319 Causes serious eye irritation.
H350 May cause cancer.
· **Precautionary statements**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 If swallowed: Immediately call a poison center/doctor.
P321 Specific treatment (see on this label).
P330 Rinse mouth.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P370+P378 In case of fire: Use CO2, powder or water spray to extinguish.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 2
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = *2
Fire = 0
Reactivity = 0

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

*
3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
CAS: 64-17-5 RTECS: KQ6300000	ethanol	90.0%

· **Other ingredients**		
2089251-47-6	SM-102	10.0%

*
4 First-aid measures

· **Description of first aid measures**
· **General information:**
Immediately remove any clothing soiled by the product.
Remove breathing apparatus only after contaminated clothing have been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.
· **After inhalation:**
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** Do not induce vomiting; immediately call for medical help.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

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5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** Mouth respiratory protective device.

*
6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
· **Protective Action Criteria for Chemicals**

· **PAC-1:**		
64-17-5	ethanol	1,800 ppm

· **PAC-2:**		
64-17-5	ethanol	3300* ppm

· **PAC-3:**		
64-17-5	ethanol	15000* ppm

*
7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
· **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store in a cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.

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· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**	
64-17-5 ethanol	
PEL	Long-term value: 1900 mg/m³, 1000 ppm
REL	Long-term value: 1900 mg/m³, 1000 ppm
TLV	Short-term value: 1000 ppm A3

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
· **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 6)

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Trade name: SM-102

(Contd. from page 5)

· **Eye protection:**

Tightly sealed goggles

*

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Liquid
Color:	According to product specification
· **Odor:**	Characteristic
· **Structural Formula**	C44H87NO5
· **Molecular Weight**	710.2
· **Odor threshold:**	Not determined.
· **Formulation**	A solution in ethanol
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	78 °C (172.4 °F)
· **Flash point:**	13 °C (55.4 °F)
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	982 °C (1,799.6 °F)
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product is not explosive. However, formation of explosive air/ vapor mixtures are possible.
· **Explosion limits:**	
Lower:	3.5 Vol %
Upper:	15 Vol %
· **Vapor pressure at 20 °C (68 °F):**	59 hPa (44.3 mm Hg)
· **Density at 20 °C (68 °F):**	1.47988 g/cm³ (12.3496 lbs/gal)
· **Bulk density:**	1,480 kg/m³
· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
Dynamic at 20 °C (68 °F):	0.56 mPas

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Trade name: SM-102

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Kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	90.0 %
VOC content:	90.00 % 1,331.9 g/l / 11.12 lb/gal
Solids content:	0.0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**		
64-17-5 ethanol		
Oral	TDLO	1.14 ml/kg (man)
	LD50	7,060 mg/kg (rat)
	TDLO	650 (man)
Dermal	LD50	40,000 mg/kg (rat)
Inhalative	LC50/4 h	5,900 mg/m³ (rat)
	LC50	20,000 mg/m³/10h (rat)
	TCLO	1,800 mg/m³/30m (hmn)
	LCLO	29,300 mg/m³/7h (mouse)
	TCLO	1,800 (hmn)
	LC50	10 h - 20,000 mg/m³ (rat)
	LD50 Inhalation TCLO	1,800 mg/m³/30m (hmn)
	LC50/4 h	20,000 mg/l (rat)
Irritation of skin	Irritation	20 mg/24h (rabbit)
	TDLO	1,800 mg/kg (wmn)
Irritation of eyes	Irritation	500 mg/24h (rabbit)
	Intraperitoneal LD50	280 mg/kg (rat)
	Data	500 mg/24h (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.

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· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Toxic
Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
64-17-5	ethanol	1

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

*
12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

*
14 Transport information

· **UN-Number**
· **DOT, IMDG, IATA** UN1170

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· **UN proper shipping name**	
· **DOT**	Ethanol solutions
· **IMDG**	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
· **IATA**	Ethanol solution
· **Transport hazard class(es)**	
· **DOT**	
· **Class**	3 Flammable liquids
· **Label**	3
· **IMDG, IATA**	
· **Class**	3 Flammable liquids
· **Label**	3
· **Packing group**	
· **DOT, IMDG, IATA**	II
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Warning: Flammable liquids
· **Hazard identification number (Kemler code):**	33
· **EMS Number:**	F-E,S-D
· **Stowage Category**	A
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **DOT**	
· **Quantity limitations**	On passenger aircraft/rail: 5 L On cargo aircraft only: 60 L
· **IMDG**	
· **Limited quantities (LQ)**	1L
· **Excepted quantities (EQ)**	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· **IATA**	

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· **Remarks:**	When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.
· **UN "Model Regulation":**	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

*
15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Sara**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

64-17-5	ethanol	ACTIVE

· **Hazardous Air Pollutants**
None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

64-17-5	ethanol

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

64-17-5	ethanol	A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **National regulations:**

· **Information about limitation of use:**
Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

(Contd. on page 11)

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Trade name: SM-102

(Contd. from page 10)

16 Other information

All chemicals may pose unknown hazards and should be used with caution. This SDS applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. Cayman Chemical Company assumes no responsibility for incidental or consequential damages, including lost profits, arising from the use of these data. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Cayman Chemical Company assumes no responsibility for the completeness or accuracy of the information contained herein.

· **Department issuing SDS:** Environment protection department.
· **Contact:** -
· **Date of preparation / last revision** 09/15/2021 / -
· **Abbreviations and acronyms:**
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
NIOSH: National Institute for Occupational Safety
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Carc. 1A: Carcinogenicity – Category 1A
· *** Data compared to the previous version altered.**

EXHIBIT H
Maxwell v CVS, et al.

ALLMTN,JD1,MJ CIV PP

U.S. District Court - District of Colorado
District of Colorado (Denver)
CIVIL DOCKET FOR CASE #: 1:21-cv-02228-RM-STV

Robert et al v. Austin et al
Assigned to: Judge Raymond P. Moore
Referred to: Magistrate Judge Scott T. Varholak
Cause: 10:1107 Armed Forces: Use Of Investigational New Drug

Date Filed: 08/17/2021
Jury Demand: None
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: Federal Question

Plaintiff

Dan Robert
SSGT, U.S. Army

represented by **Dale F. Saran**
Dale F. Saran, Attorney at Law
19744 116th Terrace
Olathe, KS 66061
508-415-8411
Email: dalesaran@gmail.com
ATTORNEY TO BE NOTICED

Todd Samson Callender
Disabled Rights Advocates PLLC
600 17th Street
Suite 2800 South
Denver, CO 80202
303-228-7065
Fax: 303-260-6401
Email: todd@dradvocates.com
ATTORNEY TO BE NOTICED

Plaintiff

Hollie Mulvihill
SSGT, USMC and Other Similarly Situated Individuals

represented by **Dale F. Saran**
(See above for address)
ATTORNEY TO BE NOTICED

Todd Samson Callender
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

Lloyd Austin
in his official capacity as Secretary of Defense, U.S. Department of Defense

Defendant

Xavier Becerra
in his official capacity as Secretary of the

U.S. Department of Health and Human Services

Defendant

Janet Woodcock
in her official capacity as Acting Commissioner of the U.S. Food & Drug Administration

Date Filed	#	Docket Text
08/17/2021	1	COMPLAINT against All Defendants (Filing fee $ 402,Receipt Number ACODC-8025727)Attorney Todd Samson Callender added to party Hollie Mulvihill(pty:pla), Attorney Todd Samson Callender added to party Dan Robert(pty:pla), filed by Dan Robert, Hollie Mulvihill. (Attachments: # 1 Exhibit Exhibits 1-8, # 2 Civil Cover Sheet Civil Cover Sheet, # 3 Summons Summons, # 4 Summons Summons, # 5 Summons Summons)(Callender, Todd) (Entered: 08/17/2021)
08/17/2021	2	ADVISORY NOTICE OF NONCOMPLIANCE WITH COURT RULES/PROCEDURES:re: 1 Complaint, filed by attorney Todd Samson Callender. **DO NOT REFILE THE DOCUMENT. Action to take -** counsel must submit a change of contact Through PACER.gov.(Text Only Entry) (cpomm,) (Entered: 08/17/2021)
08/17/2021	3	Case assigned to Magistrate Judge Scott T. Varholak. Text Only Entry (cpomm,) (Entered: 08/17/2021)
08/17/2021	4	Magistrate Judge consent form issued pursuant to D.C.COLO.LCivR 40.1, direct assignment of civil actions to full time magistrate judges. Summons submitted has incorrect caption and not issued. The summons must name all parties Please file completed summons for issuance using the event Summons Request. (cpomm,) (Entered: 08/17/2021)
08/20/2021	5	SUMMONS REQUEST as to Defendants re 1 Complaint, by Plaintiffs Hollie Mulvihill, Dan Robert. (Attachments: # 1 Summons, # 2 Summons)(Callender, Todd) (Entered: 08/20/2021)
08/25/2021	6	SUMMONSES issued by Clerk. (cmadr,) (Entered: 08/25/2021)
08/30/2021	7	MOTION for Temporary Restraining Order by Plaintiffs Hollie Mulvihill, Dan Robert. (Attachments: # 1 Exhibit 1-3)(Callender, Todd) (Entered: 08/30/2021)
08/30/2021	8	MINUTE ORDER In light of 7 Plaintiff's Motion for Temporary Restraining Order, the Clerk of Court is directed to reassign this case to a District Judge. See D.C.COLO.LCivR 40.1(c)(2)(a). SO ORDERED, by Magistrate Judge Scott T. Varholak on 8/30/2021. Text Only Entry (stvlc1,) (Entered: 08/30/2021)
08/30/2021	9	REASSIGNING JUDGE. Pursuant to 8 Order, this action is randomly reassigned to Judge Raymond P. Moore,. All future pleadings should be designated as **21-cv-2228-RM**. (Text Only Entry) (angar,) (Entered: 08/30/2021)
09/01/2021	10	ORDER REFERRING CASE to Magistrate Judge Scott T. Varholak. Pursuant to 28 U.S.C. § 636(b)(1)(A) and (B) and Fed. R. Civ. P. 72(a) and (b), this case is referred to the assigned United States Magistrate Judge to (1) convene a scheduling conference under Fed. R. Civ. P. 16(b) and enter a scheduling order meeting the requirements of D.C.COLO.LCivR 16.2, (2) conduct such status conferences and issue such orders necessary for compliance with the scheduling order, including amendments or modifications of the scheduling order upon a showing of good cause, (3) hear and determine pretrial matters, including discovery and other non-dispositive motions, (4) conduct a pretrial conference and enter a pretrial order, and (5) conduct hearings, including evidentiary hearings, and submit proposed findings of fact and recommendations for rulings on dispositive motions. Court sponsored alternative dispute resolution is governed by

		D.C.COLO.LCivR 16.6. On the recommendation or informal request of the magistrate judge or on the request of the parties by motion, this court may direct the parties to engage in an early neutral evaluation, a settlement conference, or another alternative dispute resolution proceeding. By Judge Raymond P. Moore on 9/1/2021. (Text Only Entry) (rmsec) (Entered: 09/01/2021)
09/01/2021	11	MINUTE ORDER: With the assignment of this matter, the parties are advised that throughout this case they are expected to be familiar and comply with not only the Local Rules of this District, but also Judge Raymond P. Moore's Civil Practice Standards, which may be found at: http://www.cod.uscourts.gov/JudicialOfficers/ActiveArticleIIIJudges/HonRaymondPMoore.aspx. SO ORDERED by Judge Raymond P. Moore on 9/1/2021. (Text Only Entry) (rmsec) (Entered: 09/01/2021)
09/01/2021	12	ORDER. The Court finds the requirements for a TRO are not satisfied and DENIES Plaintiffs' Motion (ECF No. 7). By Judge Raymond P. Moore on 09/01/2021. (athom,) (Entered: 09/01/2021)
09/23/2021	13	MOTION for Preliminary Injunction by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/23/2021)
09/23/2021	14	Exhibits in Support *1A_Exhibit A - Samuel N Sigoloff CV 2021* by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/23/2021)
09/23/2021	15	Exhibits in Support *2A_Exhibit B - COMIRNATY Package Insert* by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/23/2021)
09/23/2021	16	MOTION for Preliminary Injunction by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/23/2021)
09/24/2021	17	Exhibits in Support *Motion For Preliminary Injunction* by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/24/2021)
09/24/2021	18	AMENDED COMPLAINT *Robert et al v Austin et al* against Lloyd Austin, Xavier Becerra, Janet Woodcock, filed by Dan Robert, Hollie Mulvihill.(Callender, Todd) (Entered: 09/24/2021)
09/24/2021	19	ADVISORY NOTICE OF NONCOMPLIANCE WITH COURT RULES/PROCEDURES:re: 13 Final MOTION for Preliminary Injunction 16 Final MOTION for Preliminary Injunction 18 Amended Complaint filed by attorney Todd Callender. Attorney or pro se has used an incorrect signature format in violation of D.C.COLO.LCivR 5.1(a) and 4.3(a) of the Electronic Case Filing Procedures (Civil cases). **DO NOT REFILE THE DOCUMENT.** In the future, the filer must affix an electronic s/signature and s/followed by a typed, not an inked, signature to all future documents.(Text Only Entry) (evana,) (Entered: 09/24/2021)
09/24/2021	20	MINUTE ORDER: Before the Court are two Motions for Preliminary Injunction 13 16 . On or before September 29, 2021, Plaintiffs are ORDERED to file a motion withdrawing one of them. Plaintiffs have also filed an Amended Complaint 18 , albeit without seeking leave to do so. *See* Fed. R. Civ. P. 15(a)(1). Pursuant to D.C.COLO.LCivR 15.1(a), a party "who files an amended pleading under Fed. R. Civ. P. 15(a)(1) or with the consent of the opposing party shall file a separate notice of filing the amended pleading and shall attach as an exhibit a copy of the amended pleading which strikes through (e.g., ~~strikes through~~) the text to be deleted and underlines (e.g., underlines) the text to be added." Accordingly, Plaintiffs are further ORDERED to comply with the Local Rule on or before September 29, 2021. SO ORDERED by Judge Raymond P. Moore on 9/24/2021. (Text Only Entry) (rmsec) (Entered: 09/24/2021)
09/24/2021	21	Exhibits in Support 18 Amended Complaint Robert et al v Austin et al by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Modified on 9/27/2021 edited to add link)(evana,). (Entered: 09/24/2021)
09/24/2021	22	Exhibits in Support Exhibits for 18 Amended Complaint by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/24/2021)
09/24/2021	23	NOTICE of Entry of Appearance by Dale F. Saran on behalf of All Plaintiffs Attorney Dale F.

		Saran added to party Hollie Mulvihill(pty:pla), Attorney Dale F. Saran added to party Dan Robert(pty:pla) (Saran, Dale) (Entered: 09/24/2021)
09/29/2021	24	MOTION to Withdraw 15 Exhibits, 17 Exhibits, 13 Final MOTION for Preliminary Injunction , 22 Exhibits, 16 Final MOTION for Preliminary Injunction , 21 Exhibits, 14 Exhibits by Plaintiffs Hollie Mulvihill, Dan Robert. (Callender, Todd) (Entered: 09/29/2021)
09/29/2021	25	ORDER: Before the Court is Plaintiffs' Motion to Withdraw 24 , seeking to withdraw several exhibits and two motions. The Motion is GRANTED. The Motions for Preliminary Injunction 13 , 16 are deemed WITHDRAWN as well as the Exhibits 14 , 15 , 17 , 21 , 22 . SO ORDERED by Judge Raymond P. Moore on 9/29/2021. (Text Only Entry)(rmsec) (Entered: 09/29/2021)
09/29/2021	26	First MOTION to Amend/Correct/Modify *COMPLAINT* by Plaintiffs Hollie Mulvihill, Dan Robert. (Attachments: # 1 Proposed Document AMENDED COMPLAINT, # 2 Exhibit FDA BLA APPROVAL LTR, # 3 Exhibit FDA PFIZER EUA LTR 08.23.21, # 4 Exhibit BOYCE LTR TO HCP, # 5 Exhibit FDA BNT FACT SHEET, # 6 Exhibit SEC DEF MEMO, # 7 Exhibit SJA UPDATE FULL, # 8 Exhibit ASST SEC DEF MEMO 09.14.21, # 9 Exhibit DON BU-MED) (Callender, Todd) (Entered: 09/29/2021)
10/01/2021	27	ORDER: Before the Court is Plaintiffs' Motion for Leave to File Amended Complaint 26 , which the Court hereby GRANTS. Plaintiffs' Amended Complaint 18 is hereby STRICKEN, as Plaintiffs indicate in their Motion it was file erroneously. Plaintiffs are ORDERED to file a clean version of the proposed Amended Complaint attached to their Motion [23-1] on or before October 6, 2021, and the Clerk shall docket it as such. SO ORDERED by Judge Raymond P. Moore on 10/1/2021. (Text Only Entry)(rmsec) (Entered: 10/01/2021)

PACER Service Center			
Transaction Receipt			
10/03/2021 10:04:14			
PACER Login:	lmax1954	**Client Code:**	
Description:	Docket Report	**Search Criteria:**	1:21-cv-02228-RM-STV
Billable Pages:	4	**Cost:**	0.40

EXHIBIT I
Maxwell vs. CVS, et al.

EXHIBIT 4

I, Lieutenant Colonel Theresa Long, MD, MPH, FS, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

I am an adult of sound mind, 47 years old, and declare that the information herein is true, correct and complete and that I have voluntarily affirmed this affidavit based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

SUBSCRIBED AND SWORN TO BEFORE ME on the 22nd day of September 2021, to certify which witness my hand and official seal.

/S/ Nicholas S. Babel
Notary Public for the Judge Advocates General, Alabama

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

DANIEL ROBERT	*	
SSGT, U.S. ARMY	*	
	*	
HOLLI MULVIHILL	*	
SSGT, USMC	*	
	*	
Plaintiffs,	*	
	*	
v.	*	
	*	**Civil Action No. 1:21-cv-002228**
LLOYD AUSTIN	*	
Secretary of Defense,	*	
U.S. DEPARTMENT OF DEFENSE	*	
Washington, D.C. 20301	*	
	*	
and	*	
	*	
XAVIER BECERRA	*	
Secretary of the U.S. Department of	*	
Health and Human Services	*	
U.S. DEPARTMENT OF HEALTH	*	
AND HUMAN SERVICES	*	
	*	
and	*	
	*	
JANET WOODCOCK, Acting	*	
Commissioner of the Food & Drug	*	

Administration	*
U.S. FOOD AND	*
DRUG ADMINISTRATION	*
	*
UNITED STATES OF AMERICA	*
	*
Defendants.	*

AFFIDAVIT OF LTC. THERESA LONG M.D. IN SUPPORT OF A MOTION FOR A PRELIMINARY INJUNCTION ORDER

I, Lieutenant Colonel **Theresa Long**, MD, MPH, FS being duly sworn, depose and state as follows:

1. I make this affidavit, as a whistle blower under the Military Whistleblower Protection Act, Title 10 U.S.C. § 1034, in support of the above referenced MOTION as expert testimony in support thereof.

2. The expert opinions expressed here are my own and arrived at from my persons, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports and other information relevant to the subject matter and are not necessarily those of the Army or Department of Defense.

Experience & Credentials

3. I am competent to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

4. After receiving a bachelor's degree from the University of Texas Austin, completed my medical degree from the University of Texas Health Science Center at Houston Medical School in 2008. I served as a Field Surgeon for ten years and went on to complete a residency in Aerospace and Occupational Medicine at the United States Army School of Aviation Medicine, Fort Rucker, AL. I hold a Master's in Public Health, and I have been trained by the Combat Readiness Center at Ft. Rucker as an Aviation Safety Officer. Additionally, I have trained in the Medical Management of Chemical and Biological Causalities at Fort Detrick and USAMIIRD.

5. I am board certified in flight Aerospace Medicine and board eligible in Occupational Medicine.

6. I am currently serving as the Brigade Surgeon for the 1st Aviation Brigade Ft. Rucker, Alabama and am responsible for certifying the health, mental and physical ability, and readiness for all nearly 4,000 individuals on flight status on this post.

7. My appended *curriculum vitae* further demonstrates my academic and scientific achievements by me over the past thirteen years.

8. Prior to the outset of the pandemic, I received specialized military training from Infectious Disease doctors from the Army, Navy and Air Force on emerging infectious disease threats, FEMA training, Emergency preparedness training, Medical effects of Ionizing Radiation, OSHA, Aerospace Toxicology, Epidemiology, Biostatistics, medical research and disaster

planning. More recently I have functioned as a medical and scientific advisor to an Aviation training Brigade seeking to identify risk mitigation strategies, and bio statistical analysis of SARS-Cov-2 ("Covid 19") infections in both vaccinated and unvaccinated Soldiers. In so doing, I have identified, diagnosed and treated Covid 19 pathogenic infections. I have observed vaccine adverse events following the administration of EUA vaccines, and followed the success of Soldiers who obtained various Covid 19 therapies outside the military. The majority of the service members within the DOD population are young and in good physical condition. Military aviators are a subset of the military population that has to meet the most stringent medical standards to be on flight status. The population of student pilots I take care of are primarily in their 20s-30s, males and in excellent physical condition. The risk of serious illness or death in this population from SARs-CoV-2 is minimal, with a survival rate of 99.997%.

9. In observing, studying and analyzing all the available data, information, samples, experiences, histories and results of these treatments and inoculations provided, I have formulated a professional opinion, which requires me to report those findings to superiors in the chain of command and colleagues in the military. I have done so with mixed results in terms of acceptance, rejection and threats of punishment for so sharing.

10. The application of risk management is critical to the safety and success in both medicine and aviation. Aerospace Medicine is a specialty devoted to safety of flight by the aeromedical dispositioning and treatment of flight crew members, as accomplished by the consistent and careful application of risk mitigation and management strategies. ATP 5-19, 1-3. Risk Management (RM)[1] outlines a disciplined approach to express a risk level in terms readily understood at all echelons.

[1] adminpubs.tradoc.army.mil/regulations/TR385-2withChange1.docx

11. 1-6. States, "A risk decision is a commander, leader, or individual's determination to accept or not accept. The risk(s) associated with an action he or she will take or will direct others to take. RM is only effective when specific information about hazards and risks is passed to the appropriate level of command for a risk decision. Subordinates must pass specific risk information up the chain of command."

12. "When the specific information about hazards and risks is passed to the appropriate level of command for a risk decision. Subordinates must pass specific risk information up the chain of command. Conversely, the higher command must provide subordinates making risk decisions or implementing controls with the established risk tolerance—the level of risk the responsible commander is willing to accept. RM application must be inclusive; those executing an operation and those directing it participate in an integrated process".

13. 1-7. States, "In the context of RM, a control is an action taken to eliminate a hazard or to reduce its risk. Commanders establish local policies and regulations if appropriate".

14. The five steps of Risk management include; 1. Identify the hazards, 2. Assess the hazards, 3. Develop controls and make risk decisions, 4. Implement controls, 5. Supervise and evaluate.

15. It is therefore my responsibility and that of every leaders to apply the steps of risk management to the current pandemic and countermeasures used. **The CDC and the FDA are civilian agencies that do not have the mission of National Defense that the DOD has.** Guidance and recommendations made by these civilian agencies must be filtered through strategic perspective of national defense and the potential risks recommendations may have on the health

of the entire fighting force. Ensuring that the health of the fighting force is not compromised is a strategic imperative, for which **every** military physician is responsible to ensure.

16. **Step 1: Identify the hazards:** As defined by FM 1-02.1 Operational Terms, pg. 1-48, hazard is a condition with the potential to cause injury, illness, or death of personnel; damage to or loss of equipment or property; or mission degradation.

17. **Step 2: Assess the Hazards:** There are numerous therapeutic agents that have been proven to significantly reduce infection and therefore provide protection from the harmful effects of SARs-CoV-2.

18. Literature has demonstrated that natural immunity is durable, completed, and superior to vaccination immunity to SARs-CoV-2. mRNA vaccines produced by Pfizer and Moderna both have been linked to myocarditis, especially in young males between 16-24 years old,[2] The majority of young new Army aviators are in their early twenties. We know there is a risk of myocarditis with **each** mRNA vaccination. We additionally now know that vaccination does not necessarily prevent infection or transmission of SARs-CoV-2Therefore individuals fully vaccinated with mRNA vaccines have at least two independent risk factors for myocarditis after vaccination. Additional boaster shots add more risk. It is impossible to perform a risk/benefit analysis on the use of mRNA as counter measures to SARs-CoV-2 without further data... Use of mRNA vaccines in our fighting force, presents a risk of undetermined magnitude, in a population in which **less than 20 active-duty personnel out of 1.4 million, died of the underlying SARs-CoV-2.**

19. Aircrew Training Program (ATP) 5-19, 1-8. **Accept No Unnecessary Risk**, states, "An unnecessary risk is any risk that, if taken, **will not contribute meaningfully to mission**

[2] https://www.fda.gov/media/151733/download

accomplishment or will needlessly endanger lives or resources. Army leaders accept only a level of risk in which the potential benefit outweighs the potential loss.

20. Research shows that most individuals with myocarditis do not have any symptoms. Complications of myocarditis include dilated cardiomyopathy, arrhythmias, sudden cardiac death and carries a mortality rate of 20% at one year and 50% at 5 years. According to the National Center for Biotechnology Information, U.S. National Library of Medicine, "despite optimal medical management, overall mortality has not changed in the last 30 years".

21. **Step 3: Develop controls and make risk decisions:** Because vaccination with mRNA increase the risk of myocarditis, a comprehensive screening program should be implemented immediately to identify individuals who have been affected and attempt to mitigate immediate risks and long-term disability.

22. **Step 4: Implement Controls:** Send out clear guidance to all DOD healthcare professionals on risks of-vaccination myocarditis. Compulsory SARs-CoV-2 mRNA vaccination program should be immediately suspended until research can be done to determine the true magnitude of risk of myocarditis in individuals who have been vaccinated. We must evaluate and immediately implement alternatives to mRNA vaccines, to include Ivermectin (FDA approved 1996), Remdesivir (FDA approved 2020), Hydroxychloroquine (FDA approved 1955), Regeneron (FDA EU approved 2020). Review VAERS data for deaths from COVID for age-matched data and data from active duty COVID deaths within the DOD to perform a risk/benefit analysis.

23. **Step 5: Supervise and evaluate:** We must establish a screening program to identify those at increased risk of myocarditis, i.e. those that have, received mRNA vaccinations with Comirnaty, BioNTech or Moderna, or have any of the following symptoms chest pain, shortness of breath or palpitations They should have screening tested performed in accordance

with the CDC recommendations prior to return to flight duties. Per the CDC guidelines the initial evaluation of individuals identified according to the above criteria include; ECG, troponion level, inflammatory markers such as the C-reactive protein and erythrocyte sedimentation rate. It should be noted that the gold standard for diagnosis of myocarditis is end myocardial biopsy (EMB).

24. Given that the labels for Comirnaty and BioNtech clearly state that the vaccination should not be given to individuals that are allergic to ingredients. I have noted that one of the primary ingredients of the Lipid Nanoparticle delivery system is "ALC 1035" (two attachments, parts highlighted) in the Pfizer shots. The forth attachment is the toxicity report on ALC-1035, which comprises between 30-50% of the total ingredients.[3] The Safety Data Sheet, (attached as Exhibit B) for this primary ingredient states that it is Category 2 under the OSHA HCS regulations (21 CFR 1910) and includes several concerning warnings, including but not limited to:

a. Seek medical attention if it comes into contact with your skin;

b. If inhaled and If breathing is difficult, give cardiopulmonary resuscitation

c. Evacuate if there is an environmental spill

d. the chemical, physical, and toxicological properties have not been completely investigated

e. Caution: Product has not been fully validated for medical applications. For research use only

25. Other journals and scientific papers also denote that this particular ingredient has never been used in humans before.[4] To be abundantly clear, one of the listed primary

[3] https://thetattyjournal.org/2021/07/17/expert-evidence-regarding-comirnaty-pfizer-covid-19-mrna-vaccine-for-children/

[4] https://www.verywellhealth.com/peg-compound-in-covid-19-vaccine-5119161#citation-2

ingredients of these injectables is Polyethylene glycol ("PEG") which is a derivative of ethylene oxide. Polyethylene Glycol is the active ingredient in antifreeze. While it is hard to believe this is a key ingredient in these vaccines, it would explain the increased cardiovascular risk to users of the BioNTech or Comirnaty shots. I cannot discern what form of alchemy Pfizer and the FDA have discovered that would make antifreeze into a healthful cure to the human body. Others seem to agree my point per recent scientific studies that caused a group of 57 doctors and scientists to call for an immediate halt to the vaccination program.[5] In short, this antifreeze ingredient is being studied for the first time in human injectables. According to the VAERS data, which admittedly underreports by as much as 100 times the actual SAE's, there are well more than 600,000 documented Serious Adverse Events (ones requiring medical attention) alone and more than 13,000 fatalities directly linked to this particular vaccine. I cannot understand how this vaccine remains on the list of available options to treat Covid, when there are so many other non-deadly or injurious options available.

26. As such, I believe it is reasonable to conclude that many humans are allergic to these dangerous and deadly toxins and therefore should not take vaccinations with either Comirnaty or BioNtech. Again, I have identified an agent that possess a significant hazard to Soldiers, which would fall under DA Pam 385-61 Toxic Safety Standards cited in 2-11.

27. My assessment is that ALC 0315 is a known toxin with little study, specifically restricted to "research only" and effectively has no prior use history, with the SDS

[5] https://en-volve.com/2021/05/08/57-top-scientists-and-doctors-release-shocking-study-on-covid-vaccines-and-demand-immediate-stop-to-all-vaccinations/"

designation of (GHS02), listed as H315 and H319, in other words, hazardous if inhaled, ingested or in contact with skin and a health hazard with the designation (P313). A review of the SDS outlines that it is not for human or veterinary use,

28. I have not taken significant time to delineate the risks of other Covid 19 Vaccines other than the Safety Data Sheet of Moderna's key ingredient, SM-102 (attached as Exhibit C). Suffice it to say that SM-102 is significantly more dangerous than the Pfizer ALC 3015 and it appears that the DOD is not actively acquiring or distributing this IND/EUA. If the DOD were to undertake use of the Moderna vaccine, one can expect a much higher Serious Adverse Event and fatality rate given that SM-102 carries an express warning "Skull and Crossbones" characterized under the GHS06 and GHS08. In other words, this Moderna ingredient is deadly.

29. Given that these Covid 19 Vaccines were both Investigational New Drugs and Emergency Use Authorization vaccines, I have taken considerable time to understand potential risks, hazards and dangers these and any new drug or Investigational New Drug will may have on the health, safety and operational readiness or ability of pilots under my care and at this post. I have sought to research military records and track systems for recording events and Serious Adverse Events and fatalities associated with vaccines, new vaccines and Emergency Use, investigational vaccines in computer data systems recommended by the General Accounting Office in 2002 and ordered to be developed and implemented by the Secretary of Defense in 2003.

30. A weekly MEDSITREP report fails to report the CDC data from VAERS or internal data regarding vaccine adverse events. Despite recommendation made by the Government Accountability Office in the GAO's survey of Guard and Reserve Pilots and

Aircrew GAO-02-445, published Sep 20,2002, in which it was recommended that the Secretary of Defense should direct the establishment of an active surveillance program (unlike the passive VAERS) to identify and monitor adverse events, was not implemented. I have been unable to locate, access or asses any data, data base or internal system to track, store, evaluate or research the effects of vaccines on our military members or pilots.

31. I have also reviewed scientific data and peer reviewed studies that discuss, analyze results and conclude that natural immunity is at least as good if not far superior to any Covid Vaccine available at this time. I have also reviewed Dr. Peter McCullough's sworn affidavit in support of and in relation to the Complaint filed in this case and have reviewed its supporting data. An additional peer-reviewed study not referenced in Dr. McCullough's materials also supports the same conclusions drawn and reports that natural immunity provides a 13 fold better protection against Covid 19 infections than any currently available Covid 19 Vaccine[6]. More recently, in a meeting of the FDA Advisory Committee on September 17 of this year, fourteen of seventeen members voted against the authorization of any Covid booster vaccines in the juvenile age group having noted that the vaccine program has breached the defining test under the EUA statute as to whether the experimental treatment benefits outweigh the risks; in fact, they found the shots are far more dangerous than helpful in this age group and some voiced concerns that this would apply generally to all age groups.[7]

[6] https://www.sciencemag.org/news/2021/08/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-no-infection-parties

[7] https://www.thegatewaypundit.com/2021/09/fda-hearing-doctors-experts-testify-government-data-demonstrates-covid-shots-dangerous-may-kill-save-video/ & https://www.youtube.com/watch?v=WFph7-6t34M

32. I am also aware of the Secretary of Defense Austin's order in relation to Covid Vaccine mandates made this week. In an information paper, it was stated that, "Unit personnel should use only as much force as necessary to assist medical personnel with immunizations." The use of force to administer a medical treatment or therapy against the will of a mentally competent individual constitutes medical battery and universally violates medical ethics. Currently, I am not aware of the Comirnaty available within the DOD. Emergency Use Authorized vaccines, despite the attempt to characterize some of them as approved despite such approved versions not being available and regardless of a military member's prior immunity to Covid 19; even where it may be demonstrated with a recent antibody test.

33. Finally, I have reviewed a recent study *entitled "US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, All Cause Severe Morbidity," by J. Bart Classen, MD and published in Trends in Internal Medicine; August 25, 2021.* Attached as Exhibit D.

34. I have also seen policies, memoranda and guidance as it relates to exemptions for vaccinations as fully detailed in Army Regulation 40-562, which purport to eliminate any exemption for prior immunity by our military personnel.

Opinion

35. I have reviewed the Motion for a Preliminary Injunction which discusses the issue of prior immunity benefits outweighing the risks of using experimental Covid 19 Vaccines, together with proposed exhibits and materials cited therein. In opinion on this

subject matter, I am also drawing my own conclusions that will be put into practice in my current role as an Army flight surgeon knowing full well the horrific repercussions this decision may befall me in terms of my career, my relationships and life as an Army doctor.

36. I personally observed the most physically fit female Soldier I have seen in over 20 years in the Army, go from Colligate level athlete training for Ranger School, to being physically debilitated with cardiac problems, newly diagnosed pituitary brain tumor, thyroid dysfunction within weeks of getting vaccinated. Several military physicians have shared with me their firsthand experience with a significant increase in the number of young Soldiers with migraines, menstrual irregularities, cancer, suspected myocarditis and reporting cardiac symptoms after vaccination. Numerous Soldiers and DOD civilians have told me of how they were sick, bed-ridden, debilitated, and unable to work for days to weeks after vaccination. I have also recently reviewed three flight crew members' medical records, all of which presented with both significant and aggressive systemic health issues. Today I received word of one fatality and two ICU cases on Fort Hood; the deceased was an Army pilot who could have been flying at the time. All three pulmonary embolism events happened within 48 hours of their vaccination. I cannot attribute this result to anything other than the Covid 19 vaccines as the source of these events. Each person was in top physical condition before the inoculation and each suffered the event within 2 days post vaccination. Correlation by itself does not equal causation, however, significant causal patterns do exist that raise correlation into a probable cause; and the burden to prove otherwise falls on the authorities such as the

CDC, FDA, and pharmaceutical manufacturers. I find the illnesses, injuries and fatalities observed to be the proximate and causal effect of the Covid 19 vaccinations.

38. I can report of knowing over fifteen military physicians and healthcare providers who have shared experiences of having their safety concerns ignored and being ostracized for expressing or reporting safety concerns as they relate to COVID vaccinations. The politicization of SARs-CoV-2, treatments and vaccination strategies have completely compromised long-standing safety mechanisms, open and honest dialogue, and the trust of our service members in their health system and healthcare providers.

39. The subject matter of this Motion for a Preliminary Injunction and its devastating effects on members of the military compel me to conclude and conduct accordingly as follows:

a) None of the ordered Emergency Use Covid 19 vaccines can or will provide better immunity than an infection-recovered person;

b) All three of the EUA Covid 19 vaccines (Comirnaty is not available), in the age group and fitness level of my patients, are more risky, harmful and dangerous than having no vaccine at all, whether a person is Covid recovered or facing a Covid 19 infection;

c) Direct evidence exists and suggests that all persons who have received a Covid 19 Vaccine are damaged in their cardiovascular system in an irreparable and irrevocable manner;

d) Due to the Spike protein production that is engineered into the user's genome, each such recipient of the Covid 19 Vaccines already has micro clots in their cardiovascular system that present a danger to their health and safety;

e) That such micro clots over time will become bigger clots by the very nature of the shape and composition of the Spike proteins being produced and said proteins are found throughout the user's body, including the brain;

f) That at the initial stage of this damage the micro clots can only be discovered by a biopsy or Magnetic Resonance Image ("MRI") scan;

g) That due to the fact that there is no functional myocardial screening currently being conducted, it is my professional opinion that substantial foreseen risks currently exist, which require proper screening of all flight crews.

h) That, by virtue of their occupations, said flight crews present extraordinary risks to themselves and others given the equipment they operate, munitions carried thereon and areas of operation in close proximity to populated areas.

i) That, without any current screening procedures in place, including any Aero Message (flight surgeon notice) relating to this demonstrable and identifiable risk, I must and will therefore ground all active flight personnel who received the vaccinations until such time as the causation of these serious systemic health risks can be more fully and adequately assessed.

j) That, based on the DOD's own protocols and studies, the only two valuable methodologies to adequately assess this risk are through MRI imaging or cardio biopsy which must be carried-out.

k) That, in accordance with the foregoing, I hereby recommend to the Secretary of Defense that all pilots, crew and flight personnel in the military service who required hospitalization from injection or received any Covid 19 vaccination be grounded similarly for further dispositive assessment.

l) That this Court should grant an immediate injunction to stop the further harm to all military personnel to protect the health and safety of our active duty, reservists and National Guard troops.

40. I am competent to opine on the medical and flight readiness aspects of these allegations based upon my above-referenced education and professional medical, aviation and military experience and the basis of my opinions are formed as a result of my education, practice, training and experience.

41 As an Aerospace Medicine Specialist, and flight surgeon responsible for the lives of our Army pilots, I confirm and attest to the accuracy and truthfulness of my foregoing statements, analysis and attachments or references hereto:

_____/S/_____

LTC Theresa Long, MD, MPH, FS

State of Alabama §

§

County of ____Dale_____ §

The undersigned, being duly sworn, deposes and says:

I, Lieutenant Colonel Theresa Long, MD, MPH, FS, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

I am an adult of sound mind, 47 years old, and declare that the information herein is true, correct and complete and that I have voluntarily affirmed this affidavit based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

SUBSCRIBED AND SWORN TO BEFORE ME on the 22nd day of September 2021, to certify which witness my hand and official seal.

/S/ Nicholas S. Babel
Notary Public for the Judge Advocates General, Alabama

EXHIBIT 4
A - Long CV

THERESA MARIE LONG, MD, MPH, FS
LTC, MEDICAL CORPS, U.S. Army
Mobile Phone: 512-554-xxxx
theresa.m.long.mil@mail.mil

Medical Education
United States Army School of Aviation Medicine
Aerospace/Occupational Medicine Residency
University of West Florida
Graduate Student -MPH
06/2019-6/2021

Carl R. Darnall Army Medical Center, Fort Hood, Texas
Family Medicine Internship
06/2008-11/2010
Unrestricted Medical License, IN

09/2003 - 06/2008
University of Texas Medical School at Houston, Houston, Texas
06/2008 M.D.

08/2001 - 08/2004
Undergraduate - University of Texas at Austin, Austin, TX
05/2004 B.S. Neurobiology

Research Experience
08/2018 – 5/2020
School of Aviation Medicine
University of West Florida MPH program
https://tml526.wixsite.com/website
Performed a cross-sectional study on Intervertebral Disc Disease Among Army Aviators and Air Crew

08/2002 - 05/2003
University of Texas at Austin, Texas
Research Assistant, Dr. Dee Silverthorn
Performed academic research in effort to update medical facts and the latest research information for the publication of the fourth edition of Human Physiology

09/2000 - 11/2000
Neuropharmacology Research, Texas
Lab Tech, Dr. Silverthorn
Acquisition of rat cerebellums for research in gene sequencing. The focus of the project was to determine the DNA sequence of the receptor in the developing fetal brain that binds to ethanol and induces apoptosis leading to fetal alcohol syndrome.

Publications/Presentations/Poster Sessions
Presentations/Posters

Poster: Intervertebral Disc Disease Among Army Aviators and Air Crew, presented during the 2021 American Occupational Healthcare Conference.
Long, Theresa M., Sorensen, Christian, Victoria Zumberge. (2003, May). Sodium dependent transport of Chlorophenol red uptake by Malpighian tubules of acheta domesticus. Poster presented at: University of Texas at Houston; Austin, TX.

Volunteer Experience
08/ 2005 - 09/2005
University of Texas - Houston, Health Science Ctr, Texas
Medical Student -Provided medical aid and support for Acute Care and triage of Hurricane Katrina evacuees.

Work Experience

06/2021- Present
1st Aviation Brigade TOMS Surgeon
Serve as the Medical Advisor to the 1st Aviation Brigade Commander regarding health and fitness of over 3600 officers, warrant officers and Soldiers. The Brigade is comprised of three aviation training battalions, responsible for initial entry rotary wing/ fixed wing flight training, advanced aircraft training. as well as Specific duties include ensuring safety of flight in Army Aviation operations by functioning as Flight Surgeon, while ensuring the health and fitness of military police, firefighters and military working dogs that support Ft. Rucker. Tasked with conducting epidemiological and biostatistical analysis of injuries and illnesses (SARs CoV-2) and medical trends that occur during training and identify and implement strategies to mitigate delays or lost training time.
05/2018-06/2021
Aerospace and Occupational Medicine Resident

Graduate Medical Education training in Aerospace and Occupational Medicine while obtaining a Master's in Public Health. Specialty training included the Flight surgeon course, The Instructor/Trainer course, Space Cadre Course, Medical Effects of Ionizing Radiation, Medical Management of Chemical and Biological Casualties course at USAMIIRD, Ft. Detrick, NASA, 7th Special Forces, Aviation Safety Officer Course, Global Medicine Symposium, OSHA, Dept of Transportation, Textron Bell Helicopters, Brigade Healthcare Course, Preventative Medicine Senior Leaders Course, Joint Enroute Critical Care Course, Army Aeromedical Activity, research on Intervertebral Disc Disease.

05/2015-05/2018
Department of Rehabilitation Services
General Medical Officer
Assigned to Carl R. Darnall Army Medical Center Physical Medicine clinic with special duties Function as General Medical Officer, to mitigate the number of high risk patients get referred off-post to Pain management and PM&R clinics. Functioned as the Performance Improvement officer for PM&R, the Chiropractic Clinic OIC, and the MEB/IDES Subject Matter Expert to IPMC multi-disciplinary team. Significantly increased access to care to the Physical Medicine clinic. Was instrumental in leading the hospital transition for the Chiropractic clinic, contributing to the subsequent successful Joint Commission inspection. Increased access to care in the Chiropractic clinic by 500%.

9/2013- 5/2015
Department of Pediatrics/ Department of Deployment & Operational Medicine
General Medical Officer
Assigned to the Carl R. Darnall Army Medical center Pediatric Clinic with special duties within the Department of Deployment & Operational Medicine. Provided acute and routine medical care for newborn to age 18 and collaborated with Lactation Team Leader to develop research matrix to ensure effective use of resources to meet Perinatal Core Measures PC-05 for Joint Commission Accreditation. Demonstrated initiative by providing emergency medical care to one of the victims of the April 2, 2014 FT Hood shooting.

10/2012-9/2013
Department of Deployment Medicine/ Emergency Medicine
General Medical Officer
Assigned to the Department of Deployment & Operational Medicine at Carl R Darnall Army Medical Center (CRDAMC) with specific duties directed by the CRDAMC DCCS. Supported soldier deployment/redeployment from combat, while also performing clinical rotations within the Emergency and Internal Medicine Departments to increase access to care for acutely ill patients. Improved productivity of the SMRC by conducting ETS, Chapter, Special Forces, Airborne, Ranger, SERE, and OCS/WOCS physicals. Ensured DODM success with 90% CRDAMC staff compliance of their annual PHA's. Selected to become an ACLS instructor.

06/2012-10/01/2012
Department of the Army Inspector General Agency
Disability Medicine Subject Matter Expert (SME) - Temporary Dept of the Army Inspector General
Assistant Inspector General on Medical Disability (Subject Matter Expert)
Selected above my peers, from across the Army AMEDD as one of three medical NARSUM Subject Matter Experts to function as a temporary assistant Inspector General, in a SECARMY directed inspection of the MEB/IDES system. Planed, coordinated, and conducted inspections of agencies/commands and to gather required data and perspectives relevant to the inspection topic. Developed inspection concepts, objectives, methodologies while coordinating inspection site requirements with major Army Commands ASCC, DRUs, Installations and Components. Identified trends, analyzed root causes to systemic problems and proposed solutions to the IG, Army Chief of Staff and Secretary of the Army for service-wide implementation.

06/2011-06/2012
Carl R. Darnall Army Medical Center
Integrated Disability Evaluation System
Increased patient access to care by conducting 203 acute care appointments in four months. Increased productivity by 25% by completing 202 NARSUMs, 12 TDRLs, 42 Psychiatric addendums in nine months with only a single case returned from the PEB. Performed duties of MEB chief and QA physician in their absence by performing QA on seven NARSUMS, and reviewing 13 cases for initial intake. Functioned as IDES Physician Training officer, applying PDA training to develop a comprehensive training program for new MEB/IDES NARSUM physicians.

11/2010-05/2011
Carl R. Darnall Army Medical Center, Hospital Operations, Clinical Plans and Medical Operations Officer
Served as Clinical Plans and Medical Operations Officer for Hospital Operation (HOD), responsible for the synchronization of external and internal MEDCEN operations supporting over 3,000 MEDCEN employee as well as the DoD's largest military installation and surrounding civilian population; assisted in development and execution of medical plans supporting Installation, Garrison, MEDCEN and Civilian AT/FP and MASCAL events

06/2005 - 07/2005
United States Army, Texas, Officer Basic Course - Class 1st Sergeant
Supervised 306 medical, dental, and veterinarian HPSP scholarship recipients for Officer Basic training.

10/2002 - 08/2003
United States Army - **Texas National Guard, Texas Flight Medic -**EMT/BCLS Instructor Training

10/2001 - 10/2002
United States Army Reserve, Texas, Instructor/Trainer

Instructor/ Trainer of the Total Army Instructor Trainer Course and Instructor Candidate for NCO leadership development courses.

EXHIBIT 4
B

MCE MedChemExpress

Safety Data Sheet

Revision Date: Mar.-23-2021
Print Date: Sep.-9-2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name : ALC-0315

Catalog No. : HY-138170

CAS No. : 2036272-55-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company: MedChemExpress USA

Tel: 609-228-6898

Fax: 609-228-5909

E-mail: sales@medchemexpress.com

1.4 Emergency telephone number

Emergency Phone #: 609-228-6898

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin corrosion/irritation (Category 2),H315

Serious eye damage/eye irritation (Category 2A),H319

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word Warning

Hazard statement(s)

H315 Causes skin irritation

H319 Causes serious eye irritation

Precautionary statement(s)

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/attention.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula:	$C_{48}H_{95}NO_5$
Molecular Weight:	766.27
CAS No. :	2036272-55-4

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; Do NOT induce vomiting; call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.2 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate

personnel to safe areas.

Refer to protective measures listed in sections 8.

6.2 Environmental precautions

Try to prevent further leakage or spillage. Keep the product away from drains or water courses.

6.3 Methods and materials for containment and cleaning up

Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol; Dispose of contaminated material according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

Recommended storage temperature: 4°C, protect from light

* In solvent : -80°C, 6 months; -20°C, 1 month (protect from light)

Shipping at room temperature if less than 2 weeks.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

This product contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering controls

Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

Personal protective equipment

Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Viscous liquid
Odor	No data available
Odor threshold	No data available

pH	No data available
Melting/freezing point	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids/alkalis, strong oxidising/reducing agents.

10.6 Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

Other decomposition products - no data available.

11.TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Classified based on available data. For more details, see section 2

Skin corrosion/irritation

Classified based on available data. For more details, see section 2

Serious eye damage/irritation

Classified based on available data. For more details, see section 2

Respiratory or skin sensitization

Classified based on available data. For more details, see section 2

Germ cell mutagenicity

Classified based on available data. For more details, see section 2

Carcinogenicity

IARC: No component of this product present at a level equal to or greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by ACGIH.

NTP: No component of this product present at a level equal to or greater than 0.1% is identified as a anticipated or confirmed carcinogen by NTP.

OSHA: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by OSHA.

Reproductive toxicity

Classified based on available data. For more details, see section 2

Specific target organ toxicity - single exposure

Classified based on available data. For more details, see section 2

Specific target organ toxicity - repeated exposure

Classified based on available data. For more details, see section 2

Aspiration hazard

Classified based on available data. For more details, see section 2

Additional information

This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumlative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose substance in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging

Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT (US)

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IMDG

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IATA

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

15. REGULATORY INFORMATION

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.

16. OTHER INFORMATION

 The above information is correct to the best of our present knowledge but does not purport to be all inclusive and should be used only as a guide. The product is for research use only and for experienced personnel. It must only be handled by suitably qualified experienced scientists in appropriately equipped and authorized facilities. The burden of safe use of this material rests entirely with the user. MedChemExpress disclaims all liability for any damage resulting from handling or from contact with this product.

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EXHIBIT 4
C

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/11/2021 Revision date 04/11/2021

1 Identification

· **Product identifier**

· **Trade name: SM-102**
· **Synonym** 8-[(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino]-octanoic acid, 1-octylnonyl ester

· **Article number:** 33474
· **Application of the substance / the mixture** For research use only, not for human or veterinary use.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Cayman Chemical Co.
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
USA

· **Information department:** Product safety department
· **Emergency telephone number:**
During normal opening times: +1 (734) 971-3335
US/CANADA: 800-424-9300
Outside US/CANADA: 703-741-5970

2 Hazard(s) identification

· **Classification of the substance or mixture**


GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.


GHS06 Skull and crossbones

Acute Tox. 2 H310 Fatal in contact with skin.


GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.
STOT RE 1 H372 Causes damage to the central nervous system, the kidneys, the liver and the respiratory system through prolonged or repeated exposure.


GHS09 Environment

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.


GHS07

(Contd. on page 2)

EXHIBIT 4
D

Research Article

Trends in Internal Medicine

US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity"

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ABSTRACT

Three COVID-19 vaccines in the US have been released for sale by the FDA under Emergency Use Authorization (EUA) based on a clinical trial design employing a surrogate primary endpoint for health, severe infections with COVID-19. This clinical trial design has been proven dangerously misleading. Many fields of medicine, oncology for example, have abandoned the use of disease specific endpoints for the primary endpoint of pivotal clinical trials (cancer deaths for example) and have adopted "all cause mortality or morbidity" as the proper scientific endpoint of a clinical trial. Pivotal clinical trial data from the 3 marketed COVID-19 vaccines was reanalyzed using "all cause severe morbidity", a scientific measure of health, as the primary endpoint. "All cause severe morbidity" in the treatment group and control group was calculated by adding all severe events reported in the clinical trials. Severe events included both severe infections with COVID-19 and all other severe adverse events in the treatment arm and control arm respectively. This analysis gives reduction in severe COVID-19 infections the same weight as adverse events of equivalent severity. Results prove that none of the vaccines provide a health benefit and all pivotal trials show a statically significant increase in "all cause severe morbidity" in the vaccinated group compared to the placebo group. The Moderna immunized group suffered 3,042 more severe events than the control group (p=0.00001). The Pfizer data was grossly incomplete but data provided showed the vaccination group suffered 90 more severe events than the control group (p=0.000014), when only including "unsolicited" adverse events. The Janssen immunized group suffered 264 more severe events than the control group (p=0.00001). These findings contrast the manufacturers' inappropriate surrogate endpoints: Janssen claims that their vaccine prevents 6 cases of severe COVD-19 requiring medical attention out of 19,630 immunized; Pfizer claims their vaccine prevents 8 cases of severe COVID-19 out of 21,720 immunized; Moderna claims its vaccine prevents 30 cases of severe COVID-19 out of 15,210 immunized. Based on this data it is all but a certainty that mass COVID-19 immunization is hurting the health of the population in general. Scientific principles dictate that the mass immunization with COVID-19 vaccines must be halted immediately because we face a looming vaccine induced public health catastrophe.

Keywords

Clinical trial, Vaccines, COVID-19.

Introduction

For decades, true scientists have warned that pivotal clinical trial designs for vaccines are dangerously flawed and outdated [1]. Vaccines have been promoted and widely utilized under the false claim they have been shown to improve health. However, this claim is only a philosophical argument and not science based. In a true scientific fashion to show a health benefit one would need to show fewer overall deaths during an extended period in the vaccinated group compared to a control group. Less stringent

indicators of a health benefit would include fewer severe events of all kinds, fewer days hospitalized for any reason, lower heath care expenses of all types, fewer missed days from work for any health reason. No pivotal clinical trial for a vaccine preventing an infectious disease has ever demonstrated an improvement in health using these scientific measurements of health as a primary endpoint. Instead, vaccine clinical trials have relied on misleading surrogate endpoints of health such as infection rates with a specific infectious agent. Manufactures and government agents have made the scientifically disproved and dangerous philosophical argument that these surrogate endpoints equate to a health benefit.

True medical scientists, outside the vaccine fields, have embraced the use of true health measurements as the proven proper scientific endpoint of clinical trials. Decades ago, a pharmaceutical manufacturer would only need to show that a chemotherapeutic agent shrank a tumor or reduce cancer deaths to obtain FDA approval. Manufacturers would market their products under the fraudulent philosophical argument that shrinking tumors or reducing cancer deaths equates to improved survival. However, many of the toxic chemotherapeutic agents would destroy vital organs and actually reduce survival while decreasing cancer deaths at the same time. The FDA and comparable agencies around the world switched to “all cause mortality” as the primary endpoint for pivotal cancer drug trails. The gold standard for marketing approval is to show that those receiving a cancer drug actually live longer than those who do not. Typically, new “miracle” anticancer drugs only prolong survival about 2 months but this added time may be spent severely ill suffering from adverse events caused by the chemotherapy. Application of true scientific principles often severely deflates the hype promoting pharmaceutical products.

All previous vaccine trials have suffered not only from lacking a proper primary clinical endpoint put also from insufficient perspective follow up of adverse events. The trials have failed to account for the well-established toxicity data and epidemiology data that vaccines are associated with chronic immune mediated disorders that may not develop for years after immunization. These adverse events, for example type 1 diabetes, are quite common, develop 3 or more years after immunization, and can exceed the reduction in infectious complications induced by the vaccine as was shown with a hemophilus vaccine [1]. Pivotal trials for the recombinant hepatitis B vaccine prospectively recorded adverse events for about 7 days after immunization and newer vaccines typically prospectively follow patients 6 months for adverse events.

Use of “all cause morbidity or mortality” as the primary endpoint is warranted in vaccine trials for several reasons. First, the recipients are generally healthy (relative to patients with terminal cancer for example) and the risk of severe morbidity from the target infection is low so even rare adverse events can result in an unfavorable risk benefit. Second, stimulating the immune system with a vaccine can lead to almost any type of adverse event including increasing the incidence or severity of diseases already present in the population. One needs a trial design with a primary endpoint that captures both a decline in infectious complications as well as small rises in hundreds of different immune modified disorders of similar or worse severity as the infectious complications.

Three COVID-19 vaccines are approved by the US FDA under Emergency Use Authorization (EUA). These vaccines have been developed by Pfizer-BioNTech, Moderna, and Janssen. Since marketing has begun multiple reports of potential, adverse events have been recorded. These reports include prion disease [2,3] , clotting disorders [4], myocarditis, reproductive issues, death and many more. A clear difference in frequency of adverse events between different COVID-19 vaccines has been published [3]. The clinical trial designs of the pivotal trials and the resulting data was evaluated to determine if scientifically the results support mass immunization with the vaccines for COVID-19. The published data from the manufacturers’ own clinical trials was re analyzed using the proper scientific endpoint “all cause severe morbidity”.

Method

Data from all three US COVID-19 vaccines was published in the New England Journal of Medicine [4-6]. Data from these three publications and the accompanying published appendixes provided the bulk of the information analyzed. On rare occasions supplemental data was found on the FDA’s website (https://www.fda.gov/advisory-committees/advisory-committee-calendar) in briefing documents pertaining to FDA advisory panel committees for COVID-19 vaccines from Pfizer-BioNTech, Moderna, and Janssen. The scientific primary endpoint, “all severe events", in the treatment group and controls was calculated by adding all severe or life threatening events reported in the clinical trials by the manufacturers. Severe events included both severe cases of COVID-19 and all other severe events in the treatment arm and control arm respectively.

A Chi square analysis using a 2x2 table was used to calculate statistical p values. An online statistical chi square calculator (***https://www.socscistatistics.com/tests/chisquare***) was used. Statistical calculations ignored small differences in total subject number between efficacy and adverse event populations. The randomized number, shown in Table 1, was used as the study population for statistical calculations. In general, the population for adverse events was slightly higher than that for efficacy. Given the statistical significant p, values generated (see Table 1), these small differences do not appear to be material.

The FDA document entitled Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials, 2007, provided the following definitions for adverse events.

Grades 3, Severe: Prevents daily activity and requires medical intervention.
Grades 4, Potentially life threatening: ER visit or hospitalization.

Results

Moderna

The Moderna pivotal Phase III trial results and protocol are published in the New England Journal of Medicine (NEJM) [5]. The primary endpoint was COVID-19 illness starting 14 days after the second dose of vaccine however the trial had a secondary endpoint

which was patients developing severe COVID-19 symptoms. This later endpoint allowed for a direct comparison to severe adverse events. The study randomized 30,420 individuals, 15,210 were randomized to receive injections with Moderna's mRNA-1273 vaccine and 15,210 were randomized to receive injections with placebo. Two shots were administered 28 days apart. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" adverse events were reported up to 28 days after administration of each vaccine or approximately 56 days after the first dose according to protocol. Because of dropouts, adverse events were recorded on 15,185 vaccinated patients and 15,166 placebo patients (reference 5, appendix table S8). The treatment group had 11 cases of symptomatic COVID-19 infections and 0 cases severe COVID-19 infections (reference 5, appendix table S13). There were 234 cases of severe "unsolicited" adverse events in the treatment group (reference 5, appendix table S8), and an additional 3,751 "solicited" severe or life threatening (Grade 3 or Grade 4) adverse events (reference 5, appendix table S3 and S4). By contrast, the control group had 185 cases of symptomatic COVID-19 infections and 30 cases of severe COVID-19 infections. However, only one of these case of COVID-19 out of 15,166 controls required admission to an intensive care unit (see reference 5, appendix table S13). There were 202 cases of severe "unsolicited" adverse events in the placebo group and an additional 711 "solicited" severe or life threatening (Grade 3 or Grade 4) adverse events. There were 3 deaths in the placebo group and 2 in the vaccinated group (reference 5, appendix table S8).

Pfizer-BioNTech

The Pfizer-BioNTech (Pfizer) pivotal Phase III trial results are published in the New England Journal of Medicine [6]. The Pfizer trial was classified as a Phase 1/2/3 trial. Two shots were administered 21 days apart. The primary endpoint was confirmed COVID-19 infections 7 days after the second dose. A post hoc analysis of severe COVID-19 infections was included in the appendix published by the NEJM. The study randomized 43,548 individuals of which 100 did not receive injections, 21,720 received injections with the vaccine and 21,728 received injections with placebo. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" severe adverse events were reported up to 14 weeks after administration of the second dose. However, median safety follow up for "unsolicited" events was only approximately 2 months after the second dose at the time of publication in the NEJM. In the treatment arm there was 1 case of severe Covid-19 (reference 6, appendix table S5), 240 "unsolicited" severe adverse events and 21 "unsolicited" life threatening adverse events (reference 6, appendix table S3). In the placebo arm, there were 9 cases of severe COVID-19, 139 "unsolicited" severe adverse events and 24 "unsolicited" life threatening adverse events. Pfizer used a safety subset of approximately 8,183 (both vaccinated and unvaccinated) to record "solicited" adverse events at 7 days. These data that are not shown in Table 1 in part because the data was depicted graphically in the NEJM manuscript. However, graphical data in the NEJM strongly

Table 1: All Cause Severe Morbidity

	Moderna		**Control**		**Difference**	**P value**
Randomized	15,210		15,210			
Days of Safety Follow Up	56		56			
# Severe COVID-19 Cases	0		30			
# Unsolicited Severe Adverse Events	234		202			
# Solicited Grade 3 AE, Shot 1	848		361			
# Solicited Grade 4 AE, Shot 1	5		6			
# Solicited Grade 3 AE, Shot 2	2884		341			
# Solicited Grade 4 AE, Shot 2	14		3			
# Total Severe Events	3985		943		3042	p=0.00001
#Deaths	2		3			
	Pfizer		**Control**		**Difference**	**P value**
Randomized	21,720		21,728			
Days of Safety Follow Up	81		81			
# Severe COVID-19 Cases	1		9			
# Unsolicited Severe Adverse Events	240		139			
# Unsolicited Life Threatening Adverse Events	21		24			
# Total Severe Events	262		172		90	p=0.000014
#Deaths	2		4			
	Jansen	**Jansen**	**Control**	**Control**	**Difference**	**P value**
Randomized	19,630		19,691			
Safety Subset		3,356		3,386		
Days of Safety Follow Up	28		28			
# Severe COVID-19 Cases	21		78			
# Solicited Grade 3 Adverse Events						
Local (**extrapolated**)	**135**	23	**35**	6		
Systemic (**extrapolated**)	**357**	61	**122**	21		
# Unsolicited Grade 3-4 Adverse Events	83		96			
# Total Severe Events	595		331		264	p=0.00001
# Deaths	3		16			

indicates the vaccinated group has more "solicited" adverse events of all grade levels than the control group.

Janssen

The Janssen pivotal Phase III trial design and trial results are published in the New England Journal of Medicine [4]. The primary endpoint was prevention of molecularly confirmed, moderate to severe–critical COVID-19 14 days post vaccination however a secondary endpoint was prevention of molecularly confirmed, severe–critical COVID-19 14 days post vaccination. This later endpoint allowed for a direct comparison to severe adverse events. The study randomized 19,630 to receive a single injection with Janssen's adenovirus COVID-19 vaccine and randomized 19,691 to receive a single injection with placebo. "Solicited" adverse events were collected 7 days after immunization and "unsolicited" adverse events were reported up to 28 days after administration of the single dose of vaccine. The treatment group had 21 cases of severe or critical COVID-19 infections while the placebo control group had 78 (reference 4, appendix table S9). Further analysis shows that only 2 of 19,514 immunized patients needed medical intervention for COVID-19 infections starting 14 days after immunization, while only 8 of 19,544 controls needed medical intervention for COVID-19 infections starting 14 days after placebo injection where the COVID-19 infection was confirmed by a central lab (reference 4, appendix table S10). There were 83 "unsolicited" and approximately 492 "solicited" serious adverse events in the vaccinated group compared to 96 "unsolicited" and approximately 157 "solicited" serious adverse events in the control group (reference 4, appendix table S7). There were 3 deaths in the treatment group and 16 in the control group (reference 4, appendix table S7).

Janssen did not collect "solicited" adverse events from the whole group at day 7 but instead collected these adverse events from a safety group comprising 3,356 vaccinated and 3,380 control patients. FDA briefing document Table 23, page 39 [7] provided the number of "solicited" Grade 3 adverse events in each group. These figures as well as the number of patients randomized were used to extrapolate the number of solicited severe adverse events in the full vaccinated and placebo group as recorded in Table 1.

Discussion

Scientific analysis of the data from pivotal clinical trials for US COVID-19 vaccines indicates the vaccines fail to show any health benefit and in fact, all the vaccines cause a decline in health in the immunized groups. Health is the sum of all medical events or lack there of. COVID-19 vaccines are promoted as improving health while in fact there is no evidence that these vaccines actual improve health in the individual or population as a whole. The current analysis used the proper scientific endpoint of "all cause severe morbidity", a true measure of health. By contrast, manufactures and government officials promote the vaccines using a surrogate measure of health, severe infections with COVID-19, and the disproved philosophical argument that this surrogate endpoint equates to health. This substitution of philosophy for science is extremely dangerous and is certainly leading to a catastrophic public health event.

Review of data from the three COVID-19 vaccines marketed in the US shows complete lack of a health benefit and even an increase in severe events among vaccine recipients. The proper scientific clinical trial endpoint, "all cause severe morbidity" was created by combing all severe and or life threatening events, both infectious and non-infectious, occurring in the vaccinated and placebo control groups respectively. The data (Table 1) shows there are clearly more severe events in the vaccinated groups. The results are highly statistically significant. The use of a true scientific measure of health as an endpoint for a vaccine trial gives a contrasting result compared to the use of a non-scientific surrogate endpoint of heath, severe infections with COVID-19.

Clinical trial data show there were actually few very "severe" cases of COVID-19 in either the vaccinated or the placebo group. Moderna data shows that only one of 15,166 unvaccinated patients required admission to an intensive care unit for COVID-19. Data provided by Janssen shows that only a few of the "severe" COVID-19 infections required medical intervention. Table S10 in the appendix published in the New England Journal of Medicine [4] , shows only 2 of 19,514 patients immunized with the Janssen vaccine needed medical intervention for severe COVID-19 infections starting 14 days after immunization, while only 8 of 19,544 controls needed medical intervention for severe COVID-19 infections starting 14 days after placebo, where the infection was confirmed by a central lab. This benefit, reduction in 6 case of COVID-19 requiring medical intervention, in 19,630 vaccinated patients is simply statistically insignificant in a population that has a hundred fold more severe events of any cause. The Janssen vaccinated group had 595 severe Grade 3 or 4 events in the first 28 days post immunization. Science thus does not support a health benefit with COVID-19 vaccines. All arguments for immunization are purely philosophical and based on false, discredited, assumptions.

Reductions in infection rates, hospitalization rates and even death with COVID-19 are poor surrogate markers for health and are not proper primary endpoints for a vaccine clinical trial. As discussed earlier with cancer treatments, a trial endpoint showing reduced cancer deaths is not equivalent to enhanced survival. One could apply enough radiation (or cytotoxic chemotherapy) to cancer patients to kill all their cancer cells and prevent cancer deaths but these cancer patients would die of radiation sickness (or chemotherapy induced organ failure) faster than if they died naturally of cancer. In the same manner, reducing severe COVID-19 infections does not equate to enhanced survival especially when the vaccine can cause clotting, heart disease and many other severe adverse events. Potential vaccine recipients need to know if the vaccine improves their survival in order for them to make an informed consent to be immunized. Unfortunately, the current studies with COVID-19 vaccines in fact show they cause a decline in health.

The actual health decline caused by the vaccines is probably much worse than what is depicted in Table 1 for many reasons. First manufactures took a haphazardly approach to recording adverse events in contrast to recording a reduction in COVID-19 events. At

the time of publication, patients were only followed prospectively for approximately 7 days after immunization for "solicited" adverse events, and then relied on "unsolicited" reports of adverse events for approximately 30-60 days after immunization. Serious non-infectious events occurring after this 30-60 day period were not part of the published data. By contrast, infections with COVID-19 were followed indefinitely since the time of immunization. Both Janssen and Pfizer were specifically lax recording adverse events and only recorded "solicited" adverse events at day 7 in a safety cohort representing less than 20% of the study population. Given that some of the vaccine clinical trials recruited patients in the third world, patients with low education, and potentially even elderly with dementia the patients can not be expected to understand when they may be having an serious event that needs reporting or how to report it. For these and others reason only 5% of adverse events are generally ever reported [8].

COVID-19 vaccines were released for marketing under a EUA. Use of such a protocol should be reserved for outbreaks of life threatening epidemics. If this were, actually the case with COVID-19 then reduction in "all cause mortality" should be the primary outcome for the vaccine trials and "all cause severe morbidity" should be the secondary endpoint. However, the manufacturers show no evidence of a survival benefit. Deaths in the trials were extremely rare and of 30 deaths, out of roughly 110,000 trial participants, only about 6 deaths were confirmed to have COVID-19 at the time of death. Regrettably, the vaccines did not reduce morbidity but caused an increase in severe events. Worse, the pivotal clinical trials were never designed to show a benefit in "all-cause mortality" or reduction "in all cause severe morbidity". The fact that the trials were never designed to show these health benefits is an admission that those developing the vaccines never expected the vaccines to result in measurable health benefits. Regrettably some manufacturers have published the false claim [6] that the vaccine have been proven to be "effective" and that its now "unethical" to withhold immunization from the control group. They advocate abolishing the control group by immunizing them. This unscientific act only further proves the pharmaceutical industry is unaccountable to any one and does not feel the need to adhere to principles of science, ethics, or public health.

The COVID-19 vaccine pivotal clinical trials were of very short duration and the question exists whether longer-term follow up will reverse the vaccine induced health decline and show a health benefit. The question is purely philosophical. Some manufactures have already threatened to destroy the randomization by immunizing the control group, as stated above, making further scientific study impossible. While it is possible that the vaccines will continue to prevent severe infectious disease long after the immunization, the reality is that immunity wanes with time and vaccine resistant variants keep developing. Another issue is that severe adverse events will continue to occur over time. Given evidence of prion genic activity by both established pathophysiology [2], animal toxicity data [9] and epidemiology data [3] one can expect an increase in adverse events in the vaccinated group for decades.

Yearly booster are unlikely to improve the health outcome with COVID-19 vaccines. A booster may provide a small incremental benefit in preventing severe COVID-19 infections however, the boosters are likely to cause many more severe adverse events. Looking at the data on secondary injections with the Moderna vaccine (Table 1) there are approximately 3 times as many Grade 3 or 4 adverse events after the second dose than after the first dose. However, this is not the case following the second dose of placebo in the Moderna placebo group. The net is that adding a booster shot is highly unlikely to induce a favorable health benefit that was missing with the first series of immunization.

Government officials are promoting COVID-19 vaccines as a way to stop the epidemic. There is however no scientific data that the COVID-19 vaccines can improve the health of the population. In fact, the data from the clinical trials seems to point in the opposite direction. Given that the population is the sum of the individuals, and the vaccines cause a decline in health in the individuals, then mass immunization is likely to erode the health of the general population, not improve it. Immunization may even cause a selection bias for new variants. Finally, if the COVID-19 outbreak is the result of a bioweapons attack and vaccine resistant variants represent the release of different prototypes then immunization is almost certain to fail [10].

There is an old saying, fool me once shame on you, fool me twice shame on me. This saying can be applied to the COVID-19 mass immunization program. The US anthrax attack of 2001, which originated at US army is Fort Detrick, has demonstrated that there are people in the US government who desire to attack US citizens with bioweapons [10]. According to the chief FBI agent leading the investigation of the US anthrax attack, conspirators were likely not apprehended in part because the investigation was prematurely ended and prior to stopping the investigation, people at the top of the FBI deliberately tried to sabotage the investigation [11]. In the US anthrax attack of 2001, people high in the US government publicly anticipated the anthrax attack as early as 1999 [10]. Similarly with the COVID-19 attack, people high in government anticipated the COVID-19 attack [12,13] several years before the attack took place [10]. There is even data that an effort was made in 2018 to protect certain populations against COVID-19 by immunizing them with MMR vaccine [14].

In such a hostile government environment, the citizens need to individually evaluate the science of immunization with COVID-19 vaccines and not rely on philosophical arguments propagated by government officials. In this case there is no scientific evidence that the COVID-19 vaccines improve the health of the individual, much less of the population as a whole. Mass immunization with COVID-19 vaccines is certainly leading to a catastrophic public health event.

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EXHIBIT 5
Sigaloff Affidavit

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

DANIEL ROBERT	*	
SSGT, U.S. ARMY	*	
	*	
HOLLI MULVIHILL	*	
SSGT, USMC	*	
	*	
Plaintiffs,	*	
	*	
v.	*	
	*	Civil Action No. 21-02228
LLOYD AUSTIN	*	
Secretary of Defense,	*	
U.S. DEPARTMENT OF DEFENSE	*	
Washington, D.C. 20301	*	
	*	
and	*	
	*	
XAVIER BECERRA	*	
Secretary of the U.S. Department of	*	
Health and Human Services	*	
U.S. DEPARTMENT OF HEALTH	*	
AND HUMAN SERVICES	*	
	*	
and	*	
	*	

JANET WOODCOCK, Acting *
Commissioner of the Food & Drug *
Administration *
U.S. FOOD AND *
DRUG ADMINISTRATION *
*
UNITED STATES OF AMERICA *
*
Defendants. *

* * * * * * * * * * * * *

MOTION FOR PRELIMINARY INJUNCTION

AFFIDAVIT OF DR. SAMUEL SIGOLOFF IN SUPPORT OF PRELIMINARY INJUNCTION MOTION

I, Samuel N. Sigoloff, Doctor of Osteopathy, being duly sworn, depose and state as follows:

1. I make this affidavit in support of the above referenced MOTION as expert testimony in support thereof.

2. The expert opinions expressed here are my own and arrived at from my persons, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports and other information relevant to the subject matter.

Experience & Credentials

3. I am competent to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

4. After receiving a bachelor's degree from Saint Mary's University in San Antonio Texas in 2007, I completed a medical degree from Heritage College of Osteopathic Medicine in Athens, Ohio in 2012. I went on to complete a Family Medicine Residency at Martin Army Community Hospital at Fort Benning, Georgia in June 2015.

5. I have been board certified in Family Medicine since July, 2015.

6. I am currently serving as the Medical Director for Raymond W. Bliss Army Health Clinic at Fort Huachuca, Arizona. I am responsible for supervising Physician's Assistant and Nurse Practitioners and Physicians. I have held this position since August of 2021. I have held this similar position previously at Fort Sill, Oklahoma from 2016-2017 and at Camp Buehring Kuwait from 2017-2018.

7. Since before the declaration of this pandemic, which was declared by the WHO on March 11, 2020, I have been watching and studying any and all resources available so that I would be useful to my unit/community at Fort Wainwright, AK. Due to my initial concerns with SARS-CoV2 (COVID-19) and significant amount of reading that I completed about pandemics (historic references of what was done in 1918, SARS and MERS), and because I felt I had the most optimum health when compared to my peers, I felt it a duty to volunteer to work the 'covid clinic' at the hospital. I also wanted to reduce possible exposure by limiting the number of clinicians that would work in the 'covid clinic.' I was the only physician that volunteered for this role and there were no other clinicians requesting to share the work load.

8. As the clinician in charge of the 'covid clinic' I helped the nursing staff establish and improve procedures for safe handling of patient samples, which at that time it was thought to be a definite death sentence if contracted by anyone. Other hardships during this time included below 0 temperatures in the mornings (Ft Wainwright, AK). I was given very strict and narrow guidelines on when to test patients for SARS-CoV2. I believed it important to be liberal with testing prior to a clear outbreak in our community that way we can determine as early as possible when it has entered our community. My superiors did support my ideas and I was very liberal with testing. After 1-1/2 months I was moved back into the hospital, during that time not a single positive test had been resulted. This information is for a more clear understanding of how vested I am in this topic.

9. Given that these SARS-CoV2 preventative therapies were both Investigational New Drugs and

Emergency Use Authorization for biologics. I have spent a considerable amount of time to understand potential risks, hazards and dangers that these Investigational New Drug and biologics may have on the health, safety and operational readiness of patients and service members in my care.

10. As part of my investigation to determine if the only FDA approved biologic, Comirnaty, would be safe for service members and other patients, one must look at the ingredient list which is provided by the package insert (Exhibit B). The first 3 ingredients of Comirnaty are:

1. ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (alternative names ALC-0315, CAS No. 2036272-55-4)

2. 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide (Alternative names ALC-0159, CAS No. 1849616-42-7)

3. 1,2-distearoyl-sn-glycero-3-phosphocholine (Alternative name DSPC)

11. On August 24, 2021 the Secretary of Defense, Lloyd J. Austin III, issued guidance for mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members (Exhibit C).

12. The above listed chemicals are lipid-nanoparticles and the DoDI 6050.05 (DoD Hazard Communication Program) will apply for safe handling. The DoDI 6050.05 (Exhibit D) states:

1. Paragraph 3.2.2 – an inventory of all engineered nanomaterials in the work place in accordance with paragraph 3.2.c

2. Paragraph 3.2.c – All DoD workplaces, or DoD-manufactured materials where engineered nanomaterials are used, should include engineered nanomaterials that are not incorporated into articles or otherwise excluded from Part 1910.1200 of Title 29, CFR into their written HAZCOM plans when there is knowledge of the presence of such engineered nanomaterials.

3. Paragraph 3.4.b.1 – Copies of the appropriate SDS will be: (1) Readily accessible before hazardous chemicals are used and accessible at all times thereafter.

4. Paragraph 3.4.d.2 – Rejects incomplete hazardous material information that does not comply with the requirements of Part 1910.1200 of Title 29, CFR. Laboratory verification of technical elements is not required. DoD Components will return incomplete or inadequate SDSs and labels to the supplier for correction. The contracting officer or buyer must consult with the manufacturer or distributer for resolution of SDS discrepancies.

5. Paragraph G.2 DEFINITIONS: engineered nanomaterials. Discrete materials having structures with at least one dimension between 1 and 100 nanometers that are intentionally created, as opposed to those that are naturally or incidentally formed. They do not include larger materials that may have nanoscale features (e.g., etched silicon wafers), biomolecules (e.g., proteins, nucleic acids, carbohydrates), and materials with occupational exposure limits that address nanoparticles for that substance.

13. DoDI 6050.05 (DoD Hazard Communication Program) for safe handling references "Approaches to Safe Nanotechnology, Managing the Health and Safety Concerns Associated with Engineered Nanomaterials." March 2009 (Exhibit E).

Opinion

14. I have reviewed the Motion for Temporary Restraining Order which discusses the issue of prior immunity benefits outweighing the risks of using experimental genetic therapy Covid 19 Vaccines, together with proposed exhibits and materials cited therein. My opinion on this subject matter, I am drawing my own conclusions as an Army Physician and Medical Director of a Troop Medical Facility. I understand that I am willingly taking on enormous risk to my personal carrier as a physician, however it is balanced with the risk of potentially not stopping the intentional poisoning of our entire fighting force, as directed by the current Secretary of Defense Lloyd J. Austin III.

15. The first ingredient in the FDA approved Comirnaty biologic: ((4 hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (alternative names ALC-0315, CAS No. 2036272-55-4)

1. Two separate material safety data sheets (MSDS) both say that is for research use only and not for human use. (See Exhibit F and G)
2. SDS by ChemScene dated 23MAR2021 states that:

-Acute toxicity - Classified based on available data

-Skin corrosion/irritation – Classified based on available data

-Serious eye damage/irritation – Classified based on available data

-Respiratory or skin sensitization – Classified based on available data

-Germ cell mutagenicity – Classified based on available data

-Reproductive toxicity – Classified based on available data

-Specific target organ toxicity - single exposure – Classified based on available data

-Specific target organ toxicity - repeated exposure – Classified based on available data

-Aspiration hazard – Classified based on available data

-Additional information – This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

-The product is for research use only and for experienced personnel. It must only be handled by suitably qualified experienced scientists in appropriately equipped and authorized facilities. The burden of safe use of this material rests entirely with the user.

-Caution: Product has not been fully validated for medical applications. For research use only.

16. The second ingredient in the FDA approved Comirnaty biologic: 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide (Alternative names ALC-0159, CAS No. 1849616-42-7)

1. Two spate material safety data sheets (MSDS) both say that is for research use only and not for human use. (See Exhibit H and I)

2. SDS by MCE MedChemExpress dated 31JUL2021 states that:

-Acute toxicity - Classified based on available data

-Skin corrosion/irritation – Classified based on available data

-Serious eye damage/irritation – Classified based on available data

-Respiratory or skin sensitization – Classified based on available data

-Germ cell mutagenicity – Classified based on available data

-Reproductive toxicity – Classified based on available data

-Specific target organ toxicity - single exposure – Classified based on available data

-Specific target organ toxicity - repeated exposure – Classified based on available data

-Aspiration hazard – Classified based on available data

-Additional information – This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

-The product is for research use only and for experienced personnel. It must only be handled by suitably qualified experienced scientists in appropriately equipped and authorized facilities. The burden of safe use of this material rests entirely with the user. MedChemExpress disclaims all liability for any damage resulting from handling or from contact with this product.

-Caution: Product has not been fully validated for medical applications. For research use only.

17. The third ingredient in the FDA approved Comirnaty biologic: 1,2-distearoyl-sn-glycero-3-phosphocholine (Alternative name DSPC, see Exhibit J)

1. The material safety data sheet (MSDS) states:

Relevant identified uses: For research use only, not for human or veterinary use.

18. It is my opinion that the above stated chemicals listed on the package insert for Comirnaty render this product NOT safe to inject into service members nor any humans nor animals.

19. The Secretary of Defense, Lloyd J. Austin III, is in volition of DoDI 6050.05 (DoD Hazard Communication Program) and is choosing to willfully expose the entire United States Department of Defense to chemicals that are not approved for medical use and to a chemical that is not even approved for veterinary use, which may put the ability to defend this country from or foreign or domestic adversaries, in great peril.

20. I am competent to opine on the medical readiness aspects of these allegations based upon my above-referenced education and professional medical, and military experience and the basis of my opinions are formed as a result of my education, practice, training and experience.

21. As a Doctor of Osteopathy and Board Certified Family Medicine physician I am committed 'To Conserve Fighting Strength,' and as a Commissioned Officer in the US Army, I confirm and attest to the accuracy and truthfulness of my foregoing statements, analysis and attachments or references hereto:

_____/S/_____

MAJ Samuel N. Sigoloff, DO FM

State of Arizona §
§
County of Cochise §

The undersigned, being duly sworn, deposes and says:
I, Major Samuel N Sigoloff, DO, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:
I am an adult of sound mind, 36 years old, and declare that the information herein is true, correct and complete and that I have voluntarily affirmed this affidavit based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

SUBSCRIBED AND SWORN TO BEFORE ME on the 21st day of _September 22, 2021,
to certify which witness my hand and official seal.
Notary Public for the State of Arizona

My Commission Expires:
___Jonathan Smith_____ Expires: June 10, 2024
Notary Public

EXHIBIT 5
A Sigoloff CV

Samuel N. Sigoloff, DO
4290 S. Silva, Sierra Vista, AZ 85650
210-872-1357, Samuel.Sigoloff@1791.com

Employment

Raymond W. Bliss Army Health Clinic, Ft Huachuca	2021-presnt
Bassett Army Community Hospital, Ft Wainwright, AK	2018-2021
Adjunct professor for Basic EMT course with Central Texas College, At Camp Buehring, Kuwait	2017
Reynolds Army Health Clinic, Ft Sill, OK	2015-2018

Education

Family Medicine Residency at Martin Army Community Hospital, Ft Benning, GA	2012-2015
Ohio University Heritage College of Osteopathic Medicine	2007-2012
Saint Mary's University - San Antonio, Texas Bachelor of Arts Degree in Biology and Minor in Military Science	2003-2007

Licensure and Certification

American Board of Family Medicine, Diplomate ABFM ID: 164257	2015-present
Medical License, Nebraska License number 1149	2013-2021
Medical License, Texas License number S3747	2019-present

Publication

Adams, J.R & Layton, M.C. & Sigoloff, S.N.. (2015). "Folliculitis". In F. Domino (Ed.), *The 5-Minute Clinical Consult Standard 2016.* Philadelphia, PA: Wolters Kulwer.

Leadership

Medical Director, Raymond W. Bliss Army Health Clinic, Ft Huachuca	2021-present
Medical Director, Camp Buehring, Kuwait	2017-2018
Chief of Patient Centered Medical Home, Ft Sill OK	2016-2017
Clinical Pharm D OIC, Ft Sill OK	2015-2016
Association of Military Osteopathic Physicians and Surgeons (AMOPS) Ohio University Heritage College of Medicine Chapter President	2008-2010
Medical Students for Life OMSI Liaison	2007-2008
College Cadet Battalion Training Officer for ROTC	2007
College Cadet Battalion Commander for Reserve Officer Training Corps ROTC Saint Mary's University	2006
College Cadet Sergeant Major for ROTC	2005
College Ranger Challenge Team Captain	2005
Eagle Scout Project	2002

Community Service

Men's Health Fair, Camp Buehring, Kuwait	2017
TCCC training of swat team in La Grange GA	2015
Shaw High School physical, Columbus GA	2015
Health Fair, Ft Benning GA	2014
EFMP Olympics, Ft Benning GA	2014
Shaw High school physical, Columbus GA	2013
No smoking campaign at Faith Middle School, Ft Benning GA	2012

Military Training

Joint Forces Combat Trauma Management Course	2017
Basic Airborne Course, Class 21-14	2014
Combat Casualty Care Course	2012
Medical Corps Officer Basic Course	2008

EXHIBIT 5
B Comirnaty
Pkg. Insert

appendix 1

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use COMIRNATY safely and effectively. See full prescribing information for COMIRNATY.

COMIRNATY® (COVID-19 Vaccine, mRNA) suspension for injection, for intramuscular use
Initial U.S. Approval: 2021

---------- INDICATIONS AND USAGE----------
COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. (1)

----------DOSAGE AND ADMINISTRATION----------
- For intramuscular injection only. (2.2)
- COMIRNATY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart. (2.3)

---------- DOSAGE FORMS AND STRENGTHS----------
Suspension for injection. After preparation, a single dose is 0.3 mL. (3)

---------- CONTRAINDICATIONS ----------
Known history of a severe allergic reaction (e.g., anaphylaxis) to any component of COMIRNATY. (4)

---------- WARNINGS AND PRECAUTIONS ----------
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. (5.2)
- Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting. (5.4)

---------- ADVERSE REACTIONS ----------
- In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%). (6.1)
- In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc. at 1-800-438-1985 or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 8/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

COMIRNATY is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

Prior to Dilution

- COMIRNATY Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension that does not contain preservative. Each vial must be thawed and diluted prior to administration.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] *[see How Supplied/Storage and Handling (16)]*.
- Refer to thawing instructions in the panels below.

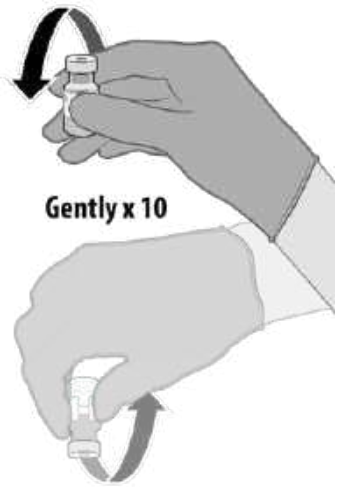
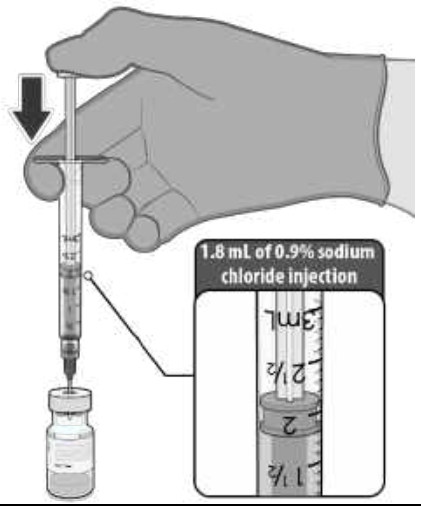
Dilution

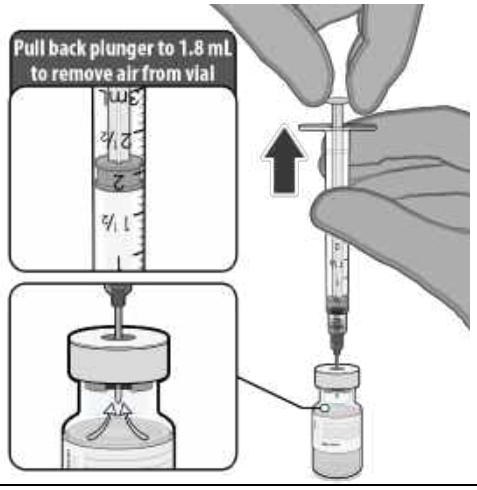
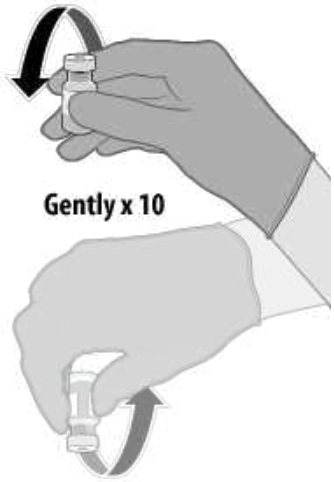
- Dilute the vial contents using 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form COMIRNATY. Do not add more than 1.8 mL of diluent.
- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- Vials of sterile 0.9% Sodium Chloride Injection, USP are provided but shipped separately. Use the provided diluent or another sterile 0.9% Sodium Chloride Injection, USP as the diluent.
    - Provided diluent vials are single-use only; discard after 1.8 mL is withdrawn.
    - If another sterile 0.9% Sodium Chloride Injection, USP is used as the diluent, discard after 1.8 mL is withdrawn.
    - Do not dilute more than 1 vial of COMIRNATY using the same diluent vial.
- After dilution, 1 vial of COMIRNATY contains 6 doses of 0.3 mL each.
- Refer to dilution and dose preparation instructions in the panels below.

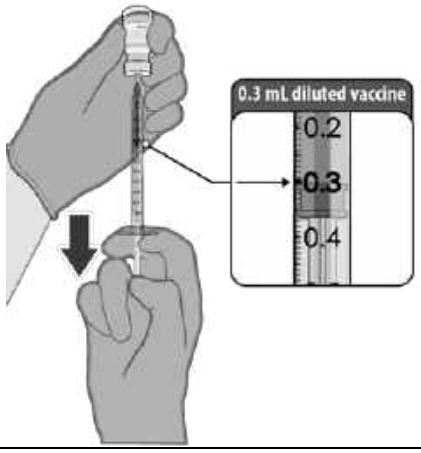
appendix 1

THAWING PRIOR TO DILUTION	

	• Thaw vial(s) of COMIRNATY before dilution either by:
	  ○ Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month.
	  ○ Allowing vial(s) to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
	• Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

	• Before dilution invert vaccine vial gently 10 times. • <u>Do not shake.</u> • Inspect the liquid in the vaccine vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
	• ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. • Withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Add 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	• Equalize vial pressure before removing the needle from the vaccine vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing COMIRNATY 10 times to mix. • Do not shake. • Inspect the vaccine in the vial. • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	• Record the date and time of dilution on the COMIRNATY vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY	
	• Withdraw 0.3 mL of COMIRNATY preferentially using low dead-volume syringes and/or needles. • Each dose must contain 0.3 mL of vaccine. • If the amount of vaccine remaining in a single vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. • Administer immediately.

After dilution, vials of COMIRNATY contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle,

- each dose must contain 0.3 mL of vaccine.
- if the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- do not pool excess vaccine from multiple vials.

2.2 Administration Information

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vaccine will be an off-white suspension. Do not administer if vaccine is discolored or contains particulate matter.

Administer a single 0.3 mL dose of COMIRNATY intramuscularly.

2.3 Vaccination Schedule

COMIRNATY is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.

There are no data available on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination series. Individuals who have received 1 dose of COMIRNATY should receive a second dose of COMIRNATY to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

COMIRNATY is a suspension for injection. After preparation, a single dose is 0.3 mL.

4 CONTRAINDICATIONS

Do not administer COMIRNATY to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the COMIRNATY *[see Description (11)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COMIRNATY.

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, including COMIRNATY. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the COMIRNATY.

5.5 Limitation of Effectiveness

COMIRNATY may not protect all vaccine recipients.

6 ADVERSE REACTIONS

In clinical studies, the most commonly reported (≥10%) adverse reactions in participants 16 through 55 years of age following any dose were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies, the most commonly reported (≥10%) adverse reactions in participants 56 years of age and older following any dose were pain at the injection site (78.2%), fatigue (56.9%), headache, (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

The safety of COMIRNATY was evaluated in participants 16 years of age and older in 2 clinical studies conducted in Germany (Study 1), United States, Argentina, Brazil, Turkey, South Africa, and Germany (Study 2). Study BNT162-01 (Study 1) was a Phase 2-part, dose-escalation trial that enrolled 60 participants, 18 through 55 years of age and 36 participants, 56 through 85 years of age. Study C4591001 (Study 2) is a Phase 1/2/3 multicenter, multinational, randomized, saline placebo-controlled, double-blinded (Phase 2/3), dose-finding, vaccine candidate-selection and efficacy study that has enrolled approximately 44,047 participants (22,026 COMIRNATY; 22,021 placebo) 16 years of age or older (including 378 and 376 participants 16 through 17 years of age in the vaccine and placebo groups, respectively). Upon issuance of the Emergency Use Authorization (December 11, 2020) for COMIRNATY, participants were unblinded to offer placebo participants COMIRNATY. Participants were unblinded in a phased manner over a period of months to offer placebo participants COMIRNATY. Study 2 also included 200 participants with confirmed stable human immunodeficiency virus (HIV) infection; HIV-positive participants are included in safety population disposition but are summarized separately in safety analyses. Confirmed stable HIV infection was defined as documented viral load <50 copies/mL and CD4 count >200 cells/mm^3 within 6 months before enrollment, and on stable antiretroviral therapy for at least 6 months.

At the time of the analysis of the ongoing Study 2 with a data cut-off of March 13, 2021, there were 25,651 (58.2%) participants (13,031 COMIRNATY and 12,620 placebo) 16 years of age and older followed for ≥4 months after the second dose.

Participants 16 years and older in the reactogenicity subset were monitored for solicited local and systemic reactions and use of antipyretic medication after each vaccination in an electronic diary. Participants are being monitored for unsolicited adverse events, including serious adverse events, throughout the study [from Dose 1 through 1 month (all unsolicited adverse events) or 6 months (serious adverse events) after the last vaccination].

Demographic characteristics in Study 2 were generally similar with regard to age, gender, race, and ethnicity among participants who received COMIRNATY and those who received placebo. Overall, among the total participants who received either COMIRNATY or placebo, 50.9% were male, 49.1% were female, 79.3% were 16 through 64 years of age, 20.7% were 65 years of age and older, 82.0% were White, 9.6% were Black or African American, 25.9% were Hispanic/Latino, 4.3% were Asian, and 1.0% were American Indian or Alaska Native.

Local and Systemic Adverse Reactions Solicited in the Study 2

Table 1 and Table 2 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days following each dose of COMIRNATY and placebo in the subset of participants 16 through 55 years of age included in the safety population who were monitored for reactogenicity with an electronic diary.

Table 3 and Table 4 present the frequency and severity of reported solicited local and systemic reactions, respectively, within 7 days of each dose of COMIRNATY and placebo for participants 56 years of age and older.

In participants 16 through 55 years of age after receiving Dose 2, the mean duration of pain at the injection site was 2.5 days (range 1 to 70 days), for redness 2.2 days (range 1 to 9 days), and for swelling 2.1 days (range 1 to 8 days) for participants in the COMIRNATY group. In participants 56 years of age and older after receiving Dose 2, the mean duration of pain at the injection site was 2.4 days (range 1 to 36 days), for redness 3.0 days (range 1 to 34 days), and for swelling 2.6 days (range 1 to 34 days) for participants in the COMIRNATY group.

Table 1: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 16 Through 55 Years of Age – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Redness[c]				
Any (>2.0 cm)	156 (5.4)	28 (1.0)	151 (5.6)	18 (0.7)
Mild	113 (3.9)	19 (0.7)	90 (3.4)	12 (0.4)
Moderate	36 (1.2)	6 (0.2)	50 (1.9)	6 (0.2)
Severe	7 (0.2)	3 (0.1)	11 (0.4)	0
Swelling[c]				
Any (>2.0 cm)	184 (6.3)	16 (0.6)	183 (6.8)	5 (0.2)
Mild	124 (4.3)	6 (0.2)	110 (4.1)	3 (0.1)
Moderate	54 (1.9)	8 (0.3)	66 (2.5)	2 (0.1)
Severe	6 (0.2)	2 (0.1)	7 (0.3)	0
Pain at the injection site[d]				
Any	2426 (83.7)	414 (14.2)	2101 (78.3)	312 (11.6)
Mild	1464 (50.5)	391 (13.4)	1274 (47.5)	284 (10.6)
Moderate	923 (31.8)	20 (0.7)	788 (29.4)	28 (1.0)
Severe	39 (1.3)	3 (0.1)	39 (1.5)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
No Grade 4 solicited local reactions were reported in participants 16 through 55 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table 2: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 16 Through 55 Years of Age – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Fever				
≥38.0°C	119 (4.1)	25 (0.9)	440 (16.4)	11 (0.4)
≥38.0°C to 38.4°C	86 (3.0)	16 (0.6)	254 (9.5)	5 (0.2)
>38.4°C to 38.9°C	25 (0.9)	5 (0.2)	146 (5.4)	4 (0.1)
>38.9°C to 40.0°C	8 (0.3)	4 (0.1)	39 (1.5)	2 (0.1)
>40.0°C	0	0	1 (0.0)	0
Fatigue[c]				
Any	1431 (49.4)	960 (33.0)	1649 (61.5)	614 (22.9)
Mild	760 (26.2)	570 (19.6)	558 (20.8)	317 (11.8)
Moderate	630 (21.7)	372 (12.8)	949 (35.4)	283 (10.5)
Severe	41 (1.4)	18 (0.6)	142 (5.3)	14 (0.5)

	COMIRNATY Dose 1 N[a]=2899 n[b] (%)	Placebo Dose 1 N[a]=2908 n[b] (%)	COMIRNATY Dose 2 N[a]=2682 n[b] (%)	Placebo Dose 2 N[a]=2684 n[b] (%)
Headache[c]				
Any	1262 (43.5)	975 (33.5)	1448 (54.0)	652 (24.3)
Mild	785 (27.1)	633 (21.8)	699 (26.1)	404 (15.1)
Moderate	444 (15.3)	318 (10.9)	658 (24.5)	230 (8.6)
Severe	33 (1.1)	24 (0.8)	91 (3.4)	18 (0.7)
Chills[c]				
Any	479 (16.5)	199 (6.8)	1015 (37.8)	114 (4.2)
Mild	338 (11.7)	148 (5.1)	477 (17.8)	89 (3.3)
Moderate	126 (4.3)	49 (1.7)	469 (17.5)	23 (0.9)
Severe	15 (0.5)	2 (0.1)	69 (2.6)	2 (0.1)
Vomiting[d]				
Any	34 (1.2)	36 (1.2)	58 (2.2)	30 (1.1)
Mild	29 (1.0)	30 (1.0)	42 (1.6)	20 (0.7)
Moderate	5 (0.2)	5 (0.2)	12 (0.4)	10 (0.4)
Severe	0	1 (0.0)	4 (0.1)	0
Diarrhea[e]				
Any	309 (10.7)	323 (11.1)	269 (10.0)	205 (7.6)
Mild	251 (8.7)	264 (9.1)	219 (8.2)	169 (6.3)
Moderate	55 (1.9)	58 (2.0)	44 (1.6)	35 (1.3)
Severe	3 (0.1)	1 (0.0)	6 (0.2)	1 (0.0)
New or worsened muscle pain[c]				
Any	664 (22.9)	329 (11.3)	1055 (39.3)	237 (8.8)
Mild	353 (12.2)	231 (7.9)	441 (16.4)	150 (5.6)
Moderate	296 (10.2)	96 (3.3)	552 (20.6)	84 (3.1)
Severe	15 (0.5)	2 (0.1)	62 (2.3)	3 (0.1)
New or worsened joint pain[c]				
Any	342 (11.8)	168 (5.8)	638 (23.8)	147 (5.5)
Mild	200 (6.9)	112 (3.9)	291 (10.9)	82 (3.1)
Moderate	137 (4.7)	55 (1.9)	320 (11.9)	61 (2.3)
Severe	5 (0.2)	1 (0.0)	27 (1.0)	4 (0.1)
Use of antipyretic or pain medication[f]	805 (27.8)	398 (13.7)	1213 (45.2)	320 (11.9)

Notes: Reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

No Grade 4 solicited systemic reactions were reported in participants 16 through 55 years of age.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction or use of antipyretic or pain medication was the same, therefore, this information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours.

f. Severity was not collected for use of antipyretic or pain medication.

Table 3: Study 2 – Frequency and Percentages of Participants with Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Redness[c]				
Any (>2.0 cm)	106 (5.3)	20 (1.0)	133 (7.2)	14 (0.8)
Mild	71 (3.5)	13 (0.7)	65 (3.5)	10 (0.5)
Moderate	30 (1.5)	5 (0.3)	58 (3.1)	3 (0.2)
Severe	5 (0.2)	2 (0.1)	10 (0.5)	1 (0.1)
Swelling[c]				
Any (>2.0 cm)	141 (7.0)	23 (1.2)	145 (7.8)	13 (0.7)
Mild	87 (4.3)	11 (0.6)	80 (4.3)	5 (0.3)
Moderate	52 (2.6)	12 (0.6)	61 (3.3)	7 (0.4)
Severe	2 (0.1)	0	4 (0.2)	1 (0.1)
Pain at the injection site[d]				
Any (>2.0 cm)	1408 (70.1)	185 (9.3)	1230 (66.1)	143 (7.8)
Mild	1108 (55.2)	177 (8.9)	873 (46.9)	138 (7.5)
Moderate	296 (14.7)	8 (0.4)	347 (18.7)	5 (0.3)
Severe	4 (0.2)	0	10 (0.5)	0

Notes: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.
No Grade 4 solicited local reactions were reported in participants 56 years of age and older.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. The N for each reaction was the same, therefore, the information was included in the column header.

b. n = Number of participants with the specified reaction.

c. Mild: >2.0 to ≤5.0 cm; Moderate: >5.0 to ≤10.0 cm; Severe: >10.0 cm.

d. Mild: does not interfere with activity; Moderate: interferes with activity; Severe: prevents daily activity.

Table 4: Study 2 – Frequency and Percentages of Participants with Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 56 Years of Age and Older – Reactogenicity Subset of the Safety Population*

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Fever				
≥38.0°C	26 (1.3)	8 (0.4)	219 (11.8)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.1)	3 (0.2)	158 (8.5)	2 (0.1)
>38.4°C to 38.9°C	2 (0.1)	3 (0.2)	54 (2.9)	1 (0.1)
>38.9°C to 40.0°C	1 (0.0)	2 (0.1)	7 (0.4)	1 (0.1)
>40.0°C	0	0	0	0

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)
Fatigue[c]				
Any	677 (33.7)	447 (22.5)	949 (51.0)	306 (16.7)
Mild	415 (20.7)	281 (14.1)	391 (21.0)	183 (10.0)
Moderate	259 (12.9)	163 (8.2)	497 (26.7)	121 (6.6)
Severe	3 (0.1)	3 (0.2)	60 (3.2)	2 (0.1)
Grade 4	0	0	1 (0.1)	0
Headache[c]				
Any	503 (25.0)	363 (18.3)	733 (39.4)	259 (14.1)
Mild	381 (19.0)	267 (13.4)	464 (24.9)	189 (10.3)
Moderate	120 (6.0)	93 (4.7)	256 (13.8)	65 (3.5)
Severe	2 (0.1)	3 (0.2)	13 (0.7)	5 (0.3)
Chills[c]				
Any	130 (6.5)	69 (3.5)	435 (23.4)	57 (3.1)
Mild	102 (5.1)	49 (2.5)	229 (12.3)	45 (2.5)
Moderate	28 (1.4)	19 (1.0)	185 (9.9)	12 (0.7)
Severe	0	1 (0.1)	21 (1.1)	0
Vomiting[d]				
Any	10 (0.5)	9 (0.5)	13 (0.7)	5 (0.3)
Mild	9 (0.4)	9 (0.5)	10 (0.5)	5 (0.3)
Moderate	1 (0.0)	0	1 (0.1)	0
Severe	0	0	2 (0.1)	0
Diarrhea[e]				
Any	168 (8.4)	130 (6.5)	152 (8.2)	102 (5.6)
Mild	137 (6.8)	109 (5.5)	125 (6.7)	76 (4.1)
Moderate	27 (1.3)	20 (1.0)	25 (1.3)	22 (1.2)
Severe	4 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
New or worsened muscle pain[c]				
Any	274 (13.6)	165 (8.3)	537 (28.9)	99 (5.4)
Mild	183 (9.1)	111 (5.6)	229 (12.3)	65 (3.5)
Moderate	90 (4.5)	51 (2.6)	288 (15.5)	33 (1.8)
Severe	1 (0.0)	3 (0.2)	20 (1.1)	1 (0.1)
New or worsened joint pain[c]				
Any	175 (8.7)	124 (6.2)	353 (19.0)	72 (3.9)
Mild	119 (5.9)	78 (3.9)	183 (9.8)	44 (2.4)
Moderate	53 (2.6)	45 (2.3)	161 (8.7)	27 (1.5)
Severe	3 (0.1)	1 (0.1)	9 (0.5)	1 (0.1)
Use of antipyretic or pain medication[f]	382 (19.0)	224 (11.3)	688 (37.0)	170 (9.3)

Notes: Reactions and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 to Day 7 after each dose.

The only Grade 4 solicited systemic reaction reported in participants 56 years of age and older was fatigue.

* Randomized participants in the safety analysis population who received at least 1 dose of the study intervention. Participants with chronic, stable HIV infection were excluded.

a. N = Number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose. N for each reaction or use of antipyretic or pain medication was the same, therefore was included in the column header.

b. n = Number of participants with the specified reaction.

	COMIRNATY Dose 1 N[a]=2008 n[b] (%)	Placebo Dose 1 N[a]=1989 n[b] (%)	COMIRNATY Dose 2 N[a]=1860 n[b] (%)	Placebo Dose 2 N[a]=1833 n[b] (%)

c. Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily activity; Grade 4 reactions were defined in the clinical study protocol as emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.
d. Mild: 1 to 2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration; Grade 4 emergency visit or hospitalization for severe vomiting.
e. Mild: 2 to 3 loose stools in 24 hours; Moderate: 4 to 5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours; Grade 4: emergency room or hospitalization for severe diarrhea.
f. Severity was not collected for use of antipyretic or pain medication.

In participants with chronic, stable HIV infection the frequencies of solicited local and systemic adverse reactions were similar to or lower than those observed for all participants 16 years of age and older.

Unsolicited Adverse Events

Overall, 11,253 (51.1%) participants in the COMIRNATY group and 11,316 (51.4%) participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 in the blinded placebo-controlled follow-up period with an additional 1,778 (8.1%) and 1,304 (5.9%) with ≥6 months of blinded follow-up time in the COMIRNATY and placebo groups, respectively.

A total of 12,006 (54.5%) participants originally randomized to COMIRNATY had ≥6 months total (blinded and unblinded) follow-up after Dose 2.

In an analysis of all unsolicited adverse events reported following any dose, through 1 month after Dose 2, in participants 16 years of age and older (N=43,847; 21,926 COMIRNATY group vs. 21,921 placebo group), those assessed as adverse reactions not already captured by solicited local and systemic reactions were nausea (274 vs. 87), malaise (130 vs. 22), lymphadenopathy (83 vs. 7), asthenia (76 vs. 25), decreased appetite (39 vs. 9), hyperhidrosis (31 vs. 9), lethargy (25 vs. 6), and night sweats (17 vs. 3).

In analyses of all unsolicited adverse events in Study 2 from Dose 1 up to the participant unblinding date, 58.2% of study participants had at least 4 months of follow-up after Dose 2. Among participants 16 through 55 years of age who received at least one dose of study vaccine, 12,995 of whom received COMIRNATY and 13,026 of whom received placebo, unsolicited adverse events were reported by 4,396 (33.8%) participants in the COMIRNATY group and 2,136 (16.4%) participants in the placebo group. In a similar analysis in participants 56 years of age and older that included 8,931 COMIRNATY recipients and 8,895 placebo recipients, unsolicited adverse events were reported by 2,551 (28.6%) participants in the COMIRNATY group and 1,432 (16.1%) participants in the placebo group. Among participants with confirmed stable HIV infection that included 100 COMIRNATY recipients and 100 placebo recipients, unsolicited adverse events were reported by 29 (29%) participants in the COMIRNATY group and 15 (15%) participants in the placebo group. The higher frequency of reported unsolicited adverse events among COMIRNATY recipients compared to placebo recipients was primarily attributed to events that are consistent with adverse reactions solicited among participants in the reactogenicity subset (Table 3 and Table 4).

Throughout the placebo-controlled safety follow-up period, Bell's palsy (facial paralysis) was reported by 4 participants in the COMIRNATY group and 2 participants in the placebo group. Onset of facial paralysis was Day 37 after Dose 1 (participant did not receive Dose 2) and Days 3, 9, and 48 after Dose 2. In the placebo group the onset of facial paralysis was Day 32 and Day 102. Currently available information is insufficient to determine a causal relationship with the vaccine. In the analysis of blinded, placebo-controlled follow-up, there

were no other notable patterns or numerical imbalances between treatment groups for specific categories of non-serious adverse events (including other neurologic or neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to COMIRNATY. In the analysis of unblinded follow-up, there were no notable patterns of specific categories of non-serious adverse events that would suggest a causal relationship to COMIRNATY.

Serious Adverse Events

In Study 2, among participants 16 through 55 years of age who had received at least 1 dose of vaccine or placebo (COMIRNATY =12,995; placebo = 13,026), serious adverse events from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 103 (0.8%) COMIRNATY recipients and 117 (0.9%) placebo recipients. In a similar analysis, in participants 56 years of age and older (COMIRNATY = 8,931; placebo = 8,895), serious adverse events were reported by 165 (1.8%) COMIRNATY recipients and 151 (1.7%) placebo recipients who received at least 1 dose of COMIRNATY or placebo, respectively. In these analyses, 58.2% of study participants had at least 4 months of follow-up after Dose 2. Among participants with confirmed stable HIV infection serious adverse events from Dose 1 up to the participant unblinding date in ongoing follow-up were reported by 2 (2%) COMIRNATY recipients and 2 (2%) placebo recipients.

In the analysis of blinded, placebo-controlled follow-up, there were no notable patterns between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to COMIRNATY. In the analysis of unblinded follow-up, there were no notable patterns of specific categories of serious adverse events that would suggest a causal relationship to COMIRNATY.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postmarketing use of COMIRNATY, including under Emergency Use Authorization. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Gastrointestinal Disorders: diarrhea, vomiting
Immune System Disorders: severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)
Musculoskeletal and Connective Tissue Disorders: pain in extremity (arm)

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to COMIRNATY during pregnancy. Women who are vaccinated with COMIRNATY during pregnancy are encouraged to enroll in the registry by visiting https://mothertobaby.org/ongoing-study/covid19-vaccines/.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to

4% and 15% to 20%, respectively. Available data on COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

A developmental toxicity study has been performed in female rats administered the equivalent of a single human dose of COMIRNATY on 4 occasions; twice prior to mating and twice during gestation. These studies revealed no evidence of harm to the fetus due to the vaccine *(see Animal Data)*.

Data

Animal Data

In a developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of COMIRNATY was administered to female rats by the intramuscular route on 4 occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

8.2 Lactation

Risk Summary

It is not known whether COMIRNATY is excreted in human milk. Data are not available to assess the effects of COMIRNATY on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for COMIRNATY and any potential adverse effects on the breastfed child from COMIRNATY or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of COMIRNATY in individuals 16 through 17 years of age is based on safety and effectiveness data in this age group and in adults *[see Adverse Reactions (6) and Clinical Studies (14.1)]*.

The safety and effectiveness of COMIRNATY in individuals younger than 16 years of age have not been established.

8.5 Geriatric Use

Of the total number of COMIRNATY recipients in Study 2 as of March 13, 2021 (N = 22,026), 20.7% (n = 4,552) were 65 years of age and older and 4.2% (n = 925) were 75 years of age and older *[see Clinical Studies (14.1)]*. No overall differences in safety or effectiveness were observed between these recipients and younger recipients.

11 DESCRIPTION

COMIRNATY (COVID-19 Vaccine, mRNA) is a sterile suspension for injection for intramuscular use. COMIRNATY is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of COMIRNATY contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the COMIRNATY also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

COMIRNATY does not contain preservative.

The vial stoppers are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

COMIRNATY has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a developmental toxicity study in rats with COMIRNATY there were no vaccine-related effects on female fertility *[see Use in Specific Populations (8.1)]*.

14 CLINICAL STUDIES

Efficacy in Participants 16 Years of Age and Older

Study 2 is an ongoing, multicenter, multinational, randomized, placebo-controlled, observer-blind, dose-finding, vaccine candidate–selection, and efficacy study in participants 12 years of age and older. Randomization was stratified by age: 12 through 15 years of age, 16 through 55 years of age, or 56 years of age and older, with a minimum of 40% of participants in the ≥56-year stratum. The study excluded participants who were immunocompromised and those who had previous clinical or microbiological diagnosis of COVID-19. Participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were included as were participants with known stable infection with HIV, hepatitis C virus (HCV), or hepatitis B virus (HBV).

In Study 2, based on data accrued through March 13, 2021, approximately 44,000 participants 16 years of age and older were randomized equally and received 2 doses of COMIRNATY or placebo. Participants are planned to be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

Overall, among the total participants who received COMIRNATY or placebo, 51.4% or 50.3% were male and 48.6% or 49.7% were female, 79.1% or 79.2% were 16 through 64 years of age, 20.9% or 20.8% were 65 years of age and older, 81.9% or 82.1% were White, 9.5% or 9.6% were Black or African American, 1.0% or 0.9% were American Indian or Alaska Native, 4.4% or 4.3% were Asian, 0.3% or 0.2% Native Hawaiian or other Pacific Islander, 25.6% or 25.4% were Hispanic/Latino, 73.9% or 74.1% were non-Hispanic/Latino, 0.5% or 0.5% did not report ethnicity, 46.0% or 45.7% had comorbidities [participants who have 1 or more

comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or body mass index (BMI) ≥30 kg/m^2], respectively. The mean age at vaccination was 49.8 or 49.7 years and median age was 51.0 or 51.0 in participants who received COMIRNATY or placebo, respectively.

Efficacy Against COVID-19

The population for the analysis of the protocol pre-specified primary efficacy endpoint included 36,621 participants 12 years of age and older (18,242 in the COMIRNATY group and 18,379 in the placebo group) who did not have evidence of prior infection with SARS-CoV-2 through 7 days after the second dose. The population in the protocol pre-specified primary efficacy analysis included all participants 12 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 through November 14, 2020. Participants 18 through 55 years of age and 56 years of age and older began enrollment from July 27, 2020, 16 through 17 years of age began enrollment from September 16, 2020, and 12 through 15 years of age began enrollment from October 15, 2020.

For participants without evidence of SARS-CoV-2 infection prior to 7 days after Dose 2, vaccine efficacy against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0% (95% credible interval: 90.3, 97.6), which met the pre-specified success criterion. The case split was 8 COVID-19 cases in the COMIRNATY group compared to 162 COVID-19 cases in the placebo group.

The population for the updated vaccine efficacy analysis included participants 16 years of age and older who had been enrolled from July 27, 2020, and followed for the development of COVID-19 during blinded placebo-controlled follow-up through March 13, 2021, representing up to 6 months of follow-up after Dose 2. There were 12,796 (60.8%) participants in the COMIRNATY group and 12,449 (58.7%) in the placebo group followed for ≥4 months after Dose 2 in the blinded placebo-controlled follow-up period.

SARS-CoV-2 variants of concern identified from COVID-19 cases in this study include B.1.1.7 (Alpha) and B.1.351 (Beta). Representation of identified variants among cases in vaccine versus placebo recipients did not suggest decreased vaccine effectiveness against these variants.

The updated vaccine efficacy information is presented in Table 5.

Table 5: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Age Subgroup – Participants 16 Years of Age and Older Without Evidence of Infection and Participants With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up Period

First COVID-19 occurrence from 7 days after Dose 2 in participants without evidence of prior SARS-CoV-2 infection*			
Subgroup	**COMIRNATY N[a]=19,993 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=20,118 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
All participants[f]	77 6.092 (19,711)	833 5.857 (19,741)	91.1 (88.8, 93.1)
16 through 64 years	70 4.859 (15,519)	709 4.654 (15,515)	90.5 (87.9, 92.7)
65 years and older	7 1.233 (4192)	124 1.202 (4226)	94.5 (88.3, 97.8)

First COVID-19 occurrence from 7 days after Dose 2 in participants with or without* evidence of prior SARS-CoV-2 infection			
Subgroup	**COMIRNATY N[a]=21,047 Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo N[a]=21,210 Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy % (95% CI[e])**
All participants	81 6.340 (20,533)	854 6.110 (20,595)	90.9 (88.5, 92.8)
16 through 64 years	74 5.073 (16,218)	726 4.879 (16,269)	90.2 (87.5, 92.4)
65 years and older	7 1.267 (4315)	128 1.232 (4326)	94.7 (88.7, 97.9)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = Number of participants in the specified group.

b. n1 = Number of participants meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of participants at risk for the endpoint.

e. Two-sided confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Subgroup analyses of vaccine efficacy (although limited by small numbers of cases in some subgroups) did not suggest meaningful differences in efficacy across genders, ethnic groups, geographies, or for participants with obesity or medical comorbidities associated with high risk of severe COVID-19.

Efficacy Against Severe COVID-19

Efficacy analyses of secondary efficacy endpoints supported benefit of COMIRNATY in preventing severe COVID-19. Vaccine efficacy against severe COVID-19 is presented only for participants with or without prior SARS-CoV-2 infection (Table 6) as the COVID-19 case counts in participants without prior SARS-CoV-2 infection were the same as those in participants with or without prior SARS-CoV-2 infection in both the COMIRNATY and placebo groups.

Table 6: Vaccine Efficacy – First Severe COVID-19 Occurrence in Participants 16 Years of Age and Older With or Without* Prior SARS-CoV-2 Infection Based on Protocol† or Centers for Disease Control and Prevention (CDC)‡ Definition From 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population During the Placebo-Controlled Follow-up

Vaccine Efficacy – First Severe COVID-19 Occurrence			
	COMIRNATY Cases n1[a] Surveillance Time[b] (n2[c])	**Placebo Cases n1[a] Surveillance Time[b] (n2[c])**	**Vaccine Efficacy % (95% CI[d])**
7 days after Dose 2[d]	1 6.353 (20,540)	21 6.237 (20,629)	95.3 (70.9, 99.9)
Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC Definition			
	COMIRNATY Cases n1[a] Surveillance Time[b] (n2[c])	**Placebo Cases n1[a] Surveillance Time[b] (n2[c])**	**Vaccine Efficacy % (95% CI[d])**
7 days after Dose 2[d]	0 6.345 (20,513)	31 6.225 (20,593)	100 (87.6, 100.0)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

* Participants who had no evidence of past SARS-CoV-2 infection (i.e., N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

† Severe illness from COVID-19 is defined in the protocol as confirmed COVID-19 and presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, saturation of oxygen ≤93% on room air at sea level, or ratio of arterial oxygen partial pressure to fractional inspired oxygen <300 mm Hg);
- Respiratory failure [defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation or extracorporeal membrane oxygenation (ECMO)];
- Evidence of shock (systolic blood pressure <90 mm Hg, diastolic blood pressure <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an Intensive Care Unit;
- Death.

‡ Severe illness from COVID-19 as defined by CDC is confirmed COVID-19 and presence of at least 1 of the following:

- Hospitalization;
- Admission to the Intensive Care Unit;
- Intubation or mechanical ventilation;
- Death.

a. n1 = Number of participants meeting the endpoint definition.
b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
c. n2 = Number of participants at risk for the endpoint.
d. Two-side confidence interval (CI) for vaccine efficacy is derived based on the Clopper and Pearson method adjusted to the surveillance time.

16 HOW SUPPLIED/STORAGE AND HANDLING

COMIRNATY Suspension for Intramuscular Injection, Multiple Dose Vials are supplied in a carton containing 25 multiple dose vials (NDC 0069-1000-03) or 195 multiple dose vials (NDC 0069-1000-02). A 0.9% Sodium Chloride Injection, USP diluent is provided but shipped separately, and should be stored at controlled room temperature 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. The provided 0.9% Sodium Chloride Injection, USP diluent will be supplied either as cartons of 10 mL single-use vials manufactured by

Hospira, Inc (NDC 0409-4888-10), or 2 mL single-use vials manufactured by Fresenius Kabi USA, LLC (NDC 63323-186-02).

After dilution, 1 vial contains 6 doses of 0.3 mL.

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Do not refreeze thawed vials.

Frozen Vials Prior to Use

Cartons of COMIRNATY Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -90ºC to -60ºC (-130ºF to -76ºF) until the expiry date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned 1 time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low temperature freezer is not available, the thermal container in which COMIRNATY arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90ºC to -60ºC (-130ºF to -76ºF). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

Transportation of Frozen Vials

If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned 1 time to the recommended storage condition of -90ºC to -60ºC (-130ºF to -76ºF).

Thawed Vials Before Dilution

Thawed Under Refrigeration

Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

Thawed at Room Temperature

For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions.

Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

Transportation of Thawed Vials

Available data support transportation of 1 or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.

Vials After Dilution

After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours. Do not refreeze.

17 PATIENT COUNSELING INFORMATION

Inform vaccine recipient of the potential benefits and risks of vaccination with COMIRNATY.

Inform vaccine recipient of the importance of completing the two dose vaccination series.

There is a pregnancy exposure registry for COMIRNATY. Encourage individuals exposed to COMIRNATY around the time of conception or during pregnancy to register by visiting https://mothertobaby.org/ongoing-study/covid19-vaccines/.

Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 and www.vaers.hhs.gov.

This product's labeling may have been updated. For the most recent prescribing information, please visit https://dailymed.nlm.nih.gov/dailymed/.

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10017

LAB-1448-0.9

US Govt. License No. x

EXHIBIT 5
C SecDef Memo

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 24 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members

To defend this Nation, we need a healthy and ready force. After careful consultation with medical experts and military leadership, and with the support of the President, I have determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people.

Mandatory vaccinations are familiar to all of our Service members, and mission-critical inoculation is almost as old as the U.S. military itself. Our administration of safe, effective COVID-19 vaccines has produced admirable results to date, and I know the Department of Defense will come together to finish the job, with urgency, professionalism, and compassion.

I therefore direct the Secretaries of the Military Departments to immediately begin full vaccination of all members of the Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard, who are not fully vaccinated against COVID-19.

Service members are considered fully vaccinated two weeks after completing the second dose of a two-dose COVID-19 vaccine or two weeks after receiving a single dose of a one-dose vaccine. Those with previous COVID-19 infection are not considered fully vaccinated.

Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance. Service members voluntarily immunized with a COVID-19 vaccine under FDA Emergency Use Authorization or World Health Organization Emergency Use Listing in accordance with applicable dose requirements prior to, or after, the establishment of this policy are considered fully vaccinated. Service members who are actively participating in COVID-19 clinical trials are exempted from mandatory vaccination against COVID-19 until the trial is complete in order to avoid invalidating such clinical trial results.

Mandatory vaccination requirements will be implemented consistent with DoD Instruction 6205.02, "DoD Immunization Program," July 23, 2019. The Military Departments should use existing policies and procedures to manage mandatory vaccination of Service members to the extent practicable. Mandatory vaccination of Service members will be subject to any identified contraindications and any administrative or other exemptions established in Military Department policy. The Military Departments may promulgate appropriate guidance to carry out the requirements set out above. The Under Secretary of Defense for Personnel and

Readiness may provide additional guidance to implement and comply with FDA requirements or Centers for Disease Control and Prevention recommendations.

The Secretaries of the Military Departments should impose ambitious timelines for implementation. Military Departments will report regularly on vaccination completion using established systems for other mandatory vaccine reporting.

Our vaccination of the Force will save lives. Thank you for your focus on this critical mission.

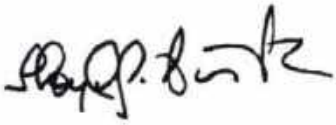


EXHIBIT 5
D DOD Hazcom program

DoD Instruction 6050.05

DoD Hazard Communication (HAZCOM) Program

Originating Component:	Office of the Under Secretary of Defense for Personnel and Readiness
Effective:	February 26, 2019
Change 1 Effective:	June 10, 2019
Releasability:	Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/.
Reissues and Cancels:	DoD Instruction 6050.05, "DoD Hazard Communication (HAZCOM) Program," August 15, 2006, as amended
Approved by:	Ellen M. Lord, Under Secretary of Defense for Acquisition and Sustainment
Change 1 Approved by:	James N. Stewart, Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Purpose: In accordance with the authority in DoD Directive (DoDD) 5124.01, DoD Instruction (DoDI) 6055.01, and the April 10, 2019 Office of the Deputy Secretary of Defense Memorandum, and the guidance in DoDI 6055.01, this issuance:

- Establishes policy, assigns responsibilities, and provides procedures for the DoD HAZCOM Program, which protects Service members and DoD civilian employees (referred to collectively in this issuance as "employee") who use or produce hazardous chemicals.
- Implements regulatory requirements of Parts 1910.120, 1910.1200, 1910.1450, 1915.1200, and 1926.59 of Title 29, Code of Federal Regulations (CFR).

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY. This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the "DoD Components").

1.2. POLICY. The DoD:

a. Protects DoD personnel from accidental death, injury, or occupational illness in accordance with DoDI 6055.01.

b. Manages hazardous materials to minimize health and environmental risks and operational costs.

c. Oversees establishment of HAZCOM programs at locations outside of the United States, where feasible, subject to the limitations detailed in DoDI 6055.01.

d. Applies HAZCOM procedures for all military personnel and civilian employees in non-uniquely military operations within the DoD and workplaces in accordance with this issuance and DoDI 6055.01.

e. Provides known hazard information to military personnel and civilian employees using hazardous chemicals, including engineered nanomaterials.

1.3. INFORMATION COLLECTIONS. The Enterprise Data Repository, referred to throughout this issuance, has been assigned report control symbol DD-A&S-1486 in accordance with the procedures in Volume 1 of DoD Manual 8910.01. The expiration date of this information collection is listed in the DoD Information Collections System at https://apps.sp.pentagon.mil/sites/dodiic/Pages/default.aspx.

1.4. SUMMARY OF CHANGE 1. This change reassigns the office of primary responsibility for this issuance to the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) in accordance with the April 10, 2019 Office of the Deputy Secretary of Defense Memorandum and updates authoritative references accordingly.

SECTION 2: RESPONSIBILITIES

2.1. USD(P&R). The USD(P&R):

a. Establishes policy for the operation of the DoD HAZCOM Program.

b. Oversees the implementation of this issuance.

2.2. ASSISTANT SECRETARY OF DEFENSE FOR READINESS. Under the authority, direction, and control of the USD(P&R), the Assistant Secretary of Defense for Readiness:

a. Advises the USD(P&R) on implementation of this issuance.

b. Develops policy and conducts advocacy and oversight of the DoD HAZCOM Program.

c. Conducts annual management reviews of the DoD Components' HAZCOM programs in accordance with DoDI 6055.01.

d. Establishes and administers a configuration control process:

(1) To support the HAZCOM requirements described in this issuance.

(2) In accordance with the DoD Business Enterprise Architecture.

(3) Pursuant to Section 2222 of Title 10, United States Code (U.S.C.).

e. Provides guidance and oversight for hazardous material management in the systems acquisition process to help program managers implement the requirements of Section 16 of Enclosure 3 of DoDI 5000.02.

2.3. DIRECTOR, DEFENSE LOGISTICS AGENCY (DLA). In addition to the responsibilities in Paragraph 2.4., and under the authority, direction, and control of the Under Secretary of Defense for Acquisition and Sustainment, the Director, DLA, as the lead DoD Component and administrator for enterprise data management:

a. Establishes and operates the Enterprise Data Repository for the storage and retrieval of data in accordance with Paragraph 3.7.b.

b. Implements and sustains the capability to store, use, and export regulatory reference data and enterprise product hazard data to DoD HAZCOM officials.

c. Receives and processes compliant hazardous materials information received from the DoD Component HAZCOM officials, General Services Administration officials, and other federal agency officials.

d. Makes available product hazard data, which is accessible to military personnel and civilian employees who use or are at risk of exposure to hazardous materials, immediately after completing quality control and records release.

e. Negotiates agreements with other federal agency offices of primary responsibility for interaction with the Enterprise Data Repository.

2.4. DOD COMPONENT HEADS. The DoD Component heads:

a. Establish and maintain a HAZCOM program and develop HAZCOM implementing guidance that conforms to the requirements of this issuance and is consistent with Parts 1910.1200, 1910.1450, 1915.1200, and 1926.59 of Title 29, CFR.

b. Designate a HAZCOM office of primary responsibility to oversee and implement policy and guidance, and report changes to the Hazardous Materials Information Systems Manager at Headquarters, DLA.

c. Designate a DoD Component HAZCOM official to:

(1) Obtain, evaluate, enter, and provide compliant hazardous material information to the Enterprise Data Repository.

(2) Represent the DoD Component in the configuration control process.

d. Assess their component's HAZCOM program during annual workplace visits in accordance with DoDI 6055.01.

e. Require contracts that purchase hazardous materials include a requirement for the contractor to provide compliant hazardous material information to the office of the contracting activity before contract award, as required by Federal Standard FED-STD-313E. The contracting activity will then forward this information to the DoD Component HAZCOM official.

f. Address multi-employer workplaces pursuant to the requirements of Part 1910.1200(e)(2) of Title 29, CFR, in their HAZCOM programs.

g. Make available appropriate occupational and environmental health, environmental, and safety personnel (including explosives safety, as appropriate) to provide installation and workplace HAZCOM support in areas such as training, safety data sheet (SDS) generation, hazard classification, and HAZCOM labeling.

SECTION 3: PROCEDURES

3.1. GENERAL. The DoD HAZCOM Program provides the framework to communicate hazards consistent with:

a. The requirements of Parts 1910.1200, 1915.1200, and 1926.59 of Title 29, CFR for hazardous chemicals, also known and referred to in this issuance as the "Occupational Safety and Health Administration (OSHA) HAZCOM Standard."

b. The requirements of Part 1910.1450 of Title 29, CFR for hazardous chemicals, also known and referred to in this issuance as the "OSHA HAZCOM Standard for Laboratories."

c. The requirements of Part 1910.120 of Title 29, CFR, also known and referred to in this issuance as the "OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard," for hazardous substance cleanup operations including:

(1) Emergency response operations in areas used primarily for hazardous waste treatment, storage, or disposal.

(2) Emergency response to hazardous substances, also known and referred to in this issuance as "HAZWOPER operations."

d. Host nation (HN) HAZCOM requirements at overseas locations when a SOFA or final governing standard (FGS) requires adoptions of HN HAZCOM requirements.

e. Paragraphs 3.2.a.(2), 3.2.c., 3.4.c., and 3.6.d., for the known presence of engineered nanomaterials that are not incorporated into an article.

3.2. WRITTEN HAZCOM PLANS.

a. All DoD workplaces using or producing hazardous chemicals must have a written HAZCOM plan that includes:

(1) A list of hazardous chemicals present in each workplace.

(2) An inventory of all engineered nanomaterials in the workplace in accordance with Paragraph 3.2.c.

(3) Hazard classification procedures in accordance with Paragraph 3.3.

(4) Container labeling procedures and requirements in accordance with Paragraph 3.5.

(5) Employee training in the safe use of hazardous materials and SDS accessibility to employees and other affected personnel in accordance with Paragraph 3.6.

(6) Procedures for preserving inventories of employee exposure records consistent with Part 1910.1020 of Title 29, CFR and pursuant to DoDI 6055.05.

(7) Procedures for informing employees regarding hazards of non-routine tasks and the hazards associated with chemicals contained in unlabeled pipes in the workplace.

(8) Requirements for contractors bringing hazardous materials onto DoD installations. These requirements will include providing hazardous material and label information compliant with Part 1910.1200 of Title 29, CFR, to the contracting officers in accordance with Subpart 223.3, Defense Federal Acquisition Regulation Supplement (DFARS). The contracting officers will then forward the information to the proper environmental, safety (including explosives safety, as appropriate), and health officials.

b. All DoD workplaces with laboratories must develop a written chemical hygiene plan in accordance with the OSHA HAZCOM Standard for Laboratories. These written chemical hygiene plans must:

(1) Be readily available to all affected personnel and include any installation-unique procedures about the local purchase of hazardous chemicals.

(2) Address engineered nanomaterials, not included in an article, used within the laboratory.

c. All DoD workplaces, or DoD-manufactured materials where engineered nanomaterials are used, should include engineered nanomaterials that are not incorporated into articles or otherwise excluded from Part 1910.1200 of Title 29, CFR into their written HAZCOM plans when there is knowledge of the presence of such engineered nanomaterials.

d. DoD Components stationed outside the United States must take measures to include HN requirements in HAZCOM plans if required to do so by SOFAs and FGSs.

e. All DoD workplaces conducting HAZWOPER operations must have a written HAZCOM plan that includes a list of hazardous wastes managed or hazardous substances that military personnel and civilian employees may encounter during emergency response or cleanup operations in accordance with Part 1910.120(b) of Title 29, CFR.

3.3. HAZARD CLASSIFICATION.

a. The DoD Components will obtain and use hazard information based on the hazard classification and any additional information provided on the SDSs. If an occupational or environmental health risk assessment or health hazard assessment is conducted in accordance with DoDI 6055.05, this information will supplement the manufacturer's information.

b. For DoD-manufactured or imported materials, the DoD activity controlling the formulation, or the DoD activity manufacturing the chemical, performs the hazard classification and produces the SDS and HAZCOM label with the required information following the guidelines specified in Part 1910.1200 of Title 29, CFR.

(1) The DoD activity producing the material will include hazard classification procedures in their written program, and train their military personnel and civilian employees on the hazards and handling of hazardous material and the prevention and handling of spillage incidents.

(2) If the DoD activity producing the material transfers the material to other organizations, they will provide the SDS and HAZCOM label to the receiving organization and the DoD Component HAZCOM official.

c. When engineered nanomaterials are present (but not incorporated into articles), regardless of quantity, the DoD activity using the material or controlling the formulation will refer to the National Institute for Occupational Safety and Health Publication Number 2009-125 (or most current report on nanomaterial toxicity and risk management) for what is currently known about the nanoparticle toxicity, process emissions, exposure assessment, engineering controls, and personal protective equipment.

d. The DoD activity will follow the guidelines in Technical Bulletin 700-2/Naval Sea Systems Command Instruction 8020.8C/Technical Order 11A-1-47 for classifying the hazards of DoD ammunition and explosives. This publication establishes procedures for classifying the physical hazards of ammunition and explosives in accordance with Department of Transportation regulations. This classification is used primarily for transporting and storing ammunition and explosives.

e. The DoD activity will identify risks at HAZWOPER operations consistent with Part 1910.120(b)(7) of Title 29, CFR.

3.4. HAZARDOUS MATERIAL INFORMATION.

a. The DoD Components will make SDSs compliant with Parts 1910.1200 and 1910.1450 of Title 29, CFR. SDSs will be readily accessible to employees at all times when they are in their work area, required to use hazardous chemicals, or at risk of exposure to hazardous chemicals.

b. Copies of the appropriate SDS will be:

(1) Readily accessible before hazardous chemicals are used and accessible at all times thereafter.

(2) Submitted for inclusion in the Enterprise Data Repository as soon as practical in accordance with Paragraph 3.7.

(3) Available to safety (including explosives safety, as appropriate), environmental, and fire officials in case of an accident.

c. DoD Components will make available their occupational and environmental health, environmental, and safety (including explosives safety, as appropriate) military personnel and civilian employees, upon request, to assess and explain SDSs and labels to supervisors and affected employees and assist in HAZCOM training.

d. Consistent with Part 1910.1200 of Title 29, CFR, the controlling DoD Component procurement activity:

(1) Electronically provides the most current, compliant SDSs and HAZCOM labels for users and the DoD Component HAZCOM official to include in the Enterprise Data Repository, as specified by the Business Enterprise Architecture; Subpart 223.3, DFARS; and Clause 52.223-3 of the Federal Acquisition Regulation Supplement.

(2) Rejects incomplete hazardous material information that does not comply with the requirements of Part 1910.1200 of Title 29, CFR. Laboratory verification of technical elements is not required. DoD Components will return incomplete or inadequate SDSs and labels to the supplier for correction. The contracting officer or buyer must consult with the manufacturer or distributer for resolution of SDS discrepancies.

e. Purchase requests for applicable supply items must include:

(1) A requirement for contracting activities to obtain manufacturer, importer, or supplier SDSs.

(2) The requirement for warning labels compliant with Part 1910.1200 of Title 29, CFR for U.S. locations or the Globally Harmonized System of Classification and Labelling of Chemicals for non-U.S. locations, in accordance with Military Standard MIL-STD-129R, Federal Standard FED-STD-313E, and Subpart 223.3, DFARS.

f. DoD Components will protect and use proprietary formulas or trade secret information in an SDS only as a management tool for exposure and mishap prevention, hazardous chemicals education, and medical diagnosis and treatment of exposed military personnel and civilian employees consistent with Part 1910.1200 of Title 29, CFR, and Volume 4 of DoD Manual 5200.01.

g. For nationally stock-listed and locally purchased nonstandard stock hazardous chemicals, the responsible contracting officer must contractually require and obtain compliant electronic SDSs and HAZCOM labels.

(1) For locally purchased chemicals, the purchaser or contracting officer confirms before the contract award or purchase:

(a) The adequate completion of an environmental, safety, and health assessment of the SDSs and HAZCOM labels.

(b) The correct SDSs and labels, as required in Part 1910.1200 of Title 29, CFR.

(2) The installation point of contact electronically forwards the SDSs and HAZCOM labels to the DoD Component HAZCOM official for processing.

h. For foreign manufactured products used outside the United States, the contracting office and purchaser will obtain SDSs and HAZCOM labels that are available in English.

(1) The SDSs and HAZCOM labels must contain all information required in Part 1910.1200 of Title 29, CFR.

(2) The contracting office and purchaser must electronically forward the SDSs, translated by other than the chemical manufacturer, to installation SDS focal points for entry into the Enterprise Data Repository with markings showing the SDS has translated hazardous material information.

i. The lead DoD Component managing the first non-U.S. entry point must establish procedures to make the appropriate SDS information available to all users of supplied hazardous chemical supply items.

(1) Unless the governing SOFA specifically mandates the use of HN SDS data and formats, SDSs will conform to Parts 1910.1200 and 1910.1450 of Title 29, CFR and Paragraph 3.4.h.

(2) Special procedures may be necessary for certain workplaces outside the United States with foreign national employees, including multi-employer sites similar to Part 1910.1200(e)(2) of Title 29, CFR. Hazardous material information and SDSs will reflect the predominant language spoken in addition to English. If required by the governing SOFA, FGS, or other binding agreement, the SDSs available in workplaces with foreign nationals may need to account for HN variations in SDS format or data. The lead DoD Component should establish those procedures using the guidance in this issuance, the relevant SOFA, the FGS for the location, or DoD 4715.05-G.

3.5. LABELING.

a. Hazardous chemicals used by the DoD Components:

(1) Must be appropriately classified and labeled consistent with Parts 1910.1200 and 1910.1450 of Title 29, CFR.

(2) That are specifically identified in Parts 1910.1001 through 1910.1052 in Subpart Z of Title 29, CFR, must be classified and labeled following additional substance-specific standards.

b. Commercial suppliers are required to label all hazardous materials with HAZCOM Standard-compliant labels consistent with Part 1910.1200 of Title 29, CFR.

c. The DoD Components will use the commercial or manufacturer's HAZCOM label for marking hazardous chemicals, including laboratory chemicals, and this label must not be removed from the products or defaced. If a DoD Component generates a hazardous chemical label, it must comply with Part 1910.1200 of Title 29, CFR.

d. If suppliers of hazardous materials have not properly labeled containers in accordance with Parts 1910.1200 and 1910.1450 of Title 29, CFR, the DoD Component must properly label containers. Hazardous material cannot be issued to downstream customers or used until compliance is met.

e. The label information must contain:

(1) Product identifier.

(2) Signal word.

(3) Hazard statements.

(4) Pictograms.

(5) Precautionary statements.

(6) Chemical manufacturer, importer, or other responsible party's name, address, and telephone number.

f. Navy ships may use alternate HAZCOM Standard-compliant labeling (e.g., tags or markings) for repackaging, breakdown containers, or unlabeled containers aboard ship, consistent with the exclusion for uniquely military equipment, systems, operations, or workplaces in Executive Order 12196. The Navy must label all hazardous chemicals in accordance with the provisions of this issuance before being off-loaded or transferred to a shore facility.

g. Hazardous chemicals excluded from HAZCOM labeling requirements are described in Part 1910.1200(b)(5) of Title 29, CFR. Outside of the United States, hazardous chemicals must be labeled in accordance with applicable HAZCOM regulations as specified in the SOFA, FGSs, or other HN agreement. Many of these chemicals, though excluded from HAZCOM, have alternative labeling requirements such as chemicals regulated by:

(1) Section 2015 of Title 15, U.S.C., also known as the "Consumer Product Safety Act."

(2) Section 136 of Title 7, U.S.C., also known as the "Federal Insecticide, Fungicide, and Rodenticide Act."

(3) Section 201 of Title 27, U.S.C., also known as the "Federal Alcohol Administration Act."

(4) Section 2601 of Title 15, U.S.C., also known as the "Toxic Substances Control Act."

3.6. EMPLOYEE INFORMATION AND TRAINING. The DoD Components will:

a. Provide HAZCOM information and training and document training to employees who may become exposed to:

(1) Hazardous chemicals while carrying out their duties, in accordance with Parts 1910.1200 and 1910.1450 of Title 29, CFR.

(2) Hazardous materials during HAZWOPER operations, consistent with the OSHA HAZWOPER Standard.

b. Inform contractors and subcontractors at DoD workplaces of site emergency response procedures consistent with Part 1910.120(b)(1)(iv) of Title 29, CFR.

c. Consider HN regulations for personnel information and training for the local national workforce if authorized or required to do so by SOFAs or FGSs.

d. Provide known hazard information of engineered nanomaterials used at DoD workplaces.

3.7. ENTERPRISE DATA REPOSITORY.

a. The DoD Components will implement procedures to provide hazardous materials information to the Enterprise Data Repository consistent with Part 1910.1200 of Title 29, CFR. They will submit the hazardous materials information through the media (hard or electronic copy) appropriate to the technological capabilities or availability suitable for the DoD Component's system.

b. The DLA operates the Enterprise Data Repository for the storage and retrieval of data and:

(1) Makes SDS image and associated ingredient, transportation, disposal, and label information accessible by national item identification number; local item identification number, if applicable; trade name and part number; SDS serial number; hazard characteristic code; hazardous ingredient(s); contract number; and manufacturer, importer, or distributor (or other responsible party) Commercial and Government Entity Codes. For local purchases of hazardous chemicals made without a formal contract number assigned, or from companies who do not have a Commercial and Government Entity Code, this information may not be available for entering into the Enterprise Data Repository. All other SDS information will be available.

(2) Allows for expansion as required by future safety, health, environmental, or transportation legislation or regulation.

(3) Permanently retains SDS information electronically.

(4) Provides SDS and corresponding product hazard data for all hazardous material inventory items for use as a reference throughout the procurement and the supply chain distribution process.

(5) Establishes a capability for the management of HN SDS information and images for hazardous materials used by the DoD outside the United States.

GLOSSARY

G.1. ACRONYMS.

CFR	Code of Federal Regulations
DFARS	Defense Federal Acquisition Regulation Supplement
DLA	Defense Logistics Agency
DoDD	DoD directive
DoDI	DoD instruction
FGS	final governing standard
HAZCOM	hazard communication
HAZWOPER	hazardous waste operations and emergency response
HN	host nation
OSHA	Occupational Safety and Health Administration
SDS	safety data sheet
SOFA	status-of-forces agreement
U.S.C.	United States Code
USD(P&R)	Under Secretary of Defense for Personnel and Readiness

G.2. DEFINITIONS. Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

article. Defined in Part 1910.1200(c) of Title 29, CFR.

DoD workplaces with laboratories. Defined in the OSHA HAZCOM Standard for Laboratories.

engineered nanomaterials. Discrete materials having structures with at least one dimension between 1 and 100 nanometers that are intentionally created, as opposed to those that are naturally or incidentally formed. They do not include larger materials that may have nanoscale features (e.g., etched silicon wafers), biomolecules (e.g., proteins, nucleic acids, carbohydrates), and materials with occupational exposure limits that address nanoparticles for that substance.

hazard classification. Defined in Part 1910.1200(c) of Title 29, CFR.

hazardous chemical. Defined in Part 1910.1200(c) of Title 29, CFR.

hazardous material. Hazardous chemicals, hazardous substances, hazardous wastes, or engineered nanomaterials, where applicable.

hazardous substance. Defined in Part 1910.120(c) of Title 29, CFR.

hazardous waste. Defined in Part 261.3 of Title 40, CFR and Part 171.8 of Title 49, CFR, in accordance with the OSHA HAZWOPER Standard.

HAZWOPER. Defined in Part 120(a)(1) of Title 29, CFR.

product hazard data. The comprehensive set of material, chemical, and regulatory data necessary to develop and implement ESOH controls for mission activities involving hazardous materials.

uniquely military equipment, systems, and operations. Defined in Part 1960.2(i) of Title 29, CFR.

REFERENCES

Code of Federal Regulations, Title 29

Code of Federal Regulations, Title 40, Part 261.3

Code of Federal Regulations, Title 49, Part 171.8

Defense Federal Acquisition Regulation Supplement, Subpart 223.3

DoD 4715.05-G, "Overseas Environmental Baseline Guidance Document," May 1, 2007

DoD Directive 5124.01, "Under Secretary of Defense for Personnel and Readiness (USD(P&R))," June 23, 2008

DoD Instruction 5000.02, "Operation of the Defense Acquisition System," January 7, 2015, as amended

DoD Instruction 6055.01, "DoD Safety and Occupational Health (SOH) Program," October 14, 2014

DoD Instruction 6055.05, "Occupational and Environmental Health (OEH)," November 11, 2008, as amended

DoD Manual 5200.01, Volume 4, "DoD Information Security Program: Controlled Unclassified Information (CUI)," February 24, 2018, as amended

DoD Manual 8910.01, Volume 1, "DoD Information Collections Manual: Procedures for DoD Internal Information Collections," June 30, 2014, as amended

Executive Order 12196, "Occupational Safety and Health Programs for Federal Employees," February 26, 1980, as amended

Federal Acquisition Regulation Supplement, Clause 52.223-3

Federal Standard FED-STD-313E, "Material Safety Data, Transportation Data, and Disposal Data for Hazardous Materials Furnished to Government Activities," July 1, 2014

Military Standard MIL-STD-129R, "Department of Defense Standard Practice: Military Marking for Shipment and Storage," February 18, 2014

National Institute for Occupational Safety and Health Publication Number 2009-125, "Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials," March 2009

Office of the Deputy Chief Management Officer, "Business Enterprise Architecture (BEA)," current edition[1]

Office of the Deputy Secretary of Defense Memorandum, "Safety and Occupational Health Policy and Oversight Functions," April 10, 2019

TB 700-2/NAVSEAINST 8020.8C/TO 11A-1-47, "Department of Defense Ammunition and Explosives Hazard Classification Procedures," July 30, 2012[2]

United Nations, "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)," Revision 4, New York and Geneva, 2011[3]

[1] Available at http://cmo.defense.gov/Products-and-Services/Business-Enterprise-Architecture/
[2] Available at https://www.ddesb.pentagon.mil/docs/TB700-2.pdf
[3] Available at http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/ST-SG-AC10-30-Rev4e.pdf

EXHIBIT 5
E Safe
Nanotech

Approaches to Safe Nanotechnology

Managing the Health and Safety Concerns Associated with Engineered Nanomaterials

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Approaches to Safe Nanotechnology

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TTY: 1–888–232–6348
E-mail: cdcinfo@cdc.gov

or visit the NIOSH Web site at **www.cdc.gov/niosh**.

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DHHS (NIOSH) Publication No. 2009–125

March 2009

SAFER • HEALTHIER • PEOPLE™

Foreword

Nanotechnology—the manipulation of matter on a near-atomic scale to produce new structures, materials, and devices—offers the promise of unprecedented scientific advancement for many sectors, such as medicine, consumer products, energy, materials, and manufacturing. Nanotechnology has the power not only to improve existing technologies, but to dramatically enhance the effectiveness of new applications.

Research on the potential applications of nanotechnology continues to expand rapidly worldwide. New nanotechnology consumer products emerge at a rate of three to four per week. Over the course of the next decade, nanotechnology could have a $1 trillion impact on the global economy and employ two million workers—half of them residing in the U.S.

While nanomaterials present seemingly limitless possibilities, they bring with them new challenges to understanding, predicting, and managing potential safety and health risks to workers. The National Institute for Occupational Safety and Health (NIOSH) remains committed to protecting workers now and in the future, as nanotechnology applications and uses expand.

As part of these efforts, in October 2005, NIOSH released for public comment the draft document, Approaches to Safe Nanotechnology: An Information Exchange with NIOSH. Based on feedback received, NIOSH revised and updated the document in July 2006 and sought further public comment. This draft report has been widely cited, and the final version of the report should serve as a vital resource for stakeholders (including occupational safety and health professionals, researchers, policy makers, risk assessors, and workers in the industry) who wish to understand more about the safety and health implications of nanotechnology in the workplace.

With the publication of the Approaches to Safe Nanotechnology document, NIOSH hopes to: raise awareness of the occupational safety and health issues involved with nanotechnology; make recommendations on occupational safety and health best practices in the production and use of nanomaterials; facilitate dialogue between NIOSH and its external partners in industry, labor and academia; respond to requests for authoritative safety and health guidelines; and, identify information gaps and areas for future study and research.

As our knowledge of nanoscience increases, so too will our efforts to provide valuable guidance on the safe handling of nanoparticles and for protecting the lives and livelihoods of nanotechnology workers.

Christine M. Branche, Ph.D.
Acting Director, National Institute
for Occupational Safety and Health
Centers for Disease Control and Prevention

Executive Summary

Nanotechnology has the potential to dramatically improve the effectiveness of a number of existing consumer and industrial products and could have a substantial impact on the development of new products in all sectors, ranging from disease diagnosis and treatment to environmental remediation. Because of the broad range of possible nanotechnology applications, continued evaluation of the potential health risks associated with exposure to nanomaterials is essential to ensure their safe handling. Engineered nanoparticles are materials purposefully produced with at least one dimension between 1 and 100 nanometers. Nanoparticles* often exhibit unique physical and chemical properties that impart specific characteristics essential in making engineered materials, but little is known about what effect these properties may have on human health. Research has shown that the physicochemical characteristics of particles can influence their effects in biological systems. These characteristics include particle size, shape, surface area, charge, chemical properties, solubility, oxidant generation potential, and degree of agglomeration. Until the results from research studies can fully elucidate the characteristics of nanoparticles that may pose a health risk, precautionary measures are warranted.

NIOSH has developed this document to provide an overview of what is known about the potential hazards of engineered nanoparticles and measures that can be taken to minimize workplace exposures. Following is a summary of findings and key recommendations.

*In an attempt at standardization of terminology, the International Organization for Standardization-Technical Committee 229 has used the term nanomaterial to describe engineered nanoparticles.

Potential Health Concerns

- The potential for nanomaterials to enter the body is among several factors that scientists examine in determining whether such materials may pose an occupational health hazard. Nanomaterials have the greatest potential to enter the body through the respiratory system if they are airborne and in the form of respirable-sized particles (nanoparticles). They may also come into contact with the skin or be ingested.
- Based on results from human and animal studies, airborne nanoparticles can be inhaled and deposit in the respiratory tract; and based on animal studies, nanoparticles can enter the blood stream, and translocate to other organs.
- Experimental studies in rats have shown that equivalent mass doses of insoluble incidental nanoparticles are more potent than large particles of similar composition in causing pulmonary inflammation and lung tumors. Results from in vitro cell culture studies with similar materials are generally supportive of the biological responses observed in animals.
- Experimental studies in animals, cell cultures, and cell-free systems have shown that changes in the chemical

composition, crystal structure, and size of particles can influence their oxidant generation properties and cytotoxicity.

- Studies in workers exposed to aerosols of some manufactured or incidental microscopic (fine) and nanoscale (ultrafine) particles have reported adverse lung effects including lung function decrements and obstructive and fibrotic lung diseases. The implications of these studies to engineered nanoparticles, which may have different particle properties, are uncertain.
- Research is needed to determine the key physical and chemical characteristics of nanoparticles that determine their hazard potential.

Potential Safety Concerns

- Although insufficient information exists to predict the fire and explosion risk associated with powders of nanomaterials, nanoscale combustible material could present a higher risk than coarser material with a similar mass concentration given its increased particle surface area and potentially unique properties due to the nanoscale.
- Some nanomaterials may initiate catalytic reactions depending on their composition and structure that would not otherwise be anticipated based on their chemical composition.

Working with Engineered Nanomaterials

- Nanomaterial-enabled products such as nanocomposites, surface-coated materials, and materials comprised of nanostructures, such as integrated circuits, are unlikely to pose a risk of exposure during their handling and use as materials of non-inhalable size. However, some of the processes used in their production (e.g., formulating and applying nanoscale coatings) may lead to exposure to nanomaterials, and the cutting or grinding of such products could release respirable-sized nanoparticles.
- Maintenance on production systems (including cleaning and disposal of materials from dust collection systems) is likely to result in exposure to nanoparticles if deposited nanomaterials are disturbed.
- The following workplace tasks can increase the risk of exposure to nanoparticles:
  - Working with nanomaterials in liquid media without adequate protection (e.g., gloves)
  - Working with nanomaterials in liquid during pouring or mixing operations, or where a high degree of agitation is involved
  - Generating nanoparticles in non-enclosed systems
  - Handling (e.g., weighing, blending, spraying) powders of nanomaterials
  - Maintenance on equipment and processes used to produce or fabricate nanomaterials and the cleaning-up of spills and waste material containing nanomaterials
  - Cleaning of dust collection systems used to capture nanoparticles
  - Machining, sanding, drilling, or other mechanical disruptions of materials containing nanoparticles

Exposure Assessment and Characterization

- Until more information becomes available on the mechanisms underlying nanomaterial toxicity, it is uncertain what measurement technique should be used to monitor exposures in the workplace. Current research indicates that mass and bulk chemistry may be less important than particle size and shape, surface area, and surface chemistry (or activity) for some nanostructured materials.
- Many of the sampling techniques that are available for measuring airborne nanoaerosols vary in complexity but can provide useful information for evaluating occupational exposures with respect to particle size, mass, surface area, number concentration, and composition. Unfortunately, relatively few of these techniques are readily applicable to routine exposure monitoring. NIOSH has initiated exposure assessment studies in workplaces that manufacture or use engineered nanoparticles (see Appendix *Nanoparticle Emission Assessment Technique for Identification of Sources and Releases of Engineered Nanomaterials*).
- Regardless of the metric or measurement method used for evaluating nanoaerosol exposures, it is critical that background nanoscale particle measurements be conducted before the production, processing, or handling of nanomaterials.
- When feasible, personal sampling is preferred to ensure an accurate representation of the worker's exposure, whereas area sampling (e.g., size-fractionated aerosol samples) and real-time (direct reading) exposure measurements may be more useful for evaluating the need for improvement of engineering controls and work practices.

Precautionary Measures

- Given the limited amount of information about health risks that may be associated with nanomaterials, taking measures to minimize worker exposures is prudent.
- For most processes and job tasks, the control of airborne exposure to nanoaerosols can be accomplished using a variety of engineering control techniques similar to those used in reducing exposure to general aerosols.
- The implementation of a risk management program in workplaces where exposure to nanomaterials exists can help to minimize the potential for exposure to nanoparticles. Elements of such a program should include the following:
  - Evaluating the hazard posed by the nanomaterial based on available physical and chemical property data, toxicology, or health-effects data
  - Assessing the worker's job task to determine the potential for exposure
  - Educating and training workers in the proper handling of nanomaterials (e.g., good work practices)
  - Establishing criteria and procedures for installing and evaluating engineering controls (e.g., exhaust ventilation) at locations where exposure to nanomaterials might occur

  - Developing procedures for determining the need for and selecting proper personal protective equipment (e.g., clothing, gloves, respirators)
  - Systematically evaluating exposures to ensure that control measures are working properly and that workers are being provided the appropriate personal protective equipment

- Engineering control techniques such as source enclosure (i.e., isolating the generation source from the worker) and local exhaust ventilation systems should be effective for capturing airborne nanoparticles. Current knowledge indicates that a well-designed exhaust ventilation system with a high-efficiency particulate air (HEPA) filter should effectively remove nanomaterials.
- The use of good work practices can help to minimize worker exposures to nanomaterials. Examples of good practices include cleaning of work areas using HEPA vacuum pickup and wet wiping methods, preventing the consumption of food or beverages in workplaces where nanomaterials are handled, providing hand-washing facilities, and providing facilities for showering and changing clothes.
- No guidelines are currently available on the selection of clothing or other apparel (e.g., gloves) for the prevention of dermal exposure to nanoaerosols. However, some clothing standards incorporate testing with nanometer-sized particles and therefore provide some indication of the effectiveness of protective clothing.
- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures. Currently, there are no specific limits for airborne exposures to engineered nanoparticles although occupational exposure limits exist for some larger particles of similar chemical composition. It should be recognized that exposure limits recommended for nonnanoscale particles may not be health protective for nanoparticle exposures (e.g., the OSHA Permissible Exposure Limit [PEL] for graphite may not be a safe exposure limit for carbon nanotubes). The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and the frequency and likelihood of the worker's exposure. While research is continuing, preliminary evidence indicates that NIOSH-certified respirators will be useful for protecting workers from nanoparticle inhalation when properly selected and fit tested as part of a complete respiratory protection program.

Occupational Health Surveillance

Occupational health surveillance is an essential component of an effective occupational safety and health program. The unique physical and chemical properties of nanomaterials, the increasing growth of nanotechnology in the workplace, and information suggesting that exposure to some engineered nanomaterials can cause adverse health effects in laboratory animals all support consideration of an occupational health surveillance program for workers potentially exposed to engineered

nanomaterials. Continued evaluation of toxicologic research and workers potentially exposed to engineered nanomaterials is needed to inform NIOSH and other groups regarding the appropriate components of occupational health surveillance for nanotechnology workers. NIOSH has formulated interim guidance relevant to medical screening (one component of an occupational health surveillance program) for nanotechnology workers (see NIOSH *Current Intelligence Bulletin Interim Guidance for Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles* at www.cdc.gov/niosh/review/public/115/). In this document NIOSH concluded that insufficient scientific and medical evidence now exist to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles. However, NIOSH did recommend that hazard surveillance be conducted as the basis for implementing control measures.

Contents

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1 Introduction

Nanotechnology is the manipulation of matter on a near-atomic scale to produce new structures, materials, and devices. This technology has the ability to transform many industries and can be applied in many ways to areas ranging from medicine to manufacturing. Research in nanoscale technologies is growing rapidly worldwide. Lux Research [2007] projects that new emerging nanotechnology applications will affect nearly every type of manufactured product through the middle of the next decade, becoming incorporated into 15% of global manufacturing output, totaling $2.6 trillion in 2014.

Nanomaterials present new challenges to understanding, predicting, and managing potential health risks to workers. As with any material being developed, scientific data on the health effects in exposed workers are largely unavailable. **In the case of nanomaterials, the uncertainties are great because the characteristics of nanoparticles may be different from those of larger particles with the same chemical composition.** Safety and health practitioners recognize the critical lack of specific guidance on the safe handling of nanomaterials—especially now, when the degree of risk to exposed workers is unknown. In the meantime, the extensive scientific literature on airborne particles—including toxicology and epidemiological studies, measurement techniques, and engineering controls—provides the best available data from which to develop interim approaches for working safely with nanomaterials and to develop hypotheses for studies of new nanomaterials.

The National Institute for Occupational Safety and Health (NIOSH) is working in parallel with the development and implementation of commercial nanotechnology through (*1*) conducting strategic planning and research, (*2*) partnering with public- and private-sector colleagues from the United States and abroad, and (*3*), making information widely available. The NIOSH goal is to provide national and world leadership for incorporating research findings about the implications and applications of nanotechnology into good occupational safety and health practice for the benefit of all nanotechnology workers. NIOSH has developed a strategic plan for coordinating nanotechnology research and for use as a guide for enhancing the development of new research efforts (www.cdc.gov/niosh/topics/nanotech/strat_plan.html).

2 Purpose

With the publication of this *Approaches to Safe Nanotechnology* document, NIOSH hopes to do the following:

- **Raise awareness** of the occupational safety and health issues being identified in the rapidly moving and changing science involving implications and applications of nanotechnology.
- **Use the best information available to make recommendations** on occupational safety and health practices in the production and use of nanomaterials (These recommendations will be updated as appropriate to reflect new information. They will address key components of occupational safety and health, including exposure monitoring, engineering controls, personal protective equipment, and administrative controls. They will draw from the ongoing NIOSH assessment of current best practices, technical knowledge, and professional judgment. Throughout the development of these guidelines, the utility of a hazard-based approach to risk assessment and control was evaluated and, where appropriate, recommendations are provided.)
- **Facilitate an exchange of information** between NIOSH and its external partners from ongoing research, including success stories, applications, and case studies.
- **Respond to requests** from industry, labor, academia, and other partners who are seeking science-based, authoritative guidelines.
- **Identify information gaps** where few or no data exist and where research is needed.

3 Scope

This document has been developed to provide a resource for stakeholders who wish to understand more about the safety and health implications and applications of nanotechnology in the workplace. The information and guidelines presented here are intended to aid in evaluating the potential hazard of exposure to engineered nanomaterials and to set the stage for the development of more comprehensive guidelines for reducing potential workplace exposures in the wide range of tasks and processes that use nanomaterials. The information in this document will be of specific interest to the following:

- Occupational safety and health professionals who must (*1*) understand how nanotechnology may affect occupational health and (*2*) devise strategies for working safely with nanomaterials
- Researchers working with or planning to work with engineered nanomaterials and studying the potential occupational safety and health impacts of nanomaterials
- Policy and decision makers in government agencies and industry
- Risk evaluation professionals
- People working with or potentially exposed to engineered nanomaterials in the workplace

Established safe work practices are generally based on an understanding of the hazards associated with the chemical and physical properties of a material. Engineered nanomaterials may exhibit unique properties that are related to their physical size, shape, structure, and chemical composition. Considerable uncertainty still exists as to whether these unique properties present occupational health risks. Current information about the potential adverse health effects of engineered nanomaterials, exposure assessment, and exposure control is limited. However, the large body of scientific literature that exists on exposures to and responses of animals and humans to ultrafine and other airborne particles may be useful in making preliminary assessments as to the health risks posed by engineered nanomaterials. **Until further information is available, interim safe working practices should be used based on the best available information.** The information and recommendations in this document are intended to aid in assessment of the potential hazard of engineered nanomaterials and to set the stage for the development of more comprehensive guidelines for reducing potential workplace exposures.

4 Descriptions and Definitions

Nanotechnology involves the manipulation of matter at nanometer[†] scales to produce new materials, structures, and devices. The U.S. National Nanotechnology Initiative (see http://nano.gov/html/facts/whatIsNano.html) defines a technology as nanotechnology only if it involves all of the following:

- Research and technology development involving structures with at least one dimension in the range of 1–100 nanometers (nm), frequently with atomic/molecular precision
- Creating and using structures, devices, and systems that have unique properties and functions because of their nanoscale dimensions
- The ability to control or manipulate on the atomic scale

Nanotechnology is an enabling technology that offers the potential for unprecedented advances in many diverse fields. The ability to manipulate matter at the atomic or molecular scale makes it possible to form new materials, structures, and devices that exploit the unique physical and chemical properties associated with nanoscale structures. The promise of nanotechnology goes far beyond extending the use of current materials. New materials and devices with intricate and closely engineered structures will allow for (*1*) new directions in optics, electronics, and optoelectronics, (*2*) development of new medical imaging and treatment technologies, and (*3*) production of advanced materials with unique properties and high-efficiency energy storage and generation.

Although nanotechnology-based products are generally thought to be at the precompetitive stage, an increasing number of products and materials are becoming commercially available. These include nanoscale powders, solutions, and suspensions of nanoscale materials as well as composite materials and devices having a nanostructure. Nanoscale products and materials are increasingly used in optoelectronic, electronic, magnetic, medical imaging, drug delivery, cosmetic, catalytic, and materials applications. New nanotechnology consumer products are coming on the market at the rate of three to four per week, a finding based on the latest update to the nanotechnology consumer product inventory maintained by the Project on Emerging Nanotechnologies (PEN)[‡] (www.nanotechproject.org/inventories/consumer). The number of consumer products using nanotechnology has grown from 212 to 609 since PEN launched the world's first online inventory of manufacturer-identified nanotech goods in March 2006.

According to Lux Research [2007], in 2006, governments, corporations, and venture capitalists worldwide spent $11.8 billion on nanotechnology research and development (R&D), which was up 13% from 2005. By 2014, Lux estimates $2.6 trillion in manufactured goods

[†]1 nanometer (nm) = 1 billionth of a meter (10^{-9}).

[‡]The Project on Emerging Nanotechnologies was established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts.

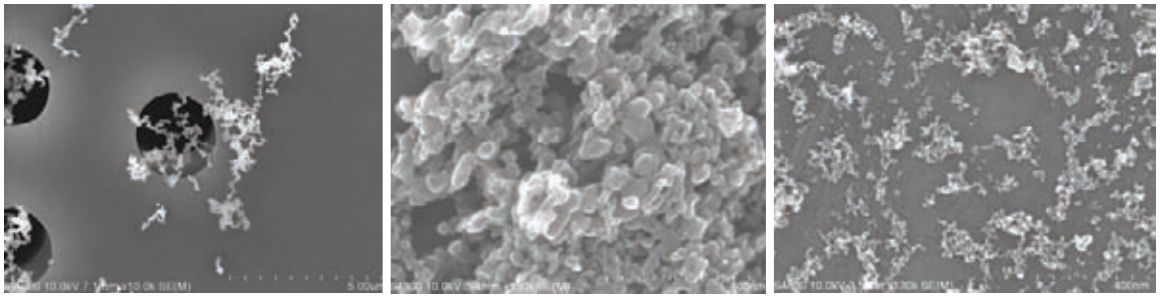

Figure 4–1. Photomicrographs of airborne exposure to ultrafine (nanoscale) particles of welding fumes, diesel exhaust, and cerium oxide

will incorporate nanotechnology—or about 15% of total global output.

4.1 Nano-objects

The International Organization for Standardization Technical Committee 229 (Nanotechnologies) is developing globally recognized nomenclature and terminology for nanomaterials. According to ISO/TS 27687:2008, *nano-object* is defined as material with one, two, or three external dimensions in the size range from approximately 1–100 nm. Subcategories of nano-object are (*1*) *nanoplate*, a nano-object with one external dimension at the nanoscale; (*2*) *nanofiber*, a nano-object with two external dimensions at the nanoscale with a nanotube defined as a hollow nanofiber and a nanorod as a solid nanofiber; and (*3*) *nanoparticle*, a nano-object with all three external dimensions at the nanoscale. Nano-objects are commonly incorporated in a larger matrix or substrate referred to as a *nanomaterial*. Nano-objects may be suspended in a gas (as a nanoaerosol), suspended in a liquid (as a colloid or nanohydrosol), or embedded in a matrix (as a nanocomposite).

The precise definition of particle diameter depends on particle shape as well as how the diameter is measured. Particle morphologies may vary widely at the nanoscale. For instance, carbon fullerenes represent nano-objects with identical dimensions in all directions (i.e., spherical), whereas single-walled carbon nanotubes (SWCNTs) typically form convoluted, fiber-like nano-objects. Many regular but nonspherical particle morphologies can be engineered at the nanoscale, including flower- and belt-like structures. Please see www.nanoscience.gatech.edu/zlwang/research.html for examples of some nanoscale structures.

4.2 Ultrafine Particles

The term *ultrafine particle* has traditionally been used by the aerosol research and occupational and environmental health communities to describe airborne particles smaller than 100 nm in diameter. *Ultrafine* is frequently used in the context of nanometer-diameter particles that have not been intentionally produced but are the incidental products of processes involving combustion, welding, or diesel engines (see Figure 4–1). The term *nanoparticle* is frequently used with respect to particles demonstrating size-dependent physicochemical properties, particularly from a materials science perspective. **The two terms are sometimes used to differentiate between engineered**

(*nanoparticle*) and incidental (*ultrafine*) nanoscale particles.

It is currently unclear whether the use of source-based definitions of nanoparticles and ultrafine particles is justified from a safety and health perspective. This is particularly the case where data on non-engineered, nanometer-diameter particles are of direct relevance to the impact of engineered particles. An attempt has been made in this document to follow the general convention of preferentially using *nanoparticle* in the context of intentionally produced or engineered particles and *ultrafine* in the context of incidentally produced particles (e.g., combustion products). However, this does not necessarily imply specific differences in the properties of these particles as related to hazard assessment, measurement, or control of exposures, and this remains an active area of research. *Nanoparticle* and *ultrafine particle* are not rigid definitions. For example, since the term *ultrafine* has been in existence longer, some intentionally produced particles with primary particle sizes in the nanosize range (e.g., TiO_2) are often called *ultrafine* in the literature.

4.3 Engineered Nanoparticles

Engineered nanoparticles are intentionally produced, whereas *ultrafine particles* (often referred to as *incidental nanoparticles)* are typically byproducts of processes such as combustion and vaporization. Engineered nanoparticles are designed with very specific properties or compositions (e.g., shape, size, surface properties, and chemistry). Incidental nanoparticles are generated in a relatively uncontrolled manner and are usually physically and chemically heterogeneous compared with engineered nanoparticles.

4.4 Nanoaerosol

A *nanoaerosol* is a collection of nanoparticles suspended in a gas. The particles may be present as discrete nano-objects, or as aggregates or agglomerates of nano-objects. These agglomerates may have diameters larger than 100 nm. In the case of an aerosol consisting of micrometer-diameter particles formed as agglomerates of nano-objects, the definition of nanoaerosol is open to interpretation. It is generally accepted that if the nanostructure associated with the nano-object is accessible (through physical, chemical, or biological interactions), then the aerosol may be considered a nanoaerosol. However, if the nanostructure within individual micrometer-diameter particles does not directly influence particle behavior (for instance, if the nanoparticles were inaccessibly embedded in a solid matrix), the aerosol would not be described as a nanoaerosol.

4.5 Agglomerate

An *agglomerate* is a group of nanoparticles held together by relatively weak forces, including van der Waals forces, electrostatic forces, and surface tension [ISO 2006].

4.6 Aggregate

An *aggregate* is a heterogeneous particle in which the various components are held together by relatively strong forces, and thus not easily broken apart [ISO 2006]. Aggregated nanoparticles would be an example of a nanostructured material.

5 Potential Health Concerns

Nanotechnology is an emerging field. As such, there are many uncertainties as to whether the unique properties of engineered nanomaterials (which underpin their commercial and scientific potential) also pose occupational health risks. These uncertainties arise because of gaps in knowledge about the factors that are essential for predicting health risks—factors such as routes of exposure, translocation of materials once they enter the body, and interaction of the materials with the body's biological systems. The potential health risk following exposure to a substance is generally associated with the magnitude and duration of the exposure, the persistence of the material in the body, the inherent toxicity of the material, and the susceptibility or health status of the person exposed. More data are needed on the health risks associated with exposure to engineered nanomaterials. Results of existing studies in animals and humans on exposure and response to ultrafine or other respirable particles provide a basis for preliminary estimates of the possible adverse health effects from exposures to similar engineered materials on a nanoscale. Experimental studies in rodents and cell cultures have shown that the toxicity of ultrafine or nanoparticles is greater than that of the same mass of larger particles of similar chemical composition [Oberdörster et al. 1992, 1994a, b; Lison et al. 1997; Tran et al. 1999, 2000; Brown et al. 2001; Barlow et al. 2005; Duffin et al. 2007]. In addition to particle surface area, other particle characteristics may influence toxicity, including surface functionalization or coatings, solubility, shape, and the ability to generate oxidant species and to adsorb biological proteins or bind to receptors [Duffin et al. 2002; Oberdörster et al. 2005a; Maynard and Kuempel 2005; Donaldson et al. 2006]. More research is needed on the influence of particle properties on interactions with biological systems and the potential for adverse effects. International research strategies for evaluating the safety of nanomaterials are actively being developed through cooperative efforts [Thomas et al. 2006].

Existing toxicity information about a given material of larger particle size can provide a baseline for anticipating the possible adverse health effects that may occur from exposure to a nanoscale material that has some of the same physicochemical properties (e.g., chemistry, density). However, predicting the toxicity of an engineered nanomaterial based on its physicochemical properties may not provide an adequate level of protection.

5.1 Exposure Routes

Inhalation is the most common route of exposure to airborne particles in the workplace. The deposition of discrete nano-objects in the respiratory tract is determined by the particle's aerodynamic or thermodynamic diameter (i.e., the particle shape and size). Agglomerates of nano-objects will deposit according to the diameter of the agglomerate, not constituent nano-objects. Research is ongoing to determine the physical factors that contribute to the agglomeration and de-agglomeration of nano-objects in air, suspended in aqueous media, or once in contact with lung lining fluid and/or biological proteins. Evidence indicates

that the degree of agglomeration can affect the toxicity of inhaled nano-objects [Shvedova et al. 2007].

Discrete nanoparticles are deposited in the lungs to a greater extent than larger respirable particles [ICRP 1994], and deposition increases with exercise due to increase in breathing rate and change from nasal to mouth breathing [Jaques and Kim 2000; Daigle et al. 2003] and among persons with existing lung diseases or conditions (e.g., asthma, emphysema) [Brown et al. 2002]. Based on animal studies, discrete nanoparticles may enter the bloodstream from the lungs and translocate to other organs [Takenaka et al. 2001; Nemmar et al. 2002; Oberdörster et al. 2002].

Discrete nanoparticles (35–37-nm median diameter) that deposit in the nasal region may be able to enter the brain by translocation along the olfactory nerve, as was observed in rats [Oberdörster et al. 2004; Oberdörster et al. 2005a; Elder et al. 2006]. The transport of insoluble particles from 20–500 nm-diameter to the brain via sensory nerves (including olfactory and trigeminus) was reported in earlier studies in several animal models [De Lorenzo 1970; Adams and Bray 1983; Hunter and Dey 1998]. This exposure route for nanoparticles and to nanoscale biological agents has not been studied in humans.

Some studies suggest that nanomaterials could potentially enter the body through the skin during occupational exposure. Tinkle et al. [2003] have shown that particles smaller than 1 μm in diameter may penetrate into mechanically flexed skin samples. A more recent study reported that nanoparticles with varying physicochemical properties were able to penetrate the intact skin of pigs [Ryman-Rasmussen et al. 2006]. These nanoparticles were quantum dots of different size, shape, and surface coatings. They were reported to penetrate the stratum corenum barrier by passive diffusion and localize within the epidermal and dermal layers within 8–24 hours. The dosing solutions were 2- to 4-fold dilutions of quantum dots as commercially supplied and thus represent occupationally relevant doses.

At this time, it is not fully known whether skin penetration of nanoparticles would result in adverse effects in animal models. However, topical application of raw SWCNT to nude mice has been shown to cause dermal irritation [Murray et al. 2007]. Studies conducted in vitro using primary or cultured human skin cells have shown that both SWCNT and multi-walled carbon nanotubes (MWCNT) can enter cells and cause release of pro-inflammatory cytokines, oxidative stress, and decreased viability [Monteiro-Riviere et al. 2005; Shvedova et al. 2003]. It remains unclear, however, how these findings may be extrapolated to a potential occupational risk, given that additional data are not yet available for comparing the cell model studies with actual conditions of occupational exposure. Research on the dermal exposure of nanomaterials is ongoing (www.uni-leipzig.de/~nanoderm/).

Ingestion can occur from unintentional hand to mouth transfer of materials; this has been found to happen with traditional materials, and it is scientifically reasonable to assume that it also could happen during handling of nanomaterials. Ingestion may also accompany inhalation exposure because particles that are cleared from the respiratory tract via the mucociliary escalator may be swallowed [ICRP 1994]. Little is known about possible adverse effects from the ingestion of nanomaterials.

5.2 Effects Seen in Animal Studies

Experimental studies in rats have shown that at equivalent mass doses, insoluble ultrafine particles are more potent than larger particles of similar composition in causing pulmonary inflammation, tissue damage, and lung tumors [Lee et al. 1985; Oberdörster and Yu 1990; Oberdörster et al. 1992, 1994a,b; Heinrich et al. 1995; Driscoll 1996; Lison et al. 1997; Tran et al. 1999, 2000; Brown et al. 2001; Duffin et al. 2002; Renwick et al. 2004; Barlow et al. 2005]. These studies have shown that for poorly-soluble low toxicity (PSLT) particles, the dose-response relationships are consistent across particle sizes when dose is expressed as particle surface area. In addition to particle size and surface area, studies have shown that other particle characteristics can influence toxicity. For example, although the relationship between particle surface area dose and pulmonary inflammation is consistent among PSLT particles, crystalline silica is much more inflammogenic than PSLT particles at a given surface area dose [Duffin et al. 2007].

Reactive oxidant generation on the particle surface is an important factor influencing lung response to particles, which can be related to crystal structure. A recent study of the lung effects of rats dosed with either ultrafine *anatase* titanium dioxide ($TiO_{2)}$ or ultrafine *rutile* TiO_2 showed that the *anatase* TiO_2 had more reactive surfaces and caused greater pulmonary inflammation and cell proliferation in the lungs of rats [Warheit et al. 2007]. In a cell-free assay designed to investigate the role of surface area and crystal structure on particle reactive oxygen species (ROS)-generation, Jiang et al. [2008] observed that size, surface area, and crystal structure all contribute to ROS generation.

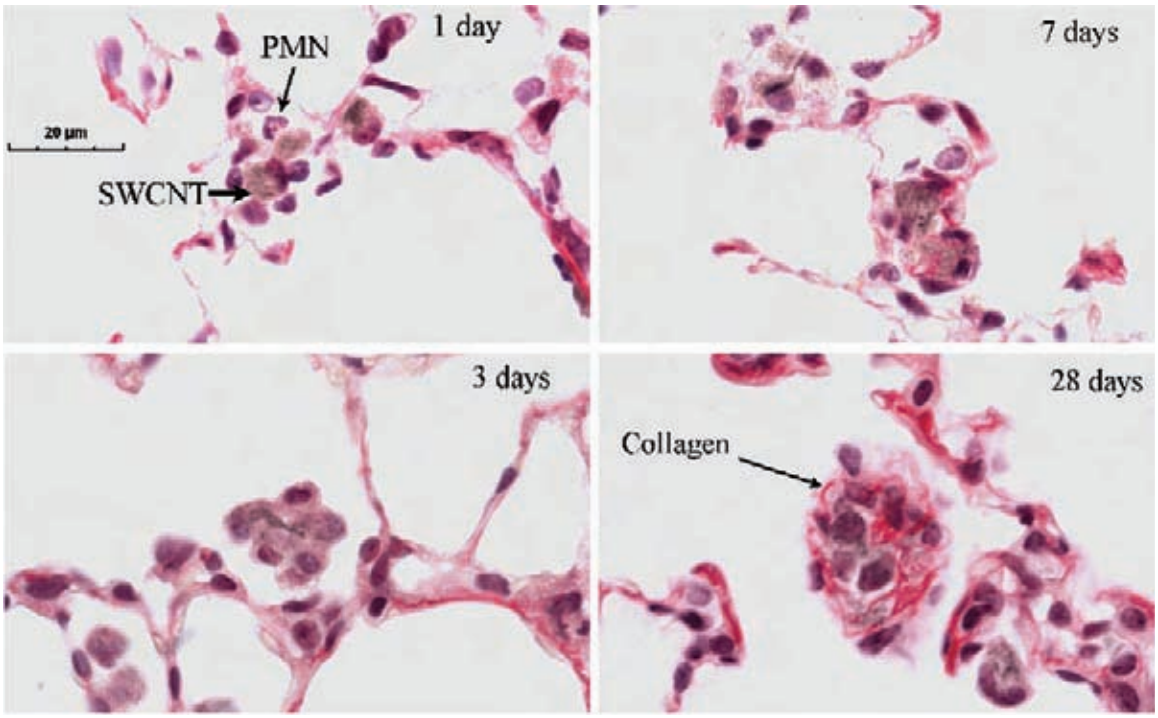

Figure 5–1. Formation of collagen following deposition of SWCNTs in the lungs of mice

Oxidant generation was apparently associated with the number of defective sites per surface area, which varied in nanoparticles in some size ranges [Jiang et al. 2008].

These studies indicate that for nanoparticles with similar properties (e.g., PSLT), the toxicity of a given mass dose will increase with decreasing particle size due to the increasing surface area. However, the dose-response relationship may differ for particles with different chemical composition and other properties. Consistent with these findings, a recent pulmonary instillation study with rats dosed with either fine or ultrafine TiO_2 reported no significant difference in lung responses when compared to controls, while crystalline silica caused more severe lung responses at the same dose [Warheit et al. 2006]. However, Warheit et al. [2006] were unable to adequately test the hypotheses about the relationship between particle surface area dose and toxicity because the diameters of the fine and ultrafine TiO_2-instilled particles did not significantly differ due to particle agglomeration, both being in excess of 2 μm. When efforts were made to more effectively disperse fine and ultrafine particles, the effect of surface area on the pulmonary response in rats after intratracheal instillation was verified [Sager et al. 2008].

5.2.1 Polytetrafluoroethylene fume

Among ultrafine particles, freshly generated polytetrafluoroethylene (PTFE) fume (generated at temperatures of more than 425°C) is known to be highly toxic to the lungs. Freshly generated PTFE fume caused hemorrhagic pulmonary edema and death in rats exposed to less than 60 $\mu g/m^3$ [Oberdörster et al. 1995]. In contrast, aged PTFE fume was much less toxic and did not result in mortality. This low toxicity was attributed to the increase in particle size from accumulation and to changes in surface chemistry [Johnston et al. 2000; Oberdörster et al. 2005a]. Human case studies have reported pulmonary edema in workers exposed to PTFE fume and an accidental death in a worker when an equipment malfunction caused overheating of the PTFE resin and release of the PTFE pyrolysis products in the workplace [Goldstein et al. 1987; Lee et al. 1997]. While PTFE fume differs from engineered nanoparticles, these studies illustrate properties of ultrafine particles that have been associated with an acute toxic hazard. Enclosed processes and other engineering controls appear to have been effective at eliminating worker exposures to PTFE fume in normal operations, and thus may provide examples of control systems that may be implemented to prevent exposure to nanoparticles that may have similar properties.

5.2.2 Carbon nanotubes

Carbon nanotubes (CNT) are specialized forms or structures of engineered nanomaterials that have had increasing production and use [Donaldson et al. 2006]. Consequently, a number of toxicologic studies of CNT have been performed in recent years. These studies have shown that the toxicity of CNT may differ from that of other nanomaterials of similar chemical composition. For example, single-walled CNTs (SWCNT) have been shown to produce adverse effects including granulomas in the lungs of mice and rats at mass doses at which ultrafine carbon black did not produce these adverse effects [Shvedova et al. 2005; Lam et al. 2004]. While both SWCNTs and carbon black are carbon-based, SWCNTs have a unique, convoluted, fibrous structure and specific surface chemistry that offers excellent electrical conductive properties. How these characteristics may influence

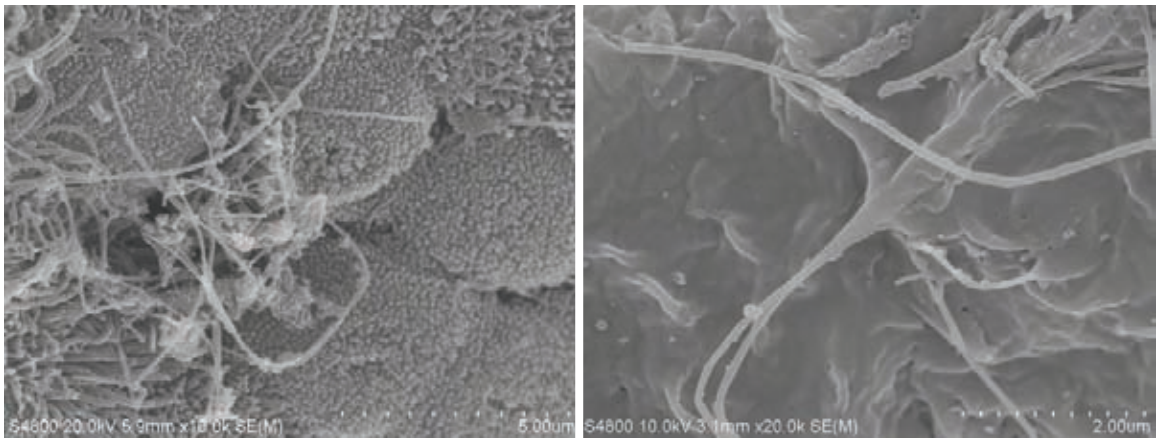

Figure 5–2. Deposition and clearance of MWCNTs from the conducting airways of mice following inhalation exposure

toxicity is not known. Carbon nanotubes may contain metal catalysts as byproducts of their production, which could contribute to their toxicity, or the CNTs may provide a structure that promotes fibroblast cell growth [Wang et al. 2008].

In a study of SWCNTs instilled into the lungs of rats, multi-focal granulomas (without transient inflammation or persistent lesions) were observed at doses of 1 or 5 mg/kg body weight [Warheit et al. 2004]. In a study of mice instilled with one of several types of SWCNTs (i.e., raw, purified, iron-containing, and nickel-containing) at doses of 0.1 or 0.5 mg/mouse (approximately 3 or 16 mg/kg body weight), dose-dependent epithelioid granulomas were observed at 7 days, which persisted at 90 days [Lam et al. 2004, 2006]. Both the raw and purified forms produced interstitial inflammation, while mortality (5/9 mice) was observed in the high dose group of the Ni-containing SWCNT.

NIOSH researchers recently reported adverse lung effects following pharyngeal aspiration of SWCNTs in mice using doses between 10–40 μg/mouse (approximately 0.5–2 mg/kg body weight) [Shvedova et al. 2005]. The findings showed that exposure to SWCNTs in mice lead to transient pulmonary inflammation, oxidative stress, decrease in pulmonary function, decrease in bacterial clearance, and early onset of interstitial fibrosis. Deposition of agglomerates resulted in development of granulomas, while deposition of dispersed nanotube structures in the aspirated suspension resulted in the rapid development of interstitial fibrosis (within 7 days), which progressed over a 30–60 day post-exposure period [Shvedova et al. 2005; Mercer et al. 2008]. Evidence indicates that when efforts were made to more fully disperse the SWCNT and obtain smaller structures in the aspiration suspension, fewer granulomas occurred but a 4-fold more potent interstitial fibrotic response was observed [Mercer et al. 2008].

Exposure to SWCNT has been observed to be more fibrogenic than an equal mass of either ultrafine carbon black or fine quartz [Shvedova et al. 2005; Lam et al. 2004]. Based on their findings in mice, Shvedova et al. [2005] estimated that workers may be at risk of developing lung lesions if they were exposed to SWCNT over a period of 20 days at the current

OSHA PEL for graphite (5 mg/m^3). Lam et al. [2004, 2006] provided similar estimates and suggested that the graphite PEL should not be used (e.g., on MSDS) as a safe concentration for workers exposed to CNTs. Compared to instillation, the pharyngeal aspiration technique may approximate more closely the particle deposition that occurs during inhalation. Inhalation studies of CNTs may provide more definitive information about their potential toxicity in humans [Donaldson et al. 2006]. Recently, NIOSH scientists designed a system to generate an aerosol of SWCNT for a rat inhalation study [Baron et al. 2008]. Results of the inhalation exposure to SWCNT [Shvedova et al. 2008] were qualitatively similar to those of the aspiration study [Shvedova et al. 2004] with a 4-fold more potent interstitial fibrotic response similar to that reported by Mercer et al. [2008]. Another NIOSH study found markers of inflammation in the lung, aorta, and heart tissues of ApoE-/- mice after a single intra-pharyngeal instillation dose of SWCNT (10 and 40 μg/mouse) and accelerated plaque formation after repeated doses (20 μg/mouse once every other week for 8 weeks in mice fed an atherogenic diet) [Li et al. 2007].

MWCNTs were recently studied by intratracheal instillation in Sprague-Dawley rats receiving 0.5, 2, or 5 mg (approximately 2, 9, or 22 mg/kg body weight) of either ground MWCNT or unground MWCNT [Muller et al. 2005]. Both forms produced pulmonary inflammation and fibrosis. Rats that received ground MWCNT showed greater dispersion in the lungs, and fibrotic lesions were observed in the deep lungs (alveolar region). In rats treated with MWCNT (not ground) fibrosis showed mainly in their airways rather than in their lungs. The biopersistence of the unground MWCNT was greater than that of the ground MWCNT, with 81% vs. 36%, respectively, remaining in the lungs at day 60. At an equal mass dose, ground MWCNT produced a similar inflammatory and fibrogenic response as chrysotile asbestos and a greater response than ultrafine carbon black [Muller et al. 2005]. Effects from the vehicle (1% Tween 80) used for administering ground and unground MWCNT to rats were not reported; the control group used in the study was exposed to only saline. NIOSH scientists have exposed mice by aspiration to MWCNT suspended in a simulated alveolar lining fluid rather than Tween 80. Control studies show that this suspension medium was not inflammatory and did not mask the biological activity of the particle surface. Data indicate that aspiration of dispersed MWCNT produced pulmonary inflammation, which peaked 7 days post exposure. The inflammatory response to MWCNT was greater than the inflammatory response to SWCNT [Sriram et al. 2007].

Two recent studies investigated the hypotheses that CNTs can behave like asbestos. In the first study, Takagi et al. [2008] administered to p53 (+/-) mice MWCNT, fullerene, or crocidolite asbestos by intraperitoneal injection at doses of 3 mg/mouse. The average width of the MWCNT was approximately 100 nm, and approximately 28% of the particles were longer than 5 μm. The particle number concentrations of MWCNT and crocidolite were 1×10^9 and 1×10^{10} (in 1-ml suspensions), respectively, although the MWCNT sample was also reported to contain mainly large aggregates, indicating that the number of MWCNT fibers was vastly underestimated and much larger than for the asbestos exposure. At the termination of the study (25 weeks), mesothelial responses in the MWCNT-treated mice included moderate to severe fibrous peritoneal adhesion and peritoneal tumors. The asbestos-treated mice had similar responses but to a lesser extent, while the

fullerene-treated group did not show these responses. Mesothelioma was considered by the authors as the primary cause of death, and constriction of the ileus due to severe peritoneal adhesion was considered to be the second major cause of death, suggesting that 3 mg/mouse exceeded the maximum tolerated dose of MWCNT. Whether mesotheliomia was a primary cause of death is somewhat speculative.

In a second study, Poland et al. [2008] administered to mice either MWCNT (two short and two long CNT samples), nanoscale carbon black, or amosite (short or long) at doses of 50 μg/mouse by intraperitoneal injection. The short CNTs were 10 nm or 15 nm in width, with no fibers larger than 15 μm in length detected; the long CNTs were 85 nm or 165 nm in width, and 24% or 84%, respectively, were larger than 15 μm in length (the percentage of fibers longer than 5 μm was not reported). After either 24 hours or 7 days, the long MWCNT caused inflammation and granulomatous lesions that were qualitatively and quantitatively similar to that caused by the long asbestos. The short, low-aspect-ratio, tangled aggregates of MWCNT did not produce these responses at the doses used in this study. Additional studies are needed to determine if this inflammatory response to MWCNT would be persistent and result in tumors of the abdominal wall. Additionally, the potential for migration of MWCNT through the lungs to the mesothelium after inhalation requires investigation. Long-term studies are also needed to determine whether CNTs can cause cancer such as mesothelioma in laboratory animals, including exposures by typical routes in humans (i.e., inhalation, dermal penetration, and ingestion) and at doses that include those equivalent to potential workplace exposures.

These studies indicate the need for more data on exposures of workers to CNTs. Maynard et al. [2004] reported relatively low short-term (approximately 30 min) airborne mass concentrations of SWCNT (0.007–0.053 mg/m^3) in a laboratory production facility. A recent study by Han et al. [2008] reported total airborne mass concentrations of MWCNT from 0.21–0.43 mg/m^3 (4–6-hr sampling) in a laboratory research facility prior to use of engineering control measures; after implementing controls, the concentration decreased to nondetectable. Workers could also be exposed to ground CNTs used in polymer composites and other matrices or during cutting, grinding, or polishing of these materials. Given that exposure to SWCNT and MWCNT causes interstitial fibrosis and pulmonary inflammation, respectively, in rodent lungs at relatively low mass doses, it is prudent to minimize worker exposure to airborne CNTs (see Chapter 8 *Guidelines for Working with Engineered Nanomaterials*).

5.3 Observations from Epidemiological Studies Involving Fine and Ultrafine Particles

Epidemiological studies in workers exposed to aerosols including fine and ultrafine particles have reported lung function decrements, adverse respiratory symptoms, chronic obstructive pulmonary disease, and fibrosis [Kreiss et al. 1997; Gardiner et al. 2001; Antonini 2003]. In addition, some studies have found lung disease including elevated lung cancer and neurological effects among workers exposed to certain ultrafine particles (i.e., diesel exhaust particulate) [Steenland et al. 1998; Garshick et al. 2004, 2006; Hart et al. 2006] or welding fumes [Antonini 2003; Park

et al. 2006; Ambroise et al. 2007; Bowler et al. 2007]. The implications of these studies to engineered nanomaterials, which may have different particle properties, are uncertain. Studies of airborne particles and fibers in the workplace do provide relevant background information about the particle-related lung diseases and mechanisms, and some limited quantitative estimates of exposures and risk of adverse health effects. As such, these studies provide a point of reference, including baseline information and estimates regarding possible health risks of exposure to other nanoscale particles depending on the extent to which the exposure conditions and particle-biological interactions may be similar.

Epidemiological studies in the general population have also shown associations between particulate air pollution and increased morbidity and mortality from respiratory and cardiovascular diseases [Dockery et al. 1993; HEI 2000; Pope et al. 2002, 2004]. Some epidemiological studies have shown adverse health effects associated with exposure to the ultrafine particulate fraction of air pollution [Peters et al. 1997, 2004; Penttinen et al. 2001; Ibald-Mulli et al. 2002; Timonen et al. 2004; Ruckerl et al. 2006] although uncertainty exists about the role of ultrafine particles relative to other air pollutants in causing the observed adverse health effects. The associations in these studies have been based on measurements of the particle number or mass concentrations of particles within certain size fractions (e.g., particulate matter with diameter of 2.5 μm and smaller [$PM_{2.5}$]). In an experimental study of healthy and asthmatic subjects inhaling ultrafine carbon particles, changes were observed in the expression of adhesion molecules by blood leukocyte, which may relate to possible cardiovascular effects of ultrafine particle exposure [Frampton et al. 2006]. Short-term diesel exhaust exposure (0.3 mg/m^3 for 1 hr) in healthy volunteers was associated with mild systemic inflammation and impaired endothelial-dependent vasodilation [Törnqvist et al. 2007].

5.4 Hypotheses from Animal and Epidemiological Studies

The existing literature on particles and fibers provides a scientific basis from which to evaluate the potential hazards of engineered nanomaterials. While the properties of engineered nanomaterials can vary widely, the basic physicochemical and toxicokinetic principles learned from the existing studies are relevant to understanding the potential toxicity of nanomaterials. For example, it is known from studies in humans that a greater proportion of inhaled nanoparticles will deposit in the respiratory tract (both at rest and with exercise) compared to larger particles [ICRP 1994; Jaques and Kim 2000; Daigle et al. 2003; Kim and Jaques 2004]. It is also known from studies in animals that nanoparticles in the lungs can be translocated to other organs in the body; how the chemical and physical properties of the nanoparticles influence this translocation is not completely known [Takenaka et al. 2001; Kreyling et al. 2002; Oberdörster et al. 2002, 2004; Semmler et al. 2004; Geiser et al. 2005]. Due to their small size, nanoparticles can cross cell membranes and interact with subcellular structures such as mitochondria, where they have been shown to cause oxidative damage and to impair function of cells in culture [Möller et al. 2002, 2005; Li et al. 2003; Geiser et al. 2005]. Nanoparticles have also been observed inside cell nuclei [Porter et al. 2007a, b]. Animal studies have shown that nanoparticles are more biologically

active due to their greater surface area per mass compared with larger-sized particles of the same chemistry [Oberdörster et al. 1992; 1994a,b; 2005a; Driscoll 1996; Lison et al. 1997; Brown et al. 2001; Duffin et al. 2002; Renwick et al. 2004; Barlow et al. 2005; Sager et al. 2008]. While this increased biological activity is a fundamental component to the utility of nanoparticles for industrial, commercial, and medical applications, the consequences of unintentional exposures of workers to nanoparticles are uncertain.

Research reported from laboratory animal studies and from epidemiological studies have lead to hypotheses regarding the potential adverse health effects of engineered nanomaterials. These hypotheses are based on the scientific literature of particle exposures in animals and humans. This literature has been recently reviewed [Donaldson et al. 2005; Maynard and Kuempel 2005; Oberdörster et al. 2005a, Donaldson et al. 2006; Kreyling et al. 2006]. In general, the particles used in past studies have not been characterized to the extent recommended for new studies in order to more fully understand the physicochemical properties of the particles that influence toxicity [Oberdörster et al. 2005b; Thomas et al. 2006]. As this research continues, more data will become available to support or refute the following hypotheses for engineered nanoparticles.

Hypothesis 1: Exposure to engineered nanoparticles is likely to cause adverse health effects similar to ultrafine particles that have similar physical and chemical characteristics.

Studies in rodents and humans support the hypothesis that exposure to ultrafine particles poses a greater respiratory hazard than exposure to the same mass of larger particles with a similar chemical composition. Studies of existing particles have shown adverse health effects in workers exposed to ultrafine particles (e.g., diesel exhaust particulate, welding fumes), and animal studies have shown that ultrafine particles are more inflammogenic and tumorigenic in the lungs of rats than an equal mass of larger particles of similar composition [Oberdörster and Yu 1990; Driscoll 1996; Tran et al. 1999, 2000]. **If engineered nanoparticles have the same physicochemical characteristics that are associated with reported effects from ultrafine particles, they may pose the same health concerns.**

Although the physicochemical characteristics of ultrafine particles and engineered nanoparticles can differ, the toxicologic and dosimetric principles derived from available studies may be relevant to postulating the health concerns for newly engineered particles. The biological mechanisms of particle-related lung diseases (i.e., oxidative stress, inflammation, and production of cytokines, chemokines, and cell growth factors) [Mossman and Churg 1998; Castranova 2000; Donaldson and Tran 2002] appear to be a consistent lung response for respirable particles including ultrafine or engineered nanoparticles [Donaldson et al. 1998; Donaldson and Stone 2003; Oberdörster et al. 2005a]. Toxicological studies have shown that the chemical and physical properties that influence the fate and toxicity of ultrafine particles may also be relevant to mechanisms influencing biological exposure and response to other nanoscale particles [Duffin et al. 2002; Kreyling et al. 2002; Oberdörster et al. 2002; Semmler et al. 2004; Nel et al. 2006].

Hypothesis 2: Surface area and activity and particle number may be better predictors of potential hazard than mass.

The greater potential hazard may relate to the greater number or surface area of nanoparticles compared with that for the same mass

concentration of larger particles [Oberdörster et al. 1992, 1994a,b; Driscoll et al. 1996; Tran et al. 2000; Brown et al. 2001; Peters et al. 1997; Moshammer and Neuberger 2003; Sager et al. 2008]. This hypothesis is based primarily on the pulmonary effects observed in studies of rodents exposed to various types of ultrafine or fine particles (i.e., TiO_2, carbon black, barium sulfate, carbon black, diesel soot, coal fly ash, toner) and in humans exposed to aerosols, including nanoscale particles (e.g., diesel exhaust, welding fumes). These studies indicate that for a given mass of particles, relatively insoluble nanoparticles are more toxic than larger particles of similar chemical composition and surface properties. Studies of fine and ultrafine particles have shown that particles with less reactive surfaces are less toxic [Tran et al. 1999; Duffin et al. 2002]. However, even particles with low inherent toxicity (e.g., TiO_2) have been shown to cause pulmonary inflammation, tissue damage, and fibrosis at sufficiently high particle surface area doses [Oberdörster et al. 1992, 1994a,b; Tran et al. 1999, 2000].

Through engineering, the properties of nanomaterials can be modified. For example, a recent study has shown that the cytotoxicity of water-soluble fullerenes can be reduced by several orders of magnitude by modifying the structure of the fullerene molecules (e.g., by hydroxylation) [Sayes et al. 2004]. These structural modifications were shown to reduce the cytotoxicity by reducing the generation of oxygen radicals—which is a probable mechanism by which cell membrane damage and death occurred in these cell cultures. Increasing the sidewall functionalization of SWCNT also rendered these nanomaterials less cytotoxic to cells in culture [Sayes et al. 2005]. Cytotoxicity studies with quantum dots have shown that the type of surface coating can have a significant effect on cell motility and viability [Hoshino et al. 2004; Shiohara et al. 2004; Lovric et al. 2005]. Differences in the phase composition of nanocrystalline structures can influence their cytotoxicity; in a recent study comparing two types of TiO_2 nanoparticles exposed to UV radiation, anatase TiO_2 was more cytotoxic and produced more reactive species than did rutile TiO_2 with similar specific surface area (153 m^2g and 123 m^2g of TiO_2, respectively) [Sayes et al. 2006]. Reactive oxygen species were also associated with the cytotoxicity of TiO_2 nanoparticles to mouse microglia (brain cells) grown in culture [Long et al. 2006]. In contrast, in vitro generation of oxidant species is relatively low in purified SWCNT (contaminating metals removed), yet this material caused progressive interstitial fibrosis in vivo [Shvedova et al. 2004; 2005]. However, recent in vitro studies indicate that purified SWCNTs enhance proliferation and collagen production in fibroblasts [Wang et al. 2008]. Therefore, oxidant generation may not be the only mechanism driving the biological activity of nanomaterials.

The studies of ultrafine particles may provide useful data to develop preliminary hazard or risk assessments and to generate hypotheses for further testing. The studies in cell cultures provide information about the cytotoxic properties of nanomaterials that can guide further research and toxicity testing in whole organisms. More research is needed of the specific particle properties and other factors that influence the toxicity and disease development, including those characteristics that may be most predictive of the potential safety or toxicity of newly engineered nanomaterials.

6 Potential Safety Hazards

Very little is known about the safety risks that engineered nanomaterials might pose, beyond some data indicating that they possess certain properties associated with safety hazards in traditional materials. Based upon currently available information, the potential safety concerns most likely would involve catalytic effects or fire and explosion hazards if nanomaterials are found to behave similarly to traditional materials.

6.1 Fire and Explosion Risk

Although insufficient information exists to predict the fire and explosion risk associated with nanoscale powders, **nanoscale combustible material could present a higher risk than a similar quantity of coarser material, given its unique properties** [HSE 2004]. Decreasing the particle size of combustible materials can increase combustion potential and combustion rate, leading to the possibility of relatively inert materials becoming highly reactive in the nanometer size range. Dispersions of combustible nanomaterial in air may present a greater safety risk than dispersions of non-nanomaterials with similar compositions. Some nanomaterials are designed to generate heat through the progression of reactions at the nanoscale. Such materials may present a fire hazard that is unique to engineered nanomaterials. In the case of some metals, explosion risk can increase significantly as particle size decreases.

The greater activity of nanoscale materials forms a basis for research into nanoenergetics. For instance, nanoscale Al/MoO_3 thermites ignite more than 300 times faster than corresponding micrometer-scale material [Granier and Pantoya 2004].

6.2 Risks of Catalytic Reactions

Nanoscale particles and nanostructured porous materials have been used as effective catalysts for increasing the rate of reactions or decreasing the necessary temperature for reactions to occur in liquids and gases. **Depending on their composition and structure, some nanomaterials may initiate catalytic reactions that, based on their chemical composition, would not otherwise be anticipated [Pritchard 2004].**

7 Exposure Assessment and Characterization

There are currently no national or international consensus standards on measurement techniques for nanomaterials in the workplace. If the qualitative assessment of a process has identified potential exposure points and leads to the decision to measure nanomaterials, several factors must be kept in mind. Current research indicates that mass and bulk chemistry may be less important than particle size, surface area, and surface chemistry (or activity) for nanostructured materials [Oberdörster et al. 1992, 1994a,b; Duffin et al. 2002]. Research is ongoing into the relative importance of these different exposure metrics, and how to best characterize exposures to nanomaterials in the workplace. In addition, the unique shape and properties of some nanomaterials may pose additional challenges. For example, the techniques used to measure fiber concentrations in the workplace (e.g., phase contrast microscopy) would not be able to detect individual carbon nanotubes with diameters less than 100 nm nor bundles of carbon nanotubes with diameters less than 250 nm [Donaldson et al. 2006]. NIOSH and the National Institute of Standards and Technology (NIST) are collaborating on efforts to develop nanoscale reference materials for exposure assessment. Initial effort is focused on development of TiO_2 reference material.

7.1 Workplace Exposures

While research continues to address questions of nanomaterial toxicity, a number of exposure assessment approaches can be used to help determine worker exposures to airborne nanomaterials. These assessments can be performed using traditional industrial hygiene sampling methods including samplers placed at static locations (area sampling), samples collected in the breathing zone of the worker (personal sampling), or real-time devices or methods that can be personal or static. In general, personal sampling is preferred to ensure an accurate representation of the worker's exposure, whereas area samples (e.g., size-fractionated aerosol samples) and real-time (direct-reading) exposure measurements may be more useful for evaluating the need for improvement of engineering controls and work practices.

Many of the sampling techniques that are available for measuring nanoaerosols vary in complexity but can provide useful information for evaluating occupational exposures with respect to particle size, mass, surface area, number concentration, composition, and surface chemistry. Unfortunately, relatively few of these techniques are readily applicable to routine exposure monitoring. Research is ongoing into developing an analytical strategy for determining both TiO_2 surface area and titanium mass from 37-mm cassette filter samplers. Current measurement techniques are described below along with their applicability for monitoring nanometer aerosols.

For each measurement technique used, it is vital that the key parameters associated with the technique and sampling methodology be recorded when measuring exposure to nanoaerosols. This should include the response range of the instrumentation,

whether personal or static measurements are made, and the location of all potential aerosol sources including background aerosols. Comprehensive documentation will facilitate comparison of exposure measurements using different instruments or different exposure metrics and will aid the re-interpretation of historic data as further information is developed on health-appropriate exposure metrics. **Regardless of the metric and method selected for exposure monitoring, it is critical that measurements be taken before production or processing of a nanomaterial to obtain background nanoparticle exposure data.** Measurements made during production or processing can then be evaluated to determine if there has been an increase in particle number concentrations in relation to background measurements and whether that change represents worker exposure to the nanomaterial. Table 7–1 gives a listing of instruments and measurement methods that can be used in the evaluation of engineered nanoparticle exposures.

7.1.1 Size-fractionated aerosol sampling

Studies indicate that particle size plays an important role in determining the potential adverse effects of nanomaterials in the respiratory system: by influencing the physical, chemical, and biological nature of the material; by affecting the surface-area dose of deposited particles; and by enabling deposited particles to more readily translocate to other parts of the body. Animal studies indicate that the toxicity of inhaled nanoparticles is more closely associated with the particle surface area and particle number than with the particle mass concentration when comparing aerosols with different particle size distributions. However, mass concentration measurements may be applicable for evaluating occupational exposure to nanometer aerosols where a good correlation between the surface area of the aerosol and mass concentration can be determined or if toxicity data based on mass dose are available for a specific nanoscale particle associated

Figure 7–1. Examples of different sampling instruments used to measure occupational exposures to nanoparticles including the determination of real-time particle number concentrations and size-fractionated mass concentrations

with a known process (e.g., diesel exhaust particulate).

Aerosol samples can be collected using inhalable, thoracic, or respirable samplers, depending on the region of the respiratory system most susceptible to the inhaled particles. Since prevailing **information suggests that a large fraction of inhaled nanoparticles will deposit in the gas-exchange region of the lungs [ICRP 1994], respirable samplers would be appropriate.** Respirable samplers will also collect a nominal amount of nanoscale particles that can deposit in the upper airways and ultimately be cleared or transported to other parts of the body.

Table 7–1. Summary of instruments and measurement methods used in the evaluation of nanomaterial exposures*

Metric	Instrument or method	Remarks
Mass-Direct (total and/or elemental)	Size Selective Static Sampler	The only instruments offering a cut point around 100 nm are cascade impactors (Berner-type low pressure impactors, or Micro orifice impactors). Allows gravimetric and chemical analysis of samples on stages below 100 nm.
	TEOM® (Tapered Element Oscillating Microbalance)	Sensitive real-time monitors such as the TEOM may be useable to measure nanoaerosol mass concentration on-line with a suitable size selective inlet.
	Filter collection and elemental analysis	Filters may be collected with size selective pre-samplers or open face. Elemental analysis (e.g., carbon, metals) for mass determination.
Mass-Indirect (calculation)	ELPI™ (Electrical Low Pressure Impactor)	Real time size-selective (aerodynamic diameter) detection of active surface area concentration giving aerosol size distribution. Mass concentration of aerosols can be calculated when particle charge and density are known or assumed.
	MOUDI (Micro-Orfice Uniform Deposit Impactor)	Real time size-selective (aerodynamic diameter) by cascade impaction.
	DMAS (Differential Mobility Analyzing System)	Real time size-selective (mobility diameter) detection of number concentration, giving aerosol size distribution. Mass concentration of aerosols can be calculated when particle shape and density are known or assumed.

(continued)

See footnotes at end of table.

Table 7–1 (Continued). Summary of instruments and measurement methods used in the evaluation of nanomaterial exposures*

Metric	Instrument or method	Remarks
Number-Direct	CPC (Condensation Particle Counter)	CPCs provide real time number concentration measurements between their particle diameter detection limits. Without a nanoparticle pre-separator they are not specific to the nanometer size range. Some models have diffusion screen to limit top size to 1 μm.
	OPC (Optical Particle Counter)	OPCs provide real time number concentration measurements between their particle diameter detection limits. Particle size diameters begin at 300 nm and may go up to 10,000 nm.
	DMAS and SMPS (Scanning Mobility Particle Sizer)	Real time size-selective (mobility diameter) detection of number concentration giving number-based size distribution.
	Electron Microscopy	Off-line analysis of electron microscope samples can provide information on size-specific aerosol number concentration.
Number-Indirect	ELPI™ and MOUDI	Real time size-selective (aerodynamic diameter) detection of active surface-area concentration giving aerosol size distribution. Data may be interpreted in terms of number concentration. Size-selective samples may be further analyzed off-line.
Surface Area-Direct	Diffusion Charger	Real-time measurement of aerosol active surface-area. Active surface-area does not scale directly with geometric surface-area above 100 nm. Note that not all commercially available diffusion chargers have a response that scales with particle active surface-area below 100 nm. Diffusion chargers are only specific to nanoparticles if used with appropriate inlet pre-separator.
	ELPI™ and MOUDI	Real-time size-selective (aerodynamic diameter) detection of active surface-area concentration. Active surface-area does not scale directly with geometric surface-area above 100 nm.

(continued)

See footnotes at end of table.

Table 7–1 (Continued). Summary of instruments and measurement methods used in the evaluation of nanomaterial exposures*

Metric	Instrument or method	Remarks
Surface Area-Direct (continued)	Electron Microscopy	Off-line analysis of electron microscope samples (previously collected on filters or other media) can provide information on particle surface-area with respect to size. TEM analysis provides direct information on the projected area of collected particles which may be related to geometric area for some particles shapes.
Surface Area-Indirect (calculation)	DMAS and SMPS	Real time size-selective (mobility diameter) detection of number concentration. Data may be interpreted in terms of aerosol surface-area under certain circumstances. For instance, the mobility diameter of open agglomerates has been shown to correlate with projected surface area.
	DMAS and ELPI™ used in parallel	Differences in measured aerodynamic and mobility can be used to infer particle fractal dimension which can be further used to estimate surface-area.

*Adapted from ISO/TR 12885

Note: Inherent to all air sampling instruments in this table is the fact that they cannot discriminate the nanoaerosol of interest from other airborne particles. Also, there is a general lack of validation regarding the response of these air sampling instruments to the full spectrum of nanoparticles that may be found in the workplace, including varieties of primary particles, agglomerates or aggregates, and other physical and chemical forms. A suite of nanoparticle reference materials are required to perform the needed validations.

Respirable samplers allow mass-based exposure measurements to be made using gravimetric and/or chemical analysis [NIOSH 1994]. However, they do not provide information on aerosol number, size, or surface-area concentration, unless the relationship between different exposure metrics for the aerosol (e.g., density, particle shape) has been previously characterized. Currently, no commercially available personal samplers are designed to measure the particle number, surface area, or mass concentration of nanoaerosols. However, several methods are available that can be used to estimate surface area, number, or mass concentration for particles smaller than 100 nm.

The use of conventional impactor samplers to assess nanoparticle exposure is limited since the impaction collection efficiencies are 200–300 nm. Low-pressure cascade impactors that can measure particles to 50 nm and larger may be used for static sampling since their size and complexity preclude their use as personal samplers [Marple et al. 2001; Hinds 1999]. A personal cascade impactor is available with a lower aerosol cut point of

250 nm [Misra et al. 2002], allowing an approximation of nanoscale particle mass concentration in the worker's breathing zone. For each method, the detection limits are on the order of a few micrograms of material on a filter or collection substrate [Vaughan et al. 1989]. Cascade impactor exposure data gathered from worksites where nanomaterials are being processed or handled can be used to make assessments as to the efficacy of exposure control measures.

7.1.2 Real-time aerosol sampling

The real-time (direct-reading) measurement of nanometer aerosol concentrations is limited by the sensitivity of the instrument to detect small particles. Many real-time aerosol mass monitors used in the workplace rely on light scattering from groups of particles (photometers). This methodology is generally insensitive to particles smaller than 100 nm [Hinds 1999]. Optical instruments that size individual particles and convert the measured distribution to a mass concentration are similarly limited to particles larger than 100 nm. Quantitative information gained by optical particle counters may also be limited by relatively poor counting efficiencies at smaller particle diameters (i.e., less than 500 nm). These instruments are capable of operating within certain concentration ranges that, when exceeded, affect the count or mass determination efficiencies due to coincidence errors at the detector. Similarly, the response of optical particle counters may be material-dependent according to the refractive index of the particle. The Scanning Mobility Particle Sizer (SMPS) is widely used as a research tool for characterizing nanoscale aerosols although its applicability for use in the workplace may be limited because of its size, cost, and the inclusion of a radioactive source. Additionally, the SMPS may take 2–3 minutes to scan an entire size distribution; thus, it may be of limited use in workplaces with highly variable aerosol size distributions, such as those close to a strong particle source. Fast (less than 1 second), mobility-based, particle-sizing instruments are now available commercially; however, having fewer channels, they lack the finer sizing resolution of the SMPS. The Electrical Low Pressure Impactor (ELPI) is an alternative instrument that combines diffusion charging and a cascade impactor with real-time (less than 1 second) aerosol charge measurements providing aerosol size distributions by aerodynamic diameter [Keskinen et al. 1992].

7.1.3 Surface-area measurements

Relatively few techniques exist to monitor exposures with respect to aerosol surface area. Particle surface is composed of internal surface area attributable to pores (cavities more deep than wide), external surface area due to roughness (cavities more wide than deep), and total surface area (the accessible area of all real particle surfaces). A standard gas adsorption technique (i.e., BET) is used to measure the total surface area of powders and can be adapted to measure the specific surface area (surface area per unit mass) of engineered nanomaterials [Brunauer et al. 1938]. However, surface-area analysis by gas adsorption requires relatively large quantities of material, is not element specific, and must be performed in a laboratory.

The first instrument designed to measure aerosol surface area was the epiphaniometer [Baltensperger et al. 1988]. This device measures the Fuchs, or active surface area, of the aerosols by measuring the attachment rate of

radioactive ions. For aerosols less than approximately 100 nm in size, measurement of the Fuchs surface area is probably a good indicator of external surface area (or geometric surface area). However, for aerosols greater than approximately 1 μm, the relationship with geometric particle surface area is lost [Fuchs 1964]. Measurements of active surface area are generally insensitive to particle porosity. The epiphaniometer is not well suited to widespread use in the workplace because of the inclusion of a radioactive source and the lack of effective temporal resolution.

This same measurement principle can be applied with the use of a portable aerosol diffusion charger. Studies have shown that these devices provide a good estimate of aerosol external surface area when airborne particles are smaller than 100 nm in diameter. For larger particles, diffusion chargers underestimate aerosol surface area. However, further research is needed to evaluate the degree of underestimation. Extensive field evaluations of commercial instruments are yet to be reported. However, laboratory evaluations with monodisperse silver particles have shown that two commercially available diffusion chargers can provide good measurement data on aerosol external surface area for particles smaller than 100 nm in diameter but underestimate the aerosol surface area for particles larger than 100 nm in diameter [Ku and Maynard 2005, 2006].

7.1.4 Particle number concentration measurement

Particle number concentration has been associated with adverse responses to air pollution in some human studies [Timonen et al. 2004; Ruckerl et al. 2005], while in toxicologic studies, particle surface area has generally been shown to be a better predictor than either particle number, mass, or volume concentration alone [Oberdörster and Yu 1990; Tran et al. 1999; Duffin et al. 2002]. A two-variable dose metric of particle size and volume has been shown to be the best predictor of lung cancer in rats from various types of particles [Borm et al. 2004; Pott and Roller 2005]. This illustrates some of the complexity of interpreting existing data on particle dose metric and response. While adverse health effects appear to be more closely related with particle surface area, the number of particles depositing in the respiratory tract or other organ systems may also play an important role.

Aerosol particle number concentration can be measured relatively easily using Condensation Particle Counters (CPCs). These are available as hand-held static instruments, and they are generally sensitive to particles greater than 10–20 nm in diameter. Condensation Particle Counters designed for the workplace do not have discrete size-selective inputs, and so they are typically sensitive to particles less than 1 μm in diameter. Commercial size-selective inlets are not available to restrict CPCs to the nanoparticle size range; however, the technology exists to construct size-selective inlets based on particle mobility or possibly on inertial pre-separation. An alternative approach to estimating nanoparticle number concentrations using a CPC is to use the instrument in parallel with an optical particle counter (OPC). The difference in particle count between the instruments will provide an indication of particle number concentration between the lower CPC detectable particle diameter and the lower OPC particle diameter (typically 300–500 nm).

A critical issue when characterizing exposure using particle number concentration

is selectivity. **Nanoscale particles are ubiquitous in many workplaces**, from sources such as combustion, vehicle emissions, and infiltration of outside air. Particle counters are generally insensitive to particle source or composition **making it difficult to differentiate between incidental and process-related nanoparticles using number concentration alone.** In a study of aerosol exposures during a carbon black bagging process, Kuhlbusch et al. [2004] found that peaks in number concentration measurements were associated with emissions from fork lift trucks and gas burners in the vicinity, rather than with the process itself. In a similar manner, during an ultrafine particle mapping exercise in an automotive facility, Peters et al. [2006] found that direct gas-fired heating systems systematically produced high particle number concentrations throughout the facility when the heating system was in operation. Through follow up measurements, Heitbrink et al. [2007] found a high proportion of ultrafine particles produced from these burners, yet little if any mass was associated with their emissions. Other non-process ultrafine sources were identified in an adjacent foundry [Evans et al. 2008]. Together with roof mounted gas-fired heating units, additional sources included cigarette-smoking and the exhaust from a propane fueled sweeper vehicle, with the latter contributing a large fraction of the ultrafine particles. Although these issues are not unique to particle number concentration measurements, orders of magnitude difference can exist in particle number concentrations depending on concomitant sources of particle emissions.

Although using nanoparticle number concentration as an exposure measurement may not be consistent with exposure metrics being used in animal toxicity studies, **such measurements may be useful for identifying nanoscale particle emissions and determining the efficacy of control measures.** Portable CPCs are capable of measuring localized particle concentrations allowing the assessment of particle releases occurring at various processes and job tasks [Brouwer et al. 2004].

7.1.5 Surface-area estimation

Information about the relationship between different measurement metrics can be used for approximating particle surface area. If the size distribution of an aerosol remains consistent, the relationship between particle number, surface area, and mass metrics will be constant. In particular, mass concentration measurements can be used for deriving surface-area concentrations, assuming the constant of proportionality is known. This constant is the specific surface area (surface to mass ratio).

Size distribution measurements may be obtained through the collection of filter samples and analysis by transmission electron microscopy to estimate particle surface area. If the measurements are weighted by particle number, information about particle geometry will be needed to estimate the surface area of particles with a given diameter. If the measurements are weighted by mass, additional information about particle density will be required. Estimates of particle-specific surface area from geometric relation with external particle dimensions depends upon the morphology regime of the material of interest and is only appropriate for smooth, regularly shaped, compact particles [Stefaniak et al. 2003; Weibel et al. 2005]. For example, Weibel et al. [2005] report that estimates of ultrafine TiO_2 surface area determined using a geometric relationship with the physical particle size

(using TEM) were 50% lower than measured using nitrogen gas adsorption.

If the airborne aerosol has a lognormal size distribution, particle surface-area concentration can be derived using three independent measurements. An approach has been proposed using three simultaneous measurements of the aerosol that included mass concentration, number concentration, and charge [Woo et al. 2001]. With knowledge of the response function of each instrument, minimization techniques can be used to estimate the parameters of the lognormal distribution leading to the three measurements used in estimating the particle surface area.

An alternative approach has been proposed whereby independent measurements of particle number and mass concentration are made, and the surface area is estimated by assuming the geometric standard deviation of the (assumed) lognormal distribution [Maynard 2003]. This method has the advantage of simplicity by relying on portable instruments that can be used in the workplace. Theoretical calculations have shown that estimates may be up to a factor of 10 different from the actual particle surface area, particularly when the aerosol has a bimodal distribution. Field measurements indicate that estimates are within a factor of 3 of the active surface area, particularly at higher concentrations. In workplace environments, particle surface-area concentrations can be expected to span up to 5 orders of magnitude; thus, surface-area estimates may be suited for initial or preliminary appraisals of occupational exposure concentrations.

Although such estimation methods are unlikely to become a long-term alternative to more accurate methods, they may provide a viable interim approach to estimating the surface area of nanoscale particles in the absence of precise measurement data. Additional research is needed on comparing methods used for estimating particle surface area with a more accurate particle surface-area-measurement method. NIOSH is conducting research in this area and will communicate results as they become available.

7.1.6 Particle number concentration mapping

To better understand particle sources and contaminant migration, some investigators have adopted an aerosol mapping technique, which integrated measurements of respirable mass, ultrafine particle number, and active surface-area concentrations in automotive manufacturing facilities [Peters et al. 2006; Heitbrink et al. 2007, 2008; Evans et al. 2008]. The process relies on portable aerosol sampling instrumentation for simultaneous measurements at predetermined positions throughout a facility. The technique is somewhat measurement-intensive but is useful for locating contaminant sources and determining the extent of contaminant migration. Leaks and other less obvious particle sources have been identified in this way and the procedure provides a powerful tool for facility staff to target their contaminant control approaches most effectively. This technique relies on successive measurements at various locations, making facilities with continuous processes or those likely to achieve steady state particle number concentrations most appropriate for this approach. The approach is less successful for facilities with batch processes or those likely to experience rapid concentration changes as, depending on where in the measurement cycle the release occurs, it may be overlooked. A high degree of variability between mapping events is expected in

facilities where sporadic or batch processing occurs.

7.2 Sampling Strategy

Currently, there is not one sampling method that can be used to characterize exposure to nanoscale aerosols. Therefore, any attempt to characterize workplace exposure to nanomaterials must involve a multifaceted approach incorporating many of the sampling techniques mentioned above. Brouwer et al. [2004] recommend that all relevant characteristics of nanomaterial exposure be measured, and a sampling strategy similar to theirs would provide a reasonable approach to characterizing workplace exposure. NIOSH has developed the Nanoparticle Emission Assessment Technique (NEAT) to qualitatively determine the release of engineered nanomaterials in the workplace (see Appendix). This approach may be helpful to others for the initial evaluation of workplaces where engineered nanomaterials are manufactured or used. If material release is found and if resources allow, then a more comprehensive and quantitative approach may be adopted [Methner et al. 2007].

The first step to characterizing workplace exposures would involve identifying the source of nanomaterial emissions. A CPC used in parallel with an OPC provides acceptable capability for this purpose. **It is critical to determine ambient or background particle counts before measuring particle counts during the manufacturing, processing, or handling of engineered nanomaterials.** However, investigators need to be aware that background nanoscale particle counts can vary both spatially and temporally depending on the unique conditions of the workplace. Subtraction of background nanoscale particle counts will be most challenging in these situations. In cases where nanomaterial handling or processing operations contribute only small elevations in particle counts, it may not be possible to adequately characterize these increases, particularly if the background particle count is relatively high.

If nanomaterials are detected in the process area at elevated concentrations relative to background particle number concentrations, then a pair of filter-based, area air samples should be collected for particle analysis via transmission electron microscopy (TEM) and for determining mass concentration. Transmission electron microscopy can provide an estimate of the particle size distribution and, if equipped with an energy dispersive X-ray analyzer (EDS), a determination of elemental composition

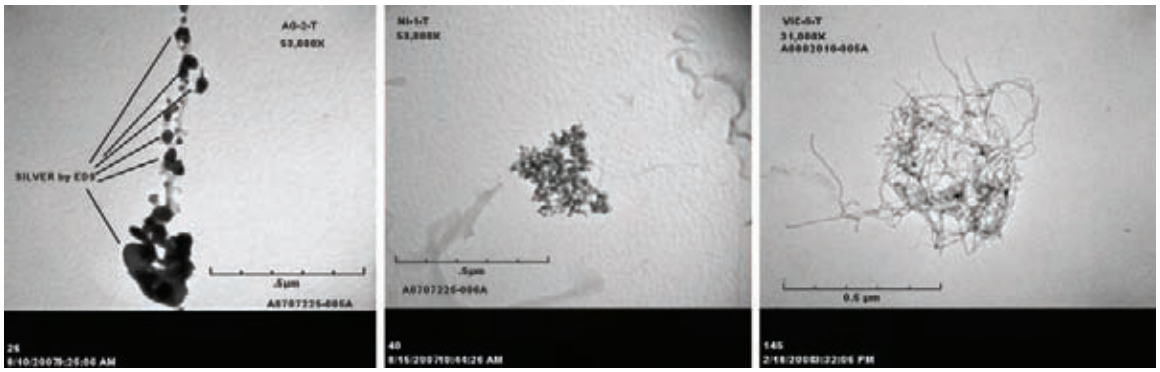

Figure 7–2. Photomicrographs of airborne engineered nanomaterials (airborne samples of engineered nanoparticles of silver, nickel, and MWCNT analyzed by TEM and EDS)

can be made to identify the nanomaterial (see Figure 7–2).

Analysis of filters for mass determination of air contaminants of interest can help identify the source of the particles. Standard analytical chemical methodologies (e.g., NMAM 5040 for carbon, NMAM 7303 for metals) should be employed [NIOSH 1994].

The combination of particle counters and samples for chemical analysis allows for an assessment of worker exposure to nanomaterials (see Figure 7–3) and the characterization of the important aerosol metrics. However, since this approach relies primarily on static or area sampling, some uncertainty will exist in estimating worker exposures.

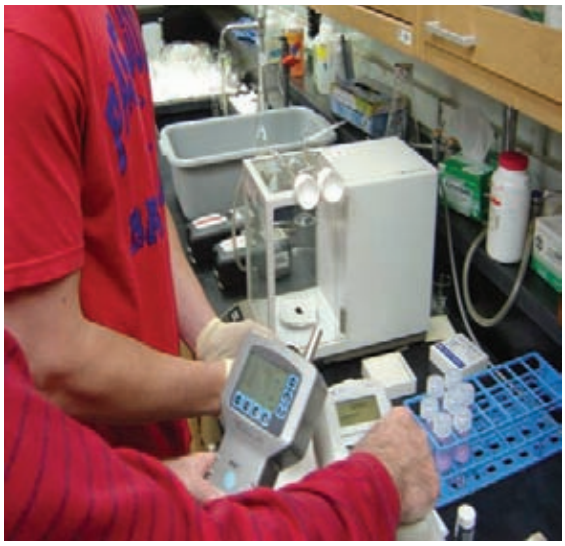

Figure 7–3. Combined use of the OPC, CPC, and two filter samples to determine the presence of nanomaterials

8 Guidelines for Working with Engineered Nanomaterials

Engineered nanomaterials are diverse in their physical, chemical, and biological nature. The processes used in research, material development, production, and use or introduction of nanomaterials have the potential to vary greatly. **Until further information on the possible health risks and extent of occupational exposure to nanomaterials becomes available, interim protective measures should be developed and implemented.** These measures should focus on the development of engineering controls and safe working practices tailored to the specific processes and materials where workers might be exposed. Hazard information that is available about common materials being manufactured in the nanoscale range (e.g., TiO_2, beryllium) should be considered as a starting point in developing appropriate controls and work practices.

The following recommendations are designed to aid in the assessment and control of workplace exposures to engineered nanomaterials. Using a hazard-based approach to evaluate exposures and for developing precautionary measures is consistent with good occupational safety and health practices [The Royal Society and The Royal Academy of Engineering 2004; Schulte et al. 2008].

8.1 Potential for Occupational Exposure

Few workplace measurement data exist on airborne exposure to nanomaterials that are purposely produced and not incidental to an industrial process. In general, it is likely that processes generating nanomaterials in the gas phase (after removal of the nanomaterial from an enclosed generation system), or using or producing nanomaterials as powders or slurries/suspensions/solutions (i.e., in liquid media), pose the greatest risk for releasing nanoparticles. In addition, **maintenance on production systems (including cleaning and disposing of materials from dust collection systems) is likely to result in exposure to nanoparticles if deposited nanomaterials are disturbed.** Exposures associated with waste streams containing nanomaterials may also occur.

The magnitude of exposure to nanomaterials when working with nanopowders depends on the likelihood of particles being released from the powders during handling. NIOSH is actively conducting research to quantitatively determine how various nanomaterials are dispersed in the workplace. Studies on exposure to SWCNTs and MWCNTs have indicated that the raw material may release visible particles into the air when handled, that the particle size of the agglomerate can be a few millimeters in diameter, and that the release rate of inhalable and respirable particles is relatively low (on a mass or number basis) compared with other nanopowders. Maynard et al. [2004] reported concentrations of respirable dust from 0.007 to 0.053 mg/m^3 when energy was applied (vortexing) to bulk SWCNT for approximately 30 minutes. Similar findings were reported by Han et al. [2008] at a laboratory producing MWCNTs in which exposure concentrations as high as 0.4 mg/m^3 were observed prior to the implementation of exposure controls. In a health hazard evaluation conducted by NIOSH at a

university-based research laboratory the potential release of airborne carbon nanotubes (CNFs) was observed at various processes [Methner et al. 2007]. General area exposure measurements indicated slight increases in airborne particle number and mass concentrations relative to background measurements during the transfer of CNFs prior to weighing and mixing, and during wet saw cutting of a composite material. Since data are lacking on the generation of inhalable/respirable particles during the production and use of engineered nanomaterials, further research is required to determine exposures under various conditions. NIOSH researchers are conducting both laboratory and field-based evaluations in order to address some of these knowledge gaps.

Devices comprised of nanostructures, such as integrated circuits, pose a minimal risk of exposure to nanomaterials during handling. However, some of the processes used in their production may lead to exposure to nanomaterials (e.g., exposure to commercial polishing compounds that contain nanoscale particles, exposure to nanoscale particles that are inadvertently dispersed or created during the manufacturing and handling processes). Likewise, large-scale components formed from nanocomposites will most likely not present significant exposure potential. However, if such materials are used or handled in such a manner that can generate nanoparticles (e.g., cutting, grinding) or undergo degradation processes that lead to the release of nanostructured material, then exposure may occur by the inhalation, ingestion, and/or dermal penetration of these particles.

8.2 Factors Affecting Exposure to Nanomaterials

Factors affecting exposure to engineered nanomaterials include the amount of material being used and whether the material can be easily dispersed (in the case of a powder) or form airborne sprays or droplets (in the case of suspensions). The degree of containment and duration of use will also influence exposure. In the case of airborne material, particle or droplet size will determine whether the material can enter the respiratory tract and where it is most likely to deposit. Respirable particles are those capable of depositing in the alveolar (gas exchange) region of the lungs, which includes particles smaller than approximately 10 μm in diameter [Lippmann 1977; ICRP 1994; ISO 1995]. The proportion of inhaled nanoparticles likely to deposit in any region of the human respiratory tract is approximately 30%–90% depending on factors such as breathing rate and particle size. Up to 50% of nanoparticles in the 10–100 nm size range may deposit in the alveolar region, while nanoparticles smaller than 10 nm are more likely to deposit in the head and thoracic regions [ICRP 1994]. **The mass deposition fraction of inhaled nanoparticles in the gas-exchange region of the lungs is greater than that for larger respirable particles.**

At present there is insufficient information to predict all of the situations and workplace scenarios that are likely to lead to exposure to nanomaterials. However, there are some workplace factors that can increase the potential for exposure:

- working with nanomaterials in liquid media without adequate protection (e.g., gloves)
- working with nanomaterials in liquid during pouring or mixing operations

or where a high degree of agitation is involved

- generating nanomaterials in the gas phase in non-enclosed systems
- handling (e.g., weighing, blending, spraying) powders of nanostructured materials
- maintenance on equipment and processes used to produce or fabricate nanomaterials
- cleaning up spills or waste material
- cleaning dust collection systems used to capture nanoparticles
- machining, sanding, drilling of nanomaterials, or other mechanical disruptions of nanomaterials can potentially lead to the aerosolization of nanoparticles.

8.3 Elements of a Risk Management Program

Given the limited information about the health risks associated with occupational exposure to engineered nanomaterials, appropriate steps should be taken to minimize the risk of worker exposure through the implementation of a risk management program [Schulte et al. 2008]. Risk management programs for nanomaterials should be seen as an integral part of an overall occupational safety and health program for any company or workplace producing or using nanomaterials or nanoenabled products. A critical element of the program should be the capability to anticipate new and emerging risks (hazard determination) and whether they are linked to changes in the manufacturing process, equipment, or the introduction of new materials. This will require an ongoing assessment of the potential risks to workers (risk evaluation) through the systematic collection of job and product information so that determinations can be made regarding scenarios (e.g., laboratory research, production and manufacture, nanoenabled product use) that place the worker in contact with nanomaterials (see Figure 8–1). This assessment should be an ongoing cyclic process that provides feedback on potential sources of exposure and solutions taken to correct those problems. For example, operations and job tasks that have the potential to aerosolize nanomaterials (e.g., handling dry powders, spray applications) deserve more attention and more stringent controls than those where the nanomaterials are imbedded in solid or liquid matrices. Elements of the risk management program should include guidelines for installing and evaluating engineering controls (e.g., exhaust ventilation, dust collection systems), the education and training of workers in the proper handling of nanomaterials (e.g., good work practices), and the selection and use of personal protective equipment (e.g., clothing, gloves, respirators).

When controlling potential exposures within a workplace, NIOSH has recommended a hierarchical approach to reduce worker exposures (see Table 8–1) [NIOSH 1990]. The philosophical basis for the hierarchy of controls is to eliminate the hazard when possible (i.e., substitute with a less hazardous material) or, if not feasible, control the hazard at or as close to the source as possible.

8.3.1 Engineering Controls

If the potential hazard can not be eliminated or substituted with a less hazardous or non-hazardous substance, then engineering controls should be installed and tailored to the process or job task. The type of engineering control used should take into

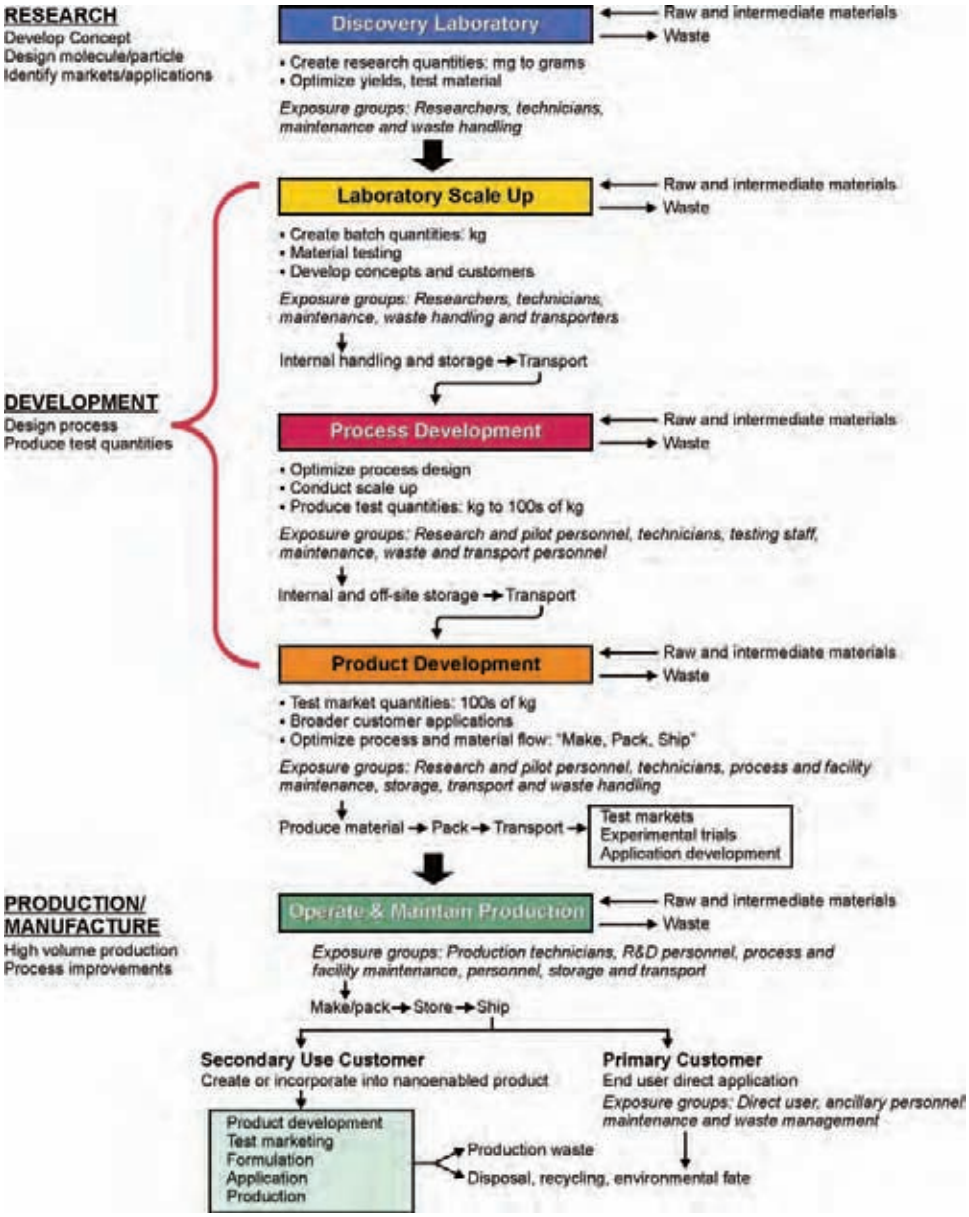

Figure 8–1. Workplaces with potential for occupational exposure to engineered nanomaterials. The figure illustrates the life cycle of nanomaterials from laboratory research development through product development, use, and disposal. Each step of the life cycle represents opportunities for potential worker exposure to nanomaterials. Adapted from Schulte et al. 2008a.

Table 8–1. Hierarchy of exposure controls*

Control method	Process, equipment, or job task
1. Elimination	Change design to eliminate hazard
2. Substitution	Replace a high hazard for a low hazard
3. Engineering	Isolation/enclosure, ventilation (local, general)
4. Administrative	Procedures, policies, shift design
5. Personal protective equipment	Respirators, clothing, gloves, goggles, ear plugs

*Control methods are typically implemented in this order to limit worker exposures to an acceptable concentration (e.g., occupational exposure limit or other pre-established limit).

Sources: Plog et al. 2002; NIOSH 1990.

account information on the potential hazardous properties of the precursor materials and intermediates as well as those of the resulting nanomaterial. In light of current scientific knowledge about the generation, transport, and capture of aerosols [Seinfeld and Pandis 1998; Hinds 1999], airborne exposure to nanomaterials can most likely be controlled at most processes and job tasks using a wide variety of engineering control techniques similar to those used in reducing exposures to general aerosols [Ratherman 1996; Burton 1997].

Engineering control techniques such as source enclosure (i.e., isolating the generation source from the worker) and local exhaust ventilation systems should be effective for capturing airborne nanomaterials, based on what is known of nanomaterial motion and behavior in air (see Figure 8–2). The quantity of the bulk nanomaterial that is synthesized or handled in the manufacture of a product will significantly influence the selection of the exposure controls.

Other factors that influence selection of engineering controls include the physical form of the nanomaterial and task duration and frequency. For instance, working with nanomaterial in the slurry form in low quantities would require a less rigorous control system than those that would be required for large quantities of nanomaterials in a free or fine powder form (see Figure 8–3). Unless cutting or grinding occurs, nanomaterials that are not in free form (encapsulated in a solid, nanocomposites, and surface coated materials) typically wouldn't require engineering controls.

Handling research quantities typically occurs in laboratories with ventilation controls. Since quantities are small, local containment and control can be applied, such as low-flow vented work stations and small glove box chambers. However, as quantities are increased, care must be taken to reduce the amount of nanomaterial that is released from the process equipment and to prevent the migration of nanomaterials into adjacent rooms or areas. For example, the installation of local exhaust ventilation at a

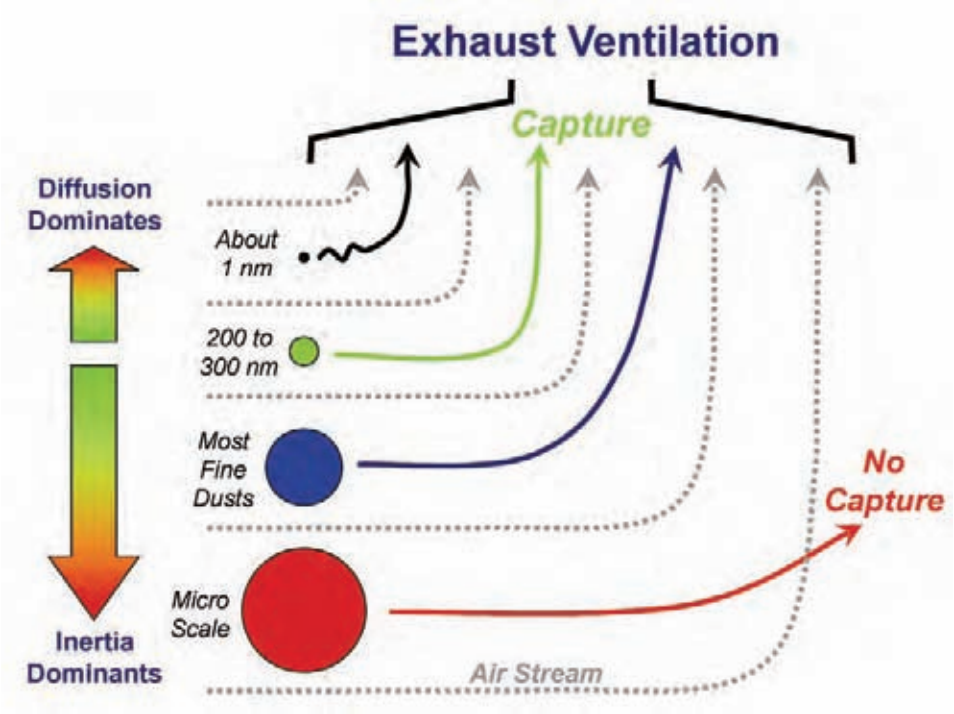

Figure 8–2. Exposure control of particles (illustration of how particle diameter-related diffusion and inertia influence particle capture efficiency in a ventilation system). Particles with a diameter of 200–300 nm have minimal diffusion and inertial properties and are easily transported by moving air and captured. Particle motion by diffusion increasingly dominates as particle diameter decreases below 200 nm. The inertial behavior of larger particles, especially those ejected from energetic processes such as grinding, increases significantly with particle diameter, enabling them to cross the streamlines of moving air and avoid capture. Adapted from Schulte et al. 2008a.

reactor used to make nanoscale engineered metal oxides and metals was found to reduce nanoparticle exposures by 96% (mean particle number concentration) [Methner 2008]. The use of exhaust ventilation systems should be designed, tested, and maintained using approaches recommended by the American Conference of Governmental Industrial Hygienists [ACGIH 2001].

A secondary but nonetheless important issue concerning the control of nanoparticle emissions is that of product loss. The properties of nanomaterials, along with the unique methods that may be employed for producing them, may mean that traditional exhaust ventilation may be more energetic than necessary for removing incidentally released nanoscale particles. For this reason, engineering controls need to be applied judiciously to ensure protection of workers without compromising production.

8.3.2 Dust collection efficiency of filters

Current knowledge indicates that a well-designed exhaust ventilation system with a

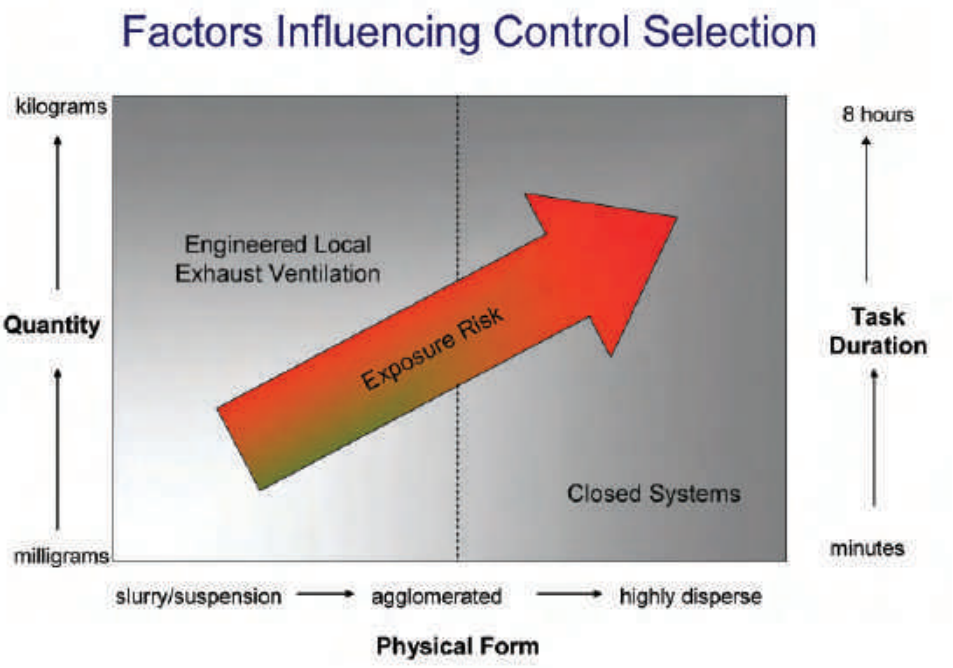

Figure 8–3. Factors influencing control selection. Several factors influence the selection of exposure controls for nanomaterials including quantity of nanomaterial handled or produced, physical form, and task duration. As each one of theses variables increase, exposure risk becomes greater as does the need for more efficient exposure control measures.

HEPA filter should effectively remove nanoparticles [Hinds 1999]. Limited studies have reported the efficacy of filter media typically found in control systems (including respirators) in capturing nanoparticles. The dearth of data on filtration performance against nanoparticles (in particular nanoparticles smaller than 20 nm) is primarily due to the challenges in generating and quantifying particles in those size ranges. Despite these limitations, the results of some studies [Van Osdell et al. 1990] using different filter media challenged with monodispersed aerosols (silver 4–10 nm and dioctylphthalate 32–420 nm) were in agreement with classical single-fiber theory showing an increase in filtration efficacy for smaller size particles. No evidence for particle thermal rebound was observed. Similar results have been recently reported by Kim et al. [2007] using different filter media challenged with particles ranging in size from 2.5–20 nm, indicating that other filter medias—including those used in air purifying respirators—would behave similarly.

If HEPA filters are used in the dust collection system, they should be coupled with well-designed filter housings. If the filter is improperly seated within the housing, nanoparticles have the potential to bypass the filter, leading to filter efficiencies much less than predicted [NIOSH 2003].

8.3.3 Work practices

An integral step in establishing good work practices is having knowledge of the potential

hazards in the workplace and developing formal procedures that describe actions to be taken to ensure the protection of workers. Incorporated in these procedures should be guidelines for good work practices intended to minimize worker exposure to nanomaterials and other potentially hazardous chemicals. Management should systemically review and update these procedures. Actions taken to resolve and/or improve workplace conditions should be routinely conveyed by management to workers.

Good practices for management

- Educating workers on the safe handling of engineered nano-objects or nano-object-containing materials to minimize the likelihood of inhalation exposure and skin contact.
- Providing information, as needed, on the hazardous properties of the precursor materials and those of the resulting nanomaterials product with instruction on measures to prevent exposure.
- Encouraging workers to use handwashing facilities before eating, smoking, or leaving the worksite.
- Providing additional control measures (e.g., use of a buffer area, decontamination facilities for workers if warranted by the hazard) to ensure that engineered nanomaterials are not transported outside the work area [US DOE 2007].
- Providing facilities for showering and changing clothes to prevent the inadvertent contamination of other areas (including take-home) caused by the transfer of nanomaterials on clothing and skin.

Good practices for workers

- Avoiding handling nanomaterials in the open air in a "*free particle*" state.
- Storing dispersible nanomaterials, whether suspended in liquids or in a dry particle form in closed (tightly sealed) containers whenever possible.
- Cleaning work areas at the end of each work shift, at a minimum, using either a HEPA-filtered vacuum cleaner or wet wiping methods. Dry sweeping or air hoses should not be used to clean work areas. Cleanup should be conducted in a manner that prevents worker contact with wastes. Disposal of all waste material should comply with all applicable Federal, State, and local regulations.
- Avoiding storing and consuming food or beverages in workplaces where nanomaterials are handled.

8.3.4 Personal protective clothing

Currently, there are no generally acceptable guidelines available based on scientific data for the selection of protective clothing or other apparel against exposure to nanomaterials. This is due in part to minimal data being available on the efficacy of existing protective clothing, including gloves. In any case, although nanoparticles may penetrate the epidermis, there has been little evidence to suggest that penetration leads to disease; and no dermal exposure standards have been proposed. However, based on a recent survey of nanotechnology workplaces [ICON 2006], 84% of employers recommended personal protective equipment and clothing for employees working with nanomaterials. These recommendations were generally based on conventional occupational hygiene practices

but also varied with the size of the company, the type of nanomaterials being handled, and the commercial sector. While some guidelines on the use of protective clothing and gloves have been developed by organizations for use in their own laboratories (e.g., US DOE 2007) or countries (e.g., British Standards Institute BSI 2008) or by consensus standards development organizations (e.g., ASTM, 2007), these are generally based upon good industrial hygiene practices rather than scientific data specific to nanomaterials.

A challenge to making appropriate recommendations for dermal protection against nanoparticles is the need to strike a balance between comfort and protection. Garments that provide the highest level of protection (e.g., an impermeable Level A suit) are also the least comfortable to wear for long periods of time, while garments that are probably the least protective (e.g., thin cotton lab coat) are the most breathable and comfortable for employees to wear. The two primary routes of exposure to particulates for workers using protective clothing are direct penetration through the materials and leakage through gaps, seams, defects, and interface and closure areas [Schneider et al. 1999, 2000]. The relative contributions from these two inward leakage sources are not well-understood. NIOSH has an active research program designed to assess the efficacy of barrier materials and ensembles for protection against particulate hazards, including nanoparticles.

The lack of available data is further complicated by the limitations and difficulties of current test methods, which fall into two basic categories: penetration tests on material swatches to determine barrier efficiency and system-level aerosol testing to determine product ensemble integrity. The former are usually bench-scale testing methods, while the latter require an exposure chamber that is large enough for at least one human test subject or mannequin. Chamber design requirements for system level aerosol testing have been reviewed by Gao et al. [2007]. Little scientific data exists, but some systems level test methods are available. ISO standard method 13982 [ISO 2004a] and EN standard method 943 [CEN 2002] specify the use of sodium chloride (NaCl) with a mass median aerodynamic diameter (MMAD) of 0.6 μm to determine the barrier efficiency of protective clothing against aerosols of dry, fine dusts. The standard method issued by National Fire Protection Association [2007] is a method that is not dependent on filtration-based approaches. Penetration of fluorophore-impregnated silica particles with a MMAD of 2.5 μm and a geometric standard deviation of 2.6 are qualitatively visualized by black light that causes the fluorescent glow of the challenge aerosol particles. Note that the polydisperse particle challenges used in these methods include a large number of nanoscale particles when measured by count rather than by mass.

Particle penetration test methods can be further categorized into those that are analogous to the process used in respirator filter testing and those that are not dependent on filtration-based approaches. Test methods that involve measuring aerosol concentrations using a sampling flow rate do not mimic in-situ situations because the skin does not "breathe." Standardized methodology is needed that is not dependent on filtration-based approaches for examining the overall barrier-effectiveness of the full protective clothing ensemble for different materials to particulate hazards. In this respect, NIOSH has presented preliminary results [Wang and Gao 2007] on development of a magnetic passive aerosol sampler for more accurate determination of particle penetration

through protective clothing. NIOSH is conducting research in this area and will communicate results as they become available.

The bulk of the penetration data available on clothing has been done with filtration based testing. One study found that penetration levels of 30–2,000-nm-sized potassium chloride particles through an unidentified military garment ranged from about 20%–60%, with the maximum penetration occurring in the range of 100–400 nm [Hofacre 2006]. Another group of researchers studied the barrier efficiency of 10 unidentified fabric samples (woven, non-woven, and laminated fabrics) using 477-nm-sized latex spheres at a flow rate of 1.8 cm/second [Shavlev et al. 2000]. Particle penetration measurements ranged from 0%–54%, with three of the fabrics exhibiting a measurable pressure drop and having penetration levels less than 1%. In general, these findings suggest that increased external air pressure (e.g., from wind) results in increased particle penetrations. Thus, only impermeable barrier materials are likely to provide complete barrier protection against aerosol penetration. Body movement (i.e., bellows effect) can also impact penetration [Bergman et al. 1989]. NIOSH will theoretically and empirically investigate wind-driven nanoparticle penetration through protective clothing in an attempt to obtain a predictive model based upon single-fiber theory. Results will be communicated as they become available.

Another widely used test method incorporates testing with nanoscale particles in solution, and therefore also provides some indication of the effectiveness of protective clothing to nanoparticles. ASTM standard F1671–03 [ASTM 2003] and ISO standard 16604 [ISO 2004b] specify the use of a 27-nm bacteriophage to evaluate the resistance of materials used in protective clothing from the penetration of blood-borne pathogens. One study [Edlich et al. 1999] evaluated the integrity of powder-free examination gloves and found that no bacteriophage penetration was detected for powder-free nitrile gloves, powder-free latex gloves, nor polyvinyl chloride synthetic gloves.

Based upon the uncertainty of the health effects of dermal exposure to nanoparticles, it is prudent to consider using protective equipment, clothing, and gloves to minimize dermal exposure, with particular attention given to preventing exposure of nanomaterials to abraded or lacerated skin. Until scientific data exist specific to the performance of protective clothing and gloves against nanomaterials, current industrial hygiene best practices should be followed.

8.3.5 Respirators

The use of respirators is often required when engineering and administrative controls do not adequately keep worker exposures to an airborne contaminant below a regulatory limit or an internal control target. Currently, there are no specific exposure limits in the United States for airborne exposures to engineered nanomaterials although occupational exposure limits and guidelines exist for airborne particles of similar chemical composition regardless of particle size. Current scientific evidence indicates that nanoparticles may be more biologically reactive than larger particles of similar chemical composition and thus may pose a greater health risk when inhaled. In determining the need for respirators, it would therefore be prudent to consider current exposure limits or guidelines (e.g., OSHA PELs, NIOSH RELs, ACGIH TLVs) for larger particles of similar composition, existing toxicologic

data on the specific nanoparticle, and the likelihood of worker exposure (e.g., airborne concentration, time exposed, job task).

The decision to institute respiratory protection should be based on a combination of professional judgment and the results of the hazard assessment and risk management practices recommended in this document. The effectiveness of administrative, work-practice, and engineering controls can be evaluated using the measurement techniques described in Chapter 7 Exposure Assessments and Characterization. If worker exposure to airborne nanomaterials remains a concern after instituting control measures, the use of respirators can provide further worker protection. Several classes of respirators exist that can provide different levels of protection when properly fit tested on the worker. Table 8–2 lists various types of particulate respirators that can be used; information is also provided on the level of exposure reduction that can be expected along with the advantages and disadvantages of each respirator type. To assist respirator users, NIOSH has published the document *NIOSH Respirator Selection Logic (RSL)* that provides a process that respirator program administrators can use to select appropriate respirators [NIOSH 2004] (see www.cdc.gov/niosh/docs/2005-100/default.html). As new toxicity data for individual nanomaterials become available, NIOSH will review the data and make recommendations for respirator protection.

When respirators are required for use in the workplace, the Occupational Safety and Health Administration (OSHA) respiratory protection standard [29 CFR 1910.134] requires that a respiratory program be established that includes the following program elements: (*1*) an evaluation of the worker's ability to perform the work while wearing a respirator, (*2*) regular training of personnel, (*3*) periodic environmental monitoring, (*4*) respirator fit testing, and (*5*) respirator maintenance, inspection, cleaning, and storage. The standard also requires that the selection of respirators be made by a person knowledgeable about the workplace and the limitations associated with each type of respirator. OSHA has also issued guidelines for employers who choose to establish the voluntary use of respirators [29 CFR 1910.134 Appendix D].

Table 8–2 lists the NIOSH assigned protection factors (APF) for various classes of respirators. The APF is defined as the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users. The APF values developed by NIOSH are based in part on laboratory studies and take into consideration a variety of factors including the inward leakage caused by penetration through the filter and leakage around the respirator face seal. The relative contributions of these two sources of inward leakage are critical because for many applications the predominant source of exposure to the respirator wearer results from leakage around the face seal (due to a poor fit) and not penetration directly through the filter media. In 2006, OSHA published updated APF values that supersede the NIOSH APF values [Federal Register 2006]. In general there is good agreement between the NIOSH and OSHA APF values, but management should consult the OSHA standard prior to using the values in Table 8–2 directly.

NIOSH is not aware of any data specific to respirator face seal leakage of nanoparticles. However, numerous studies have

been conducted on larger particles and on gases/vapors with one total inward leakage (TIL) study that used nanoparticles. For example, work done by researchers at the U.S. Army RDECOM on a head-form showed that mask leakage (i.e., simulated respirator fit factor) measured using submicron aerosol challenges (0.72 μm polystyrene latex spheres) was representative of vapor challenges such as sulfur hexafluoride (SF_6) and isoamyl acetate (IAA) [Gardner et al. 2004]. Other studies using particles larger than 100 nm have shown that face seal leakage can be affected by particle size, however, the impact of this is still the subject of some debate. A recently completed laboratory study to measure TIL protection factors of four NIOSH certified N95 filtering facepiece respirator models donned by human test subjects exposed to 40–1,300 nm particles found that the minimal protection factors were observed for particles between 80–200 nm [Lee 2008]. The geometric mean of the protection factors for all four models across all particle sizes tested was 21.5; but wide model-to-model variation was observed. NIOSH is conducting a laboratory study to determine whether nanoparticle face seal leakage is consistent with the leakage observed for larger particles and gases/vapors. Results will be communicated as they become available.

NIOSH certifies respirators in accordance with 42 CFR Part 84. As noted earlier, the NIOSH RSL contains a process for selecting respirators for protection against particular hazards. The two respirator classes (air purifying respirators and powered air purifying respirators) most commonly used for protection against particulates use filter media to collect/trap particles before they reach the user's breathing zone. Among the various test methods and criteria NIOSH uses as part of the certification process, respirator filter performance testing is the one most affected by the particle size. Since respirator users are exposed to a variety of hazards in different scenarios, respirator certification filtration testing was designed to use worst-case test conditions (e.g., different particle sizes and flow rates), so that filter performance in the workplace would not be worse. The NIOSH certification test for N-designated respirators uses a polydisperse distribution of NaCl particles with a count median diameter (CMD) of 0.075 +/-0.020 μm and a geometric standard deviation (GSD) of less than 1.86 [NIOSH 2005a]. NIOSH tests R- and P-designated respirators using a polydispersal of dioctyl phthalate (DOP) particles with a CMD of 0.185 +/-0.020 μm and a GSD of less than 1.60 [NIOSH 2005b]. For the lognormal distribution of NaCl aerosols used in the N series certification test, a broad range of particle sizes (e.g., 95% of the particles lie in the range of 22–259 nm) with a MMD of about 240 nm is used to determine whether the respirator filter performance is at least 95, 99, or 99.97% efficient. Most of the particles penetrating through the filter are measured simultaneously using a forward light scattering photometer. However, as noted in a recent review, the instrumentation used in the NIOSH certification test is not capable of measuring the light scattering of all particles less than 100 nm [Eninger et al. 2008a].

Particles larger than 0.3 μm are collected most efficiently by impaction, interception, and gravitational settling, while particles smaller than 0.3 μm are collected most efficiently by diffusion or electrostatic attraction [Hinds 1999]. In the development of the test method used for respirator certification, penetration by particles with an approximate 0.3 μm diameter was considered

to be the worst case because these particles were considered to be in the range of the most penetrating particle size [Stevens and Moyer 1989; TSI 2005; NIOSH 1996]. However, in practice, the most penetrating particle size range (MPPS) for a given respirator can vary based on the type of filter media employed and the condition of the respirator. For example, the most penetrating particle size for N95 air purifying respirators containing electrostatically charged filter media can range from 50–100 nm [Martin and Moyer 2000; Richardson et al. 2005] to 30–70 nm [Balazy et al. 2006; Eninger et al. 2008b]. These test results were recently confirmed by NIOSH [Rengasamy et al. 2007] in which five different models of respirators with N95 filters were challenged with 11 different monodisperse NaCl particles ranging in size from 20–400 nm. The monodisperse aerosol penetrations showed that the MPPS was in the 40-nm range for all respirator models tested. Under the aggressive laboratory test conditions employed in the study, mean penetration levels for 40-nm particles ranged from 1.4%–5.2%, which suggested that the respirators would be effective at capturing nanoparticles in the workplace. The NIOSH study also investigated whether there was a correlation between filtration performance using the existing NIOSH certification protocol for N series air purifying respirators and the filtration performance against monodisperse particles at the MPPS. A good correlation ($r = 0.95$) was found (e.g., respirators that performed better using the NIOSH certification test also had higher filter efficiencies against monodisperse 40-nm nanoparticles), which is not surprising given that changes in filtration performance follow a consistent trend as a function of particle size.

According to single fiber filtration theory, below the most penetrating particle size, filtration efficiency will increase as particle size decreases. This trend will continue until the particles are so small that they behave like vapor molecules. As particles approach molecular size, they may be subject to thermal rebound effects, in which particles literally bounce through a filter. As a result, particle penetration will increase. The exact size at which thermal rebound will occur is unclear. However, a study by Heim et al. [2005] found that there was no discernable deviation from classical single-fiber theory for particles as small as 2.5-nm diameter. Subsequently, a NIOSH-funded contract with the University of Minnesota [Kim et al. 2007; Pui et al. 2006] and another study [Kim et al. 2006] showed that the penetration of nanoparticles through fibrous filter media decreased down to 2.5 nm as expected by the single fiber filtration theory. Thermal rebound phenomena were observed for nanoparticles below 2 nm diameter [Kim et al. 2006]. Recent studies provide additional data on nanoparticle penetration for NIOSH certified N95 and P100 filtering face-piece respirators [Rengasamy et al. 2008a], NIOSH certified N95 and European Certified FFP1 respirators [Huang et al. 2007], and FFP3 filter media [Golanski et al. 2008] using particles greater than 4 nm.

Based on these preliminary findings, NIOSH-certified respirators should provide the expected levels of protection if properly selected and fit tested as part of a complete respiratory protection program. However, as noted elsewhere [Rengsamy et al. 2007], in the unlikely event that the workplace exposure consists of a large percentage of particles in the most penetrating particle size range, management should take this information into account during the respirator

selection process, perhaps by choosing a respirator with higher levels of filtration performance (e.g., changing from an N95 to a P100, even though the APF will remain the same) as suggested by OSHA [Federal Register 2006] or by selecting a respirator with a higher APF (e.g., full face-piece respirator or powered air purifying respirator). Dust masks, commercially available at hardware/home improvement stores, are often confused with NIOSH approved N95 filtering facepiece respirators because of their similar appearance. However, dust masks are not respirators and are not approved by NIOSH for respiratory protection. One study found that penetration of 40-nm NaCl nanoparticles range from 4.3%–81.6% for the seven dust mask models studied [Rengasamy et al. 2008b]. **Dust masks should not be used in place of NIOSH-approved respirators for protection against nanoparticles**.

NIOSH is continuing to study the protection afforded by NIOSH-certified respirators against emerging hazards such as engineered nanomaterials—including workplace-protection-factor studies—to ensure they provide expected levels of protection. NIOSH is also committed to updating 42 CFR Part 84—the regulatory language that provides NIOSH the authority to certify the performance of respirators in the United States—using a modular approach to rulemaking. Recently, NIOSH proposed the use of a TIL test as part of the respirator certification process for half-mask air purifying particulate respirators, including those having elastomeric and filtering face-pieces. The test protocol used to obtain benchmark TIL data for 101 half-face piece respirator models used 40–60 nm size ambient nanoparticles [NIOSH 2007]. Once implemented as part of the NIOSH certification process, the TIL tests should result in half-mask respirators with increased fitting performance. Future rulemaking activities may also include revisions to the filtration test to reflect changes in filtration performance resulting from use of new technologies (e.g., electret filter media). Results will be communicated as they become available.

8.3.6 Cleanup and disposal of nanomaterials

No specific guidance is currently available on cleaning up nanomaterial spills or contamination on surfaces; however, recommendations developed in the pharmaceutical industry for the handling and cleanup of pharmaceutical compounds might be applicable to worksites where engineered nanomaterials are manufactured or used [Wood 2001]. Until relevant information is available, it would be prudent to base strategies for dealing with spills and contaminated surfaces on current good practices, together with available information on exposure risks including the relative importance of different exposure routes. Standard approaches for cleaning powder spills include using HEPA-filtered vacuum cleaners, or wiping up the powder using damp cloths or wetting the powder prior to dry wiping. Liquid spills are typically cleaned by applying absorbent materials/liquid traps.

Damp cleaning methods with soaps or cleaning oils are preferred. Cleaning cloths should be properly disposed. Use of commercially available wet or electrostatic microfiber cleaning cloths may also be effective in removing particles from surfaces with minimal dispersion into the air. Drying and reusing contaminated cloths can result in re-dispersion of particles.

Energetic cleaning methods such as dry sweeping or the using of compressed air

should be avoided or only used with precautions that assure that particles suspended by the cleaning action are trapped by HEPA filters. If vacuum cleaning is employed, care should be taken that HEPA filters are installed properly and bags and filters changed according to manufacturer's recommendations.

While vacuum cleaning may prove to be effective for many applications, the following issues should be considered. Forces of attraction may make it difficult to entrain particles off surfaces with a vacuum cleaner. The electrostatic charge on particles will cause them to be attracted to oppositely charged surfaces and repelled by similarly charged surfaces. A similarly charged vacuum brush or tool may repel particles, making it difficult to capture the aerosol or even causing it to be further dispersed. Vigorous scrubbing with a vacuum brush or tool or even the friction from high flow rates of material or air on the vacuum hose can generate a charge. The vacuum cleaners recommended for cleaning copier and printer toners have electrostatic-charge-neutralization features to address these issues.

When developing procedures for cleaning up nanomaterial spills or contaminated surfaces, consideration should be given to the potential for exposure during cleanup. Inhalation exposure and dermal exposure will likely present the greatest risks. Consideration will therefore need to be given to appropriate levels of personal protective equipment. Inhalation exposure in particular will be influenced by the likelihood of material reaerosolization. In this context, it is likely that a hierarchy of potential exposures will exist, with dusts presenting a greater inhalation exposure potential than liquids, and liquids in turn presenting a greater potential risk than encapsulated or immobilized nanomaterials and structures.

As in the case of any material spill or cleaning of contaminated surfaces, the handling and disposal of the waste material should follow existing federal, state, or local regulations.

Table 8–2. Air-purifying particulate respirators

Respirator type	NIOSH assigned protection factor	Advantages	Disadvantages
Filtering facepiece (disposable)	10	– Lightweight – No maintenance or cleaning needed – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Some do not have adjustable head straps – Difficult for a user to do a seal check – Level of protection varies greatly among models – Communication may be difficult

(continued)

Table 8–2 (Continued). Air-purifying particulate respirators

Respirator type	NIOSH assigned protection factor	Advantages	Disadvantages
Filtering facepiece (disposable) (continued)			– Fit testing required to select proper facepiece size – Some eyewear may interfere with the fit
Elastomeric half-facepiece	10	– Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility	– Provides no eye protection – Can add to heat burden – Inward leakage at gaps in face seal – Communication may be difficult – Fit testing required to select proper facepiece size – Some eyewear may interfere with the fit
Powered with loose-fitting facepiece	25	– Provides eye protection – Offers protection for people with beards, missing dentures or facial scars – Low breathing resistance – Flowing air creates cooling effect – Face seal leakage is generally outward – Fit testing is not required – Prescription glasses can be worn – Communication easier than with elastomeric half-facepiece or full-facepiece respirators – Reusable components and replaceable filters	– Added weight of battery and blower – Awkward for some tasks – Battery requires charging – Air flow must be tested with flow device before use

(continued)

Table 8–2 (Continued). Air-purifying particulate respirators

Respirator type	NIOSH assigned protection factor	Advantages	Disadvantages
Elastomeric full-facepiece with N-100, R-100, or P-100 filters	50	– Provides eye protection – Low maintenance – Reusable facepiece and replaceable filters and cartridges – No effect on mobility – More effective face seal than that of filtering facepiece or elastomeric half-facepiece respirators	– Can add to heat burden – Diminished field-of-vision compared to half-facepiece –Inward leakage at gaps in face seal –Fit testing required to select proper facepiece size –Facepiece lens can fog without nose cup or lens treatment –Spectacle kit needed for people who wear corrective glasses
Powered with tight-fitting half-facepiece or full-facepiece	50	–Provides eye protection with full-facepiece –Low breathing resistance –Face seal leakage is generally outward –Flowing air creates cooling effect –Reusable components and replaceable filters	–Added weight of battery and blower –Awkward for some tasks –No eye protection with half-facepiece –Fit testing required to select proper facepiece size –Battery requires charging –Communication may be difficult –Spectacle kit needed for people who wear corrective glasses with full face-piece respirators –Air flow must be tested with flow device before use

9 Occupational Health Surveillance

Occupational health surveillance is an essential component of an effective occupational safety and health program. The unique physical and chemical properties of nanomaterials, the increasing growth of nanotechnology in the workplace, and information suggesting that exposure to some engineered nanomaterials can cause adverse health effects in laboratory animals all support consideration of an occupational health surveillance program for workers potentially exposed to engineered nanomaterials [Schulte et al. 2008a]. Continued evaluation of toxicologic research and workers potentially exposed to engineered nanomaterials is needed to inform NIOSH and other groups regarding the appropriate components of occupational health surveillance for nanotechnology workers.

NIOSH has developed interim guidance relevant to medical screening (one component of an occupational health surveillance program) for nanotechnology workers (see NIOSH Current Intelligence Bulletin: *Interim Guidance on Medical Screening and Hazard Surveillance for Workers Potentially Exposed to Engineered Nanoparticles,* www.cdc.gov/niosh/review/public/115/). Medical screening is only part of a complete safety and health management program that follows the hierarchy of controls and involves various occupational health surveillance measures. Since specific medical screening of workers exposed to engineered nanoparticles has not been extensively discussed in the scientific literature, this document is intended to fill the knowledge gap on an interim basis.

Increasing evidence indicates that exposure to some engineered nanoparticles can cause adverse health effects in laboratory animals, but no studies of workers exposed to the few engineered nanoparticles tested in animals have been published. The current body of evidence about the possible health risks of occupational exposure to engineered nanoparticles is quite small. Insufficient scientific and medical evidence now exists to recommend the specific medical screening of workers potentially exposed to engineered nanoparticles. Nonetheless, the lack of evidence on which to recommend specific medical screening does not preclude its consideration by employers interested in taking precautions beyond standard industrial hygiene measures [Schulte et al. 2008b]. If medical screening recommendations exist for chemical or bulk materials of which nanoparticles are composed, they would apply to nanoparticles as well.

Ongoing research on the hazards of engineered nanoparticles is needed along with the continual reassessment of available data to determine whether specific medical screening is warranted for workers who are producing or using nanoparticles. In the meantime, the following recommendations are provided for the management of workplaces where employees may be exposed to engineered nanoparticles in the course of their work:

- Take prudent measure to control workers' exposures to nanoparticles.
- Conduct hazard surveillance as the basis for implementing controls.

- Continue use of established medical surveillance approaches.

NIOSH will continue to examine new research findings and update its recommendations about medical screening programs for workers exposed to nanoparticles. Additionally, NIOSH is seeking comments on the strengths and weaknesses of exposure registries for workers potentially exposed to engineered nanoparticles.

10 Research Needs

NIOSH has developed a strategic plan for research on several occupational safety and health aspects of nanotechnology. The plan is available at www.cdc.gov/niosh/topics/nanotech/strat_plan.html. NIOSH has focused its research efforts in the following 10 critical topic areas to guide in addressing knowledge gaps, developing strategies, and providing recommendations.

1. **Exposure Assessment**

   - Determine key factors that influence the production, dispersion, accumulation, and re-entry of nanomaterials into the workplace.
   - Determine how possible exposures to nanomaterials differ by work process.
   - Assess possible exposure when nanomaterials are inhaled or settle on the skin.

2. **Toxicity and Internal Dose**

   - Investigate and determine the physical and chemical properties (e.g., size, shape, solubility, surface area, oxidant generation potential, surface functionalization, surface charge, chemical composition) that influence the potential toxicity of nanomaterials.
   - Determine the deposition pattern of nanoparticles in the lung and their translocation to the interstitium and to extrapulmonary organs.
   - Evaluate short- and long-term effects of pulmonary exposure to nanomaterials in various organ systems and tissues (e.g., lungs, brain, cardiovascular).
   - Determine if intratracheal instillation or pharyngeal aspiration can mimic the biological response to inhalation exposure to nanomaterials.
   - Determine the dermal effects of topical exposure to nano-objects, whether these nano-objects can penetrate into the skin, and whether they can cause immune alterations.
   - Determine the genotoxic and carcinogenic potential of nano-objects.
   - Determine biological mechanisms for potential toxic effects.
   - Determine whether in vitro screening tests can be predictive on in vivo response.
   - Create and integrate models to help assess potential hazards.
   - Determine whether a measure other than mass is more appropriate for determining toxicity.

3. **Epidemiology and Surveillance**

   - Evaluate existing exposure and health data for workers employed in workplaces where nanomaterials are produced and used, with emphasis on improving our understanding of the value and

utility of establishing exposure registries for workers potentially exposed to engineered nanomaterials.

- Assess the feasibility of industry-wide exposure and epidemiological studies of workers exposed to engineered nanomaterials, with emphasis on workers potentially exposed to engineered carbonaceous nanomaterials.
- Integrate nanotechnology safety and health issues into existing hazard surveillance mechanisms and continue reassessing guidance related to occupational health surveillance for workers potentially exposed to engineered nanomaterials.
- Build on existing public health geographical information systems and infrastructure to enable effective and economic development of methods for sharing nanotechnology safety and health data.

4. Risk Assessment

- Determine how existing exposure-response data for fine and ultrafine particles (human or animal) may be used to identify the potential hazards and estimate the potential risks of occupational exposure to nanomaterials.
- Develop a framework for assessing the potential hazards and risks of occupational exposure to nanomaterials, using new toxicologic data on engineered nanomaterials and standard risk assessment models and methods.

5. Measurement Methods

- Evaluate methods used to measure the mass of respirable particles in the air and determine whether this measurement can be used to measure nanomaterials.
- Develop and field-test practical methods to accurately measure airborne nanomaterials in the workplace.
- Develop, test, and evaluate systems to compare and validate sampling.

6. Engineering Controls and Personal Protective Equipment

- Evaluate the effectiveness of engineering controls in reducing occupational exposures to nanoaerosols and developing new controls when needed.
- Evaluate the suitability of control-banding techniques when additional information is needed and evaluate the effectiveness of alternative materials.
- Evaluate and improve current personal protective equipment.
- Develop recommendations (e.g., use of respiratory protection) to prevent or limit occupational exposures to nanomaterials.

7. Fire and Explosion Safety

- Identify physical and chemical properties that contribute to dustiness, combustibility, flammability, and conductivity of nanomaterials.

- Recommend alternative work practices to eliminate or reduce work place exposures to nanomaterials.

8. Recommendations and Guidance

- Use the best available science to make interim recommendations for workplace safety and health practices during the production, use, and handling of nanomaterials.
- Evaluate and update mass-based occupational exposure limits for airborne particles to ensure good, continuing precautionary practices.

9. Communication and Information

- Establish partnerships to allow for identification and sharing of research needs, approaches, and results.
- Develop and disseminate training and education materials to workers, employers, and occupational safety and health professionals.

10. Applications

- Identify uses of nanotechnology for application in occupational safety and health.
- Evaluate and disseminate effective applications to workers, employers, and occupational safety and health professionals.

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Appendix

Nanoparticle Emission Assessment Technique for Identification of Sources and Releases of Engineered Nanomaterials

1.0 Introduction

This appendix describes a technique that can be used by industrial hygienists for conducting initial workplace assessments for possible nanoparticle emissions. It allows a semi-quantitative evaluation of processes and tasks in the workplace where releases of engineered nanoparticles may occur. NIOSH uses several sampling approaches simultaneously with the goal of obtaining key physicochemical particle metrics: number concentration, qualitative size, shape, degree of agglomeration, and mass concentration of elemental constituents of interest.

2.0 Scope

Employers, workers, and researchers engaged in the production and use of engineered nanomaterials have expressed an interest in determining whether these nanomaterials are hazardous and if the potential for worker exposure exists. NIOSH has an active toxicology program to assess the potential hazards of engineered nanoparticles. Unfortunately these studies require long time periods and fall behind the pace of production and use of these nanomaterials. To assist in answering the latter of these questions, NIOSH established a nanotechnology field research team tasked with visiting facilities and collecting information about the potential for release of nanomaterials and worker exposure at those facilities. The initial challenges that the field research team encountered were: 1) determining which exposure metric (e.g., mass, particle number concentration, particle surface area) for engineered nanoparticles would provide a consistent body of knowledge to align with the toxicological results observed in experimental animal studies; and 2) selecting a sampling method based on metrics that were practical and would provide reproducible results. Engineered nanomaterials can be measured in the workplace using a variety of instrumentation including: condensation particle counter (CPC); optical particle counter (OPC); scanning mobility particle sizer (SMPS); electric low pressure impactor (ELPI); aerosol diffusion charger; and tapered element oscillating microbalance (TOEM), which vary in complexity and field portability. Unfortunately, relatively few of the above instruments are readily applicable to routine exposure monitoring due to non-specificity, lack of portability, difficulty of use, and high cost. NIOSH researchers have developed and used a field assessment strategy for determining exposures to engineered nanoparticles that could be adopted by other health and safety professionals in the evaluation of occupational exposures [Methner, et. al. 2007; Methner, 2008].

Since there are currently no exposure limits specific to engineered nanomaterials, this technique is used to determine whether

airborne releases of engineered nanomaterials occur. This assessment, which compares particle number concentrations and relative particle size at the potential emission source to background particle number concentrations and particle size, provides a semi-quantitative means for determining the effectiveness of existing control measures in reducing engineered nanoparticle exposures. This procedure utilizes portable direct-reading instrumentation supplemented by filter-based air samples (source-specific and personal breathing zone [PBZ]). The use of filter samples is crucial for particle identification because direct-reading instruments used for determining particle number concentrations are incapable of identifying the composition of the particles.

3.0 Summary of the On-Site Initial Assessment

The initial assessment uses a combination of direct-reading, handheld instruments (CPC and OPC) and filter-based sampling (e.g. 37-mm diameter filter cassettes) for subsequent chemical and microscopic analyses (Figure 1). This semi-quantitative approach was first described by Maynard et al. [2004] and NIOSH has adopted a similar approach. The technique includes determining particle number concentration using direct-reading, handheld particle counters at potential emission sources and comparing those data to background particle number concentrations. If elevated concentrations of suspected nanoparticles are detected at potential emission sources, relative to the background particle number concentrations, then a pair of filter-based, source-specific air samples are collected with one sample analyzed by transmission electron microscopy (TEM) or scanning electron microscopy (SEM) for particle identification and characterization, and the other used for determining the elemental mass concentration (Figure 2). A second pair of filter-based air samples may also be collected in the personal breathing zone of workers. Breathing zone samples are analyzed in the same manner as the area air samples (i.e., by TEM and elemental mass).

4.0 Air Sampling Instrumentation and Filter Media Used in the Initial Assessment

The following instrumentation is used by NIOSH; however, use does not constitute endorsement.

4.1 TSI model 3007 (or model 8525) (TSI Inc, Shoreview, MN), handheld condensation particle counter (CPC), which uses isopropanol to condense on particles so they can be counted

The TSI units provide a non-specific measure of the total number of particles independent of chemical identity per cubic centimeter of air (P/cm^3). The measureable range is between 10–1,000 nm for model 3007, or between 20–1,000 nm for model 8525. The range of detection for these instruments is reported by the manufacturer to be 0–100,000 P/cm^3.

4.2 ART Instruments Hand Held Particle Counter (HHPC-6, ART Instruments, Grants Pass, Oregon), which operates on optical counting principles using laser light scattering.

The HHPC-6 optical particle counter (OPC) can measure the total number of particles per liter (P/L)

of air independent of chemical identity within six specific size ranges. The OPC used by the NIOSH field research team provides particle counts in the following size cut-points: 300 nm; 500 nm; 1,000 nm; 3,000 nm; 5,000 nm; and 10,000 nm. The range of detection for this instrument is reported by the manufacturer to be 0–70,000 P/L. Different manufacturers' OPCs may have slightly different particle size ranges and could be substituted.

4.3 Appropriate air sampling filter media (e.g. mixed cellulose ester, quartz fiber filter) are selected depending on nanoparticle type and desired analytical information (e.g., determination of particle morphology using TEM or SEM, elemental analysis for metals, elemental analysis for carbon)

4.4 Air sampling pumps capable of sampling at high flow rates (e.g., 7 liters per minute or other flow rate depending upon the duration of the task and the appropriate NIOSH method, if a method is available)

4.5 Sampling pump flow calibrator

4.6 If desired, personal cascade impactor or respirable cyclone (see 5.3.3)

4.7 If desired, cassette conductive cowl (see 5.3.3)

4.8 Optional research-grade particle analyzers for expanded surveys (see 5.6.1)

4.9 Optional surface sampling supplies such as substrate (e.g., Ghost Wipes™), disposable 10 cm × 10 cm templates, sterile containers, and nitrile gloves for handling media (see 5.6.2)

5.0 Evaluation of Potential Releases of Engineered Nanomaterials

5.1 Identify Potential Sources of Emissions

The overall purpose of this step is to develop a list of target areas and tasks that will be evaluated with the particle analyzers.

The initial assessment involves identifying the potential sources of engineered nanomaterial emissions by reviewing the type of process, process flow, material inputs and discharges, tasks, and work practices. When available, literature (e.g., MSDS, records of feedstock materials) is reviewed to gain an understanding of the engineered nanomaterials being produced or used, including their physicochemical properties such as size, shape, solubility, and reactivity. Once the potential sources of emissions have been identified from the process review, the industrial hygienist (or other qualified person):

- Conducts an observational walk-through survey of the production area and processes to locate potential sources of emissions.
- Determines the frequency and duration of each operation and the type of equipment used for handling and containment of the material.

- Determines the presence/absence of general and local exhaust ventilation and other engineering controls. (This initial assessment includes identifying points of potential system failure that could result in emission from the containment/control system [e.g., hole in duct, deteriorated sealing gasket]).
- Determines the process points where containment is deliberately breached (e.g., opening system for product retrieval or for cleaning).

5.2 Conduct Particle Concentration Sampling

5.2.1 Background measurements

Determining the contribution of background particle concentrations on measurements made for the particles of interest (e.g., engineered nanoparticles) is an important evaluation of assessing the possible airborne release of engineered nanoparticles.

Ideally, during the initial assessment, the industrial hygienist (or other qualified person), will determine the average airborne particle concentration at various processes and adjacent work areas with the CPC and OPC *before* the processing or handling of nanomaterials begins. If the background particle concentrations are high (values are relative and will vary with processes and facilities), an assessment is made as to whether there may be a source of incidental nanoparticles in the area. Incidental nanoparticles may be generated from a variety of sources, including vacuum pumps, natural gas heating units, gasoline/propane/diesel powered fork lift trucks, or other combustion activities such as welding, soldering, or heat-sealing. The CPC and OPC can be used to check these sources for incidental nanoparticle releases. Outdoor or re-circulated air supply from the building ventilation system should also be considered as a possible source of nanoparticles [Peters et al. 2006].

Measurements of background particle concentrations are repeated after the active processing, manufacturing, or handling of the nanomaterial has ended. An average background concentration is then computed and subtracted from the measurements made during processing, manufacturing, or the handling of engineered nanomaterials. This approach is acceptable only if background particle counts remain relatively stable throughout the measurement period and particle emissions from the process under investigation are sufficiently elevated above background. For other situations, correcting for particle background concentrations becomes more complex requiring additional sampling over an extended time period to determine the source(s) and magnitude of background particle concentrations. This type of evaluation is generally outside the scope of the initial assessment described here.

5.2.2 Area sampling

Once initial background particle concentrations have been determined, measurements of airborne particle concentrations and size ranges are

made with the CPC and OPC simultaneously at locations near the suspected or likely emission source (e.g., opening a reactor, handling product, potential leak points in the ventilation system). Airborne particle concentrations are determined before, during, and after each task or operation to identify those factors (e.g., controls, worker interaction, work practices) that may affect airborne particle concentrations. This information is used to identify processes, locations, and personnel for filter-based air sampling (5.3).

5.3 Conduct Filter-based Area and Personal Air Sampling

5.3.1 *Area air sampling*

A pair of filter-based, air samples are collected at process/task locations and/or workers engaged in process operations where suspected engineered nanomaterial emissions may occur, based on air sampling results using the CPC and OPC.

Filter-based area air samples provide more specific information on the engineered nanomaterial of interest (e.g., size, shape, mass). The pair of air samples includes one sample analyzed for elemental mass and one sample analyzed by electron microscopy. For example, one sample might be collected for metals determination (e.g., NIOSH Method 7300, 7303) or elemental carbon (e.g., NIOSH Method 5040) depending on the composition of the engineered nanomaterial. The other sample would be collected for particle characterization (e.g., size, shape, dimension, degree of agglomeration) by TEM or SEM using the measurement techniques specified in NIOSH Methods 7402, 7404, or other equivalent methods [NIOSH 1994].

The source-specific air samples are collected as close as possible to the suspected emission source but outside of any existing containment, to increase the probability of detecting any possible release of engineered nanomaterials. Sampling duration generally matches the length of time in which the potential exposure to the engineered nanomaterial exists at the task or specific process. In cases where the duration of the tasks associated with the potential airborne release of nanomaterials is short (e.g., minutes), a relatively high air sampling flow rate may be required (approximately 7 liters per minute) to ensure adequate particle loading on the filter media. If specific information is desired on the worker's potential exposure to the engineered nanomaterial then PBZ samples should be collected using the two- sample filter-based sampling strategy described above.

If the particle number concentrations (using CPC or OPC) are substantially high, then shorter sampling times for the TEM or SEM sample may be necessary to avoid overloading the filter and interfering with particle characterization. The specific sampling time should be based on direct-reading instrument results and professional judgment of the industrial hygienist. In general, filter samples are collected for the duration of a given task, normally 15–30 minutes. If the

direct-reading instruments indicate a high particle number concentration the sampling time can be shortened to 5–10 minutes, or both a short- and long-duration sample may be collected to ensure an adequate sample for electron microscopy analysis. See Table 1 for additional sampling time guidance. However, the sampling times in Table 1 were based on collection of asbestos fibers by NIOSH Method 7402 and may not be applicable for much smaller engineered nanoparticles. See Figures 3–5 for example TEM micrographs.

A minimum of 2 background filter samples are collected distant from the potential sources of engineered nanoparticle exposure to serve as an indicator of ambient particle identification and concentration.

5.3.2 *Personal air samples*

When possible, personal breathing zone (PBZ) air samples are collected on workers likely to be exposed to engineered nanomaterials (e.g., engaged in active handling of nanomaterials or operating equipment previously identified as emitting nanoparticles). If measurements obtained with the CPC and OPC indicate that nanoparticles are being emitted at a specific process where a worker is located, then the collection of PBZ samples may be warranted.

PBZ samples are analyzed in the same manner as the area air samples (i.e., by TEM and elemental mass). It may be necessary to collect samples at a relatively high flow rate (e.g., 7 liters per minute) if the duration of the task and the resulting potential exposure is short.

5.3.3 *Optional sample collection*

In the event that measurements made by the OPC indicate a large fraction (over 50%) of particles exceeding 1,000 nm in size, the use of a personal cascade impactor or respirable cyclone sampler in tandem with a filter-based air sampling cassette may be required for both the mass and TEM/SEM analyses to eliminate large particles that may interfere with analysis and be of limited interest. The use of an impactor or cyclone will require using a flow rate appropriate for the particle cut size and is usually in the range of 1.7–2.5 liters per minute. Open-face, and impactor or cyclone samples may be collected side by side to allow a more thorough interpretation of analytical results. Additionally, if it is anticipated that the nanoparticles of interest will have a tendency to be electrostatically attracted to the sides of the plastic air sampling cassette, a conductive cowl may be necessary to eliminate particle loss and subsequent underestimation of the airborne nanoparticle concentration. The use of a personal cascade impactor, respirable cyclone, or conductive cowl is made at the discretion of the industrial hygienist (or other qualified person).

If the facility is manufacturing or using TiO_2, then the sampling should include the sampling recommendations found in the NIOSH *Draft Document: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide* (www.cdc.gov/

niosh/review/public/TiO2/default.html),which recommends collecting a mass-based airborne measurement using NIOSH Method 0600.

5.4 Quality Assurance and Quality Control

To ensure valid emission measurements, the following quality assurance and control steps should be taken:

- Use factory calibrated direct-reading particle analyzers
- Perform daily zero-checks on all particle counters before each use
- Calibrate pumps before and after each sampling day
- Submit for analysis any process, background, and bulk material samples along with field and media blanks to a laboratory accredited by the American Industrial Hygiene Association (AIHA)

5.5 Data Interpretation

Since the size of airborne engineered nanoparticles and the degree of agglomeration may be unknown at the time of sample collection, the use of direct-reading, particle sizing/counting instruments may provide a semi-quantitative indication of the magnitude of potential emissions, provided background particle number subtraction can be successfully accomplished. The particle number concentration measurements taken with the CPC and OPC will provide a measurement of particles larger than the ASTM definition of nanoparticles (1–100 nm) [ASTM 2006]. However, the two particle counters can be used simultaneously to obtain a semi-quantitative size differential evaluation of the aerosol being sampled. The CPC provides a measure of total particles per cm^3 in the size range of 10–1,000 nm (or 20–1,000 nm). The OPC provides the total number of particles per liter of air within six specific size ranges: 300 nm; 500 nm; 1,000 nm, 3,000 nm, 5,000 nm and > 10,000 nm. If necessary, the data from the CPC and OPC can be used together to determine the number concentration of nanoscale particles. For example, a high particle number concentration on the CPC, in combination with a high particle number concentration in the small size ranges (300–500 nm) on the OPC, may indicate the possible presence of nanoscale particles. Conversely, a low CPC particle number concentration, in combination with a high OPC particle number concentration in the larger size ranges (> 1,000 nm) may indicate the presence of larger particles and/or engineered nanoparticle agglomerates. These assumptions of nanoparticles versus larger particles and/or nanoparticle agglomerates may be verified by TEM or SEM analysis.

5.5.1 *Selectivity*

Selectivity is a critical issue when characterizing exposure using airborne particle number concentration. Airborne nanoparticles are present in many workplaces and often originate from multiple sources such as combustion, vehicle emissions, and

infiltration of outside air. Particle counters are generally not selective to particle source or composition, making it difficult to differentiate between incidental and process-related nanoparticles using number concentration alone. The CPC and OPC are used to identify sources of nanoparticles and the filter-based samples are used to verify the size, shape, and chemical composition of the nanoparticles with the goal of differentiating between incidental and engineered nanoparticles.

5.5.2 *Limitations*

The exposure assessment technique does have some limitations including:

- Although this issue is not unique to particle number concentration measurements, orders of magnitude difference can exist in aerosol number concentrations, depending on the number and types of sources of particle emissions. Monitoring over several days and during different seasons can provide a better understanding of the variability that might exist in airborne particle number concentrations found in background measurements and in measurements made at sources where engineered nanomaterials are handled.
- The upper dynamic range of the CPC is 100,000 P/cm^3. A dilutor, consisting of a modified HEPA filter cartridge placed upstream of the inlet, can extend the range of the CPC when particle number concentrations are greater than 100,000 P/cm^3 [Peters et al. 2006; Heitbrink et al. 2007; Evans et al. 2008].
- The analysis of air samples by TEM or SEM with energy dispersive X-ray spectrometry can provide information on the elemental composition of the nanomaterials. However, TEM and SEM analysis can be compromised if there is particle overload on the filter. Alternatively, if the loading is too sparse, an accurate assessment of particle characteristics may not be possible (see 5.3.1).
- Note that area samples are collected as closely as possible to the source of emission to allow for more accurate determination of a nanoparticle release and to identify locations most likely to result in worker exposure. **Therefore, results from this type of sampling should not be interpreted as representative of worker exposure.** However, samples collected in such a fashion should serve as an indicator of material release and the possible need for controls.

5.6 Expanded Research (In Depth Assessments)

5.6.1 *Research instrumentation*

A major obstacle in conducting more specific measurement of engineered nanomaterials in the workplace is a lack of field-portable instruments that can be easily maneuvered within

a facility or easily worn by a worker to provide an indication of PBZ exposure. Additionally, there is no single instrument capable of measuring the numerous potential exposure metrics associated with engineered nanomaterials (e.g., number concentration, surface area, size, shape, mass concentration) [Maynard and Aitken 2007]. Although the following instruments lack field portability and ease of use, they can measure many of the desirable exposure metrics and provide information about the particle size distribution. These research-grade particle analyzers are not usually part of the initial assessment but are used when additional knowledge about the nanoscale particle temporal or spatial exposure variation or size distribution is desired.

5.6.1.1 *Particle Surface-Area Analyzers*

Toxicology studies have indicated that surface area of nanoparticles may be an important exposure dose metric. Portable aerosol diffusion chargers may be used to provide estimates of external aerosol surface area when airborne particles are smaller than 100 nm in diameter, but these may tend to overestimate external surface area when particles are larger than 100 nm in diameter. These instruments are based on diffusion charging followed by detection of the charged aerosol using an electrometer.

The TSI Aerotrak™ 9000 Nanoparticle Aerosol Monitor does not measure total active surface area but indicates the surface area of particles which may be deposited in the lung in units of square micrometers per cubic centimeter, corresponding to either the tracheobronchial or alveolar regions of the lung. The Ecochem DC 2000-CE measures the total particle surface area. These devices are currently being evaluated as part of the process used by NIOSH to conduct initial assessments. These particle surface analyzers are used as area samplers.

5.6.1.2. *Scanning Mobility Particle Sizer*

More specific depictions of particles by size (diameter) and number can greatly improve the ability to evaluate possible releases of engineered nanoparticles. One particular instrument, the Scanning Mobility Particle Sizer (SMPS) measures particle diameters from 2.5–1,000 nm and can display data as a size and number distribution using up to 167 size channels. The SMPS is widely used as a research tool for characterizing nanoscale aerosols. The SMPS employs a continuous, fast-scanning technique to provide high-resolution measurements. However, the SMPS may take 2–3 minutes to scan which may not be useful for the process screening in workplaces with highly variable aerosol size distributions. Its applicability for use in the workplace may be limited because of its size, cost, and use of an internal radioactive source.

The Fast Mobility Particle Sizer (FMPS) is similar to the SMPS but has a much faster response time (approximately 1 second). However, because it has fewer particle size channels, it does not include the same level of detail on particle size distributions that can be determined with the SMPS.

The FMPS and SMPS are used as area samplers.

5.6.1.3 *Low Pressure Impactors*

The Electrical Low Pressure Impactor (ELPI) combines diffusion charging and a cascade impactor to provide aerosol size distributions by aerodynamic diameter as determined real time by mass and number collected on a series of plates.

Low pressure cascade impactors offer the ability to size particles and then conduct secondary analyses (e.g., metals analysis). However, these instruments are sensitive to harsh field conditions and are not considered portable. The ELPI is used as an area sampler.

5.6.1.4 *Tapered Element Oscillating Microbalance*

The tapered element oscillating microbalance (TEOM) is commonly used for sampling aerosols less than 1 μm in diameter, however, the sampling inlet can be set to select different size fractions. The TEOM determines mass by detecting a change in vibration frequency across a particle-collecting substrate. The TEOM can be configured to provide size-differentiated mass measurements and is used as an area sampler.

5.6.2 *Surface sampling*

Surface sampling to detect the presence of engineered nanomaterials is not routinely part of the initial assessment but may be conducted to determine if surface contamination exists. Surface sampling does not provide size-specific information but may be useful for determining whether engineered nanomaterials have migrated away from active production or handling areas and have contaminated nonproduction work areas. The decision to collect surface samples is made in the field at the discretion of the industrial hygienist (or other qualified person), and is dependent on direct observation and the nanomaterial of interest. For example, surface sampling was completed at a quantum dot facility after observing dusty surfaces in areas adjacent to the production area. In order to determine if the dust was contaminated with quantum dots, surface samples were collected and analyzed for the chemical components of the quantum dots produced by that facility.

Surface wipe samples are collected using a pre-moistened substrate such as Ghost Wipe™ towelettes in accordance with NIOSH Method 9102 for elements or the NIOSH method for specific elements (e.g., NIOSH Method 9100 for lead). When collecting wipe samples, the following steps should be followed:

- Don a pair of nitrile disposable gloves
- Wipe the surface within a disposable 10 cc × 10 cc template using four horizontal s-shaped strokes
- Fold the exposed side of the wipe in and wiping the same area with four vertical s-shaped strokes
- Fold the wipe, exposed side in, and placing it into a sterile container

Gloves and template are discarded after each sample collection to eliminate the possibility of cross-contaminating successive samples. Wipe samples may be collected from undisturbed horizontal surfaces throughout the facility at locations suspected to be contaminated and in areas expected to be free of engineered nanomaterials. Wipe samples are analyzed following the appropriate NIOSH method for the chemical substance of interest.

6.0 Conclusions

The NIOSH initial assessment technique uses complimentary approaches to semi-quantitatively evaluate the potential releases of engineered nanoparticles. Two different particle counters are used in a parallel and differential manner to evaluate the total particle number relative to background and the relative size distribution of the particles. If this initial evaluation indicates an elevated number of small particles, which could potentially be the engineered nanoparticle of interest, then the particle counters are used to detect the source of the emissions. If nanoparticles are found and determined to be emitted from a specific process (versus background incidental nanoscale particles), then additional samples are collected for qualitative measurement of particle size and shape, (by TEM or SEM analysis) and for determination of elemental mass concentration (by chemical analysis).

The initial assessment technique is useful for determining whether airborne releases of engineered nanomaterials are occurring at potential emission sources. This assessment provides a semi-quantitative means for determining whether existing measures are adequate for controlling nanomaterial emissions or if additional controls may be required.

The NIOSH emission assessment technique may be useful to health and safety professionals who are interested in determining whether release of nanomaterials occurs in the workplace. Where possible, use of the technique should be repeated in workplaces of interest to gain a better understanding of the daily fluctuations in airborne exposures at processes and tasks in which engineered nanomaterials occur and for determining potential sources of background particle number concentrations. A more systematic and routine assessment of the workplace can provide more definitive information on the performance of control measures and if additional actions are needed to reduce worker exposure.

The initial assessment technique can be expanded or modified to determine additional metrics (Figure 6). Research initiatives addressing more comprehensive process monitoring, particle metrics, personal exposure monitoring, and method/approach development and validation are currently underway within NIOSH. As this information becomes available, revisions to the Approaches to Safe Nanotechnology document will be made.

Information about contacting the nanotechnology field research team is available at: [www.cdc.gov/niosh/

docs/2008-121], see the Fact Sheet: NIOSH Nanotechnology Field Research Effort [NIOSH 2008].

7.0 References

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Table 1. Approximate sampling times for TEM grid based on particle number concentrations*.

		Open-faced cassettes		
	TEM grid	**25-mm**	**37-mm**	**47-mm**
Diameter (mm)	3.0	25.0	37.0	47.0
Effective diameter (mm)	3.0	22.2	34.2	44.2
Effective collection area (mm^2)	7	385	916	1531
Flow (L/min)	0.1	7	7	7
Desired Loading ($\#/mm^2$)	1.E+06	1.E+06	1.E+06	1.E+06
Air concentration ($\#/cm^3$)	**Time (min)**			
250	282.7	220.2	523.4	874.8
500	141.4	110.1	261.7	437.4
1,000	70.7	55.0	130.8	218.7
2,000	35.3	27.5	65.4	109.4
4,000	17.7	13.8	32.7	54.7
8,000	8.8	6.9	16.4	27.3
16,000	4.4	3.4	8.2	13.7
32,000	2.2	1.7	4.1	6.8
64,000	1.1	0.9	2.0	3.4
128,000	0.6	0.4	1.0	1.7

*NIOSH NMAM Method 7402 Asbestos by TEM and personal communication with Dr. Aleksandr Stefaniak (NIOSH)

Figure 1. A demonstration of the initial assessment technique with side-by-side sampling using (from left to right) the OPC, co-located open-face filter cassettes, and the CPC: examples of PBZ and source-specific filter-based sampling setup.

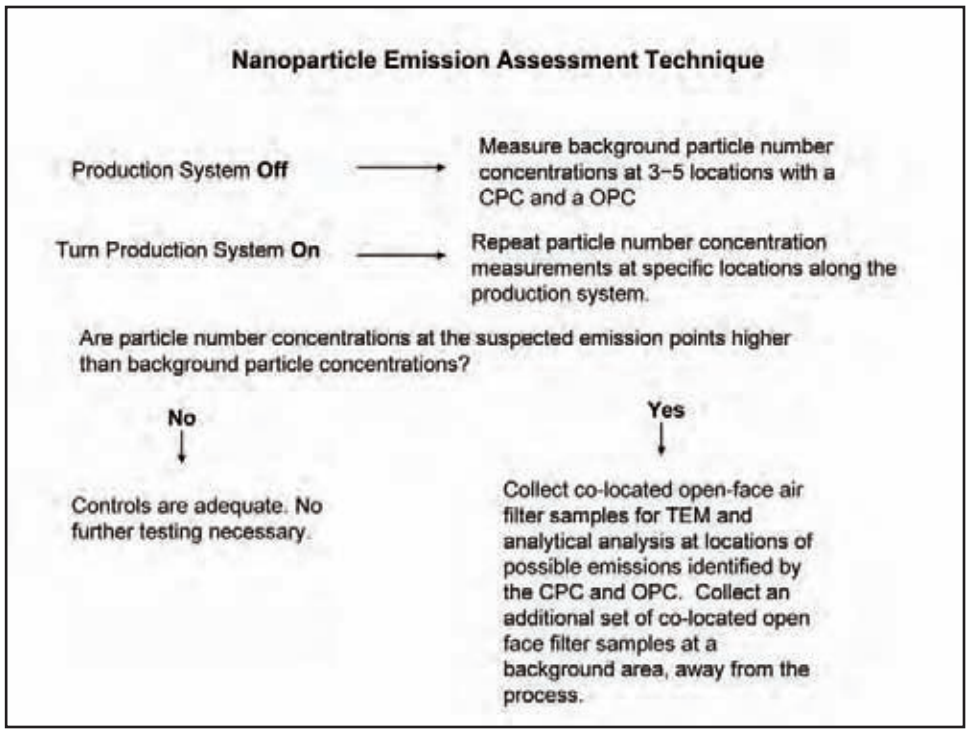

Figure 2. Summary of the initial assessment technique

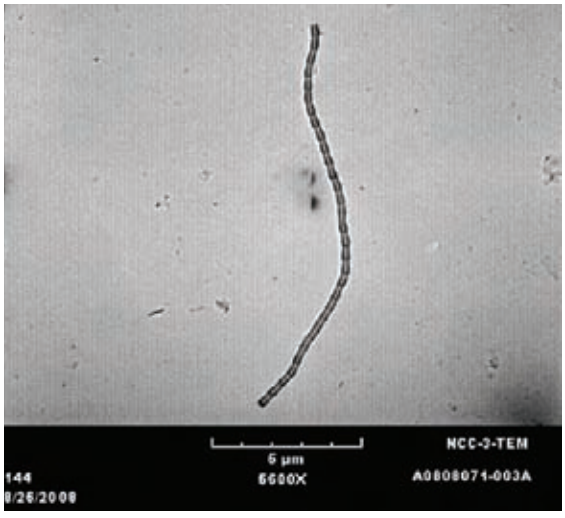

Figure 3. Electron microscopy micrograph of a carbon nanofiber

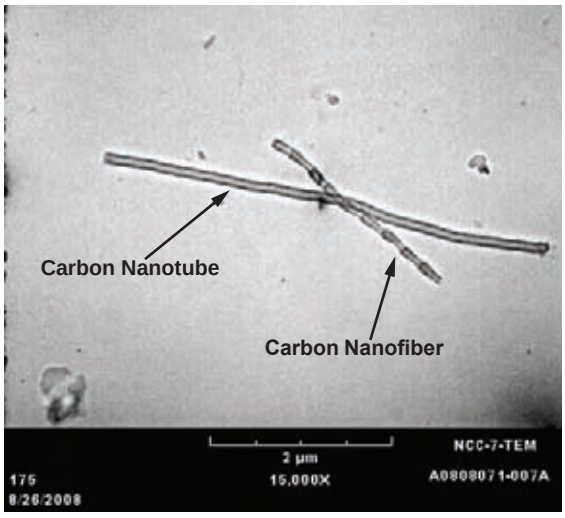

Figure 4. Electron microscopy micrograph of a carbon nanofiber and carbon nanotube

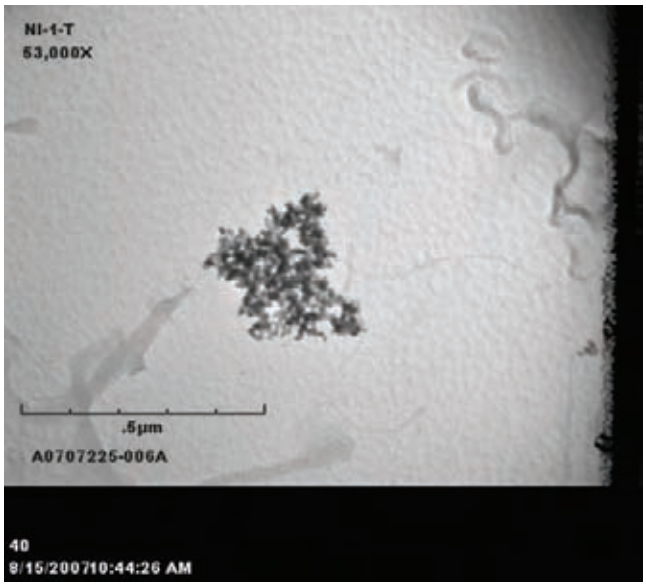

Figure 5. Electron microscopy micrograph of an agglomerated nanoparticle of nickel oxide

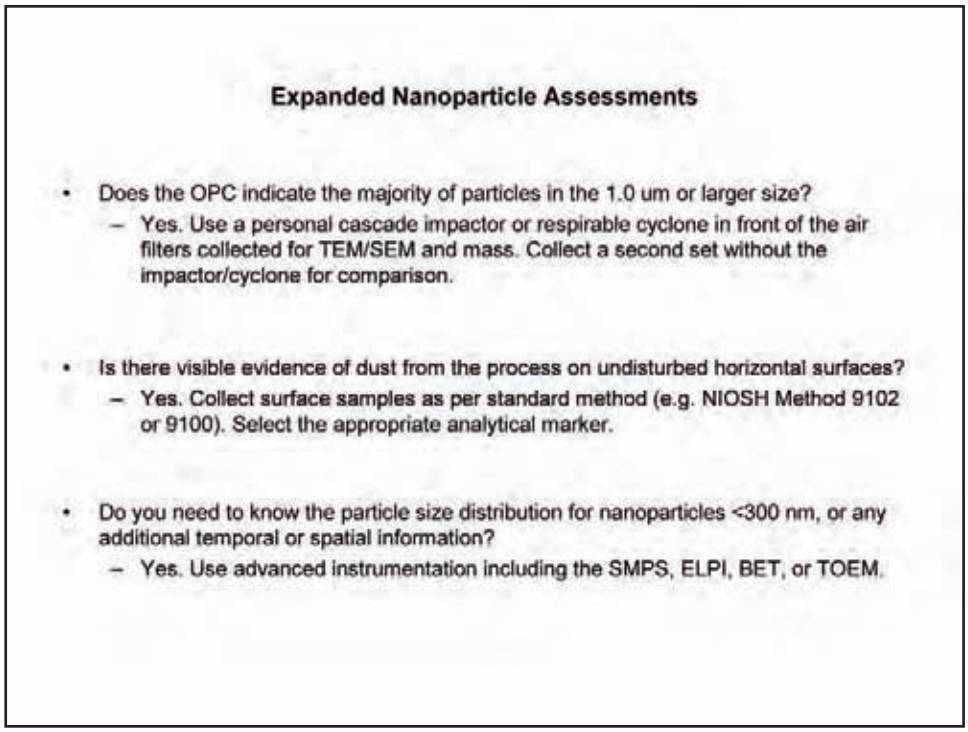

Figure 6. Considerations for expanded nanomaterial assessments

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DHHS (NIOSH) Publication No. 2009–125

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EXHIBIT 5
F Echelon
3015

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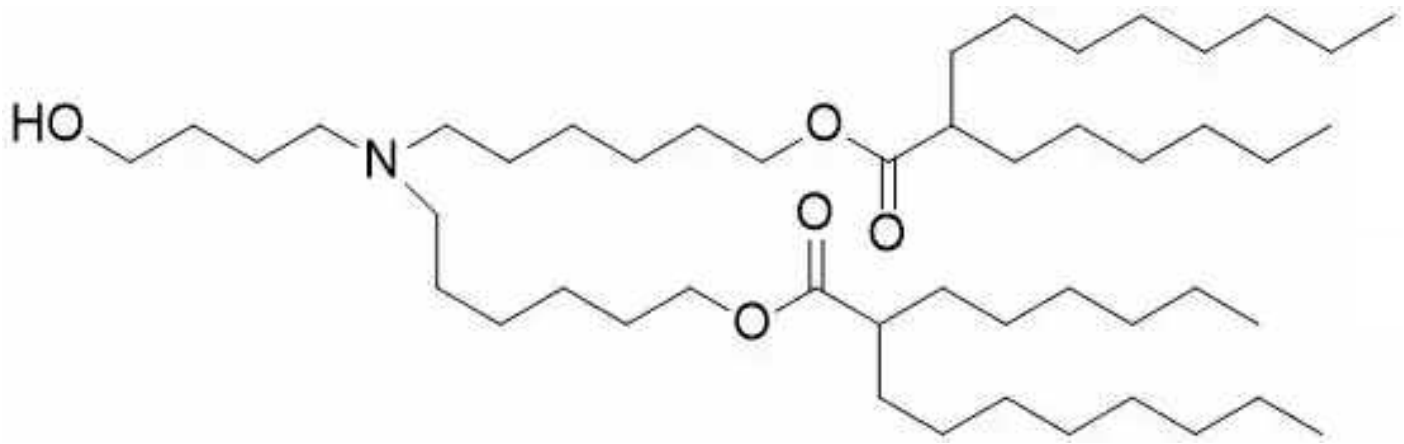

ALC-0315

Product Number: N-1020

$75.00 – $390.00

-	0	+	5mg (N-1020)	$75.00
-	0	+	10mg (N-1020)	$125.00
-	0	+	50mg (N-1020)	$390.00

Add to cart

SKU: N-1020

Category: Lipids

Tag: nanoparticles

Description Additional Information Documentation

ALC-0315 is an ionizable lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0315 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0159, DSPC, and cholesterol. This product is for research use only and not for human use.

References

1) R. Tenchov, R. Bird, A. E. Curtze, Q. Zhou (2021) "Lipid Nanoparticles—From Liposomes to mRNA Vaccine Delivery, a Landscape of Research Diversity and Advancement" ACS Nano, DOI: 10.1021/acsnano.1c04996.
2) K.H. Moss, P. Popova, et al. (2019) "Lipid Nanoparticles for Delivery of Therapeutic RNA Oligonucleotides" Mol. Pharmaceutics 16, 2265–2277, DOI: 10.1021/acs.molpharmaceut.8b01290.
3) Y. Duan, A. Dhar, et al. (2020) "A brief review on solid lipid nanoparticles: part and parcel of contemporary dru delivery systems" RSC Adv.,10, 26777-26791.

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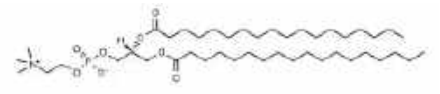


Lipids

DSPC (18:0/18:0 PC)

Product Number: L-1118

94 / 100
Bioz Stars

$30.00 – $240.00

View products

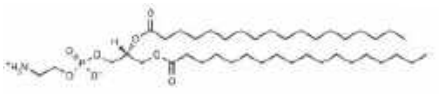
Lipids

ALC-0159

Product Number: N-2010

$125.00 – $495.00

View products



Lipids

DSPE (18:0/18:0 PE)

Product Number: L-2118

91 / 100
Bioz Stars

$94.00 – $340.00

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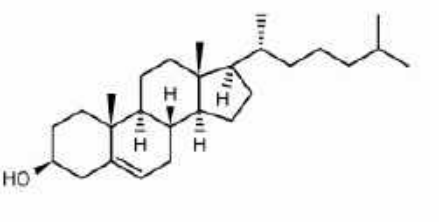

Lipids

Cholesterol

Product Number: L-6012

93 / 100

Bioz Stars
$30.00 – $150.00

View products

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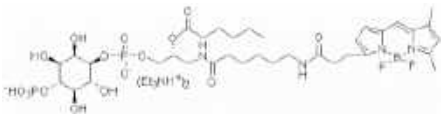
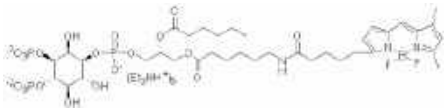


Lipids

GloPIPs BODIPY FL-PI(4)P

Product Number: C-04F6A

View products

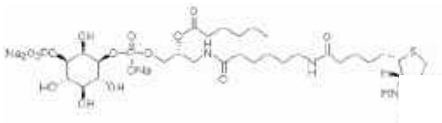


Lipids

BODIPY FL PI(3,4)P2

Product Number: C-34F6
$448.00 – $770.00

View products



Lipids

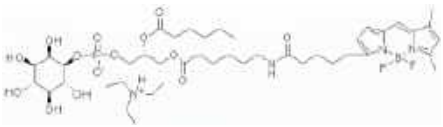
GloPIPs Biotin-PI(3)P

Product Number: C-03B6A

85 / 100
Bioz Stars

$277.00 – $846.00

View products



Lipids

BODIPY FL Phosphatidylinositol

Product Number: C-00F6

91 / 100
Bioz Stars

$280.00 – $446.00

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EXHIBIT 5
G Chem 0315

Safety Data Sheet

Revision Date: Mar.-23-2021
Print Date: Jun.-28-2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name : ALC-0315

Catalog No. : CS-0145622

CAS No. : 2036272-55-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company: ChemScene LLC

Tel: 732-484-9848

Fax: 888-484-5008

E-mail: sales@chemscene.com

1.4 Emergency telephone number

Emergency Phone #: 732-484-9848

· 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin corrosion/irritation (Category 2),H315

Serious eye damage/eye irritation (Category 2A),H319

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word Warning

Hazard statement(s)

H315 Causes skin irritation

H319 Causes serious eye irritation

Precautionary statement(s)

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/attention.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula:	$C_{48}H_{95}NO_5$
Molecular Weight:	766.27
CAS No. :	2036272-55-4

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; Do NOT induce vomiting; call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.2 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Refer to protective measures listed in sections 8.

6.2 Environmental precautions

Try to prevent further leakage or spillage. Keep the product away from drains or water courses.

6.3 Methods and materials for containment and cleaning up

Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol; Dispose of contaminated material according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

Recommended storage temperature: 2-8°C, protect from light

Shipping at room temperature if less than 2 weeks.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

This product contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering controls

Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

Personal protective equipment

Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Viscous liquid
Odor	No data available
Odor threshold	No data available
pH	No data available
Melting/freezing point	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water Solubility	No data available

Partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids/alkalis, strong oxidising/reducing agents.

10.6 Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

Other decomposition products - no data available.

11.TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Classified based on available data. For more details, see section 2

Skin corrosion/irritation

Classified based on available data. For more details, see section 2

Serious eye damage/irritation

Classified based on available data. For more details, see section 2

Respiratory or skin sensitization

Classified based on available data. For more details, see section 2

Germ cell mutagenicity

Classified based on available data. For more details, see section 2

Carcinogenicity

IARC: No component of this product present at a level equal to or greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by ACGIH.

NTP: No component of this product present at a level equal to or greater than 0.1% is identified as a anticipated or confirmed carcinogen by NTP.

OSHA: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed

carcinogen by OSHA.

Reproductive toxicity

Classified based on available data. For more details, see section 2

Specific target organ toxicity - single exposure

Classified based on available data. For more details, see section 2

Specific target organ toxicity - repeated exposure

Classified based on available data. For more details, see section 2

Aspiration hazard

Classified based on available data. For more details, see section 2

Additional information

This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumlative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose substance in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging

Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT (US)

This substance is considered to be non-hazardous for transport.

IMDG

This substance is considered to be non-hazardous for transport.

IATA

This substance is considered to be non-hazardous for transport.

15. REGULATORY INFORMATION

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.

16. OTHER INFORMATION

 The above information is correct to the best of our present knowledge but does not purport to be all inclusive and should be used only as a guide. The product is for research use only and for experienced personnel. It must only be handled by suitably qualified experienced scientists in appropriately equipped and authorized facilities. The burden of safe use of this material rests entirely with the user. ChemScene disclaims all liability for any damage resulting from handling or from contact with this product.

EXHIBIT 5
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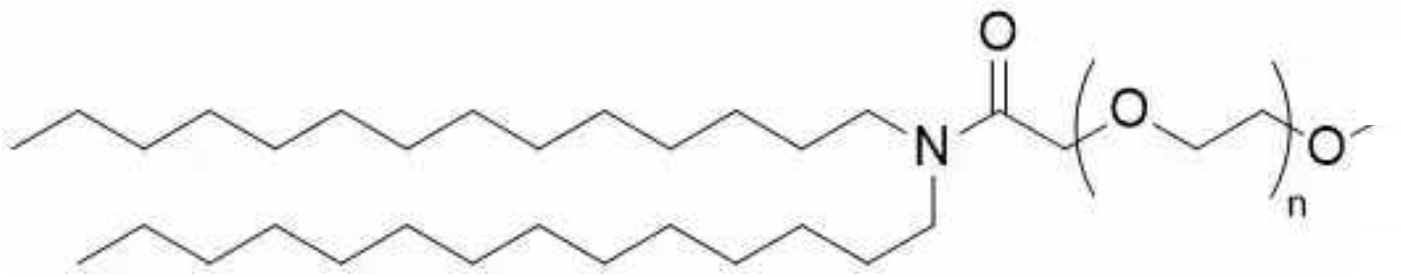

ALC-0159

Product Number: N-2010

$125.00 – $495.00

-	0	+	5mg (N-2010)	$125.00
-	0	+	10mg (N-2010)	$225.00
-	0	+	25mg (N-2010)	$495.00

Add to cart

SKU: N-2010

Category: Lipids

Tag: nanoparticles

Description Additional Information Documentation

ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0315, DSPC, and cholesterol.

This product is for research use only and not for human use.

References

1) R. Tenchov, R. Bird, A. E. Curtze, Q. Zhou (2021) "Lipid Nanoparticles—From Liposomes to mRNA Vaccine Delivery, a Landscape of Research Diversity and Advancement" ACS Nano, DOI: 10.1021/acsnano.1c04996.

2) K.H. Moss, P. Popova, et al. (2019) "Lipid Nanoparticles for Delivery of Therapeutic RNA Oligonucleotides" Mol. Pharmaceutics 16, 2265–2277, DOI: 10.1021/acs.molpharmaceut.8b01290.

3) Y. Duan, A. Dhar, et al. (2020) "A brief review on solid lipid nanoparticles: part and parcel of contemporary drug delivery systems" RSC Adv.,10, 26777-26791.

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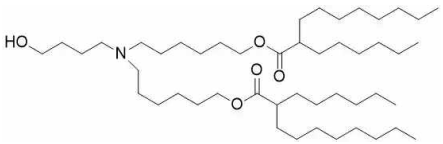

Lipids

ALC-0315

Product Number: N-1020
$75.00 – $390.00

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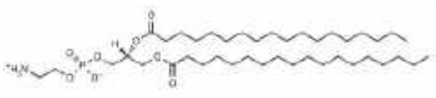


Lipids

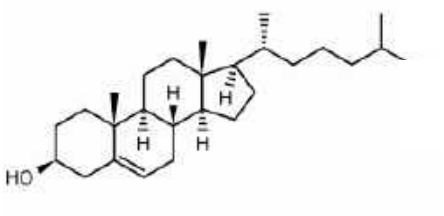
DSPE (18:0/18:0 PE)

Product Number: L-2118

91 / 100
Bioz Stars

$94.00 – $340.00

View products



Lipids

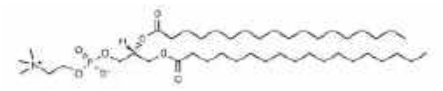
Cholesterol

Product Number: L-6012

93 / 100
Bioz Stars

$30.00 – $150.00

View products



Lipids

DSPC (18:0/18:0 PC)

Product Number: L-1118

94 / 100
Bioz Stars

$30.00 – $240.00

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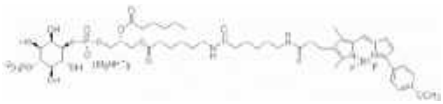

Lipids

BODIPY TMR PI(4)P

Product Number: C-04M6

85 / 100
Bioz Stars

$430.00 – $739.00

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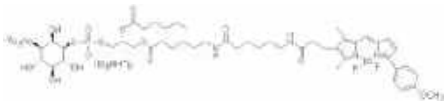
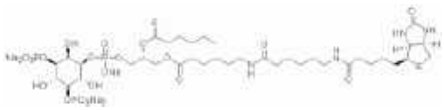


Lipids

BODIPY TMR PI(3)P

Product Number: C-03M6
$448.00 – $770.00

View products



Lipids

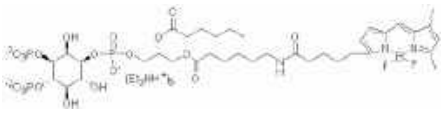
Biotin Phosphatidylinositol 3,5-bisphosphate

Product Number: C-35B6

93 / 100
Bioz Stars

$255.00 – $783.00

View products



Lipids

BODIPY FL PI(3,4)P2

Product Number: C-34F6
$448.00 – $770.00

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EXHIBIT 5
I MEC 0159

MCE MedChemExpress

Safety Data Sheet

Revision Date: May.-18-2021
Print Date: Jul.-31-2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name : ALC-0159
Catalog No. : HY-138300
CAS No. : 1849616-42-7

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company: MedChemExpress USA
Tel: 609-228-6898
Fax: 609-228-5909
E-mail: sales@medchemexpress.com

1.4 Emergency telephone number

Emergency Phone #: 609-228-6898

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture.

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula: $(C_2H_4O)nC_{31}H_{63}NO_2$
Molecular Weight: N/A
CAS No. : 1849616-42-7

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; Do NOT induce vomiting; call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.2 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Refer to protective measures listed in sections 8.

6.2 Environmental precautions

Try to prevent further leakage or spillage. Keep the product away from drains or water courses.

6.3 Methods and materials for containment and cleaning up

Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol; Dispose of contaminated material according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

Recommended storage temperature:	Powder	-20°C	3 years
		4°C	2 years
	In solvent	-80°C	6 months
		-20°C	1 month

Shipping at room temperature if less than 2 weeks.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

This product contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering controls

Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

Personal protective equipment

Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid
Odor	No data available
Odor threshold	No data available
pH	No data available
Melting/freezing point	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids/alkalis, strong oxidising/reducing agents.

10.6 Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

Other decomposition products - no data available.

11.TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Classified based on available data. For more details, see section 2

Skin corrosion/irritation

Classified based on available data. For more details, see section 2

Serious eye damage/irritation

Classified based on available data. For more details, see section 2

Respiratory or skin sensitization

Classified based on available data. For more details, see section 2

Germ cell mutagenicity

Classified based on available data. For more details, see section 2

Carcinogenicity

IARC: No component of this product present at a level equal to or greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by ACGIH.

NTP: No component of this product present at a level equal to or greater than 0.1% is identified as a anticipated or confirmed carcinogen by NTP.

OSHA: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by OSHA.

Reproductive toxicity

Classified based on available data. For more details, see section 2

Specific target organ toxicity - single exposure

Classified based on available data. For more details, see section 2

Specific target organ toxicity - repeated exposure

Classified based on available data. For more details, see section 2

Aspiration hazard

Classified based on available data. For more details, see section 2

Additional information

This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumlative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose substance in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging

Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT (US)

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IMDG

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IATA

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

15. REGULATORY INFORMATION

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.

16. OTHER INFORMATION

Caution: Product has not been fully validated for medical applications. For research use only.

Tel: 609-228-6898 Fax: 609-228-5909 E-mail: tech@MedChemExpress.com

Address: 1 Deer Park Dr, Suite Q, Monmouth Junction, NJ 08852, USA

EXHIBIT 5
J DSPC

SAFETY DATA SHEET
1,2-Distearoyl-sn-glycero-3-PC

Revision: 09/02/2018
Supersedes Revision: 05/28/2014

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 2015/830 and US OSHA HCS 2015

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Code: 15100

Product Name: 1,2-Distearoyl-sn-glycero-3-PC

Synonyms: 1,2-distearoyl-sn-glycero-3-phosphatidylcholine; Coatsome MC 8080; 1,2-Distearoyl-sn-glycero-3-Phosphocholine; 1,2-DSPC;

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Relevant identified uses: For research use only, not for human or veterinary use.

1.3 Details of the Supplier of the Safety Data Sheet:

Company Name: Cayman Chemical Company
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108

Web site address: www.caymanchem.com

Information: Cayman Chemical Company +1 (734)971-3335

1.4 Emergency telephone number:

Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300
CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

2.1 Classification of the Substance or Mixture:

2.2 Label Elements:

GHS Signal Word: **None**

GHS Hazard Phrases:

Based on evaluation of currently available data this substance or mixture is not classifiable according to GHS.

GHS Precaution Phrases:

No phrases apply.

GHS Response Phrases:

No phrases apply.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3 Adverse Human Health Effects and Symptoms: Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation, ingestion, or skin absorption. May cause eye, skin, or respiratory system irritation. To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	GHS Classification
816-94-4 NA	1,2-Distearoyl-sn-glycero-3-PC	100.0 %	212-440-2 NA	No data available.

Cayman CHEMICAL

SAFETY DATA SHEET
1,2-Distearoyl-sn-glycero-3-PC

Revision: 09/02/2018
Supersedes Revision: 05/28/2014

Section 4. First Aid Measures

4.1 Description of First Aid Measures:

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards: No data available.

No data available.

Flash Pt: No data.

Explosive Limits: LEL: No data. UEL: No data.

Autoignition Pt: No data.

5.3 Fire Fighting Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation.
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material For Containment and Cleaning Up: Contain spill and collect, as appropriate.
Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

7.1 Precautions To Be Taken in Handling: Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken in Storing: Keep container tightly closed.
Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices: Do not take internally.
Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
Wash thoroughly after handling.

No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States:	[ ] Gas [ ] Liquid [X] Solid
Appearance and Odor:	A crystalline solid
pH:	No data.
Melting Point:	No data.
Boiling Point:	No data.
Flash Pt:	No data.
Evaporation Rate:	No data.
Flammability (solid, gas):	No data available.
Explosive Limits:	LEL: No data. UEL: No data.
Vapor Pressure (vs. Air or mm Hg):	No data.
Vapor Density (vs. Air = 1):	No data.
Specific Gravity (Water = 1):	No data.
Solubility in Water:	No data.
Solubility Notes:	~25 mg/ml in EtOH;
Octanol/Water Partition Coefficient:	No data.
Autoignition Pt:	No data.
Decomposition Temperature:	No data.
Viscosity:	No data.

9.2 Other Information

Percent Volatile:	No data.
Molecular Formula & Weight:	C44H88NO8P 790.2

SAFETY DATA SHEET
1,2-Distearoyl-sn-glycero-3-PC

Revision: 09/02/2018
Supersedes Revision: 05/28/2014

Section 10. Stability and Reactivity

10.1 Reactivity: No data available.

10.2 Stability: Unstable [ ] Stable [X]

10.3 Stability Note(s): Stable if stored in accordance with information listed on the product insert.

Polymerization: Will occur [ ] Will not occur [X]

10.4 Conditions To Avoid: No data available.

10.5 Incompatibility - Materials To Avoid: strong oxidizing agents

10.6 Hazardous Decomposition or Byproducts: carbon dioxide
carbon monoxide
nitrogen oxides
phosphorous oxides

Section 11. Toxicological Information

11.1 Information on Toxicological Effects: The toxicological effects of this product have not been thoroughly studied.

CAS #	Hazardous Components (Chemical Name)	NTP	IARC	ACGIH	OSHA
816-94-4	1,2-Distearoyl-sn-glycero-3-PC	n.a.	n.a.	n.a.	n.a.

Section 12. Ecological Information

12.1 Toxicity: Avoid release into the environment.
Runoff from fire control or dilution water may cause pollution.

12.2 Persistence and Degradability: No data available.

12.3 Bioaccumulative Potential: No data available.

12.4 Mobility in Soil: No data available.

12.5 Results of PBT and vPvB assessment: No data available.

12.6 Other adverse effects: No data available.

Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.
DOT Hazard Class:
UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.
UN Number:
Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
816-94-4	1,2-Distearoyl-sn-glycero-3-PC	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
816-94-4	1,2-Distearoyl-sn-glycero-3-PC	CAA HAP,ODC: No; CWA NPDES: No; TSCA: No; CA PROP.65: No

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008.

Section 16. Other Information

Revision Date: 09/02/2018

Additional Information About This Product: No data available.

Company Policy or Disclaimer: DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.

EXHIBIT 6
Grams Affidavit

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

DANIEL ROBERT	*	
SSGT, U.S. ARMY	*	
	*	
HOLLI MULVIHILL	*	
SSGT, USMC	*	
	*	
Plaintiffs,	*	
	*	
v.	*	
	*	Civil Action No. 21-02228
LLOYD AUSTIN Secretary of Defense,	*	*
U.S. DEPARTMENT OF DEFENSE	*	
Washington, D.C. 20301	*	
	*	
and	*	
	*	
XAVIER BECERRA	*	
Secretary of the U.S. Department of		*
Health and Human Services	*	
U.S. DEPARTMENT OF HEALTH	*	
AND HUMAN SERVICES	*	
	*	
and	*	
	*	

JANET WOODCOCK, Acting *
Commissioner of the Food & Drug *
Administration *
U.S. FOOD AND *
DRUG ADMINISTRATION *
*
UNITED STATES OF AMERICA *
*
Defendants. *

* * * * * * * * * * * *

Exhibit 2 of Motion for Temporary Restraining Order and Amended Complaint

AFFIDAVIT OF DR. RALPH GRAMS IN SUPPORT OF TEMPORARY RESTRAINING ORDER MOTION

I, Doctor **Ralph Grams**, MD, FCAP, FACMI being duly sworn, depose and state as follows:

1. I make this affidavit in support of the above referenced MOTION as expert testimony in support thereof.

2. The expert opinions expressed here are my own and arrived at from my persons, professional and educational experiences taken in context, where appropriate, by scientific data, publications, treatises, opinions, documents, reports and other information relevant to the subject matter.

Experience & Credentials

3. I am competent to testify to the facts and matters set forth herein. I have provided written testimony previously to this Court, wherein I provided my credentials and bona fides to render this and other opinions.

4. May it please the Court, I will provide said CV, evidence of my expertise and bona fides as requested or directed.

5. Said experience and expertise in pathology and work in the biological and chemical weapons field is the basis upon which I am rendering this opinion

6. Since the last sworn affidavit that I provided in this case, I was asked to conduct further analysis of the same samples, using the same equipment in the same laboratory and per the same protocols and procedures. In fact, the mass spectrometry that was relied upon in my last statement is effectively the same for purposes of this sworn statement.

7. In particular, I was asked to look at the publicly available documents attached hereto as they relate to a key ingredient in both the Pfizer and Moderna Covid 19 vaccines Appendices A & B respectively, attached and annexed hereto. I did not test the Johnson & Johnson samples, so there is no further discussion of that EAU Covid 19 Vaccine and I express no opinion about it. Of importance to note is that the Pfizer sample is that of BioNTech and not the FDA approved Comirnaty, because Pfizer has not yet started production of Comirnaty for sale or distribution into the United States. Accordingly the BioNTech remains for Emergency Use only and to my knowledge is the only Covid 19 vaccine being provided members of the Armed Services per Secretary Austin's orders for mandatory inoculations for all Services dated August 19, 2021.

8. The key ingredient in each of the samples is a compound used by the different manufacturers to achieve the same result, which is delivery of RNA fragments to a broad distribution of cells in the user's genome using lipid nanoparticles. The main difference between the two different sets of lipid nano particles are the composition of some ingredients.

Pfizer's BioNTech

9. Pfizer uses Acuitas Therapeutics Inc. "Acuitas LNP Technology" under Intellectual Property licensing agreements[1], also commonly referred to simply as "hydrogel,' which has a chemical composition of:

[1] See: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7836001/ & https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7836001/

a. 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]- N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3- phosphocholine, and cholesterol; also known as
b. ALC 1035, ALC-0159 and DSCP[2]

10. The UK government in its Health Safety Executive office states the following about the ALC 3015 ingredient, as echoed by the NARH states the following:

a. The ALC-0315 is a hexane containing compound and these are known to be potentially neurotoxic. ALC-0159 contains polyethylene glycol (PEG) that is associated with hypersensitivity and allergenic reactions. The toxicological profile of the mRNA delivery system cannot be determined because neither have the concentrations been declared, nor has the nanoparticle delivery system, surface charges and other physicochemical characteristics been declared. These may dramatically increase the toxicological profile. [3]
b. Regarding it's other toxicity, the Safety Data Page reflects the terms "unknown" or "Classified" thereby making a complete assessment of its toxicity impossible to know absent significant scientific study, which has not been completed as of this date.

11. Furthermore the Safety Data Sheet states in the very heading, "**Danger**" and it additionally cautions "Evidence for human carcinogenicity Current classification: **Group 1 a** "

12. In studying the contents of Pfizer's key Lipid Nanoparticle ingredient by utilizing a MALDI TOF MS (Matrix Assisted Laser Desorption Ionization Time of Flight Mass Spectrometer) laboratory instrument, I was able to observe the spectrographic data provided by this instrument with the use of standards and controls; which reveal that this ingredient does appear in the 767.33 range as demonstrated in the spectrometry results attached hereto as Appendix C (pages 5 & 7)

Moderna Vaccine

[2] See: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1016212/Temporary_Authorisation_Patient_Information_BNT162__-_09-09-2021.pdf

[3] See: https://www.hsl.gov.uk/media/480242/material%20safety%20data%20sheet%20quartz%20final%20v2%202019.pdf *https://www.anhinternational.org/news/have-you-decided-what-youll-do-or-say-if-offered-a-covid-vaccine/*

13. Moderna, on the other hand, delivers its RNA fragments through a slightly different Lipid Nanoparticle called "SM-102" and it's scientific composition is: polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]

14. According to its (SM-102) patent, WO2020/160397, the compound designed and described, in pertinent part:

> The present disclosure provides novel methods of producing nucleic acid lipid Nanoparticle (LNP) formulations ,the produced formulations thereof, and the related therapeutic and/or diagnostic uses, such as methods involving the nucleic acid lipid nanoparticles to deliver one or more therapeutics and/or prophylactics, such as a nucleic acid, to and/or produce polypeptides in mammalian cells or organs.

The Patent is attached and annexed as a part hereto as Exhibit C.

15. The safety Data Sheet for SM-102 describes it as:

a. "not for human or veterinary use"
b. "GHS06 Skull and crossbones"
c. "H310 Fatal in contact with skin "
d. "GHS08 Health hazard "
e. "H351 Suspected of causing cancer"
f. "H361 Suspected of damaging fertility or the unborn child"
g. "H372 Causes damage to the central nervous system, the kidneys, the liver and the
respiratory system through prolonged or repeated exposure"

16. In studying the contents of Moderna's key Lipid Nanoparticle ingredient I used the same spectrographic instruments to provide the data with the use of standards and controls; which reveal that this Lipid Nanoparticle ingredient (SM-102) does appear in the 711.08 range also demonstrated in Appendix C (page 11). In each such case, the spectrometry demonstrates significant prevalence as a key ingredient.

17. Given that these Covid 19 Vaccines were both Investigational New Drugs and Emergency Use Authorization vaccines, manufacturers are allowed to substitute ingredients during the testing process because the IND's are experimental and therefore not necessarily the final product that will be approved. On this note, the FDA's prospective approval of Comirnaty may or may not be accurate and will not be dispositive until such time as the Comirnaty product has been manufactured and all ingredients disclosed in accordance with FDA labeling regulations.

18. For this reason, it is impossible to characterize BioNTech as being interchangeable with the Comirnaty approved drug until such time as the phase III clinical studies being conducted at this moment under the current IND/EUA regulations are completed. These tests are not scheduled for completion until 2025, at which time we will then be able to re-test the contents of the drug to verify if the ingredients are the same, substantially the same or different. As such, at no time should the DOD or any other agency presume that BioNTech is an approved drug; it is not and this is why it continues to carry the characterization of an Investigational New Drug for Emergency Use only.

Opinion

19. I have reviewed the second Motion for Temporary Restraining Order and Amended Complaint, which delineates the subject matter relating to studies I performed and conclude as follows:

a) The key Lipid Nanoparticle RNA delivery system ingredients of Moderna's vaccine are pathological toxins and dangerous or deadly to humans and should therefore be considered allergens to all humans;
b) The Key Lipid Nanoparticle RNA delivery system in and Pfizer's BioNTech vaccine are also pathological toxins and dangerous or deadly to humans
c) The amount of each such ingredient is not divulged at this time and by virtue of being in the Investigational state of the IND process, may change between lots and batches, so it is impossible to know how much of these toxins are being delivered to the users without mass spectrometry analysis for each such batch and lot.
d) The only difference between the two Moderna and Pfizer Covid 19 Vaccines is the slight difference in composition of the Lipid Nanoparticles and amount of each other nearly identical ingredient together with the actual composition and sequencing of the RNA

fragments being delivered to cause cell mutation and production of abnormal cells ("Spike Proteins.'

e) Each such Covid 19 Vaccine is potentially dangerous or deadly to the users.

f) Each such Covid 19 Vaccine contains known allergens whereby effectively all humans are allergic to some of the key ingredients.

g) Each such Covid 19 Vaccine is demonstrably dangerous or deadly as demonstrated by the notoriously high fatalities and Serious Adverse Events published by the VAERS system.

h) Each such Covid 19 Vaccine should be immediately recalled and all authorization for use should immediately be terminated or cancelled.

i) All unused supplies of the said Covid 19 Vaccines should be treated as hazardous materials, accounted for and disposed of in accordance with the terms of the OSHA or other responsible body's disposal guidelines.

20. I am competent to opine on the medical aspects of these allegations based upon my above-referenced education and professional medical experience and the basis of my opinions are formed as a result of my education and experience.

21. As a Medical Doctor and scientist in the biological health and treatment of human beings, I confirm and attest to the accuracy and truthfulness of my foregoing statements, analysis and attachments hereto:

_____/s/_____
Ralph Grams, MD

State of Florida §
§
County of Flagler §

The undersigned, being duly sworn, deposes and says:

I, Ralph Grams, MD, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

I am an adult of sound mind, ___ years old, and declare that the information herein is true, correct and complete and that I have voluntarily affirmed this affidavit based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

SUBSCRIBED AND SWORN TO BEFORE ME on the 23 day of September 2021, to certify which witness my hand and official seal.

/S/

Kay Kanter

Notary Public for the State of Colorado

My Commission Expires: _____

APPENDIX A

List of Pfizer BioNTech ALC 0315 Safety Data Sheet

MCE MedChemExpress

Safety Data Sheet

Revision Date: Mar.-23-2021
Print Date: Sep.-9-2021

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

Product name : ALC-0315

Catalog No. : HY-138170

CAS No. : 2036272-55-4

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, manufacture of substances.

1.3 Details of the supplier of the safety data sheet

Company: MedChemExpress USA

Tel: 609-228-6898

Fax: 609-228-5909

E-mail: sales@medchemexpress.com

1.4 Emergency telephone number

Emergency Phone #: 609-228-6898

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin corrosion/irritation (Category 2),H315

Serious eye damage/eye irritation (Category 2A),H319

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word Warning

Hazard statement(s)

H315 Causes skin irritation

H319 Causes serious eye irritation

Precautionary statement(s)

P264 Wash hands thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P313 Get medical advice/attention.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula:	$C_{48}H_{95}NO_5$
Molecular Weight:	766.27
CAS No. :	2036272-55-4

4. FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact

Remove any contact lenses, locate eye-wash station, and flush eyes immediately with large amounts of water. Separate eyelids with fingers to ensure adequate flushing. Promptly call a physician.

Skin contact

Rinse skin thoroughly with large amounts of water. Remove contaminated clothing and shoes and call a physician.

Inhalation

Immediately relocate self or casualty to fresh air. If breathing is difficult, give cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion

Wash out mouth with water; Do NOT induce vomiting; call a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

5.2 Special hazards arising from the substance or mixture

During combustion, may emit irritant fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use full personal protective equipment. Avoid breathing vapors, mist, dust or gas. Ensure adequate ventilation. Evacuate

personnel to safe areas.

Refer to protective measures listed in sections 8.

6.2 Environmental precautions

Try to prevent further leakage or spillage. Keep the product away from drains or water courses.

6.3 Methods and materials for containment and cleaning up

Absorb solutions with finely-powdered liquid-binding material (diatomite, universal binders); Decontaminate surfaces and equipment by scrubbing with alcohol; Dispose of contaminated material according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes and skin. Avoid dust and aerosol formation. Use only in areas with appropriate exhaust ventilation.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly sealed in cool, well-ventilated area. Keep away from direct sunlight and sources of ignition.

Recommended storage temperature: 4°C, protect from light

* In solvent : -80°C, 6 months; -20°C, 1 month (protect from light)

Shipping at room temperature if less than 2 weeks.

7.3 Specific end use(s)

No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

This product contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering controls

Ensure adequate ventilation. Provide accessible safety shower and eye wash station.

Personal protective equipment

Eye protection	Safety goggles with side-shields.
Hand protection	Protective gloves.
Skin and body protection	Impervious clothing.
Respiratory protection	Suitable respirator.
Environmental exposure controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Viscous liquid
Odor	No data available
Odor threshold	No data available

pH	No data available
Melting/freezing point	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water Solubility	No data available
Partition coefficient	No data available
Auto-ignition temperature	No data available
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong acids/alkalis, strong oxidising/reducing agents.

10.6 Hazardous decomposition products

Under fire conditions, may decompose and emit toxic fumes.

Other decomposition products - no data available.

11.TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Classified based on available data. For more details, see section 2

Skin corrosion/irritation

Classified based on available data. For more details, see section 2

Serious eye damage/irritation

Classified based on available data. For more details, see section 2

Respiratory or skin sensitization

Classified based on available data. For more details, see section 2

Germ cell mutagenicity

Classified based on available data. For more details, see section 2

Carcinogenicity

IARC: No component of this product present at a level equal to or greater than 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by ACGIH.

NTP: No component of this product present at a level equal to or greater than 0.1% is identified as a anticipated or confirmed carcinogen by NTP.

OSHA: No component of this product present at a level equal to or greater than 0.1% is identified as a potential or confirmed carcinogen by OSHA.

Reproductive toxicity

Classified based on available data. For more details, see section 2

Specific target organ toxicity - single exposure

Classified based on available data. For more details, see section 2

Specific target organ toxicity - repeated exposure

Classified based on available data. For more details, see section 2

Aspiration hazard

Classified based on available data. For more details, see section 2

Additional information

This information is based on our current knowledge. However the chemical, physical, and toxicological properties have not been completely investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumlative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose substance in accordance with prevailing country, federal, state and local regulations.

Contaminated packaging

Conduct recycling or disposal in accordance with prevailing country, federal, state and local regulations.

14. TRANSPORT INFORMATION

DOT (US)

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IMDG

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

IATA

Proper shipping name: Not dangerous goods

UN number: -

Class: -

Packing group: -

15. REGULATORY INFORMATION

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

No SARA Hazards.

Massachusetts Right To Know Components:

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components:

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components:

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or anyother reproductive harm.

16. OTHER INFORMATION

APPENDIX B

List of Moderna Covid 19 Vaccine SM-102 Safety Data Sheet

Safety Data Sheet
acc. to OSHA HCS

Printing date 04/11/2021 Revision date 04/11/2021

1 Identification

· **Product identifier**

· **Trade name: SM-102**
· **Synonym** 8-[(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino]-octanoic acid, 1-octylnonyl ester

· **Article number:** 33474
· **Application of the substance / the mixture** For research use only, not for human or veterinary use.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
Cayman Chemical Co.
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108
USA

· **Information department:** Product safety department
· **Emergency telephone number:**
During normal opening times: +1 (734) 971-3335
US/CANADA: 800-424-9300
Outside US/CANADA: 703-741-5970

2 Hazard(s) identification

· **Classification of the substance or mixture**


GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.


GHS06 Skull and crossbones

Acute Tox. 2 H310 Fatal in contact with skin.


GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.
STOT RE 1 H372 Causes damage to the central nervous system, the kidneys, the liver and the respiratory system through prolonged or repeated exposure.


GHS09 Environment

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.


GHS07

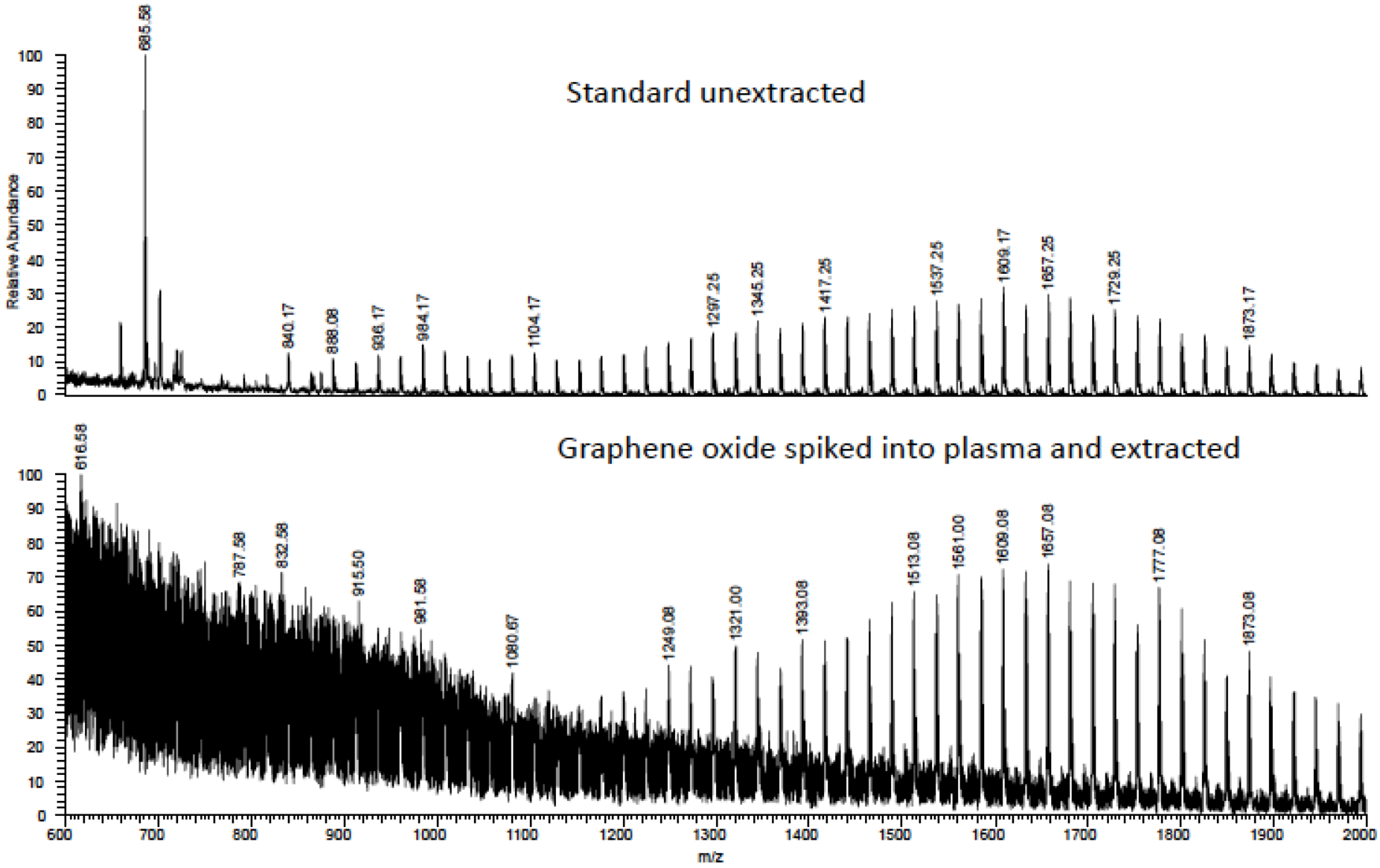
(Contd. on page 2)

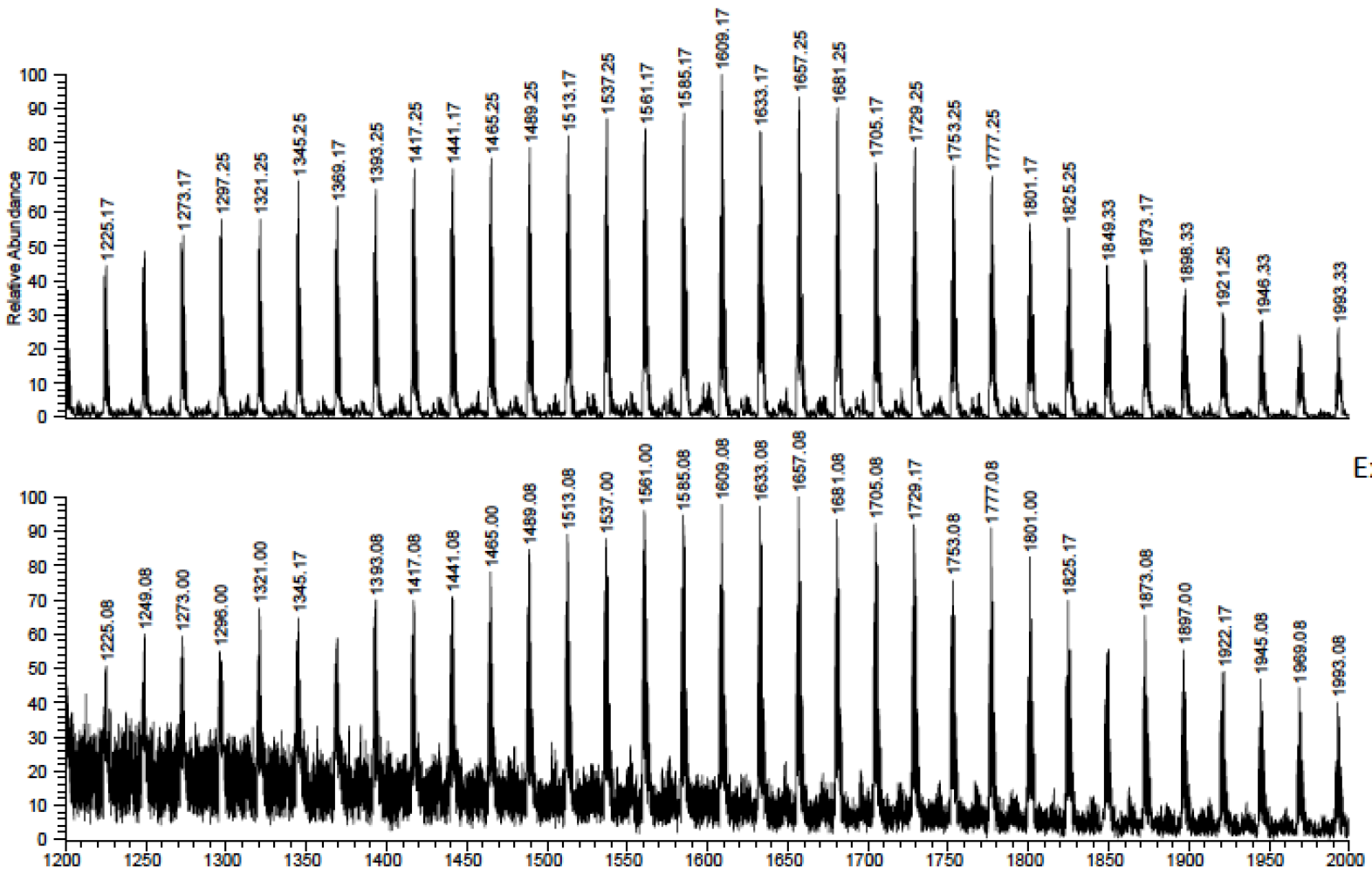
APPENDIX C

Mass Spectrometry Results

Graphene oxide analysis

- A method was developed to analyze Graphene oxide using MALDI ion trap mass spectrometry
- Graphene oxide readily absorbs the laser energy and so analysis can be conducted without the addition of a traditional MALDI matrix
  - This enables reduction of ionization from other molecules that do not absorb the laser energy
- We tested Graphene oxide as a standard
- We tested Graphene oxide spiked into plasma and whole blood
  - We successfully extracted and analyzed Graphene oxide from both matrices
- We tested for the presence of Graphene Oxide in the vaccines provided
  - We observed a large polymeric background in both unextracted and extracted samples
  - We did not observe Graphene oxide in the tested samples


Standard unextracted
Relative Abundance
685.58
840.17
888.08
936.17
984.17
1104.17
1297.25
1345.25
1417.25
1537.25
1609.17
1657.25
1729.25
1873.17
Graphene oxide spiked into plasma and extracted
616.58
787.58
832.58
915.50
981.58
1080.67
1249.08
1321.00
1393.08
1513.08
1561.00
1609.08
1657.08
1777.08
1873.08
m/z


Standard
Relative Abundance
1225.17
1273.17
1297.25
1321.25
1345.25
1369.17
1393.25
1417.25
1441.17
1465.25
1489.25
1513.17
1537.25
1561.17
1585.17
1609.17
1633.17
1657.25
1681.25
1705.17
1729.25
1753.25
1777.25
1801.17
1825.25
1849.33
1873.17
1898.33
1921.25
1946.33
1993.33
Extracted from plasma
1225.08
1249.08
1273.00
1296.00
1321.00
1345.17
1393.08
1417.08
1441.08
1465.00
1489.08
1513.08
1537.00
1561.00
1585.08
1609.08
1633.08
1657.08
1681.08
1705.08
1729.17
1753.08
1777.08
1801.00
1825.17
1873.08
1897.00
1922.17
1945.08
1969.08
1993.08
0
10
20
30
40
50
60
70
80
90
100
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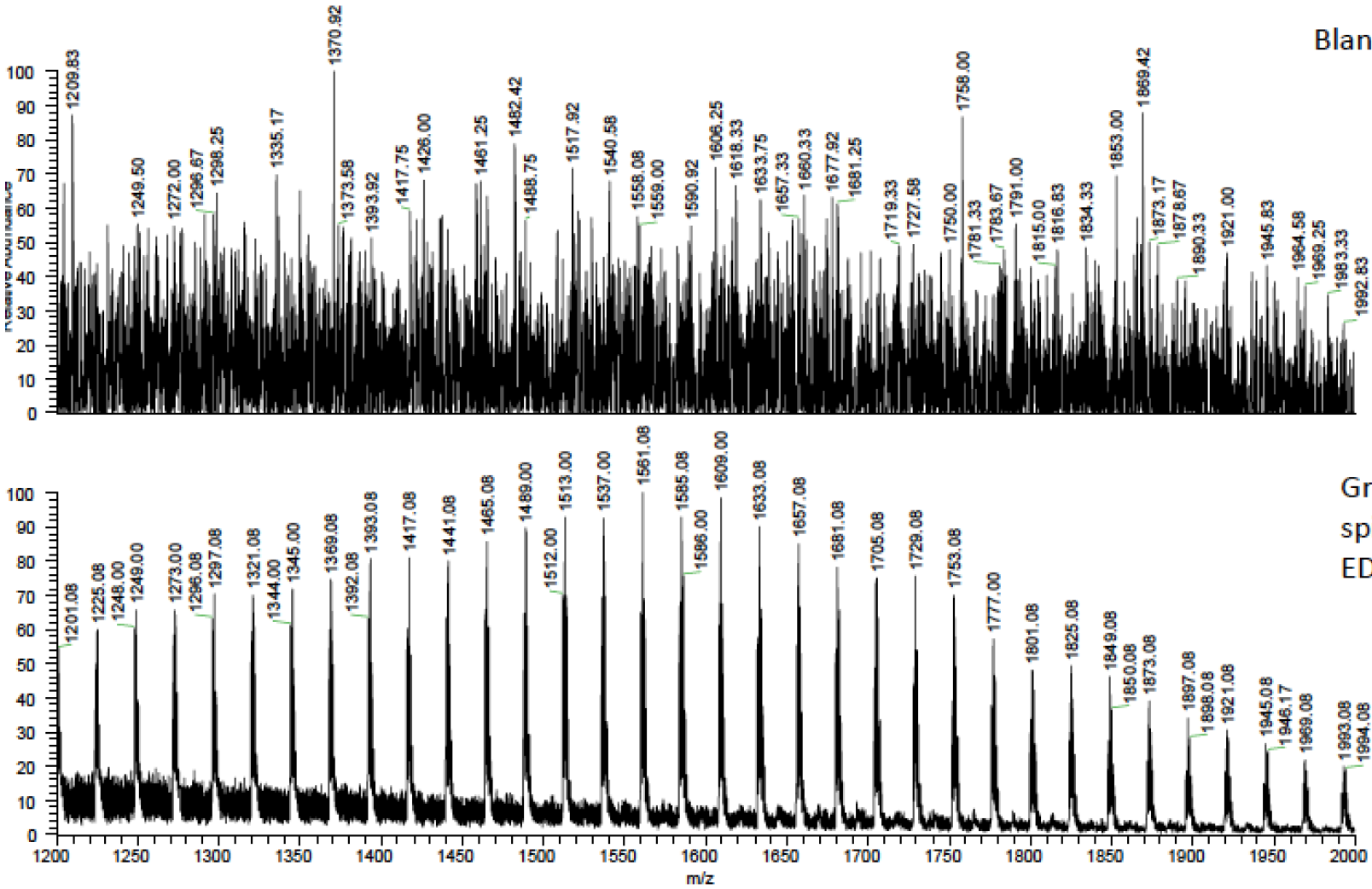
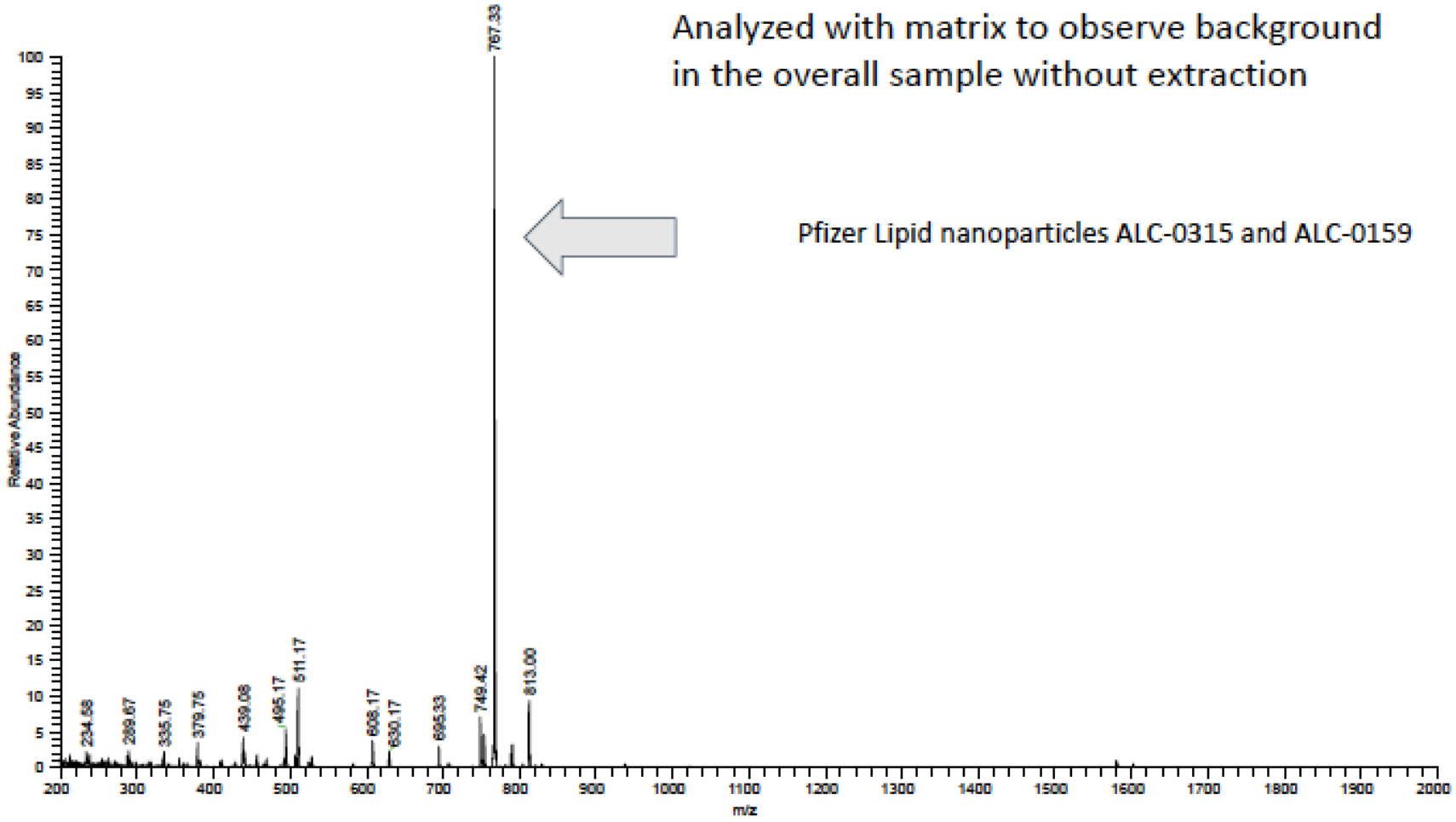
1650
1700
1750
1800
1850
1900
1950
2000


Blank EDTA blood
Graphene oxide spiked and extracted EDTA blood
m/z

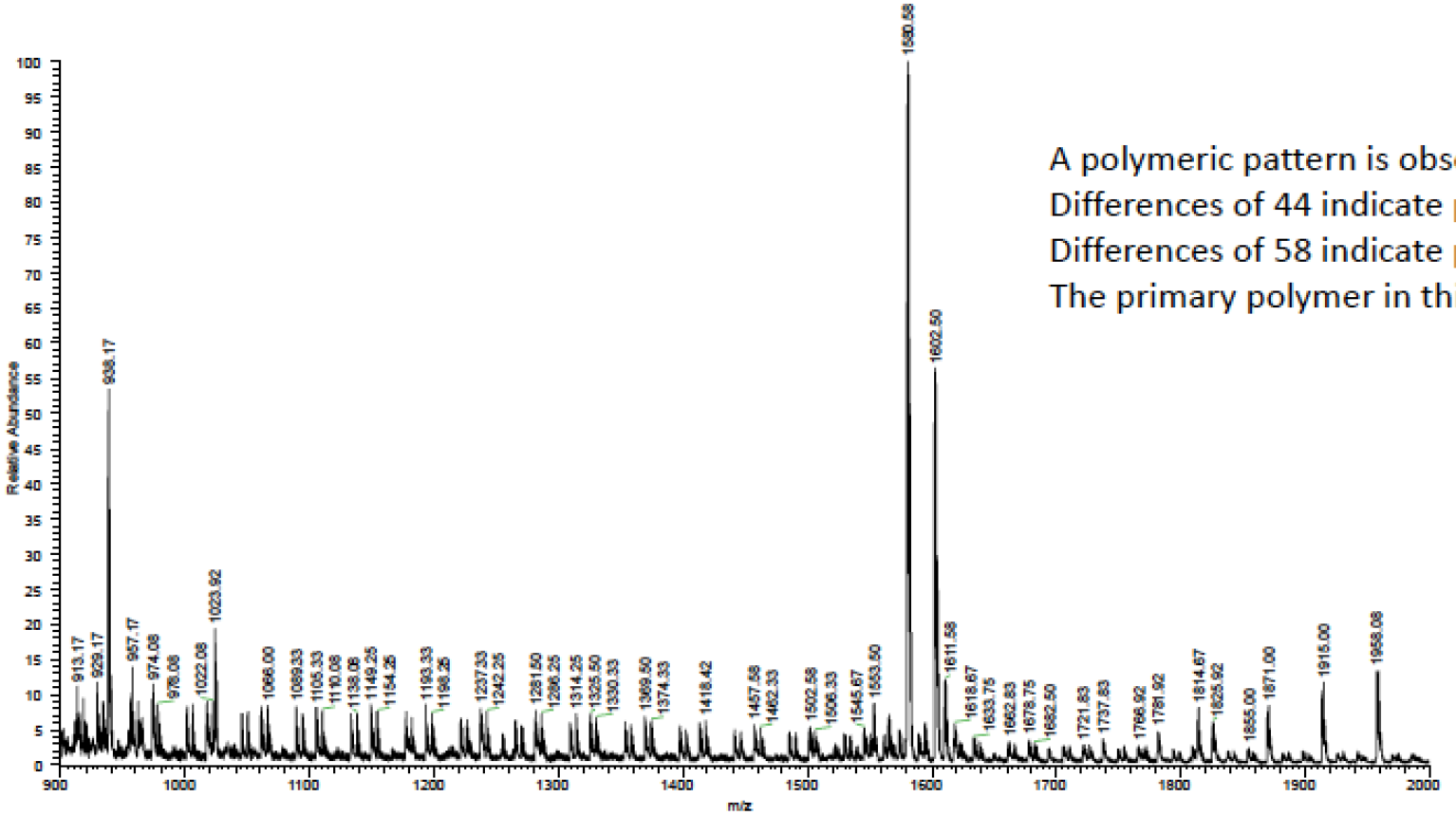
EF123 analyzed with MALDI matrix, unextracted



Analyzed with matrix to observe background in the overall sample without extraction

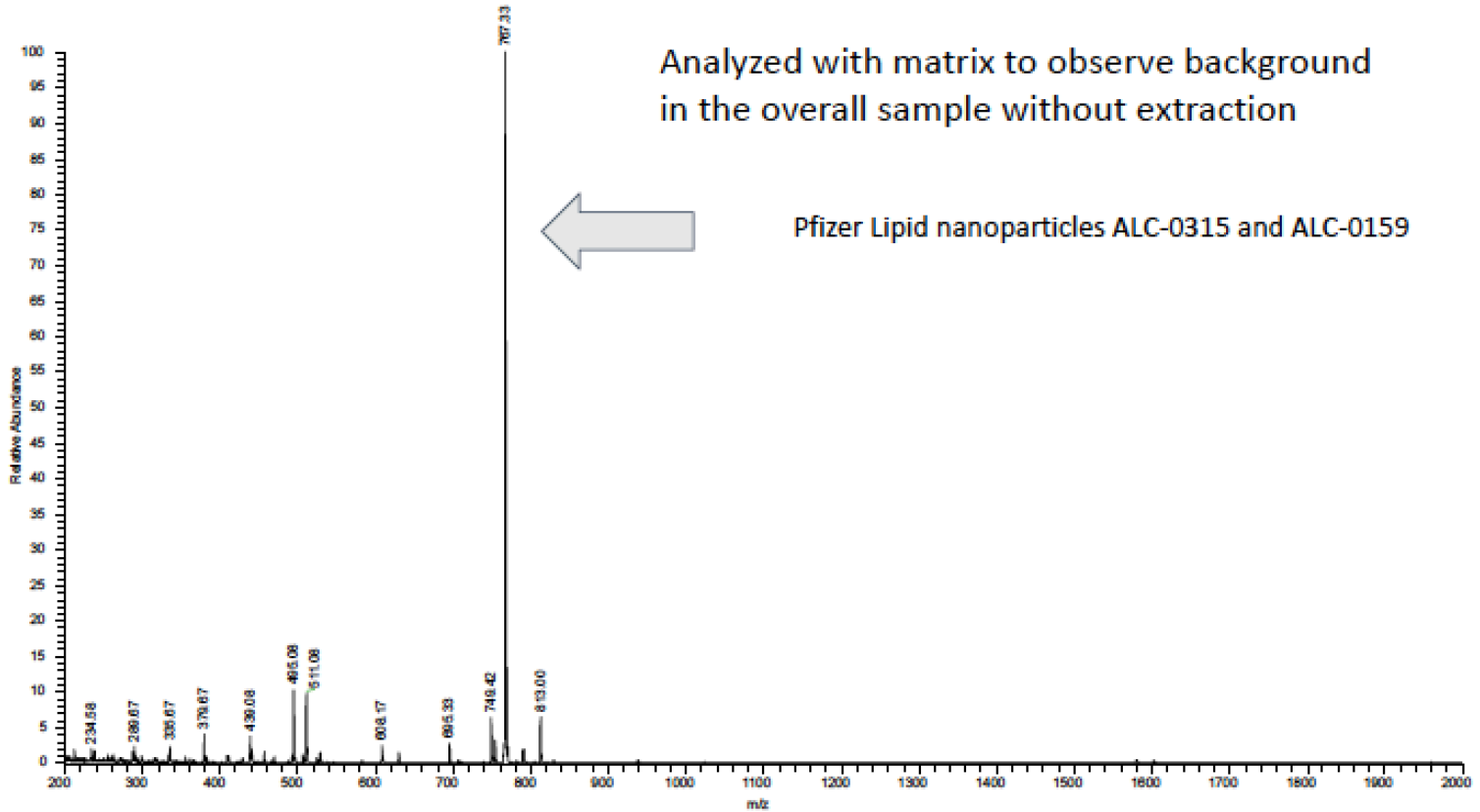
Pfizer Lipid nanoparticles ALC-0315 and ALC-0159

EF123, HCCA matrix, unextracted, 900-2000 mass range



A polymeric pattern is observed
Differences of 44 indicate polyethylene glycol
Differences of 58 indicate polypropylene glycol
The primary polymer in this vaccine is PEG

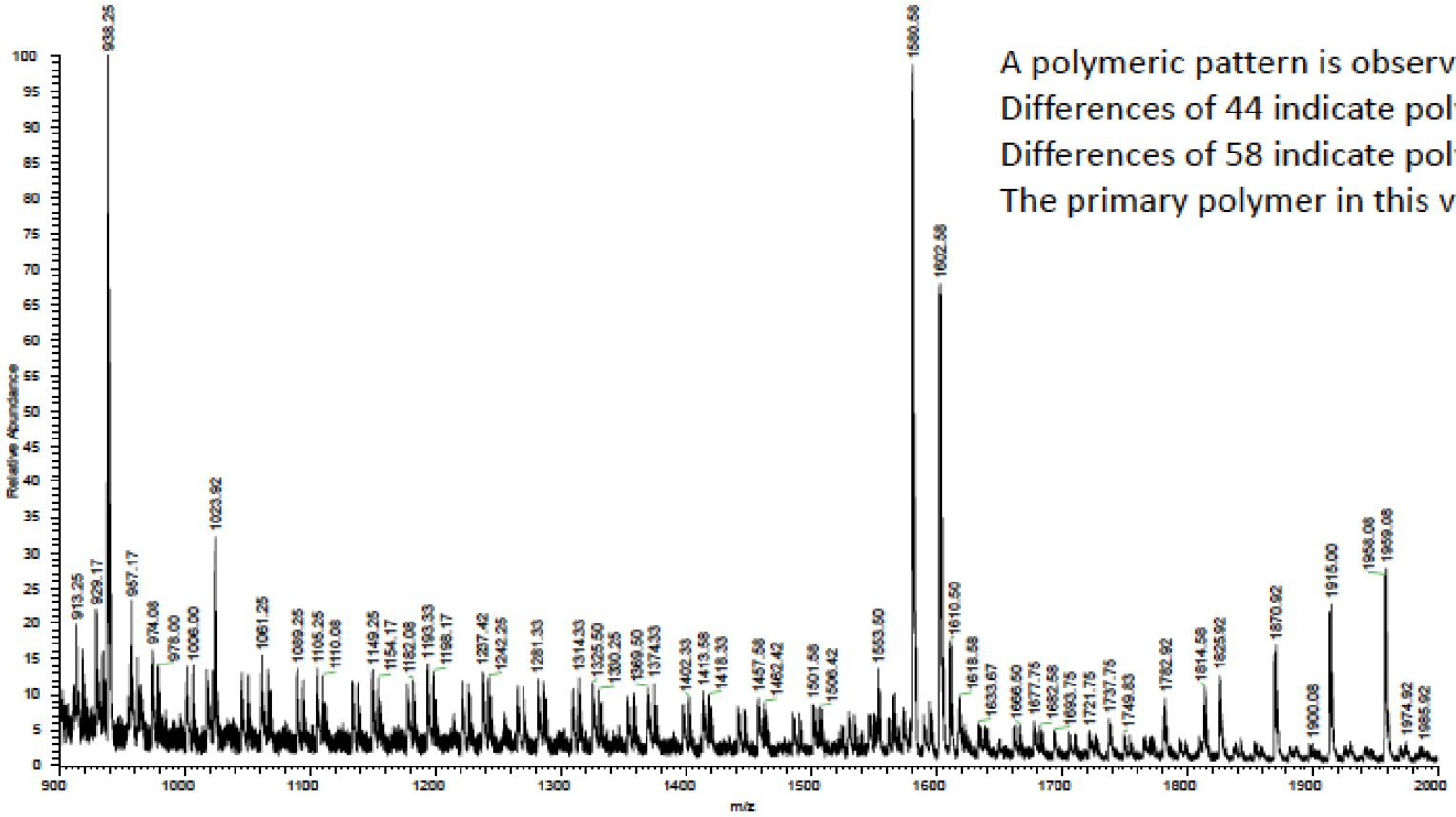
EF456, unextracted, HCCA matrix



Analyzed with matrix to observe background in the overall sample without extraction

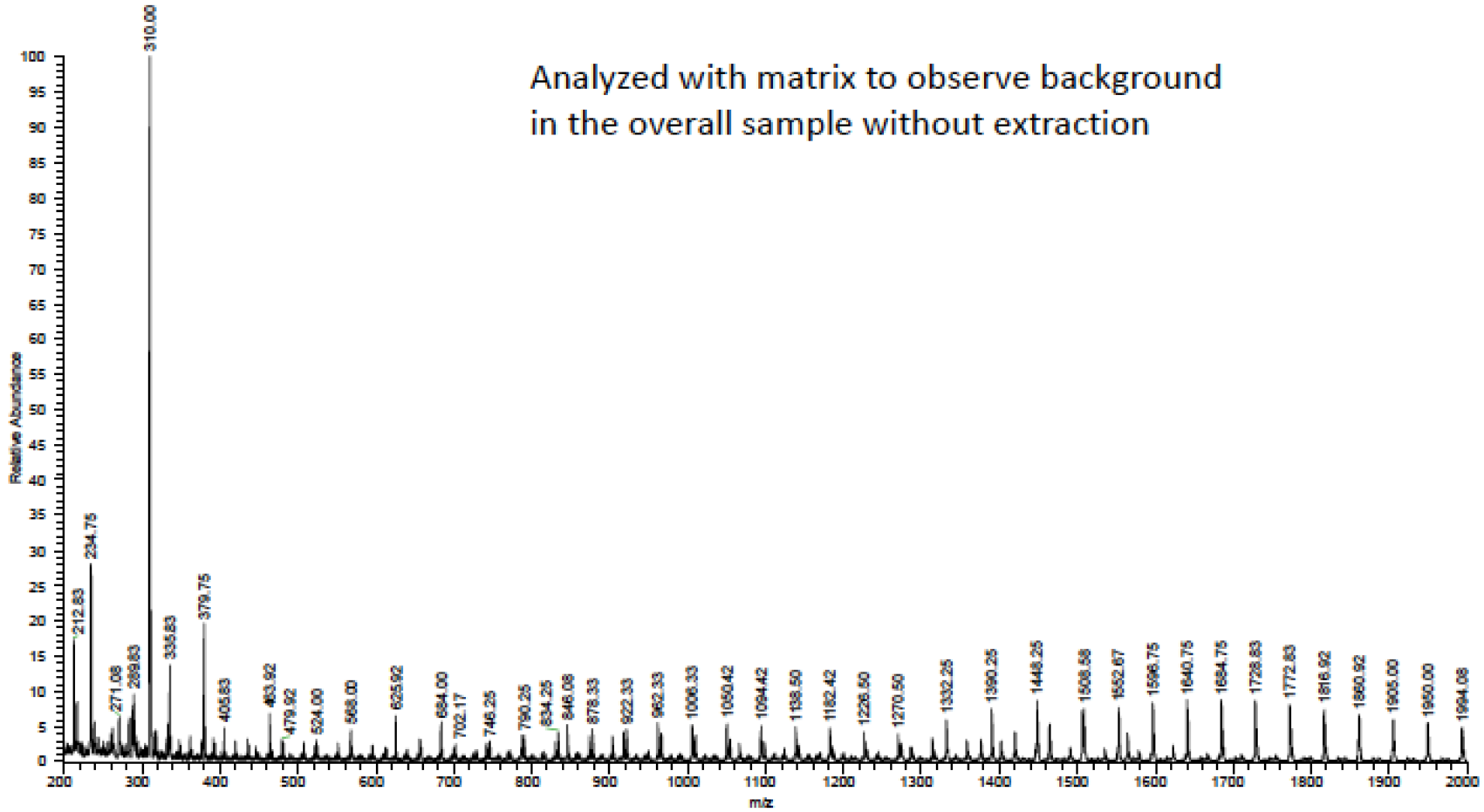
Pfizer Lipid nanoparticles ALC-0315 and ALC-0159

EF456, unextracted, mass 900-2000



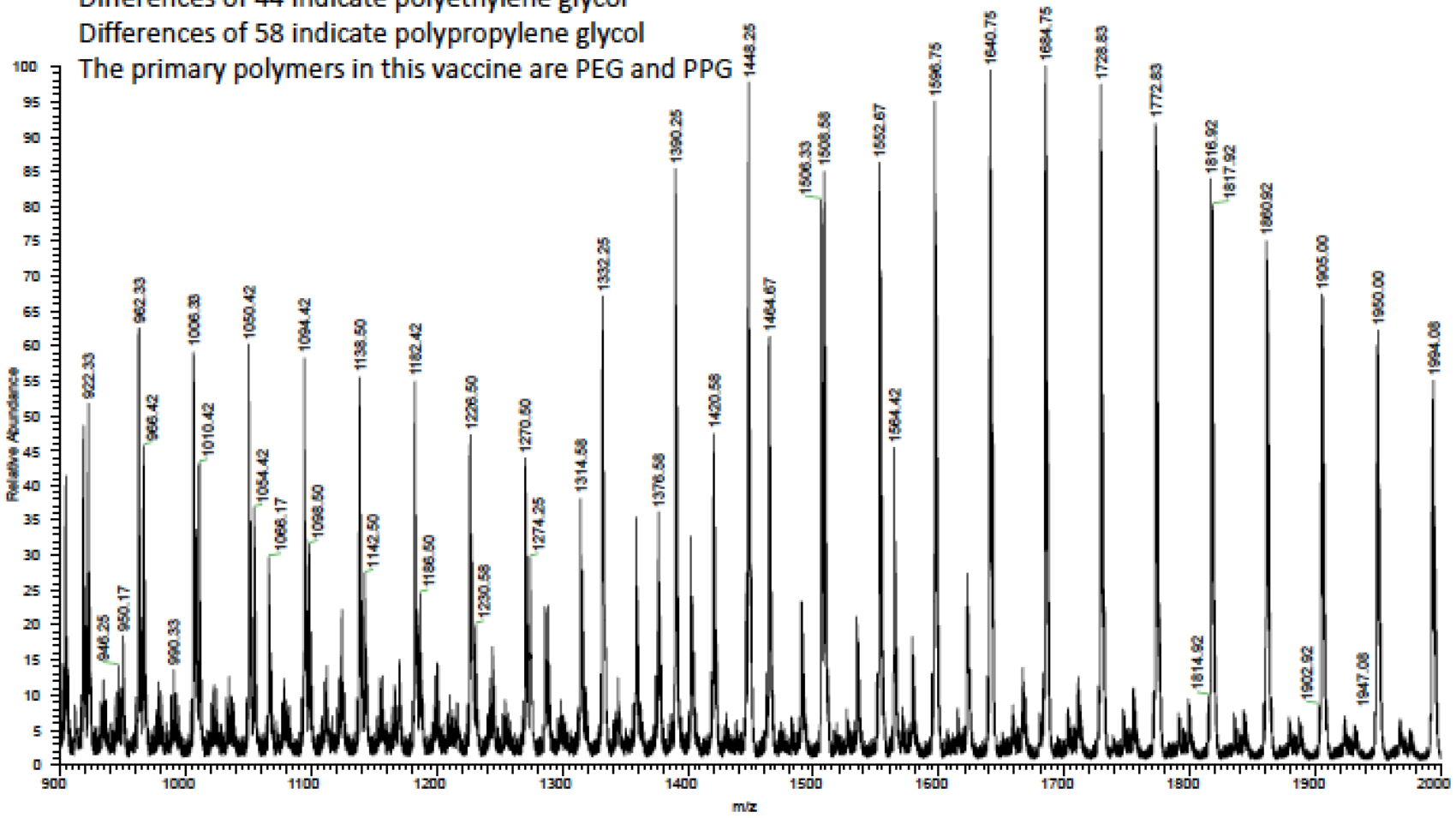
A polymeric pattern is observed as with EF123
Differences of 44 indicate polyethylene glycol
Differences of 58 indicate polypropylene glycol
The primary polymer in this vaccine is PEG

J2, unextracted, HCCA matrix

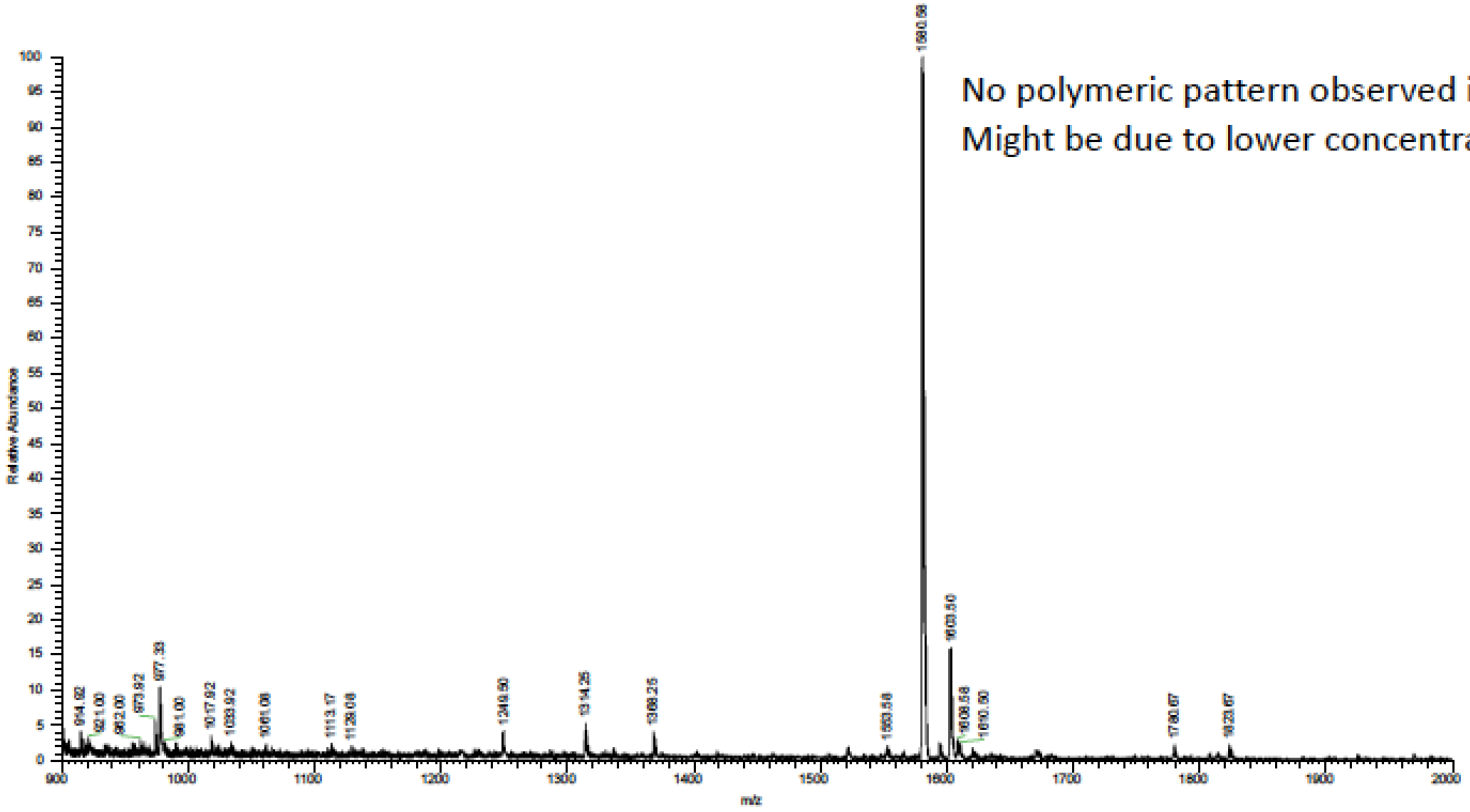


J2, unextracted, mass 900-2000

A polymeric pattern is observed as with EF123
Differences of 44 indicate polyethylene glycol
Differences of 58 indicate polypropylene glycol
The primary polymers in this vaccine are PEG and PPG

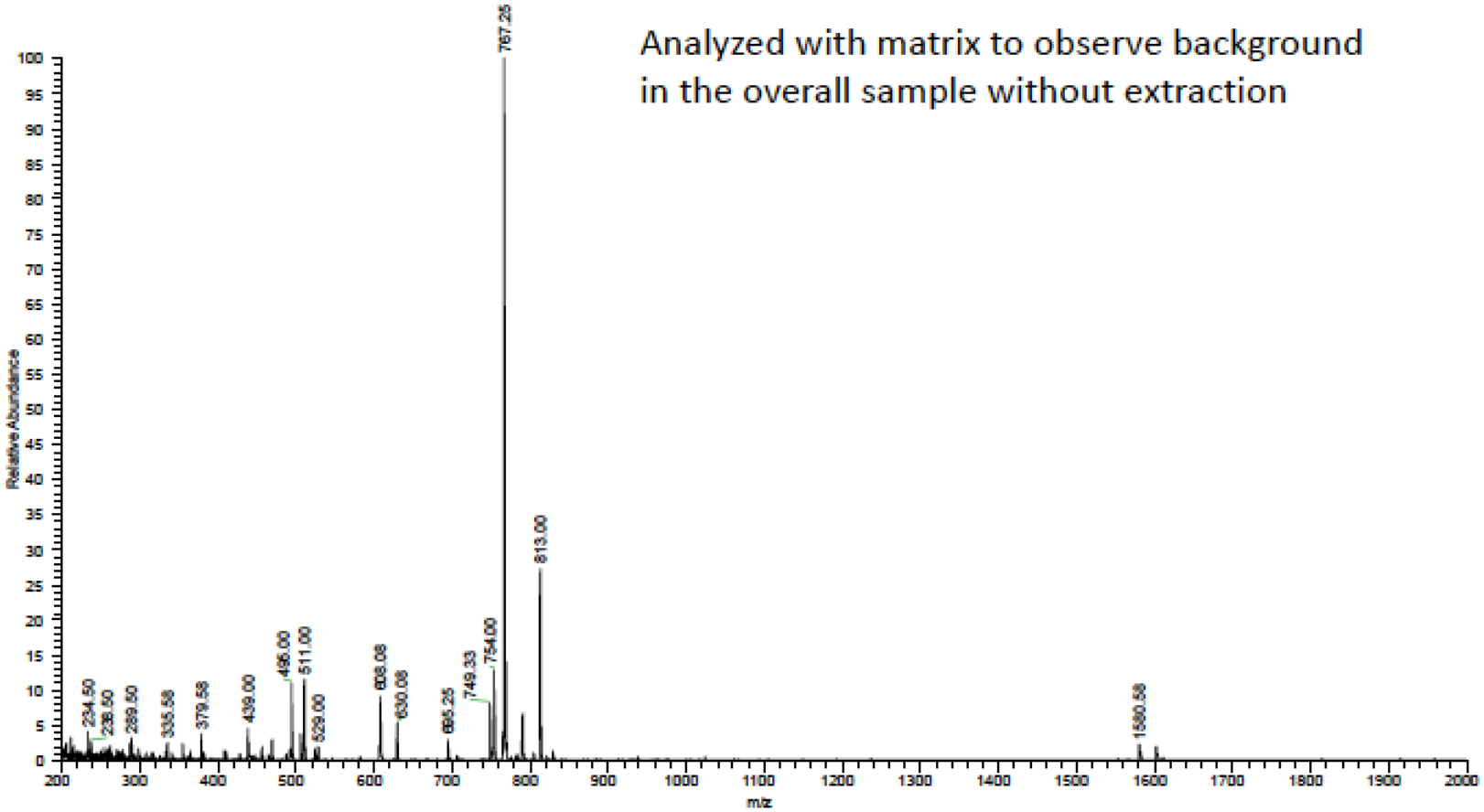


M2, unextracted, mass range 900-2000



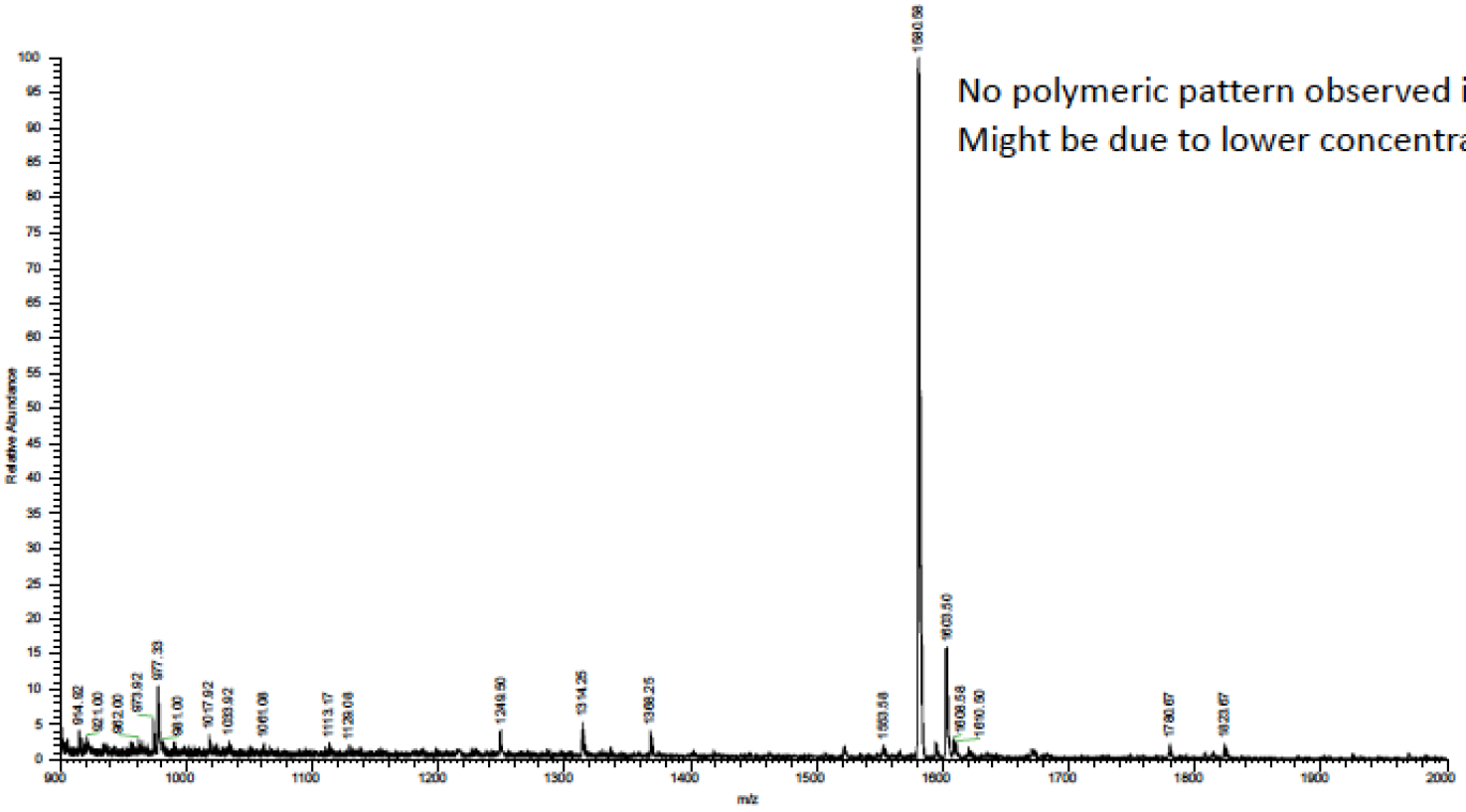
No polymeric pattern observed in this sample
Might be due to lower concentration of polymer

PKI, unextracted, HCCA matrix



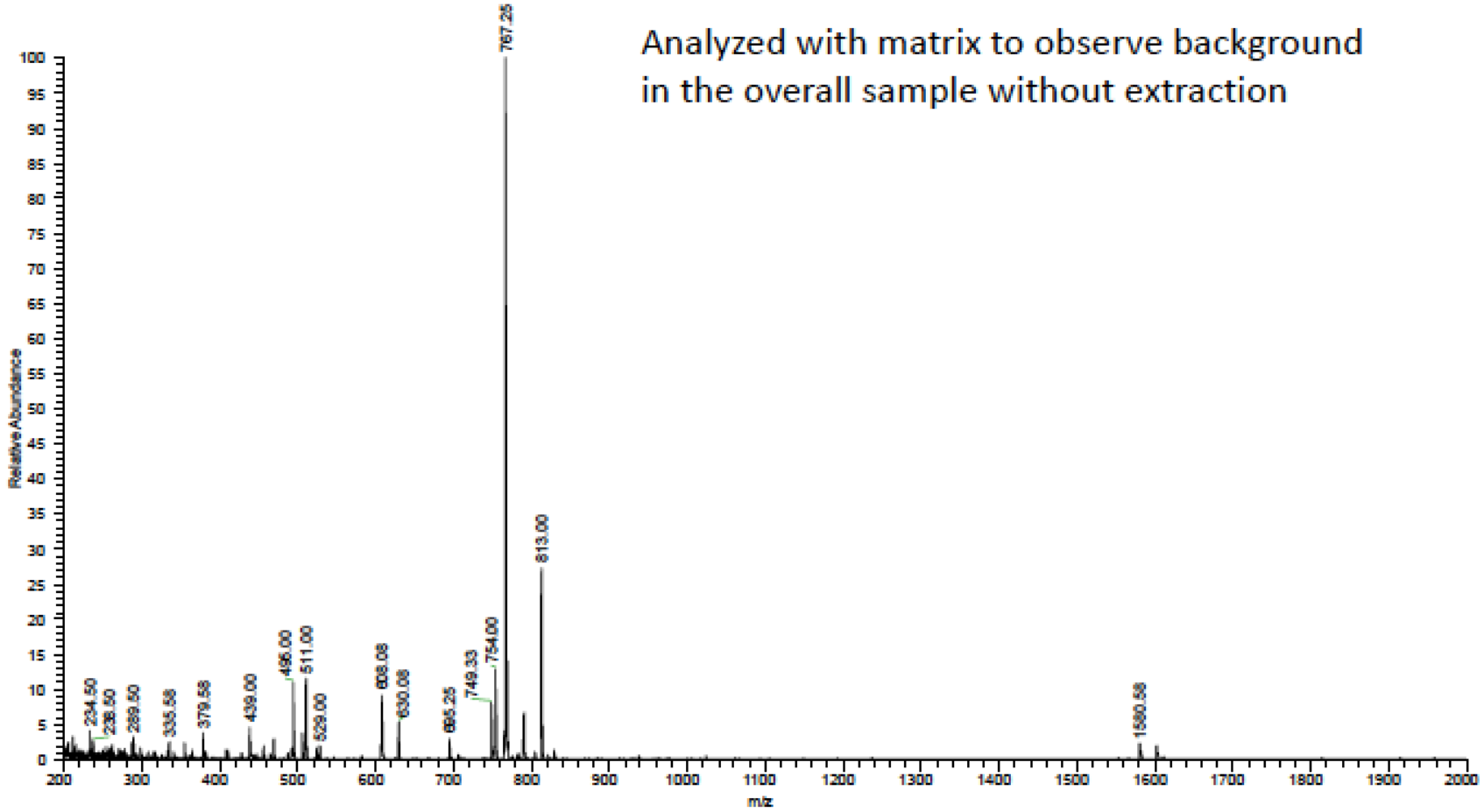
Analyzed with matrix to observe background in the overall sample without extraction

M2, unextracted, mass range 900-2000



No polymeric pattern observed in this sample
Might be due to lower concentration of polymer

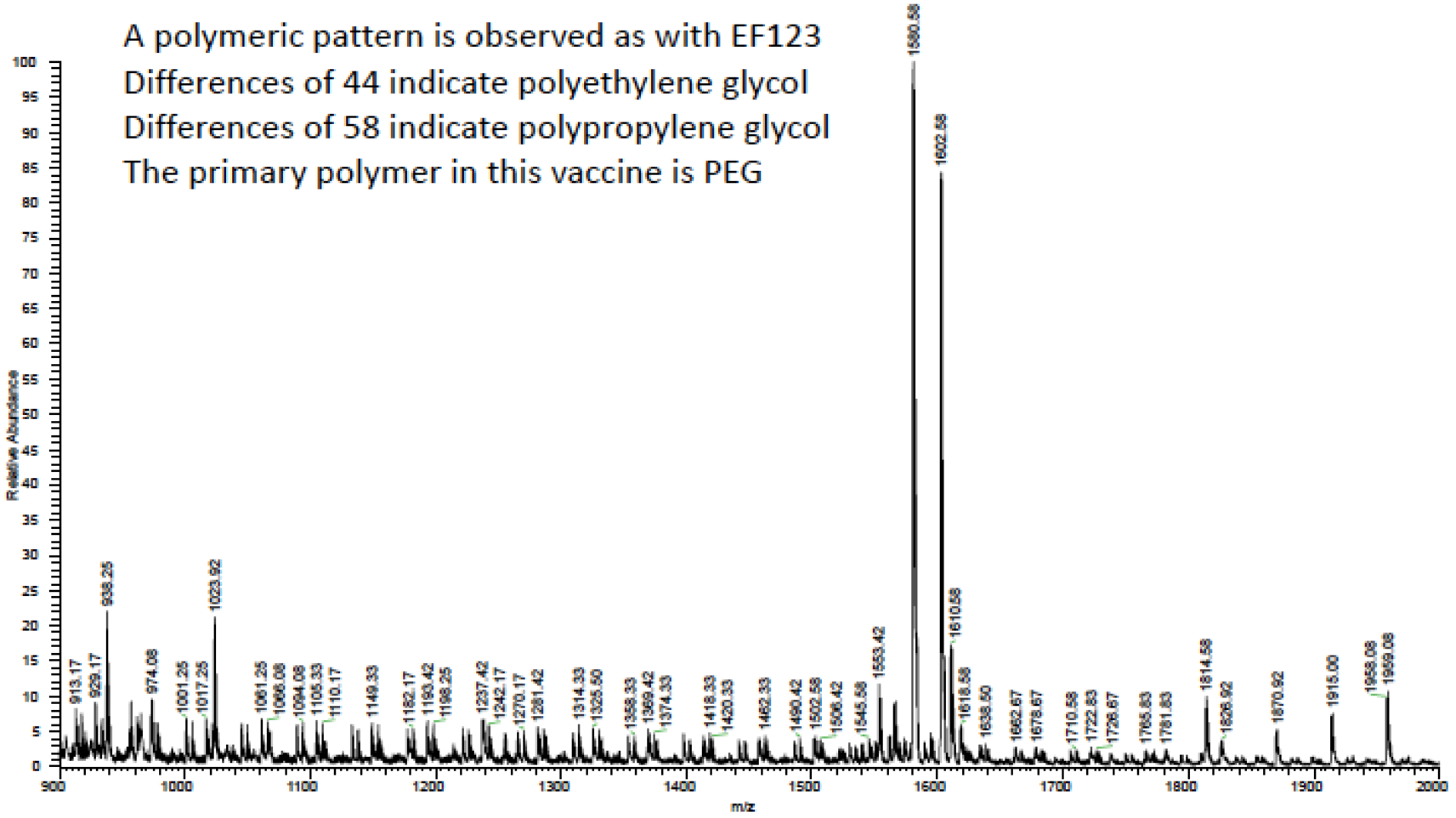
PKI, unextracted, HCCA matrix



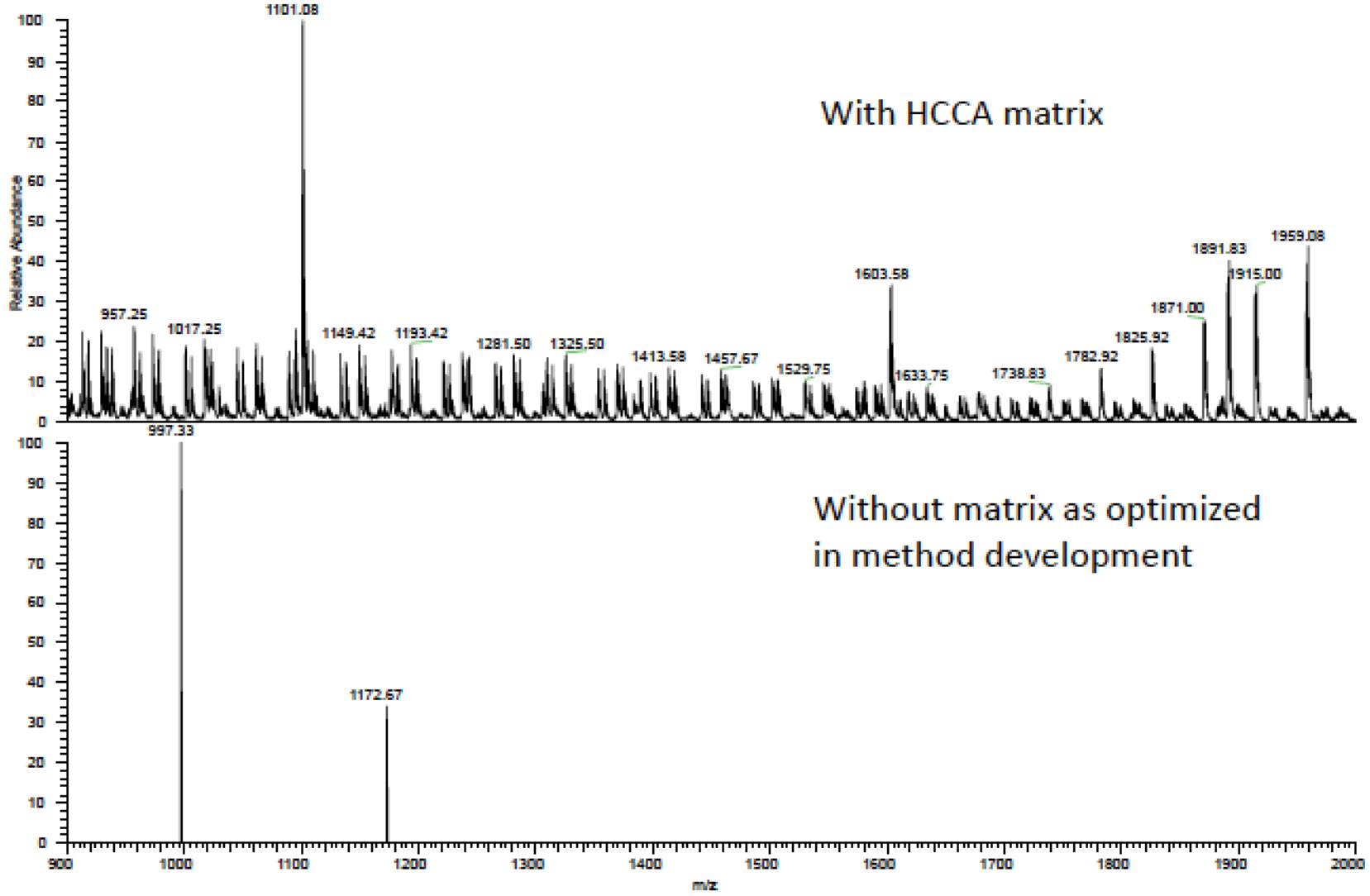
Analyzed with matrix to observe background in the overall sample without extraction

PKI, unextracted, mass range 900-2000

A polymeric pattern is observed as with EF123
Differences of 44 indicate polyethylene glycol
Differences of 58 indicate polypropylene glycol
The primary polymer in this vaccine is PEG



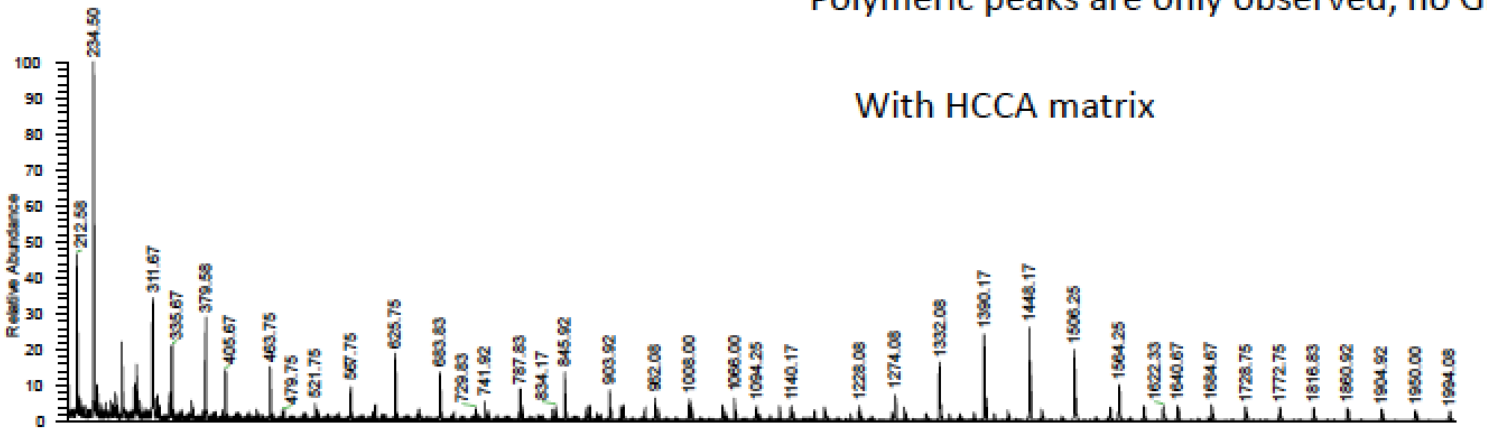
EF456, extracted



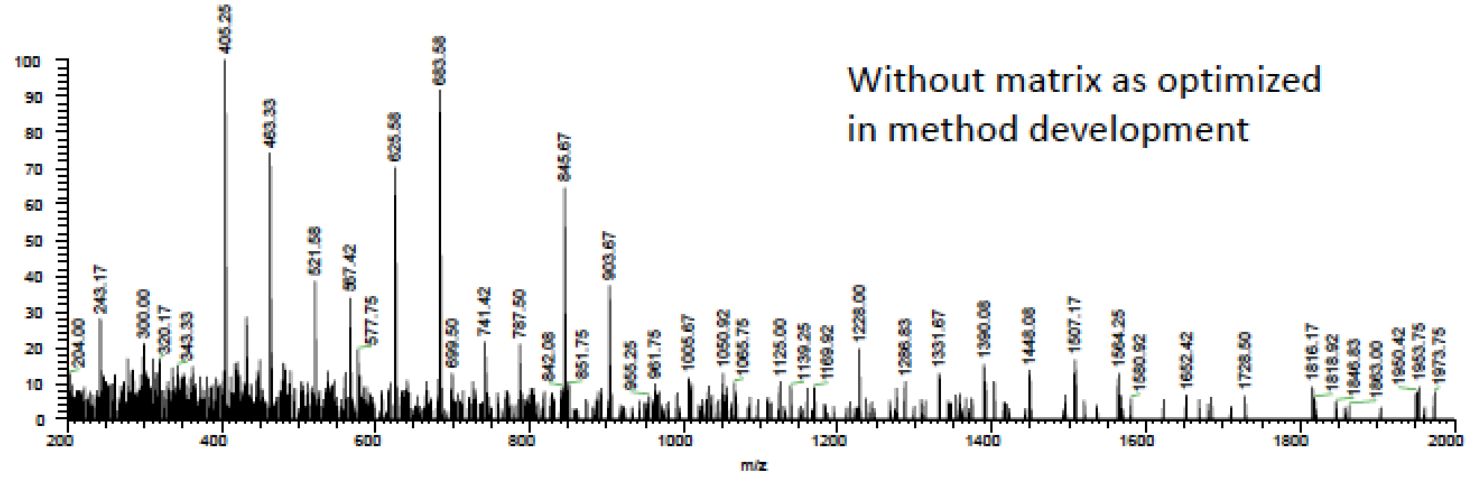
J2, extracted

Polymeric peaks are only observed, no Graphene oxide

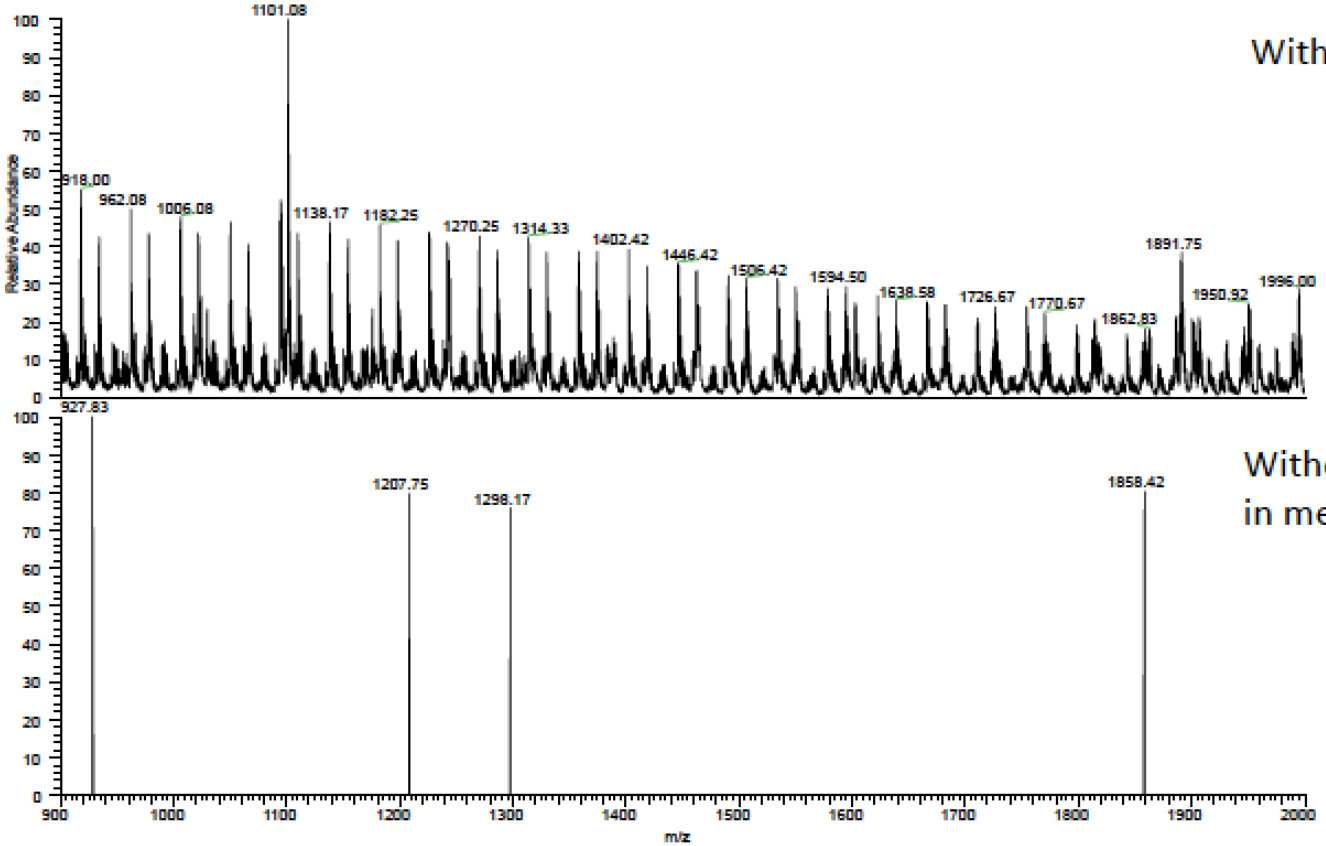
With HCCA matrix



Without matrix as optimized in method development



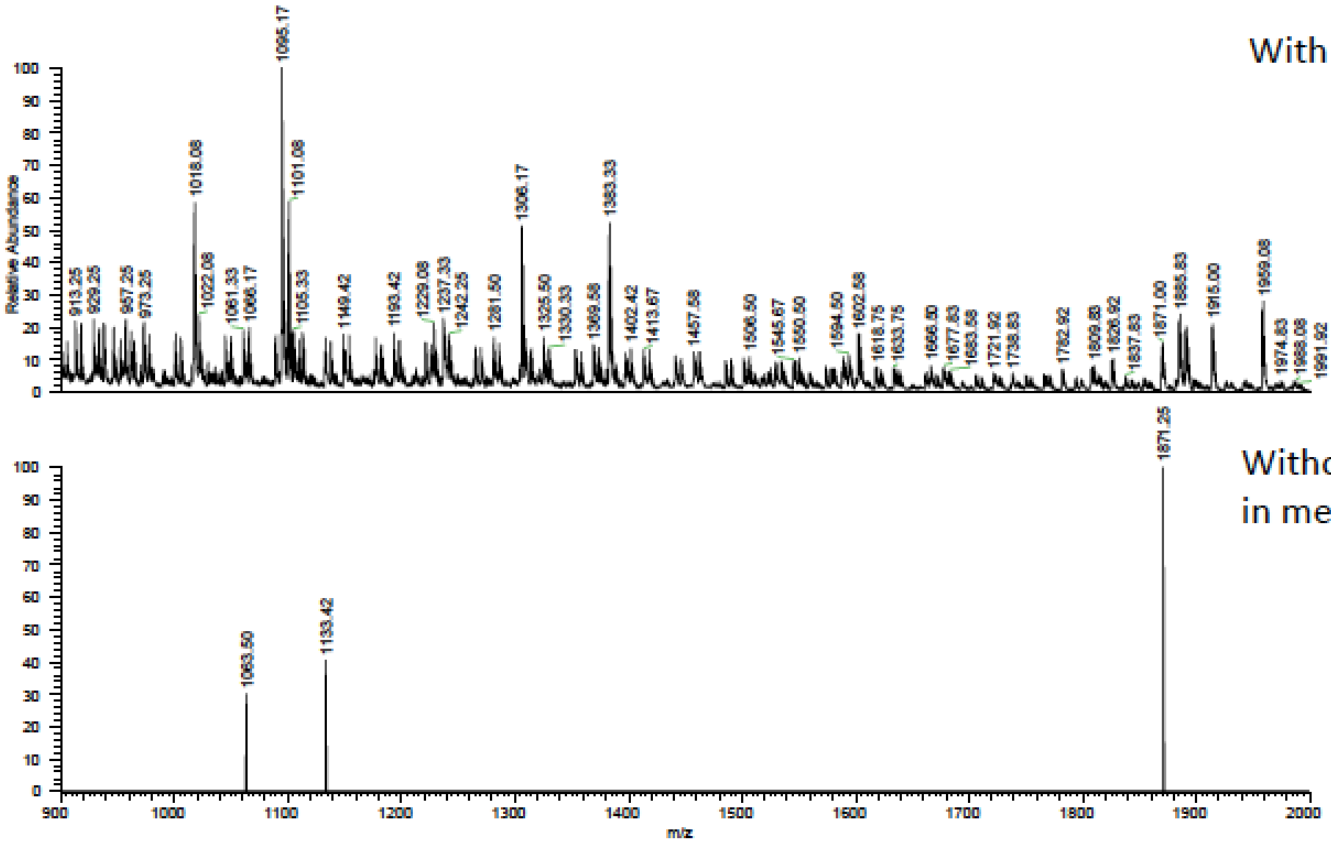
M2, extracted



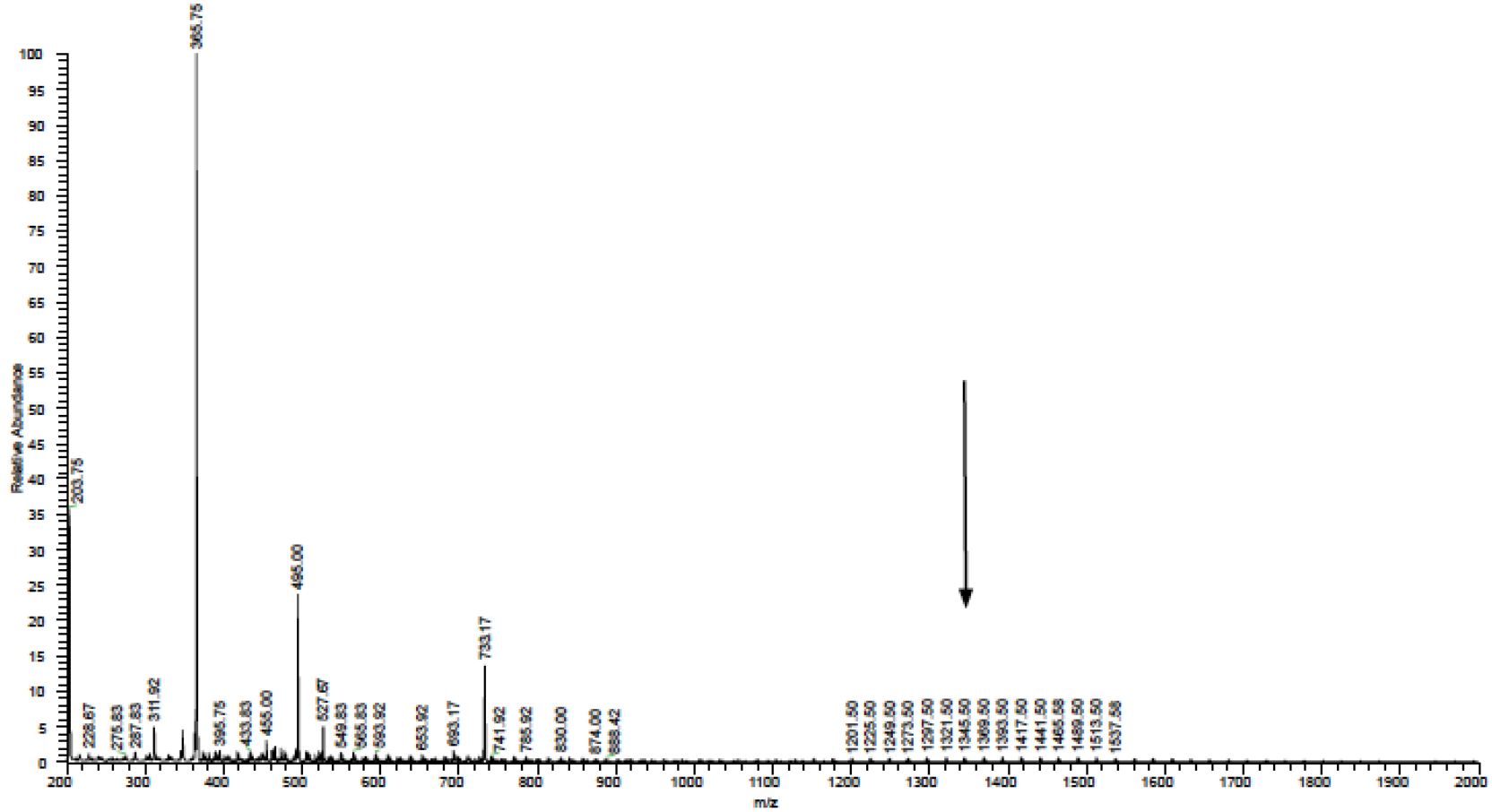
With HCCA matrix

Without matrix as optimized in method development

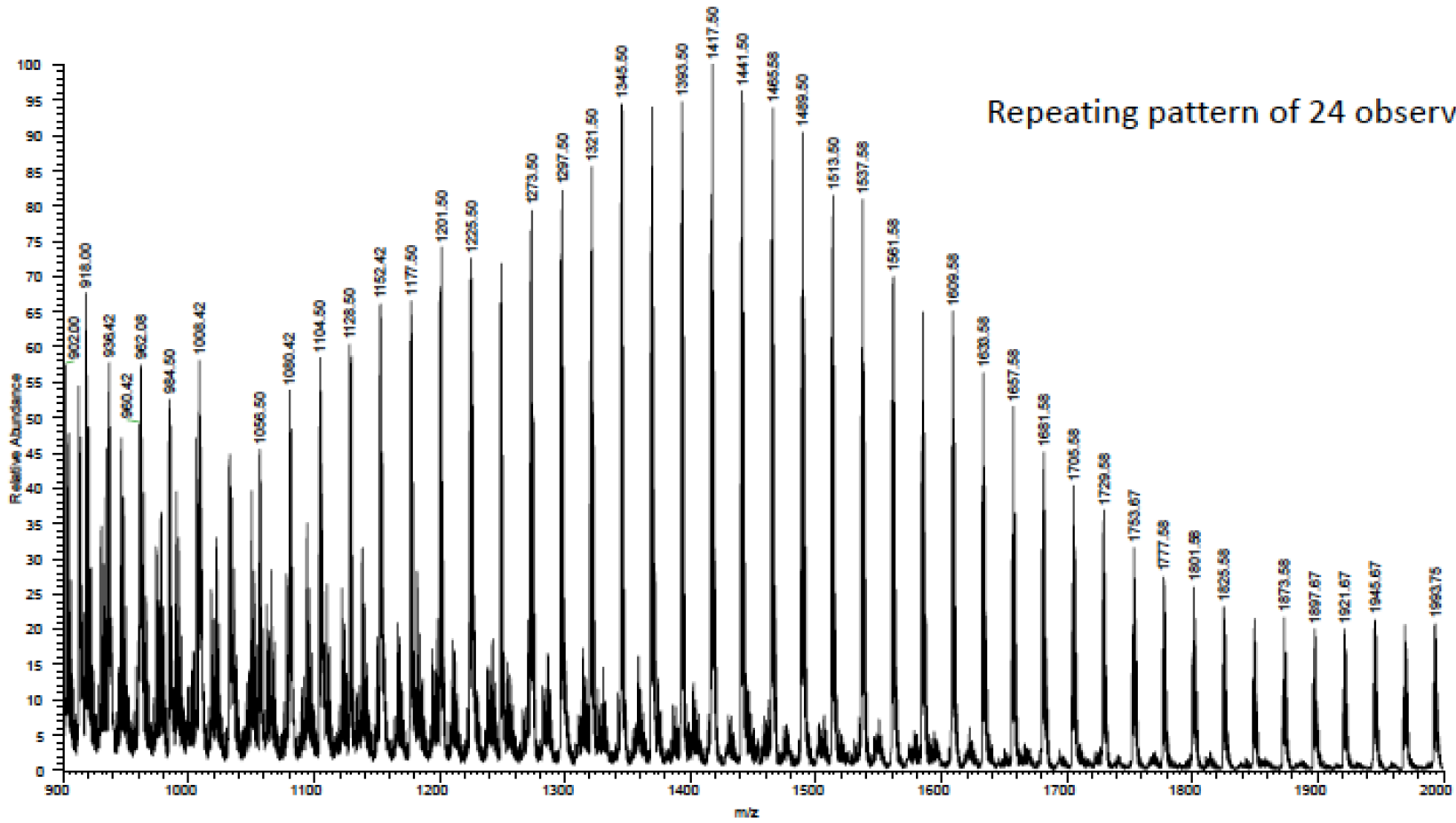
PKI, extracted

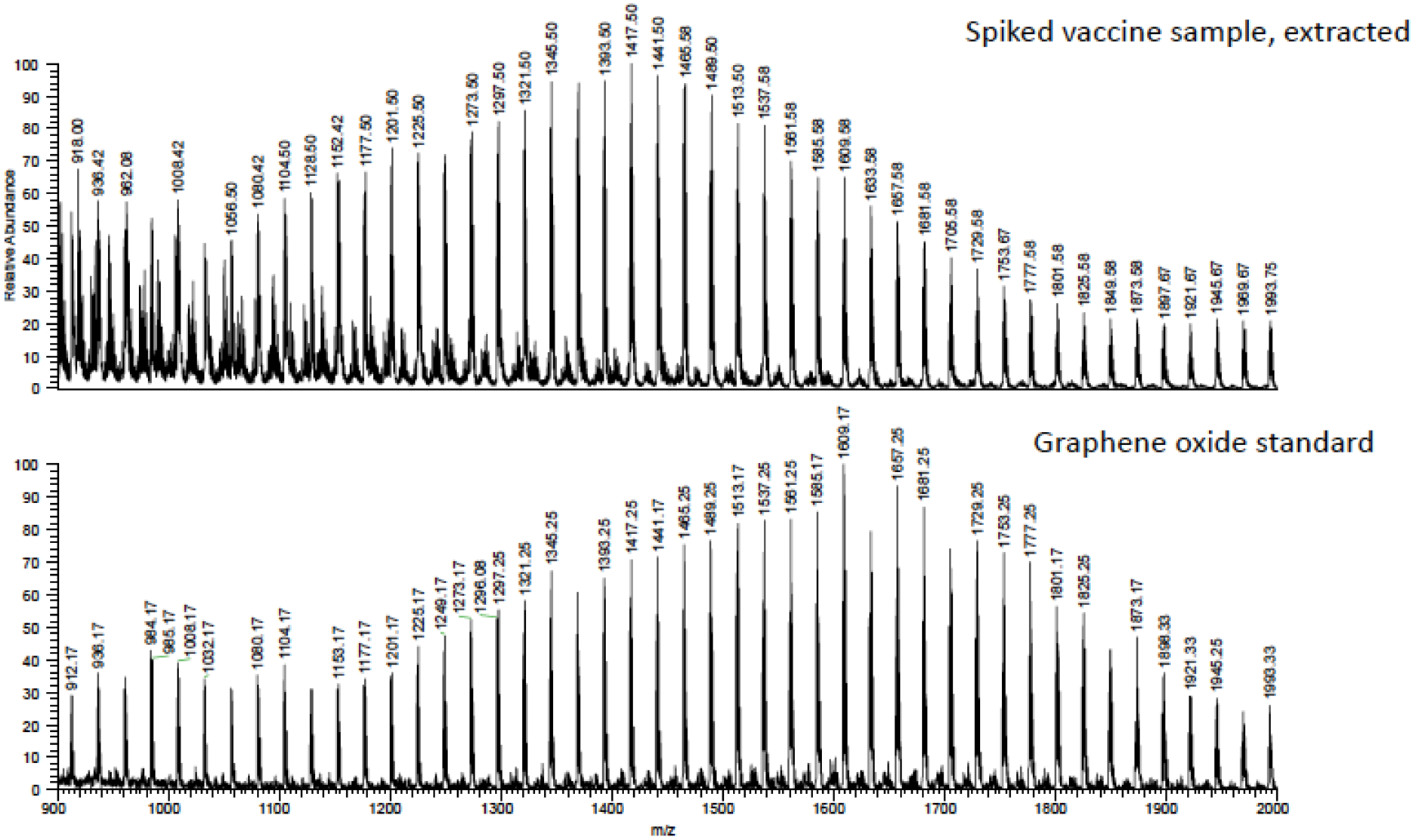


M2 Vaccine spiked with GO



M2 vaccine spiked with GO, mass range 900-2000




Spiked vaccine sample, extracted
Relative Abundance
100
90
80
70
60
50
40
30
20
10
0
918.00
936.42
962.08
1008.42
1056.50
1080.42
1104.50
1128.50
1152.42
1177.50
1201.50
1225.50
1273.50
1297.50
1321.50
1345.50
1393.50
1417.50
1441.50
1465.58
1489.50
1513.50
1537.58
1561.58
1585.58
1609.58
1633.58
1657.58
1681.58
1705.58
1729.58
1753.67
1777.58
1801.58
1825.58
1849.58
1873.58
1897.67
1921.67
1945.67
1969.67
1993.75
Graphene oxide standard
912.17
936.17
984.17
985.17
1008.17
1032.17
1080.17
1104.17
1153.17
1177.17
1201.17
1225.17
1249.17
1273.17
1296.08
1297.25
1321.25
1345.25
1393.25
1417.25
1441.17
1465.25
1489.25
1513.17
1537.25
1561.25
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m/z

AFTER VISIT SUMMARY

minute clinic®

Larry Maxwell CSN: 467699176 DoB: [redacted]

8/17/2021 12:20 PM MinuteClinic TX5877

Instructions from Bianca Lynch, NP

Your personalized instructions can be found at the end of this document.

Today's Visit

You saw Bianca Lynch, NP on Tuesday August 17, 2021. The following issue was addressed: Encounter for screening for COVID-19.

Done Today

COVID 19 Antibody IgG/IgM Rapid POC Test for Encounter for screening for COVID-19

Disposition Today

	8/17/2021 0000
Disposition :	Home

Non-Urgent Follow Up

	8/17/2021 0000
Follow up with:	Established Primary Care Provider
How:	Call to make appointment
When:	See patient instructions
Why:	As needed (PRN)

minute clinic | MyChart

Hi Larry!

MyChart allows you to view your test results, your medical records, and more. To sign in, go to https://mychart.minuteclinic.com

If you have questions, you can e-mail us at MCmycharthelp@cvshealth.com. Remember, MyChart is NOT to be used for urgent needs. For medical emergencies, dial **911**.

Your Medication List as of August 17, 2021 12:37 PM

ⓘ Always use your most recent med list.

budesonide 0.5 mg/2 mL nebulizer solution
Commonly known as: PULMICORT

furosemide 40 MG tablet
Commonly known as: LASIX

olmesartan 40 MG tablet
Commonly known as: BENICAR

Allergies as of 8/17/2021

Never Reviewed

Not on File

Medical History

No past medical history documented.

Results

COVID 19 Antibody IgG/IgM Rapid POC Test

Component
IgG Covid19 Antibody
Positive
IgM Covid19 Antibody
Negative
INTERNAL CONTROLS VALID
Yes--Test working appropriately
Expiration Date
4/2,022
Lot Number
COV20040085
Test Brand
Premier Biotech

Instructions from Bianca Lynch, NP

Minute Clinic COVID-19 Rapid Antibody Test Results Reference

IgG Positive
Explanation:

You have been exposed to SARS-CoV-2 either by infection more than 14 days ago. A COVID vaccination may also cause a positive antibody test. IgG antibodies are more mature and are responsible for longer term immunity than IgM antibodies after a viral infection or vaccination.

Recommendation:
Antibodies are present which means you have been exposed to SARS-CoV-2 either by infection more than 14 days ago. A COVID vaccination more than 14 days ago may cause a positive antibody test.

If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last. If you do have antibodies that developed after first vaccine, it is imperative that you receive the second dose to receive the full effect of the vaccine. Please note that no test is perfect, and this antibody test can result in "false positives" where the test says you have antibodies to the COVID-19 virus when in fact you do not.
For all of these reasons, regardless of your test result, you should continue to follow CDC COVID-19 guidelines to protect yourself and others from the COVID-19 virus and proceed with standard vaccination recommendations.

IgM Positive
Explanation:
You have had SARS-CoV-2 exposure due to infection greater than 14 days ago and your body is currently making antibodies. A COVID vaccination may also cause a positive antibody test. If due to infection, you can still spread the virus during this early phase.

Recommendation:
Antibodies are present which means you have recently been exposed to SARS-CoV-2 by infection. A COVID vaccination may also cause a positive antibody test.

You should have diagnostic testing and isolate per CDC recommendations until COVID 19 diagnostic test results are received, if your exposure was not a vaccination.

If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last. If you do have antibodies that developed after first vaccine, it is imperative that you receive the second dose to receive the full effect of the vaccine. Please note that no test is perfect, and this antibody test can result in "false positives" where the test says you have antibodies to the COVID-19 virus when in fact you do not.

For all these reasons, regardless of your test result, you should continue to follow CDC COVID-19 guidelines to protect yourself and others from the COVID-19 virus and proceed with standard vaccination recommendations.

IgM and IgG Positive
Explanation:
You have been exposed to SARS-CoV-2 by infection more than 14 days ago. A COVD vaccination may also cause a positive antibody test. IgG antibodies are more mature and are responsible for longer term immunity than IgM antibodies after a viral infection vaccination.

If due to infection, you can still spread the virus during this early phase.

Recommendation:
Antibodies are present which means you have been exposed to SARS-CoV-2 by infection more than 14 days ago. A COVID vaccination may also cause a positive antibody test.
You should have diagnostic testing and isolate per CDC recommendations until COVID 19 diagnostic test results are received, if your exposure was not a vaccination

If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last. If you do have antibodies that developed after first vaccine, it is imperative that you receive the second dose to receive the full effect of the vaccine. Please note that no test is perfect, and this antibody test can result in "false positives" where the test says you have antibodies to the COVID-19 virus when in fact you do not.
For all these reasons, regardless of your test result, you should continue to follow CDC COVID-19 guidelines to protect yourself and others from the COVID-19 virus and proceed with standard vaccination recommendations.

Negative
Explanation:
No detectable antibodies could mean:

- You have never been infected with SARS-CoV-2 virus
- You could have had the virus or COVID vaccine within the past 14 days but not developed antibodies yet
- You could have had the virus or vaccine, but antibody production is not yet detectable

Recommendation:
Continue to follow current CDC guidance around protective measures including vaccination.
Diagnostic testing should be done if symptoms develop.

For all test results, continue to follow current guidance from the CDC. For more information about COVID 19, visit:
https://www.cdc.gov/coronavirus or www.coronavirus.gov
FACT SHEET FOR RECIPIENTS
COVID-19 Antibody IgG/IgM Rapid POC Test

You are being given this Fact Sheet because your sample(s) is being tested or was tested for antibodies to the virus that causes Coronavirus Disease 2019 (COVID-19) using the COVID-19 IgG/IgM Rapid POC Test.

You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.

This Fact Sheet contains information to help you understand the risks and benefits of using this test to evaluate your adaptive immune response to SARS-CoV2, the virus that causes COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider. You have the option to refuse use of this test. However, your doctor may be recommending this test because they believe it could help with your care.

For the most up to date information on COVID19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage: https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019ncov/symptomstesting/symptoms.html.

How are people tested for COVID-19?

Two kinds of tests are currently available for COVID19: diagnostic tests and antibody tests.

- A diagnostic test tells you if you have a current infection.
- An antibody test tells you if you had a previous infection

What is the COVID-19 Antibody IgG/IgM Rapid POC Test?

This test is an antibody test. It will help assess if you have antibodies to the virus that causes COVID-19. An antibody test may not be able to show if you have a current infection, because it can take 1-3 weeks after infection to make antibodies.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.

Where can I go for updates and more information?

The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

What does it mean if I have a positive test result?

If you have a positive test result, it is possible that you have or previously had COVID-19 and that you have developed an antibody response to the virus. Your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, your symptoms, possible exposures, and geographic location of places you have recently traveled. There is also a chance that this test can give a positive result that is wrong (a false positive result). Even a high-performing antibody test when used in a population without many cases of COVID-19 infection may produce as many or more false results as true results because the likelihood of finding someone who has been infected is very small.

Your healthcare provider will work with you to determine the likelihood of false result.

It is not known how long antibodies to SARS-CoV-2 will remain present in the body after infection. It is not known whether having antibodies to SARS-CoV2 will protect you from getting infected again or help reduce the severity or duration of a future COVID-19 infection. Regardless of your test result, you should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.

What does it mean if I have a negative test result?

A negative test result means that the antibodies to the virus that causes COVID-19 were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. Additionally, a negative result may occur if you are tested early in your illness and your body hasn't had time to produce antibodies to infection. This means that you could possibly still have COVID-19 even though the test is negative. If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDAapproved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's

(HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-andpolicyframework/emergency-use-authorization.

Where can I go for updates and more information?
The most up-to-date information on COVID-19 is available at the CDC General webpage: https://www.cdc.gov/COVID19. In addition, please also contact your healthcare provider with any questions/concerns.

Antibodies are present which means you have been exposed to SARS-CoV-2 either by infection more than 14 days ago. A COVID vaccination more than 14 days ago may cause a positive antibody test. If you have antibodies due to prior infection, it is not known if they give you immunity to COVID-19 at all, or how long that immunity might last. If you do have antibodies that developed after first vaccine, it is imperative that you receive the second dose to receive the full effect of the vaccine. Please note that no test is perfect, and this antibody test can result in "false positives" where the test says you have antibodies to the COVID-19 virus when in fact you do not. For all of these reasons, regardless of your test result, you should continue to follow CDC COVID-19 guidelines to protect yourself and others from the COVID-19 virus and proceed with standard vaccination recommendations. For further information, please refer to patient education handouts.

Primary Care Provider Information

MinuteClinic encourages all patients to have a relationship with a primary care provider. If you do not have a primary care provider, the resources below can help you to locate one.

- If you have insurance: Check your insurance plan's list of health care providers by either looking on the plan's website or by calling your health plan (phone number and website should be on your health insurance card).
- If you do not have health insurance: HealthCare.gov is a website run by the United States government. HealthCare.gov has tools and resources to help you obtain insurance coverage, find low cost care in your area and more. Go to www.healthcare.gov or call 1-800-318-2596 (TTY: 1-855-889-4325).
- Local health systems can provide you with information on providers who are accepting new patients & who accept your health insurance.

Additional Information

We want your feedback!
If you have opted in to complete a survey by providing us with your email address, you will automatically receive an email to complete a brief Patient Experience Survey in 24 hours. It only takes a few minutes to complete. Please have this Patient Visit Receipt available when you take the survey. Thank you!

Additional Information (continued)

For information or questions regarding this visit, please contact MinuteClinic at 866-389-ASAP (2727). If you feel MinuteClinic has not addressed your concern, you may contact the Joint Commission via their website: jointcommission.org

Patient: Larry Maxwell
Visit Date: 8/17/2021

minute clinic®

Patient Visit Receipt

Practitioner:	LYNCH, BIANCA TX5877, PEARLAND	**Federal Tax ID:**	20-4768243, 20-4768243
Clinic Address:	2900 BROADWAY ST PEARLAND TX 77581	**POS Code:** **Group NPI:**	11 1609076330, 1609076330

General Patient Information

Patient:	Larry Maxwell	**Patient ID:**	E53646026
Home Phone:	There is no home phone number on file.	**Visit ID:**	467699176
Patient DOB:	[redacted]	**Primary Care Provider:**	PCP NOT FOUND
Patient Address:			

Detailed Charges

86328: IA NFCT AB SARSCOV2 COVID19, mod QW	x 1	$38.00
Diagnoses:	*Patient amt:*	*$38.00*
Z11.52		

Payment Summary

Transaction Type: SALE

Payment Sources

Visa x $38.00

Authorization number: 07064D
Application ID:A0000000031010
Application Name:VISA CREDIT
Card Entry Mode:Chip read
Card Holder Verfication:5E0000
Terminal Verification Results:0800008000
Issuer Application Data:06021203A0A004
Transaction Status Information:E800
Application Response Code:approved

We want your feedback!
If you have opted in to complete a survey by providing us with your email address you will automatically receive an email to complete a brief Patient Experience Survey in 24 hours. It only takes a few minutes to complete. Please have this Patient Visit Receipt available when you take the survey. Thank you!

For information or questions regarding this visit, please contact MinuteClinic at 866-389-ASAP (2727). If you feel MinuteClinic has not addressed your concern, you may contact the Joint Commission via their website: jointcommission.org.

EXHIBIT K
(Maxwell v CVS, et al.)

*** This Declaration by Dr. Noorchasm was filed in Zywicki vs. Washington, et al.**

ATTACHMENT B

EXHIBIT K (Maxwell v CVS, et al.)

Exhibit A

Declaration of Dr. Hooman Noorchashm, MD, PhD

I, Dr. Hooman Noorchashm, MD, PhD, provide the following Declaration:

Background

1. I graduated from the Perelman School of Medicine at the University of Pennsylvania with a Doctorate degree in immunology and have taught and practiced clinical medicine for nearly two decades. In addition to an academic career in medicine, I am an advocate for patient safety and medical ethics.

2. I have served faculty appointments at the University of Pennsylvania School of Medicine, Harvard Medical School Brigham and Women's Hospital, Thomas Jefferson University Hospital, and Philadelphia VA Hospital. I have authored over 65 articles, abstracts, and reviews in peer-reviewed medical journals, including the New England Journal of Medicine, Journal of Immunology, Nature Medicine, American Journal of Transplantation, Critical Care Medicine, and Diabetes. I have testified on numerous occasions before the Food and Drug Administration (FDA) and state legislatures on issues related to medicine, patient safety, and patients' rights.

3. In 2013, my wife Dr. Amy Reed underwent an unnecessary hysterectomy operation, which we later learned caused stage 4 leiomyosarcoma, and she eventually died.

4. Before her death, my wife and I began spreading awareness of the procedure's danger and advocating for patient safety and patients' rights. In recognition of those efforts, I received a Health Policy Heroes Award from the National Center for Health Research in 2015.

5. To continue the work that Amy and I started, I founded the American Patient Defense Union, Inc. (APDU), an organization dedicated to advocating for patient rights and

autonomy, preserving the integrity and sacred relationship between doctors and their patients, and protecting doctor and patient decisions about medical treatments from third-party influence.[1]

Professor Zywicki's Medical Condition

6. On May 27, 2021, Professor Zywicki contacted me for advice on how to determine the status of his immunity to COVID-19 and the likelihood of having been infected. I agreed to review his case and provide my opinion.

7. During a phone call that same day, Professor Zywicki informed me of the following relevant facts:

a. In early March 2020 he fell ill with a set of symptoms (chills, night sweats, fatigue, mental fogginess) that have been identified as consistent with a COVID-19 infection.

b. At this early stage of the pandemic, COVID-19 tests were scarce and required a doctor's prescription, so Professor Zywicki tried but was unable to procure one.

c. Professor Zywicki subsequently tested positive several times for COVID-19 antibodies when donating blood at the American Red Cross.

d. He further informed me that he had recently recovered from a severe shingles infection that had caused paralysis in the left side of his face for nearly two weeks. Professor Zywicki was concerned by news reports that suggested a possible relationship between the COVID-19 vaccine and reemergence of shingles, which is a virus.[2]

[1] *See* Hooman Noorchashm, *Why Does Every American Need The American Patient Defense Union (APDU)?*, MEDIUM.COM (Oct. 17, 2017), https://noorchashm.medium.com/why-every-american-needs-the-american-patient-defense-union-apdu-2912e1fee5d4.

[2] *See*, *e.g.*, American Academy of Allergy Asthma & Immunology, *Shingles following Pfizer COVID-19 vaccine* (Apr. 29, 2021), https://www.aaaai.org/allergist-resources/ask-the-expert/answers/2021/shingles-covid.

e. After an extensive discussion about his medical condition, I issued a prescription for full COVID-19 serological screening, which was conducted on June 1, 2021, at LabCorp. I examined the results and, as expected, the test confirmed that Professor Zywicki had previously recovered from SARS-CoV-2 and had a positive IgG Spike Antibody assay and a positive SARS-CoV-2 Nucleocapsid result.

f. Professor Zywicki's semiquantitative antibody reading measured 715.6 U/ml—approximately 900 times higher than the baseline level of <0.8. This level is comparable to that I have seen empirically in vaccinated persons who share his age and health profile, including myself. In my opinion, Professor Zywicki's spike antibody level is highly likely to be far above the minimum necessary to provide adequate protection against re-infection from the SARS-CoV-2 virus.

Principles of Medical Ethics and George Mason University's (GMU's) Vaccine Mandate

8. There are four basic principles governing medical ethics in the United States: (1) autonomy, (2) justice, (3) beneficence, and (4) non-maleficence.

9. A highly influential public health framework proposed by Childress, et al., lists five conditions that public health interventions must satisfy: (1) effectiveness, (2) proportionality, (3) necessity, (4) least infringement, and (5) public justification.[3]

10. The principle of necessity is reinforced by the principle of "least infringement," which requires that any intervention "seek to minimize the infringement of general moral considerations." In particular, "when a policy infringes autonomy, public health agents should seek

[3] James F. Childress, et al., *Public Health Ethics: Mapping the Terrain*, 30(2) J. LAW & MED. ETHICS 170 (2002).

the least restrictive alternative; when it infringes privacy, they should seek the least intrusive alternative."[4]

11. The principle of proportionality is also a defense against one-size-fits-all approaches that can cause harm in the context of medicine.

It is Medically Unnecessary for Professor Zywicki to Undergo Vaccination Against SARS-CoV-2, and Forcing Him to Do So Would Subject Him to an Elevated Risk of Adverse Side Effects

12. It is my opinion that undergoing a full course vaccination (two doses of an mRNA vaccination or one dose of the Johnson and Johnson [J&J] vaccine) is medically unnecessary, creates a risk of harm, and provides no benefit either to Professor Zywicki or the GMU community.

13. Multiple positive antibody tests conducted over the past year have confirmed that Professor Zywicki contracted and recovered from the SARS-CoV-2 virus at some point in the past. His recent semi-quantitative antibodies screening test establish that his immune protection, as measured by his repeated antibody tests, remains quite high.

14. A series of epidemiological studies have demonstrated to a reasonable degree of medical certainty that natural immunity following infection and recovery from the SARS-CoV-2 virus provides robust and durable protection against reinfection, at levels equal to or better than the *most effective* vaccines currently available.[5]

15. For example, according to the Centers for Disease Control (CDC), in clinical trials the J&J vaccine provides an efficacy of only 66.3%—*far* below any measured efficacy of natural immunity to date.

[4] *Id.*
[5] Cites (Cleveland clinic, England, Israel, etc.); N. Kojima, et al., *Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees*, https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2 (July 8, 2021).

16. Natural immunity protection to SARS-CoV-2 has already proven long-lasting and experience with prior coronaviruses strongly indicates that T-cell immunity provided by natural immunity could last years or even decades.

17. I also believe that natural infection provides broad-based protection against current SARS-CoV-2 variants. Unlike vaccine-induced immunity, which is specialized to target the Spike-protein of the original Wuhan variant of the SARS-CoV-2 virus, natural immunity recognizes the full complement of SARS-CoV-2 proteins, enabling it to provide protection against a greater array of variants. Of course, my opinion will be subject to revision as variants arise in the future and clinical information becomes available.

18. Furthermore, based on my analysis of the clinical medical literature to date, undergoing a full course of vaccine treatment (two doses of mRNA or one dose of J&J vaccine) as required by GMU's vaccine mandate, in a setting of a prior infection and being immune, would expose Professor Zywicki to an elevated risk of adverse effects, including serious ones, when compared with individuals who have never contracted COVID-19.

19. In particular, Professor Zywicki's bout of Shingles concerns me because the causal virus, Herpes Zoster, resides in nerves and, in my opinion, can be reactivated by an unnecessary COVID-19 vaccination.

20. Any medical procedure carries the risk of adverse side effects. The SARS-CoV-2 vaccines are no exception. In many cases, the benefits of curing, mitigating, or preventing greater harm justifies undertaking a particular medical intervention notwithstanding any associated risk. But basic principles of medical ethics mandate that any potential benefits be weighed against the risks associated with the procedure.

21. Because Professor Zywicki has previously been infected with and recovered from SARS-CoV-2, in my opinion, a vaccination is unnecessary and could only subject the professor to the risk of harm.

22. Additionally, it is becoming clear that undergoing vaccination in the setting of having had a prior infection subjects him to an elevated risk of adverse side effects compared to those who have not previously been infected. Existing clinical reports indicate that individuals with a prior infection and natural immunity actually face an *elevated* risk of adverse effects from receiving the vaccine compared to those who have never contracted COVID-19.

23. According to a study in the medical journal *Life* (March 2021), "*our study links prior COVID-19 illness with an increased incidence of vaccination side effects* and demonstrates that mRNA vaccines cause milder, less frequent systemic side effects but more local reactions."[6] The elevated side effects identified in the article include events such as anaphylaxis, swelling, flu-like illness, breathlessness, fatigue, and others, some requiring hospitalization.

24. A study published in *The Lancet Infectious Diseases* (July 1, 2021) examined reports from 627,383 individuals using the COVID Symptom Study app. The authors reported a higher incidence of both systemic and local side effects from receiving the first vaccine dose for those who had previously been infected with COVID-19 compared to those who had not previously been infected.[7]

25. A study conducted at Mount Sinai Icahn School of Medicine also found among those receiving their first vaccine dose, "vaccine reactogenicity" was "substantially more pronounced in individuals with pre-existing immunity" than those who had not previously been

[6] Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, 11 LIFE 249 (Mar. 2021).
[7] Cristina Menni, *Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study*, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021).

infected and those with pre-existing immunity experienced "systemic side effects with a significantly higher frequency" than those who had not previously been infected.

26. In addition, there are numerous nonsystematic reports of individuals who have had unusually severe adverse reactions to vaccination shortly after recovering from COVID-19 infections.[8]

27. Notably many of these studies focused on the adverse effects of receiving just the *first* dose of a vaccine. They do not examine the frequency or severity of receiving a second dose of a vaccine. This uncertainly is especially important in light of the widespread recognition that those with natural immunity gain no significant benefit from receipt of a second vaccine dose (as is required by GMU's mandatory vaccination policy).

28. It is a fundamental principle of immunology that "vaccinating a person who is recently or concurrently infected can reactivate, or exacerbate, a harmful inflammatory response to the virus. This is NOT a theoretical concern."[9] This applies to SARS-CoV-2 just as it does to viruses such as shingles.

29. Notably, Professor Zywicki was specifically cautioned against receiving a shingles vaccine for several months after recovering from his shingles infection this spring. This is proper medical advice.

30. To date, none of the vaccines in current application have been systematically or adequately tested for safety or efficacy in individuals who have previously been infected and

[8] *See Multisystem Inflammatory Syndrome after SARS-CoV-2 Infection and COVID-19 Vaccination*, 27 (Number 7) EMERGING INFECTIOUS DISEASE (July 2021) (Centers for Disease Control and Prevention Dispatch); *see also* Hooman Noorchashm, *CDC Knows Vaccine Associated Critical Illness and Myocarditis are Linked to Prior COVID-19 Infections*, MEDIUM.COM (Jun 2, 2021), https://noorchashm.medium.com/cdc-knows-vaccine-associated-critical-illness-and-myocarditis-are-linked-to-prior-covid-19-62942c39c5ca.

[9] Homman Noorchashm, *The Recently Infected and Already Immune DO NOT Benefit from COVID-19 Vaccination*, MEDIUM.COM (Jun 1, 2021), https://noorchashm.medium.com/the-recently-infected-and-already-immune-do-not-benefit-from-covid-19-infection-7453886e8c89.

recovered from SARS-CoV-2. In fact, Covid survivors *have overall been largely excluded* from Phase III vaccine clinical trials.[10] Thus, any determination with respect to the safety profile of the vaccines in this population, of which Professor Zywicki is a member, can only be inferred from clinical studies in the time since the vaccines have been put into widespread application.

31. In contrast to the determination that Professor Zywicki and I have reached after consultation about the details of his personal situation and medical history, GMU is inappropriately, and in violation of the rules governing medical ethics, imposing a "one-size-fits-all" vaccine mandate on every member of the GMU community.

32. GMU does not know the details of Professor Zywicki's situation, including preexisting conditions he may have that could exacerbate the potential for adverse effects, the recentness of any COVID-19 infection, the presence of any other infections that might be relevant to his decision, and evidence of his existing immunity levels or potential for adverse effects, such as the results of any quantitative antibodies screening test.

33. GMU's vaccine mandate is forcing Professor Zywicki to choose between following his doctor's medical advice on one hand and being subject to GMU's punishment – which includes being forced to socially distance, wear a mask, and undergo frequent COVID-19 testing – on the other. No patient should be put in such a position.

34. As with all patients, Professor Zywicki and his doctors should determine his future course of medical treatment. Thus, I will continue to monitor Professor Zywicki's antibody levels as SARS-CoV-2 variants arise and/or immune protection starts to wane.

[10] *See* Fabio Angeli, *SARS-CoV-2 vaccines: Lights and shadows*, 88 EUROPEAN J. OF INTERNAL MEDICINE 1-8 (2021).

GMU's Goals in Promoting Community Safety Can Be Accomplished More Effectively and with Less Harm Through Alternative, Less-Restrictive Means

35. Protecting the GMU community from COVID-19 transmission can be achieved without exposing COVID survivors in the community to the risk of harm, in contrast to GMU's current vaccination plan.

36. The emerging consensus in the clinical literature on the protective benefits of natural immunity compared to the elevated risks of indiscriminately vaccinating these individuals has led me to start the #ScreenB4Vaccine movement.[11] #ScreenB4Vaccine contains two elements: (1) testing for the presence of natural immunity through widespread antibody testing, and (2) for those who lack natural immunity or sufficient immunity protection, to test for presence of an active infection, before vaccination.

37. In fact, growing recognition of the highly protective character of natural immunity in preventing reinfection, along with the elevated risk of vaccinating those who have natural immunity, has recently led the European Union to recognize "a record of previous infection" as a valid substitute for vaccination.[12]

38. In short, just because an individual is vaccinated does not guarantee he is immune and just because he is not vaccinated does not mean he is not immune.

39. Instead of focusing its policy on blanket vaccination, therefore, GMU's policy should instead focus on *immunity*, regardless of how it is obtained.

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[11] *See* Hooman Noorchashm, *What is #ScreenB4Vaccine? And Why Is It Necessary for Keeping Every American Maximally Safe in the COVID-19 Pandemic?* MEDIUM.COM (May 7, 2021), https://noorchashm.medium.com/what-is-screenb4vaccine-80b639c4984e.

[12] *See* Julia Buckley, *EU Digital Covid Certificate: Everything you need to know*, CNN.COM (June 9, 2021), https://www.cnn.com/travel/article/eu-covid-certificate-travel-explainer/index.html.

Conclusion

40. I call on GMU to act responsibly and, based on the principles of sound medical ethics and immunology, to recognize the importance of natural immunity in providing equal or better protection than existing vaccines. Such a policy would also acknowledge, and therefore avoid, the elevated risk of side effects from vaccination among those who have already survived a SARS-CoV-2 infection.

Respectfully submitted,

/s/ Hooman Noorchasm

Hooman Noorchashm MD, PhD.

EXHIBIT L (Maxwell v CVS, et al.)

Vaccine Administration Record (VAR)—Informed Consent for Vaccination

Walgreens

Store number: _____
Rx number: _____
Store address: _____

SECTION A Please print clearly.

First name: _____ **Last name:** _____

Date of birth: _____ **Age:** _____ **Gender:** ☐ Female ☐ Male **Phone:** _____

☐ **I wish to receive text message alerts regarding my prescriptions.**

Home address: _____ **City:** _____

State: _____ **ZIP code:** _____ **Email address:** _____

Race: ☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Black or African American ☐ White ☐ Other Race _____ ☐ Unknown

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ethnicity

Walgreens will send vaccination information from this visit to your doctor/primary care provider using the contact information provided below.

Doctor/primary care provider name: _____ **Phone:** _____

Address: _____ **City:** _____ **State:** _____ **ZIP code:** _____

I want to receive the following vaccination(s): _____

SECTION B The following questions will help us determine your eligibility to be vaccinated today.

All vaccines

1.	Do you feel sick today?	☐ Yes	☐ No	☐ Don't know
2.	Have you been diagnosed with or tested positive for COVID-19 in the last 14 days?	☐ Yes	☐ No	☐ Don't know
3.	In the past 14 days have you been identified as a close contact to someone with COVID-19?	☐ Yes	☐ No	☐ Don't know
4.	Do you have a history of allergic reaction or allergies to latex, medications, food or vaccines (examples: polyethylene glycol, polysorbate, eggs, bovine protein, gelatin, gentamicin, polymyxin, neomycin, phenol, yeast or thimerosal)? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
5.	Have you ever had a reaction after receiving a vaccination, including fainting or feeling dizzy?	☐ Yes	☐ No	☐ Don't know
6.	Have you ever had a seizure disorder for which you are on seizure medication(s), a brain disorder, Guillain-Barré syndrome (a condition that causes paralysis) or other nervous system problem?	☐ Yes	☐ No	☐ Don't know
7.	Have you received any vaccinations or skin tests in the past eight weeks? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
8.	Have you ever received the following vaccinations? ☐ Pneumonia: Date received _____ ☐ Shingles: Date received _____ ☐ Whooping cough: Date received _____			
9.	Do you have any chronic health condition such as cancer, chronic kidney disease, immunocompromised, chronic lung disease, obesity, sickle cell disease, diabetes, heart disease? If yes, please list: _____	☐ Yes	☐ No	☐ Don't know
10.	For women: Are you pregnant or considering becoming pregnant in the next month?	☐ Yes	☐ No	☐ Don't know
11.	**For COVID-19 vaccine only**: Have you been treated with antibody therapy specifically for COVID-19 (monoclonal antibodies or convalescent plasma)?	☐ Yes	☐ No	☐ Don't know

For chickenpox, MMR® II, shingles, Vaxchora®, yellow fever only:
Answer the following questions only if you are receiving any vaccinations listed above.

12.	Do you have a condition that may weaken your immune system (e.g., cancer, leukemia, lymphoma, HIV/AIDS, transplant)?	☐ Yes	☐ No	☐ Don't know
13.	Are you currently on home infusions, weekly injections such as Humira® (adalimumab), Remicade® (infliximab) or Enbrel® (etanercept), high-dose methotrexate, azathioprine or 6-mercaptopurine, antivirals, anticancer drugs or radiation treatments?	☐ Yes	☐ No	☐ Don't know
14.	Are you currently taking high-dose steroid therapy (prednisone > 20mg/day or equivalent) for longer than 2 weeks?	☐ Yes	☐ No	☐ Don't know
15.	Have you received a transfusion of blood or blood products or been given a medication called immune (gamma) globulin in the past year?	☐ Yes	☐ No	☐ Don't know
16.	Do you have a history of thymus disease (including myasthenia gravis, DiGeorge syndrome or thymoma), or had your thymus removed? (yellow fever only)	☐ Yes	☐ No	☐ Don't know
17.	Do you have a history of thrombocytopenia or thrombocytopenic purpura? (MMR only)	☐ Yes	☐ No	☐ Don't know
18.	Have you consumed any food or drink in the last hour? (Vaxchora® only)	☐ Yes	☐ No	☐ Don't know
19.	Have you taken antibiotics in the last 14 days or antimalarials in the last 10 days? (Vaxchora® only)	☐ Yes	☐ No	☐ Don't know

SECTION C

I certify that I am: (a) the patient and at least 18 years of age; (b) the legal guardian of the patient; or (c) a person authorized to consent on behalf of the patient where the patient is not otherwise competent or unable to consent for themselves. Further, I hereby give my consent to Walgreens or Duane Reade and the licensed healthcare professional administering the vaccine, as applicable (each an "applicable Provider"), to administer the vaccine(s) I have requested above. I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine(s) and have received, read and/or had explained to me the EUA Fact Sheet on the vaccine(s) I have elected to receive. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. Further, I acknowledge that I have been advised that the patient should remain near the vaccination location for observation for approximately 15 minutes after administration. On behalf of the patient, the patient's heirs and personal representatives, I hereby release and hold harmless each applicable Provider, its staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of the vaccine(s) listed above. I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registry ("State Registry") and my state's health information exchange ("State HIE"); and (b) the applicable Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, or to any state or federal governmental agencies or authorities ("Government Agencies"), such as state, county, or local Departments of Health or the federal Department of Health and Human Services, the Centers for Disease Control and Prevention, or their respective designees as may be required by law, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination. I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the applicable Provider: (a) the disclosure of my vaccination information by the applicable Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The applicable Provider will, if my state permits, provide me with an Opt-Out Form. I understand that, depending on my state's law, I may need to specifically consent, and, to the extent required by my state's law, by signing below, I hereby do consent to the applicable Provider reporting my vaccination information to the Government Agencies, State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent form. Unless I provide the applicable Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the applicable Provider and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws or federal law may permit certain disclosures of my vaccination information to or through the State HIE or to Government Agencies as required or permitted by law. I further authorize the applicable Provider to: (a) release my medical or other information, including any communicable disease (including HIV) and mental health information, to, or through, the State HIE or Government Agencies to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment; (b) submit a claim to my insurer for the above requested items and services; and (c) request payment of authorized benefits be made on my behalf to the applicable Provider with respect to the above requested items and services. I further agree to be fully financially responsible for any cost-sharing amounts, including copays, coinsurance and deductibles, for the requested items and services, as well as for any requested items and services not covered by my insurance benefits. I understand that any payment for which I am financially responsible is due at the time of service or, if the applicable Provider invoices me after the time of service, upon receipt of such invoice. Walgreens or its affiliates may contact you, including by autodialed and prerecorded calls and texts, at any time, using the contact information provided in your patient record regarding health and safety matters, such as vaccine reminders.

Patient signature: _____ **Date:** _____

(Parent or guardian, if minor)

SECTION D INSURANCE–PATIENT OR AUTHORIZED PERSON TO COMPLETE

Please ensure to record BOTH pharmacy AND medical insurance information since there are multiple ways vaccinations can be billed at Walgreens.

	Pharmacy card	Medical card
Insurance Plan/Plan ID:		
Member/Recipient ID #:		
RX BIN:		N/A
RX PCN:		N/A
Group Number:		

Are you the cardholder? ☐ Yes ☐ No
If no, please provide cardholder's name, date of birth (MM/DD/YYY) and relationship:

_____

Medicare	Medicare Part B
Medicare number:*	
Last 4 digits of SSN:†	

*Number on the red, white and blue Medicare card.
†For insurance confirmation purposes only.

COVID-19 VACCINATION ONLY

If uninsured: I attest that I do not have any medical or pharmacy insurance. ☐ Yes

Drivers license/State ID number* (circle one) _____ Issuing state: _____
*For verification and coverage Initial here: _____

Healthcare provider only: Individual refused to provide insurance information when I attempted to obtain the insurance information from the individual. ☐ Yes

SECTION E HEALTHCARE PROVIDER ONLY

Complete <u>BEFORE</u> vaccine administration

1. I have reviewed the **Patient Information and Screening Questions.** Initial here: _____
2. I have verified that this is the **vaccine requested** by the patient. Initial here: _____
3. This vaccine is appropriate for this patient based on the **Age Guidelines** provided by federal and/or state regulations and company policies. Initial here: _____
   3a. Does this patient have a high-risk medical condition? ☐ Yes ☐ No
   If yes, please list medical condition(s): _____
4. I have discussed with the patient additional immunizations the patient may be eligible for based on age and/or health conditions Initial here: _____
5. The **Vaccine NDC matches** the NDC on the bottom of this VAR form and the NDC on the patient leaflet. (**Perform 3-way NDC match**.) Initial here: _____
6. I have verified the **Expiration Date** is greater than today's date and have entered the **Lot # and Expiration Date** in the field below. Initial here: _____
7. I have made every attempt to obtain and confirm patient insurance information Initial here: _____

For COVID-19, Shingrix®, MMR® II, Varivax®, YF-Vax®, Menveo®, Imovax®, Vaxchora® and RabAvert®, ensure the vaccine is reconstituted following the package insert's instructions.

SECTION F

Complete <u>DURING</u> the patient interaction

1. I have asked the patient to confirm their **Name, DOB and Requested Vaccine** and verified it matches the information on the VAR form. Initial here: _____
2. I have reviewed the **Screening Questions** with the patient. Initial here: _____
3. I have reviewed the **VIS/Patient Fact Sheet** with the patient. Initial here: _____

SECTION G

Complete <u>AFTER</u> vaccine administration

Vaccine	NDC	Manufacturer	Dosage	Dose # (if applicable)	Site of Administration	Vaccine Lot #	Vaccine Expiration	Diluent Lot # (if applicable)	Diluent Expiration (if applicable)	VIS/Patient Fact Sheet Published Date

Clinician's name (print): _____ **Clinician signature:** _____ **Title:** _____
If applicable, intern/tech name (print): _____ **Administration date:** _____
Date EUA Fact Sheet/VIS given to patient: _____

Notes

_____
_____
_____

Reminder

1. Update the patient's record with any new allergy, health condition or primary care provider information.
2. Enter vaccine lot #, expiration date and site of administration, then scan the VAR form into the patient's record.

EXHIBIT M (Maxwell v CVS, et al.)

COVID Vaccine Intake Consent Form

Version 3 Form 1 of 2 to be completed

CVS pharmacy

Clinic Information

Clinic ID | Clinic Name | Telephone | Store Number

Address | City | State | Zip

Patient Information

Last Name | First Name | Date of Birth | Gender

Address | City | State | Zip

Primary Care Provider (PCP) Name | PCP Phone Number | PCP Fax Number

PCP Address | City | State | Zip

Are you a resident ◯ of a Long Term Care facility or an employee/staff member ◯ ?

Is this the patient's first ◯ or second ◯ dose of the COVID-19 vaccination?

Insurance Information: (For onsite clinics, please ensure a copy of the patient's insurance card(s) was collected)

*** INDICATES REQUIRED FIELDS**

Prescription Insurance: ◯ Yes ◯ No

*Are you the primary cardholder? | ***If no**, include the primary cardholder's DOB

*Prescription Benefit Plan Name | *Cardholder ID # | *RX Group ID | *BIN | *PCN

Medicare Fields:

◯ Yes ◯ No

*Is the Patient age 65 or older or Medicare Eligible?

*Medicare Part A/B ID Number (MBI) **Note:** *MBI is required for all patients age 65 and older, or Medicare eligible. Refer to your Medicare Red, White, and Blue card*

Medical Insurance:

*Medical Insurance Provider | *Cardholder ID # | *Group ID | *Payer ID

◯ Yes ◯ No

*Is the patient the primary cardholder? | ***If no**, include primary cardholder's DOB

***If uninsured, you must check the box below to attest that the following information is true and accurate:**

◯ I I do not have any insurance, including but not limited to Medicare, Medicaid or any other private or government-funded health benefit plan.

In order to have your vaccine administration fee paid for by the United States Health Resources & Services Administration's COVID-19 Program for Uninsured Patients, please provide either (a) a valid Social Security number, (b) state identification number and state of issuance, OR (c) a driver's license number and the state of issuance.

*Social Security Number | or State Identification Number & State | or Driver's License Number & State

Potential Contraindications

	YES	NO	DON'T KNOW
1. Are you feeling sick today?	◯	◯	◯
2. Have you ever received a dose of COVID-19 vaccine? **If yes**, which vaccine product? ◯ Pfizer ◯ Moderna ◯ Another product: _____	◯	◯	◯
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) in the past? *Example: a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?*	◯	◯	◯
Was the severe allergic reaction after receiving a COVID-19 vaccine?	◯	◯	◯
Was the severe allergic reaction after receiving another vaccine or injectable medication?	◯	◯	◯
Was the severe allergic reaction related to receiving Polyethylene Glycol or products containing Polyethylene Glycol?	◯	◯	◯
Was the severe allergic reaction related to receiving Polysorbate or products containing Polysorbate?	◯	◯	◯

Version 3 **Form 2 of 2 to be completed**

Last Name | First Name | Date of Birth

Potential Contraindications continued

	YES	NO	DON'T KNOW
4. Have you received any vaccines in the past 14 days?	◯	◯	◯
5. Have you received monoclonal antibodies or convalescent plasma as part of a COVID-19 treatment in the past 90 days?	◯	◯	◯

Potential Considerations

	YES	NO	DON'T KNOW
6. Do you have a bleeding disorder or are you taking a blood thinner?	◯	◯	◯
7. For women, are you currently pregnant or breastfeeding?	◯	◯	◯

CONSENT FOR SERVICES: I have been provided with the Vaccine Information Sheet(s) or patient fact sheet corresponding to the vaccine(s) that I am receiving. I have read the information provided about the vaccine I am to receive. I have had the chance to ask questions that were answered to my satisfaction. I understand the benefits and risks of vaccination and I voluntarily assume full responsibility for any reactions that may result. I understand that I should remain in the vaccine administration area for 15 minutes after the vaccination to be monitored for any potential adverse reactions. I understand if I experience side effects that I should do the following: call pharmacy, contact doctor, call 911. I request that the vaccine be given to me or to the person named above for whom I am authorized to make this request. State of Georgia only: I verify a pharmacist asked for my health history and whether I have had a physical exam within the past year. Health care providers did not identify condition(s) that would mean I should not receive vaccine(s).

AUTHORIZATION TO REQUEST PAYMENT: I do hereby authorize CVS Pharmacy® ("CVS®") to release information and request payment. I certify that the information given by me in applying for payment under Medicare or Medicaid, or the HRSA COVID-19 Program for Uninsured Patients, is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

DISCLOSURE OF RECORDS: I understand that CVS® may be required to or may voluntarily disclose my health information to the physician responsible for this protocol of specific health information of people vaccinated at CVS (if applicable), my Primary Care Physician (if I have one), my insurance plan, health systems and hospitals, and/or state or federal registries, for purposes of treatment, payment or other health care operations (such as administration or quality assurance). I also understand that CVS will use and disclose my health information as set forth in the CVS Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy). State of California only: I agree to have CAIR share my immunization data with Health Care Providers, agencies or schools. Vaccine Clinics: If I am receiving a vaccine through a vaccine clinic, I understand that my name, vaccine appointment date and time will be provided to the clinic coordinator.

X

Signature of patient to receive vaccine (or parent, guardian, or authorized representative) Date

If signing on behalf of the patient, you are stating that you are authorized to provide the required consents on behalf of the patient.

Name of parent, guardian, or authorized representative | Phone Number | Relationship

Vaccine Administration Information for Immunizer/Pharmacist use only

Administration Date | Vaccine | VIS Date | Manufacturer ◯ L ◯ R | Volume (mL)

Lot # | Exp. Date | Route | Site

If patient's body temperature is 100.4˚F or greater, inform them they should not receive the vaccine at this time.

Patient Temperature

Administering Immunizer Name & Title | Administering Immunizer Signature

To be filled out by immunizer, as required for state immunization registry reporting. Only for states listed.

MS: Check all fields for patients 18 years of age and younger

OK: Check Race and Ethnicity for all patients. Select Next of Kin for patients 18 years of age and younger.

Race: ◯ **1** - American Indian or Alaska Native ◯ **2** - Asian ◯ **3** - Native Hawaiian/Other Pacific Islander ◯ **4** - Black or African American ◯ **5** - White ◯ **6** - Other Race

Ethnicity: ◯ **1** - Hispanic ◯ **2** - Not Hispanic or Latino ◯ **3** - Unknown

Next of Kin (18 or younger)

Name | Phone Number | Relationship

Address

State of NJ only

Prescriber Name | Prescriber Address

For CA, MA, MT, NJ, NM, NY, TX (For CA, this indicator means the registry will not share with Universities, Schools or other agencies) **Registry Sharing Indicator:** ◯ Yes ◯ No

EXHIBIT N (Maxwell v CVS, et al.)

COVID-19 VACCINE ADMINISTRATION FORM

SECTION 1 – INFORMATION ABOUT THE PERSON RECEIVING THE VACCINE

Name: _____ Date of Birth: _____ / _____ / _____ Age: _____

Phone: (_____)_____ ☐ This is a mobile phone ☐ I wish to receive text message alerts regarding my vaccine(s) -OR-

Email address: _____ ☐ I wish to receive email alerts regarding my vaccine(s)

Address: _____ City: _____

County: _____ State: _____ Zip Code: _____

Have you ever received a COVID-19 vaccine? ☐ Yes ☐ No If yes, manufacturer name: _____ Date received: _____

Race: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Other ☐ Prefer not to disclose

Gender: ☐ Male ☐ Female ☐ Other

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Prefer not to disclose

H-E-B Pharmacy will contact your primary care provider informing them of vaccine(s) given today using the information provided below

Primary Care Provider Name: _____ Phone: (_____)_____ Fax: (_____)_____

SECTION 2A – QUESTIONS TO DETERMINE VACCINE ELIGIBILITY (circle YES or NO)

1. Do you currently have COVID-19 or have you had it in the last 90 days?	YES	NO
2. Have you been treated with antibody therapy specifically for COVID-19 (monoclonal antibodies or convalescent plasma)?	YES	NO
3. Are you sick today or do you have any of these symptoms: fever, chills, shortness of breath, body aches, loss of taste/smell	YES	NO
4. Have you ever had an anaphylactic reaction, serious allergic reaction, or any other serious reaction to a vaccine?	YES	NO
5. Have you had any vaccinations in the past 14 days?	YES	NO

SECTION 2B – CLINICAL CONSIDERATIONS (circle YES or NO)

6. Are you pregnant or breastfeeding?	YES	NO
7. Are you immunocompromised or taking medications that affect your immune system?	YES	NO
8. Are you taking blood-thinning medications or do you have a bleeding disorder?	YES	NO

SECTION 3 – PLEASE READ CAREFULLY AND ACKNOWLEDGE WHERE APPROPRIATE

I hereby give my consent to the H-E-B Pharmacy ("H-E-B") to administer the vaccine(s) (the "Services") I have requested below. Section Date: Dec 2020

With my initials, I certify that:

_____ I am: (i) the Patient and at least 18 years of age; (ii) the parent or guardian of the minor Patient; or (iii) the legal guardian of the Patient; or (iv) a person authorized under the law of another state or a court order to consent for the child; OR

_____ The persons identified under (ii), (iii), or (iv), in the preceding sentence are unavailable and I have authority to consent to the immunization of the child because I am a (i) grandparent; (ii) adult brother or sister; (iii) adult aunt or uncle; (iv) stepparent; or (v) another adult who has actual care, control, and possession of the child and has written authorization to consent for the child from a parent, managing conservator, guardian, or other person who, under the law of another state or a court order, may consent for the child; additionally, I certify that I do not have knowledge of any express refusals or withdrawn authorizations of consent and have not been told not to give consent for the child.

I understand that any Protected Health Information ("PHI") I provide H-E-B will only be used or disclosed by H-E-B in accordance with H-E-B's Health Insurance Portability and Accountability Act ("HIPAA") Notice of Privacy Practices. By signing below I acknowledge receipt of such HIPAA Notices of Privacy Practices and consent to the uses and disclosures of PHI described therein. While H-E-B reserves the right to not do so, I consent to H-E-B reporting my immunization information to the State Immunization Registry. Should H-E-B elect to report my immunization history to the Texas central immunization registry, ImmTrac, I further understand that my immunization information may be accessed by other health care providers, educators, public health representatives, state agencies and certain insurance payers. I further authorize H-E-B to (1) release my medical or other information to my healthcare professionals, Medicare, Medicaid, or other third-party payer as necessary to effectuate care or payment or otherwise, (2) submit a claim to my insurer for the below requested items and services, and (3) request payment of authorized benefits be made on my behalf to H-E-B with respect to the below requested items and services.

NOT A SUBSTITUTE FOR A PHYSICIAN

I understand that H-E-B Pharmacy representatives are not physicians trained to diagnose and treat medical problems. I acknowledge that the administration of Services does not constitute, and should not be interpreted as, medical advice or opinions substituting for the advice of a physician. I understand that the administration of Services does not create a doctor-patient relationship between myself and H-E-B. I agree to consult a physician if I require medical advice or services at any time.

RELEASE, IMDEMNITY AND DISCLAIMER

I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s), including novel COVID-19 vaccine(s). I understand the risks and benefits associated with novel vaccine(s) and elect to receive a COVID-19 vaccine. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. I additionally acknowledge that I have received a copy of the H-E-B Pharmacy notice of privacy. Further, I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering health care provider. I understand that in the course of the requested vaccine administration, an H-E-B Pharmacy representative could possibly be exposed to my blood or bodily fluids. In such event, I agree to review and execute the "H-E-B Post-exposure Consent for Testing" form.

On behalf of myself, my heirs and personal representatives, I further hereby WAIVE, RELEASE, and AGREE TO INDEMNIFY, DEFEND AND HOLD HARMLESS (including for costs and attorney's fees) H-E-B, its staff, agents, employees and corporate affiliates from any and all liabilities or claims whether known or unknown arising out of, in connection with, or in any way related to the administration of COVID-19 vaccine(s) and related services, even should such damages or losses result from H-E-B's negligence.

I have received, read and/or had explained to me the Emergency Use Authorization Fact Sheet or the Vaccination Information Statement for the vaccine I have elected to receive.

Patient Signature: _____ **Date:** _____
(Parent or Legal Guardian, if minor)

SECTION 4 – INSURANCE INFORMATION

Please record both pharmacy and medical insurance information:

	PHARMACY CARD	MEDICAL CARD
Plan/Carrier Name		
Member ID #		
Group #		
RX BIN		Not applicable
RX PCN		Not applicable

Policy Holder Name (if different):

_____

Policy Holder Date of Birth: _____

FOR MEDICARE PART B:

	MEDICARE PART B
Medicare Number*	
Last 4 digits of SSN**	

*number on red, white, & blue Medicare card

**for insurance verification, if needed

MEDICARE STATEMENT: I request that payment of authorized Medicare benefits be made either to me or on my behalf to HEB Pharmacy for any service furnished to me by HEB Pharmacy. I authorize release to the Centers for Medicare and Medicaid Services and its agents any medical information about me needed to determine the payments for related services.

Name of Beneficiary: _____

Signature: _____ **Date**: _____

IF UNINSURED:

I attest that I do not have any medical or pharmacy insurance. ☐Yes

Social Security Number: _____-_____-_____ (this is needed by the federal government if you do not have health insurance)

SECTION 5 – PHARMACY USE ONLY

Temperature checked by (Partner initials): _____

Vaccine	Amount Administered	Manufacturer	Dose # (circle)	Route	Lot Number / Expiration Date	Site of Administration*	Reviewed Vaccine Complete (initial)
COVID-19 vaccine	0.3 ml	Pfizer	1 or 2	IM		RD LD	Initial here
COVID-19 vaccine	0.5 ml	Moderna	1 or 2	IM		RD LD	Initial here
COVID-19 vaccine	0.5 ml	Janssen	1 only	IM		RD LD	Initial here
COVID-19 vaccine						RD LD	Initial here

* RD - Right Deltoid, LD - Left Deltoid, RA - Right Arm, LA - Left Arm

Vaccine Information

Pfizer – 2 shot series at 0 and 21 days, authorized for 16 years of age and older
Moderna – 2 shot series at 0 and 28 days, authorized for 18 years of age and older
Janssen (Johnson & Johnson) – single shot (1 dose), authorized for 18 years of age and older

H-E-B Pharmacy Location	To Be Completed by Pharmacist	Technician Immunizer (if applicable)
Corp #:	Pharmacist Initials: _____	Immunizer Initials: _____
Address:	TX License #: _____	TX Registration #: _____
City, State:	Signature: _____	Signature: _____
	Clinic Location: _____	
	Date of Immunization: _____ **Next Dose Due Date:** _____	

Step 5

Vaccine Consent

EXHIBIT O (Maxwell v CVS, et al.)

I hereby give my consent to the health care provider of The Kroger Co., its affiliates and subsidiaries, to administer the vaccine(s) I have requested above. I understand the risks and benefits associated with the vaccine(s) being administered and have received, read and/or had explained to me the CDC's Vaccine Information Statement (VIS) or the FDA's Emergency Use Authorization (EUA) on the vaccine(s) I have elected to receive. I have had the opportunity to ask questions that were answered to my satisfaction. As with all medical treatment, there is no guarantee that I will not experience an adverse reaction from the vaccine. I understand that the information contained on this form may be shared with the Stated Health Division (SHD) and/or state immunization registries and will remain confidential and will not be released except as permitted or required by law. If eligible, I authorize Kroger to submit a claim for reimbursement on my behalf to Medicare or any other contracted third party payor. If the claim is denied, I understand that I will be responsible for payment. I understand if my claim to the HRSA Uninsured Fund is not reimbursed because it is determined that I have third-party insurance, I authorize The Kroger Co. to utilize my protected health information and other identifiers to try to identify and bill my insurance. I acknowledge that I have received a copy of the Notice of Privacy Practices. Furthermore, I agree to remain near the vaccination location for approximately 15-30 minutes after administration for observation by the administering Healthcare Provider.

☐ I accept the consent

☐ I have read and agree to the Terms of use and Notice of Privacy Practices.

Patient's Legal Name

Date

10/19/2021

Full Name of Legal Guardian or Power of Attorney (If Applicable)

Relationship (If Applicable)

Relationship ex. mother

Submit to confirm your appointments.

Submit

Back

Patient consent

EXHIBIT P (Maxwell v CVS, et al.)

Acknowledgement of notice receipt

Consent for vaccine administration

I hereby give my consent to Walmart, on behalf of myself and/or my minor dependent as applicable, to administer the medications(s) I have requested above. I understand the benefits and risks of receiving this medication and have received, read and/or had explained to me the Vaccine Information Statement and/or Vaccine Patient Fact Sheet for the vaccine(s) I have elected to receive. I acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. I acknowledge that I, and/or my minor dependent, have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation by the administering healthcare provider. On behalf of myself, my heirs, and personal representatives, I fully release and discharge Walmart, its staff, agents, successor, division, affiliates, officers, directors, contractors, and

☐ I consent to the treatment

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Feedback

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