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ERICH SMITH, FRANK E. GARWOOD, JR., MARIBEL LORENZO, and Dr. DANIEL DONOFRIO Plaintiffs, vs. PRESIDENT JOSEPH R. BIDEN, JR. (in his official capacity and any successor to the Office of the President) Defendants.	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CIVIL ACTION **AMENDED VERIFIED COMPLAINT FOR DELCARATORY AND INJUNCTIVE RELIEF**

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Erich Smith, Frank E. Garwood, Jr., Maribel Lorenzo, and Dr. Daniel Donofrio by and through their counsel file this action against Defendant President Joseph R. Biden in his official capacity as President of the United States, and any successors to the Office of President who continue the actions complained of within, as follows:

INTRODUCTION

1. This is a civil action for declaratory and injunctive relief arising under the Fifth Amendment to the United States Constitution.
2. It concerns the constitutionality of the "vaccine mandates" enacted pursuant to Executive Order 14043 ("EO 14043") and

Executive Order 14042 ("EO 14042").

3. The Executive Orders, as written and as applied, violate the liberty and privacy rights protected by the Fifth Amendment to the U.S. Constitution, including the right to refuse medical procedures and the right to protect private medical information.
4. All individuals subject to EO 14043 are required to receive a final injection by November 8, 2021.
5. All individuals subject to EO 14042 are required to receive a final injection by November 10, 2021.

JURISDICTION AND VENUE

6. This action arises under the Fifth Amendment to the U.S. Constitution.
7. This Court has jurisdiction over all claims pursuant to the Declaratory Judgment Act as codified at 28 *U.S.C.* Sections 2201 and 2202.
8. Venue is proper under 28 *U.S.C.* Section 1391(e)(1) because Defendant is an officer of the United States acting in his official capacity, Plaintiffs are located in this District, and a substantial part of the events giving rise the action occurred in this District.

PARTIES

9. Plaintiffs Erich Smith, Frank E. Garwood, Jr., and Dr. Daniel Donofrio are Federal Employees and subject to

Executive Order 14043.

10. Plaintiff Maribel Lorenzo is an employee of Horizon BlueCross BlueShield and is subject to Executive Order 14042.

11. Defendant President Joseph R. Biden is the president of the United States and it was under his purported authority that The Mandates were issued.

FACTUAL BACKGROUND

I. The President Announced the Mandates

12. On September 9, 2021 President Joseph Biden gave a national speech announcing "vaccine" mandates for more than 100 million Americans. Exhibit 1 (transcript of the speech as transcribed by the New York Times).

13. The speech divided Americans into two groups: "the vaccinated" and "the unvaccinated."

14. The President held "the vaccinated" up as having done "the right thing," while he vilified "the unvaccinated" for making a personal choice to not undergo a medical procedure the president wants them to undergo, namely injection with one of the so-called Covid-19 vaccines.

15. In his speech, the President implied and stated outright that "the unvaccinated" are a danger to others and society at large:

a. He stated that the unvaccinated "can cause a lot of

damage, and they are."

b. He blamed the unvaccinated for failures of the healthcare system stating "[t]he unvaccinated overcrowd our hospitals or overrun the emergency rooms and intensive care units, leaving no room for someone with a heart attack or pancreatitis or cancer."

c. He stated that the unvaccinated have harmed the vaccinated: "your refusal has cost all of us."

d. He stated that the vaccinated need to be protected from the unvaccinated: "We're going to protect vaccinated workers from unvaccinated co-workers."

e. He blamed the unvaccinated for impending economic problems: "We cannot let unvaccinated do this [economic] progress — undo it."

f. He blamed the unvaccinated for the virus still existing and people dying: "[A] distinct minority of Americans, supported by a distinct minority of elected officials, *are keeping us from turning the corner.* These pandemic politics, as I refer to, are making people sick, causing unvaccinated people to die."

g. He labeled the unvaccinated as "those blocking public health."

h. He blamed the unvaccinated group's "failures" for a variety of societal ills, including the pandemic

itself:

> This is a pandemic of the unvaccinated. And it's caused by the fact that despite America having unprecedented and successful vaccination program — despite the fact that for almost five months, free vaccines have been available in 80,000 different locations — we still have nearly 80 million Americans who have failed to get the shot.

16. Unsurprisingly, given the range of ills laid at the feet of the unvaccinated, the President told the nation that the group he favors and to which he belongs, the vaccinated, are feeling strong negative emotions toward the unvaccinated. He sympathized with and condoned those negative emotions between groups of Americans who have made different medical decisions about their bodies.

17. He condoned anger of the vaccinated against the unvaccinated stating "[t]he vast majority of you who have gotten vaccinated, I understand your anger at those who haven't gotten vaccinated."

18. He condoned feelings frustration from the vaccinated toward the unvaccinated: "Many of us are frustrated with the nearly 80 million Americans who are still not vaccinated..."

19. He warned that he and others in the vaccinated group are losing patience with the unvaccinated: "We've been patient,

but our patience is wearing thin."

20. In the same speech where he vowed to "protect vaccinated workers from unvaccinated co-workers" he repeatedly stated that if people had received the so-called vaccines, they are already protected, raising questions as to why the vaccinated need to be protected from the unvaccinated. Specifically, he stated:

    a. "I want to emphasize that the vaccines provide very strong protection from Covid-19. I know there's a lot of confusion and misinformation, but the world's leading scientists confirm that if you're fully vaccinated, your risk of severe illness from Covid-19 is very low."

    b. "[A]s the science makes clear, if you're fully vaccinated, you're highly protected from severe illness even if you get Covid-19."

21. The President's speech culminated with the announcement of a number of "vaccine mandates" intended to coerce people who have chosen not to take any of the so-called vaccines into submitting to his will under the threat of losing their livelihood.

22. In announcing the mandates, the President was very clear that his goal is to coerce the largest number of people as possible into submitting to the medical procedure the

government wants them to undergo.

23. He described the mandates as intended to "*combat* those blocking public health." (emphasis added)

24. He told those who have not yet submitted that "the time for waiting is over."

25. He dismissed the individual liberty to decline medical procedures, stating that this "is not about freedom or personal choice."

26. He told "100 million Americans — two-thirds of all workers" that they will be shut out from a huge portion of the economy and job market if they do not submit to the government's demand that they undergo the medical procedure: "If you want to work with the federal government and do business with us, get vaccinated.

27. He directed private employers to coerce their employees into submitting to the shot: "If you want to do business with the federal government, vaccinate your work force."

28. In short, the President blamed a specific group of Americans, the unvaccinated, for a variety of societal ills, stoked anger and frustration toward the unvaccinated, said that unvaccinated Americans are a danger to others, and then told unvaccinated Americans that they must undergo a medical procedure the US Government wants them to undergo or lose their jobs.

II. The Nature of the Mandated Pharmaceuticals

29. The Mandates require people to undergo the medical procedure of being injected with one of three pharmaceutical products authorized for "emergency use" by the Food and Drug Administration ("the FDA").

30. The three products are produced by Pfizer Inc. ("Pfizer"), Moderna, and Johnson and Johnson subsidiary Janssen ("J&J").

31. The pharmaceuticals mandated by the President are almost universally called "vaccines," but it is not clear how they came to be categorized as "vaccines" because they do not fall under any relevant statutory definition or traditional dictionary definition of the word "vaccine."

32. The word "vaccine" is not defined in the Vaccination Assistance Act, the first national statute concerning vaccination, or the National Childhood Vaccine Injury Act.

33. In most dictionaries "vaccines" are defined by two factors: 1) their composition and 2) their mechanism of action.

34. The composition part of the definition has expanded as technology has progressed.

35. Most dictionary definitions from 1905 to the present encompass within the composition of "vaccine" substances that contain: the vaccinia virus, whole microorganisms, or

structural parts of microorganisms.

36. The pharmaceuticals being mandated by the President are not composed of the vaccinia virus, microorganisms, or structural parts of microorganisms.

37. They are excluded from these dictionary definitions of the word "vaccine" because their composition is outside the defined parameters.

38. Instead, the mandated pharmaceuticals are composed of genetic material. The Pfizer and Moderna products are composed of synthetic nucleoside-modified mRNA that has swapped out the nucleic acid uracil with "the non-natural RNA nucleobase N1-methylpseudouridine which enhances immune evasion and protein production." Exhibit 2

39. The mRNA in the Pfizer and Moderna pharmaceuticals encode for the spike protein, but the mRNA is not the same as the viral mRNA due to these alterations to the genetic code.

40. The Johnson and Johnson product is composed of DNA, which is also genetic material, but not the same genetic material of the Sars-Cov2 coronavirus.

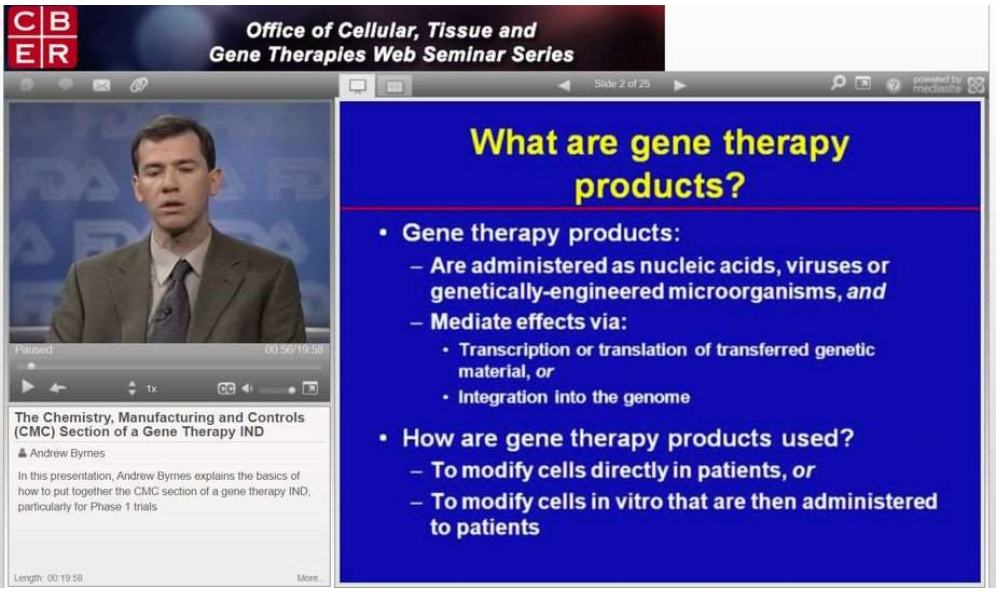
41. All three of the mandated pharmaceuticals mediate effects *via* the transferred genetic materials through translation (mRNA) or transcription (DNA) into the eventual spike protein. Exhibit 3.

42. The mandated pharmaceuticals do not fall under the dictionary definitions of "vaccine" because they are excluded by their composition, but they do fall under the FDA Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products."

43. The Office of Cellular, Tissue, and Gene Therapies defines gene therapy products by their composition and mechanism of action.

a. The composition is: "nucleic acids, viruses or genetically-engineered microorganism;

b. The mechanism of action is to "mediate effects via: transcription or translation of the transferred genetic material..."



44. The Pfizer and Moderna products are administered as synthetic RNA, which is a nucleic acid, and mediate effects

by translation of that nucleic acid into a spike protein. Exhibit 3.

45. Moderna's S-1 statement confirms that the FDA regulates mRNA products as gene therapy products. Exhibit 4.

46. The J&J product is administered as DNA, which is a nucleic acid, and mediates effects by transcription of that DNA into mRNA and then translation of the mRNA into the spike protein. Exhibit 3.

47. The Pfizer, Moderna, and J&J products are gene therapy products (hereinafter "the GTPs").

48. It is not known how long or how well the GTPs work to prevent viral transmission of Sars-Cov2. Information is being learned in real time.

49. The Fact Sheets for Recipients for each of the GTPs states that there are known and unknown side effects that may occur. "Fact Sheet for Recipients and Caregivers" for Pfizer, Moderna, and J&J are attached here to as Exhibits 5, 6, and 7 respectively.

50. Data from the clinical trials shows that most people experience systemic illness following injection of the GTPs. The CDC reports on "Local reactions, Systemics Reactions, Adverse Events, and Serious Adverse Events" for Pfizer, Moderna, and J&J are attached hereto as Exhibits 8, 9, and 10 respectively.

III. The Corporations Manufacturing the GTPS

51. Pfizer, Johnson and Johnson, and their subsidiaries have significant criminal records.

52. In 2009, Pfizer and its subsidiary Pharmacia & Upjohn Company Inc. agreed to pay $2.3 billion to settle criminal charges and civil claims that they:

a. illegally "promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns";

b. Illegally promoted three other drugs;

c. submitted false claims to government health care programs in contravention to the False Claims Act; and

d. Paid kickbacks to health care providers.

Exhibit 11.

53. In 2012 Pfizer settled charges brought by the Securities and Exchange Commission that Pfizer violated the Foreign Corrupt Practices Act by bribing doctors and other health care professionals employed by foreign governments. Exhibit 12.

54. In 2011 Pfizer paid $14.5 million to resolve government charges that it violated the False Claims Act by illegally promoting the drug Detrol. Exhibit 13.

55. In 2009 Pfizer paid $75 million to settle criminal and

civil charges with the Nigerian government that it experimented on children. Exhibit 14.

56. This is just a sampling of criminal and civil charges lodged against Pfizer by the federal government; there are more.

57. Johnson and Johnson and its subsidiaries also have significant criminal records and prominent drug and medical product safety failures.

58. In 2013, Johnson and Johnson and its subsidiaries paid more than $2.2 Billion to settle criminal and civil charges that they promoted drugs for uses not approved as safe by the FDA and paid kickbacks to doctors and pharmacy providers. Exhibit 15.

59. In its press release announcing the settlement, the DOJ stated that J&J and its subsidiaries had "jeopardized the health and safety of patients and damaged the public trust" and referred to them as "companies that corrupt our health care system." Exhibit 15.

60. J&J subsidiary Janssen was charged by the US Government for promoting a drug for off-label and unapproved uses, making false and misleading statements about the safety and efficacy of its drug, and paying kickbacks to doctors. The government stated that Janssen's behavior "threatened the most vulnerable populations of our society, children,

the elderly and those with developmental disabilities." *Id.*

61. Forty states sued J&J and its subsidiary Ethicon for "misrepresenting the safety and efficacy" and "failing to sufficiently disclose risks" of vaginal mesh devices, which seriously injured thousands of women. Exhibit 16.

62. J&J paid a $21.4 million criminal penalty to resolve criminal charges that its subsidiaries violated the Foreign Corrupt Practices Act by bribing foreign government officials and doctors. Exhibit 17.

63. One J&J subsidiary pled guilty to causing contaminated infant and children's medicine to enter interstate commerce and failing to remedy the contamination when it was made aware of it. Exhibit 18.

64. Another J&J subsidiary was fined for obstructing justice and "corruptly persuading others" to shred evidential documents. Exhibit 19.

65. This is just a sampling of Johnson and Johnson and its subsidiaries' criminal records.

66. Moderna has no track record at all as it has never brought a product to market before and has never had a product approved by the FDA.

67. The Food and Drug Administration, the federal agency charged with overseeing the safety and efficacy of the GTPs

has a history of failing to prevent the public from dangerous pharmaceuticals.

IV. The Employee Mandate

68. On September 9, 2021 President Biden signed Executive Order 14043, which stated that "to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require Covid-19 vaccination for all Federal employees, subject to such exceptions as required by law" ("EO 14043"). A copy of EO 14043 is attached hereto as Exhibit 20.

69. The Employee Mandate does not state what exceptions are required by law.

70. The Employee Mandate directed the Safer Federal Workforce Task Force ("The Task Force"), a task force established pursuant to Executive Order 13991 on January 20, 2021, to issue guidance "on agency implementation of this requirement for all agencies covered by this order."

71. On September 13, 2021, The Task Force issued an update to its "Covid-19 Workplace Safety: Agency Model Safety Principles" (collectively EO 14043 and the Task Force Guidance concerning federal employees are referred to herein as "The Employee Mandate"). A true and accurate copy of the Task Force Guidance, updated as of September 13, 2021 is attached hereto as Exhibit 21.

72. The Federal Employee Task Force Guidance provides that "Federal Executive Branch employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation." It requires agencies to "work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021." *Id.*

73. The Federal Employee Task Force Guidance establishes "different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated." *Id.* at pg. 2.

74. Federal employees who are not "fully vaccinated" or who choose not to disclose that private medical information to the government are subject to restrictions and requirements that do not apply to individuals who report that they are "fully vaccinated." These include:

a. They must provide proof a negative Covid-19 test no later than the previous 3 days prior to entry to a Federal building;

b. They must wear a mask when in a federal building, even if community transmission level is low;

c. They are subject to agency "testing" programs;

d. They must segregate themselves from other people by

maintaining at least a 6 foot distance from others;

e. They must wear a mask outside when conditions are "crowded" or if they will be in "sustained close contact with other people who are not fully vaccinated";

f. If exposed to someone else who tests positive for covid, they are required to quarantine for 14 days, even if they test negative and even if they are already immune through recovery.

75. Federal employees who are not "fully vaccinated" by this date and who do not qualify or receive an "exception required by law" will be in noncompliance with The Mandate and will, presumably, be terminated from their jobs.

76. Employees who are already immune to covid through recovery are still required to take a GTP.

77. Employees who are remote full-time and do not interact with others are required to take a GTP.

78. Employees subject to the Mandate are required to receive an injection by November 8, 2021.

79. The words "immunity" and "immune" do not appear anywhere in either EO 14043 or the Federal Employee Task Force Guidance.

V. The Contractor Mandate

80. On September 9, 2021 President Biden signed Executive

Order 14042 titled "Ensuring Adequate COVID Safety Protocols for Federal Contractors" ("EO 14042"). A true and accurate copy of EO 14042 is annexed hereto as Exhibit 22.

81. The claimed authority for EO 14042 is "the Constitution and the laws of the United States of America, including the Federal Property and Administrative Services Act, 40 U.S.C. 101 *et seq.*, and section 301 of title 3, United States Code."

82. The purported purpose of EO 14042 is "to promote economy and efficiency in procurement by contracting with sources that provide adequate Covid-19 safeguards for their workforce."

83. EO 14042 purports that it will "decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government."

84. No data is cited to support that the claimed mechanism or purpose will be achieved by EO 14042.

85. Pursuant to EO 14042 all contracts and contract-like instruments must "include a clause that the contractor and any subcontractor (at any tier)" include a clause in all lower-tier contracts that the contractor or subcontractor "shall, for the duration of the contract, comply with all

guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force."

86. The requirement applies to "any workplace locations (as specified by the Task Force Guidance) in which an individual is working on or in connection with a Federal Government contract or contract-like instrument."

87. EO 14043 required the Task Force to provide definitions of relevant terms and explanations of required protocols.

88. On September 24, 2021, The Task Force issued guidance titled "COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors" ("The Contractor Task Force Guidance") (EO 14043 and The Contractor Task Force Guidance are collectively referred to herein as "The Contractor Mandate"). A true and accurate copy of the Federal Contractor Task Force Guidance is attached hereto as Exhibit 23.

89. The Contractor Task Force Guidelines state that "Federal contractors and subcontractors with a covered contract will be required to conform" to three "workplace safety protocols":

1. Covid-19 vaccination of covered contractor employees except in limited circumstances where an employee is legally entitled to an accommodation;
2. Compliance by individuals, including

covered contractor employees and visitors, with the Guidance related to masking and physical distancing while in covered contractor workplaces; and

3. Designation by covered contractors of a person or persons to coordinate Covid-19 workplace safety efforts at covered contractor workplaces.

90. The Contractor Mandate is intended to include as many people as possible. The Contractor Task Force Guidance contains a Frequently Asked Questions section that highlights its breadth.

a. People who are not involved in a federal contract, but work in a "building, site, or facility" or campus for an employer who holds a federal contract are required to take a GTP unless the employer "affirmatively determines" that the non-covered contractor employees will not interact with covered employees in any common area such as lobbies, elevator, and parking garages.(Exhibit 23 Questions 8 and 9);

b. Employees of subcontractors to a federal government contract must take a GTP even if they themselves are not working on the subcontract if they work in the same building, site, facility, or campus unless the subcontractor affirmatively determines that employees working on a subcontract will not interact with any

employee not working on a subcontract (Exhibit 23, Q10);

c. Covered contractor employees working fully remotely must take a GTP (*Id.* at Q11);

d. All "subcontractors at all tiers" are required to take a GTP unless the subcontract is just for the provision of products (*Id.* at Q13); and

e. Employees who work in human resources, billing, legal review, and similar positions who "are not directly engaged in performing the specific work called for by the covered contract" are required to take a GTP.

91. The words "immunity" and "immune" do not appear in either EO 14042 or the Federal Contractor Task Force Guidance.

VI. Plaintiffs

92. Plaintiff Erich Smith works for the Department of Justice, Federal Bureau of Prisons. He is a foreman for a factory within the prison. He has worked full time in person through the entire pandemic. During the height of the pandemic, in May 2020, he volunteered to go to New York City, then an epicenter of the pandemic, as part of the Disturbance Control Team, which handles unusual disturbances that occur in the prisons. He did his duty with the expired n95 mask provided by the government. Through the entire pandemic he worked without complaint.

Now the government is demanding that he take a novel pharmaceutical that he does not want to take as a condition of his job. He has never been required to take any vaccination or undergo any other medical procedure for his job. He feels this is a violation of his right to bodily autonomy and to make his own decisions concerning his health. He is subject to EO 14043.

93. Plaintiff Frank Garwood is also an employee of the U.S. Department of Justice, Federal Bureau of Prisons as a training instructor teaching the inmate population vocational trades. He had made the personal choice not to receive any of the GTPs. He has never been required to take any vaccine or undergo any other medical procedure as part of his employment. He has been working in person with inmates for the past 7 months without issue. He is subject to EO 14043.

94. Plaintiff Maribel Lorenzo has been an underwriter for Horizon BlueCross BlueShield for the last 15 years. She was notified by her employer that they are subject to EO 14042 and that she is therefore required to take one of the GTPs. Ms. Lorenzo does not want to take any of the GTPs for a variety of personal reasons, including the fact that her father died as a result of an adverse reaction to his cancer medication, that she had a miscarriage due to

an adverse reaction to a medication prescribed to her when she was pregnant, and that her son suffered through surgery awake when anesthesia failed to work for him. She is skeptical of pharmaceuticals due to these experiences.

95. Plaintiff Dr. Daniel Donofrio is a licensed chiropractor who has never taken any vaccine in his entire life. For the last 12 years he has worked for the Social Security Administration and is subject to EO 14043. Through hard work he moved rapidly up the ranks and is now an Operations Supervisor, a position he has held for the last 6 years. He has never been required to undergo any medical procedure for his job before. He is now being harassed with automated emails demanding that he disclose his medical status to the government. He worked through the entire pandemic in person without any vaccine. He takes excellent care of his health, riding his bike 80 miles a week and eating healthy foods.

CONSTITUTIONAL CLAIMS

I.

THE MANDATES VIOLATE PLAINIFFS' 5th AMENDENT RIGHTS TO LIBERTY AND PRIVACY

96. Plaintiffs repeat and reallege each of the preceding paragraphs.

97. The Mandates require Plaintiffs to disclose personal

health information to their employers and the government, which is a violation of their privacy rights under the 5th Amendment.

98. The Mandates require Plaintiffs to undergo a medical procedure they do not want, which is a violation of their liberty and privacy rights under the 5th Amendment.

99. The medical procedure will permanently alter their body and cannot be undone.

100. The medical procedure carries risk.

101. Plaintiffs have a constitutionally protected liberty and privacy rights to exercise sovereignty over their body and to decline medical procedures they do not want.

102. The government's asserted interests must be weighed against the individual right to decline medical procedures.

103. The individual right to decline the medical procedure outweighs the government interests because:

a. It is not known how long or how well the GTPs work to prevent viral transmission or sickness;

b. There are known risks of taking the GTPs;

c. The long term risks of the GTPs are totally unknown;

d. The targeted disease has a low mortality rate;

e. There are a wide range of treatments available for people who do become sick with the virus;

f. The medical procedure is likely to make an individual

sick in the short term;

g. The medical procedure was been invented by and is manufactured by corporations with criminal track records or no track record at all;

h. The federal agency tasked with oversight of public safety is plagued by scandals and high profile failures directly related to drug safety;

i. The medical procedure involves a new technology that has never before been approved for or used in healthy humans;

j. The Mandates are an executive order, not legislative action;

k. The Mandates do not account for immunity acquired through recovery.

104. The Mandates are unconstitutional.

PRAYER FOR RELIEF

Wherefore, Plaintiffs request the following relief:

105. Declare The Mandates unconstitutional;

106. Enjoin The US Government from enforcing the Mandates;

107. Grant any and all other such relief as this Court deems just and equitable.

Respectfully submitted,

Dated: October 29, 2021

s/ Dana Wefer, Esq.

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Attorney for Plaintiffs

COMPLAINT VERIFICATION

I, DANA WEFER, am over the age of eighteen years and counsel for all Plaintiffs in this action. The statements and allegations included in the foregoing Verified Complaint are based upon reports and information known to me, provided to me by Plaintiffs, and/or available as public information. I declare under penalty of perfury that everything represented herein is true to the best of my knowledge, information, and belief.

Dated: October 29, 2021

/s/ Dana Wefer
Dana Wefer

Counsel for Plaintiffs

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

The matter in controversy is being litigated in several other district courts around the country, but counsel is not aware of any cases pending in this jurisdiction. The Plaintiffs in this case are not Plaintiffs in any other litigation against this Defendant.

Dated: October 29, 2021

/s Dana Wefer, Esq.
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Attorney for Plaintiffs

VERIFICATION

I, ERICH SMITH, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this Verified Complaint are true and correct and based upon my personal knowledge. If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

October 29, 2021

_____

VERIFICATION

I, FRANK E. GARWOOD, JR., am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this Verified Complaint are true and correct and based upon my personal knowledge. If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

October 29,

2021

Frank E. Garwood, Jr.

VERIFICATION

I, MARIBEL LORZENZO, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this Verified Complaint are true and correct and based upon my personal knowledge. If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

October 29,

2021

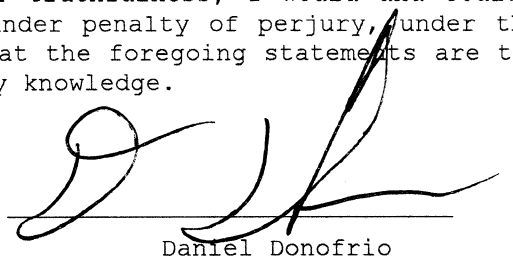
Maribel Lorenzo

VERIFICATION

I, DANIEL DONOFRIO, am over the age of eighteen years and a Plaintiff in this action. The statements and allegations that pertain to me or which I make in this Verified Complaint are true and correct and based upon my personal knowledge. If called upon to testify to their truthfulness, I would and could do so competently. I declare under penalty of perjury, under the laws of the United States, that the foregoing statements are true and correct to the best of my knowledge.

October 29,

2021



Daniel Donofrio

EXHIBIT 1

The New York Times https://www.nytimes.com/2021/09/09/us/politics/biden-vaccine-mandates-transcript.html

Biden's Speech on Vaccine Mandates and the Delta Variant: Full Transcript

"My message to unvaccinated Americans is this: What more is there to wait for?" President Biden said on Thursday. "We've been patient, but our patience is wearing thin."

Sept. 9, 2021

The following is a transcript of President Biden's remarks on Thursday about his administration's push to mandate coronavirus vaccines for two-thirds of American workers as the Delta variant surges across the United States.

Good evening, my fellow Americans. I want to talk to you about where we are in the battle against Covid-19 — the progress we've made and the work we have left to do, and it starts in understanding this: Even as the Delta variant 19 has — Covid-19 has been hitting this country hard, we have the tools to combat the virus, if we can come together as a country and use those tools. If we raise our vaccination rate, protect ourselves and others with masking, expanding testing and identify people who are infected, we can and we will turn the tide on Covid-19.

It will take a lot of hard work, and it's going to take some time. Many of us are frustrated with the nearly 80 million Americans who are still not vaccinated, even though the vaccine is safe, effective and free. You might be confused about what is true and what is false about Covid-19. So, before I outline the new steps to fight Covid-19 that I'm going to be announcing tonight, let me give you some clear information about where we stand.

First, we've made considerable progress in battling Covid-19. When I became president, about two million Americans were fully vaccinated. Today, over 175 million Americans have that protection. Before I took office, we hadn't ordered enough vaccine for every American. Just weeks in office, we did. The week before I took office on Jan. 20 of this year, over 25,000 Americans died that week from Covid-19.

Last week, that grim weekly toll was down 70 percent. And then three months before I took office, our economy was faltering, creating just 50,000 jobs a month. We're now averaging 700,000 new jobs a month in the past three months. This progress is real. But while America is in much better shape than it was seven months ago, when I took office, I need to tell you a second fact. We're in the tough stretch, and it could last for a while.

Highly contagious Delta variant that I began to warn America back in July, spread late summer, like it did in other countries before us. While the vaccines provide strong protection for the vaccinated, we read about and hear about and we see the stories of hospitalized people, people on their death beds among the unvaccinated over the past few weeks. This is a pandemic of the unvaccinated.

And it's caused by the fact that despite America having unprecedented and successful vaccination program — despite the fact that for almost five months, free vaccines have been available in 80,000 different locations — we still have nearly 80 million Americans who have failed to get the shot. And to make matters worse, there are elected officials actively working to undermine the fight against Covid-19. Instead of encouraging people to get vaccinated and mask up, they are ordering mobile morgues for the unvaccinated dying from Covid in our communities. This is totally unacceptable.

Third, if you wonder how all this adds up, here's the math. The vast majority of Americans are doing the right thing. Nearly three-quarters of the eligible have gotten at least one shot. But one-quarter has not gotten any. That's nearly 80 million Americans not vaccinated. In a country as large as ours, that's 25 percent minority. That 25 percent can cause a lot of damage, and they are. The unvaccinated overcrowd our hospitals or overrun the emergency rooms and intensive care units, leaving no room for someone with a heart attack or pancreatitis or cancer.

And fourth, I want to emphasize that the vaccines provide very strong protection from Covid-19. I know there's a lot of confusion and misinformation, but the world's leading scientists confirm that if you're fully vaccinated, your risk of severe illness from Covid-19 is very low. In fact, based on available data from the summer, only one out of every 160,000 fully vaccinated Americans was hospitalized for Covid per day. These are the facts.

So here's where we stand. The path ahead, even with the Delta variant, is not nearly as bad as last winter. What makes it incredibly more frustrating is that we have the tools to combat Covid-19, and a distinct minority of Americans, supported by a distinct minority of elected officials, are keeping us from turning the corner. These pandemic politics, as I refer to, are making people sick, causing unvaccinated people to die.

We cannot allow these actions to stand in the way of the large majority of Americans who have done their part and want to get back to life as normal. As your president, I'm announcing tonight a new plan to require more Americans to be vaccinated to combat those blocking public health. My plan also increases testing, protects our economy and will make our kids safer in schools.

It consists of six broad areas of action and many specific measures of each of those actions that you can read more about at Whitehouse.gov. Whitehouse.gov. The measures, these are going to take time to have full impact. But if we implement them, I believe and the scientists indicate that the months ahead, we can reduce the number of unvaccinated Americans, decrease hospitalizations and deaths, and allow our children to go to school safely, and keep our economy strong by keeping businesses open.

First, we must increase vaccinations among the unvaccinated with new vaccination requirements. With nearly 80 million eligible Americans who have not gotten vaccinated, many said they were waiting for approval from the Food and Drug Administration, the F.D.A. Well, last month the F.D.A. granted that approval. So, the time for waiting is over.

This summer, we made progress through a combination of vaccine requirements and incentives as well as the F.D.A. approval. Four million more people got their first shot in August than they did in July. But we need to do more. This is not about freedom or personal choice. It's about protecting yourself and those around you — the people you work with, the people you care about, the people you love.

My job as president is to protect all Americans. So tonight, I'm announcing that the Department of Labor is developing an emergency rule to require all employers with 100 or more employees that together employ over 80 million workers to ensure their work forces are fully vaccinated or show a negative test at least once a week.

Some of the biggest companies are already requiring this: United Airlines, Disney, Tyson Foods and even Fox News. The bottom line: We're going to protect vaccinated workers from unvaccinated co-workers. We're going to reduce the spread of Covid-19 by increasing the share of the work force that is vaccinated in businesses all across America.

My plan will extend the vaccination requirements that I previously issued in the health care field. Already, I've announced we'll be requiring vaccinations that all nursing home workers who treat patients on Medicare and Medicaid, because I have that federal authority.

Tonight I'm using that same authority to expand that to cover those who work in hospitals, home health care facilities or other medical facilities. A total of 17 million health care workers. If you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated — simple, straightforward, period.

Next, I will sign an executive order that will now require all executive branch federal employees to be vaccinated — all. I've signed another executive order that will require federal contractors to do the same. If you want to work with the federal government and do business with us, get vaccinated. If you want to do business with the federal government, vaccinate your work force.

And tonight I'm removing one of the last remaining obstacles that make it difficult for you to get vaccinated. The Department of Labor will require employers with 100 or more workers to give those workers paid time off to get vaccinated. No one should lose pay in order to get vaccinated or take a loved one to get vaccinated.

Today, in total, the vaccine requirements in my plan will affect about 100 million Americans — two-thirds of all workers. And for other sectors, I issue this appeal: To those of you running large entertainment venues from sports arenas to concert venues to movie theaters, please require folks to get vaccinated or show a negative test as a condition of entry.

And to the nation's family physicians, pediatricians, G.P.s — general practitioners — you're the most trusted medical voice to your patients. You may be the one person who can get someone to change their mind about being vaccinated. Tonight, I'm asking each of you to reach out to your unvaccinated patients over the next two weeks and make a personal appeal to them to get the shot. America needs your personal involvement in this critical effort.

My message to unvaccinated Americans is this: What more is there to wait for? What more do you need to see? We've made vaccinations free, safe and convenient. The vaccine is F.D.A. approved. Over 200 million Americans have gotten at least one shot. We've been patient, but our patience is wearing thin. And your refusal has cost all of us.

So, please, do the right thing. But don't just take it from me. Listen to the voices of unvaccinated Americans who are lying in hospital beds, taking their final breath, saying, "If only I had gotten vaccinated." If only. It's a tragedy. Please don't let it become yours.

The second piece of my plan is continuing to protect the vaccinated. The vast majority of you who have gotten vaccinated, I understand your anger at those who haven't gotten vaccinated. I understand the anxiety about getting a breakthrough case. But as the science makes clear, if you're fully vaccinated, you're highly protected from severe illness even if you get Covid-19.

In fact, recent data indicates there's only one confirmed positive case per 5,000 fully vaccinated Americans per day. You're as safe as possible, and we're doing everything we can to keep it that way — keep it that way and keep you safe. That's where boosters come in — the shots that give you even more protection than after your second shot.

Now, I know there's been some confusion about boosters, so let me be clear. Last month, our top government doctors announced an initial plan for booster shots for vaccinated Americans. They believe that a booster is likely to provide the highest level of protection yet. Of course, the decision of which booster shots to give or when to start them and who will give them will be left completely to the scientists at the F.D.A. and the Centers for Disease Control.

But while we wait, we've done our part. We bought enough boosters, enough booster shots, and the distribution shot is ready to administer them. As soon as they are authorized, those eligible will be able to get a booster right away at tens of thousands of sites across the country — for most Americans, at your nearby drugstore and for free.

The third piece of my plan is keeping — and maybe the most important — is keeping our children safe and our schools open. For any parent, it doesn't matter how low the risk of any illness or accident is when it comes to your child or grandchild. Trust me. I know. So, let me speak to you directly. Let me speak to you directly to help ease some of your worries.

It comes down to two separate categories: children ages 12 and older, who are eligible for a vaccine now, and children ages 11 and under, who are not yet eligible. The safest thing for your child 12 and older is to get them vaccinated. They get vaccinated for a lot of things. That's it. Get them vaccinated.

As with the adults, almost all of the serious Covid-19 cases we're seeing among adolescents are in unvaccinated 12- to 17-year-olds, an age group that lags behind in vaccination rates. So parents, please get your teenager vaccinated.

What about children under the age of 12 who can't get vaccinated yet? Well, the best way for a parent to protect their child under the age of 12 starts at home. Every parent, every teen sibling, every caregiver around them should be vaccinated. Children have a four times higher chance of getting hospitalized if they live in a state with low vaccination rates rather than states with high vaccination rates.

Now if you're a parent of a young child and you're wondering when will it be, when will it be — the vaccine — available for them? I strongly support independent scientific review for vaccine uses for children under 12. We can't take shortcuts of that scientific work.

But I've made it clear, I will do everything within my power to support the F.D.A. with any resource it needs to continue to do this as safely and as quickly as possible. And our nation's top doctors are committed to keeping the public at large updated on the process so parents can plan.

What to Know About Covid-19 Booster Shots

Who is eligible for a booster shot?

The F.D.A. has authorized booster shots for millions of recipients of the Pfizer-BioNTech, Moderna and Johnson & Johnson vaccines. Pfizer and Moderna recipients who are eligible for a booster include people 65 and older, and younger adults at high risk of severe Covid-19 because of medical conditions or where they work. Eligible Pfizer and Moderna recipients can get a booster at least six months after their second dose. All Johnson & Johnson recipients will be eligible for a second shot at least two months after the first.

Can I switch Covid vaccines for a booster?

What underlying medical conditions qualify for a booster shot?

What occupations are eligible for boosters?

Can I get a flu shot at the same time as a Covid vaccine or booster shot?

Now to the schools. We know that if schools follow the science and implement the safety measures like testing, masking, adequate ventilation systems that we provided the money for, social distancing and vaccinations, then children can be safe from Covid-19 in schools. Today, about 90 percent of school staff and teachers are vaccinated. We should get that to 100 percent.

My administration has already required teachers at the schools run by the Defense Department — because I have the authority, as president, in the federal system, the Defense Department and the Interior Department — to get vaccinated. That's the authority I possess. Tonight I'm announcing that we'll require all of nearly 300,000 educators in the federal paid program, Head Start program, must be vaccinated as well to protect your youngest, our youngest, most precious Americans, and give parents the comfort.

And tonight I'm calling on all governors to require vaccinations for all teachers and staff. Some already have done so. We need more to step up. Vaccination requirements in schools are nothing new. They work. They are overwhelmingly supported by educators and their unions and all school officials trying do the right thing by our children. I'll always be on your side.

Let me be blunt. My plan also takes on elected officials in states that are undermining you and these lifesaving actions. Right now, local school officials are trying to keep children safe in a pandemic while their governor picks a fight with them and even threatens their salaries or their jobs. Talk about bullying in schools.

If they will not help, if those governors won't help us beat the pandemic, I'll use my power as president to get them out of the way. The Department of Education has already begun to take legal action against states undermining protection that local school officials have ordered. Any teacher or school official whose pay is withheld for doing the right thing, we will have that pay restored by the federal government, 100 percent. I promise you, I will have your back.

The fourth piece of my plan is increasing testing and masking. From the start, America has failed to do enough Covid-19 testing. In order to better detect and control the Delta variant, I'm taking steps tonight to make testing more available, more affordable and more convenient. I'll use the Defense Production Act to increase production of rapid tests, including those that you can use at home.

While that production is ramping up, my administration has worked with top retailers like Walmart, Amazon and Kroger, and tonight we're announcing that no later than next week each of these outlets will start to sell at-home rapid test kits at cost for the next three months.

This is immediate price reduction for at-home test kits for up to 35 percent reduction. We'll also expand free testing at 10,000 pharmacies around the country. And we'll commit, we're committing $2 billion to purchase nearly 300 million rapid tests for distribution to community health centers, food banks, schools, so that every American, no matter their income, can access free and convenient tests.

This is important to everyone, particularly for a parent or a child — with a child not old enough to be vaccinated. You'll be able to test them at home and test those around them. In addition to testing, we know masking helps stop the spread of Covid-19. That's why when I came into office, I required masks for all federal buildings and on federal lands, on airlines and other modes of transportation.

Today, tonight, I'm announcing that the Transportation Safety Administration, the T.S.A., will double the fines on travelers that refuse to mask. If you break the rules, be prepared to pay. And by the way, show some respect. The anger you see on television toward flight attendants and others doing their jobs is wrong. It's ugly.

The fifth piece of my plan is protecting our economic recovery. Because of our vaccination program, and the American Rescue Plan, which we passed early in my administration, we've had record job creation for a new administration. Economic growth unmatched in 40 years. We cannot let unvaccinated do this progress — undo it. Turn it back. So tonight I'm announcing additional steps to strengthen our economic recovery.

We'll be expanding Covid-19 economic injury disaster loan programs. That's a program that's going to allow small businesses to borrow up to $2 million, from the current $500,000, to keep going if Covid-19 impacts on their sales. These low-interest, long-term loans require no repayment for two years and can be used to hire and retain workers, purchase inventory or even pay down higher-cost debt racked up since the pandemic began. I'll also be taking additional steps to help small businesses stay afloat during the pandemic.

Sixth, we're going to continue to improve the care of those who do get Covid-19. In early July, I announced the deployment of surge response teams. These are teams comprised of experts from the Department of Health and Human Services, the C.D.C., the Defense Department and the Federal Emergency Management Agency, FEMA, to areas in the country that need help to stem the spread of Covid-19. Since then, the federal government has deployed nearly 1,000 staff including doctors, nurses, paramedics, into 18 states. Today, I'm announcing that the Defense Department will double the number of military health teams that they will deploy to help their fellow Americans and hospitals around the country.

Additionally, we're increasing the availability of new medicines recommended by real doctors, not conspiracy theorists. The monoclonal antibody treatments have been shown to reduce the risk of hospitalization by up to 70 percent for unvaccinated people at risk of developing severe disease. We've already distributed 1.4 million courses of these treatments to save lives and reduce the strain on hospitals. Tonight, I'm announcing we'll increase the average pace of shipment across the country of free monoclonal antibody treatments by another 50 percent.

Before I close, let me say this: Communities of color are disproportionately impacted by this virus. As we continue to battle Covid-19, we will ensure that equity continues to be at the center of our response. We'll ensure that everyone is reached. My first responsibility as president is to protect the American people and make sure we have enough vaccine for every American, including enough boosters for every American who's approved to get one.

We also know this virus transcends borders. That's why even as we execute this plan at home we need to continue fighting the virus overseas, continue to be the arsenal of vaccines. We're proud to have donated nearly 140 million vaccines to over 90 countries, more than all other countries combined — including Europe, China and Russia combined. That's American leadership on a global stage, and that's just the beginning. We've also now started to ship another 500 million Covid vaccines, Pfizer vaccines, purchased to donate to 100 lower-income countries in need of vaccines, and I'll be announcing additional steps to help the rest of the world later this month.

As I recently released the key parts of my pandemic preparedness plan so that America isn't caught flat-footed with a new pandemic comes again, as it will. Next month I'm also going to release a plan in greater detail.

So let me close with this: We've made so much progress during the past seven months of this pandemic. The recent increases in vaccinations in August already are having an impact in some states, where case counts are dropping in recent days. Even so, we remain at a critical moment, a critical time. We have the tools. Now we just have to finish the job with truth, with science, with confidence, and together as one nation.

Look, we're the United States of America. There's nothing, not a single thing we're unable to do if we do it together. So let's stay together.

God bless you all, and all those who continue to serve of on the front lines of this pandemic, and may God protect our troops.

Get vaccinated.

EXHIBIT 2

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Outlook

Modifications in an Emergency: The Role of N1-Methylpseudouridine in COVID-19 Vaccines

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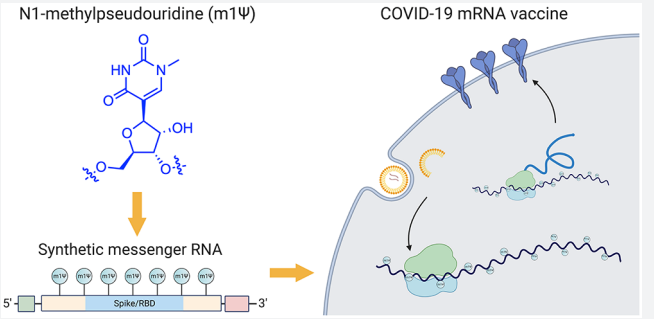
ABSTRACT: The novel coronavirus SARS-CoV-2, the cause of the COVID-19 pandemic, has inspired one of the most efficient vaccine development campaigns in human history. A key aspect of COVID-19 mRNA vaccines is the use of the modified nucleobase N1-methylpseudouridine (m1Ψ) to increase their effectiveness. In this Outlook, we summarize the development and function of m1Ψ in synthetic mRNAs. By demystifying how a novel element within these medicines works, we aim to foster understanding and highlight future opportunities for chemical innovation.



INTRODUCTION

On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued the first emergency use authorization (EUA) for a vaccine to prevent COVID-19, a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] Approval of a second COVID-19 vaccine followed 1 week later.[2] These approvals represent a public health breakthrough, providing the first protective measures against the largest global pandemic to strike in over 100 years, and were the first fruit of a vaccine development process akin in scope and urgency to the famed Manhattan Project. These two vaccines are also notable for being the first FDA-approved therapeutics to use a novel therapeutic platform: synthetic mRNA (mRNA).

Messenger RNAs are used in every cell of our body, where they serve the central relay between the instructions of the genome and protein production. Synthetic mRNAs tap into this same natural process but are designed to encode proteins with therapeutic effects.[3] The COVID-19 mRNA vaccines produce a full-length SARS-CoV-2 spike protein with two mutations (K986P and V987P) that ensure it remains in an antigenically favorable prefusion conformation.[4,5] Upon injection, mRNA is taken up by muscle and infiltrating immune cells that use it to produce spike protein (Figure 1a). A transmembrane anchor causes the spike protein to be displayed on the cell surface, allowing it to be recognized by the immune system. This triggers the production of antibodies and T-cells that protect against natural infection and prevent serious disease. Since synthetic mRNAs produce only a single component of the SARS-CoV-2 genome, they cannot cause COVID-19. It is also important to note these vaccines are nonreplicating mRNAs that naturally decompose and do not integrate into genomes. Detailed descriptions of the development and characterization of these vaccines can be found in the primary literature reporting them as well as several excellent reviews.[3,6−8]

The chemical components of mRNA vaccines are pleasantly unremarkable, consisting primarily of RNA plus "water, salt, sugar, and fat," with two notable exceptions. The first is the lipid nanoparticles that encapsulate the mRNA and facilitate its delivery, which are excellently reviewed elsewhere.[9] The second is the non-natural RNA nucleobase N1-methylpseudouridine (m1Ψ; Figure 1b), which enhances immune evasion and protein production. In this Outlook, we briefly review the development and function of m1Ψ in synthetic mRNA. By demystifying how a critical component of these new medicines work, we hope to help foster their acceptance and highlight future areas for chemical innovation.

PRIMARY STRUCTURE OF THE COVID-19 MRNA VACCINES

The two approved COVID-19 mRNA vaccines are marketed by Pfizer-BioNTech (BNT162b2; trade name: Comirnaty; generic name: tozinameran) and Moderna (mRNA-1273). The sequence of the former has been disclosed (Figure 2).[10] The active payload of the Pfizer-BioNTech vaccine is a 4284 nucleotide linear sequence of RNA consisting of five main elements:[11]

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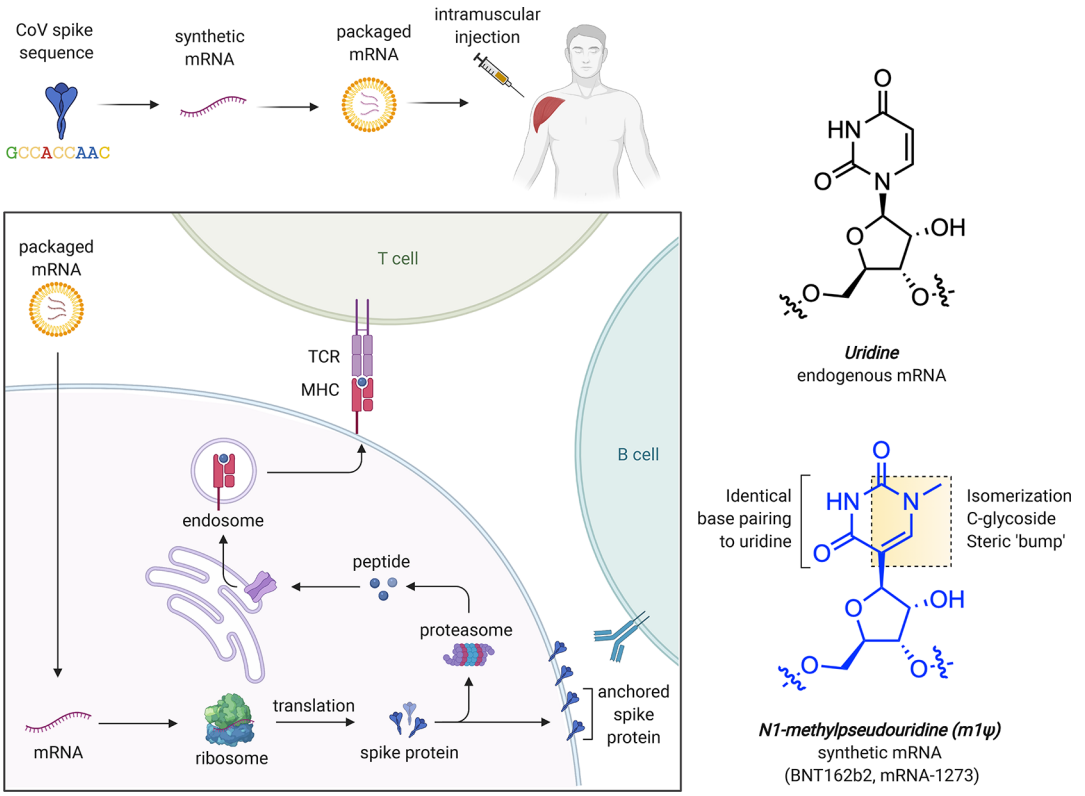

Figure 1. (a) mRNA-based COVID-19 vaccine strategy. (b) Structural features of uridine and m1Ψ. TCR = T-cell receptor. MHC = major histocompatibility complex.

- A 5′-cap (m7(3′OMeG)(5′)ppp(5′)(2′OMeA)pG, commonly referred to as trinucleotide "cap 1") that helps recruit the ribosome and protect the RNA from degradation.[12]
- A 5′-untranslated region (UTR) derived from the human α-globin mRNA with an optimized Kozak sequence that helps drive high levels of translation from the correct start codon.[13]
- A codon-optimized coding sequence that specifies production of the transmembrane-anchored immunogenic SARS-CoV-2 spike glycoprotein.
- A 3′-UTR consisting of two sequences derived from the amino-terminal enhancer of split mRNA and the mitochondrial encoded 12S rRNA, which aids high levels of protein expression by stabilizing the RNA.[14]
- An unusual 3′-terminus consisting of two segmented poly(adenosine) tracts. The poly(adenosine) stretches increase mRNA stability, while the segmented structure helps reduce unwanted recombination during plasmid production.[15]

The swift design of these vaccines has been deservedly celebrated.[16,17] However, it is important to gently push back on the narrative that this process was hurried, which may invite skepticism. Each of the elements above were highly intentional choices that in many cases reflect decades of fundamental research in the RNA biology field.[18,19] Below, we first review how these modified mRNAs are made, followed by an analysis of the modification's biological effects.

> Each of the elements [in the COVID-19 mRNA vaccines] were highly intentional choices that in many cases reflect decades of fundamental research in the RNA biology field.

INCORPORATION OF N1-METHYLPSEUDOURIDINE INTO MRNA VACCINES

To evaluate the design above requires first overcoming a technical challenge: how does one produce (at scale) a synthetic mRNA with a linear sequence far longer than can be chemically synthesized while simultaneously preserving the flexibility to incorporate modified nucleobases such as m1Ψ? The answer has been to take a cue from nature and make them enzymatically (Figure 3). This approach takes advantage of the fact that DNA (which is far easier to synthesize than RNA) can be stitched together into large synthetic fragments. These fragments are used to construct plasmids, in which the code for the COVID-19 vaccine is placed downstream of a sequence that promotes its transcription into mRNA by recombinant T7 RNA polymerase. By incubating these plasmids with T7 polymerase and nucleotide triphosphates (NTPs), high yields of mRNA are produced. Decades of research have characterized T7 polymerase as a remarkable enzyme, which can produce RNAs longer than 20 000 nucleotides without making an error.[20,21] Another feature of T7 polymerase is its tolerance for non-natural NTPs. Over 50 years ago, Goldberg and Rabinowitz demonstrated that

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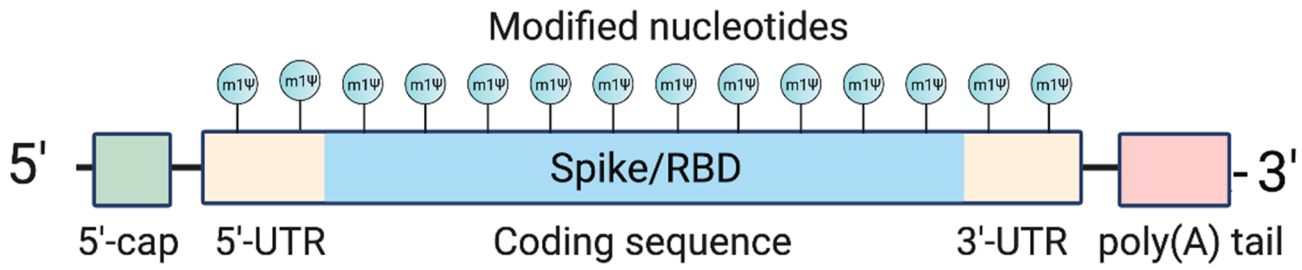

BNT162b2 sequence (U = m1Ψ)

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UGAACCUGAC CACCAGAACA CAGCUGCCUC CAGCCUACAC CAACAGCUUU ACCAGAGGCG UGUACUACCC CGACAAGGUG UUCAGAUCCA GCGUGCUGCA  200
CUCUACCCAG GACCUGUUCC UGCCUUUCUU CAGCAACGUG ACCUGGUUCC ACGCCAUCCA CGUGUCCGGC ACCAAUGGCA CCAAGAGAUU CGACAACCCC  300
GUGCUGCCCU UCAACGACGG GGUGUACUUU GCCAGCACCG AGAAGUCCAA CAUCAUCAGA GGCUGGAUCU UCGGCACCAC ACUGGACAGC AAGACCCAGA  400
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CAAGAGCUGG AUGGAAAGCG AGUUCCGGGU GUACAGCAGC GCCAACAACU GCACCUUCGA GUACGUGUCC CAGCCUUUCC UGAUGGACCU GGAAGGCAAG  600
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UGUGUACGCC UGGAACCGGA AGCGGAUCAG CAAUUGCGUG GCCGACUACU CCGUGCUGUA CAACUCCGCC AGCUUCAGCA CCUUCAAGUG CUACGGCGUG 1200
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CAAUUACCUG UACCGGCUGU UCCGGAAGUC CAAUCUGAAG CCCUUCGAGC GGGACAUCUC CACCGAGAUC UAUCAGGCCG GCAGCACCCC UUGUAACGGC 1500
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GGACGUGGUC AACCAGAAUG CCCAGGCACU GAACACCCUG GUCAAGCAGC UGUCCUCCAA CUUCGGCGCC AUCAGCUCUG UGCUGAACGA UAUCCUGAGC 3000
AGACUGGACC CUCCUGAGGC CGAGGUGCAG AUCGACAGAC UGAUCACAGG CAGACUGCAG AGCCUCCAGA CAUACGUGAC CCAGCAGCUG AUCAGAGCCG 3100
CCGAGAUUAG AGCCUCUGCC AAUCUGGCCG CCACCAAGAU GUCUGAGUGU GUGCUGGGCC AGAGCAAGAG AGUGGACUUU UGCGGCAAGG GCUACCACCU 3200
GAUGAGCUUC CCUCAGUCUG CCCCUCACGG CGUGGUGUUU CUGCACGUGA CAUAUGUGCC CGCUCAAGAG AAGAAUUUCA CCACCGCUCC AGCCAUCUGC 3300
CACGACGGCA AAGCCCACUU UCCUAGAGAA GGCGUGUUCG UGUCCAACGG CACCCAUUGG UUCGUGACAC AGCGGAACUU CUACGAGCCC CAGAUCAUCA 3400
CCACCGACAA CACCUUCGUG UCUGGCAACU GCGACGUCGU GAUCGGCAUU GUGAACAAUA CCGUGUACGA CCCUCUGCAG CCCGAGCUGG ACAGCUUCAA 3500
AGAGGAACUG GACAAGUACU UUAAGAACCA CACAAGCCCC GACGUGGACC UGGGCGAUAU CAGCGGAAUC AAUGCCAGCG UCGUGAACAU CCAGAAAGAG 3600
AUCGACCGGC UGAACGAGGU GGCCAAGAAU CUGAACGAGA GCCUGAUCGA CCUGCAAGAA CUGGGGAAGU ACGAGCAGUA CAUCAAGUGG CCCUGGUACA 3700
UCUGGCUGGG CUUUAUCGCC GGACUGAUUG CCAUCGUGAU GGUCACAAUC AUGCUGUGUU GCAUGACCAG CUGCUGUAGC UGCCUGAAGG GCUGUUGUAG 3800
CUGUGGCAGC UGCUGCAAGU UCGACGAGGA CGAUUCUGAG CCCGUGCUGA AGGGCGUGAA ACUGCACUAC ACAUGAUGAC UCGAGCUGGU ACUGCAUGCA 3900
CGCAAUGCUA GCUGCCCCUU UCCCGUCCUG GGUACCCCGA GUCUCCCCCG ACCUCGGGUC CCAGGUAUGC UCCCACCUCC ACCUGCCCCA CUCACCACCU 4000
CUGCUAGUUC CAGACACCUC CCAAGCACGC AGCAAUGCAG CUCAAAACGC UUAGCCUAGC CACACCCCCA CGGGAAACAG CAGUGAUUAA CCUUUAGCAA 4100
UAAACGAAAG UUUAACUAAG CUAUACUAAC CCCAGGGUUG GUCAAUUUCG UGCCAGCCAC ACCCUGGAGC UAGCAAAAAA AAAAAAAAAA AAAAAAAAAA 4200
AAAAGCAUAU GACUAAAAAA AAAAAAAAAA AAAAAAAAAA AAAAAAAAAA AAAAAAAAAA AAAAAAAAAA AAAA                           4284
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Figure 2. Top: Design elements found in synthetic mRNA therapeutics. Bottom: Sequence of the COVID-19 mRNA vaccine tozinameran (BNT162b2) from Pfizer/BioNTech. Green: 5′-cap. Yellow: 5′- and 3′-UTR sequences. Blue: SARS-CoV-2 spike glycoprotein coding sequence. Red: Segmented poly(A) tail.

RNA polymerases can incorporate pseudouridine triphosphate into RNA.[22] In one early study (which makes one quite thankful for the Sigma-Aldrich catalogue), pseudouridine was isolated from 20 L of urine donated by patients with leukemia, polycythemia, or gout, converted to a radiolabeled triphosphate by a mixed chemoenzymatic approach, and found to replace uridine in RNA during in vitro transcription when UTP was omitted.[23] Early studies of T7 RNA polymerase found it was also permissive of modified NTPs that do not alter base pairing,[24] and this strategy has since been applied to many different bases.[25−29] One caveat to this enzymatic approach is that it replaces the natural nucleobase with a non-natural residue homogeneously; in the case of BNT162b2, every uridine residue in the mRNA is replaced with m1Ψ. This means to be useful in a therapeutic mRNA, a modified nucleobase must be compatible with all of its functional elements, including UTRs and the coding sequence recognized by the ribosome. With this understanding of the primary sequence of modified mRNA vaccines and how they are produced, we can proceed to a discussion of what they do.

N1-METHYLPSEUDOURIDINE REDUCES MRNA IMMUNOGENICITY

Early studies showed that synthetic mRNAs entrapped in cationic lipid vesicles can be transfected into cultured cells.[30] When injected into mouse muscle, reporter mRNAs produced

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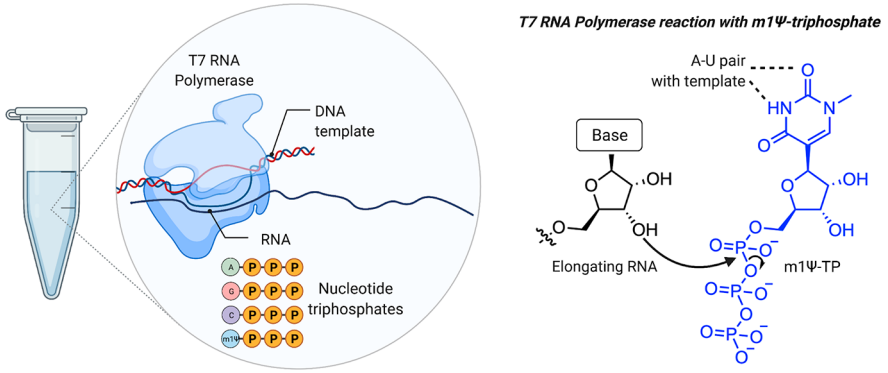

Figure 3. Production of m1Ψ mRNAs by *in vitro* transcription. Left: Components of *in vitro* transcription reaction. Right: Incorporation of m1Ψ-triphosphate into RNA is guided by m1Ψ's ability to form a canonical base pair with adenine of the DNA template in the T7 RNA polymerase active site.

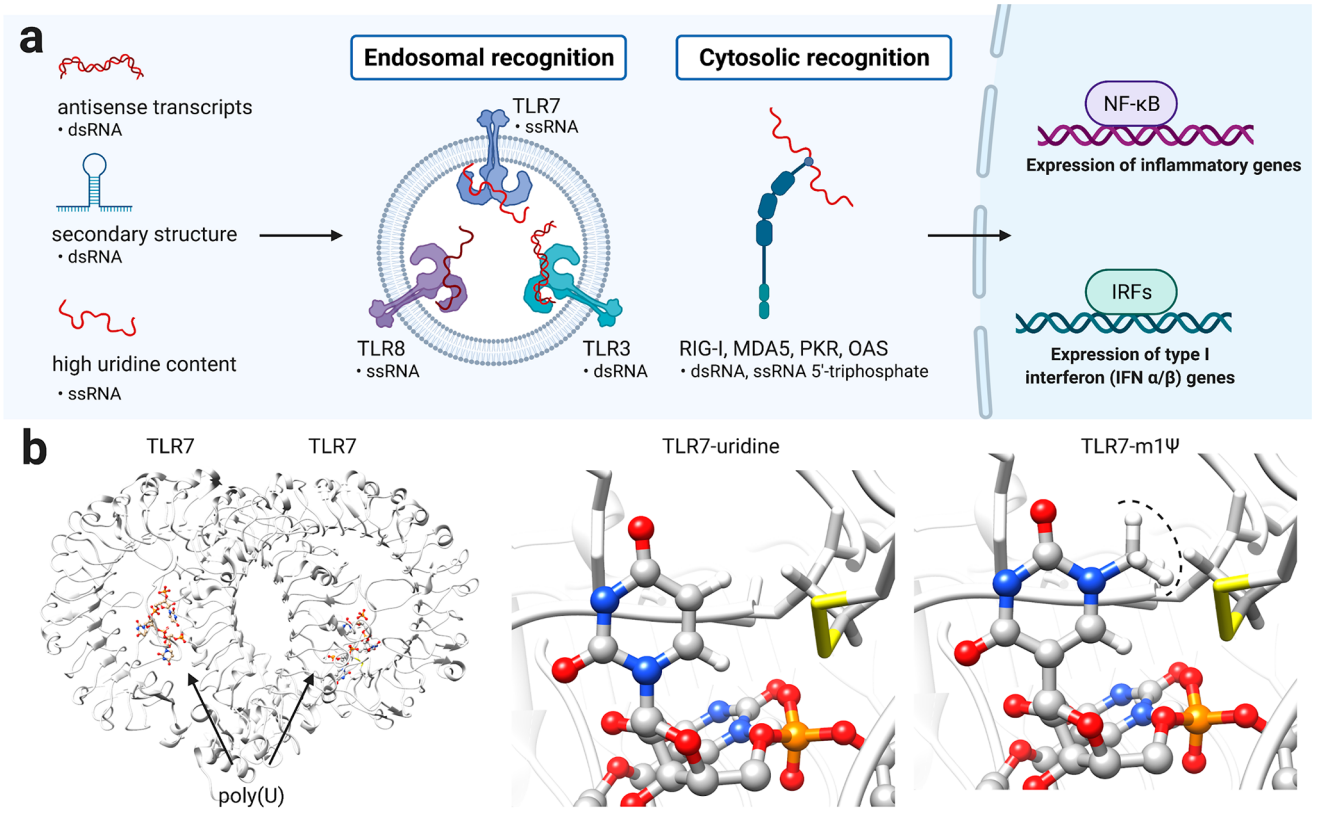

Figure 4. (a) Activation of innate immune response by mRNA secondary structures (b) Structure of the single-stranded RNA sensor TLR7 in complex with a polyuridine (poly(U)) ligand (PDB ID: 5GMF). Replacing uridine with m1Ψ demonstrates the steric incompatibility of the modified nucleobase with TLR7 binding and immune activation.

detectable proteins for weeks.[31] However, a challenge to application of these agents as vaccines and protein replacement therapies was their immunogenicity. Cells contain a variety of pattern recognition receptors whose natural role is to identify and respond to viral RNAs by inducing downstream signaling. These include the endosomal receptors TLR3, TLR7, and TLR8, which recognize double- and single-stranded RNA, and the cytosolic receptors RIG-I and MDA-5, which recognize double-stranded and 5′-triphosphate-modified RNA. While induction of an immune response is theoretically a positive attribute for a vaccine, uncontrolled immune activation can lead to allergic reactions and anaphylactic shock. Furthermore, at a molecular level, overstimulation of immune signaling is known to silence protein translation, with the potential outcome of limiting antigen expression and vaccine efficacy. A breakthrough came from the fundamental studies of Kariko and co-workers, who showed that many modifications naturally found in human RNA such as pseudouridine, thiouridine, and 5-methylcytidine reduce its immunostimulatory potential.[32] This inspired follow-up studies demonstrating that these same nucleobase modifications could increase protein production from synthetic mRNAs[33−35] and be applied in many applications, including the generation of induced pluripotent stem cells.[36−38] Further development of this concept led to m1Ψ, which in mRNA was found to increase protein output while decreasing TLR3 activation.[39] The ability of m1Ψ and related modifications to

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reduce the immunogenicity of synthetic mRNA has been attributed to at least three mechanisms (Figure 4):

> A breakthrough came from the fundamental studies of Kariko and co-workers, who showed that many modifications naturally found in human RNA. . .reduce its immunostimulatory potential.

- **Reduced synthesis of antisense RNA**: Under high-yielding conditions, T7 RNA polymerase sometimes uses the RNA it has produced to "self-prime", leading to the synthesis of small amounts of duplexed antisense mRNA (Figure 4).[40] Removal of these double-stranded RNA impurities by chromatography does not eliminate differences in immunogenicity observed between m1Ψ-modified and unmodified RNAs but does reduce it.[41] Other studies have also found that using base-modified NTPs yields noninflammatory mRNAs without the need for purification.[34,42] This suggests that using the non-natural NTP for RNA synthesis may disfavor this side product.
- **Altering interaction with RNA secondary structure**: In addition to antisense impurities, mRNA can form secondary structures such as hairpins that may be recognized by immune receptors such as TLR3 and RIG-I (Figure 4).[43] Incorporation of modified bases has the potential to reduce these recognition events by altering secondary structure and protein/double-stranded RNA interactions. In the related C-glycoside pseudouridine, isomerization shifts the structural equilibrium of the nucleotide toward a C3′-endo ribose sugar and an anti orientation of the base, a conformation that favors helicity and stacking.[44−46] Consistent with this, a recent study used chemical probing reagents to find evidence that RNAs containing m1Ψ and uridine form distinct secondary structures.[47] Modified nucleotides have also been found to reduce the ability of mRNAs to propagate immune signaling through RIG-I, indicative of their ability to influence protein−RNA interactions.[48]
- **Altering interaction with single-stranded RNA immune receptors**: In immune cells, single-stranded poly(uridine) RNA is one of the most potent inducers of interferon and is sensed by TLR7.[49,50] To define whether m1Ψ alters immune recognition of single-stranded RNA, a recent study assessed the ability of RNAs containing this species to activate inflammatory gene expression.[41,47] To ensure any differences were not due to double-stranded RNA, the authors employed a mouse model where the immune response to these structures was silenced. Even in the absence of double-stranded RNA sensing, m1Ψ RNAs were less inflammatory than those containing canonical uridine. This suggests the altered hydrogen bonding face and steric "bump" presented by m1Ψ disrupts the interaction of immune sensors such as TLR7 with single-stranded segments of synthetic mRNA (Figure 4c).

It is important to note that in many studies, the specific contributions of each of these mechanisms to mRNA immunogenicity have not been explicitly defined. In such cases, an mRNA modification may be exerting its activity by altering antisense transcript synthesis, mRNA structure, immune recognition, or some combination thereof.

Vaccines often require coadministration of adjuvants, which are agents that prime the immune system to respond to an antigen of interest. In the case of tozinameran and mRNA-1273, this role appears to be fulfilled by the lipid nanoparticle, which can be tailored to predictably activate the immune response via mechanisms that do not halt protein production.[51−53] Separating the adjuvant from the nucleic acid component of the vaccine reduces the chance that the mRNA sequence composition may influence vaccine efficacy. This potentially increases the strategy's generality and also opens the door to other applications, such as treatment of autoimmune disorders[54] and therapeutic protein replacement.[55]

Interestingly, at least two groups have reported that pseudouridine, the natural analogue of m1Ψ, does not measurably alter mRNA immunogenicity *in vivo*[56] and that many of the benefits of m1Ψ can be obtained by simply engineering a synthetic mRNA's sequence to limit the use of uridine-containing codons.[57] A comparative analysis of codons used in tozinameran relative to the spike glycoprotein encoded by the SARS-CoV-2 genome observes a disproportionate depletion of uridine residues, indicative of sequence engineering (Figure S1). In the context of the COVID-19 vaccine, the relative effects of sequence engineering and m1Ψ incorporation on the immunogenic mechanisms specified above remains to be reported.

N1-METHYLPSEUDOURIDINE CAN ALTER MRNA TRANSLATION

The ultimate purpose of an mRNA medicine is to express a therapeutic protein. Thus, m1Ψ and other modified bases have been explored for their ability to facilitate the translation of mRNA into protein via the ribosome. These studies are naturally intertwined with those above, as immune activation can limit translation by shutting down the ribosome and activating ribonucleases that degrade mRNA. Consistent with this, in the initial report where m1Ψ-containing mRNA was found to drive high levels of protein production, this was attributed in part to its ability to blunt TLR3 activation.[39] To decouple translation and immune activation, Svitkin and co-workers analyzed the translation of m1Ψ mRNAs in a cell-free translation system.[58] They observed that incorporation of m1Ψ increases the size and abundance of polysomes, leading them to propose that the more rapid translation initiation and slower elongation of m1Ψ mRNAs may coordinately increase their half-life as well as induce productive interactions with the ribosome. These studies provided the first evidence that m1Ψ may directly impact mRNA translation.

Natural RNA modifications are known to be context-dependent.[59] This means they can exert different effects on different RNAs. Those effects may also be dependent on where in the RNA they lie (e.g., UTR, coding sequence).[60,61] Two studies have examined the context-dependence of m1Ψ in a high-throughput fashion (Figure 5).[47,62] In the first, Sample et al. used RNA sequencing of polysomes to compare how a library of uridine and m1Ψ mRNAs containing 280 000 different 5′-UTRs was loaded onto the ribosome. Across all sequences tested, ribosome loading was found to be anticorrelated with predicted mean free energy. This is consistent with the classical view that structured 5′-UTRs can repress translation.[63]

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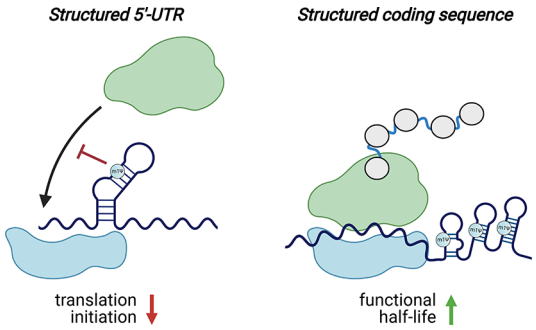

Figure 5. m1Ψ exerts context-dependent effects on translation. Left: m1Ψ-dependent enforcement of secondary structure in the 5′-UTR of synthetic mRNAs can inhibit translation initiation. Right: m1Ψ-dependent enforcement of secondary structure in the coding sequences of synthetic mRNAs can increase their functional half-life. Note: While m1Ψ is homogeneously incorporated throughout synthetic mRNA vaccines, in these illustrations, m1Ψ is only specified in duplexes to emphasize its potential to influence mRNA structure.

However, this anticorrelation was stronger for m1Ψ than uridine, indicating that by stabilizing RNA structure, the modified base may actually decrease protein production in these contexts.[46,64] A second study by Mauger et al. examined the relationship between m1Ψ, RNA structure, and protein production in even greater detail. They evaluated modified (m1Ψ, pseudouridine, methoxyuridine) and unmodified (uridine) mRNAs across multiple synonymous versions of three different reporters, amounting to over 150 synthetic mRNAs in total. Within this library, modified and unmodified mRNAs were found to exhibit distinct "fingerprints" of codon optimality. Assuming uridine and m1Ψ are decoded similarly by the ribosome, this suggested that a feature other than codon optimality is responsible for tuning synthetic mRNA translation. To examine the potential role of structure in this process, the authors used a biochemical probing technique (SHAPE-MaP)[65] to study modified and unmodified mRNAs. As in the case of 5′-UTRs, it was found that m1Ψ stabilizes structure. Further studies provided support for a model in which secondary structure in the coding sequence, which can be enforced by m1Ψ, may increase mRNA functional half-life independent of codon optimality.[47,62]

One important aspect revealed by these studies is that m1Ψ is not a panacea for protein production. While for most mRNA sequences m1Ψ performed as well or better than uridine, in some it performed worse. Similar observations have been made for pseudouridine, which in one study was found to be incompatible with protein output from mRNAs containing structured viral internal ribosomal entry sites in their 5′-UTR region.[57] The efficient translation of many different m1Ψ-containing mRNAs suggests that the secondary structures induced by this modification do not activate immune sensors. This may reflect their small size or greater dynamics relative to the stable duplexes found in classic TLR3 agonists such as poly(I:C) or the intrinsic ability of m1Ψ to impede the protein−mRNA interactions responsible for immune activation.

CONCLUSIONS

The shock of the COVID-19 pandemic mobilized the biomedical research community on an unprecedented scale and enabled the most rapid vaccine production process in human history. This success also presents a unique challenge to scientific communication, which is how to highlight the decades of fundamental research that underlie these medicines. In this Outlook, we describe for a scientific lay audience the development and application of m1Ψ, a chemical component of COVID-19 mRNA vaccines. The modified nucleobase helps cloak mRNA vaccines from the immune system, limiting their undesired immune stimulation, and in certain circumstances may also enhance the synthesis of antigens by the protein-producing machinery of the cell. This allows these vaccines to tap into the natural process of mRNA translation without triggering harmful side effects such as anaphylaxis.

In light of the current concern over emerging SARS-CoV-2 variants, it is worth highlighting how synthetic mRNAs are being developed for use in personalized cancer immunotherapy.[66,67] In this approach, clinicians remove a tumor, sequence it to identify coding mutations, and use this information to design custom mRNAs that express those mutant peptides at high levels, which helps train the immune system to selectively attack tumor tissue.[68] In other words, synthetic mRNA platforms have been built with the express purpose of rapidly addressing newly discovered mutations. This bodes well for the potential of these medicines to be reconfigured to combat emerging viral strains and suggests one unexpected legacy of this pandemic may be to accelerate the use of synthetic mRNAs in cancer treatment.

Finally, our review of m1Ψ highlights future areas where chemical innovation may help extend the reach of therapeutic mRNAs. First, while the modular nature of mRNA vaccines has led to considerable enthusiasm, the combinatorial space of elements that contribute to their activity (including caps, coding sequence, codons, UTRs, and modifications) is massive in scale, and relatively few RNA modifications have been comparatively evaluated in a systematic manner. High-throughput approaches will be critical to help define this space and develop optimized agents.[69] The exploration of novel nucleobases may be also be aided by efficient routes to nucleoside triphosphates[70] as well as biological insights arising from the recent renaissance in the study of endogenous mRNA modifications.[71,72] The production of novel mRNA therapies may also be aided by the evolution of RNA polymerases with improved synthetic properties such as expanded nucleobase tolerance or a reduced production of antisense transcripts. The successful engineering of DNA polymerases for genome sequencing speaks to the feasibility and potential impact of this goal.

Almost 60 years ago in "Meditations in an Emergency" the poet Frank O'Hara wrote, "*I am needed by things as the sky must be above the earth./And lately, so great has their anxiety become, I can spare myself little sleep.*" O'Hara's passage resonates with our current era and the tremendous strain felt by patients, families, and healthcare providers during this pandemic. The nucleobase m1Ψ, a "modification in an emergency", provides an example of how contemplation can also lead to intervention, offering hope and rest in a time of crisis.

ASSOCIATED CONTENT

Supporting Information

The Supporting Information is available free of charge at https://pubs.acs.org/doi/10.1021/acscentsci.1c00197.

Full sequences for SARS-CoV-2 spike glycoprotein, tozinameran, and Supplementary Figures (PDF)

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Notes

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NOTE ADDED IN PROOF

A putative sequence for the Moderna vaccine was reported while this manuscript was in production.[73] Although this sequence has not been validated, the initial report does include the statement that, "the RNAs that are now a part of the human ecosystem and that are likely to appear in numerous other high throughput RNA-seq studies in which a fraction of the individuals may have previously been vaccinated." In our view this is likely erroneous, as there is no evidence for long-term detection of mRNA vaccines in vaccinated individuals by RNA-seq. Indeed, all experimental evidence to date supports the view that synthetic mRNAs are efficiently destroyed by the body in the days following after vaccination.

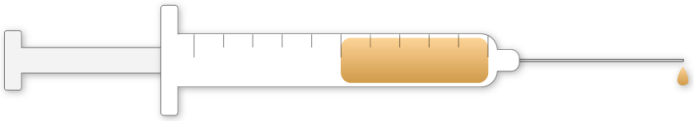
https://doi.org/10.1021/acscentsci.1c00197
ACS Cent. Sci. 2021, 7, 748−756

EXHIBIT 3

The New York Times https://nyti.ms/2WuvMsA

How the Johnson & Johnson Vaccine Works

By Jonathan Corum and Carl Zimmer Updated May 7, 2021

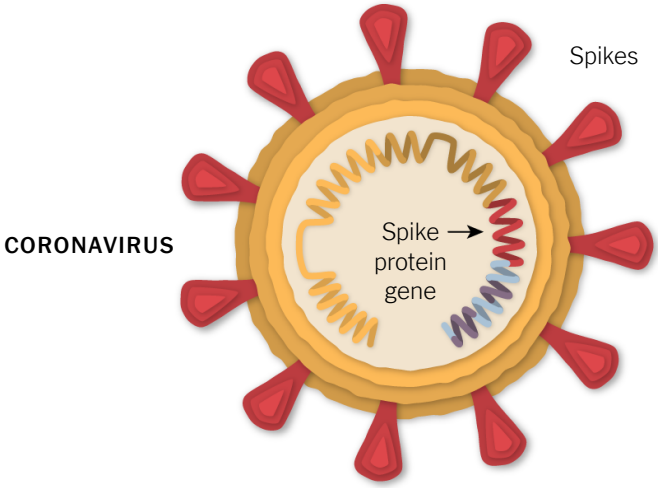


Johnson & Johnson is testing a coronavirus vaccine known as **JNJ-78436735** or **Ad26.COV2.S**. Clinical trials showed that a single dose of the vaccine had an efficacy rate of 72 percent in the United States, and a lower efficacy in countries where more contagious variants are widespread. The vaccine has been authorized for emergency use by the European Union, the United States and other countries.

Janssen Pharmaceutica, a Belgium-based division of Johnson & Johnson, developed the vaccine in collaboration with Beth Israel Deaconess Medical Center.

A Piece of the Coronavirus

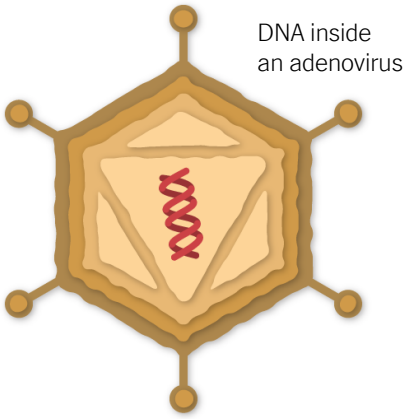
The SARS-CoV-2 virus is studded with proteins that it uses to enter human cells. These so-called spike proteins make a tempting target for potential vaccines and treatments.



The Johnson & Johnson vaccine is based on the virus's genetic instructions for building the spike protein. But unlike the Pfizer-BioNTech and Moderna vaccines, which store the instructions in single-stranded RNA, the Johnson & Johnson vaccine uses double-stranded DNA.

DNA Inside an Adenovirus

The researchers added the gene for the coronavirus spike protein to another virus called Adenovirus 26. Adenoviruses are common viruses that typically cause colds or flu-like symptoms. The Johnson & Johnson team used a modified adenovirus that can enter cells but can't replicate inside them or cause illness.

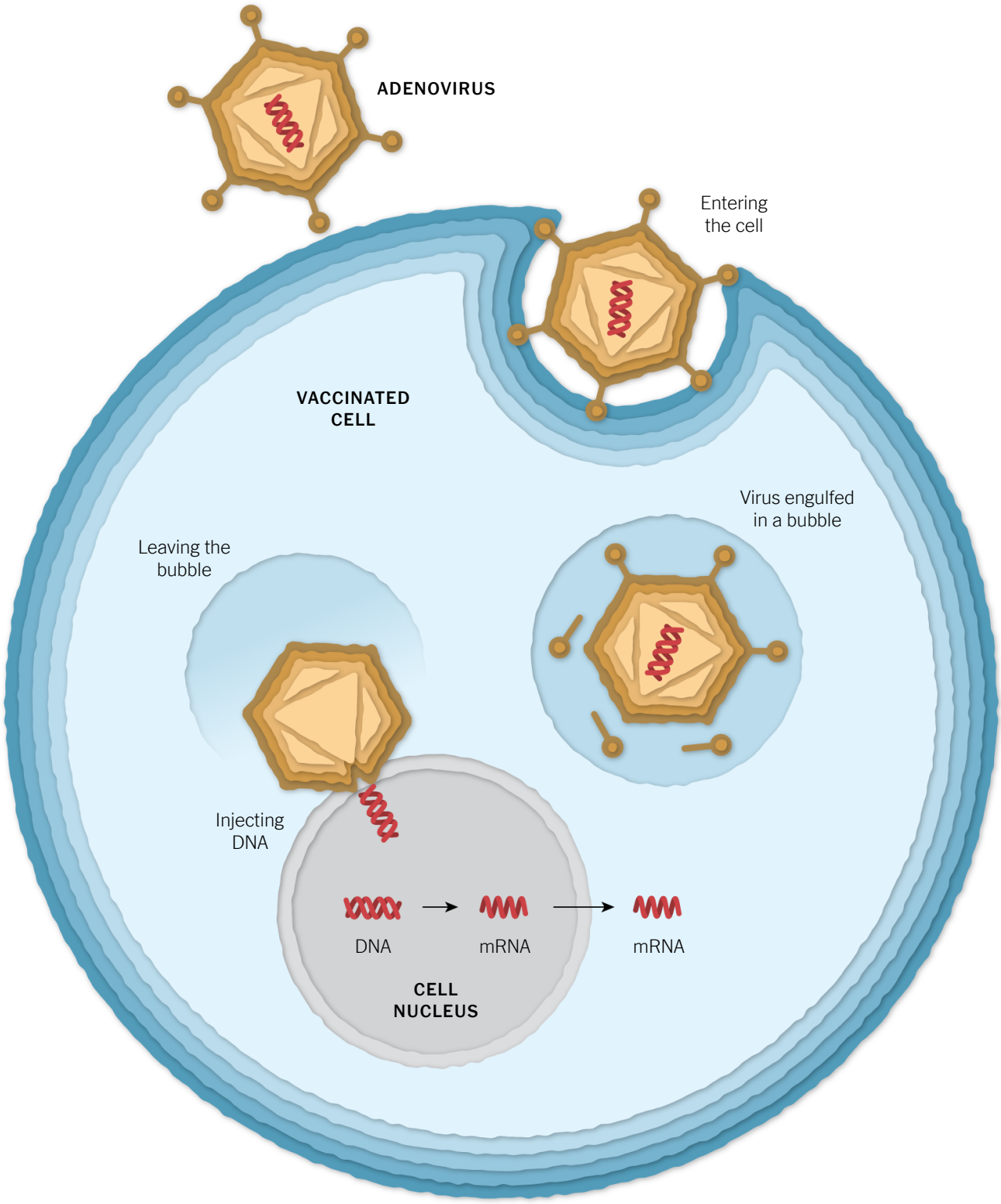


Johnson & Johnson's vaccine comes out of decades of research on adenovirus-based vaccines. In July, the first one was approved for general use — a vaccine for Ebola, also made by Johnson & Johnson. The company is also running trials on adenovirus-based vaccines for other diseases, including H.I.V. and Zika. Some other coronavirus vaccines are also based on adenoviruses, such as the one developed by the University of Oxford and AstraZeneca using a chimpanzee adenovirus.

Adenovirus-based vaccines for Covid-19 are more rugged than mRNA vaccines from Pfizer and Moderna. DNA is not as fragile as RNA, and the adenovirus's tough protein coat helps protect the genetic material inside. As a result, the Johnson & Johnson vaccine can be refrigerated for up to three months at 36–46°F (2–8°C).

Entering a Cell

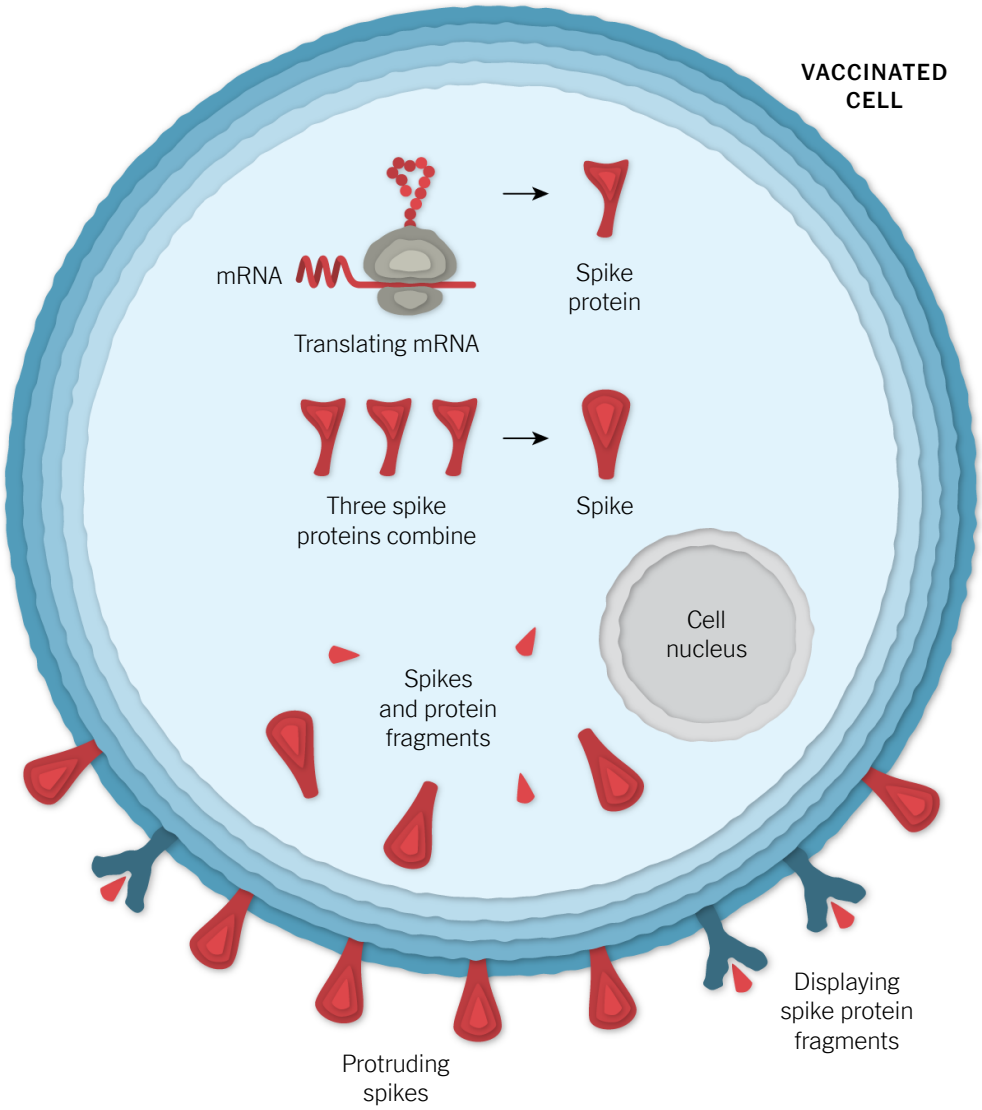
After the vaccine is injected into a person's arm, the adenoviruses bump into cells and latch onto proteins on their surface. The cell engulfs the virus in a bubble and pulls it inside. Once inside, the adenovirus escapes from the bubble and travels to the nucleus, the chamber where the cell's DNA is stored.



The adenovirus pushes its DNA into the nucleus. The adenovirus is engineered so it can't make copies of itself, but the gene for the coronavirus spike protein can be read by the cell and copied into a molecule called messenger RNA, or mRNA.

Building Spike Proteins

The mRNA leaves the nucleus, and the cell's molecules read its sequence and begin assembling spike proteins.

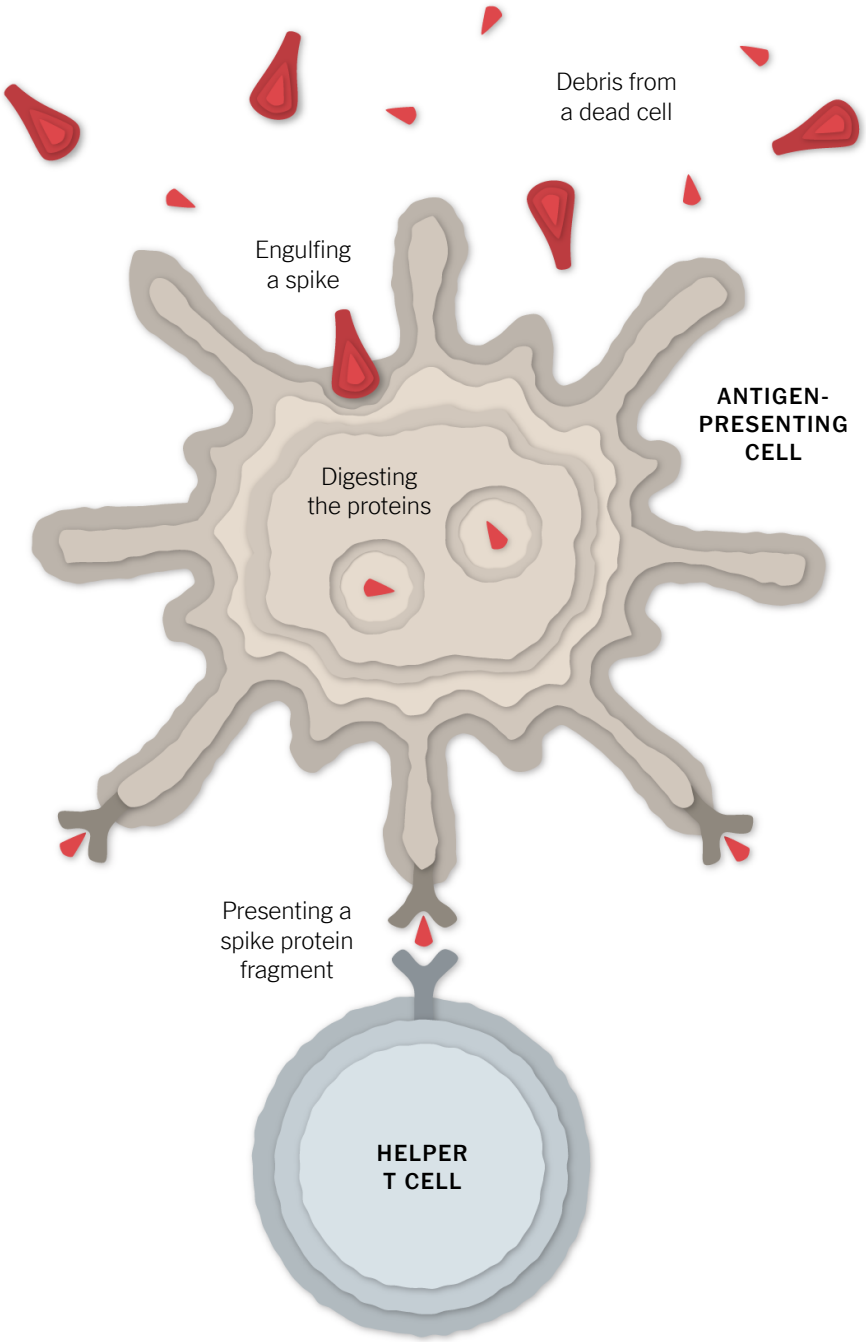


Some of the spike proteins produced by the cell form spikes that migrate to its surface and stick out their tips. The vaccinated cells also break up some of the proteins into fragments, which they present on their surface. These protruding spikes and spike protein fragments can then be recognized by the immune system.

The adenovirus also provokes the immune system by switching on the cell's alarm systems. The cell sends out warning signals to activate immune cells nearby. By raising this alarm, the Johnson & Johnson vaccine causes the immune system to react more strongly to the spike proteins.

Spotting the Intruder

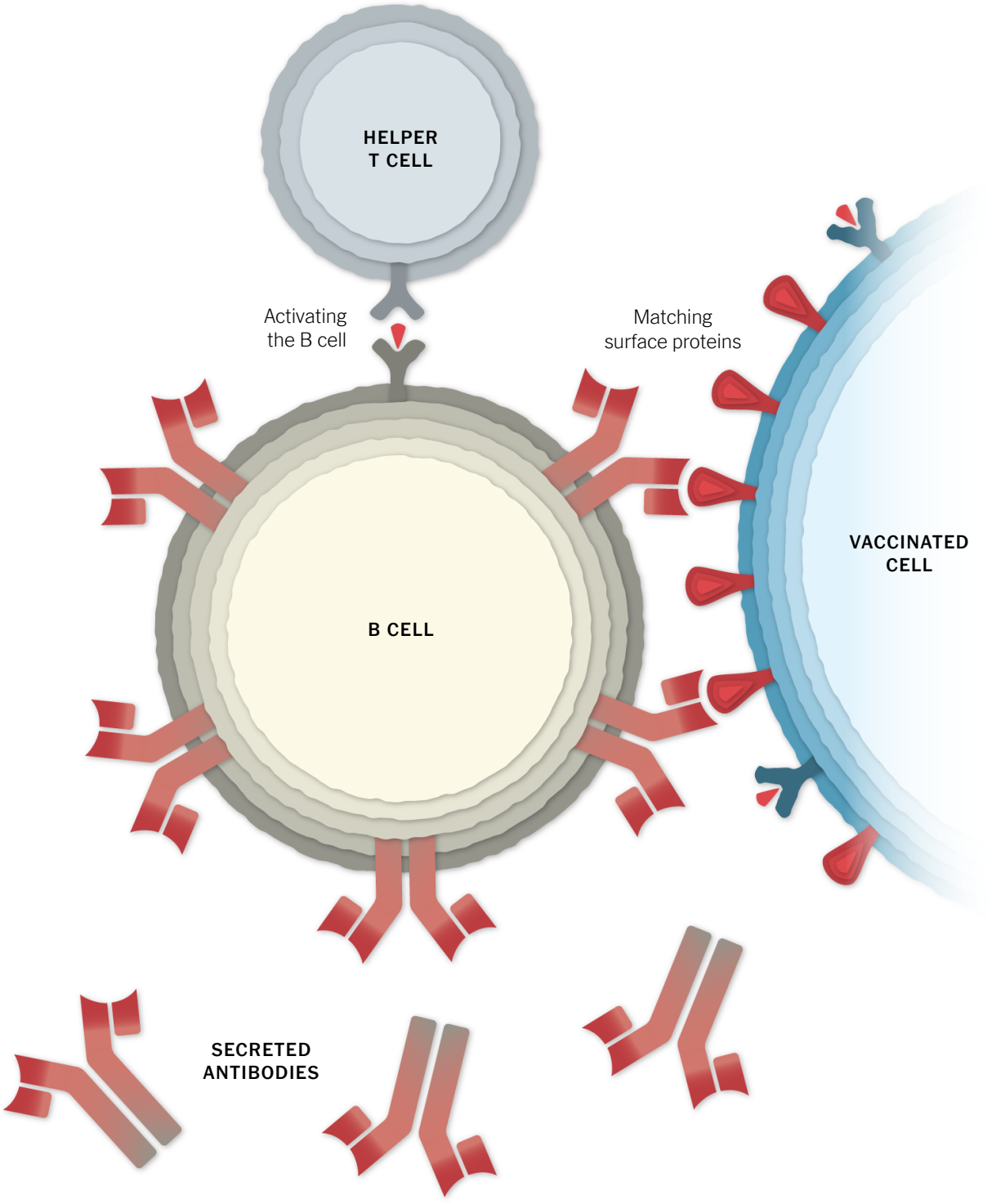
When a vaccinated cell dies, the debris contains spike proteins and protein fragments that can then be taken up by a type of immune cell called an antigen-presenting cell.



The cell presents fragments of the spike protein on its surface. When other cells called helper T cells detect these fragments, the helper T cells can raise the alarm and help marshal other immune cells to fight the infection.

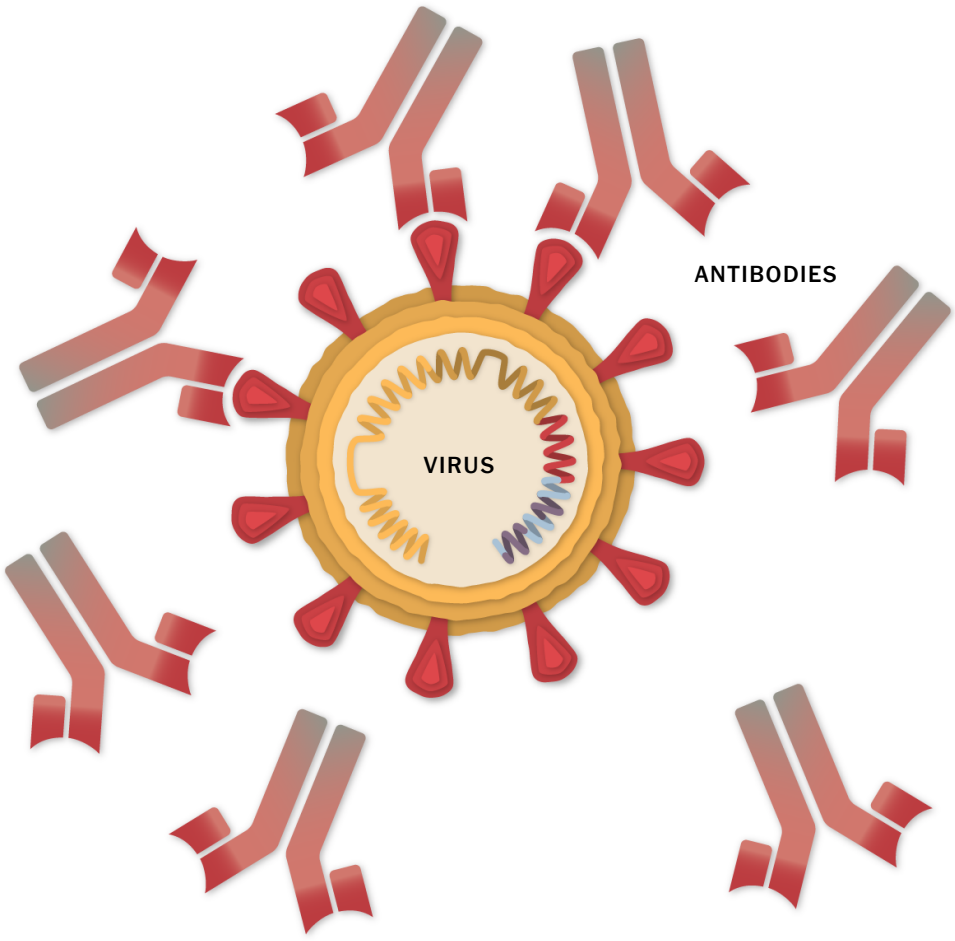
Making Antibodies

Other immune cells, called B cells, may bump into the coronavirus spikes on the surface of vaccinated cells, or free-floating spike protein fragments. A few of the B cells may be able to lock onto the spike proteins. If these B cells are then activated by helper T cells, they will start to proliferate and pour out antibodies that target the spike protein.



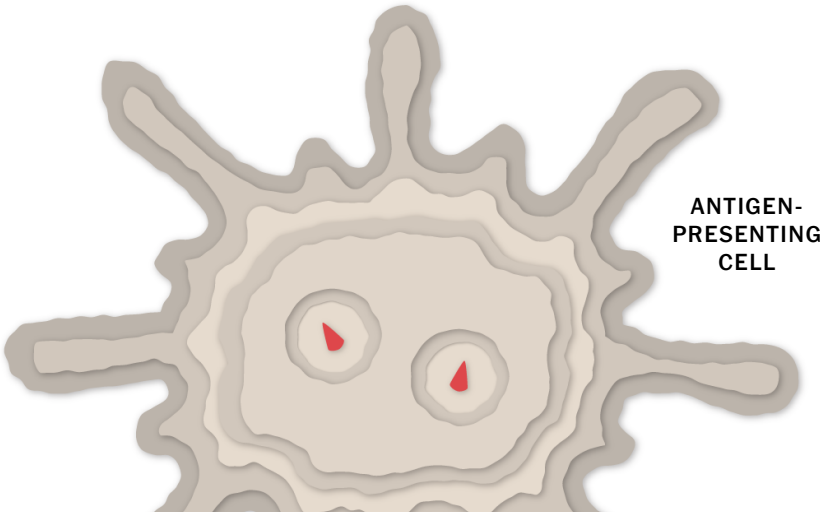
Stopping the Virus

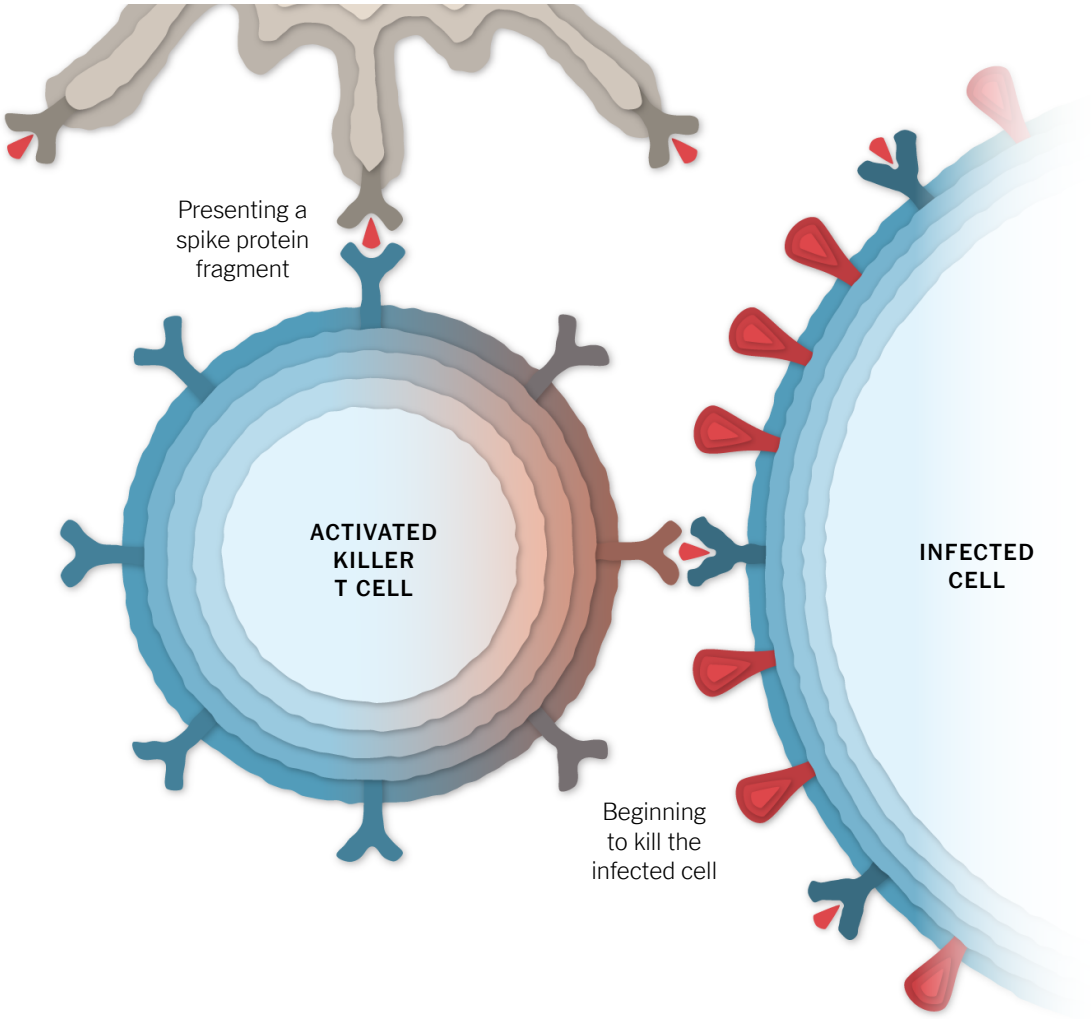
The antibodies can latch onto coronavirus spikes, mark the virus for destruction and prevent infection by blocking the spikes from attaching to other cells.



Killing Infected Cells

The antigen-presenting cells can also activate another type of immune cell called a killer T cell to seek out and destroy any coronavirus-infected cells that display the spike protein fragments on their surfaces.





Remembering the Virus

Johnson & Johnson's vaccine is given as a single dose, unlike the two-dose coronavirus vaccines from Pfizer, Moderna and AstraZeneca.

Researchers don't yet know how long the vaccine's protection might last. It's possible that the number of antibodies and killer T cells will drop in the months after vaccination. But the immune system also contains special cells called memory B cells and memory T cells that might retain information about the coronavirus for years or even decades.

Vaccine Timeline

January, 2020 Johnson & Johnson begins work on a coronavirus vaccine.

March Johnson & Johnson receives $456 million from the United States government to help develop and produce the vaccine.

July A Phase 1/2 trial begins. Unlike the clinical trials for other leading vaccines, the trial involves one dose, not two.

A dose of the Johnson & Johnson vaccine. Michael Ciaglo/Getty Images

August The federal government agrees to pay Johnson & Johnson $1 billion for 100 million doses, if the vaccine is approved.

September Johnson & Johnson launches a Phase 3 trial.

Oct. 8 The European Union reaches a deal to obtain 200 million doses.

Oct. 12 The company pauses its Phase 3 trial to investigate an adverse reaction in a volunteer.

Oct. 23 The trial resumes.

Nov. 16 Johnson & Johnson announces a second Phase 3 trial to observe the effects of two doses of their vaccine, instead of just one.

Dec. 17 Johnson & Johnson announces its Phase 3 trial is fully enrolled, with around 45,000 participants.

January, 2021 Preliminary results from the Phase 3 trial are expected in January. The company is aiming to produce at least a billion doses this year.

Jan. 13 Johnson & Johnson expects to release trial results in as little as two weeks. But the company is falling behind on its original production schedule.

Feb. 24 The vaccine had a 72 percent overall efficacy rate in the United States and 64 percent in South Africa, where a highly contagious variant called B.1.351 emerged in the fall and is now driving most cases. The vaccine also showed efficacy against severe forms of Covid-19.

Feb. 27 The Food and Drug Administration authorizes the vaccine for emergency use.

March 2 Merck will help manufacture the Johnson & Johnson vaccine.

April A plant in Baltimore run by Emergent BioSolutions ruined 15 million doses of the Johnson & Johnson vaccine.

April 13 Federal health officials call for a halt in the use of Johnson & Johnson's vaccine, after six women develop a rare blood-clotting disorder.

April 23 Researchers are examining how components of the Oxford-AstraZeneca vaccine might disrupt the normal blood clotting process under certain rare conditions.

April 23 Use of the vaccine will resume within days in the United States, but with a warning label about the risk of rare blood-clots.

May 3 Denmark announces it will no longer use Johnson & Johnson's vaccine, citing a risk of rare blood clots and the country's ample supply of other vaccines.

Sources: National Center for Biotechnology Information; Nature; Lynda Coughlan, University of Maryland School of Medicine.

Tracking the Coronavirus

United States

Latest Maps and Data
Cases and deaths for every county

Vaccinations
How many have been vaccinated, and who's eligible

Your Places
Build your own dashboard to track cases

Mask Mandates
See state mask guidance for schools and indoors

Your County's Risk
See guidance for your local area

Hospitals Near You
How many I.C.U. beds are occupied

World

Latest Maps and Data
Cases and deaths for every country

Global Vaccinations
How many have been vaccinated, by country

Health

Vaccines
Track their development

Treatments
Rated by effectiveness and safety

Previous Projects

Nursing Homes
The hardest-hit states and facilities

Colleges and Universities
Cases at more than 1,800 schools

Deaths Above Normal
The true toll of the pandemic in the U.S.

Deaths Above Normal
The true toll of coronavirus around the world

Countries

Australia
Brazil
Canada
France
Germany
India
Italy
Japan
Mexico
Spain
U.K.
United States

States, Territories and Cities

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
Florida
Georgia
Guam
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Northern Mariana Islands
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
U.S. Virgin Islands
Utah
Vermont
Virginia
Washington
Washington, D.C.
West Virginia
Wisconsin
Wyoming

Data

Frequently Asked Questions About the Covid Data

Access the Open Source Covid Data

EXHIBIT 4

EXCERPT PAGES 1 AND 20

Table of Contents

As filed with the Securities and Exchange Commission on November 28, 2018.

Registration No. 333-228300

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 1
to
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

MODERNA, INC.
(Exact name of registrant as specified in its charter)

Delaware	2836	81-3467528
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

200 Technology Square
Cambridge, MA 02139
(617) 714-6500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Stéphane Bancel
Chief Executive Officer
200 Technology Square
Cambridge, MA 02139
(617) 714-6500
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Stuart Cable, Esq. Kingsley Taft, Esq. Gregg Katz, Esq. Goodwin Procter LLP 100 Northern Avenue Boston, MA 02210 (617) 570-1000	Lori Henderson, Esq. General Counsel Moderna, Inc. 200 Technology Square Cambridge, MA 02139 (617) 714-6500	Patrick O'Brien, Esq. Michael S. Pilo, Esq. Ropes & Gray LLP Prudential Tower 800 Boylston Street Boston, MA 02116 (617) 951-7527

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☐
		Emerging Growth Company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)(4)
Common Stock, par value $0.0001 per share	25,000,000	$24.00	$600,000,000	$72,720.00

(1) Includes 3,260,869 shares that the underwriters have an option to purchase.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.
(3) Calculated pursuant to Rule 457(a) under the Securities Act of 1933, as amended, based on an estimate of the proposed maximum aggregate offering price.
(4) $60,600 of this registration fee was previously paid by the Registrant in connection with the filing of its Registration Statement on Form S-1 on November 9, 2018.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

- our improvements in the manufacturing processes for this new class of potential medicines may not be sufficient to satisfy the clinical or commercial demand of our mRNA investigational medicines or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability, and efficacy of our investigational medicines and development candidates;
- pricing or reimbursement issues or other factors that delay clinical trials or make any mRNA medicine uneconomical or noncompetitive with other therapies;
- failure to timely advance our programs or receive the necessary regulatory approvals or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, biologics license application, or BLA, or the equivalent application, discussions with the FDA or EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights of others and their competing products and technologies that may prevent our mRNA medicines from being commercialized.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and could act as a source of side effects, mRNA based medicines are designed to not irreversibly change cell DNA; however, side effects observed in gene therapy could negatively impact the perception of mRNA medicines despite the differences in mechanism. In addition, because no product in which mRNA is the primary active ingredient has been approved, the regulatory pathway for approval is uncertain. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one pharmaceutical product to the next, and may be difficult to predict.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred net losses in each year since our inception in 2009, including net losses of $216.2 million and $255.9 million for the years ended December 31, 2016 and 2017, respectively. As of December 31, 2017, we had an accumulated deficit of $621.9 million. As of September 30, 2018, we had an accumulated deficit of $865.2 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our platform. To date, we have financed our operations primarily through the sale of equity securities and proceeds from strategic alliances and, to a lesser extent, through grants from governmental and private organizations. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, strategic alliances, or additional grants. We have not commenced or completed pivotal clinical studies for any of our programs in clinical trials, or investigational medicines, and it will be several years, if ever, before we or our strategic collaborators have an investigational medicine ready for commercialization. Even if we obtain regulatory approval to market an investigational medicine, our future revenues will depend upon the size of any markets in which our investigational medicines have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue or expand our research or development of our programs in preclinical development;

EXHIBIT 5

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 be administered to:**
  - **prevent COVID-19 in individuals 12 through 15 years, and**
  - **provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.**

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

- **prevent COVID-19 in individuals 12 years of age and older, and**
- **provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.**

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.

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine are administered as a 2-dose series, 3 weeks apart, into the muscle.

[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.

Under EUA for individuals who are determined to have certain kinds of immunocompromise, a third dose may be administered at least 4 weeks after the second dose.

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

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.

[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.

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
- 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

WHO SHOULD GET THE VACCINE?

FDA has approved COMIRNATY (COVID-19 Vaccine, mRNA) for use in individuals 16 years of age and older and has authorized it for emergency use in individuals 12 through 15 years.

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

WHO SHOULD <u>NOT</u> GET THE VACCINE?

You should not get the COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 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 COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine include 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.

HOW IS THE VACCINE GIVEN?

COMIRNATY (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the vaccine, you should receive a second dose of the vaccine 3 weeks later to complete the vaccination series.

HAVE COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 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 Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020.

WHAT ARE THE BENEFITS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 VACCINE?

The vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF COMIRNATY (COVID-19 VACCINE, mRNA) AND THE PFIZER-BIONTECH COVID-19 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 COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 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 COMIRNATY (COVID-19 Vaccine, mRNA) or the Pfizer-BioNTech COVID-19 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)
- diarrhea
- vomiting
- arm pain

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 COMIRNATY (COVID-19 VACCINE, mRNA) OR THE PFIZER-BIONTECH COVID-19 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 second dose or if you have certain kinds of immunocompromise, your third dose of COMIRNATY (COVID-19 Vaccine, mRNA) or Pfizer-BioNTech COVID-19 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.

Pfizer

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

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

LAB-1451-7.2

Revised: 23 August 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

EXHIBIT 6

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. 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. 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 THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

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 MODERNA COVID-19 VACCINE?

Tell your 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
- 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

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 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 MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 Vaccine at least 1 month after the second dose.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?
In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
There is a remote chance that the Moderna COVID-19 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 Moderna COVID-19 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 Moderna COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Moderna COVID-19 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 Moderna COVID-19 Vaccine:

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

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is 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 "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

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 THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 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 MODERNA COVID-19 VACCINE?
Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM IMMUNOCOMPROMISED?
If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 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 MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 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.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

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 state or local 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, 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 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)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The 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 Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the 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 during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Moderna US, Inc.
Cambridge, MA 02139

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

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Barcode Date: 04/2021

EXHIBIT 7

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. 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. Symptoms may appear 2 to 14 days after exposure to the virus. Common 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 THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

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 JANSSEN COVID-19 VACCINE?

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

- have any allergies,
- have a fever,
- 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.

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.
- Swollen lymph nodes.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

Severe Allergic Reactions

There is a remote chance that the Janssen COVID-19 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 Janssen COVID-19 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.

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,

- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

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 "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

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

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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 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 THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 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 JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

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. 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, 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 TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE 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 for 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.

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The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: Aug/27/2021

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EXHIBIT 8

Centers for Disease Control and Prevention

Pfizer-BioNTech COVID-19 Vaccine Reactions & Adverse Events

On This Page

Persons Aged ≥18 Years

Local Reactions

Among all study vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 84.7% reported at least one local injection site reaction. By age group, 88.7% in the younger group (aged 18 to 55 years) and 79.7% in the older group (aged >55 years) reported at least one local reaction. Pain at the injection site was the most frequent and severe solicited local reaction among vaccine recipients. After dose 1, the younger age group reported pain more frequently than the older age group (83.1% vs 71.1%); a similar pattern was observed after dose 2 (77.8% vs 66.1%). Injection site redness and swelling following either dose were reported less frequently than injection site pain. Redness and swelling were slightly more common after dose 2. No grade 4 local reactions were reported. Overall, the median onset of local reactions in the vaccine group was 0 (day of vaccination) to 2 days after either dose and lasted a median duration between 1 and 2 days. Data on local reactions were not solicited from persons aged 16-17 years. However, their reactions to vaccination are expected to be similar to those of young adults who were included. In addition, reactogenicity data from adolescents aged 12-15 years were obtained and reviewed, and were similar to those from adults aged 18-55 years. This data is presented in Table 1 and Table 2 immediately below this paragraph.

Table 1. Local reactions in persons aged 18–55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Redness[a], n (%)				
Any	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Mild	70 (3.1)	16 (0.7)	73 (3.5)	8 (0.4)
Moderate	28 (1.2)	6 (0.3)	40 (1.9)	6 (0.3)
Severe	6 (0.3)	4 (0.2	10 (0.5)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Swelling[a], n (%)				
Any	132 (5.8)	11 (0.5)	132 (6.3)	5 (0.2)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Mild	88 (3.8)	3 (0.1)	80 (3.8)	3 (0.1)
Moderate	39 (1.7)	5 (0.2)	45 (2.1)	2 (0.1)
Severe	5 (0.2)	3 (0.1)	7 (0.3)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Pain at the injection site[b], n (%)				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Mild	1170 (51.1)	308 (13.4)	1039 (49.5)	225 (10.7)
Moderate	710 (31.0)	12 (0.5)	568 (27.1)	20 (1.0)
Severe	24 (1.0)	2 (0.1)	25 (1.2)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)

[a]Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b]Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Table 2. Local reactions in persons aged >55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Redness[a], n (%)				
Any	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Mild	55 (3.1)	12 (0.7)	59 (3.6)	8 (0.5)
Moderate	27 (1.5)	5 (0.3)	53 (3.2)	3 (0.2)
Severe	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Grade 4	0 (0.0)	0 (0)	0 (0)	0 (0)
Swelling[a], n (%)				
Any	118 (6.5)	21 (1.2)	124 (7.5)	11 (0.7)
Mild	71 (3.9)	10 (0.6)	68 (4.1)	5 (0.3)
Moderate	45 (2.5)	11 (0.6)	53 (3.2)	5 (0.3)
Severe	2 (0.1)	0 (0)	3 (0.2)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Pain at the injection site[b], n (%)				
Any	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Mild	1008 (55.9)	160 (8.9)	792 (47.7)	127 (7.7)
Moderate	270 (15.0)	6 (0.3)	298 (18.0)	2 (0.1)
Severe	4 (0.2)	0 (0)	8 (0.5)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)

[a] Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b] Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Systemic Reactions

Among all vaccine recipients asked to complete diaries of their symptoms during the 7 days after vaccination, 77.4% reported at least one systemic reaction. The frequency of systemic adverse events was higher in the younger than the older age group (82.8% vs 70.6%). Within each age group, the frequency and severity of systemic adverse events was higher after dose 2 than dose 1. Vomiting and diarrhea were exceptions, and similar between vaccine and placebo groups and regardless of dose. For both age groups, fatigue, headache and new or worsened muscle pain were most common. The majority of systemic events were mild or moderate in severity, after both doses and in both age groups. Fever was more common after the second dose and in the younger group (15.8%) compared to the older group (10.9%). Overall, the median onset of systemic adverse events in the vaccine group in general was 1 to 2 days after either dose and lasted a median duration of 1 day. Four grade 4 fevers (>40.0°C) were reported, two in the vaccine group and two in the placebo group. No other systemic grade 4 reactions were reported. Data on systemic reactions were not solicited from persons aged 16-17 years. However, their reactions to vaccination are expected to be similar to those of young adults who were included. In addition, reactogenicity data from adolescents aged 12-15 years were obtained and reviewed, and were similar to those from adults aged 18-55 years. This data is presented in Table 3 and Table 4 immediately below this paragraph.

Table 3. Systemic reactions in persons aged 18–55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Fever, n (%)				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0)	2 (0.1)	1 (0)	0 (0)
Fatigue[a], n (%)				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)
Mild	597 (26.1)	467 (20.3)	442 (21.1)	248 (11.8)
Moderate	455 (19.9)	289 (12.6)	708 (33.7)	217 (10.3)
Severe	33 (1.4)	11 (0.5)	97 (4.6)	14 (0.7)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Headache[a], n (%)				
Any	959 (41.9)	775 (33.7)	1085 (51.7)	506 (24.1)
Mild	628 (27.4)	505 (22.0)	538 (25.6)	321)15.3)
Moderate	308 (13.4)	251 (10.9)	480 (22.9)	170 (8.1)
Severe	23 (1.0)	19 (0.8)	67 (3.2)	15 (0.7)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Chills[a], n (%)				
Any	321 (14.0)	146 (6.4)	737 (35.1)	79 (3.8)
Mild	230 (10.0)	111 (4.8)	359 (17.1)	65 (3.1)
Moderate	82 (3.6)	33 (1.4)	333 (15.9)	14 (0.7)
Severe	9 (0.4)	2 (0.1)	45 (2.1)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting[b], n (%)				
Any	28 (1.2)	28 (1.2)	40 (1.9)	25 (1.2)
Mild	24 (1.0)	22 (1.0)	28 (1.3)	16 (0.8)
Moderate	4 (0.2)	5 (0.2)	8 (0.4)	9 (0.4)
Severe	0 (0)	1 (0)	4 (0.2)	0 (0)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=2291	Placebo N=2298	Pfizer-BioNTech Vaccine N=2098	Placebo N=2103
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhea[c], n (%)				
Any	255 (11.1)	270 (11.7)	219 (10.4)	177 (8.4)
Mild	206 (9.0)	217 (9.4)	179 (8.5)	144 (6.8)
Moderate	46 (2.0)	52 (2.3)	36 (1.7)	32 (1.5)
Severe	3 (0.1)	1 (0)	4 (0.2)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening muscle pain[a], n (%)				
Any	487 (21.3)	249 (10.8)	783 (37.3)	173 (8.2)
Mild	256 (11.2)	175 (7.6)	326 (15.5)	111 (5.3)
Moderate	218 (9.5)	72 (3.1)	410 (19.5)	59 (2.8)
Severe	13 (0.6)	2 (0.1)	47 (2.2)	3 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening joint pain[a], n (%)				
Any	251 (11.0)	138 (6.0)	459 (21.9)	109 (5.2)
Mild	147 (6.4)	95 (4.1)	205 (9.8)	54 (2.6)
Moderate	99 (4.3)	43 (1.9)	234 (11.2)	51 (2.4)
Severe	5 (0.2)	0 (0)	20 (1.0)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Use of antipyretic or pain medication	638 (27.8)	332 (14.4)	945 (45.0)	266 (12.6)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c]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 visit or hospitalization for severe diarrhea.

Table 4. Systemic reactions in persons aged >55 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0)	0 (0)	0 (0)
Fatigue[a], n (%)				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)
Mild	373 (20.7)	252 (14.1)	351 (21.1)	161 (9.8)
Moderate	240 (13.3)	150 (8.4)	442 (26.6)	114 (6.9)
Severe	2 (0.1)	3 (0.2)	46 (2.8)	2 (0.1)

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	Placebo N=1792	Pfizer-BioNTech Vaccine N=1660	Placebo N=1646
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Headache[a], n (%)				
Any	454 (25.2)	325 (18.1)	647 (39.0)	229 (13.9)
Mild	348 (19.3)	242 (13.5)	422 (25.4)	165 (10.0)
Moderate	104 (5.8)	80 (4.5)	216 (13.0)	60 (3.6)
Severe	2 (0.1)	3 (0.2)	9 (0.5)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Chills[a], n (%)				
Any	113 (6.3)	57 (3.2)	377 (22.7)	46 (2.8)
Mild	87 (4.8)	40 (2.2)	199 (12.0)	35 (2.1)
Moderate	26 (1.4)	16 (0.9)	161 (9.7)	11 (0.7)
Severe	0 (0)	1 (0.1)	17 (1.0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting[b], n (%)				
Any	9 (0.5)	9 (0.5)	11 (0.7)	5 (0.3)
Mild	8 (0.4)	9 (0.5)	9 (0.5)	5 (0.3)
Moderate	1 (0.1)	0 (0)	1 (0.1)	0 (0)
Severe	3 (0.2)	0 (0)	1 (0.1)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhea[c], n (%)				
Any	147 (8.2)	118 (6.6)	137 (8.3)	99 (6.0)
Mild	118 (6.5)	100 (5.6)	114 (6.9)	73 (4.4)
Moderate	26 (1.4)	17 (0.9)	21 (1.3)	22 (1.3)
Severe	3 (0.2)	1 (0.1)	2 (0.1)	4 (0.2)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening muscle pain[a], n (%)				
Any	251 (13.9)	149 (8.3)	477 (28.7)	87 (5.3)
Mild	168 (9.3)	100 (5.6)	202 (12.2)	57 (3.5)
Moderate	82 (4.6)	46 (2.6)	259 (15.6)	29 (1.8)
Severe	1 (0.1)	3 (0.2)	16 (1.0)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
New or worsening joint pain[a], n (%)				
Any	155 (8.6)	109 (6.1)	313 (18.9)	61 (3.7)
Mild	101 (5.6)	68 (3.8)	161 (9.7)	35 (2.1)
Moderate	52 (2.9)	40 (2.2)	145 (8.7)	25 (1.5)
Severe	2 (0.1)	1 (0.1)	7 (0.4)	1 (0.1)
Grade 4	0 (0)	0 (0)	0 (0)	0 (0)
Use of antipyretic or pain medication	358 (19.9)	213 (11.9)	625 (37.7)	161 (9.8)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c] 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 visit or hospitalization for severe diarrhea.

Unsolicited Adverse Events

Reports of lymphadenopathy were imbalanced with 58 more cases in the vaccine group (64) than the placebo group (6); lymphadenopathy is plausibly related to the vaccine. Lymphadenopathy occurred in the arm and neck region and was reported within 2 to 4 days after vaccination. The average duration of lymphadenopathy was approximately 10 days. Bell's palsy was reported by four vaccine recipients and none of the placebo recipients. The observed frequency of reported Bell's palsy in the vaccine group is consistent with the background rate in the general population, and there is no basis upon which to conclude a causal relationship.

Serious Adverse Events

Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent disability/incapacity. The proportions of participants who reported at least 1 serious adverse event were 0.6% in the vaccine group and 0.5% in the placebo group. The most common serious adverse events in the vaccine group which were numerically higher than in the placebo group were appendicitis (7 in vaccine vs 2 in placebo), acute myocardial infarction (3 vs 0), and cerebrovascular accident (3 vs 1). Cardiovascular serious adverse events were balanced between vaccine and placebo groups. Two serious adverse events were considered by U.S. Food and Drug Administration (FDA) as possibly related to vaccine: shoulder injury possibly related to vaccine administration or to the vaccine itself, and lymphadenopathy involving the axilla contralateral to the vaccine injection site. Otherwise, occurrence of severe adverse events involving system organ classes and specific preferred terms were balanced between vaccine and placebo groups.

Data source: FDA briefing document

Persons Aged 12 – 15 Years

Local Reactions

Among all study vaccine recipients aged 12–15 years, 90.9% reported at least one local injection site reaction in the 7 days after vaccination. Pain at the injection site was the most frequent and severe solicited local reaction among vaccine recipients and was slightly more common after dose 2. No grade 4 local reactions were reported. The median onset of local reactions in the vaccine group was 0 (day of vaccination) to 2 days after either dose and lasted a median duration between 1 and 3 days. This data is presented in Table 5 below.

Table 5. Local reactions in persons aged 12-15 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1 12-15 Years		Dose 2 12-15 Years	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Redness[a], n (%)				
Any	65 (5.8)	12 (1.1)	55 (5.0)	10 (0.9)
Mild	44 (3.9)	11 (1.0)	29 (2.6)	8 (0.7)
Moderate	20 (1.8)	1 (0.1)	26 (2.4)	2 (0.2)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
Swelling[a], n (%)				
Any	78 (6.9)	11 (1.0)	54 (4.9)	6 (0.6)
Mild	55 (4.9)	9 (0.8)	36 (3.3)	4 (0.4)
Moderate	23 (2.0)	2 (0.2)	18 (1.6)	2 (0.2)
Severe	0	0	0	0
Grade 4	0	0	0	0

	Dose 1 12-15 Years		Dose 2 12-15 Years	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Pain at the injection site[b], n (%)				
Any	971 (86.2)	263 (23.3)	866 (78.9)	193 (17.9)
Mild	467 (41.4)	227 (20.1)	466 (42.5)	164 (15.2)
Moderate	493 (43.7)	36 (3.2)	393 (35.8)	29 (2.7)
Severe	11 (1.0)	0	7 (0.6)	0
Grade 4	0	0	0	0

[a]Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).

[b]Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.

Systemic Reactions

Among all vaccine recipients, 90.7% reported at least one systemic reaction in the 7 days after vaccination. The frequency and severity of systemic adverse events was higher after dose 2 than dose 1. Vomiting and diarrhea were exceptions, and similar between vaccine and placebo groups and regardless of dose. Fatigue, headache, chills, and new or worsened muscle pain were most common. The majority of systemic events were mild or moderate in severity, after both doses. Fever was more common after the second dose than after the first dose. Overall, the median onset of systemic adverse events in the vaccine group in general was 1 to 3 days after either dose and lasted a median duration of 1 to 2 days. One grade 4 fever (>40.0°C) was reported in the vaccine group. No other systemic grade 4 reactions were reported. This data is presented in Table 6 below.

Table 6. Systemic reactions in persons aged 12-15 years, Pfizer-BioNTech COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Fever, n (%)				
≥38.0°C	114 (10.1)	12 (1.1)	215 (19.6)	7 (0.6)
≥38.0°C to 38.4°C	74 (6.6)	8 (0.7)	107 (9.8)	5 (0.5)
>38.4°C to 38.9°C	29 (2.6)	2 (0.2)	83 (7.6)	1 (0.1)
>38.9°C to 40.0°C	10 (0.9)	2 (0.2)	25 (2.3)	1 (0.1)
>40.0°C	1 (0.1)	0	0	0
Fatigue[a], n (%)				
Any	677 (60.1)	457 (40.6)	726 (66.2)	264 (24.5)
Mild	278 (24.7)	250 (22.2)	232 (21.1)	133 (12.3)
Moderate	384 (34.1)	199 (17.7)	468 (42.7)	127 (11.8)
Severe	15 (1.3)	8 (0.7)	26 (2.4)	4 (0.4)
Grade 4	0	0	0	0
Headache[a], n (%)				
Any	623 (55.3)	396 (35.1)	708 (64.5)	263 (24.4)
Mild	361 (32.0)	256 (22.7)	302 (27.5)	169 (15.7)
Moderate	251 (22.3)	131 (11.6)	384 (35.0)	93 (8.6)
Severe	11 (1.0)	9 (0.8)	22 (2.0)	1 (0.1)
Grade 4	0	0	0	0

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1127	Placebo N=1127	Pfizer-BioNTech Vaccine N=1097	Placebo N=1078
Chills[a], n (%)				
Any	311 (27.6)	109 (9.7)	455 (41.5)	73 (6.8)
Mild	195 (17.3)	82 (7.3)	221 (20.1)	52 (4.8)
Moderate	111 (9.8)	25 (2.2)	214 (19.5)	21 (1.9)
Severe	5 (0.4)	2 (0.2)	20 (1.8)	0
Grade 4	0	0	0	0
Vomiting[b], n (%)				
Any	31 (2.8)	10 (0.9)	29 (2.6)	12 (1.1)
Mild	30 (2.7)	8 (0.7)	25 (2.3)	11 (1.0)
Moderate	0	2 (0.2)	4 (0.4)	1 (0.1)
Severe	1 (0.1)	0	0	0
Grade 4	0	0	0	0
Diarrhea[c], n (%)				
Any	90 (8.0)	82 (7.3)	65 (5.9)	43 (4.0)
Mild	77 (6.8)	72 (6.4)	59 (5.4)	38 (3.5)
Moderate	13 (1.2)	10 (0.9)	6 (0.5)	5 (0.5)
Severe	0	0	0	0
Grade 4	0	0	0	0
New or worsening muscle pain[a], n (%)				
Any	272 (24.1)	148 (13.1)	355 (32.4)	90 (8.3)
Mild	125 (11.1)	88 (7.8)	152 (13.9)	51 (4.7)
Moderate	145 (12.9)	60 (5.3)	197 (18.0)	37 (3.4)
Severe	2 (0.2)	0	6 (0.5)	2 (0.2)
Grade 4	0	0	0	0
New or worsening joint pain[a], n (%)				
Any	109 (9.7)	77 (6.8)	173 (15.8)	51 (4.7)
Mild	66 (5.9)	50 (4.4)	91 (8.3)	30 (2.8)
Moderate	42 (3.7)	27 (2.4)	78 (7.1)	21 (1.9)
Severe	1 (0.1)	0	4 (0.4)	0
Grade 4	0	0	0	0
Any systemic event	877 (77.8)	636 (56.4)	904 (82.4)	439 (40.7)
Use of antipyretic or pain medication, n (%)	413 (36.6)	111 (9.8)	557 (50.8)	95 (8.8)

[a] Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe muscle pain, or severe joint pain.

[b] Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.

[c] 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 visit or hospitalization for severe diarrhea.

Unsolicited Adverse Events

Reports of lymphadenopathy were imbalanced with 6 more cases in the vaccine group (7) than the placebo group (1); lymphadenopathy is plausibly related to the vaccine. Lymphadenopathy occurred in the arm and neck region and was reported within 2 to 4 days after vaccination. Most cases of lymphadenopathy resolved in 10 days or less. No bell's palsy or anaphylaxis was reported among vaccine recipients in this age group.

Serious Adverse Events

The proportions of participants who reported at least 1 serious adverse event were 0.4% in the vaccine group and 0.2% in the placebo group. No serious adverse events were considered by FDA as possibly related to vaccine.

Data source: FDA Decision Memo

Page last reviewed: October 12, 2021

EXHIBIT 9

Centers for Disease Control and Prevention

The Moderna COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events

Local Reactions

Local reactions were reported by the majority of vaccine recipients and at higher rates than placebo recipients. Vaccine recipients reported higher rates of local reactions after dose 2 than dose 1. The frequency of local reactions was higher in the younger age group (aged 18 to 64 years) than the older age group (aged ≥65 years) (90.5% vs 83.9% after dose 2). Pain at the injection site was the most frequent and severe reported solicited local reaction among vaccine recipients. After dose 1, the younger age group reported pain more frequently than the older age group (86.9% vs 74.0%); a similar pattern was observed after dose 2 (90.1% vs 83.4%). Axillary swelling or tenderness was the second most frequently reported local reaction. Axillary swelling or tenderness was reported more frequently in the younger age group than the older age group (16.0% vs 8.4% after dose 2). Injection site redness and swelling following either dose were reported less frequently. Redness and swelling were slightly more common after dose 2. No grade 4 local reactions were reported. Overall, the median onset of local reactions in the vaccine group was 1 day after either dose, with a median duration between 2 and 3 days. (Table 1, Table 2)

Table 1. Local reactions in persons aged 18-64 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=11401	Placebo N=11404	Moderna Vaccine N=10357	Placebo N=10317
Any Local, n (%)				
Any	9960 (87.4)	2432 (21.3)	9371 (90.5)	2134 (20.7)
Grade 3	452 (4.0)	39 (0.3)	766 (7.4)	41 (0.4)
Pain[a], n (%)				
Any	9908 (86.9)	2179 (19.1)	9335 (90.1)	1942 (18.8)
Grade 3	367 (3.2)	23 (0.2)	479 (4.6)	21 (0.2)
Redness[a], n (%)				
Any	345 (3.0)	46 (0.4)	928 (9.0)	42 (0.4)
Severe	34 (0.3)	11 (<0.1)	206 (2.0)	12 (0.1)
Swelling[b], n (%)				
Any	768 (6.7)	33 (0.3)	1309 (12.6)	35 (0.3)
Grade 3	62 (0.5)	3 (<0.1)	176 (1.7)	4 (<0.1)
Axillary Swelling/Tenderness[c], n (%)				
Any	1322 (11.6)	567 (5.0)	1654 (16.0)	444 (4.3)
Grade 3	36 (0.3)	13 (0.1)	45 (0.4)	10 (<0.1)

[a] Pain grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.

[b] Swelling grade 3: >100mm/>10cm; grade 4: necrosis/exfoliative dermatitis.

[c] Axillary swelling or tenderness was collected as a solicited local adverse reaction (i.e., lymphadenopathy: localized axillary swelling or tenderness ipsilateral to the vaccination arm); grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.

Note: No grade 4 local reactions were reported.

Table 2. Local reactions in persons aged ≥65 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=3762	Placebo N=3746	Moderna Vaccine N=3587	Placebo N=3549
Any Local, n (%)				
Any	2805 (74.6)	566 (15.1)	3010 (83.9)	473 (13.3)
Grade 3	77 (2.0)	39 (1.0)	212 (5.9)	29 (0.8)
Pain[a], n (%)				
Any	2782 (74.0)	481(12.8)	2990 (83.4)	421 (11.9)
Grade 3	50 (1.3)	32 (0.9)	96 (2.7)	17 (0.5)
Redness[a], n (%)				
Any	86 (2.3)	19 (0.5)	265 (7.4)	13 (0.4)
Grade 3	8 (0.2)	2 (<0.1)	75 (2.1)	3 (<0.1)
Swelling[b], n (%)				
Any	166 (4.4)	19 (0.5)	386 (10.8)	13 (0.4)
Grade 3	20 (0.5)	3 (<0.1)	69 (1.9)	7 (0.2)
Axillary Swelling/Tenderness[c], n (%)				
Any	231 (6.1)	155 (4.1)	302 (8.4)	90 (2.5)
Grade 3	12 (0.3)	14 (0.4)	21 (0.6)	8 (0.2)

[a] Pain grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.

[b] Swelling grade 3: >100mm/>10cm; grade 4: necrosis/exfoliative dermatitis.

[c] Axillary swelling or tenderness was collected as a solicited local adverse reaction (i.e. lymphadenopathy: localized axillary swelling or tenderness ipsilateral to the vaccination arm); grade 3: any use of prescription pain reliever or prevented daily activity; grade 4: required emergency room visit or hospitalization.

Note: No grade 4 local reactions were reported.

Systemic Reactions

Systemic reactions were reported by the majority of vaccine recipients and at higher rates than placebo recipients. The frequency of systemic reactions was higher in the younger age group than the older age group (81.9% vs 71.9% after dose 2). Within each age group, the frequency and severity of systemic reactions was higher after dose 2 than dose 1. For both age groups, fatigue, headache and myalgia were the most common. The majority of systemic reactions were mild or moderate in severity, after both doses and in both age groups. Fever was more common after the second dose and in the younger group (17.6%) compared to the older group (10.2%). Among vaccine recipients, the median onset of systemic reactions was 1 to 2 days after either dose, with a median duration of 2 days. Grade 4 fever (>40.0°C) was reported by four vaccine recipients after dose 1 and 11 vaccine recipients after dose 2. There was one report of grade 4 fatigue and one report of grade 4 arthralgia, both in the younger age group after dose 1. In the older age group, there was one report of grade 4 nausea or vomiting after dose 2. No other systemic grade 4 reactions were reported. (Table 3, Table 4)

Table 3. Systemic reactions in persons aged 18-64 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=11405	Placebo N=11406	Moderna Vaccine N=10358	Placebo N=10320
Any systemic, n (%)				
Any	6503 (57.0)	5063 (44.4)	8484 (81.9)	3967 (38.4)
Grade 3	363 (3.2)	248 (2.2)	1801 (17.4)	215 (2.1)
Grade 4	5 (<0.1)	4 (<0.1)	10 (<0.1)	2 (<0.1)
Fever[a], n (%)				
Any	105 (0.9)	39 (0.3)	1806 (17.4)	38 (0.4)
Grade 3	10 (<0.1)	1 (<0.1)	168 (1.6)	1 (<0.1)
Grade 4	4 (<0.1)	4 (<0.1)	10 (<0.1)	1 (<0.1)
Headache[b], n (%)				
Any	4031(35.4)	3303 (29.0)	6500 (62.8)	2617 (25.4)
Grade 3	219 (1.9)	162 (1.4)	515 (5.0)	124 (1.2)
Fatigue[c], n (%)				
Any	4384 (38.5)	3282 (28.8)	7002 (67.6)	2530 (24.5)
Grade 3	120 (1.1)	83 (0.7)	1099 (10.6)	81 (0.8)
Grade 4	1 (<0.1)	0 (0)	0 (0)	0 (0)
Myalgia[c], n (%)				
Any	2698 (23.7)	1626 (14.3)	6353 (61.3)	1312 (12.7)
Grade 3	73 (0.6)	38 (0.3)	1032 (10.0)	39 (0.4)
Arthralgia[c], n (%)				
Any	1892 (16.6)	1327 (11.6)	4685 (45.2)	1087 (10.5)
Grade 3	47 (0.4)	29 (0.3)	603 (5.8)	36 (0.3)
Grade 4	1 (<0.1)	0 (0)	0 (0)	0 (0)
Nausea/Vomiting[d], n (%)				
Any	1069 (9.3)	908 (8.0)	2209 (21.3)	754 (7.3)
Grade 3	6 (<0.1)	8 (<0.1)	8 (<0.1)	8 (<0.1)
Chills[e], n (%)				
Any	1051 (9.2)	730 (6.4)	5001 (48.3)	611 (5.9)
Grade 3	17 (0.1)	8 (<0.1)	151 (1.5)	14 (0.1)

[a] Fever – Grade 3: ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: >40.0°C or >104.0°F
[b] Headache – Grade 3: significant; any use of prescription pain reliever or prevented daily activity; Grade 4: required emergency room visit or hospitalization.
[c] Fatigue, Myalgia, Arthralgia – Grade 3: significant; prevented daily activity; Grade 4: required emergency room visit or hospitalization.
[d] Nausea/Vomiting – Grade 3: prevented daily activity, required outpatient intravenous hydration; Grade 4: required emergency room visit or hospitalization for hypotensive shock.
[e] Chills – Grade 3: prevented daily activity and required medical intervention; Grade 4: required emergency room visit or hospitalization.

Table 4. Systemic reactions in persons aged ≥65 years, Moderna COVID-19 vaccine and placebo

	Dose 1		Dose 2	
	Moderna Vaccine N=3761	Placebo N=3748	Moderna Vaccine N=3589	Placebo N=3549

	Dose 1		Dose 2	
	Moderna Vaccine N=3761	Placebo N=3748	Moderna Vaccine N=3589	Placebo N=3549
Any systemic, n (%)				
Any	1818 (48.3)	1335 (35.6)	2580 (71.9)	1102 (31.1)
Grade 3	84 (2.2)	63 (1.7)	387 (10.8)	58 (1.6)
Grade 4	0 (0)	0 (0)	2 (<0.1)	1 (<0.1)
Fever[a], n (%)				
Any	10 (0.3)	7 (0.2)	366 (10.2)	5 (0.1)
Grade 3	1 (<0.1)	1 (<0.1)	18 (0.5)	0 (0)
Grade 4	0 (0)	2 (<0.1)	1 (<0.1)	1 (<0.1)
Headache[b], n (%)				
Any	921 (33.3)	443 (11.8)	1665 (46.4)	635 (17.9)
Grade 3	30 (0.8)	34 (0.9)	107 (3.0)	32 (0.9)
Fatigue[c], n (%)				
Any	1251 (38.5)	851 (22.7)	2094 (58.4)	695 (19.6)
Grade 3	120 (1.1)	23 (0.6)	248 (6.9)	20 (0.6)
Myalgia[c], n (%)				
Any	743 (19.8)	443 (11.8)	1683 (46.9)	385 (10.8)
Grade 3	17 (0.5)	9 (0.3)	201 (5.6)	10 (0.3)
Arthralgia[c], n (%)				
Any	618 (16.4)	456 (12.2)	1252 (34.9)	381 (10.7)
Grade 3	13 (0.3)	8 (0.2)	122 (3.4)	7 (0.2)
Nausea/Vomiting[d], n (%)				
Any	194 (5.2)	166 (4.4)	425 (11.8)	129 (3.6)
Grade 3	4 (0.1)	4 (0.1)	10 (0.3)	3 (<0.1)
Grade 4	0 (0)	0 (0)	1 (<0.1)	0 (0)
Chills[e], n (%)				
Any	202 (5.4)	148 (4.0)	1099 (30.6)	144 (4.1)
Grade 3	7 (0.2)	6 (0.2)	27 (0.8)	2 (<0.1)

[a] Fever – Grade 3: ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F; Grade 4: >40.0°C or >104.0°F

[b] Headache – Grade 3: significant; any use of prescription pain reliever or prevented daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, Myalgia, Arthralgia – Grade 3: significant; prevented daily activity; Grade 4: required emergency room visit or hospitalization.

[d] Nausea/Vomiting – Grade 3: prevented daily activity, required outpatient intravenous hydration; Grade 4: Requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills – Grade 3: prevented daily activity and required medical intervention; Grade 4: required emergency room visit or hospitalization.

Unsolicited Adverse Events

A higher frequency of unsolicited adverse events was reported in the vaccine group compared to the placebo group and was primarily attributed to local and systemic reactogenicity following vaccination. Reports of lymphadenopathy were imbalanced with 1.1 % of persons in the vaccine group and 0.6% in the placebo group reporting such events; lymphadenopathy is plausibly related to the vaccine. Lymphadenopathy occurred in the arm and neck region and was reported within 2 to 4 days after vaccination. The median duration of lymphadenopathy was 1 to 2 days. Bell's palsy was reported by three vaccine recipients and one placebo recipient. One case of Bell's palsy in the vaccine group was considered a serious adverse event. Currently available information is insufficient to determine a causal relationship with the vaccine.

Serious Adverse Events

Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent disability or incapacity. The proportions of participants who reported at least one serious adverse event were 1% in the vaccine group and 1% in the placebo group. The most common serious adverse events occurring at higher rates in the vaccine group than the placebo group were myocardial infarction (5 cases in vaccine group vs. 3 cases in placebo group), cholecystitis (3 vs. 0), and nephrolithiasis (3 vs. 0). Three serious adverse events were considered by the U.S. Food and Drug Administration (FDA) as possibly related to vaccine: the one report of intractable nausea/vomiting and two reports of facial swelling in persons who had a previous history of cosmetic filler injections. The possibility that the vaccine contributed to the serious adverse event reports of rheumatoid arthritis (n=1), peripheral edema/dyspnea with exertion (n=1), and autonomic dysfunction (n=1) cannot be excluded.

Data source: FDA briefing document

Page last reviewed: August 9, 2021

EXHIBIT 10

Centers for Disease Control and Prevention

The Janssen COVID-19 Vaccine's Local Reactions, Systemic Reactions, Adverse Events, and Serious Adverse Events

Local Reactions

Local reactions were reported at higher rates by vaccine recipients than placebo recipients. The frequency of any local reaction was higher in participants aged 18 to 59 years than participants aged ≥60 years (59.8% vs 35.4%). Pain at the injection site was the most frequently reported solicited local reaction among vaccine recipients (58.6% of 18-59-year-olds and 33.3% ≥60-year-olds). Erythema and swelling were reported less frequently. No grade 4 local reactions were reported. Overall, the median onset of local reactions in the vaccine group was within two days of vaccination, with a median duration 2 days for erythema and pain and 3 days for swelling. (Table 1)

Table 1. Local reactions in persons aged 18-59 years and persons aged ≥60 years, Janssen COVID-19 vaccine and placebo[a]

	18-59 years		≥60 years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
Any Local, n (%)				
Any	1218 (59.8)	413 (20.2)	467 (35.4)	244 (18.3)
Grade 3	18 (0.9)	4 (0.2)	5 (0.4)	2 (0.2)
Pain[b], n (%)				
Any	1193 (58.6)	357 (17.4)	439 (33.3)	207 (15.6)
Grade 3	8 (0.4)	0 (0.0)	3 (0.2)	2 (0.2)
Erythema[c], n (%)				
Any	184 (9.0)	89 (4.3)	61 (4.6)	42 (3.2)
Grade 3	6 (0.3)	2 (0.1)	1 (0.1)	0 (0.0)
Swelling[c], n (%)				
Any	142 (7.0)	32 (1.6)	36 (2.7)	21 (1.6)
Grade 3	5 (0.2)	2 (0.1)	2 (0.2)	0 (0.0)

[a] Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

[b] Pain – Grade 3: any use of prescription pain reliever or prevented daily activity

[c] Erythema and Swelling – Grade 3: >100mm

Note: No grade 4 local reactions were reported.

Systemic Reactions

Systemic reactions were reported at higher rates by vaccine recipients than placebo recipients. The frequency of systemic reactions was higher in participants aged 18-59 years than participants ≥60 years (61.5% vs 45.3%). For both age groups, fatigue and headache were the most commonly reported systemic reactions. Fever was more common in participants 18-59

years (12.8%) compared to those ≥60 years (3.1%). The majority of systemic reactions were mild or moderate in severity. The most common grade 3 reactions were fatigue and myalgia. No grade 4 reactions were reported. Among vaccine recipients, the median onset of systemic reactions within 2 days of vaccination, with a median duration of 1-2 days. (Table 2)

Table 2. Systemic reactions in persons aged 18–59 years and persons aged ≥60 years, Janssen COVID-19 vaccine and placebo[a]

	18-59 years		≥60 years	
	Janssen Vaccine N=2036	Placebo N=2049	Janssen Vaccine N=1320	Placebo N=1331
Any systemic, n (%)				
Any	1252 (61.5)	745 (36.4)	598 (45.3)	440 (33.1)
Grade 3	47 (2.3)	12 (0.6)	14 (1.1)	9 (0.7)
Fatigue[b], n (%)				
Any	891 (43.8)	451 (22.0)	392 (29.7)	277 (20.8)
Grade 3	25 (1.2)	4 (0.2)	10 (0.8)	5 (0.4)
Headache[b], n (%)				
Any	905 (44.4)	508 (24.8)	401 (30.4)	294 (22.1)
Grade 3	18 (0.9)	5 (0.2)	5 (0.4)	4 (0.3)
Myalgia[b], n (%)				
Any	796 (39.1)	248 (12.1)	317 (24.0)	182 (13.7)
Grade 3	29 (1.4)	1 (<0.1)	3 (0.2)	5 (0.4)
Nausea[c], n (%)				
Any	315 (15.5)	183 (8.9)	162 (12.3)	144 (10.8)
Grade 3	3 (0.1)	3 (0.1)	3 (0.2)	3 (0.2)
Fever[d], n (%)				
Any	261 (12.8)	14 (0.7)	41 (3.1)	6 (0.5)
Grade 3	7 (0.3)	0 (0.0)	1 (0.1)	0 (0.0)

[a] Solicited local and systemic adverse reactions collected for participants in a safety subset (N=6,736)

[b] Fatigue, Headache, Myalgia – Grade 3: use of prescription pain reliever or prevented daily activity

[c] Nausea – Grade 3: prevented daily activity

[d] Fever – Grade 3: ≥39.0 – ≤40.0°C or ≥102.1 – ≤104.0°F

Note: No grade 4 systemic reactions were reported.

Analgesic/Antipyretics Use

Among vaccine recipients aged 18-59 years, 26.4% reported using antipyretic or analgesic medications, compared to 6.0% of placebo recipients. Among vaccine recipients aged ≥60 years, 9.8% reported using antipyretic or analgesic medications, compared to 5.1% of placebo recipients. The reason for medication use (e.g. fever, pain) was not ascertained.

Unsolicited Adverse Events

Overall, rates of reported unsolicited adverse events were similar in the vaccine and placebo groups (13.1% vs 12.0%). Reports of embolic and thrombotic events had a slight numerical imbalance with 0.06% of vaccine recipients and 0.05% of placebo recipients reporting such events. Risk factors for these events were present in the participants, however vaccine cannot be excluded as a contributing factor. Reports of tinnitus had a numerical imbalance with 6 events in vaccine recipients and no events in placebo recipients. Data are insufficient at this time to determine if there is a casual relationship between the

vaccine and tinnitus. Angioedema demonstrated a numerical imbalance with events reported among 0.2% of vaccine recipients and 0.1% of placebo recipients. Of these, urticaria was reported in 8 vaccine recipients and 3 placebo recipients. Based on temporal and biologic plausibility, reports of urticaria are possibly related to vaccine.

Serious Adverse Events

Serious adverse events were defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, or resulted in persistent disability or incapacity. The proportions of participants who reported at least one serious adverse event, excluding those attributed to COVID-19, were 0.4% in the vaccine group and 0.4% in the placebo group. The most common serious adverse event occurring at higher rates in the vaccine group than the placebo group was appendicitis (6 cases in vaccine group vs. 5 cases in placebo group). Three serious adverse events occurring among vaccine recipients were considered by the U.S. Food and Drug Administration (FDA) as likely related to vaccine: the one report of hypersensitivity reaction to study vaccine, one report of pain at the injection site initially evaluated for brachial neuritis, and one report of systemic reactogenicity.

Data source: FDA briefing document

Page last reviewed: August 12, 2021

EXHIBIT 11

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, September 2, 2009

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than $102 million from the federal share of the civil recovery.

The U.S. Attorney's offices for the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, and the Civil Division of the Department of Justice handled these cases. The U.S. Attorney's Office for the District of Massachusetts led the criminal investigation of Bextra. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services (HHS), the FBI, the Defense Criminal Investigative Service (DCIS), the Office of Criminal Investigations for the Food and Drug Administration (FDA), the

Veterans' Administration's (VA) Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management (OPM), the Office of the Inspector General for the United States Postal Service (USPS), the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

"Today's landmark settlement is an example of the Department of Justice's ongoing and intensive efforts to protect the American public and recover funds for the federal treasury and the public from those who seek to earn a profit through fraud. It shows one of the many ways in which federal government, in partnership with its state and local allies, can help the American people at a time when budgets are tight and health care costs are increasing," said Associate Attorney General Tom Perrelli. "This settlement is a testament to the type of broad, coordinated effort among federal agencies and with our state and local partners that is at the core of the Department of Justice's approach to law enforcement."

"This historic settlement will return nearly $1 billion to Medicare, Medicaid, and other government insurance programs, securing their future for the Americans who depend on these programs,"said Kathleen Sebelius, Secretary of Department of Health and Human Services"The Department of Health and Human Services will continue to seek opportunities to work with its government partners to prosecute fraud wherever we can find it. But we will also look for new ways to prevent fraud before it happens. Health care is too important to let a single dollar go to waste."

"Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars," said Tony West, Assistant Attorney General for the Civil Division. "This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare."

"The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

"Although these types of investigations are often long and complicated and require many resources to achieve positive results, the FBI will not be deterred from continuing to ensure that pharmaceutical companies conduct business in a lawful manner," said Kevin Perkins, FBI Assistant Director, Criminal Investigative Division.

"This resolution protects the FDA in its vital mission of ensuring that drugs are safe and effective. When manufacturers undermine the FDA's rules, they interfere with a doctor's judgment and can put patient health at risk," commented Michael L. Levy, U.S. Attorney for the Eastern District of Pennsylvania. "The public trusts companies to market their drugs for uses that FDA has approved, and trusts that doctors are using independent judgment. Federal health dollars should only be spent on treatment decisions untainted by misinformation from manufacturers concerned with the bottom line."

"This settlement demonstrates the ongoing efforts to pursue violations of the False Claims Act and recover taxpayer dollars for the Medicare and Medicaid programs," noted Jim Zerhusen, U.S. Attorney for the Eastern District of Kentucky.

"This historic settlement emphasizes the government's commitment to corporate and individual accountability and to transparency throughout the pharmaceutical industry," said Daniel R. Levinson, Inspector General of the United States Department of Health and Human Services. "The corporate integrity agreement requires senior Pfizer executives and board members to complete annual compliance certifications and opens Pfizer to more public scrutiny by requiring it to make detailed disclosures on its Web site. We expect this agreement to increase integrity in the marketing of pharmaceuticals."

"The off-label promotion of pharmaceutical drugs by Pfizer significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Sharon Woods, Director, Defense Criminal Investigative Service. "This illegal activity increases patients' costs, threatens their safety and negatively affects the delivery of healthcare services to the over nine million military members, retirees and their families who rely on this system. Today's charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its law

enforcement partners to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that it must observe those standards and reflects the commitment of federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Health care fraud has a significant financial impact on the Postal Service. This case alone impacted more than 10,000 postal employees on workers' compensation who were treated with these drugs," said Joseph Finn, Special Agent in Charge for the Postal Service's Office of Inspector General. "Last year the Postal Service paid more than $1 billion in workers' compensation benefits to postal employees injured on the job."

Component(s):
Civil Division

Press Release Number:
09-900

Updated September 15, 2014

EXHIBIT 12

Press Release

SEC Charges Pfizer with FCPA Violations

FOR IMMEDIATE RELEASE
2012-152

Washington, D.C., Aug. 7, 2012 — The Securities and Exchange Commission today charged Pfizer Inc. with violating the Foreign Corrupt Practices Act (FCPA) when its subsidiaries bribed doctors and other health care professionals employed by foreign governments in order to win business.

The SEC alleges that employees and agents of Pfizer's subsidiaries in Bulgaria, China, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia made improper payments to foreign officials to obtain regulatory and formulary approvals, sales, and increased prescriptions for the company's pharmaceutical products. They tried to conceal the bribery by improperly recording the transactions in accounting records as legitimate expenses for promotional activities, marketing, training, travel and entertainment, clinical trials, freight, conferences, and advertising.

The SEC separately charged another pharmaceutical company that Pfizer acquired a few years ago – Wyeth LLC – with its own FCPA violations. Pfizer and Wyeth agreed to separate settlements in which they will pay more than $45 million combined to settle their respective charges. In a parallel action, the Department of Justice announced that Pfizer H.C.P. Corporation agreed to pay a $15 million penalty to resolve its investigation of FCPA violations.

"Pfizer subsidiaries in several countries had bribery so entwined in their sales culture that they offered points and bonus programs to improperly reward foreign officials who proved to be their best customers," said Kara Brockmeyer, Chief of the SEC Enforcement Division's Foreign Corrupt Practices Act Unit. "These charges illustrate the pitfalls that exist for companies that fail to appropriately monitor potential risks in their global operations."

According to the SEC's complaint against Pfizer filed in U.S. District Court for the District of Columbia, the misconduct dates back as far as 2001. Employees of Pfizer's subsidiaries authorized and made cash payments and provided other incentives to bribe government doctors to utilize Pfizer products. In China, for example, Pfizer employees invited "high-prescribing doctors" in the Chinese government to club-like meetings that included extensive recreational and entertainment activities to reward doctors' past product sales or prescriptions. Pfizer China also created various "point programs" under which government doctors could accumulate points based on the number of Pfizer prescriptions they wrote. The points were redeemed for various gifts ranging from medical books to cell phones, tea sets, and reading glasses. In Croatia, Pfizer employees created a "bonus program" for Croatian doctors who were employed in senior positions in Croatian government health care institutions. Once a doctor agreed to use Pfizer products, a percentage of the value purchased by a doctor's institution would be funneled back to the doctor in the form of cash, international travel, or free products.

According to the SEC's complaint, Pfizer made an initial voluntary disclosure of misconduct by its subsidiaries to the SEC and Department of Justice in October 2004, and fully cooperated with SEC investigators. Pfizer took such extensive remedial actions as undertaking a comprehensive worldwide review of its compliance program.

The SEC further alleges that Wyeth subsidiaries engaged in FCPA violations primarily before but also after the company's acquisition by Pfizer in late 2009. Starting at least in 2005, subsidiaries marketing Wyeth nutritional products in China, Indonesia, and Pakistan bribed government doctors to recommend their products to patients by making cash payments or in some cases providing BlackBerrys and cell phones or travel incentives. They often used fictitious invoices to conceal the true nature of the payments. In Saudi Arabia, Wyeth's subsidiary made an

improper cash payment to a customs official to secure the release of a shipment of promotional items used for marketing purposes. The promotional items were held in port because Wyeth Saudi Arabia had failed to secure a required Saudi Arabian Standards Organization Certificate of Conformity.

Following Pfizer's acquisition of Wyeth, Pfizer undertook a risk-based FCPA due diligence review of Wyeth's global operations and voluntarily reported the findings to the SEC staff. Pfizer diligently and promptly integrated Wyeth's legacy operations into its compliance program and cooperated fully with SEC investigators.

In settling the SEC's charges, Wyeth neither admitted nor denied the allegations. Pfizer consented to the entry of a final judgment ordering it to pay disgorgement of $16,032,676 in net profits and prejudgment interest of $10,307,268 for a total of $26,339,944. Wyeth also is required to report to the SEC on the status of its remediation and implementation of compliance measures over a two-year period, and is permanently enjoined from further violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Securities Exchange Act of 1934. Wyeth consented to the entry of a final judgment ordering it to pay disgorgement of $17,217,831 in net profits and prejudgment interest of $1,658,793, for a total of $18,876,624. As a Pfizer subsidiary, the status of Wyeth's remediation and implementation of compliance measures will be subsumed in Pfizer's two-year self-reporting period. Wyeth also is permanently enjoined from further violations of Sections 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act. The settlements are subject to court approval.

The SEC's investigation was conducted by Michael Catoe and Charles Cain of the Enforcement Division's FCPA Unit. The SEC acknowledges the assistance of the U.S. Department of Justice's Criminal Division's Fraud Section and the Federal Bureau of Investigation in this matter.

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Related Materials

- SEC Complaint Against Pfizer
- SEC Complaint Against Wyeth
- More SEC FCPA Cases

EXHIBIT 13

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Friday, October 21, 2011

Pfizer to Pay $14.5 Million for Illegal Marketing of Drug Detrol

Settlement Involves False Claims Act Lawsuit Not Resolved at the Time of the Government's $2.3 Billion Dollar Settlement with Pfizer in 2009

WASHINGTON – American pharmaceutical company Pfizer Inc. has agreed to pay $14.5 million to resolve False Claims Act allegations related to its marketing of the drug Detrol, the Justice Department announced today. The settlement resolves the last of a group of 10 *qui tam*, or whistleblower, suits that were filed in the District of Massachusetts and two other districts, beginning in 2003. The other nine suits were settled or dismissed in 2009 as part of the government's global resolution with Pfizer, under which the company agreed to pay $2.3 billion dollars to resolve civil claims and criminal charges regarding multiple drugs.

The current settlement addresses allegations that Pfizer illegally marketed Detrol, a drug for the treatment of overactive bladder, for use in male patients suffering from benign prostatic hypertrophy and several allied conditions, notably lower urinary tract symptoms and bladder outlet obstruction – all uses for which the Food and Drug Administration (FDA) had not approved the drug as safe and effective. Under the terms of the settlement, the $14.5 million recovery will be divided between the United States and participating state Medicaid programs, with $11,878,846 going to the federal government and $2,621,154 going to state Medicaid programs. Under the *qui tam* provisions of the False Claims Act, whistleblowers will receive a $3,282,019 share of the federal recovery.

"Whistleblowers play an important role in protecting taxpayer funds from fraud and abuse," said Tony West, Assistant Attorney General of the Justice Department's Civil Division. "Settlements like this one help maintain the integrity of FDA's drug approval process and support important federal and state health care programs."

"The United States is pleased that Pfizer has agreed to resolve the last of the pending cases that were not settled as part of the 2009 resolution and plea," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts. "We hope and expect that this is indicative of a commitment to move forward in compliance with the law, and we will continue to watch vigilantly to ensure that Pfizer complies with the law in its sales and marketing of drugs sold to the public."

The case is *U.S. ex rel. Wetherholt and Drimer v. Pfizer*, which the United States declined to intervene in and was independently litigated by the relators. The United States subsequently participated closely in efforts to resolve the case.

This settlement is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $6.3 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 exceed $8.1 billion.

Component(s):
Civil Division

Press Release Number:
11-1389

Updated September 15, 2014

EXHIBIT 14

Pfizer to Pay $75 Million to Settle Nigerian Trovan Drug-Testing Suit

By Joe Stephens
Washington Post Staff Writer
Friday, July 31, 2009

Pfizer signed a $75 million agreement Thursday with Nigerian authorities to settle criminal and civil charges that the pharmaceutical company illegally tested an experimental drug on children during a 1996 meningitis epidemic.

Nigerian authorities say Pfizer's test of the antibiotic Trovan killed 11 children and disabled scores more. Pfizer says the deaths and injuries were the result of meningitis.

An attorney for the state of Kano, where the charges were lodged, said the settlement was a long time in coming but welcome because it set the record straight about Pfizer's culpability. "People and entities can and must be held accountable for the consequences of their conduct," the attorney, Babatunde Irukera, said. "People around the world are no different and must be accorded the same levels of protections, always."

Charges filed against Pfizer by Nigeria's federal government, which is seeking about $6 billion in damages, are unaffected by the settlement, Irukera said. Two lawsuits related to the Trovan experiment also remain pending in New York.

In a news release, Pfizer said that it "specifically denies" any wrongdoing or liability. The company said its researchers conducted the clinical trial of the antibiotic Trovan legally, with the approval of the Nigerian government and the consent of guardians of the children. The company said the settlement was the best way to "allow Pfizer and the Nigerian governments to focus on what matters -- improving healthcare for all Nigerians."

Under the agreement, the world's largest drug company agreed to pay $30 million over two years toward health-care initiatives chosen by the Kano state government. It will reimburse the state for $10 million in legal costs. And Pfizer agreed to create a fund that will pay up to $35 million toward "valid claims" for financial support submitted by patients who took part in the clinical trial. A panel appointed by Pfizer and Kano state will determine eligibility and levels of support.

In return, Kano officials agreed to drop civil and criminal actions against the company. Kano and the Nigerian federal government originally filed legal actions naming as defendants Pfizer and 10 individuals, including former Pfizer chief executive William C. Steere Jr. The actions sought $9 billion in restitution and damages and included 31 criminal counts, including homicide.

Details of the drug trial were first made public in December 2000 in a Washington Post investigative series. The articles reported that the trial did not conform to U.S. patient-protection standards and that the oral form of the drug used in the trial had not been previously tested in children. Pfizer had no signed consent forms for the children, the articles said, and the company relied on a falsified ethics approval letter.

Five years later, in May 2006, The Post obtained and published a confidential report that concluded that Pfizer violated Nigerian and international law in the experiment. That set in motion the criminal charges.

Trovan was never approved for use by children in the United States. The Food and Drug Administration approved it for adults in 1998 but later severely restricted its use after reports of liver failure. The European Union banned it in 1999.

EXHIBIT 15

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, November 4, 2013

Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations

Allegations Include Off-label Marketing and Kickbacks to Doctors and Pharmacists

WASHINGTON - Global health care giant Johnson & Johnson (J&J) and its subsidiaries will pay more than $2.2 billion to resolve criminal and civil liability arising from allegations relating to the prescription drugs Risperdal, Invega and Natrecor, including promotion for uses not approved as safe and effective by the Food and Drug Administration (FDA) and payment of kickbacks to physicians and to the nation's largest long-term care pharmacy provider. The global resolution is one of the largest health care fraud settlements in U.S. history, including criminal fines and forfeiture totaling $485 million and civil settlements with the federal government and states totaling $1.72 billion.

"The conduct at issue in this case jeopardized the health and safety of patients and damaged the public trust," said Attorney General Eric Holder. "This multibillion-dollar resolution demonstrates the Justice Department's firm commitment to preventing and combating all forms of health care fraud. And it proves our determination to hold accountable any corporation that breaks the law and enriches its bottom line at the expense of the American people."

The resolution includes criminal fines and forfeiture for violations of the law and civil settlements based on the False Claims Act arising out of multiple investigations of the company and its subsidiaries.

"When companies put profit over patients' health and misuse taxpayer dollars, we demand accountability," said Associate Attorney General Tony West. "In addition to significant monetary sanctions, we will ensure that non-monetary measures are in place to facilitate change in corporate behavior and help ensure the playing field is level for all market participants."

In addition to imposing substantial monetary sanctions, the resolution will subject J&J to stringent requirements under a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). This agreement is designed to increase accountability and transparency and prevent future fraud and abuse.

"As patients and consumers, we have a right to rely upon the claims drug companies make about their products," said Assistant Attorney General for the Justice Department's Civil Division Stuart F. Delery. "And, as taxpayers, we have a right to ensure that federal health care dollars are spent appropriately. That is why this Administration has continued to pursue aggressively – with all of our available law enforcement tools -- those companies that corrupt our health care system."

J&J Subsidiary Janssen Pleads Guilty to Misbranding Antipsychotic Drug

In a criminal information filed today in the Eastern District of Pennsylvania, the government charged that, from March 3, 2002, through Dec. 31, 2003, Janssen Pharmaceuticals Inc., a J&J subsidiary, introduced the antipsychotic drug Risperdal into interstate commerce for an unapproved use, rendering the product misbranded. For most of this time period, Risperdal was approved only to treat schizophrenia. The information alleges that Janssen's sales representatives promoted Risperdal to physicians and other prescribers who treated elderly dementia patients by urging the prescribers to use Risperdal to treat symptoms such as anxiety, agitation, depression, hostility and confusion. The information alleges that the company created written sales aids for use by Janssen's ElderCare sales force that emphasized symptoms and minimized any mention of the FDA-approved use, treatment of schizophrenia. The company also provided incentives for off-label promotion and intended use by basing sales representatives' bonuses on total sales of Risperdal in their sales areas, not just sales for FDA-approved uses.

In a plea agreement resolving these charges, Janssen admitted that it promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly, non-schizophrenic dementia patients. Under the terms of the plea agreement, Janssen will pay a total of $400 million, including a criminal fine of $334 million and forfeiture of $66 million. Janssen's guilty plea will not be final until accepted by the U.S. District Court.

The Federal Food, Drug, and Cosmetic Act (FDCA) protects the health and safety of the public by ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bear true, complete and accurate information. Under the FDCA, a pharmaceutical company must specify the intended uses of a drug in its new drug application to the FDA. Before approval, the FDA must determine that the drug is safe and effective for those specified uses. Once the drug is approved, if the company intends a different use and then introduces the drug into interstate commerce for that new, unapproved use, the drug becomes misbranded. The unapproved use is also known as an "off-label" use because it is not included in the drug's FDA-approved labeling.

"When pharmaceutical companies interfere with the FDA's mission of ensuring that drugs are safe and effective for the American public, they undermine the doctor-patient relationship and put the health and safety of patients at risk," said Director of the FDA's Office of Criminal Investigations John Roth. "Today's settlement demonstrates the government's continued focus on pharmaceutical companies that put profits ahead of the public's health. The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the drug approval process and recklessly promote drugs for uses that have not been proven to be safe and effective."

J&J and Janssen Settle Civil Allegations of Targeting Vulnerable Patients with the Drugs Risperdal and Invega for Off-Label Uses

In a related civil complaint filed today in the Eastern District of Pennsylvania, the United States alleges that Janssen marketed Risperdal to control the behaviors and conduct of the nation's most vulnerable patients: elderly nursing home residents, children and individuals with mental disabilities. The government alleges that J&J and Janssen caused false claims to be submitted to federal health care programs by promoting Risperdal for off-label uses that federal health care programs did not cover, making false and misleading statements about the safety and efficacy of Risperdal and paying kickbacks to physicians to prescribe Risperdal.

"J&J's promotion of Risperdal for unapproved uses threatened the most vulnerable populations of our society – children, the elderly and those with developmental disabilities," said U.S. Attorney for the Eastern District of Pennsylvania Zane Memeger. "This historic settlement sends the message that drug manufacturers who place profits over patient care will face severe criminal and civil penalties."

In its complaint, the government alleges that the FDA repeatedly advised Janssen that marketing Risperdal as safe and effective for the elderly would be "misleading." The FDA cautioned Janssen that behavioral disturbances in elderly dementia patients were not necessarily manifestations of psychotic disorders and might even be "appropriate

responses to the deplorable conditions under which some demented patients are housed, thus raising an ethical question regarding the use of an antipsychotic medication for inappropriate behavioral control."

The complaint further alleges that J&J and Janssen were aware that Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but that the companies downplayed these risks. For example, when a J&J study of Risperdal showed a significant risk of strokes and other adverse events in elderly dementia patients, the complaint alleges that Janssen combined the study data with other studies to make it appear that there was a lower overall risk of adverse events. A year after J&J had received the results of a second study confirming the increased safety risk for elderly patients taking Risperdal, but had not published the data, one physician who worked on the study cautioned Janssen that "[a]t this point, so long after [the study] has been completed … we must be concerned that this gives the strong appearance that Janssen is purposely withholding the findings."

The complaint also alleges that Janssen knew that patients taking Risperdal had an increased risk of developing diabetes, but nonetheless promoted Risperdal as "uncompromised by safety concerns (does not cause diabetes)." When Janssen received the initial results of studies indicating that Risperdal posed the same diabetes risk as other antipsychotics, the complaint alleges that the company retained outside consultants to re-analyze the study results and ultimately published articles stating that Risperdal was actually associated with a lower risk of developing diabetes.

The complaint alleges that, despite the FDA warnings and increased health risks, from 1999 through 2005, Janssen aggressively marketed Risperdal to control behavioral disturbances in dementia patients through an "ElderCare sales force" designed to target nursing homes and doctors who treated the elderly. In business plans, Janssen's goal was to "[m]aximize and grow RISPERDAL's market leadership in geriatrics and long term care." The company touted Risperdal as having "proven efficacy" and "an excellent safety and tolerability profile" in geriatric patients.

In addition to promoting Risperdal for elderly dementia patients, from 1999 through 2005, Janssen allegedly promoted the antipsychotic drug for use in children and individuals with mental disabilities. The complaint alleges that J&J and Janssen knew that Risperdal posed certain health risks to children, including the risk of elevated levels of prolactin, a hormone that can stimulate breast development and milk production. Nonetheless, one of Janssen's Key Base Business Goals was to grow and protect the drug's market share with child/adolescent patients. Janssen instructed its sales representatives to call on child psychiatrists, as well as mental health facilities that primarily treated children, and to market Risperdal as safe and effective for symptoms of various childhood disorders, such as attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder and autism. Until late 2006, Risperdal was not approved for use in children for any purpose, and the FDA repeatedly warned the company against promoting it for use in children.

The government's complaint also contains allegations that Janssen paid speaker fees to doctors to influence them to write prescriptions for Risperdal. Sales representatives allegedly told these doctors that if they wanted to receive payments for speaking, they needed to increase their Risperdal prescriptions.

In addition to allegations relating to Risperdal, today's settlement also resolves allegations relating to Invega, a newer antipsychotic drug also sold by Janssen. Although Invega was approved only for the treatment of schizophrenia and schizoaffective disorder, the government alleges that, from 2006 through 2009, J&J and Janssen marketed the drug for off-label indications and made false and misleading statements about its safety and efficacy.

As part of the global resolution, J&J and Janssen have agreed to pay a total of $1.391 billion to resolve the false claims allegedly resulting from their off-label marketing and kickbacks for Risperdal and Invega. This total includes $1.273 billion to be paid as part of the resolution announced today, as well as $118 million that J&J and Janssen paid to the state of Texas in March 2012 to resolve similar allegations relating to Risperdal. Because Medicaid is a joint federal-state program, J&J's conduct caused losses to both the federal and state governments. The additional payment made by J&J as part of today's settlement will be shared between the federal and state governments, with the federal government recovering $749 million, and the states recovering $524 million. The federal government and Texas each received $59 million from the Texas settlement.

Kickbacks to Nursing Home Pharmacies

The civil settlement also resolves allegations that, in furtherance of their efforts to target elderly dementia patients in nursing homes, J&J and Janssen paid kickbacks to Omnicare Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients. In a complaint filed in the District of Massachusetts in January 2010, the United States alleged that J&J paid millions of dollars in kickbacks to Omnicare under the guise of market share rebate payments, data-purchase agreements, "grants" and "educational funding." These kickbacks were intended to induce Omnicare and its hundreds of consultant pharmacists to engage in "active intervention programs" to promote the use of Risperdal and other J&J drugs in nursing homes. Omnicare's consultant pharmacists regularly reviewed nursing home patients' medical charts and made recommendations to physicians on what drugs should be prescribed for those patients. Although consultant pharmacists purported to provide "independent" recommendations based on their clinical judgment, J&J viewed the pharmacists as an "extension of [J&J's] sales force."

J&J and Janssen have agreed to pay $149 million to resolve the government's contention that these kickbacks caused Omnicare to submit false claims to federal health care programs. The federal share of this settlement is $132 million, and the five participating states' total share is $17 million. In 2009, Omnicare paid $98 million to resolve its civil liability for claims that it accepted kickbacks from J&J and Janssen, along with certain other conduct.

"Consultant pharmacists can play an important role in protecting nursing home residents from the use of antipsychotic drugs as chemical restraints," said U.S. Attorney for the District of Massachusetts Carmen Ortiz. "This settlement is a reminder that the recommendations of consultant pharmacists should be based on their independent clinical judgment and should not be the product of money paid by drug companies."

Off-Label Promotion of the Heart Failure Drug Natrecor

The civil settlement announced today also resolves allegations that J&J and another of its subsidiaries, Scios Inc., caused false and fraudulent claims to be submitted to federal health care programs for the heart failure drug Natrecor. In August 2001, the FDA approved Natrecor to treat patients with acutely decompensated congestive heart failure who have shortness of breath at rest or with minimal activity. This approval was based on a study involving hospitalized patients experiencing severe heart failure who received infusions of Natrecor over an average 36-hour period.

In a civil complaint filed in 2009 in the Northern District of California, the government alleged that, shortly after Natrecor was approved, Scios launched an aggressive campaign to market the drug for scheduled, serial outpatient infusions for patients with less severe heart failure – a use not included in the FDA-approved label and not covered by federal health care programs. These infusions generally involved visits to an outpatient clinic or doctor's office for four- to six-hour infusions one or two times per week for several weeks or months.

The government's complaint alleged that Scios had no sound scientific evidence supporting the medical necessity of these outpatient infusions and misleadingly used a small pilot study to encourage the serial outpatient use of the drug. Among other things, Scios sponsored an extensive speaker program through which doctors were paid to tout the purported benefits of serial outpatient use of Natrecor. Scios also urged doctors and hospitals to set up outpatient clinics specifically to administer the serial outpatient infusions, in some cases providing funds to defray the costs of setting up the clinics, and supplied providers with extensive resources and support for billing Medicare for the outpatient infusions.

As part of today's resolution, J&J and Scios have agreed to pay the federal government $184 million to resolve their civil liability for the alleged false claims to federal health care programs resulting from their off-label marketing of Natrecor. In October 2011, Scios pleaded guilty to a misdemeanor FDCA violation and paid a criminal fine of $85 million for introducing Natrecor into interstate commerce for an off-label use.

"This case is an example of a drug company encouraging doctors to use a drug in a way that was unsupported by valid scientific evidence," said First Assistant U.S. Attorney for the Northern District of California Brian Stretch. "We are committed to ensuring that federal health care programs do not pay for such inappropriate uses, and that pharmaceutical companies market their drugs only for uses that have been proven safe and effective."

Non-Monetary Provisions of the Global Resolution and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, J&J has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General (HHS-OIG). The CIA includes provisions

requiring J&J to implement major changes to the way its pharmaceutical affiliates do business. Among other things, the CIA requires J&J to change its executive compensation program to permit the company to recoup annual bonuses and other long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. J&J may recoup monies from executives who are current employees and from those who have left the company. The CIA also requires J&J's pharmaceutical businesses to implement and maintain transparency regarding their research practices, publication policies and payments to physicians. On an annual basis, management employees, including senior executives and certain members of J&J's independent board of directors, must certify compliance with provisions of the CIA. J&J must submit detailed annual reports to HHS-OIG about its compliance program and its business operations.

"OIG will work aggressively with our law enforcement partners to hold companies accountable for marketing and promotion that violate laws intended to protect the public," said Inspector General of the U.S. Department of Health and Human Services Daniel R. Levinson. "Our compliance agreement with Johnson & Johnson increases individual accountability for board members, sales representatives, company executives and management. The agreement also contains strong monitoring and reporting provisions to help ensure that the public is protected from future unlawful and potentially harmful off-label marketing."

Coordinated Investigative Effort Spans Federal and State Law Enforcement

This resolution marks the culmination of an extensive, coordinated investigation by federal and state law enforcement partners that is the hallmark of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaborations to fight fraud. Announced in May 2009 by Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius, the HEAT initiative has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation.

The criminal cases against Janssen and Scios were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania and the Northern District of California and the Civil Division's Consumer Protection Branch. The civil settlements were handled by the U.S. Attorney's Offices for the Eastern District of Pennsylvania, the Northern District of California and the District of Massachusetts and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division, the FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

This matter was investigated by HHS-OIG, the Department of Defense's Defense Criminal Investigative Service, the FDA's Office of Criminal Investigations, the Office of Personnel Management's Office of Inspector General, the Department of Veterans Affairs, the Department of Labor, TRICARE Program Integrity, the U.S. Postal Inspection Service's Office of the Inspector General and the FBI.

One of the most powerful tools in the fight against Medicare and Medicaid financial fraud is the False Claims Act. Since January 2009, the Justice Department has recovered a total of more than $16.7 billion through False Claims Act cases, with more than $11.9 billion of that amount recovered in cases involving fraud against federal health care programs.

The department enforces the FDCA by prosecuting those who illegally distribute unapproved, misbranded and adulterated drugs and medical devices in violation of the Act. Since 2009, fines, penalties and forfeitures that have been imposed in connection with such FDCA violations have totaled more than $6 billion.

The civil settlements described above resolve multiple lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the government and to share in any recovery. From the federal government's share of the civil settlements announced today, the whistleblowers in the Eastern District of Pennsylvania will receive $112 million, the whistleblowers in the District of Massachusetts will receive $27.7 million and the whistleblower in the Northern District of California will receive $28 million. Except to the extent that J&J subsidiaries have pleaded guilty or agreed to plead guilty to the criminal charges discussed above, the claims settled by the civil settlements are allegations only, and there has been no determination of liability.
Court documents related to today's settlement can be viewed online at www.justice.gov/opa/jj-pc-docs.html.

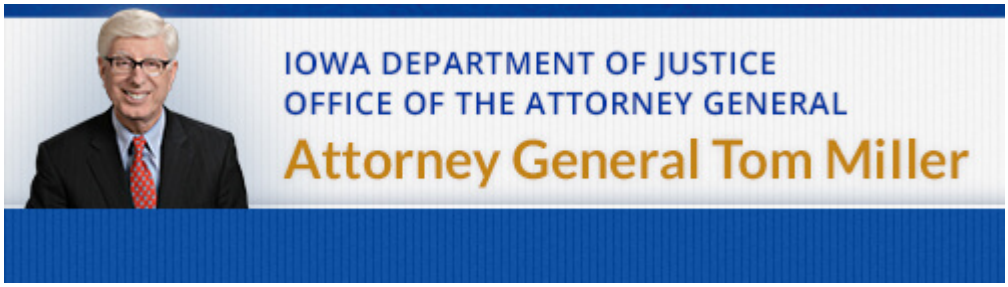
Topic(s):
Consumer Protection

Component(s):
Office of the Attorney General

Press Release Number:
13-1170

Updated October 22, 2014

EXHIBIT 16



October 17, 2019

AGs reach $116.9 million settlement with Johnson & Johnson, Ethicon

Surgical mesh devices caused serious complications for women

DES MOINES — Iowa Attorney General Tom Miller announced a multistate settlement along with 40 states and the District of Columbia requiring Johnson & Johnson and its subsidiary Ethicon, Inc. to pay nearly $116.9 million for their deceptive marketing of transvaginal surgical mesh devices.

A multistate investigation found the companies violated state consumer protection laws by misrepresenting the safety and effectiveness of the devices and failing to sufficiently disclose risks associated with their use, according to a petition filed in Polk County District Court. Iowa will receive $1,884,129.41 under the settlement.

“For years, women have suffered debilitating symptoms and other serious problems after surgeons implanted these devices. The companies failed to adequately disclose the possible complications and risks,” Miller said.

Transvaginal surgical mesh is a synthetic material that is surgically implanted through the vagina to support the pelvic organs of women who suffer from stress urinary incontinence or pelvic organ prolapse.

The multistate investigation found the companies misrepresented or failed to adequately disclose the products’ possible adverse effects, including the risk of chronic pain and inflammation, mesh erosion through the vagina, incontinence developing after surgery, painful sexual relations, and vaginal scarring. Evidence shows the companies were aware of the possibility for serious medical complications but did not provide sufficient warnings to consumers or surgeons who implanted the devices.

Patients around the country have filed thousands of private lawsuits against Johnson & Johnson and other makers of transvaginal mesh. Many of the lawsuits have been consolidated into a multi-district litigation in the U.S. District Court in the Southern District of West Virginia.

Under the settlement, Johnson & Johnson has agreed to pay $116.86 million to the 41 participating states and District of Columbia. The settlement also provides injunctive relief, requiring full disclosure of the device's risks and accurate information on promotional material, in addition to the product's "information for use" package inserts.

According to the consent judgment, the companies must:

- Refrain from referring to the mesh as "FDA approved" when that is not the case;
- Refrain from representing in promotions that risks associated with mesh can be eliminated with surgical experience or technique alone;
- Ensure that product training provided to medical professionals covers the risks associated with the mesh;
- Omit claims that surgical mesh stretches after implantation, that it remains soft after implantation, that foreign body reactions are transient and that foreign body reactions "may" occur (when in fact they will occur);
- Disclose that mesh risks include: fistula formation, inflammation, as well as mesh extrusion, exposure and erosion into the vagina and other organs;
- Disclose risks of tissue contraction, pain with intercourse, loss of sexual function, urge incontinence, de novo incontinence, infection following transvaginal implantation and vaginal scarring;
- Disclose that risks include that revision surgeries may be necessary to treat complications, that revision surgeries may not resolve complications and that revision surgeries are also associated with a risk of adverse reactions.

Joining Iowa in this multistate settlement are Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin.

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EXHIBIT 17

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Friday, April 8, 2011

Johnson & Johnson Agrees to Pay $21.4 Million Criminal Penalty to Resolve Foreign Corrupt Practices Act and Oil for Food Investigations

Company to Pay Total Penalties of $70 Million in Resolutions with Justice Department and U.S. Securities and Exchange Commission (SEC)

WASHINGTON – Johnson & Johnson (J&J) has agreed to pay a $21.4 million criminal penalty as part of a deferred prosecution agreement with the Department of Justice to resolve improper payments by J&J subsidiaries to government officials in Greece, Poland and Romania in violation of the Foreign Corrupt Practices Act (FCPA), the Justice Department's Criminal Division announced today. The agreement also resolves kickbacks paid to the former government of Iraq under the United Nations Oil for Food Program.

J&J is headquartered in New Brunswick, N.J., and is listed on the New York Stock Exchange. The company manufactures and sells medical devices, pharmaceuticals and consumer health care products.

"Today, Johnson & Johnson has admitted that its subsidiaries, employees and agents paid bribes to publicly-employed health care providers in Greece, Poland and Romania, and that kickbacks were paid on behalf of Johnson & Johnson subsidiary companies to the former government of Iraq under the United Nations Oil for Food program," said Principal Deputy Assistant Attorney General Mythili Raman of the Justice Department's Criminal Division." "Johnson & Johnson, however, has also cooperated extensively with the government and, as a result, has played an important role in identifying improper practices in the life sciences industry. As today's agreement reflects, we are committed to holding corporations accountable for bribing foreign officials while, at the same time, giving meaningful credit to companies that self-report and cooperate with our investigations."

According to the agreement, J&J has acknowledged responsibility for the actions of its subsidiaries, employees and agents who made various improper payments to publicly-employed health care providers in Greece, Poland and Romania in order to induce the purchase of medical devices and pharmaceuticals manufactured by J&J subsidiaries. J&J also acknowledged that kickbacks were paid on behalf of J&J subsidiary companies to the former government of Iraq under the United Nations Oil for Food Program in order to secure contracts to provide humanitarian supplies. A criminal information, filed in U.S. District Court in the District of Columbia in connection with the deferred prosecution agreement, charges J&J subsidiary DePuy Inc. with conspiracy and violations of the FCPA in connection with the payments to public physicians in Greece.

The agreement recognizes J&J's timely voluntary disclosure, and thorough and wide-reaching self-investigation of the underlying conduct; the extraordinary cooperation provided by the company to the department, the SEC and multiple foreign enforcement authorities, including significant assistance in the industry-wide investigation; and the extensive remedial efforts and compliance improvements undertaken by the company. In addition, J&J received a reduction in its criminal fine as a result of its cooperation in the ongoing investigation of other companies and individuals, as outlined in the U.S. Sentencing Guidelines. J&J's fine was also reduced in light of its anticipated resolution in the United Kingdom. Due to J&J's pre-existing compliance and ethics programs, extensive remediation, and improvement of its compliance systems and internal controls, as well as the enhanced compliance undertakings included in the agreement, J&J was not required to retain a corporate monitor, but it must report to the department on implementation of its remediation and enhanced compliance efforts every six months for the duration of the agreement.

In a related matter, J&J reached a settlement today with the SEC under which it agreed to pay more than $48.6 million in disgorgement of profits, including pre-judgment interest.

This case is being prosecuted by Trial Attorney Kathleen M Hamann of the Criminal Division's Fraud Section with assistance from the FBI's Washington Field Office's dedicated FCPA squad. The Criminal Division's Office of International Affairs provided assistance in this matter.

The Justice Department acknowledges and expresses its appreciation for the significant assistance provided by the authorities of the 8th Ordinary Interrogation Department of the Athens Court of First Instance and the Athens Economic Crime Squad in Greece; the 5th Investigation Department of the Regional Prosecutor's Office in Radom, Poland; the Fraud Squad of the West Yorkshire Police Department in the United Kingdom; and the SEC's Division of Enforcement, as well as the coordination and cooperation with the authorities of the United Kingdom's Serious Fraud Office.

Component(s):
Criminal Division

Press Release Number:
11-446

Updated September 15, 2014

EXHIBIT 18

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, March 10, 2015

McNeil-PPC Inc. Pleads Guilty in Connection with Adulterated Infants' and Children's Over-the-Counter Liquid Drugs

McNeil-PPC Inc. entered a guilty plea in Federal District Court in Philadelphia today to one count of an information charging the company with delivering for introduction into interstate commerce adulterated infants' and children's over-the-counter (OTC) liquid medicines, the Department of Justice announced today. As part of the criminal resolution, McNeil, a wholly owned subsidiary of Johnson & Johnson, agreed to pay a criminal fine of $20 million and forfeit $5 million.

Acting Assistant Attorney General Benjamin C. Mizer of the Justice Department's Civil Division and First Assistant U.S. Attorney Louis D. Lappen of the Eastern District of Pennsylvania today announced the filing of a criminal Information against McNeil for delivering for introduction into interstate commerce infants' and children's liquid OTC drugs that were adulterated. According to the criminal charge, the infants' and children's liquid medicines were adulterated because they were not manufactured, processed, packed or held in conformance with current Good Manufacturing Practices (cGMP), in violation of the federal Food, Drug and Cosmetic Act (FDCA).

The U.S. District Court for the Eastern District of Pennsylvania accepted McNeil's guilty plea.

In addition to McNeil's guilty plea, McNeil remains subject to a permanent injunction entered by the U.S. District Court in 2011, requiring the company, among other things, to make remedial measures before reopening its manufacturing facility in Fort Washington, Pennsylvania.

"McNeil's failure to comply with current good manufacturing practices is seriously troubling," said Acting Assistant Attorney General Mizer. "The Department of Justice will continue to be aggressive in pursuing and punishing companies such as McNeil that disregard a process designed to assure quality medicines, especially OTC drugs for infants and children."

"The law requires that drugs be produced under the most rigorous of quality standards," said First Assistant U.S. Attorney Lappen. "When companies fail to exercise the vigilance that the law demands, they will held be accountable. Drug companies should be aware that failing to adhere to good manufacturing practices subjects them to penalties and prosecution."

According to the information, the OTC liquid drugs manufactured by McNeil at its Fort Washington facility, including Infants' and Children's Tylenol and Infants' and Children's Motrin, were bottled on four lines of machinery dedicated to liquid formulations. As alleged in the information, on or about May 1, 2009, McNeil received a complaint from a consumer regarding the presence of "black specks in the liquid on the bottom of the bottle" of Infants' Tylenol. According to the information, the foreign material was later identified as including nickel/chromium-rich inclusions, which were not intended ingredients in this OTC liquid drug. In connection with receiving this consumer complaint, McNeil did not initiate or complete a Corrective Action Preventive Action (CAPA) plan, as alleged in the charging document.

The information alleges numerous other instances in which McNeil found metal particles in bottles of Infants' Tylenol at its Fort Washington facility but failed to initiate or complete a CAPA. According to the information, during a 2010

Inspection of McNeil's Fort Washington facility, the U.S. Food and Drug Administration (FDA) asked McNeil for a list with all non-conformances for particles and the associated OTC drug batches that had occurred since an FDA inspection in 2009. As noted in the information, this document revealed 30 batches of OTC liquid drugs, including Infants' Tylenol, Children's Tylenol, and Children's Motrin. During the 2010 inspection, the FDA asked McNeil for the CAPA plan covering the particles and foreign material found in the Infants' and Children's OTC drugs, and a McNeil employee confirmed that McNeil did not have such a CAPA plan.

On or about April 30, 2010, McNeil Consumer Health Care, a division of McNeil, in consultation with the FDA, announced that the company was recalling all lots of certain unexpired Infants' and Children's OTC drugs manufactured at McNeil's Fort Washington facility and distributed in the United States and other countries around the world. McNeil's recall included, but was not limited to, Infants' and Children's Tylenol and Infants' and Children's Motrin. According to a press release issued by McNeil on April 30, 2010, some of the recalled OTC drugs "may contain tiny particles."

The FDCA prohibits causing the introduction or delivery for introduction into interstate commerce of any adulterated drug. Under the law, a drug is adulterated if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding and distribution of drugs and components were not in conformance with cGMP requirements for drugs. Drugs not manufactured, processed, packed, labeled, held and distributed in conformance with cGMP requirements are adulterated as a matter of federal law, without any showing of actual defect.

"Drug quality – and especially with the medicines we give our children – is of paramount concern to the FDA," said Commissioner Margaret A. Hamburg M.D. of the FDA. "The FDA expects manufacturers to have systems in place that will quickly discover and correct problems with medical products before they enter the U.S. marketplace. Today's guilty plea holds accountable those corporations who risk jeopardizing the public health by not adhering to the high standards set for drug manufacturers."

Acting Assistant Attorney General Mizer and First Assistant U.S. Attorney Lappen commended the investigative efforts of the FDA's Office of Criminal Investigations. The government is represented in this case by Assistant Director Jeffrey Steger and Trial Attorney Kathryn Drenning of the Civil Division's Consumer Protection Branch and Assistant U.S. Attorney Mary Beth Leahy of the Eastern District of Pennsylvania, with the assistance of Associate Chief Counsel for Enforcement Laura Pawloski of the Department of Health and Human Services' Office of General Counsel's Food and Drug Division.

Attachment(s):
Download mcneil_information.pdf
Download united_states_plea_and_sentencing_memorandum_with_plea_agreement.pdf

Topic(s):
Consumer Protection

Component(s):
Civil Division

Press Release Number:
15-289

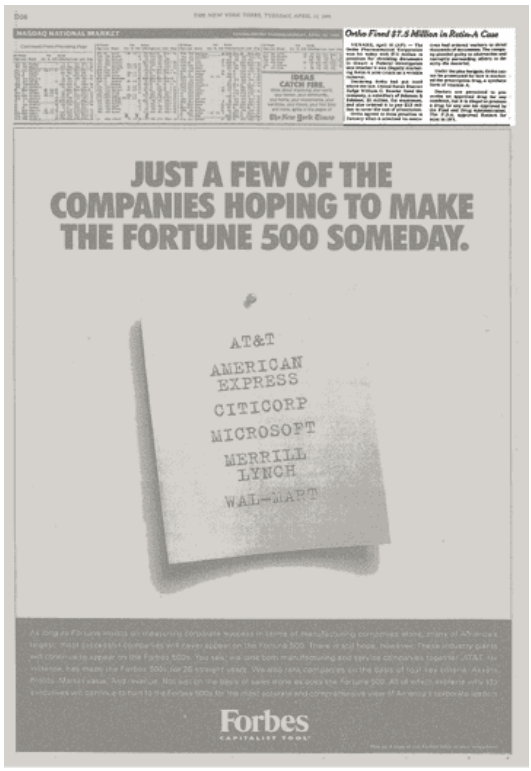
Updated March 10, 2015

EXHIBIT 19

The New York Times
https://www.nytimes.com/1995/04/11/business/ortho-fined-7.5-million-in-retin-a-case.html

Ortho Fined $7.5 Million in Retin-A Case

By The Associated Press
April 11, 1995



About the Archive

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Occasionally the digitization process introduces transcription errors or other problems; we are continuing to work to improve these archived versions.

The Ortho Pharmaceutical Corporation was hit today with $7.5 million in penalties for shredding documents to thwart a Federal investigation into whether it was illegally marketing Retin-A acne cream as a wrinkle remover.

Declaring Ortho had put itself above the law, United States District Judge William G. Bassler fined the company, a subsidiary of Johnson & Johnson, $5 million, the maximum, and also ordered it to pay $2.5 million to cover the cost of prosecution.

Ortho agreed to those penalties in January when it admitted its executives had ordered workers to shred thousands of documents. The company pleaded guilty to obstruction and corruptly persuading others to destroy the material.

Under the plea bargain, Ortho cannot be prosecuted for how it marketed the prescription drug, a synthetic form of vitamin A.

Doctors are permitted to prescribe an approved drug for any condition, but it is illegal to promote a drug for any use not approved by the Food and Drug Administration. The F.D.A. approved Retin-A for acne in 1971.

A version of this article appears in print on , Section D, Page 26 of the National edition with the headline: Ortho Fined $7.5 Million in Retin-A Case

EXHIBIT 20

Presidential Documents

Executive Order 14043 of September 9, 2021

Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 3302, and 7301 of title 5, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID–19), including the B.1.617.2 (Delta) variant, by relying on the best available data and science-based public health measures. The Delta variant, currently the predominant variant of the virus in the United States, is highly contagious and has led to a rapid rise in cases and hospitalizations. The nationwide public health emergency, first declared by the Secretary of Health and Human Services on January 31, 2020, remains in effect, as does the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) declared pursuant to the National Emergencies Act in Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak). The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services has determined that the best way to slow the spread of COVID–19 and to prevent infection by the Delta variant or other variants is to be vaccinated.

COVID–19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID–19 vaccines, the Pfizer-BioNTech COVID–19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID–19 Vaccine and the Janssen COVID–19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

The health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service. I have determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service requires immediate action to protect the Federal workforce and individuals interacting with the Federal workforce. It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID–19 to their co-workers and members of the public. The CDC has found that the best way to do so is to be vaccinated.

The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce. Agencies have also taken important actions, including in some cases requiring COVID–19 vaccination for members of their workforce.

Accordingly, building on these actions, and in light of the public health guidance regarding the most effective and necessary defenses against COVID–19, I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID–19 vaccination for all Federal employees, subject to such exceptions as required by law.

Sec. 2. *Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees.* Each agency shall implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law. The Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order.

Sec. 3. *Definitions.* For the purposes of this order:

(a) The term ''agency'' means an Executive agency as defined in 5 U.S.C. 105 (excluding the Government Accountability Office).

(b) The term ''employee'' means an employee as defined in 5 U.S.C. 2105 (including an employee paid from nonappropriated funds as referenced in 5 U.S.C. 2105(c)).

Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

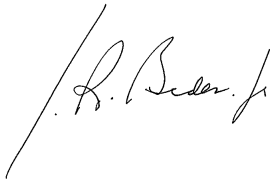
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.



THE WHITE HOUSE,
September 9, 2021.

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EXHIBIT 21

Safer Federal Workforce Task Force

COVID-19 Workplace Safety: Agency Model Safety Principles

Last Updated September 13, 2021 (Previously Updated July 29, 2021)

Recent Updates

- Federal Executive Branch employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. Agencies must work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021.
- With the government-wide adoption and implementation of these vaccination requirements, agencies are no longer required to establish a screening testing program for employees or onsite contractor employees who are not fully vaccinated, although they may do so.
- The President has announced that Federal contractor employees will be required to be vaccinated. Prior to being contractually required to be vaccinated, onsite contractor employees who are not fully vaccinated and are not part of an agency testing program must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building.

Purpose

The purpose of this document is to provide model safety principles for executive departments and agencies (hereafter, "agency" and collectively, "agencies") for their COVID-19 workplace safety plans. In Executive Order No. 13991, President Biden established the Safer Federal Workforce Task Force to oversee the development and implementation of agency COVID-19 workplace safety plans across the Federal Government. In his Executive Order on *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees* and his Executive Order on *Ensuring Adequate COVID Safety Protocols for Federal Contractors*, President Biden directed the Task Force to issue guidance on implementation of the requirements in those Orders.

Agencies should incorporate these model safety principles into their existing COVID-19 workplace safety plans.

Agencies with onsite contractor employees should address how the protocols below are applied to those individuals to promote Federal workplace safety in the context of COVID-19.

Overview of Model Principles

The Federal Government is committed to addressing essential work requirements consistent with best public health practices. The Administration's paramount concern is the health and safety of all Federal employees, onsite contractor employees, and individuals interacting with the Federal workforce.

The principles presented here are aligned with the latest guidance from the Centers for Disease Control and Prevention (CDC) for employers and for fully vaccinated people and the Occupational Safety and Health Administration (OSHA) on protecting workers, based on evolving understanding of the pandemic. These principles will be reassessed over time, as conditions warrant and as CDC guidelines are updated.

Where a locality has imposed additional pandemic-related requirements more protective than those set forth in these model safety principles, those requirements should be followed in Federal buildings and on Federal land in that locality.

Goal

The health and safety of the Federal workforce is the Administration's highest priority.

Health and Safety

Vaccination

To ensure the safety of the Federal workforce, Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. Agencies must work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021.

When a Federal employee is required to be vaccinated, the time the employee spends obtaining any COVID-19 vaccination (including travel time) is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. Employees may not be credited with administrative leave for time spent getting a vaccination. If, due to unforeseen circumstances, the employee is unable to obtain the vaccine during basic tour of duty hours the normal overtime hours of work rules apply.

Employees will receive paid time off to address any side effects. Employees will also receive paid time off to accompany a family member being vaccinated. For this purpose, a "family member" is an individual who meets the definition of that term in OPM's leave regulations (see 5 CFR 630.201).

Some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status. Given the different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated, agencies need to ask about the vaccination status of visitors to Federal buildings and onsite contractor employees who are not yet contractually required to be vaccinated. Individuals must attest to the truthfulness of the response they provide. When an individual discloses that they are not fully vaccinated or declines to provide information on their vaccination status, agencies should treat that individual as not fully vaccinated for purposes of implementing safety measures, including with respect to mask wearing and physical distancing.

Onsite contractor employees who are not yet contractually required to be vaccinated and who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building—as noted below, if a contractor employee is regularly tested pursuant to an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Visitors to Federal buildings who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building. See the section below on Meetings, Events, and Conferences

for how visitor requirements apply to in-person participants in meetings, events, and conferences hosted by agencies.

These requirements related to the provision of information about vaccination and provision of proof of a recent negative COVID-19 test do not apply to members of the public entering a Federal building or Federal land to obtain a public service or benefit. If they are not fully vaccinated, these visitors must comply with all relevant CDC guidance, including wearing a mask and physically distancing from other people.

Levels of Community Transmission

For purposes of this guidance, when determining levels of community transmission in a given area, agencies should reference the CDC COVID-19 Data Tracker County View. Agencies can use discretion in determining the counties relevant to the determination of the level of community transmission in a given area for a given Federal facility. For example, agencies may consider the county in which an agency facility is located as well as the transmission levels of surrounding local counties from which employees commute to the facility.

Telework and Remote Work

Agencies should utilize telework and remote work consistent with the principles set forth in OMB Memorandum M-21-25 and agency plans for reentry and post-reentry.

COVID-19 Coordination Team

Each agency should maintain its COVID-19 Coordination Team, as detailed in OMB Memorandum M-21-15. This team should, at a minimum, include a representative from: each component agency (if applicable); the appropriate human resources office(s); occupational safety and health experts; executive leadership; legal counsel; and a public health expert. If such a public health expert does not exist at the agency, the Safer Federal Workforce Task Force will designate someone. The team should meet regularly to review compliance with agency COVID-19 workplace safety plans and protocols, consider potential revisions to agency COVID-19 workplace safety plans and protocols pursuant to guidance from the Safer Federal Workforce Task Force and current CDC guidelines, and evaluate any other operational needs related to COVID-19 workplace safety. The team should coordinate all decisions with Facility Security Committees, as appropriate. For privately owned facilities leased by the Federal Government, the team must coordinate with the General Services Administration (GSA), where appropriate, and the lessor's designated representative.

Face Masks and Physical Distancing

Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. In addition, some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status.

Individuals who are not fully vaccinated must wear a mask regardless of community transmission level. In areas of high or substantial transmission, fully vaccinated people must wear a mask in public indoor settings, except for limited exceptions discussed in this section.

In areas of low or moderate transmission, in most settings, fully vaccinated people generally do not need to wear a mask or physically distance in Federal buildings or on Federal land, except where required by Federal, State, local, Tribal, or territorial laws, rules, or regulations. Fully vaccinated individuals might choose to wear a mask regardless of the level of transmission for a variety of reasons. Nothing in CDC guidance precludes an employee from wearing a mask, if the employee so chooses. CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, should be followed, as applicable.

Individuals who are not fully vaccinated or who decline to provide their vaccination status—or who are in an area of substantial or high transmission—must wear a mask that covers their nose and mouth, and that is in accordance with current CDC guidance. CDC recommends the following: disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source), masks with two or three layers, and masks with inner filter pockets. Agencies should not allow novelty or non-protective masks, masks with ventilation valves, or face shields as a substitute for masks.

In addition to properly wearing a mask, individuals who are not fully vaccinated or who decline to provide information about their vaccination status must maintain distance. To the extent practicable, individuals who are not fully vaccinated or who decline to provide information about their vaccination status should maintain a distance of at least six feet from others at all times, consistent with CDC guidelines, including in offices, conference rooms, and all other communal and work spaces.

For individuals who are required to wear a mask:

- Appropriate masks should be worn consistently and correctly (over mouth and nose).
- Appropriate masks should be worn in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- In general, people do not need to wear masks when outdoors. However, consistent with CDC guidance, those who are not fully vaccinated should wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated.
- Agencies may provide for exceptions consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining distancing in accordance with CDC guidelines.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Masks do not provide the same level of protection as respirators and should not replace personal protective equipment required or recommended at the workplace.

Testing

Agencies may establish a program to test Federal employees who are not fully vaccinated for COVID-19. Agencies may also test contractor employees working onsite who are not fully vaccinated as part of a

testing program—if contractor employees are tested as part of an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Agencies must have a process in place for employee diagnostic testing after a workplace exposure.

Contact Tracing

The agency's COVID-19 Coordination Team will collaborate with and support the contact tracing programs of local health departments to help identify, track, and manage contacts of COVID-19 cases.

The team will engage in coordination with facilities staff to implement infection control and workplace safety efforts once informed of a known or suspected case of COVID-19 (due either to specific symptoms or a positive test).

The team should ensure that the agency makes disclosures to local public health officials, as required or necessary, to provide for the health and safety of Federal employees, contractor employees, and the general public, in accordance with local public health mandates. If COVID-19 cases occur within a specific building or work setting, it will be the responsibility of that agency's COVID-19 Coordination Team (or a field office or agency component designee) to determine—in consultation with local public health officials—appropriate next steps. Agencies should be transparent in communicating related information to the workforce, as relevant and appropriate; disclosures must be consistent with Federal, State, and local privacy and confidentiality laws and regulations.

Travel

Federal employees should adhere strictly to CDC guidelines before, during, and after travel.

For Federal employees who are fully vaccinated, there are no Government-wide restrictions on travel (although agency travel policies still apply).

For the limited number of Federal employees who are not fully vaccinated, agencies should generally observe the following guidance, unless it is contrary to a reasonable accommodation to which an employee is legally entitled. Official domestic travel should be limited to only necessary mission-critical trips. International travel should also be avoided, if at all possible, unless it is mission critical (e.g., military deployments, COVID-19 response deployments or activities, diplomats traveling, high-level international negotiations that cannot occur remotely). Heads of agencies should issue specific guidance to account for the particulars of their agency's mission.

Meetings, Events, and Conferences

Should an agency intend to host an in-person meeting, conference, or event that will be attended by more than 50 participants—regardless of whether participants include members of the public—the agency must first seek the approval of its agency head, in consultation with the agency's COVID-19 Coordination Team.

In-person attendees at any meetings, conferences, and events hosted by an agency, regardless of size, must be asked to provide information about vaccination status. In requesting this information, agencies should comply with any applicable Federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act. In-person attendees who are not fully vaccinated or decline to provide

information about their vaccination status must provide proof of a negative COVID-19 test completed no later than the previous 3 days and comply with masking and physical distancing requirements for individuals who are not fully vaccinated consistent with the requirements for visitors in the Face Masks and Physical Distancing section above. In-person attendees in areas of high or substantial transmission must wear a mask in public indoor settings regardless of vaccination status.

Symptom Monitoring

If Federal employees, onsite contractors, or visitors have symptoms consistent with COVID-19, they should not enter a Federal workplace.

Federal employees and contractor employees working on site should regularly complete virtual or in-person health checks (ask about symptoms, close contact with someone with SARS-CoV-2 infection, and SARS-CoV-2 testing and diagnosis status). The agency will use this information to assess the individual's risk level and to determine whether the individual should be allowed entry to the workplace. Visitors may be asked to complete symptom screening before entering a Federal facility. In developing these tools, agencies may adapt the one developed by CDC.

Any individual, regardless of vaccination status, who develops any symptoms consistent with COVID-19 during the workday must immediately isolate, wear a mask (if the individual is not already doing so and one is available), notify their supervisor, and promptly leave the workplace. Agencies should have processes in place to provide advice and support to supervisors on any related reporting or human resources requirements.

Quarantine, Isolation, and Steps for Fully Vaccinated Individuals Following Exposure to Someone with Suspected or Confirmed COVID-19

Any individual with a suspected or confirmed case of COVID-19 will be advised to isolate, pursuant to CDC guidelines, and in compliance with State, local, and Tribal laws and regulations. Personnel who are not fully vaccinated and who have had a close contact with someone who has tested positive for COVID-19 should follow CDC and State, local, and Tribal guidance for quarantine.

Individuals who have been fully vaccinated and have had close contact with someone with suspected or confirmed COVID-19 should get tested 3-5 days after exposure, even if they do not have symptoms. They should also wear a mask indoors in public for 14 days following exposure or until their test result is negative. If their test result is positive, they should isolate for 10 days.

Confidentiality and Privacy

All medical information collected from individuals, including vaccination information, test results, and any other information obtained as a result of testing and symptom monitoring, will be treated in accordance with applicable laws and policies on confidentiality and privacy, and will be accessible only to those with a need to know. Agencies should consult their Senior Agency Officials for Privacy on matters related to the handling of personally identifiable information and identify a point of contact for all questions relating to personal medical information.

Workplace Operations

Occupancy

Agencies may establish occupancy limits for specific workplaces as a means of facilitating physical distancing. Note that by reducing the number of people in a space, occupancy limits also increase the heating, ventilation, and air conditioning delivery of outdoor air per person.

Environmental Cleaning

Agencies should ensure regular cleaning of common use, high-touch, and high-density spaces, such as lobbies, restrooms, elevators, and stairwells. Office space that is in regular use is to be cleaned regularly, and in accordance with CDC guidelines. Wipes and other Environmental Protection Agency-approved disinfectants will be made available for use by individuals to wipe down workstations and related personal property. Physical barriers, such as plexiglass shields, may be installed, where appropriate.

In the event of a suspected or confirmed case of COVID-19 in the workplace, agencies should ensure enhanced environmental cleaning of the spaces that the individual occupied or accessed in accordance with CDC and, where applicable, GSA guidance, which provides as follows:

- If fewer than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, clean and disinfect the space.
- If more than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, cleaning is enough. You may choose to also disinfect depending on certain conditions or everyday practices required by your facility.
- If more than 3 days have passed since the person who is sick or diagnosed with COVID-19 has been in the space, no additional cleaning (beyond regular cleaning practices) is needed.

If enhanced cleaning is required, wait as long as possible (at least several hours) before cleaning and disinfecting. Extended wait periods allow increased opportunity for viral deactivation to occur naturally, while also allowing time for aerosols to settle, prior to surface disinfection.

The agency's COVID-19 Coordination Team will determine the appropriate scope of workplace closures needed—in some cases, it may be a suite or individual offices or part of a floor, in other cases, it may include an entire building.

Hygiene

Hand sanitizer stations are to be available at the building entrance and throughout workspaces. Hand sanitizers should contain at least 60% alcohol and be manufactured in accordance with the requirements of the U.S. Food and Drug Administration (FDA). Ingredients should be listed on a "Drug Facts" label. Agencies should ensure the hand sanitizer is not on the FDA's do not use list.

Ventilation and Air Filtration

Modifications to ventilation systems should be considered in accordance with CDC guidance, especially as building population density increases. To the maximum extent feasible, indoor ventilation will be optimized to increase the proportion of outdoor air and improve filtration. Deployment of portable high-efficiency particulate air (HEPA) cleaners should be considered for higher-risk spaces (e.g., health clinics).

Collective Bargaining Obligations

Consistent with President Biden's policy to support collective bargaining, agencies are reminded to satisfy applicable collective bargaining obligations under 5 U.S.C. Chapter 71 when implementing workplace safety plans, including on a post-implementation basis where necessary. Agencies are also strongly encouraged to communicate regularly with employee representatives on workplace safety matters.

EXHIBIT 22

Presidential Documents

Executive Order 14042 of September 9, 2021

Ensuring Adequate COVID Safety Protocols for Federal Contractors

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Property and Administrative Services Act, 40 U.S.C. 101 *et seq.,* and section 301 of title 3, United States Code, and in order to promote economy and efficiency in procurement by contracting with sources that provide adequate COVID–19 safeguards for their workforce, it is hereby ordered as follows:

Section 1. *Policy.* This order promotes economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID–19 safeguards to their workers performing on or in connection with a Federal Government contract or contract-like instrument as described in section 5(a) of this order. These safeguards will decrease the spread of COVID–19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government. Accordingly, ensuring that Federal contractors and subcontractors are adequately protected from COVID–19 will bolster economy and efficiency in Federal procurement.

Sec. 2. *Providing for Adequate COVID–19 Safety Protocols for Federal Contractors and Subcontractors.* (a) Executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. 102(4)(A) (agencies), shall, to the extent permitted by law, ensure that contracts and contract-like instruments (as described in section 5(a) of this order) include a clause that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance or Guidance), provided that the Director of the Office of Management and Budget (Director) approves the Task Force Guidance and determines that the Guidance, if adhered to by contractors or subcontractors, will promote economy and efficiency in Federal contracting. This clause shall apply to any workplace locations (as specified by the Task Force Guidance) in which an individual is working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(b) By September 24, 2021, the Safer Federal Workforce Task Force (Task Force) shall, as part of its issuance of Task Force Guidance, provide definitions of relevant terms for contractors and subcontractors, explanations of protocols required of contractors and subcontractors to comply with workplace safety guidance, and any exceptions to Task Force Guidance that apply to contractor and subcontractor workplace locations and individuals in those locations working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order).

(c) Prior to the Task Force publishing new Guidance related to COVID–19 for contractor or subcontractor workplace locations, including the Guidance developed pursuant to subsection (b) of this section, the Director shall, as an exercise of the delegation of my authority under the Federal Property

and Administrative Services Act, *see* 3 U.S.C. 301, determine whether such Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. Upon an affirmative determination by the Director, the Director's approval of the Guidance, and subsequent issuance of such Guidance by the Task Force, contractors and subcontractors working on or in connection with a Federal Government contract or contract-like instrument (as described in section 5(a) of this order), shall adhere to the requirements of the newly published Guidance, in accordance with the clause described in subsection (a) of this section. The Director shall publish such determination in the *Federal Register*.

(d) Nothing in this order shall excuse noncompliance with any applicable State law or municipal ordinance establishing more protective safety protocols than those established under this order or with any more protective Federal law, regulation, or agency instructions for contractor or subcontractor employees working at a Federal building or a federally controlled workplace.

(e) For purposes of this order, the term ''contract or contract-like instrument'' shall have the meaning set forth in the Department of Labor's proposed rule, ''Increasing the Minimum Wage for Federal Contractors,'' 86 FR 38816, 38887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, that term shall have the meaning set forth in that final rule.

Sec. 3. *Regulations and Implementation.* (a) The Federal Acquisition Regulatory Council, to the extent permitted by law, shall amend the Federal Acquisition Regulation to provide for inclusion in Federal procurement solicitations and contracts subject to this order the clause described in section 2(a) of this order, and shall, by October 8, 2021, take initial steps to implement appropriate policy direction to acquisition offices for use of the clause by recommending that agencies exercise their authority under subpart 1.4 of the Federal Acquisition Regulation.

(b) By October 8, 2021, agencies shall take steps, to the extent permitted by law, to exercise any applicable authority to ensure that contracts and contract-like instruments as described in section 5(a) of this order that are not subject to the Federal Acquisition Regulation and that are entered into on or after October 15, 2021, consistent with the effective date of such agency action, include the clause described in section 2(a) of this order.

Sec. 4. *Severability.* If any provision of this order, or the application of any provision of this order to any person or circumstance, is held to be invalid, the remainder of this order and its application to any other person or circumstance shall not be affected thereby.

Sec. 5. *Applicability.* (a) This order shall apply to any new contract; new contract-like instrument; new solicitation for a contract or contract-like instrument; extension or renewal of an existing contract or contract-like instrument; and exercise of an option on an existing contract or contract-like instrument, if:

(i) it is a procurement contract or contract-like instrument for services, construction, or a leasehold interest in real property;

(ii) it is a contract or contract-like instrument for services covered by the Service Contract Act, 41 U.S.C. 6701 *et seq.;*

(iii) it is a contract or contract-like instrument for concessions, including any concessions contract excluded by Department of Labor regulations at 29 CFR 4.133(b); or

(iv) it is a contract or contract-like instrument entered into with the Federal Government in connection with Federal property or lands and related to offering services for Federal employees, their dependents, or the general public;

(b) This order shall not apply to:

(i) grants;

(ii) contracts, contract-like instruments, or agreements with Indian Tribes under the Indian Self-Determination and Education Assistance Act (Public Law 93–638), as amended;

(iii) contracts or subcontracts whose value is equal to or less than the simplified acquisition threshold, as that term is defined in section 2.101 of the Federal Acquisition Regulation;

(iv) employees who perform work outside the United States or its outlying areas, as those terms are defined in section 2.101 of the Federal Acquisition Regulation; or

(v) subcontracts solely for the provision of products.

Sec. 6. *Effective Date.* (a) Except as provided in subsection (b) of this section, this order is effective immediately and shall apply to new contracts; new contract-like instruments; new solicitations for contracts or contract-like instruments; extensions or renewals of existing contracts or contract-like instruments; and exercises of options on existing contracts or contract-like instruments, as described in section 5(a) of this order, where the relevant contract or contract-like instrument will be entered into, the relevant contract or contract-like instrument will be extended or renewed, or the relevant option will be exercised, on or after:

(i) October 15, 2021, consistent with the effective date for the action taken by the Federal Acquisition Regulatory Council pursuant to section 3(a) of this order; or

(ii) for contracts and contract-like instruments that are not subject to the Federal Acquisition Regulation and where an agency action is taken pursuant to section 3(b) of this order, October 15, 2021, consistent with the effective date for such action.

(b) As an exception to subsection (a) of this section, where agencies have issued a solicitation before the effective date for the relevant action taken pursuant to section 3 of this order and entered into a new contract or contract-like instrument resulting from such solicitation within 30 days of such effective date, such agencies are strongly encouraged to ensure that the safety protocols specified in section 2 of this order are applied in the new contract or contract-like instrument. But if that contract or contract-like instrument term is subsequently extended or renewed, or an option is subsequently exercised under that contract or contract-like instrument, the safety protocols specified in section 2 of this order shall apply to that extension, renewal, or option.

(c) For all existing contracts and contract-like instruments, solicitations issued between the date of this order and the effective dates set forth in this section, and contracts and contract-like instruments entered into between the date of this order and the effective dates set forth in this section, agencies are strongly encouraged, to the extent permitted by law, to ensure that the safety protocols required under those contracts and contract-like instruments are consistent with the requirements specified in section 2 of this order.

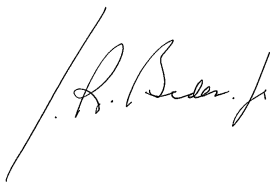
Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
September 9, 2021.

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EXHIBIT 23

Safer Federal Workforce Task Force
COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors
Issued September 24, 2021

Introduction

On September 9, President Biden announced his Path Out of the Pandemic: COVID-19 Action Plan. One of the main goals of this science-based plan is to get more people vaccinated. As part of that plan, the President signed Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, ("the order") which directs executive departments and agencies, including independent establishments subject to the Federal Property and Administrative Services Act, 40 U.S.C. § 102(4)(A), to ensure that covered contracts and contract-like instruments include a clause ("the clause") that the contractor and any subcontractors (at any tier) shall incorporate into lower-tier subcontracts. This clause shall specify that the contractor or subcontractor shall, for the duration of the contract, comply with all guidance for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force ("Task Force"), provided that the Director of the Office of Management and Budget ("OMB") approves the Task Force Guidance (the or this "Guidance") and determines that the Guidance, if adhered to by covered contractors, will promote economy and efficiency in Federal contracting.

The actions directed by the order will ensure that parties who contract with the Federal Government provide COVID-19 safeguards in workplaces with individuals working on or in connection with a Federal Government contract or contract-like instrument. These workplace safety protocols will apply to all covered contractor employees, including contractor or subcontractor employees in covered contractor workplaces who are not working on a Federal Government contract or contract-like instrument. These safeguards will decrease the spread of SARS-CoV-2, the virus that causes COVID-19, which will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors performing work for the Federal Government.

Pursuant to this Guidance, and in addition to any requirements or workplace safety protocols that are applicable because a contractor or subcontractor employee is present at a Federal workplace, Federal contractors and subcontractors with a covered contract will be required to conform to the following workplace safety protocols:

1. COVID-19 vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation;
2. Compliance by individuals, including covered contractor employees and visitors, with the Guidance related to masking and physical distancing while in covered contractor workplaces; and
3. Designation by covered contractors of a person or persons to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.

The order also sets out a process for OMB and the Safer Federal Workforce Task Force to update the Guidance for covered contractors, which the Task Force will consider doing based on future changes to Centers for Disease Control and Prevention ("CDC") COVID-19 guidance and as warranted by the circumstances of the pandemic and public health conditions. It also sets out a process for the Federal Acquisition Regulatory Council ("FAR Council") to implement such protocols and guidance for covered Federal procurement solicitations and contracts subject to the Federal Acquisition Regulation ("FAR") and for agencies that are responsible for covered contracts and contract-like instruments not subject to the FAR to take prompt action to ensure that those covered contracts and contract-like instruments include the clause, consistent with the order.

Covered contractors shall adhere to the requirements of this Guidance. The Director of OMB has, as authorized by Executive Order 14042, approved this Guidance and has, an exercise of the delegation of authority (see 3 U.S.C. § 301) under the Federal Property and Administrative Services Act determined that this Guidance will promote economy and efficiency in Federal contracting if adhered to by Government contractors and subcontractors. The Director has published such determination in the Federal Register.

Definitions

Community transmission – means the level of community transmission as set forth in the CDC COVID-19 Data Tracker County View.

Contract and contract-like instrument – has the meaning set forth in the Department of Labor's proposed rule, "Increasing the Minimum Wage for Federal Contractors," 86 Fed. Reg. 38,816, 38,887 (July 22, 2021). If the Department of Labor issues a final rule relating to that proposed rule, this term shall have the meaning set forth in that final rule.

That proposed rule defines a contract or contract-like instrument as an agreement between two or more parties creating obligations that are enforceable or otherwise recognizable at law. This definition includes, but is not limited to, a mutually binding legal relationship obligating one party to furnish services (including construction) and another party to pay for them. The term contract includes all contracts and any subcontracts of any tier thereunder, whether negotiated or advertised, including any procurement actions, lease agreements, cooperative agreements, provider agreements, intergovernmental service agreements, service agreements, licenses, permits, or any other type of agreement, regardless of nomenclature, type, or particular form, and whether entered into verbally or in writing. The term contract shall be interpreted broadly as to include, but not be limited to, any contract within the definition provided in the FAR at 48 CFR chapter 1 or applicable Federal statutes. This definition includes, but is not limited to, any contract that may be covered under any Federal procurement statute. Contracts may be the result of competitive bidding or awarded to a single source under applicable authority to do so. In addition to bilateral instruments, contracts include, but are not limited to, awards and notices of awards; job orders or task letters issued under basic ordering agreements; letter contracts; orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; exercised contract options; and bilateral contract modifications. The term contract includes contracts covered by the Service Contract Act, contracts covered by the Davis-Bacon Act, concessions contracts not otherwise subject to the Service Contract Act, and contracts in connection with Federal property or land and related to offering services for Federal employees, their dependents, or the general public.

Contractor or subcontractor workplace location – means a location where covered contract employees work, including a covered contractor workplace or Federal workplace.

Covered contract – means any contract or contract-like instrument that includes the clause described in Section 2(a) of the order.

Covered contractor – means a prime contractor or subcontractor at any tier who is party to a covered contract.

Covered contractor employee – means any full-time or part-time employee of a covered contractor working on or in connection with a covered contract or working at a covered

contractor workplace. This includes employees of covered contractors who are not themselves working on or in connection with a covered contract.

Covered contractor workplace – means a location controlled by a covered contractor at which any employee of a covered contractor working on or in connection with a covered contract is likely to be present during the period of performance for a covered contract. A covered contractor workplace does not include a covered contractor employee's residence.

Federal workplace – means any place, site, installation, building, room, or facility in which any Federal executive department or agency conducts official business, or is within an executive department or agency's jurisdiction, custody, or control.

Fully vaccinated – People are considered fully vaccinated for COVID-19 two weeks after they have received the second dose in a two-dose series, or two weeks after they have received a single-dose vaccine. There is currently no post-vaccination time limit on fully vaccinated status; should such a limit be determined by the Centers for Disease Control and Prevention, that limit will be considered by the Task Force and OMB for possible updating of this Guidance.

For purposes of this Guidance, people are considered fully vaccinated if they have received COVID-19 vaccines currently approved or authorized for emergency use by the U.S. Food and Drug Administration (Pfizer-BioNTech, Moderna, and Johnson & Johnson [J&J]/Janssen COVID-19 vaccines) or COVID-19 vaccines that have been listed for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford). More information is available at Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.

Clinical trial participants from a U.S. site who are documented to have received the full series of an "active" (not placebo) COVID-19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), can be considered fully vaccinated two weeks after they have completed the vaccine series. Currently, the Novavax COVID-19 vaccine meets these criteria. More information is available at the CDC website here.

Mask – means any mask that is consistent with CDC recommendations as set forth in Types of Masks and Respirators | CDC. This may include the following: disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source), masks with two or three layers, masks with inner filter pockets, and filtering facepiece respirators that are approved by the National Institute for Occupational Safety and Health or consistent with international standards. The following do not constitute masks for purposes of this Guidance: masks with exhalation valves, vents, or other openings; face shields only (without mask); or masks with single-layer fabric or thin fabric that does not block light.

Guidance

Covered contractors are responsible for ensuring that covered contractor employees comply with the workplace safety protocols detailed below. Covered contractor employees must also comply with agency COVID-19 workplace safety requirements while in Federal workplaces.

Consistent with applicable law, agencies are strongly encouraged to incorporate a clause requiring compliance with this Guidance into contracts that are not covered or directly addressed by the order because the contract is under the Simplified Acquisition Threshold as defined in section 2.101 of the FAR or is a contract or subcontract for the manufacturing of products. Agencies are also strongly encouraged to incorporate a clause requiring compliance with this Guidance into existing contracts and contract-like instruments prior to the date upon which the order requires inclusion of the clause.

1. *Vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation*

Covered contractors must ensure that all covered contractor employees are fully vaccinated for COVID-19, unless the employee is legally entitled to an accommodation. Covered contractor employees must be fully vaccinated no later than December 8, 2021. After that date, all covered contractor employees must be fully vaccinated by the first day of the period of performance on a newly awarded covered contract, and by the first day of the period of performance on an exercised option or extended or renewed contract when the clause has been incorporated into the covered contract.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they are not vaccinated against COVID-19 because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer. Requests for "medical accommodation" or "medical exceptions" should be treated as requests for a disability accommodation.

Should a Federal agency have an urgent, mission-critical need for a covered contractor to have covered contractor employees begin work on a covered contract or at a covered workplace before becoming fully vaccinated, the agency head may approve an exception for the covered contractor —in the case of such limited exceptions, the covered contractor must ensure these covered contractor employees are fully vaccinated within 60 days of beginning work on a covered contract or at a covered workplace. The covered contractor must further ensure that such employees comply with masking and physical distancing requirements for not fully vaccinated individuals in covered workplaces prior to being fully vaccinated.

The covered contractor must review its covered employees' documentation to prove vaccination status. Covered contractors must require covered contractor employees to show or provide their

employer with one of the following documents: a copy of the record of immunization from a health care provider or pharmacy, a copy of the COVID-19 Vaccination Record Card (CDC Form MLS-319813_r, published on September 3, 2020), a copy of medical records documenting the vaccination, a copy of immunization records from a public health or State immunization information system, or a copy of any other official documentation verifying vaccination with information on the vaccine name, date(s) of administration, and the name of health care professional or clinic site administering vaccine. Covered contractors may allow covered contractor employees to show or provide to their employer a digital copy of such records, including, for example, a digital photograph, scanned image, or PDF of such a record.

The covered contractor shall ensure compliance with the requirements in this Guidance related to the showing or provision of proper vaccination documentation.

Covered contractors are strongly encouraged to incorporate similar vaccination requirements into their non-covered contracts and agreements with non-covered contractors whose employees perform work at covered contractor workplaces but who do not work on or in connection with a Federal contract, such as those contracts and agreements related to the provision of food services, onsite security, or groundskeeping services at covered contractor workplaces.

2. *Requirements related to masking and physical distancing while in covered contractor workplaces*

Covered contractors must ensure that all individuals, including covered contractor employees and visitors, comply with published CDC guidance for masking and physical distancing at a covered contractor workplace, as discussed further in this Guidance.

In addition to the guidance set forth below, CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, must be followed, as applicable.

In areas of high or substantial community transmission, fully vaccinated people must wear a mask in indoor settings, except for limited exceptions discussed in this Guidance. In areas of low or moderate community transmission, fully vaccinated people do not need to wear a mask. Fully vaccinated individuals do not need to physically distance regardless of the level of transmission in the area.

Individuals who are not fully vaccinated must wear a mask indoors and in certain outdoor settings (see below) regardless of the level of community transmission in the area. To the extent practicable, individuals who are not fully vaccinated should maintain a distance of at least six feet from others at all times, including in offices, conference rooms, and all other communal and work spaces.

Covered contractors must require individuals in covered contractor workplaces who are required to wear a mask to:

- Wear appropriate masks consistently and correctly (over mouth and nose).
- Wear appropriate masks in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- For individuals who are not fully vaccinated, wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated, consistent with CDC guidance.

A covered contractor may be required to provide an accommodation to covered contractor employees who communicate to the covered contractor that they cannot wear a mask because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer.

Covered contractors may provide for exceptions to mask wearing and/or physical distancing requirements consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining appropriate distancing. Covered contractors may also provide exceptions for covered contractor employees engaging in activities in which a mask may get wet; high intensity activities where covered contractor employees are unable to wear a mask because of difficulty breathing; or activities for which wearing a mask would create a risk to workplace health, safety, or job duty as determined by a workplace risk assessment. Any such exceptions must be approved in writing by a duly authorized representative of the covered contractor to ensure compliance with this Guidance at covered contractor workplaces, as discussed further below.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Covered contractors must check the CDC COVID-19 Data Tracker County View website for community transmission information in all areas where they have a covered contractor workplace at least weekly to determine proper workplace safety protocols. When the level of community transmission in the area of a covered contractor workplace increases from low or moderate to substantial or high, contractors and subcontractors should put in place more protective workplace safety protocols consistent with published guidelines. However, when the level of community transmission in the area of a covered contractor workplace is reduced from high or substantial to moderate or low, the level of community transmission must remain at that lower level for at least two consecutive weeks before the covered contractor utilizes those protocols recommended for areas of moderate or low community transmission.

3. *Designation by covered contractors of a person or persons to coordinate COVID-19 workplace safety efforts at covered contractor workplaces.*

Covered contractors shall designate a person or persons to coordinate implementation of and compliance with this Guidance and the workplace safety protocols detailed herein at covered contractor workplaces. The designated person or persons may be the same individual(s) responsible for implementing any additional COVID-19 workplace safety protocols required by local, State, or Federal law, and their responsibilities to coordinate COVID-19 workplace safety protocols may comprise some or all of their regular duties.

The designated individual (or individuals) must ensure that information on required COVID-19 workplace safety protocols is provided to covered contractor employees and all other individuals likely to be present at covered contractor workplaces, including by communicating the required workplace safety protocols and related policies by email, websites, memoranda, flyers, or other means and posting signage at covered contractor workplaces that sets forth the requirements and workplace safety protocols in this Guidance in a readily understandable manner. This includes communicating the COVID-19 workplace safety protocols and requirements related to masking and physical distancing to visitors and all other individuals present at covered contractor workplaces. The designated individual (or individuals) must also ensure that covered contractor employees comply with the requirements in this guidance related to the showing or provision of proper vaccination documentation.

Frequently Asked Questions

Vaccination and Safety Protocols

Q1: How do covered contractors determine vaccination status of visitors to covered contractor workplaces?

A: Covered contractors should post signage at entrances to covered contractor workplaces providing information on safety protocols for fully vaccinated and not fully vaccinated individuals, including the protocols defined in the masking and physical distancing section above, and instruct individuals to follow the appropriate workplace safety protocols while at the covered contractor workplace. Covered contractors may take other reasonable steps, such as by communicating workplace safety protocols to visitors prior to their arrival at a covered contractor workplace or requiring all visitors to follow masking and physical distancing protocols for not fully vaccinated individuals.

Q2: Do covered contractors need to provide onsite vaccinations to their employees?

A: Covered contractors should ensure their employees are aware of convenient opportunities to be vaccinated. Although covered contractors may choose to provide vaccinations at their facilities or workplaces, given the widespread availability of vaccinations, covered contractors are not required to do so.

Q3: What should a contractor employee do if a covered contractor employee has lost or does not have a copy of required vaccination documentation?

A: If covered contractor employees need new vaccination cards or copies of other documentation proof of vaccination, they should contact the vaccination provider site where they received their vaccine. Their provider should be able to provide them with new cards or documentation with up-to-date information about the vaccinations they have received. If the location where the covered contractor employees received their COVID-19 vaccine is no longer operating, the covered contractor employees should contact their State or local health department's immunization information system (IIS) for assistance. Covered contractor employees should contact their State or local health department if they have additional questions about vaccination cards or vaccination records.

An attestation of vaccination by the covered contractor employee is not an acceptable substitute for documentation of proof of vaccination.

Q4: Who is responsible for determining if a covered contractor employee must be provided an accommodation because of a disability or because of a sincerely held religious belief, practice, or observance?

A: A covered contractor may be required to provide an accommodation to contractor employees who communicate to the covered contractor that they are not vaccinated for COVID-19, or that they cannot wear a mask, because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance. A covered contractor should review and consider what, if any, accommodation it must offer. The contractor is responsible for considering, and dispositioning, such requests for accommodations regardless of the covered contractor employee's place of performance. If the agency that is the party to the covered contract is a "joint employer" for purposes of compliance with the Rehabilitation Act and Title VII of the Civil Rights Act, both the agency and the covered contractor should review and consider what, if any, accommodation they must offer.

Q5: Are covered contractor employees who have a prior COVID-19 infection required to be vaccinated?

A: Yes, covered contractor employees who have had a prior COVID-19 infection are required to be vaccinated. More information from CDC can be found here.

Q6: Can a covered contractor accept a recent antibody test from a covered contractor employee to prove vaccination status?

A: No. A covered contractor cannot accept a recent antibody test from a covered contractor employee to prove vaccination status.

Workplaces

Q7: Does this Guidance apply to outdoor contractor or subcontractor workplace locations?

A: Yes, this Guidance applies to contractor or subcontractor workplace locations that are outdoors.

Q8: If a covered contractor employee is likely to be present during the period of performance for a covered contract on only one floor or a separate area of a building, site, or facility controlled by a covered contractor, do other areas of the building, site, or facility controlled by a covered contractor constitute a covered contractor workplace?

A: Yes, unless a covered contractor can affirmatively determine that none of its employees on another floor or in separate areas of the building will come into contact with a covered contractor employee during the period of performance of a covered contract. This would include affirmatively determining that there will be no interactions between covered contractor employees and non-covered contractor employees in those locations during the period of performance on a covered contract, including interactions through use of common areas such as lobbies, security clearance areas, elevators, stairwells, meeting rooms, kitchens, dining areas, and parking garages.

Q9: If a covered contractor employee performs their duties in or at only one building, site, or facility on a campus controlled by a covered contractor with multiple buildings, sites, or facilities, are the other buildings, sites, or facility controlled by a covered contractor considered a covered contractor workplace?

A: Yes, unless a covered contractor can affirmatively determine that none of its employees in or at one building, site, or facility will come into contact with a covered contractor employee during the period of performance of a covered contract. This would include affirmatively determining that there will be no interactions between covered contractor employees and non-covered contractor employees in those locations during the period of performance on a covered contract, including interactions through use of common areas such as lobbies, security clearance areas, elevators, stairwells, meeting rooms, kitchens, dining areas, and parking garages.

Q10: Are the workplace safety protocols enumerated above the same irrespective of whether the work is performed at a covered contractor workplace or at a Federal workplace?

A: Yes. The Guidance applies to all covered contractor employees and to all contractor or subcontractor workplace locations. While at a Federal workplace, covered contractor employees must also comply with any additional agency workplace safety requirements for that workplace. Because covered contractor employees working on a covered contract need to be fully vaccinated after December 8, 2021, covered contractor employees who work only at a Federal workplace need to be fully vaccinated by that date as well, unless legally entitled to an accommodation.

Q11: How does this Guidance apply to covered contractor employees who are authorized under the covered contract to perform work remotely from their residence?

A: An individual working on a covered contract from their residence is a covered contractor employee, and must comply with the vaccination requirement for covered contractor employees, even if the employee never works at either a covered contractor workplace or Federal workplace during the performance of the contract. A covered contractor employee's residence is not a covered contractor workplace, so while in the residence the individual need not comply with requirements for covered contractor workplaces, including those related to masking and physical distancing, even while working on a covered contract.

Scope and Applicability

Q12: By when must the requirements of the order be reflected in contracts?

A: Section 6 of the order lays out a phase-in of the requirements for covered contracts as follows:

- *Contracts awarded prior to October 15 where performance is ongoing* – the requirements must be incorporated at the point at which an option is exercised or an extension is made.
- *New contracts* – the requirements must be incorporated into contracts awarded on or after November 14. Between October 15 and November 14, agencies must include the clause in the solicitation and are encouraged to include the clause in contracts awarded during this time period but are not required to do so unless the solicitation for such contract was issued on or after October 15.

Q13: Must the order's requirements be flowed down to all lower-tier subcontractors and, if so, who is responsible for flowing the clause down?

A: Yes. The requirements in the order apply to subcontractors at all tiers, except for subcontracts solely for the provision of products. The prime contractor must flow the clause down to first-tier subcontractors; higher-tier subcontractors must flow the clause down to the next lower-tier subcontractor, to the point at which subcontract requirements are solely for the provision of products.

Q14: Does the Guidance apply to small businesses?

A: Yes, the requirement to comply with this Guidance applies equally to covered contractors regardless of whether they are a small business. This broad application of COVID-19 guidance will more effectively decrease the spread of COVID-19, which, in turn, will decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at workplaces where they are performing work for the Federal Government.

Q15: What steps are being taken to promote consistent application of the order's requirements across agencies?

A: The FAR Council will conduct a rulemaking to amend the FAR to include a clause that requires covered contractors performing under FAR-based contracts to comply with this Guidance for contractor and subcontractor workplace locations. Prior to rulemaking, by October 8, 2021, the FAR Council will develop a clause and recommend that agencies exercise their authority to deviate from the FAR using the procedures set forth in subpart 1.4. Agencies responsible for contracts and contract-like instruments that are not subject to the FAR, such as concession contracts, will be responsible for developing appropriate guidance by October 8, 2021 to incorporate requirements into their covered instruments entered into on or after October 15, 2021.

Q16: If the Safer Federal Workforce Task Force updates this Guidance to add new requirements, do those requirements apply to existing contracts?

A: Yes. Covered contractors are required to, for the duration of the contract, comply with all Task Force Guidance for contractor or subcontractor workplace locations, including any new

Guidance where the OMB Director approves the Guidance and determines that adherence to the Guidance will promote economy and efficiency in Federal contracting. The Task Force and OMB plan to ensure any workplace safety protocols reflect what is necessary to decrease the spread of COVID-19.

Q17: What constitutes work performed "in connection with" a covered contract?

A: Employees who perform duties necessary to the performance of the covered contract, but who are not directly engaged in performing the specific work called for by the covered contract, such as human resources, billing, and legal review, perform work in connection with a Federal Government contract.

Q18: Do the workplace safety protocols in the Guidance apply to covered contractor employees who perform work outside the United States?

A: No. The workplace safety protocols in the Guidance do not apply to covered contractor employees who only perform work outside the United States or its outlying areas, as those terms are defined in section 2.101 of the FAR.

Compliance

Q19: Does this clause apply in States or localities that seek to prohibit compliance with any of the workplace safety protocols set forth in this Guidance?

A: Yes. These requirements are promulgated pursuant to Federal law and supersede any contrary State or local law or ordinance. Additionally, nothing in this Guidance shall excuse noncompliance with any applicable State law or municipal ordinance establishing more protective workplace safety protocols than those established under this Guidance.

Q20: Can a covered contractor comply with workplace safety requirements from the Occupational Safety and Health Administration, including pursuant to any current or forthcoming Emergency Temporary Standard related to COVID-19, instead of the requirements of this Guidance?

A: No. Covered contractors must comply with the requirements set forth in this Guidance regardless of whether they are subject to other workplace safety standards.

Q21: What is the prime contractor's responsibility for verifying that subcontractors are adhering to the mandate?

A: The prime contractor is responsible for ensuring that the required clause is incorporated into its first-tier subcontracts in accordance with the implementation schedule set forth in section 6 of the order. When the clause is incorporated into a subcontract, a subcontractor is required to

comply with this Guidance and the workplace safety protocols detailed herein. Additionally, first-tier subcontractors are expected to flow the clause down to their lower-tier subcontractors in similar fashion so that accountability for compliance is fully established throughout the Federal contract supply chain for covered subcontractor employees and workplaces at all tiers through application of the clause.