IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 22-2230

KATIE SCZESNY, MARIETTE VITTI, DEBRA HAGEN, AND JAIME RUMFIELD,

Plaintiffs-Appellants

v.

Governor PHILIP MURPHY,

Defendant-Appellee,

On appeal from the United States District Court of New Jersey's denial of a temporary restraining order pursuant to *Fed. R. Civ. P.* 65

JOINT APPENDIX VOLUME II

Pages 38-238

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ADMCLOSED,APPEAL,STAYED

U.S. District Court
District of New Jersey [LIVE] (Trenton)
CIVIL DOCKET FOR CASE #: 3:22-cv-02314-GC-RLS

SCZESNY et al v. MURPHY et al
Assigned to: Judge Georgette Castner
Referred to: Magistrate Judge Rukhsanah L. Singh
Case in other court: 3rd circuit, 22-02230
Cause: 42:1981 Civil Rights

Date Filed: 04/21/2022
Date Terminated: 08/01/2022
Jury Demand: Plaintiff
Nature of Suit: 440 Civil Rights: Other
Jurisdiction: Federal Question

Plaintiff

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Plaintiff

DEBRA HAGEN represented by **DANA WEFER**
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Plaintiff

MARIETTE VITTI represented by **DANA WEFER**
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V.

Defendant

PHILIP MURPHY
in his official and personal capacity

represented by **DANIEL MICHAEL VANNELLA**
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DEPARTMENT OF LAW & PUBLIC SAFETY
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Defendant

STATE OF NEW JERSEY

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Date Filed	#	Docket Text
04/21/2022	1	COMPLAINT against PHILIP MURPHY, STATE OF NEW JERSEY (Filing and Admin fee $ 402 receipt number CNJDC-13353418) with JURY DEMAND, filed by Mariette Vitti, Katie Sczesny, Debra Hagen, Jaime Rumfield. (Attachments: # 1 Civil Cover Sheet)(WEFER, DANA) (Entered: 04/21/2022)
04/21/2022		CLERK'S QUALITY CONTROL MESSAGE - The case you electronically filed has been processed, however, the following deficiencies were found: Party Information is to be entered in **CAPITAL LETTERS**. The Clerk's Office has made the appropriate changes. Please refer to the Attorney Case Opening Guide for processing electronically filed cases. (jjc,) (Entered: 04/21/2022)
04/21/2022	2	Emergency MOTION for Temporary Restraining Order by Debra Hagen, Jaime Rumfield, Katie Sczesny, Mariette Vitti. (Attachments: # 1 Declaration Declaration of Counsel with all exhibits, # 2 Text of Proposed Order)(WEFER, DANA) (Entered: 04/21/2022)
04/21/2022		Chief Judge Freda L. Wolfson and Magistrate Judge Rukhsanah L. Singh added. (jdg,) (Entered: 04/21/2022)
04/21/2022	3	SUMMONS ISSUED as to PHILIP MURPHY, STATE OF NEW JERSEY. Attached is the official court Summons, please fill out Defendant and Plaintiffs attorney information and serve. (jdg,) (Entered: 04/21/2022)
04/21/2022	4	CERTIFICATE OF SERVICE by DEBRA HAGEN, JAIME RUMFIELD, KATIE SCZESNY, MARIETTE VITTI re 2 Emergency MOTION for Temporary Restraining Order (WEFER, DANA) (Entered: 04/21/2022)
04/22/2022	5	TEXT ORDER REASSIGNING CASE. Case reassigned to Judge Georgette Castner for all further proceedings. Chief Judge Freda L. Wolfson no longer assigned to case. So Ordered by Chief Judge Freda L. Wolfson on 4/22/2022. (jjc,) (Entered: 04/22/2022)
04/22/2022	6	ORDER setting briefing schedule. Defendant shall file responding papers on or before 4/29/2022. Plaintiff shall file reply papers on or before 5/4/2022. Signed by Judge Georgette Castner on 4/22/2022. (abr,) (Entered: 04/22/2022)
05/04/2022	7	NOTICE of Appearance by DANIEL MICHAEL VANNELLA on behalf of PHILIP MURPHY, STATE OF NEW JERSEY (VANNELLA,

		DANIEL) (Entered: 05/04/2022)
05/04/2022	8	Letter from Defendants requesting amended scheduling order (with consent) re 2 Emergency MOTION for Temporary Restraining Order , 6 Order. (Attachments: # 1 Text of Proposed Order)(VANNELLA, DANIEL) (Entered: 05/04/2022)
05/04/2022	9	TEXT ORDER: The Court is in receipt of Defendant's letter (ECF No. 8) requesting an amended briefing schedule to Plaintiffs' Motion for a Temporary Restraining Order and/or Preliminary Injunction (ECF No. 2), and Plaintiffs having consented to the request. The Court grants the request. Defendant shall file an opposition on or before 5/9/2022, and Plaintiffs shall file a reply on or before 5/12/2022. So Ordered by Judge Georgette Castner on 5/4/2022. (adi,) (Entered: 05/04/2022)
05/09/2022	10	RESPONSE in Opposition filed by PHILIP MURPHY, STATE OF NEW JERSEY re 2 Emergency MOTION for Temporary Restraining Order (Attachments: # 1 Declaration of Counsel, # 2 Exhibit 1-17, # 3 Certificate of Service)(VANNELLA, DANIEL) (Entered: 05/09/2022)
05/09/2022	11	Application and Proposed Order for Clerk's Order to extend time to answer as to Defendants Murphy and State of New Jersey. Attorney DANIEL MICHAEL VANNELLA for PHILIP MURPHY,DANIEL MICHAEL VANNELLA for STATE OF NEW JERSEY added. (VANNELLA, DANIEL) (Entered: 05/09/2022)
05/10/2022		Clerk`s Text Order - The Application for Clerk's Order to Extending Time to Answer 11 submitted by PHILIP MURPHY, STATE OF NEW JERSEY has been GRANTED. The answer due date has been set for 5/26/2022. (jdg) (Entered: 05/10/2022)
05/13/2022	12	Letter from Plaintiffs' Attorney regarding Plaintiffs' reply brief. (WEFER, DANA) (Entered: 05/13/2022)
05/13/2022	13	REPLY BRIEF to Opposition to Motion filed by DEBRA HAGEN, JAIME RUMFIELD, KATIE SCZESNY, MARIETTE VITTI re 2 Emergency MOTION for Temporary Restraining Order (WEFER, DANA) (Entered: 05/13/2022)
05/16/2022	14	TEXT ORDER: The Court is in receipt of Plaintiff's letter (ECF No. 12) and Plaintiff's Reply (ECF No. 13). The Court accepts Plaintiff's Reply out of time. So Ordered by Judge Georgette Castner on 5/16/22. (adi,) (Entered: 05/16/2022)
05/23/2022	15	Letter from Defendants requesting adjournment of time to file responsive pleading re Update Answer Due Deadline, 1 Complaint,.

		(Attachments: # 1 Text of Proposed Order)(VANNELLA, DANIEL) (Entered: 05/23/2022)
05/23/2022	16	Letter re 15 Letter. (WEFER, DANA) (Entered: 05/23/2022)
05/24/2022	17	NOTICE of Appearance by STEPHEN J. SLOCUM on behalf of All Defendants (SLOCUM, STEPHEN) (Entered: 05/24/2022)
05/25/2022	18	TEXT ORDER: The Court is in receipt of Defendants' request to adjourn the deadline to Answer, Move or Otherwise Respond to Plaintiffs' Complaint (ECF No. 15) and Plaintiffs' response (ECF No. 16). The Court grants Defendants' request. Defendants' deadline to answer, move or otherwise respond to Plaintiffs' Complaint is adjourned and the Court will set a new date after it disposes of Plaintiffs' Application for a temporary restraining order and/or preliminary injunction. So Ordered by Judge Georgette Castner on 5/25/22. (adi,) (Entered: 05/25/2022)
06/07/2022	19	OPINION filed. Signed by Judge Georgette Castner on 6/7/2022. (abr,) (Entered: 06/07/2022)
06/07/2022	20	ORDER denying 2 Motion for TRO; Defendants shall respond to the Complaint by no later than 7/5/2022. Signed by Judge Georgette Castner on 6/7/2022. (abr,) (Entered: 06/07/2022)
07/05/2022	21	MOTION to Dismiss *Plaintiffs' Complaint* by PHILIP MURPHY, STATE OF NEW JERSEY. (Attachments: # 1 Brief, # 2 Text of Proposed Order, # 3 Certificate of Service)(VANNELLA, DANIEL) (Entered: 07/05/2022)
07/05/2022		Set Deadlines as to 21 MOTION to Dismiss *Plaintiffs' Complaint*. Motion set for 8/1/2022 before Judge Georgette Castner. Unless otherwise directed by the Court, this motion will be decided on the papers and no appearances are required. Note that this is an automatically generated message from the Clerk`s Office and does not supersede any previous or subsequent orders from the Court. (jdg) (Entered: 07/05/2022)
07/06/2022	22	NOTICE OF INTERLOCUTORY APPEAL as to 20 Order on Motion for TRO by DEBRA HAGEN, JAIME RUMFIELD, KATIE SCZESNY, MARIETTE VITTI. Filing fee $ 505, receipt number BNJDC-13538669. The Clerk's Office hereby certifies the record and the docket sheet available through ECF to be the certified list in lieu of the record and/or the certified copy of the docket entries. Appeal Record due by 7/7/2022. (WEFER, DANA) (Entered: 07/06/2022)
07/07/2022	23	USCA Case Number 22-2230 for 22 Notice of Interlocutory Appeal,

		filed by JAIME RUMFIELD, MARIETTE VITTI, KATIE SCZESNY, DEBRA HAGEN. USCA Case Manager Tim McIntyre (Document Restricted - Court Only) (ca3tmm,) (Entered: 07/07/2022)
07/27/2022	24	Letter from Plaintiffs' Counsel (with consent of Defendants) requesting a stay pending appeal. (WEFER, DANA) (Entered: 07/27/2022)
08/01/2022	25	TEXT ORDER: The Court is in receipt of the parties' consented-to request to stay further proceedings in this case pending final resolution of Plaintiffs' appeal of the denial of their motion for a preliminary injunction (ECF No. 24). The Court grants this request. The parties are required to submit a joint status report to the Court addressing further proceedings within fifteen (15) days of the Third Circuit mandate issuing. This matter shall be stayed and administratively terminated, and the Motion to Dismiss (ECF No. 21) shall be administratively terminated, pending the final resolution of Plaintiffs' appeal of the denial of their motion for a preliminary injunction. So Ordered by Judge Georgette Castner on 8/1/22. (adi,) (Entered: 08/01/2022)
08/01/2022		***Civil Case Terminated. (abr,) (Entered: 08/01/2022)

PACER Service Center			
Transaction Receipt			
09/01/2022 17:28:04			
PACER Login:	danawefer	**Client Code:**	
Description:	Docket Report	**Search Criteria:**	3:22-cv-02314-GC-RLS Start date: 1/1/1980 End date: 9/1/2022
Billable Pages:	4	**Cost:**	0.40

EXECUTIVE ORDER NO. 283

WHEREAS, on March 9, 2020, I issued Executive Order No. 103, declaring the existence of a Public Health Emergency, pursuant to the Emergency Health Powers Act ("EHPA"), N.J.S.A. 26:13-1 et seq., and a State of Emergency, pursuant to the New Jersey Civilian Defense and Disaster Control Act ("Disaster Control Act"), N.J.S.A. App A:9-33 et seq., in the State of New Jersey for Coronavirus disease 2019 ("COVID-19"), the facts and circumstances of which are adopted by reference herein; and

WHEREAS, through Executive Order Nos. 119, 138, 151, 162, 171, 180, 186, 191, 200, 210, 215, 222, 231, 235, and 240, which were issued each month between April 7, 2020 and May 14, 2021, the facts and circumstances of which are adopted by reference herein, I declared that the COVID-19 Public Health Emergency in effect at the time continued to exist; and

WHEREAS, New Jersey made significant progress in responding to COVID-19 and mitigating its devastating effects, in particular in light of the advent of three effective vaccines that, among other things, had significantly reduced the likelihood of both contracting and transmitting the variants of COVID-19 that were present in the United States at the time; and

WHEREAS, on June 4, 2021, in light of these developments, I signed Assembly Bill No. 5820 into law as P.L.2021, c.103, and issued Executive Order No. 244, which terminated the Public Health Emergency declared in Executive Order No. 103 (2020); and

WHEREAS, P.L.2021, c.103 sought to enable the State to bring an end to its prior Public Health Emergency while still allowing for an orderly continuation of the Administration's ability to order certain public health measures relating to COVID-19, including but not limited to vaccine distribution, administration, and management, COVID-19 testing, health resource and personnel allocation, data collection, and implementation of recommendations of the Centers for Disease

Control and Prevention (“CDC”) to prevent or limit the transmission of COVID-19, including in specific settings; and

WHEREAS, P.L.2021, c.103 explicitly maintained the State of Emergency declared in Executive Order No. 103 (2020), and stated it would in no way diminish, limit, or impair the powers of the Governor to respond to any of the threats presented by COVID-19 pursuant to the Disaster Control Act; and

WHEREAS, in addition to leaving the prior State of Emergency in effect, nothing in P.L.2021, c.103 prevented the Governor from declaring any new public health emergency under the EHPA, N.J.S.A. 26:13-1 et seq., should the evolving circumstances on the ground require such a declaration; and

WHEREAS, Executive Order No. 252, issued August 6, 2021, requires all covered health care and high-risk congregate settings to maintain a policy that requires all covered workers to either provide adequate proof to the health care and high-risk congregate settings that they have been fully vaccinated or submit to COVID-19 testing at minimum one to two times weekly beginning September 7, 2021; and

WHEREAS, the Department of Health (“DOH”) issued Executive Directive 21-001 (October 7, 2021), establishing reporting protocol and extending the requirements of Executive Order No. 252 (2021) to group homes and psychiatric community homes licensed by the Department of Children and Families (“DCF”); and

WHEREAS, as the CDC has recognized, viruses can change through mutation and mutations can result in new variants of the virus, and these variants can have meaningfully distinct impacts from the original virus; and

WHEREAS, as the CDC has recognized, some variants spread more easily and quickly than other variants of the same virus, which may lead to more cases of COVID-19, increased strain on healthcare resources, more hospitalizations, and more deaths; and

WHEREAS, new variants are classified based on how easily the variant spreads, how severe its symptoms are, how it responds to treatments, and how well vaccines protect against the variant; and

WHEREAS, since Executive Order No. 244 (2021) took effect, the CDC has reported that new variants of concern of COVID-19 have been identified in the United States, particularly the B.1.617.2 (“Delta”) variant and most recently the B1.1.529 (“Omicron”) variant; and

WHEREAS, although New Jersey was able to end the prior Public Health Emergency on account of the effectiveness of vaccines in reducing transmissibility of COVID-19, the Omicron variant appears to spread more easily than other variants, including Delta; early evidence suggests people who have received a primary series of a COVID-19 vaccine but have not yet received the recommended booster shot are more likely to become infected with this variant than prior variants and to be able to spread the virus to others; and some monoclonal antibody treatments may not be as effective against infection with the Omicron variant; and

WHEREAS, on January 11, 2022, I issued Executive Order No. 280, declaring the existence of a new Public Health Emergency, pursuant to the EHPA, N.J.S.A. 26:13-1 et seq., in the State of New Jersey due to the surge of cases and hospitalizations tied to the new variants of COVID-19; and

WHEREAS, on January 11, 2022, I issued Executive Order No. 281, extending various orders, including Executive Order No. 252 (2021), to ensure the State continues to have the necessary resources in place to respond to the new variants of COVID-19; and

WHEREAS, because vaccines are effective at preventing severe illness, hospitalizations, and death, including from the Omicron variant, the CDC has noted that the recent emergence of this variant emphasizes the importance of vaccination and boosters; and

WHEREAS, according to the CDC, studies show after getting the primary series of a COVID-19 vaccine, protection against the virus and the ability to prevent infection may decrease over time, in particularly due to changes in variants; and

WHEREAS, although the COVID-19 vaccines remain effective in preventing severe disease, recent data suggests their effectiveness at preventing infection or severe illness wanes over time; and

WHEREAS, the CDC has reported that vaccinated people who receive a COVID-19 booster are likely to have a stronger protection against contracting and transmitting COVID-19, particularly the Omicron variant, and stronger protection against serious illness, including hospitalizations and death; and

WHEREAS, the CDC has advised that expedient and additional public health action is necessary to prevent severe impacts on the health of individuals and the health care system due to the rapid spread of the Omicron variant; and

WHEREAS, the CDC has confirmed that the rapid increase of infections is due to the increased transmissibility of the Omicron variant and its increased ability to evade immunity conferred by past infection or vaccination; and

WHEREAS, the State has thus far administered approximately 13.2 million doses of COVID-19 vaccines, with over 7.4 million New Jerseyans having received at least one dose of a vaccine and over 6.5 million having received the primary series of a vaccine; and

WHEREAS, as of December 2021, according to the data provided by licensees to the State, about 88 percent of health care workers, 87 percent of long-term care workers, and 73 percent of workers in high-risk congregate settings licensed by the Department of Human Services and DCF that are subject to Executive Order No. 252 (2021) and DOH Executive Directive 21-001 (October 7, 2021) have received their primary series of the COVID-19 vaccination; and

WHEREAS, as of January 18, 2022, only 48 percent of eligible individuals statewide have received their booster shot; and

WHEREAS, while over 75 percent of people in the State have received the primary series of a COVID-19 vaccine, the booster rates remain significantly lower and additional steps are necessary to ensure continued vaccinations, especially boosters, of individuals to protect against spread of COVID-19; and

WHEREAS, on July 6, 2021, the U.S. Department of Justice, Office of Legal Counsel issued an opinion concluding that Section 564 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 does not prohibit public or private entities from imposing vaccination requirements while vaccinations are only available pursuant to Emergency Use Authorization (“EUA”); and

WHEREAS, on November 5, 2021, the federal Centers for Medicare & Medicaid Services (“CMS”) issued the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (CMS-3415-IFC) (“CMS Rule”), which was upheld by the United States Supreme Court on January 13, 2022, requiring most Medicare and Medicaid-certified providers’ and suppliers’ staff to be vaccinated against COVID-19 in order to participate in the Medicare and Medicaid programs; and

WHEREAS, in order to comply with the CMS rule, providers in New Jersey subject to the rule must require their staff to have received their first dose of the vaccine by January 27, 2022 and all doses to complete a primary series of the vaccine by February 28, 2022; and

WHEREAS, waning immunity among health care workers increases their susceptibility to the virus and can place further strain on the State’s health care workforce, threatening the State’s ability to provide critical care to individuals; and

WHEREAS, it is necessary to rapidly increase the number of health care workers who are up to date with their COVID-19 vaccinations; and

WHEREAS, the CDC has repeatedly emphasized the importance of heightened mitigation protocols in certain congregate and health care settings because of the significant risk of spread and vulnerability of the populations served; and

WHEREAS, requiring workers in those congregate and health care settings to be up to date with their COVID-19 vaccinations can help prevent outbreaks and reduce transmission to vulnerable individuals who may be at a higher risk of severe disease; and

WHEREAS, the Constitution and statutes of the State of New Jersey, particularly the provisions of N.J.S.A. 26:13-1 et seq., N.J.S.A. App. A: 9-33 et seq., N.J.S.A. 38A:3-6.1, and N.J.S.A. 38A:24 and all amendments and supplements thereto, confer upon the Governor of the State of New Jersey certain emergency powers, which I have invoked;

NOW, THEREFORE, I, PHILIP D. MURPHY, Governor of the State of New Jersey, by virtue of the authority vested in me by the Constitution and by the Statutes of this State, do hereby ORDER and DIRECT:

1. Covered health care settings subject to the CMS rule must maintain a policy that requires covered workers to provide adequate proof that they are up to date with their COVID-19 vaccinations according to the following schedule:

   a. Unvaccinated covered workers must obtain their first dose of the primary series of a COVID-19 vaccination by January 27, 2022; and

   b. All covered workers must provide adequate proof that they are up to date with their COVID-19 vaccination by February 28, 2022; provided however, that as to having received a booster dose, covered workers must provide adequate proof that they are up to date with their COVID-19 vaccinations by February 28, 2022, or

within 3 weeks of becoming eligible for a booster dose, whichever is later.

2. Covered health care settings not subject to the CMS rule and covered high-risk congregate settings must maintain a policy that requires covered workers to provide adequate proof that they are up to date with their COVID-19 vaccinations according to the following schedule:

a. Unvaccinated covered workers must obtain their first dose of the primary series of a COVID-19 vaccination by February 16, 2022; and

b. All covered workers must provide adequate proof that they are up to date with their COVID-19 vaccination by March 30, 2022; provided however, that as to having received a booster dose, covered workers must provide adequate proof that they are up to date with their COVID-19 vaccinations by March 30, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

3. The policies adopted by covered health care settings and covered high-risk congregate settings (collectively "covered settings") pursuant to this Order must require covered workers currently submitting to COVID-19 testing pursuant to Executive Order No. 252 (2021) to continue undergoing once or twice weekly testing until they submit adequate proof that they are up to date with their vaccination pursuant to the schedules set forth in paragraphs 1 and 2 of this Order.

4. The policies adopted by covered settings pursuant to this Order must include a disciplinary process for covered workers' noncompliance, which may include termination of employment.

5. Covered workers may demonstrate adequate proof they are up to date with their COVID-19 vaccinations by presenting the following documents if they list COVID-19 vaccines authorized for EUA in the

United States and/or the World Health Organization ("WHO"), along with an administration date for each dose:

a. The CDC COVID-19 Vaccination Card issued to the vaccine recipient by the vaccination site, or an electronic or physical copy of the same;

b. Official record from the New Jersey Immunization Information System (NJIIS) or other State immunization registry;

c. A record from a health care provider's portal/medical record system on official letterhead signed by a licensed physician, nurse practitioner, physician's assistant, registered nurse or pharmacist;

d. A military immunization or health record from the United States Armed Forces; or

e. A Docket mobile phone application record or any state specific application that produces a digital health record.

Covered settings collecting vaccination information from covered workers must comport with all federal and state laws, including but not limited to the Americans with Disabilities Act, that regulate the collection and storage of that information.

6. For purposes of this Order, consistent with the definition provided by Executive Order No. 252 (2021) and DOH Executive Directive 21-001 (October 7, 2021), covered settings shall be defined as follows: "Health care settings" shall include acute, pediatric, inpatient rehabilitation, and psychiatric hospitals, including specialty hospitals, and ambulatory surgical centers; long-term care facilities; intermediate care facilities; residential detox, short-term, and long-term residential substance abuse disorder treatment facilities; clinic-based settings like ambulatory care, urgent care clinics, dialysis centers, Federally Qualified Health Centers, family planning sites, and Opioid Treatment Programs; community-based

healthcare settings including Program of All-inclusive Care for the Elderly, pediatric and adult medical day care programs, and licensed home health agencies and registered health care service firms operating within the State. "High-risk congregate settings" include State and county correctional facilities; all congregate care settings operated by the Juvenile Justice Commission, which includes secure care facilities and residential community homes; licensed community residences for individuals with individuals with intellectual and developmental disabilities ("IDD") and traumatic brain injury ("TBI"); licensed community residences for adults with mental illness; certified day programs for individuals with IDD and TBI, and group homes and psychiatric community homes licensed by DCF.

7. For purposes of this Order, consistent with the definition provided by Executive Order No. 252 (2021), "covered workers" shall include employees, both full- and part-time, contractors, and other individuals working in covered settings, including individuals providing operational or custodial services or administrative support.

8. For purposes of this Order, a covered worker shall be considered "up to date with their COVID-19 vaccinations" if they have received a primary series, which consists of either a 2-dose series of an mRNA COVID-19 vaccine or a single dose COVID-19 vaccine, and any booster doses for which they are eligible as recommended by the CDC. Covered workers will only be considered up to date with their vaccinations where they have received a COVID-19 vaccine that is currently authorized for emergency use by the U.S. Food and Drug Administration (FDA) or the WHO, or that are approved for use by the same. Covered workers who are not up to date with their vaccinations, or for whom vaccination status is unknown or who have not provided sufficient proof of documentation, must be considered noncompliant for purposes of this Order.

9. Nothing in this Order shall prevent a covered setting from instituting a vaccination policy that includes additional or stricter requirements, so long as such policy comports with the minimum requirements of this Order.

10. The policies adopted by covered settings pursuant to this Order must provide appropriate accommodations, to the extent required by federal and/or state law, for employees who request and receive an exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance. The policies adopted by covered settings pursuant to this Order must require covered workers that receive an exemption pursuant to this paragraph to continue weekly or twice weekly testing as required by Executive Order No. 252 (2021).

11. The Commissioner of DOH is hereby authorized to issue a directive supplementing the requirements outlined in this Order, which may include, but not be limited to, any requirements for reporting vaccination data to the DOH. Action taken by the Commissioner of DOH pursuant to this Order shall not be subject to the requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

12. Any provision of Executive Order No. 252 (2021) that is inconsistent with this Order is superseded.

13. The State Director of Emergency Management, who is the Superintendent of State Police, shall have the discretion to make additions, amendments, clarifications, exceptions, and exclusions to the terms of this Order.

14. It shall be the duty of every person or entity in this State or doing business in this State and of the members of the governing body and every official, employee, or agent of every political subdivision in this State and of each member of all other governmental bodies, agencies, and authorities in this State of any nature whatsoever, to cooperate fully in all matters concerning this

Order, and to cooperate fully with any Administrative Orders issued pursuant to this Order.

15. No municipality, county, or any other agency or political subdivision of this State shall enact or enforce any order, rule, regulation, ordinance, or resolution which will or might in any way conflict with any of the provisions of this Order, or which will or might in any way interfere with or impede its achievement.

16. Penalties for violations of this Order may be imposed under, among other statutes, N.J.S.A. App. A:9-49 and -50.

17. This Order shall take effect immediately and shall remain in effect until revoked or modified by the Governor.

GIVEN, under my hand and seal this 19th day of January, Two Thousand and Twenty-two, and of the Independence of the United States, the Two Hundred and Forty-Sixth.

[seal]

/s/ Philip D. Murphy

Governor

Attest:

/s/ Parimal Garg

Chief Counsel to the Governor

EXECUTIVE ORDER NO. 290

WHEREAS, on March 9, 2020, I issued Executive Order No. 103, declaring the existence of a Public Health Emergency, pursuant to the Emergency Health Powers Act ("EHPA"), N.J.S.A. 26:13-1 et seq., and a State of Emergency, pursuant to the New Jersey Civilian Defense and Disaster Control Act ("Disaster Control Act"), N.J.S.A. App. A:9-33 et seq., in the State of New Jersey for Coronavirus disease 2019 ("COVID-19"), the facts and circumstances of which are adopted by reference herein; and

WHEREAS, through Executive Order Nos. 119, 138, 151, 162, 171, 180, 186, 191, 200, 210, 215, 222, 231, 235, and 240, which were issued each month between April 7, 2020 and May 14, 2021, the facts and circumstances of which are adopted by reference herein, I declared that the COVID-19 Public Health Emergency in effect at the time continued to exist; and

WHEREAS, New Jersey made significant progress in responding to COVID-19 and mitigating its devastating effects, in particular in light of the advent of three effective vaccines that, among other things, had significantly reduced the likelihood of both contracting and transmitting the variants of COVID-19 that were present in the United States at the time; and

WHEREAS, on June 4, 2021, in light of these developments, I signed Assembly Bill No. 5820 into law as P.L.2021, c.103, and issued Executive Order No. 244, which terminated the Public Health Emergency declared in Executive Order No. 103 (2020); and

WHEREAS, P.L.2021, c.103 sought to enable the State to bring an end to its prior Public Health Emergency while still allowing for an orderly continuation of the Administration's ability to order certain public health measures relating to COVID-19, including but not limited to vaccine distribution, administration, and management, COVID-19 testing, health resource and personnel

allocation, data collection, and implementation of recommendations of the Centers for Disease Control and Prevention ("CDC") to prevent or limit the transmission of COVID-19, including in specific settings; and

WHEREAS, P.L.2021, c.103 explicitly maintained the State of Emergency declared in Executive Order No. 103 (2020), and stated it would in no way diminish, limit, or impair the powers of the Governor to respond to any of the threats presented by COVID-19 pursuant to the Disaster Control Act; and

WHEREAS, in addition to leaving the prior State of Emergency in effect, nothing in P.L.2021, c.103 prevented the Governor from declaring any new public health emergency under the EHPA, N.J.S.A. 26:13-1 et seq., should the evolving circumstances on the ground require such a declaration; and

WHEREAS, on July 6, 2021, the U.S. Department of Justice, Office of Legal Counsel issued an opinion concluding that Section 564 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 does not prohibit public or private entities from imposing vaccination requirements while vaccinations are only available pursuant to Emergency Use Authorization (EUA); and

WHEREAS, on November 5, 2021, the federal Centers for Medicare & Medicaid Services ("CMS") issued the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (CMS-3415-IFC) ("CMS Rule"), which was upheld by the United States Supreme Court on January 13, 2022, requiring most Medicare and Medicaid-certified providers' and suppliers' staff to be vaccinated against COVID-19 in order to participate in the Medicare and Medicaid programs; and

WHEREAS, on December 29, 2021, CMS issued guidance for the CMS Rule clarifying the timeframes for compliance and the enforcement actions to which facilities will be subject if their

vaccination rates are less than 100 percent by the deadlines set forth therein and are therefore considered non-compliant; and

WHEREAS, on January 11, 2022, due to the surge of cases and hospitalizations tied to the new variants of COVID-19, I signed Executive Order No. 280, declaring the existence of a new Public Health Emergency, pursuant to the EHPA, N.J.S.A. 26:13-1 et seq., and continuing the State of Emergency declared in Executive Order No. 103 (2020) pursuant to the Disaster Control Act, N.J.S.A. App. A:9-33 et seq., in the State of New Jersey; and

WHEREAS, on January 19, 2022, I signed Executive Order No. 283, requiring all covered health care and high-risk congregate settings to maintain a policy that requires all covered workers to provide adequate proof to the health care and high-risk congregate settings that they are up to date with their COVID-19 vaccinations, including any booster shots for which they are eligible; and

WHEREAS, Executive Order No. 283 (2022) requires that covered health care settings subject to the CMS Rule maintain a policy requiring unvaccinated covered workers to obtain their first dose of the primary series of a COVID-19 vaccination by January 27, 2022 and that all covered workers must be up to date with their COVID-19 vaccination by February 28, 2022; including up to date with their booster dose by February 28, 2022 or within 3 weeks of becoming eligible for a booster dose, whichever is later; and

WHEREAS, Executive Order No. 283 (2022) requires that covered health care settings not subject to the CMS Rule and covered high-risk congregate settings maintain a policy requiring unvaccinated covered workers to obtain their first dose of the primary series of a COVID-19 vaccination by February 16, 2022 and that all covered workers must be up to date with their COVID-19 vaccination by March 30, 2022; including up to date with their booster dose by

March 30, 2022 or within 3 weeks of becoming eligible for a booster dose, whichever is later; and

WHEREAS, on February 10, 2022, I signed Executive Order No. 288, which declared that the Public Health Emergency declared in Executive Order No. 280 (2022) continues to exist and that all Executive Orders issued, in whole or in part in response to the COVID-19 Public Health Emergency, including Executive Order No. 283 (2022), remain in full force and effect; and

WHEREAS, because vaccines are effective at preventing severe illness, hospitalizations, and death, including from the Omicron variant, the CDC has noted that the recent emergence of this variant emphasizes the importance of vaccination and boosters; and

WHEREAS, according to the CDC, studies show after getting the primary series of a COVID-19 vaccine, protection against the virus and the ability to prevent infection may decrease over time, in particularly due to changes in variants; and

WHEREAS, although the COVID-19 vaccines remain effective in preventing severe disease, recent data suggests their effectiveness at preventing infection or severe illness wanes over time; and

WHEREAS, the CDC has reported that vaccinated people who receive a COVID-19 booster are likely to have a stronger protection against contracting and transmitting COVID-19, particularly the Omicron variant, and stronger protection against serious illness, including hospitalizations and death; and

WHEREAS, the CDC has advised that expedient and additional public health action is necessary to prevent severe impacts on the health of individuals and the health care system due to the rapid spread of the Omicron variant; and

WHEREAS, the CDC has confirmed that the rapid increase of infections is due to the increased transmissibility of the Omicron variant and its increased ability to evade immunity conferred by past infection or vaccination; and

WHEREAS, on February 22, 2022, the CDC updated their recommendations regarding the optimal interval between the first and second dose of an mRNA COVID-19 vaccination series; and

WHEREAS, the CDC recommends that some people aged 12 through 64 years, especially males aged 12 through 39 years, would benefit from getting their second mRNA vaccine dose eight weeks after receiving their first dose based on individual risk assessment; and

WHEREAS, it is necessary to modify the timeframes for compliance set forth in Executive Order No. 283 (2022) to allow covered workers additional time to determine the appropriate interval between receiving their first and second dose based on the CDC's recommendations; and

WHEREAS, the Constitution and statutes of the State of New Jersey, particularly the provisions of N.J.S.A. 26:13-1 et seq., N.J.S.A. App. A:9-33 et seq., N.J.S.A. 38A:3-6.1, and N.J.S.A. 38A:24 and all amendments and supplements thereto, confer upon the Governor of the State of New Jersey certain emergency powers, which I have invoked;

NOW, THEREFORE, I, PHILIP D. MURPHY, Governor of the State of New Jersey, by virtue of the authority vested in me by the Constitution and by the Statutes of this State, do hereby ORDER and DIRECT:

1. The timeframes set forth in Paragraph 1(b) of Executive Order No. 283 (2022) are hereby modified as follows: Covered health care settings subject to the CMS Rule must maintain a policy pursuant to Executive Order No. 283 (2022) that requires covered

workers to provide adequate proof that they are up to date with their COVID-19 vaccinations according to the following schedule:

a. Unvaccinated covered workers must obtain their primary series of a COVID-19 vaccination pursuant to the timeframes set forth by CMS; and

b. All covered workers must provide adequate proof that they have received a booster dose by April 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

2. The timeframes set forth in Paragraph 2(b) of Executive Order No. 283 (2022) are hereby modified as follows: Covered health care settings not subject to the CMS Rule and covered high-risk congregate settings must maintain a policy pursuant to Executive Order No. 283 (2022) that requires covered workers to provide adequate proof that they are up to date with their COVID-19 vaccinations according to the following schedule:

a. Unvaccinated covered workers must obtain their first dose of the primary series of a COVID-19 vaccination by February 16, 2022; and

b. All covered workers must provide adequate proof that they are up to date with their COVID-19 vaccination by May 11, 2022; provided however, that as to having received a booster dose, covered workers must provide adequate proof that they are up to date with their COVID-19 vaccinations by May 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

3. A covered setting must take the first step toward bringing a noncompliant covered worker into compliance as part of the disciplinary policy required by paragraph 4 of Executive Order No. 283 (2022) within two weeks of the dates set forth in

paragraphs 1(b) and 2(b) of this Order. Failure to take such action may result in penalties and other corrective actions allowed pursuant to federal or state regulation or statute.

4. The Commissioner of the Department of Health ("DOH") is hereby authorized to issue a directive supplementing the requirements outlined in this Order, which may include, but not be limited to, any requirements for reporting vaccination data to the DOH. Action taken by the Commissioner of DOH pursuant to this Order shall not be subject to the requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

5. Paragraphs 1 and 2 of Executive Order No. 283 (2022) are hereby superseded to the extent they are inconsistent with this Order.

6. The State Director of Emergency Management, who is the Superintendent of State Police, shall have the discretion to make additions, amendments, clarifications, exceptions, and exclusions to the terms of this Order.

7. It shall be the duty of every person or entity in this State or doing business in this State and of the members of the governing body and every official, employee, or agent of every political subdivision in this State and of each member of all other governmental bodies, agencies, and authorities in this State of any nature whatsoever, to cooperate fully in all matters concerning this Order, and to cooperate fully with any Administrative Orders issued pursuant to this Order.

8. No municipality, county, or any other agency or political subdivision of this State shall enact or enforce any order, rule, regulation, ordinance, or resolution which will or might in any way conflict with any of the provisions of this Order, or which will or might in any way interfere with or impede its achievement.

9. Penalties for violations of this Order may be imposed under, among other statutes, N.J.S.A. App. A:9-49 and -50.

10. This Order shall take effect immediately and shall remain in effect until revoked or modified by the Governor.

GIVEN, under my hand and seal this 2nd day of March, Two Thousand and Twenty-two, and of the Independence of the United States, the Two Hundred and Forty-Sixth.

[seal]

/s/ Philip D. Murphy

Governor

Attest:

/s/ Parimal Garg

Chief Counsel to the Governor

EXECUTIVE ORDER NO. 294

WHEREAS, on March 9, 2020, I issued Executive Order No. 103, declaring the existence of a Public Health Emergency, pursuant to the Emergency Health Powers Act ("EHPA"), N.J.S.A. 26:13-1 et seq., and a State of Emergency, pursuant to the New Jersey Civilian Defense and Disaster Control Act ("Disaster Control Act"), N.J.S.A. App. A:9-33 et seq., in the State of New Jersey for Coronavirus disease 2019 ("COVID-19"), the facts and circumstances of which are adopted by reference herein; and

WHEREAS, through Executive Order Nos. 119, 138, 151, 162, 171, 180, 186, 191, 200, 210, 215, 222, 231, 235, and 240, which were issued each month between April 7, 2020 and May 14, 2021, the facts and circumstances of which are adopted by reference herein, I declared that the COVID-19 Public Health Emergency in effect at the time continued to exist; and

WHEREAS, New Jersey made significant progress in responding to COVID-19 and mitigating its devastating effects, in particular in light of the advent of three effective vaccines that, among other things, had significantly reduced the likelihood of both contracting and transmitting the variants of COVID-19 that were present in the United States at the time; and

WHEREAS, on June 4, 2021, in light of these developments, I signed Assembly Bill No. 5820 into law as P.L.2021, c.103, and issued Executive Order No. 244, which terminated the Public Health Emergency declared in Executive Order No. 103 (2020); and

WHEREAS, P.L.2021, c.103 sought to enable the State to bring an end to its prior Public Health Emergency while still allowing for an orderly continuation of the Administration's ability to order certain public health measures relating to COVID-19, including but not limited to vaccine distribution, administration, and management, COVID-19 testing, health resource and personnel allocation, data collection, and implementation of recommendations of the Centers for Disease

Control and Prevention (“CDC”) to prevent or limit the transmission of COVID-19, including in specific settings; and

WHEREAS, P.L.2021, c.103 explicitly maintained the State of Emergency declared in Executive Order No. 103 (2020), and stated it would in no way diminish, limit, or impair the powers of the Governor to respond to any of the threats presented by COVID-19 pursuant to the Disaster Control Act; and

WHEREAS, in addition to leaving the prior State of Emergency in effect, nothing in P.L.2021, c.103 prevented the Governor from declaring any new public health emergency under the EHPA, N.J.S.A. 26:13-1 et seq., should the evolving circumstances on the ground require such a declaration; and

WHEREAS, on July 6, 2021, the U.S. Department of Justice, Office of Legal Counsel issued an opinion concluding that Section 564 of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3 does not prohibit public or private entities from imposing vaccination requirements while vaccinations are only available pursuant to Emergency Use Authorization (EUA); and

WHEREAS, on November 5, 2021, the federal Centers for Medicare & Medicaid Services (“CMS”) issued the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (CMS-3415-IFC) (“CMS Rule”), which was upheld by the United States Supreme Court on January 13, 2022, requiring most Medicare and Medicaid-certified providers’ and suppliers’ staff to be vaccinated against COVID-19 in order to participate in the Medicare and Medicaid programs; and

WHEREAS, on December 29, 2021, CMS issued guidance for the CMS Rule clarifying the timeframes for compliance and the enforcement actions to which facilities will be subject if their vaccination rates are less than 100 percent by the deadlines set forth therein and are therefore considered non-compliant; and

WHEREAS, on January 11, 2022, due to the surge of cases and hospitalizations tied to the new variants of COVID-19, I signed Executive Order No. 280, declaring the existence of a new Public Health Emergency, pursuant to the EHPA, N.J.S.A. 26:13-1 et seq., and continuing the State of Emergency declared in Executive Order No. 103 (2020) pursuant to the Disaster Control Act, N.J.S.A. App. A:9-33 et seq., in the State of New Jersey; and

WHEREAS, on January 19, 2022, I signed Executive Order No. 283, requiring all covered health care and high-risk congregate settings to maintain a policy that requires all covered workers to provide adequate proof to the health care and high-risk congregate settings that they are up to date with their COVID-19 vaccinations, including any booster shots for which they are eligible; and

WHEREAS, on February 10, 2022, I signed Executive Order No. 288, which declared that the Public Health Emergency declared in Executive Order No. 280 (2022) continued to exist and that all Executive Orders issued, in whole or in part in response to the COVID-19 Public Health Emergency, including Executive Order No. 283 (2022), remain in full force and effect; and

WHEREAS, on March 2, 2022, I issued Executive Order No. 290, clarifying and extending the timeframes within which covered settings must require their covered workers to comply with the vaccination and booster requirements set forth in Executive Order No. 283 (2020); and

WHEREAS, on March 4, 2022, I issued Executive Order No. 292 terminating the public health emergency declared in Executive Order No. 280 (2022) effective March 7, 2022, while continuing the State of Emergency declared in Executive Order No. 103 (2020); and

WHEREAS, Executive Order No. 292 (2022) stated that Executive Order Nos. 283 and 290 remain in full force and effect pursuant to the Disaster Control Act, N.J.S.A. App. A:9-33 et seq.; and

WHEREAS, because vaccines are effective at preventing severe illness, hospitalizations, and death, including from the Omicron variant, the CDC has noted that the recent emergence of this variant emphasizes the importance of vaccination and boosters; and

WHEREAS, according to the CDC, studies show that after getting the primary series of a COVID-19 vaccine, protection against the virus and the ability to prevent infection may decrease over time, in particular due to transmissibility and severity of different variants circulating at different times; and

WHEREAS, although the COVID-19 vaccines remain effective in preventing severe disease, recent data suggests their effectiveness at preventing infection or severe illness wanes over time; and

WHEREAS, the CDC has reported that vaccinated people who receive a COVID-19 booster are likely to have a stronger protection against contracting and transmitting COVID-19, particularly the Omicron variant, and stronger protection against serious illness, including hospitalizations and death; and

WHEREAS, the CDC has advised that additional public health action is necessary to prevent severe impacts on the health of individuals and the health care system due to the spread of the Omicron variant as well as other new variants; and

WHEREAS, the CDC has confirmed that the Omicron variant and other new variants have increased transmissibility and an increased ability to evade immunity conferred by past infection or vaccination; and

WHEREAS, on March 29, 2022, the Food and Drug Administration (“FDA”) issued an updated emergency use authorization for a second mRNA booster dose; and

WHEREAS, on March 30, 2022, the CDC updated their guidance to allow certain populations to receive a second booster dose to increase their individual protection; and

WHEREAS, the CDC advised that all people 50 years of age and older, people 12 years of age and older who are moderately or severely immunocompromised, and people 18 through 49 years of age who received a Johnson & Johnson/Janssen primary series and a Johnson & Johnson/Janssen first booster are eligible for a second mRNA booster dose at least four months after their first booster dose; and

WHEREAS, as of March 30, 2022, the CDC advised that, while some individuals are eligible to get a second booster dose, the CDC currently considers a person boosted and up to date with their COVID-19 vaccination after receiving their first booster dose at this time; and

WHEREAS, because the CDC has not recommended that a second booster dose is necessary to be up to date with the COVID-19 vaccination at this time, and to ensure the flexibility to act consistently with the most current and appropriate scientific research, it is appropriate to clarify the requirements for compliance set forth in Executive Order No. 283 (2022) and further revised in Executive Order No. 290 (2022) to limit the definition of "up to date" to include only one booster dose and to clarify that a second booster dose is not required; and

WHEREAS, the Constitution and statutes of the State of New Jersey, particularly the provisions of N.J.S.A. 26:13-1 et seq., N.J.S.A. App. A:9-33 et seq., N.J.S.A. 38A:3-6.1, and N.J.S.A. 38A:24 and all amendments and supplements thereto, confer upon the Governor of the State of New Jersey certain emergency powers, which I have invoked;

NOW, THEREFORE, I, PHILIP D. MURPHY, Governor of the State of New Jersey, by virtue of the authority vested in me by the Constitution and by the Statutes of this State, do hereby ORDER and DIRECT:

1. Covered health care settings subject to the CMS Rule must maintain a policy pursuant to Executive Order No. 283 (2022) that requires covered workers to provide adequate proof that they are up

to date with their COVID-19 vaccinations according to the following schedule:

a. Unvaccinated covered workers must obtain their primary series of a COVID-19 vaccination pursuant to the timeframes set forth by CMS; and

b. All covered workers must provide adequate proof that they have received their first booster dose by April 11, 2022, or within 3 weeks of becoming eligible for their first booster dose, whichever is later.

2. Covered health care settings not subject to the CMS Rule and covered high-risk congregate settings must maintain a policy pursuant to Executive Order No. 283 (2022) that requires covered workers to provide adequate proof that they are up to date with their COVID-19 vaccinations according to the following schedule:

c. Unvaccinated covered workers must obtain their first dose of the primary series of a COVID-19 vaccination by February 16, 2022; and

d. All covered workers must provide adequate proof that they are up to date with their COVID-19 vaccination by May 11, 2022; provided however, that as to having received their first booster dose, covered workers must provide adequate proof that they are up to date with their COVID-19 vaccinations by May 11, 2022, or within 3 weeks of becoming eligible for their first booster dose, whichever is later.

3. Paragraph 8 of Executive Order No. 283 (2022) is hereby modified as follows: For purposes of this Order, a covered worker shall be considered “up to date with their COVID-19 vaccinations” if they have received a primary series, which consists of either a 2-dose series of an mRNA COVID-19 vaccine or a single dose COVID-19 vaccine, and the first booster dose for which they are eligible as recommended by the CDC. Covered workers will only be considered up to date with their vaccinations where they have received a COVID-19

vaccine that is currently authorized for emergency use by the FDA or the World Health Organization (WHO), or that is approved for use by the same. Covered workers who are not up to date with their vaccinations, or for whom vaccination status is unknown or who have not provided sufficient proof of documentation, must be considered noncompliant for purposes of this Order.

4. The Commissioner of the Department of Health ("DOH") is hereby authorized to issue a directive supplementing the requirements outlined in this Order, which may include, but not be limited to, any requirements for reporting vaccination data to the DOH. Action taken by the Commissioner of DOH pursuant to this Order shall not be subject to the requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

5. Paragraphs 1, 2, and 8 of Executive Order No. 283 (2022) and Paragraphs 1 and 2 of Executive Order No. 290 (2022) are hereby superseded to the extent they are inconsistent with this Order.

6. The State Director of Emergency Management, who is the Superintendent of State Police, shall have the discretion to make additions, amendments, clarifications, exceptions, and exclusions to the terms of this Order.

7. It shall be the duty of every person or entity in this State or doing business in this State and of the members of the governing body and every official, employee, or agent of every political subdivision in this State and of each member of all other governmental bodies, agencies, and authorities in this State of any nature whatsoever, to cooperate fully in all matters concerning this Order, and to cooperate fully with any Administrative Orders issued pursuant to this Order.

8. No municipality, county, or any other agency or political subdivision of this State shall enact or enforce any order, rule, regulation, ordinance, or resolution which will or might in any way conflict with any of the provisions of this Order, or which will or might in any way interfere with or impede its achievement.

9. Penalties for violations of this Order may be imposed under, among other statutes, N.J.S.A. App. A:9-49 and -50.

10. This Order shall take effect immediately and shall remain in effect until revoked or modified by the Governor.

GIVEN, under my hand and seal this 13th day of April, Two Thousand and Twenty-two, and of the Independence of the United States, the Two Hundred and Forty-Sixth.

[seal]

/s/ Philip D. Murphy

Governor

Attest:

/s/ Parimal Garg

Chief Counsel to the Governor

Law Offices of Dana Wefer, LLC
Dana Wefer, Esq. Bar No: 036062007
375 Sylvan Avenue, Suite 32
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KATIE SCZESNY, JAMIE RUMFIELD, DEBRA HAGEN, and MARIETTE VITTI, Plaintiffs, vs. THE STATE OF NEW JERSEY, GOVERNOR PHILIP MURPHY (in his official and personal capacity) Defendants.	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CIVIL ACTION **VERIFIED COMPLAINT FOR DELCARATORY AND INJUNCTIVE RELIEF**

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Katie Sczesny ("Ms. Sczesny"), Jamie Rumfield ("Ms. Rumfield"), Debra Hagen ("Ms. Hagen"), and Mariette Vitti ("Ms. Vitti") (collectively "Plaintiffs") by and through their counsel, complain against Defendants, The State of New Jersey, Governor Philip Murphy in his official and personal capacity, as follows:

INTRODUCTION

1. This is a civil action for declaratory and injunctive relief arising under the Fourteenth and Fourth Amendments to the United States Constitution.
2. It concerns the constitutionality of Executive Order 283 ("EO 283"), which requires Plaintiffs to receive a

"booster" shot as a condition of working in healthcare in New Jersey.

3. EO 283 violates the liberty and privacy rights protected by the Fourteenth Amendment to the U.S. Constitution, including the right to refuse medical procedures and the right to not be medically surveilled by government actors. It also violates the Equal Protection clause of the 14th Amendment, and the Fourth Amendment prohibition of unreasonable search and seizure, and the procedural due process clause.

JURISDICTION AND VENUE

4. This action arises under the Fourteenth Amendment and Fourth Amendment to the U.S. Constitution.

5. This Court has jurisdiction over all claims pursuant to the Declaratory Judgment Act as codified at 28 *U.S.C.* Sections 2201 and 2202.

6. Venue is proper under 28 *U.S.C.* Section 1391(b) because Defendant is located in this District and because a substantial part of the events giving rise the claim occurred in this District.

PARTIES

7. Plaintiffs are all current employees of Hunterdon Medical Center subject to Executive Order 283.

8. Defendant Philip Murphy ("Governor Murphy") is the governor of the State of New Jersey and is responsible for Executive Order 283.

FACTUAL BACKGROUND

I. THE PLAINTIFFS

9. Plaintiff Debra Hagen has been a nurse for 30 years and employed by Hunterdon Medical Center for 16 years. Exhibit A.

10. Ms. Hagen has a long and complicated medical history that includes seizures and serious adverse reactions to vaccines and medications.

11. At the age of 14 she was diagnosed with a seizure disorder due to hormones related to puberty. She developed reactions to the initial medications used to treat her seizures. At the age of 23 she weaned off the seizure medications because her neurologist believed her hormones were stable enough for her to do so. Declaration of Debra Hagen at ¶5.

12. For the next 15 years Ms. Hagen continued to suffer neurological symptoms, including migraines and vertigo, but no additional seizures, to her knowledge. Id. at ¶6.

13. However, in 2009 when pregnant with her fourth child, she developed shingles four times prior to giving birth and suffered a seizure when her son was 5 months old. An

EEG showed that she had persistent seizure activity in her brain and she was referred to an epileptologist. Id. at ¶7.

14. Unfortunately, Ms. Hagen suffered reactions to available seizure medications and was not able to tolerate many of them. She was instructed to manage her seizure condition to the best of her ability with strict lifestyle guidelines. She states: "I have been very careful with any medications, treatments, beverages, and anything else that I put into my body because I know that triggering another seizure would mean loss of my driver's license and likely my job." She avoids alcohol, certain medications, and strictly monitors and limits caffeine intake. She must be careful to get regular and sufficient sleep, to eat frequent meals, and avoid stressful situations to avoid seizure breakthroughs. Id. at ¶8.

15. Her body is susceptible to neurological and immune issues and she continues to develop Shingles 2-3 times per year when she has times of increased stress. Id. at ¶9.

16. In January 2016, Ms. Hagen fell down a flight of stairs and suffered a concussion. Her recovery was prolonged and she suffered post-concussion symptoms of brain fog, headaches, fatigue, and lack of concentration. Her doctor treated these symptoms with Adderall, which allowed her to

go back to work, but puts her at an increased risk for another seizure, especially as she suffers from tachycardia (increased heart rate) as a side effect of the medication. Id. at ¶11.

17. In 2019, Ms. Hagen underwent titer testing for measles, mumps, rubella, and varicella (chicken pox). Despite having had 3 MMR vaccines in the past, she did not show immunity to measles. Neither did she show immunity to chicken pox, despite the fact that she had chicken pox and suffers from regular shingles because she has had chicken pox. Id. at ¶13.

18. Ms. Hagen received a fourth MMR vaccine and still did not develop immunity to measles. Id.

19. Ms. Hagen received another chicken pox vaccine and developed two back-to-back cases of shingles within 2 weeks of having received the vaccine and another case of shingles six months later. Shingles is a known adverse event following the chicken pox vaccine Id.

20. Ms. Hagen's seizures have always been linked to her hormones and she is currently perimenopausal, which puts her at an even more increased risk of seizures. Id. at ¶14.

21. Ms. Hagen's complex neurological and immunological medical history makes her high-risk for neurological reactions and complications from medications, vaccines,

and even beverages. She was nervous about taking any of the Covid-19 injections authorized for emergency use in the United States because she became aware of reports and data that people were suffering neurological side effects such as headaches, brain fog, fatigue, and Guillen-Barre syndrome. These are symptoms that Ms. Hagen could not risk because she is already being treated to control these symptoms. Id. at 15.

22. Shingles is also a suspected adverse event for some people following the Covid-19 shots.

23. Ms. Hagen tried everything she could to avoid getting any of the Covid-19 injections authorized for use in the United States, hoping that she would be able to get the Novovax vaccine instead because it has a safer side effect profile and does not use fetal cells, which goes against Ms. Hagen's religious beliefs. Id. at ¶¶15-16.

24. Ms. Hagen's requests for a religious accommodation and medical accomodations were both denied. Given Governor Murphy mandate and the CMS (federal) mandate, she felt boxed into a corner, especially because both she and her husband work in the medical field and cannot afford to be out of work with 6 children to support. Id. at ¶¶15-16.

25. Ms. Hagen took a chance on the J&J injection, which she received on January 26, 2022. Id. at ¶17.

26. 48 hours after receiving the J&J injection, she began to experience neurological symptoms. The symptoms began with numbness, tingling, and sciatic pain through her entire left leg, which spread to her left arm within an hour. Her pain continued over the next several days and she developed additional symptoms, including: pain, numbness, and tingling in her right leg; headaches; dizziness; severe fatigue, and an inability to concentrate. Id.

27. She sought medical help and was told by her doctor that she was having a reaction to the J&J shot and was presenting with symptoms of "demyelinating neuritis" that may progress into Guillen-Barre. Id.

28. Ms. Hagen received an EMG on February 4, 2022, which showed that certain sensory nerves could not feel the electric stimulation. She was diagnosed with "sensory neuropathy" and her doctor told her that she should not receive any further covid vaccinations and signed a medical exemption form for her stating the same. Id. at ¶18.

29. Ms. Hagen's request for a medical accommodation was denied twice. Id. at ¶¶ 19-20.

30. Ms. Hagen does not want to take any more of the Covid-19 injections because she does not want to risk exacerbating her health problems further. She feels that she needs to be able to make her own decisions about what

to put into her body, considering her doctor's advice, her personal medical history, and her life circumstances. Id. at ¶24.

31. Plaintiff Jaime Rumfield is a labor and delivery nurse at Hunterdon Medical Center. Exhibit B, Declaration of Jaime Rumfield at ¶4.

32. She received the Moderna Covid-19 injections on March 8, 2021 and April 8, 2021. Id. at ¶5.

33. After receiving the injections she experienced severe headache, body aches, chills, fever, and a red rash surrounding the injection site. Id. at ¶5.

34. She tested positive for Covid-19 on December 31, 2021. She experienced headache, head congestion, runny nose, body aches, sore throat, and extreme exhaustion. Id. at ¶6.

35. Six days after testing positive, while still symptomatic and likely still contagious, she was told she could return to work because her symptoms were resolving. Id. at ¶7.

36. Ms. Rumfield requested a 90 day extension on her deadline to take the booster after testing positive, but was told by HMC that she was eligible to receive the booster 5 days after testing positive for Covid-19. Id. at ¶¶ 8-9.

37. Ms. Rumfield submitted a request for a religious exemption, but it was denied on the basis that accommodating her would pose an undue burden on the

hospital. Id. at ¶10.

38. Ms. Rumfield will not take any more Covid-19 injections because she has natural immunity, does not need her immunity to Covid-19 boosted due to her recent acute infection, and because it would violate her sincerely held religious beliefs. Id. at ¶11.

39. Ms. Rumfield wants to make her own decisions with regard to her body, especially what is injected into her body. She feels that there is risk to the Covid-19 injections. Id. at ¶12.

40. Plaintiff Katie Sczesny is a nurse employed by HMC. She is pregnant. Declaration of Katie Sczesny at ¶ 4, Exhibit C.

41. Ms. Sczesny received two shots of the Pfizer Covid-19 injection in September, 2021. She had severe spinal pain, joint aches, and a fever for 48 hours following the second shot. Id. at ¶7.

42. Three months later, in December 2021, she became infected with Covid-19. Id. at ¶8.

43. Ms. Sczesny was told by HMC that her recent Covid-19 infection and being fully vaccinated was not a legitimate reason to wait to get the booster. Id. at ¶10.

44. Ms. Sczesny was told that her pregnancy was not a legitimate reason to wait to receive her booster. Id. at

¶11.

45. Ms. Sczesny underwent IVF to become pregnant with the baby she is currently carrying. Id. at ¶ 13.

46. Ms. Sczesny does not want to get the booster while pregnant. She does not want to take any risks with her baby and feels should have the right to make that decision for herself and her baby. Id. at ¶14.

47. HMC has denied Ms. Sczesny's request to wait to get her booster, despite a note from her doctor. Id. at ¶15.

48. Ms. Sczesny has been told by multiple people at HMC that Executive Order 283 is the reason she must receive the booster or lose her job. Id. at ¶16.

49. Plaintiff Mariette Vitti, RN, BSN-BC is board certified in Medical Surgical Nursing. She received two doses of the Moderna Covid-19 injection in May and June of 2021. Declaration of Mariette Vitti at ¶5, Exhibit D.

50. After receiving the second shot, she began having pain at the injection site, which progressed as the day went on to tingling in her fingers and then body aches for four days. Id. at ¶6.

51. The body aches were so severe that her clothing hurt to touch her. She had to tell her husband to keep her children away from her because anything touching her caused terrible pain. Id.at ¶6.

52. However, her scariest and most severe side effect was rapid heart palpitations and her heart skipping beats, which appeared about 8 hours after her second shot. Ms. Vitti describes the experience thusly:

> I was putting clothes from the washer into the dryer and walked up the stairs and I felt my heart pounding like it was about to come out of my chest. I told my husband I was scared, and he may have to take me to the ER. I checked my apple watch and the heart rate was 168 after doing very minimal activity. I felt the need to lay down so I layed down on the couch and tried to bare down to decrease my heart rate down to 128 but no lower. From that day forward things that require minimal activity, walking up the stairs at home, leisurely walking to my car after work, can lead to heart rates up into the 130's and 140's and significant palpitations.

53. Ms. Vitti visited a cardiologist and her ECG was found to be normal. She wore a heart monitor for two weeks. The report from her time wearing the monitor shows that she had a heart rate of up to 160 with trigeminy (an irregular heart beat). Id. at ¶¶8-9.

54. Ms. Vitti does not want to take any more of the Covid-19 shots. She feels she was injured by the first one and does not want to further risk her health. She wishes to make her own decisions about what pharmaceuticals to put into her body.

II. Executive Order 283

55. In January 2022, Governor Murphy signed Executive Order 283, which requires all covered workers in covered settings to be "up to date" on Covid-19 "vaccination" as a condition of continued employment. Exhibit E, Executive Order 283.

56. "Covered workers" is defined as: "employees, both full- and part-time, contractors, and other individuals working in covered settings, including individuals providing operational or custodial services or administrative support."

57. "Covered settings" is defined as:

> Health care settings" shall include acute, pediatric, inpatient rehabilitation, and psychiatric hospitals, including specialty hospitals, and ambulatory surgical centers; long-term care facilities; intermediate care facilities; residential detox, shortterm, and long-term residential substance abuse disorder treatment facilities; clinic-based settings like ambulatory care, urgent care clinics, dialysis centers, Federally Qualified Health Centers, family planning sites, and Opioid Treatment Programs; community-based 9 healthcare settings including Program of All-inclusive Care for the Elderly, pediatric and adult medical day care programs, and licensed home health agencies and registered health care service firms operating within the State. "High-risk congregate settings" include State and county correctional facilities; all congregate care settings operated by the Juvenile Justice Commission, which includes secure care facilities and residential

> community homes; licensed community residences for individuals with individuals with intellectual and developmental disabilities ("IDD") and traumatic brain injury ("TBI"); licensed community residences for adults with mental illness; certified day programs for individuals with IDD and TBI, and group homes and psychiatric community homes licensed by DCF.

58. "Up to date" is defined as having received "a primary series, which consists of either a 2-dose series of an mRNA COVID-19 vaccine or a single dose COVID-19 vaccine, and any booster doses for which they are eligible as recommended by the CDC."

59. On or around March 2, 2022, Governor Murphy signed Executive Order 290, which modified the time requirements set forth in Executive Order 283. Exhibit F, Executive 290.

60. This was necessary because the CDC changed its recommendations for time between first and second mRNA shots from six weeks to eight weeks.

61. Upon information, belief, and local reporting, the extended deadline was also necessary to prevent staffing shortages because a significant percentage of healthcare workers had chosen not to get a third Covid-19 shot.

62. On April 13, 2022, Governor Murphy signed executive order 294 changing the definition of "up to date" in

Executive Order 283. This was necessary because on March 29th the FDA issued an updated emergency use authorization for a second "booster" dose and on March 30, 2022 the CDC advised that all people 50 years or older and all people 18-29 who received two Janssen shots are eligible for a second "booster." Exhibit G.

63. Executive Order 294 states "Whereas, as of March 30, 2022, the CDC advised that, while some individuals are eligible for a second mRNA booster dose, the CDC currently considered a person boosted and up to date with their Covid-19 vaccination after receiving their first booster dose at this time."

64. Executive Order 283 requires any covered workers who are not "up to date" on their Covid-19 shots to test weekly or twice weekly until they "submit adequate proof that they are up to date with their vaccination."

65. EO 283 requires all covered settings to include a disciplinary process for "noncompliance," which New Jersey says may include termination of employment.

66. Executive Order 283 requires covered settings to allow for medical and religious exemptions to vaccination, however the State of New Jersey itself has mass-denied religious exemptions in state institutions, stating that accommodating people with religious exemptions would

constitute an "undue burden" on the state because the employees with religious objections to the Covid-19 injections are a "threat" to the safety of others.

67. The Superintendent of Police is given full "discretion to make additions, amendments, clarifications, exceptions, and exclusions to the terms" of Executive Orders 283, 290 and 294.

CONSTITUTIONAL CLAIMS

I.

EXECUTIVE ORDER 283 VIOLATES PLAINTIFFS' 14TH AMENDMENT RIGHTS TO LIBERTY AND PRIVACY

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

69. People have a strong liberty and privacy interest and right in exercising sovereignty over their body and declining unwanted medical procedures like the Covid-19 injections.

70. Plaintiffs have strong liberty and privacy rights to decline medical procedures that have injured them or made them ill when they have taken them before.

71. The state's interest in stemming the spread of Covid-19 through requiring people to undergo an unwanted medical procedure must be weighed against the individual right to decline medical procedures that are novel, have hurt them

in the past, and that carry known and unknown risks.

72. The individual's right to decline further injections with the Covid-19 pharmaceuticals outweighs the state's interest when:

a. It is common knowledge that the injections do not prevent infection and transmission and that people who have received the injections can still become infected with and transmit Covid-19;

b. There are known and unknown risks of taking the pharmaceuticals;

c. The person being mandated to take the pharmaceuticals has taken them in the recent past and been hurt by them;

d. There are no long-term studies on the pharmaceuticals and long-term effects are unknown;

e. The person being mandated to take the pharmaceuticals has taken in the past and the pharmaceuticals did not work to prevent them from getting sick;

f. The targeted disease has a low mortality rate overall and a very low mortality rate for the individual;

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

h. the individual who the government wishes to compel to take the pharmaceutical has been advised by their

doctor not to take the pharmaceutical;

i. The medical procedure the government wishes to compel is novel and experimental with unknown long-term effects;

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

k. The FDA advisory committee voted 16-2 to NOT recommend the medical procedure citing safety concerns;

l. The CDC advisory panel on immunizations voted against recommending the procedure for adults under 50;

m. The federal agency tasked with oversight of public safety (FDA) is plagued by scandals and high profile failures and acted contrary to its own advisory committee's recommendations;

n. The medical procedure involves a new technology that has never before been approved for or used in healthy humans, never mind three doses in less than a year period;

o. It does not account for immunity gained through infection and recovery.

73. The Mandate is unconstitutional.

II.
THE MANDATE VIOLATES THE EQUAL PROTECTION CLAUSE OF THE 14TH AMENDMENT

74. Plaintiffs repeat and reallege each of the preceding paragraphs as if set forth at length herein.

75. Plaintiffs are subject to a disciplinary process based on their assertion of their fundamental rights to liberty and privacy.

76. Plaintiffs are subject to search and seizure of their bodily fluids based on their assertion of fundamental rights to liberty and privacy.

77. The unequal treatment is not narrowly tailored to serve a compelling government interest.

78. The unequal treatment is based on the exercise of a fundamental right and violates the constitution.

III.

EXECUTIVE ORDER 283 VIOLATES PLAINTIFFS' RIGHT TO DUE PROCESS UNDER THE 14TH AMENDMENT TO THE U.S. CONSTITUTION

79. Plaintiffs all attended college to obtain their nursing degrees.

80. Plaintiffs all passed board examinations to obtain their nursing licenses.

81. Plaintiffs Debra Hagen and Mariette Vitti have obtained higher degrees, certifications, and licenses to practice their profession.

82. Plaintiffs all have property interests in their degrees,

certifications, and licenses.

83. Executive Order 283 essentially regulates Plaintiffs out of practicing in the healthcare field in New Jersey unless they surrender their bodies for injection with another Covid-19 shot.

84. Plaintiffs have all been *de facto* barred from using their licenses and degrees in New Jersey without due process of law.

85. Executive Order 283 deprives Plaintiffs of liberty and property rights without due process of law.

86. Executive Order 283 violates the due process clause of the 14th Amendment to the United States Constitution.

IV.

EXECUTIVE ORDER 283 IS AN UNCONSTITUTIONAL TAKING WITHOUT COMPENSATION UNDER THE FIFTH AMENDMENT, APPLIED TO NEW JERSEY THROUGH THE 14TH AMENDMENT

87. Plaintiffs all have property interests in their degrees, certifications, and licenses.

88. Executive Order 283 essentially regulates Plaintiffs out of practicing in the healthcare field in New Jersey unless they surrender their bodies for injection with another Covid-19 shot.

89. Plaintiffs have all been *de facto* barred from using their licenses and degrees in New Jersey without due process of law.

90. Executive Order 283 takes away Plaintiffs' ability to practice in their chosen professions and purports to do so for the public good.

91. Executive Order 283 violates the takings clause of the 5th Amendment because it regulates Plaintiffs out of the healthcare field, purportedly for the public good, and without compensation for the loss of property rights inherent in their degrees and licenses.

V.

THE MANDATORY MEDICAL TESTING VIOLATES PLAINTIFFS' RIGHT TO BE FREE FROM UNREASONABLE SEARCH AND SEIZURE

92. The medical testing that is required of Plaintiffs if they remain employed and do not receive a booster is an unreasonable search and seizure.

93. It requires Plaintiffs to surrender their bodily fluids for analysis without any particularized suspicion, without a warrant, and without due process.

94. The medical testing requires Plaintiffs to surrender and report personal information about their health status without any particularized suspicion, without a warrant, and without due process.

95. The medical testing violates the 4th Amendment.

VI.

VIOLATION OF 42 U.S.C. §1983

96. Plaintiffs repeat and reallege each of the preceding paragraphs as if set forth fully herein.

97. Governor Philip Murphy has, while acting under the color and authority of law, deprived Plaintiffs of their constitutional rights.

PRAYER FOR RELIEF

Wherefore, Plaintiffs request the following relief:

98. Declare Executive Orders 283, 290 and 294 unconstitutional;

99. Declare Executive Order 283, 290, and 294 unconstitutional as applied to each Plaintiff;

100. Enjoin HMC and the State of New Jersey from enforcing the Mandate;

101. Grant Plaintiffs their costs and attorneys' fees under 42 U.S.C. Section 1988 and any other applicable authority; and

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

Respectfully submitted,

Dated: April 18, 2022

s/ Dana Wefer, Esq.

Dana Wefer, Esq.
Attorney at Law

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Englewood Cliffs, NJ 07075
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Attorney for Plaintiffs

COMPLAINT VERIFICATION

Each of the Plaintiffs has sworn in the attached and incorporated Declarations that all facts pertaining or relating to them are true under penalty of perjury.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

The matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: April 20, 2022

/s Dana Wefer, Esq.
Dana Wefer, Esq.
Attorney at Law
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Email: DWefer@WeferLawOffices.com
Attorney for Plaintiffs

EXHIBIT A

DECLARATION OF DEBRA HAGEN

I, Debra Hagen, being of full age and sound mind do hereby swear and affirm:

1. I have personal knowledge of myself, my activities, and my intentions.
2. If called on to testify I would competently testify as to the matters stated herein and concerning me and my activities in the Verified Complaint.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements contained herein are true and correct.
4. I have been a Nurse since 1992 and started working at Hunterdon Medical Center ("HMC") in October of 2006 as an Emergency Department RN. I worked in the emergency department for 10 years.
5. I have a long history of Neurologic problems. I was diagnosed with a seizure disorder at age 14, during puberty, which they had difficulty controlling with medications and I suffered severe side effects from some of the medications they tried. At age 23, I was weaned off the medications, as the neurologist believed my hormones were stable enough for my seizures to subside.

6. Through the next 15 years I had issues with migraines related to my hormones and occasional vertigo, but no additional seizures that I was aware of.
7. At age 38 in 2009, while pregnant with my fourth child, I developed shingles 4 times prior to giving birth, and then had a seizure when he was 5 months old. I was working at HMC at the time and was seen by Dr. Viradia, a neurologist. He sent me for an EEG which was abnormal and then a 72-hour EEG, which showed persistent seizure activity in my brain that was not manifesting physically. He referred me to an epileptologist in Princeton who tried a couple other seizure medications, which I had reactions to and was not able to tolerate.
8. I was given strict guidelines to avoid certain over the counter medications, alcoholic beverages, more than 1 cup of caffeine per day and stressful situations. I need regular sleep and frequent meals to avoid these seizure breakthroughs. Since then, I have been very careful with any medications, treatments, beverages, and anything else that I put into my body because I know that triggering another seizure would mean loss of my driver's license and likely my job.
9. I continued to develop Shingles every time that I had increased stress approximately 2-3 episodes per year for

the next 10 years, which I always get in the same area of my lower back and causes sciatic pain down my right leg.

10. In 2014, I started a "Behavioral Health hold committee" that resulted in The Joint Commission awarding HMC with Excellence of Behavioral Health in the Emergency Department. During this time, I also had gotten divorced and was the sole income for 5 children.

11. My time as an ED nurse at HMC ended when I fell down the stairs at home in January of 2016 and suffered a concussion. I was out of work for 8 months with that injury. I returned to Dr. Viradia who treated my concussion. My prolonged recovery, caused him to suspect underlying ADHD and he treated my post-concussion symptoms of headaches, brain fog, fatigue and lack of concentration with Adderall. This treatment worked and I was able to work again, however it is also a stimulant, and it makes me nervous that I may have another seizure. I am currently taking the maximum dose and have side effects of tachycardia and severe dry mouth, so I have been trying to wean down to a lower dose.

12. After returning to the workforce in September, I was employed at Compassionate care hospice until I returned to HMC in March 2020 to work at Hunterdon Hospice where I am presently still employed.

13. I had returned to school 3 years ago and as part of the physical exam required for clinical, I had blood work to check my immunity status of Measles, Mumps, Rubella, and varicella (chicken pox). To my surprise, my lab results said that I was not immune to Measles or varicella, which I had shown immunity on prior bloodwork. I already had 3 MMRs in my history, and I obviously had chicken pox as that is what causes shingles. I received another MMR, my fourth, which after another round of bloodwork still did not show immunity.

14. When I received the varicella vaccine (which did show immunity post-vaccination) within 2 weeks of the vaccine, I suffered from 2 back-to-back cases of shingles (which is listed on the WHO information sheet as a "Severe Adverse Event"). I thought maybe my immunity status was why I had suffered with them so frequently and now that I am immune on blood tests, I would no longer suffer from these shingles' episodes, however 6 months later I broke out again.

15. I just graduated in December with my MSN as a Family Nurse Practitioner. I am also currently perimenopausal and with fluctuating hormone levels at increased seizure risk.

16. Taking all that history into consideration, neurologically I am high risk. I was very nervous when the

vaccine came out and I saw reports and data of people were having side effects of headaches, brain fog, fatigue and Guillen Barre syndrome, symptoms that I could not afford since I am already being treated to control most of those symptoms. I tried everything to try to avoid getting the vaccine. My religious exemption was denied, they would not even consider my medical exemption because I did not have an anaphylactic reaction to a covid vaccine. I knew that if I were to have a reaction it would most likely neurologically related, and my gut was telling me that not enough research has been done on the long-term effects of the mRNA vaccines and these were the vaccines with the brain fog and fatigue side effects.

17. I also noticed that every time the vaccines were pushed on elderly, we would have a large increase in admissions onto hospice. Most of these patients had cancer that was in remission, but after receiving the vaccine (or booster) the cancer would spread. I had read that the MRNA vaccines cause the killer T cells to decrease for at least 4 weeks. Killer T cells are the part of the immune system that keep cancer cells in check and defend the body from these invaders. Some of the patients signed on with a sudden decline in status after the MRNA vaccine and died prior to their second shot.

18. With the Governors mandate as well as the CMS mandate I felt boxed into a corner. My husband and I are both in the medical field and cannot afford to be out of work with 6 children between us. We had been waiting for the Novavax vaccine to be approved as it is being used in other countries and has a much safer side effect profile and does not use fetal cells. After much research, I decided to take a chance with the J&J vaccine, to try to save my job, as it seemed the better choice neurologically and it was only 1 shot (hoping for Novavax prior to the booster).

19. I received the J&J vaccine on January 26th at the HMC clinic in Lebanon and I was very happy that I initially felt fine for the first two days after the vaccine. Exactly 48 hours after the vaccine on Friday January 28th, without doing anything strenuous, I suddenly felt like I pulled a muscle in my left leg, then within 20 minutes I had numbness, tingling and sciatic pain through my entire left leg. Approximately 1 hour later I had numbness in my left arm as well. I contacted Dr. Viradia Friday night, and he said he would see me Monday at the office. On Saturday, Sunday, and Monday I had pain, numbness and tingling in both of my legs, headaches, dizziness, inability to concentrate, and severe fatigue. Dr. Viradia said that I was having a reaction to the vaccine and was presenting

with symptoms of a "demyelinating neuritis" that may progress into Guillen Barre and instructed me to go directly to the emergency room if I have any shortness of breath.

20. I tried to get as much rest as possible, took vitamins and supplements to help my body respond to this attack on its system. I returned to his office on February 4th for an EMG seemed to be showing improvement. The EMG showing my muscle response to stimulation was normal, however certain sensory nerves could not feel the electric stimulation. He diagnosed me with "Sensory neuropathy" and stated again that I should not receive any further covid vaccinations and signed a medical exemption form sent to me from Occupational health which is a very basic form asking for my information, provides information of what is considered a contraindication or precaution, then has a very small space for the physician to write what contraindication or precaution the patient has, the date that this extends until, and the Physicians information and signature.

21. I submitted the form and my portion to occupational health on February 5th and they denied my medical exemption on February 6th stating that my exact reaction was not described and that a reaction to the J&J vaccine does not excuse me from receiving one of the MRNA boosters.

22. In the meantime, I was still struggling with pain and numbness, headaches, dizziness, and brain fog that varies depending on if I get at least 8-12 hours of sleep. That is very difficult to do with children who need to get up at 6am for school and working evenings from 430pm – 1 am. A workers compensation case was opened as I have been unable to work my 8 hours during the day.

23. I re-submitted a second form and a letter from Dr. Viradia stating that I am still under his care for the reaction to the covid vaccines on March 25th. The second request was also quickly denied citing the same reasons.

24. On March 31, 2022, I sent a letter to Patrick Gavin, CEO, David Christiansen, MD (head of Occupational health), Barbara Tofani, MSN administrator of home health, Yeung Bae, Director of Hospice, and David Skillinge, DO, who had promised me a position as an NP in January if I stayed with Hunterdon Healthcare Systems (HHS). This email requested a temporary medical exemption citing some articles explaining the reaction I am having and that it has been found to be an auto-immune response to the spike protein in the vaccines, which causes "Long Covid" symptoms in certain people, mostly women under the age of 55. I have received a response from Yeung Bae discussing possible future

employment as an NP if by some miracle this medical exemption is granted, or the mandate is discontinued.

25. On April 12, 2022, I received a response from both Dr. Christiansen and Antoinette Rice (on behalf of Patrick Gavin) stating that they reviewed my case, that Dr. Christiansen contacted the CDC and that they cannot grant my exemption. I am still waiting to hear about continued workers compensation.

26. The original plan with Dr. Viradia at my routine visit was to try to decrease my dose of Adderall once I complete my boards. I originally was scheduled to take my boards on February 18th. Due to the reaction of fatigue and brain fog (confusion), I needed to delay taking my exam for 2 months. I passed my boards on April 7, 2022, however it was followed by two days of severe fatigue, confusion, and dizziness.

27. Since these symptoms are persisting, I will not be able to decrease the medication as planned. How long these symptoms will last is unknown now. I am still receiving worker's compensation benefits 8 hours per week and do not foresee how I would be able to function in an 830am-5pm position Monday through Friday

28. I do not want to take any more of the covid-19 vaccines. I feel that I need to be able to make my own

decisions about what to put in my body, considering my doctor's advice, my personal medical history, and my life circumstances.

Dated: 04/15/2022

Debra Hagen, MSN, FNP, RN

EXHIBIT B

DECLARATION OF JAMIE RUMFIELD

I, Jamie Rumfield, being of full age and sound mind do hereby swear and affirm:

1. I have personal knowledge of myself, my activities, and my intentions.
2. If called on to testify I would competently testify as to the matters stated herein and in the Verified Complaint.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements contained herein are true and correct.
4. I am an RN, and have been a labor and delivery nurse at Hunterdon Medical Center (HMC) since May 2019.
5. I received the Moderna COVID-19 Vaccine on 3/8/21 and 4/8/21. I had severe headache, body aches, chills, fever, and a red rash surrounding the injection site.
6. I tested positive for COVID-19 on 12/31/21. I had a headache, head congestion, runny nose, body aches, sore throat, and extreme exhaustion.
7. I was allowed to return to work on 1/6/22 as my symptoms were resolving. This was 6 days after testing positive, likely still contagious and potentially exposing my patients.

8. Occupational health (the department that is dedicated to the well-being and safety of employees in the work place) told me I was eligible for the booster 5 days from the date of my positive test.

9. Both Dr. David Christiansen, Director of Occupational & Corporate Health Services at HMC, and my primary doctor, Dr. Dierdre Andrews, denied my request for a 90-day extension from the date of my positive test. They both stated that the booster can be administered as soon as I recovered from COVID-19 and completed the required isolation period.

10. I submitted a request for religious exemption and was denied on 2/16/22 by the committee who reviews all religious exemptions at HMC- stating that an accommodation for my religious beliefs cannot be granted without creating an undue hardship on the organization.

11. I am being suspended/terminated 4/12/22 because I refuse to be administered the booster after having natural immunity following my recent acute infection, and due to my sincerely held religious beliefs.

12. I do not want to take the booster because it is not necessary to boost my immune system after infection, and because I was born with the God-given right to bodily autonomy without controlling influences. I want to make my

own decisions with regard to my body, especially what is injected into my body. When there is risk, there must be consent.

13. I feel that my liberty is being impinged upon by the government conditioning my employment upon undergoing further medical procedures/treatment I do not want.

Dated: 4/11/22

Jamie J Rumfield, RN

Jamie Rumfield, RN

EXHIBIT C

DECLARATION OF KATIE SCZESNY

I, Katie Sczesny, being of full age and sound mind do hereby swear and affirm:

1. I have personal knowledge of myself, my activities, and my intentions.
2. If called on to testify I would competently testify as to the matters stated herein and concerning me and my activities in the Verified Complaint.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements contained herein are true and correct.
4. I am a 34 year old pregnant nurse employed by Hunterdon Medical Center in Flemington, NJ.
5. I have been a nurse for 6 1/2 years.
6. I have been with HMC for 3 1/2 years, and with an affiliated facility for 4 1/2 years.
7. I received both Pfizer vaccines in Sept. 2021, before we planned on getting pregnant again. I had severe spinal pain, joint aches, and a fever for 48 hours following my second vaccine.
8. I was diagnosed with Covid after showing symptoms on Dec. 29, 2021.

9. I was informed that I have until April 11, 2022 to get the booster, as per the NJ state mandate set in place by Governor Murphy.

10. I was told having Covid recently on top of being fully vaccinated were not legitimate reasons to wait to receive my booster.

11. I was told being pregnant is not a legitimate reason to wait to receive my booster.

12. I was diagnosed with infertility for no known medical reasons in 2019, after trying to get pregnant for 2 years. We had to go through IVF to get pregnant with our daughter in 2019.

13. After trying to get pregnant with baby #2 for 9 months, we had to undergo IVF again to get pregnant.

14. I do NOT want to get the booster while pregnant. We paid out of pocket for IVF and don't want to risk ANYTHING. I should have a right to make that decision for my unborn baby and myself.

15. I have been denied a request to extend the date of my booster until after I deliver, even with a note from my primary doctor requesting the extension.

16. I have emailed my request for extension to the medical director of our occupational health. After he denied me and I questioned his decision, he told me to email the Chief

Medical Director of the hospital. The chief medical director then forwarded my email to the chief of nursing of the hospital. The chief of nursing then informed me she will forward my email to the committee who makes those decisions, which seems to be the person my request first started with. I am being given the runaround and Governor Murphy's executive order is cited as the reason I must receive the booster or lose my job.

17. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: 4-10-2022

Katie Sczesny, RN

EXHIBIT D

DECLARATION OF MARIETTE VITTI

I, Mariette Vitti, being of full age and sound mind do hereby swear and affirm:

1. I have personal knowledge of myself, my activities, and my intentions.
2. If called on to testify I would competently testify as to the matters stated herein and concerning me and my activities in the Verified Complaint.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements contained herein are true and correct.
4. My name is Mariette Vitti RN, BSN-BC (RN with my bachelors and board certified in Medical Surgical nursing).
5. I received the first two doses of Moderna COVID-19 vaccine in May and June of 2021.
6. After receiving the second Moderna vaccine dose I began having pain at the injection site which progressed as the day went to tingling in my fingers and then just body aches for 4 days following. The body aches were so bad my clothes hurt to touch me. I told my husband to keep my children away from me because anything touching me caused terrible pains. But the most serious and scary side effect that began just eight hours after the vaccine administration was the rapid heart rate with palpitations and skipping beats.
7. I got the vaccine around 0945 and around 1930 I was putting clothes from the washer into the dryer and walked up the stairs and I felt my heart pounding like it was about to come out of my chest. I told my husband I was scared, and he may have to take me to the ER. I checked my apple watch, and my heart rate was 168 after doing very minimal activity. I felt the need to lay down so I layed down on the couch and tried to bare down to decrease my heart rate and with doing this I was able to get my heart rate down to 128 but no lower. From that day forward things that require minimal activity, walking up the stairs at home, leisurely walking to my car after work, can lead to heart rates up into the 130's and 140's and significant palpitations.
8. I saw a cardiologist where my ECG was found to be normal and I wore a monitor for two weeks which per the cardiologist RN "you have a lot of PVCs with sinus tachycardia, so you're a nurse you know what to do just stop drinking coffee and drink more water."
9. When I obtained my records, it was noted on the report that I had a heart rate of up to 160 at its highest with trigeminy (an irregular heart beat).
10. I do not want to take any more of the covid-19 vaccines. I feel that I need to be able to make my own decisions about what to put in my body, taking into account my doctor's advice, my personal medical history, and my life circumstances. I am afraid that taking more of the Covid-19 shots will hurt me.

Dated: 4/10/2022

Mariette Vitti RN

Mariette Vitti RN, BSN-BC

Vaccine

Vaccine

Vac"cine (?), *a.* [L. *vaccinus*, fr. *vacca* a cow; cf. Skr. *vāc* to bellow, to groan.] Of or pertaining to cows; pertaining to, derived from, or caused by, vaccinia; as, *vaccine* virus; the *vaccine* disease. -- *n.* The virus of vaccinia used in vaccination.

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1954

BOOKS, INC.

NEW YORK

V

V, v (vē) *n.* [V's; v's] The twenty-second letter of the English alphabet, a labiodental voiced open consonant; anything having the sound or shape of *v;* the Roman numeral five; used as a symbol to denote anything standing twenty-second in rank or class.

vacancy (vā'kan si) *n.* [vacancies] The state of being empty or unoccupied; empty-mindedness; an office or position to be filled.

vacant (vā'kant) *adj.* Empty, unoccupied; lacking intelligence, as a *vacant* look. *Syn.* Unfilled, void, thoughtless, idle, unthinking, unencumbered, untenanted, blank, expressionless. *Ant.* Occupied, full, busy, crowded, tenanted, employed, filled, intelligent. **-ly** *adv.*

vacate (vā'kāt) *vi.&vt.* To give up and leave, as a house, office, or position of employment; to make empty, as, to *vacate* a house; to set aside, nullify, and make void, as, to *vacate* a court order.

vacation (vā kā'shun) *n.* The act of leaving without occupants, as, the *vacation* of premises; a period of absence from work, for recreation. **-ist** *n.* One who takes a vacation.

vaccinate (vak'si nāt) *vi.&vt.* To inoculate with germs developing resistance and giving immunity from a disease, as smallpox. **vac'cination** *n.* The practice of vaccinating. **vaccina'tionist** *n.* An advocate of the practice of vaccination. **vac'cinator** *n.* A person who vaccinates; a device used in vaccination.

vaccine (vak' sēn) *n.* The substance taken from a cow with cowpox and the fluid used in inoculating the body against smallpox.

vaccine (vak'sēn) *adj.* Appearing in or characteristic of the disease of cowpox; pertaining to vaccination.

vacillate (vas'i lāt) *vi.* To waver, be unsteady, move one way and then the other; to hesitate in making up one's mind. *Syn.* Fluctuate, oscillate, waver. *Ant.* Determine, resolve. **vac'illating, vac'illatory** *adj.* Wavering. **vac'illatingly** *adv.* — **vacilla'tion** *n.* The condition of vacillating; changeableness.

vacuity (va kū'i ti) *n.* [*pl.* vacuities] Emptiness; complete inactivity of the mind.

vacuole (vak'ū ōl) *n.* A small cavity or vesicle in organic tissue of protoplasm.

vacuous (vak'ū us) *adj.* Empty; blank, as a *vacuous* expression; stupid. *Syn.* Dull, blank, stupid, inane, idle. *Ant.* Alert, intelligent, keen, [illegible] **-ness** *n.*

vacuum (vak'u um) *n.* [illegible] A space devoid of [illegible] void.

vacuum (vak'ū um) *vt.* To use a vacuum device, esp. a cleaner.

vacuum bottle (vak'ū um bot'l). A container in which liquids are kept at the temperature they had when poured in.

vacuum pump (vak'ū um pump). A machine through a pipe by [illegible] machine to remove air [illegible] space.

vagabond (vag'a bond) *n.* [illegible] who rambles about [illegible] tramp. **-age** *n.* The [illegible] vagabond; vagrancy.

vagabond (vag'a bond) *adj.* [illegible] and wandering.

vagary (va gâr'i) *n.* [pl. [illegible] a fanciful turn of the [illegible]

vagina (va jī'na) *n.* [illegible] vaginas (va jī'naz) [illegible] canal leading from the [illegible] in female mammals; a [illegible] **vag'inal** (vaj'i nal) [illegible] vagina.

vagrancy (vā'gran si) *n.* [illegible] state of wandering [illegible] home.

vagrant (vā'grant) *n.* A [illegible] idly wanders from [illegible] Beggar, tramp, rogue, [illegible]

vagrant (vā'grant) *adj.* [illegible] place to place; rambling, [illegible] sometimes, esp. in [illegible] *adv.* — **-ness** *n.*

vague (vāg) *adj.* Indefinite, [illegible] *Syn.* Indistinct, unsettled, [illegible] termined, ill-defined, [illegible] ous, pointless, obscure, [illegible] owy, loose. *Ant.* Definite, [illegible] concrete, distinct, palpable. **-'ness** *n.*

vagus (vā'gus) *n.* [vagi (vā'ji) [illegible] **nerve.** The pneumogastric [illegible]

vain (vān) *adj.* Without value, [illegible] force, fruitless; conceited. *Syn.* useless, worthless, inflated, [illegible] silly, unreal, futile, unavailing, [illegible] vapid. *Ant.* Effectual, valuable,

vaccine

3 entries found for **vaccine**.
To select an entry, click on it.

vaccine
BCG vaccine
Salk vaccine
Go

Main Entry: **vac·cine**
Pronunciation: `vak-'sEn, 'vak-"`
Function: *noun*
Etymology: French *vaccin,* from *vaccine* cowpox, from New Latin *vaccina* (in *variolae vaccinae* cowpox), from Latin, feminine of *vaccinus,* adjective, of or from cows, from *vacca* cow; akin to Sanskrit *vasa* cow
1 : matter or a preparation containing the virus of cowpox in a form used for vaccination
2 : a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease
- **vaccine** *adjective*

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Pronunciation Symbols

vaccine Video pronunciation English: vacci ▸

Definition of 'vaccine'

vaccine

Word Frequency ○○○○○

(væksi:n, US væksi:n)

Word forms: plural **vaccines**

VARIABLE NOUN

A vaccine is a substance containing a harmless form of the germs that cause a particular disease. It is given to people, usually by injection, to prevent them getting that disease.

Anti-malarial vaccines are now undergoing trials.
Fortunately there are two types of vaccine against the disease.
...the rabies vaccine.

Synonyms: inoculation, injection, immunization More Synonyms of **vaccine**

vaccine

• You may also like •

English Quiz

in British English

('væksi:n)

NOUN medicine

1. a suspension of dead, attenuated, or otherwise modified microorganisms (viruses, bacteria, or rickettsiae) for inoculation to produce immunity to a disease by stimulating the production of antibodies
2. (originally) a preparation of the virus of cowpox taken from infected cows and inoculated in humans to produce immunity to smallpox
3. (*modifier*)
   of or relating to vaccination or vaccinia
4. *computing*
   a piece of software designed to detect and remove computer viruses from a system

Word origin

C18: from New Latin *variolae vaccīnae* cowpox, title of medical treatise (1798) by Edward Jenner, from Latin *vacca* a cow

in American English

(vækˈsin; ˈvæksin)

NOUN

1. *Originally*
   lymph, or a preparation of this, from a cowpox vesicle, containing the causative virus and used in vaccination against cowpox or smallpox
2. any preparation of killed microorganisms, living weakened organisms, etc. introduced into the body to produce immunity to a specific disease by causing the formation of antibodies

ADJECTIVE

3. *Rare*
   of cowpox or vaccination

Word origin

L *vaccinus*, from cows < *vacca,* cow; akin ? to Sans *vaś*, rogue cow

in American English

(vækˈsin, esp Brit ˈvæksin, -sɪn)

NOUN

1. any preparation used as a preventive inoculation to confer immunity against a specific disease, usually employing an innocuous form of the disease agent, as killed or weakened bacteria or viruses, to stimulate antibody production
2. the virus of cowpox, used in vaccination, obtained from pox vesicles of a cow or person
3. a software program that helps to protect against computer viruses, as by detecting them and warning the user

ADJECTIVE

4. of or pertaining to vaccination
5. of or pertaining to vaccinia
6. of, pertaining to, or derived from cows

Word origin

[‹ NL (*variolae*) *vaccīnae* cowpox (in title of E. Jenner's treatise of 1798), equiv. to *vacc*(*a*) cow + *-īnae*, fem. pl. of *-īnus* -INE[1]]

vaccine

These examples have been automatically selected and may contain sensitive content. Read more...

We may need to rethink the way we produce and sell vaccines.
***McKenzie, James F. & Pinger, Robert R.** A...*

It was his case that the brain damage was caused by the vaccine.
Times, Sunday Times (2007)

We look to the vaccine industry to produce the required quantities of vaccine as quickly as possible.
Times, Sunday Times (2009)

One particular challenge has been finding enough sterile manufacturing capacity to produce the vaccine.
Times, Sunday Times (2015)

This would mean stopping the production of seasonal vaccines that protect against infections that cause hundreds of thousands of deaths each year.
Times, Sunday Times (2009)

It could also trigger a recommendation that drug companies switch production from vaccines for seasonal strains of flu to the pandemic virus.
Times, Sunday Times (2009)

He was the first to use vaccines for rabies, anthrax and chicken cholera.
Times, Sunday Times (2007)

If you can get a vaccine for this disease, then you can talk about elimination.
Times, Sunday Times (2010)

There are now 27 vaccines available to combat different diseases.
Times, Sunday Times (2008)

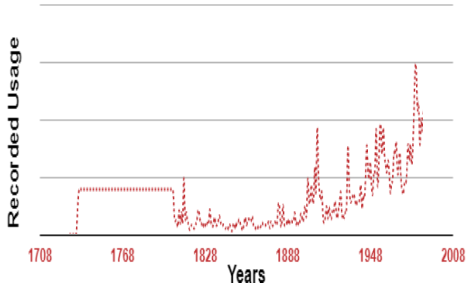
vaccine

effective vaccine
potential vaccine
target a vaccine
vaccine development
vaccine schedule

Trends of

vaccine

View usage for: All Years



vaccine

British English: vaccine noun /ˈvæksiːn/
A *vaccine* is a substance containing a harmless form of a particular disease. It is given to people to prevent them from getting that disease.
Anti-malarial vaccines are now undergoing trials.

American English: vaccine /vækˈsin/
Brazilian Portuguese: vacina
Chinese: 疫苗
European Spanish: vacuna
French: vaccin
German: Impfstoff
Italian: vaccino
Japanese: ワクチン
Korean: 백신
European Portuguese: vacina
Latin American Spanish: vacuna
Thai: วัคซีน

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vaccinator
vaccinatory
vaccine
vaccine development
vaccine dose
vaccine efficacy

All ENGLISH words that begin with 'V'

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vaccine

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Definition of **vaccine** from the Collins English Dictionary

- New from Collins -

Quick Word Challenge

Question: 1 - Score: 0 / 5

palate or palette or pallet?

Which version is correct?

Smooth the top using a **palette** knife.

Smooth the top using a **pallet** knife.

Smooth the top using a **palate** knife.

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vaccine

Chambers 21st Century Dictionary

SEARCH

Search Tips & Abbreviations

Search results for 'vaccine':

vaccine noun 1 medicine a preparation containing killed or weakened (attenuated) bacteria or viruses, or serum containing specific antibodies, used in vaccination to confer temporary or permanent immunity to a bacterial or viral disease by stimulating the body to produce antibodies to a specific bacterium or virus. 2 medicine, historical cowpox virus, or lymph containing it, used for inoculation against smallpox. 3 computing a piece of software designed to detect and remove computer viruses (see virus 5) from a floppy disk, program, etc. vaccinal adj.
ETYMOLOGY: 18c: from viriolae vaccinae cowpox, the title of a paper (1798) by E Jenner, from Latin vacca cow.

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vac·cine (văk-sēn , văk sēn′)

Share:

n.
1.
a. A preparation of a weakened or killed pathogen, such as a bacterium or virus, or of a portion of the pathogen's structure, that is administered to prevent or treat infection by the pathogen and that functions by stimulating the production of an immune response.
b. A preparation from the cowpox virus that protects against smallpox when administered to an individual.
2. *Computers* A software program designed to detect and stop the progress of computer viruses.

[From Latin *vaccīnus*, of cows, from *vacca*, cow.]

Indo-European & Semitic Roots Appendices

Thousands of entries in the dictionary include etymologies that trace their origins back to reconstructed proto-languages. You can obtain more information about these forms in our online appendices:

Indo-European Roots

Semitic Roots

The Indo-European appendix covers nearly half of the Indo-European roots that have left their mark on English words. A more complete treatment of Indo-European roots and the English words derived from them is available in our Dictionary of Indo-European Roots.

This website is best viewed in Chrome, Firefox, Microsoft Edge, or Safari. Some characters in pronunciations and etymologies cannot be displayed properly in Internet Explorer.

SINCE 1828

vaccine

noun

Save Word

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vac·cine | \ vak-ˈsēn , ˈvak-ˌsēn \

Definition of *vaccine*

: a preparation of killed microorganisms, living attenuated organisms, or living fully virulent organisms that is administered to produce or artificially increase immunity to a particular disease

Other Words from *vaccine* Example Sentences Learn More about *vaccine*

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Other Words from *vaccine*

vaccine adjective

Examples of *vaccine* in a Sentence

Recent Examples on the Web In the headlines: ► One million California health care workers, nursing home residents and staff will receive the COVID-19 *vaccine* by week's end, Gov. Gavin Newsom promised Monday. — Elinor Aspegren, *USA TODAY*, "Coronavirus updates: Disneyland to be transformed into mass vaccination site; Indiana is 10th state to report virus variant; 376K US deaths," 12 Jan. 2021 Houston Health Department Director Stephen Williams said the city administered more than 14,000 doses of the COVID-19 *vaccine* thus far. — Shelby Stewart, *Chron*, "Mayor Turner says COVID-19 numbers are 'moving in the wrong direction'," 12 Jan. 2021

These example sentences are selected automatically from various online news sources to reflect current usage of the word 'vaccine.' Views expressed in the examples do not represent the opinion of Merriam-Webster or its editors. Send us feedback.

See More

First Known Use of *vaccine*

1882, in the meaning defined above

History and Etymology for *vaccine*

earlier, "fluid from cowpox pustules used in inoculation," noun use of *vaccine* "of cowpox" (in the phrases *vaccine disease, vaccine matter*), borrowed from New Latin *vaccina* (in *variolae vaccinae* "cowpox"), going back to Latin, feminine of *vaccīnus* "of or from a cow," from *vacca* "cow" (perhaps akin to Sanskrit *vaśā* "cow") + *-īnus* -ine entry 1; in extended sense, "preparation of organisms administered to produce immunity," in part borrowed from French *vaccin*, masculine derivative of *vaccine* "cowpox, matter from cowpox pustules," borrowed from New Latin or English

Keep scrolling for more

Learn More about *vaccine*

SINCE 1828

vaccine

noun

vac·cine | \ vak-ˈsēn , ˈvak-ˌsēn \

Definition of *vaccine*

: a preparation that is administered (as by injection) to stimulate the body's immune response against a specific infectious disease:
a **:** an antigenic preparation of a typically inactivated or attenuated (see attenuated sense 2) pathogenic agent (such as a bacterium or virus) or one of its components or products (such as a protein or toxin)
b **:** a preparation of genetic material (such as a strand of synthesized messenger RNA) that is used by the cells of the body to produce an antigenic substance (such as a fragment of virus spike protein)

Other Words from *vaccine* Example Sentences Learn More about *vaccine*

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Other Words from *vaccine*

vaccine adjective

Examples of *vaccine* in a Sentence

Recent Examples on the Web One million California health care work
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TODAY, "Coronavirus updates: Disneyland to be transformed into mas
report virus variant; 376K US deaths," 12 Jan. 2021 Watson Colman p
Pfizer/BioNTech COVID-19 *vaccine*, which was made available to top lawmakers in December for the purpose of ensuring continuity in government. — Emily Brooks, *Washington Examiner*, "House Democrat tests positive for COVID-19, blames maskless Republicans," 11 Jan. 2021

*Meaning of **vaccine** in English*

vaccine

noun [C or U]

UK /ˈvæk.siːn/ **US** /ˈvæk.siːn/

C2

a substance containing a virus or bacterium in a form that is not harmful, given to a person or animal to prevent them from getting the disease that the virus or bacterium causes:

- *This vaccine protects against some kinds of the bacteria.*

SMART Vocabulary: related words and phrases

Immunology & vaccination

active immunity
anti-vax
antibody
antiserum
antivaxxer
antivenin
gamma globulin
herd immunity
immune
immunity
immunization
immunize

immunocompromised

immunology

immunosuppressed

immunosuppression

interferon

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*(Definition of **vaccine** from the **Cambridge Advanced Learner's Dictionary & Thesaurus** © Cambridge University Press)*

vaccine | AMERICAN DICTIONARY

vaccine

noun [C]

US /ˈvæk·sin, vækˈsin/

a special substance that you take into your body to prevent a disease, and that contains a weakened or dead form of the disease-causing organism

vaccinate

verb [T] **US** /ˈvæk·səˌneɪt/

- *Our children have been vaccinated for measles and other childhood diseases.*

vaccination

*Meaning of **vaccine** in English*

vaccine

noun [C or U]

UK /ˈvæk.siːn/ **US** /ˈvæk.siːn/

C2

a substance that is put into the body of a person or animal to protect them from a disease by causing them to produce antibodies (=proteins that fight diseases):

- *This vaccine protects against some kinds of the bacteria.*
- *The measles vaccine is one of the immunizations that is recommended for all children.*

− More examples

- *Scientists have announced that they are experimenting with vaccines against ovarian cancer.*
- *The speedy use of animal vaccines has helped make anthrax a rarity in the region.*
- *A vaccine containing dead, or inactive, poliovirus was licensed in 1955.*

+ SMART Vocabulary: related words and phrases

vaccine

Contents To top

a special substance that you take into your body to prevent a disease, and that contains a weakened or dead form of the disease-causing organism

vaccinate

verb [T] US /ˈvæk·səˌneɪt/

- *Our children have been vaccinated for measles and other childhood diseases.*

vaccination

noun [C] US /ˌvæk·səˈneɪ·ʃən/

- *Most states require all children to receive the vaccination before beginning elementary school.*

*(Definition of **vaccine** from the **Cambridge Academic Content Dictionary** © Cambridge University Press)*

EXAMPLES of **vaccine**

vaccine

All of these adhesion molecules have been proposed as *vaccine* targets.

From the Cambridge English Corpus

In the majority of patients (influenza *vaccine*, 98 % and pneumococcal *vaccine*, 94 %), vaccination was carried out in general practice.

From the Cambridge English Corpus

Centers for Disease Control and Prevention

Glossary

A

Acellular vaccine: Listen [MP3]
A vaccine containing partial cellular material as opposed to complete cells.

Acquired Immune Deficiency Syndrome (AIDS): A medical condition where the immune system cannot function properly and protect the body from disease. As a result, the body cannot defend itself against infections (like pneumonia). AIDS is caused by the Human Immunodeficiency Virus (HIV). This virus is spread through direct contact with the blood and body fluids of an infected individual. High risk activities include unprotected sexual intercourse and intravenous drug use (sharing needles). There is no cure for AIDS, however, research efforts are on-going to develop a vaccine.

Active immunity: The production of antibodies against a specific disease by the immune system. Active immunity can be acquired in two ways, either by contracting the disease or through vaccination. Active immunity is usually permanent, meaning an individual is protected from the disease for the duration of their lives.

Acute: Listen [MP3]
A short-term, intense health effect.

Adjuvant: Listen [MP3]
A vaccine component distinct from the antigen that enhances the immune response to the antigen.

Adverse events: An “adverse event” is any health problem that happens after a shot or other vaccine. An adverse event might be truly caused by a vaccine, or it might be pure coincidence.

Advisory Committee on Immunization Practices (ACIP): A group of medical and public health experts who develop recommendations on the use of vaccines in the U.S. civilian population. The recommendations stand as public health guidance for the safe use of vaccines and related biological products.

Allergy: A condition in which the body has an exaggerated response to a substance (e.g. food or drug). Also known as hypersensitivity.

Anaphylaxis: Listen [MP3]
An immediate and severe allergic reaction to a substance (e.g. food or drugs). Symptoms of anaphylaxis include breathing difficulties, loss of consciousness and a drop in blood pressure. This condition can be fatal and requires immediate medical attention.

Anthrax: Listen [MP3]
An acute infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. Anthrax most commonly occurs in hoofed mammals and can also infect humans.

Antibiotic: Listen [MP3]
A substance that fights bacteria.

Antibody: Listen [MP3]
A protein found in the blood that is produced in response to foreign substances (e.g. bacteria or viruses) invading the body. Antibodies protect the body from disease by binding to these organisms and destroying them.

Antigens: Listen [MP3]
Foreign substances (e.g. bacteria or viruses) in the body that are capable of causing disease. The presence of antigens in the body triggers an immune response, usually the production of antibodies.

Sudden Infant Death Syndrome (SIDS): The sudden and unexpected death of a healthy infant under 1 year of age. A diagnosis of SIDS is made when an autopsy cannot determine another cause of death. The cause of SIDS is unknown. Also known as "crib" or "cot" death.

Susceptible: Unprotected against disease.

T

Temporal association: Two or more events that occur around the same time but may be unrelated, chance occurrences.

Teratogenic: Listen [MP3]
Of, relating to, or causing developmental malformations.

Tetanus: Listen [MP3]
Toxin-producing bacterial disease marked by painful muscle spasms.

Thimerosal: Listen [MP3]
Thimerosal is a mercury-containing preservative used in some vaccines and other products since the 1930's. There is no convincing evidence of harm caused by the low concentrations of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure. Today, all routinely recommended childhood vaccines manufactured for the U.S. market contain either no thimerosal or only trace amounts with the exception of some flu vaccines. There are thimerosal-free influenza vaccines available.

Typhoid Fever: Typhoid fever is a life-threatening illness caused by the bacterium *Salmonella* Typhi. Persons with typhoid fever carry the bacteria in their bloodstream and intestinal tract.

Titer: Listen [MP3]
The detection of antibodies in blood through a laboratory test.

Transverse Myelitis: Listen [MP3]
The sudden onset of spinal cord disease. Symptoms include general back pain followed by weakness in the feet and legs that moves upward. There is no cure and many patients are left with permanent disabilities or paralysis. Transverse Myelitis is a demyelinating disorder that may be associated with Multiple Sclerosis (MS). Also see demyelinating disorders.

U

Urticaria: Listen [MP3]
The eruption of red marks on the skin that are usually accompanied by itching. This condition can be caused by an allergy (e.g. to food or drugs), stress, infection or physical agents (e.g. heat or cold). Also known as hives.

V

Vaccination: Listen [MP3]
The physical act of administering any vaccine or toxoid.

Vaccinia: Listen [MP3]
A virus related to the smallpox and cowpox viruses, which is used in smallpox vaccine.

Vaccine: Listen [MP3]
A suspension of live (usually attenuated) or inactivated microorganisms (e.g. bacteria or viruses) or fractions thereof administered to induce immunity and prevent infectious diseases and their sequelae. Some vaccines contain highly defined antigens (e.g., the polysaccharide of *Haemophilus influenzae* type b or the surface antigen of hepatitis B); others have antigens that are complex or incompletely defined (e.g. *Bordetella pertussis* antigens or live attenuated viruses).

Centers for Disease Control and Prevention

Immunization: The Basics

Understanding mRNA COVID-19 Vaccines

mRNA vaccines are a new type of vaccine to protect against infectious diseases. Learn about how COVID-19 mRNA vaccines work.

Definition of Terms

Immunity: Protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected.

Vaccine: A preparation that is used to stimulate the body's immune response against diseases. Vaccines are usually administered through needle injections, but some can be administered by mouth or sprayed into the nose.

Vaccination: The act of introducing a vaccine into the body to produce protection from a specific disease.

Immunization: A process by which a person becomes protected against a disease through vaccination. This term is often used interchangeably with vaccination or inoculation.

Page last reviewed: September 1, 2021

The New York Times https://www.nytimes.com/2021/09/24/world/covid-boosters-vaccine-cdc-director.html

C.D.C. Chief Overrules Agency Panel and Recommends Pfizer-BioNTech Boosters for Workers at Risk

In a highly unusual decision, the C.D.C. director, Rochelle Walensky, reversed a move by agency advisers and endorsed additional doses of the Pfizer-BioNTech vaccine for health care workers, teachers and other workers at risk.


By Apoorva Mandavilli and Benjamin Mueller

Published Sept. 24, 2021 Updated Oct. 21, 2021

The director of the Centers for Disease Control and Prevention on Friday overruled a recommendation by an agency advisory panel that had refused to endorse booster shots of the Pfizer-BioNTech Covid vaccine for frontline workers. It was a highly unusual move for the director, Dr. Rochelle Walensky, but aligned C.D.C. policy with the Food and Drug Administration's endorsements over her own agency's advisers.

The C.D.C.'s Advisory Committee on Immunization Practices on Thursday recommended the boosters for a wide range of Americans, including tens of millions of older adults and younger people at high risk for the disease. But they excluded health care workers, teachers and others whose jobs put them at risk. That put their recommendations at odds with the F.D.A.'s authorization of booster shots for all adults with a high occupational risk.

Dr. Walensky's decision was a boost for President Biden's campaign to give a broad segment of Americans access to boosters. The White House had come under criticism for getting ahead of the regulatory process.

The White House could begin promoting and rolling out a plan for booster shots as soon as Friday. That would be in keeping with the administration's previously announced plan to offer the additional doses this week.

The C.D.C.'s statement arrived well past midnight, a sign of the complicated and confusing decision-making surrounding the boosters. The C.D.C. advisers similarly spent two days debating who should get boosters and when, and could not agree on whether occupational risk should qualify as a criterion.

"I am surprised that Dr. Walensky overturned one of the four A.C.I.P. votes today, and I believe others will be as well," said Dr. Yvonne Maldonado, an infectious disease expert at Stanford and the American Academy of Pediatrics liaison to the committee.

But the vote on boosters for occupational risk "was close," Dr. Maldonado said, and agreed with Dr. Walensky's decision.

"This addresses not only waning immunity but those at high risk of exposure," Dr. Maldonado added.

Minutes before Dr. Walensky's statement, Dr. Amanda Cohn, who oversaw the two-day meeting of the panel, tried to prepare the advisers for the director's decision.

"Dr. Walensky is reversing the decision to not recommend use of a booster dose in persons at high risk for occupational or institutional exposure," Dr. Cohn wrote in the email. "I am hoping to share this news with you before you see it in the press."

Dr. Walensky's decision to go against her own agency's advisers came as a surprise to at least some of her staff members: The C.D.C. director's endorsement of the advisory committee's recommendations is typically just a formality. Hours before her statement, agency insiders predicted she would stick with the usual protocol because doing otherwise would undermine the process and upset the advisers as well as her own staff.

But experts outside the C.D.C. said Dr. Walensky may have had no choice but to align herself with the F.D.A.'s decision. "There's a complexity here, because Dr. Walensky was part of the White House announcement" on boosters, noted Dr. Ashish Jha, dean of the Brown University School of Public Health.

Dr. Walensky said providing booster shots to health care workers and others who risk contracting the disease on the job would "best serve the nation's public health needs."

She approved the panel's decision to endorse third shots for people over 65, patients in nursing homes and other institutional settings, and those with underlying medical conditions.

Dr. Walensky's decision revealed the continuing divisions and confusion among federal regulators and outside advisers about how to contain the virus nearly two years into the pandemic.

On Wednesday, the Food and Drug Administration authorized booster shots for certain frontline workers. But the C.D.C.'s advisers disagreed that the doses were needed by so many healthy people.

Whatever the scientific reservations, millions are expected to seek out booster shots. In one recent poll, about three-quarters of vaccinated Americans said they would opt for a booster if the doses were available.

Connie Williams, left, administered a dose of the Pfizer-BioNTech vaccine to Mercedes Carrera, 71, right, in Portland, Ore., this month. Alisha Jucevic for The New York Times

State health departments generally follow the recommendations of the C.D.C. But many Americans were scrambling for boosters even before the F.D.A.'s authorization, typically by finding a cooperative pharmacist or by claiming to be unvaccinated.

The C.D.C.'s advisers acted on what they described — with considerable frustration — as scant research, mulling over conflicting data points that seldom pointed in one direction.

In the end, the panel unanimously endorsed booster shots for adults over 65 and for residents of long-term care facilities, who most clearly will benefit.

The committee also backed the shots for people 50 to 64 with medical conditions that leave them at risk for severe Covid-19, as well as those 18 to 49 who have certain medical conditions, based on an assessment of their individual needs.

Only Americans who already have received two doses of the Pfizer-BioNTech vaccine will qualify for booster shots. The panel was not asked to judge whether people who received the Moderna and Johnson & Johnson vaccines should receive the additional doses, which have not been authorized by the F.D.A.

Several experts on the C.D.C. panel nevertheless urged a mix-and-match strategy, saying that they could see little reason not to offer a Pfizer-BioNTech booster to someone who qualified but had received, for example, the J. & J. vaccine. Some members warned that delivering multiple rounds of booster shots, available periodically when authorized, would tax an already burdened health care system.

The C.D.C. panel's guidance followed weeks of internal disagreement and public debate among American health officials and advisers. In mid-August, President Biden announced plans for a booster rollout, but scientists and regulators were quick to point out there was little research on who might benefit and how the doses should be distributed.

The F.D.A.'s acting commissioner, Janet Woodcock, said on Wednesday that the agency's authorization would allow for booster doses "in certain populations such as health care workers, teachers and day care staff, grocery workers and those in homeless shelters or prisons, among others."

But some members of the committee said there was little evidence to suggest that vaccinated teachers, and even health care workers, were at risk of repeated exposure to the virus. The decision reflected fears that such a broad recommendation would effectively throw the doors open to an all-adults booster campaign.

"My sense was that the committee felt that that was sort of a hole that you could drive a truck through," Dr. Paul Offit, a professor at the University of Pennsylvania and a member of the F.D.A.'s vaccine advisory panel, told reporters at an online briefing on Thursday.

Over the two days, the panel wrestled with the public's expectations for Covid vaccines, the safety of third doses and how a booster program would affect nursing home residents. Booster doses alone would not turn back the pandemic, some scientists noted: Only vaccinating the unvaccinated would do that.

“We may move the needle a little bit by giving a booster dose to people,” said Dr. Helen Talbot, an associate professor of medicine at Vanderbilt University. But, she added, “the hospitals are full because people are not vaccinated.”

The advisers also grappled with a lack of clarity on the goal of the vaccines: Should it be to prevent all infections, or to forestall severe illness and hospitalization?

Many suggested that booster doses could do only the latter, and that trying to thwart all infections was impossible. That reasoning supported limiting who should receive the doses, the experts said.

On Thursday, C.D.C. scientists presented models indicating that, if booster doses were to slightly increase people’s protection against hospitalization, the additional shots could prevent more than 2,000 hospitalizations for every million doses given.

But it was not clear how long additional protection from a booster would last, raising the prospect that boosters would need to be given repeatedly.

Boosters can reduce infections in nursing home residents, who are among those at highest risk. Even so, cases in nursing homes will persist when community transmission is high, according to a modeling study presented at the meeting.

The advisers also wrestled with the practicalities of endorsing a booster shot for only Pfizer-BioNTech recipients, when close to half of vaccinated Americans have received Moderna or J. & J. vaccines.

“I just don’t understand how, later this afternoon, we can say to people 65 and older, ‘You’re at risk for severe disease and death, but only half of you can protect yourselves right now,’” said Dr. Sarah Long, a pediatrician and infectious diseases expert at Drexel University College of Medicine in Pennsylvania.

Committee members also expressed concern on Thursday that some recommendations — particularly that certain younger Americans be allowed booster shots after an assessment of individual risks — would mean that only the wealthy and educated would gain access to additional shots.

Some experts seemed to suggest on Wednesday that it might be better to hold off on recommending any booster shots until recipients of all three vaccines could qualify for them.

Moderna’s booster authorization may arrive in a few days to weeks. The company has applied to the F.D.A. for authorization of a booster shot carrying half the dosage given in the first two shots, which has complicated the agency’s deliberations.

Some global health experts have criticized the Biden administration for pushing booster shots when much of the world has yet to receive a first dose. But analysts noted that even if the United States distributes booster shots, there should still be considerable excess vaccine supply this year, and they urged the government to begin sending the extra doses abroad.

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PBS NEWS HOUR

WATCH: FDA panel shows frustration in booster dose debate

Health Updated on Sep 17, 2021 4:53 PM EDT — Published on Sep 16, 2021 6:29 PM EDT

WASHINGTON (AP) — An influential federal advisory panel overwhelmingly rejected a plan Friday to offer Pfizer booster shots against COVID-19 to most Americans, dealing a heavy blow to the Biden administration's effort to shore up people's protection amid the highly contagious delta variant.

Watch the debate in the player above.

An influential federal advisory panel has overwhelmingly rejected a plan to give Pfizer booster shots against COVID-19 to most Americans, but it endorsed the extra shots for those who are 65 or older or run a high risk of severe disease.

The twin votes Friday represented a heavy blow to the Biden administration's sweeping effort to shore up nearly all Americans' protection amid the spread of the highly contagious delta variant.

The first by the committee of outside experts assembled by the Food and Drug Administration was 16-2, with members expressing frustration that Pfizer had provided little data on the safety of extra doses.

"There's several key points, I think, that we're lacking right now," said panelist Dr. Hayley Gans. "One of them is the very strong safety data that we could have actually with all the third doses that have been given."

Many also raised doubts about the value of mass boosters, rather than ones targeted to specific groups.

"There are some very clear populations that have impaired or diminished good cellular responses, and a boost may be very appropriate for them." said committee member Dr. Michael Kurilla. "It's not clear to me that the data we're seeing right now is applicable and necessary to the general population."

In an extraordinary move, the group took a second vote Friday afternoon recommending the booster shots for older Americans and other high-risk groups.

That would help salvage part of the Biden administration's campaign but would still be a huge step back from the sweeping plan proposed by the White House a month ago to offer booster shots of both the Pfizer and Moderna vaccines to nearly all Americans eight months after they get their second dose.

The vote by the committee of outside experts assembled by the Food and Drug Administration was 16-12, with members expressing frustration that Pfizer had provided little data on the safety of extra doses. Many also raised doubts about the value of mass boosters, rather than ones targeted to specific groups.

In an extraordinary move, both FDA leaders and the panel indicated they were likely to take a second vote Friday afternoon on recommending the booster shots for older Americans and other high-risk groups.

That would help salvage part of the Biden administration's campaign but would still be a huge step back from the sweeping plan proposed by the White House a month ago to offer booster shots of both the Pfizer and Moderna vaccines to nearly all Americans eight months after they get their second dose.

During several hours of vigorous debate Friday, members of the panel questioned the value of offering boosters to nearly everyone.

"I don't think a booster dose is going to significantly contribute to controlling the pandemic," said Dr. Cody Meissner of Tufts University. "And I think it's important that the main message we transmit is that we've got to get everyone two doses."

Dr. Amanda Cohn of the Centers for Disease Control and Prevention said: "At this moment it is clear that the unvaccinated are driving transmission in the United States."

Panel members also complained that data provided by Israeli researchers about their booster campaign might not be suitable for predicting the U.S. experience.

Scientists inside and outside the government have been divided in recent days over the need for boosters and who should get them, and the World Health Organization has strongly objected to rich nations giving a third round of shots when poor countries don't have enough vaccine for their first.

While research suggests immunity levels in those who have been vaccinated wane over time and boosters can reverse that, the Pfizer vaccine is still highly protective against severe illness and death, even amid the spread of the highly contagious delta variant.

The FDA advisory panel was the first major hurdle that the Biden administration plan faced. The FDA itself has yet to make its own determination but typically follows the recommendations of its expert panel.

In yet another step to the process, a CDC advisory committee that sets policy for U.S. vaccinations campaigns is set meet on Wednesday to debate who, exactly, should get boosters and how many months after their second dose should them receive the extra shot.

The CDC has said it is considering boosters for older people, nursing home residents and front-line health care workers, rather than all adults.

Separate FDA and CDC decisions will be needed in order for people who received the Moderna or J&J shots to get boosters.

The FDA panel's overwhelming rejection came despite full-throated arguments about the need for boosters from both Pfizer and health officials from Israel, which began offering boosters to its citizens in July.

Sharon Alroy-Preis of Israel's Ministry of Health said the booster dose improves protection tenfold against infection in people 60 and older.

"It's like a fresh vaccine," bringing protection back to original levels and helping Israel "dampen severe cases in the fourth wave," she said.

And representatives for Pfizer argued that it is important to shore up immunity before protection against severe disease starts to erode. A company study of 44,000 people showed effectiveness against symptomatic COVID-19 was 96 percent two months after the second dose, but had dropped to 84 percent by around six months.

Both Pfizer and the Israeli representatives faced pushback from panelists. Several expressed skepticism about the relevance of Israel's experience to the U.S. Also complicating the committee's decision: No one yet knows the antibody level below which infection is likely and boosters are needed.

Another concern was whether third doses would exacerbate serious side effects.

Dr. Cody Meissner of Tufts Medical Center said he is worried about extra doses for younger age groups given the risk of heart inflammation that has been seen in mostly younger men after a second dose. While the condition is very rare, he said, it is not clear if that risk would increase with another dose.

Pfizer pointed to Israeli data from nearly 3 million boosters to suggest side effect rates would be similar to that seen after second doses.

Dr. Paul Offit, a vaccine expert at Children's Hospital of Philadelphia, said he was more likely to support approving a third dose for adults over 60 or 65 but "I really have trouble" supporting it for anyone down to age 16.

While an extra shot likely will at least temporarily decrease cases with mild or no symptoms, "the question becomes what will be the impact of that on the arc of the pandemic, which may not be all that much," Offit said.

President Joe Biden's top health advisers, including the heads of the FDA and CDC, first announced plans for widespread booster shots a month ago, targeting the week of Sept. 20 as an all-but-certain start date. It said boosters would be dispensed eight months after the second dose of the Pfizer and Moderna vaccines.

But that was before FDA staff scientists had completed their own assessments of the data. Some experts questioned whether Biden was breaking his own pledge to "follow the science" on COVID-19 by getting out ahead of government scientists.

Earlier this week, two top FDA vaccine reviewers joined a group of international scientists in publishing an editorial rejecting the need for boosters in healthy people. The scientists said continuing studies show the shots are working well despite the delta variant.

On Friday, U.S. Surgeon General Dr. Vivek Murthy said that in announcing its booster plan, the Biden administration was not trying to pressure regulators to act but was instead trying to be transparent with the public and be prepared in the event that extra shots won approval.

"We have always said that this initial plan would be contingent on the FDA and the CDC's independent evaluation," Murthy said.

The Biden plan has also raised major ethical concerns about impoverished parts of the world still clamoring for vaccine. But the administration has argued that the plan is not an us-or-them choice, noting that the U.S. is supplying large quantities of vaccine to the rest of the globe.

The U.S. has already approved Pfizer and Moderna boosters for certain people with weakened immune systems, such as cancer patients and transplant recipients.

Some Americans, healthy or not, have managed to get boosters, in some cases simply by showing up and asking for a shot. And some health systems already are offering extra doses to high-risk people.

Editor's note: Johnson & Johnson is a funder for the PBS NewsHour.

By – **Lauran Neergaard, Associated Press**

By – **Matthew Perrone, Associated Press**

By – **Associated Press**

CDC director on COVID boosters, global vaccine supply, evolving virus science

Health Sep 14

The New York Times https://www.nytimes.com/2021/08/31/us/politics/fda-vaccine-regulators-booster-shots.html

Two Top F.D.A. Vaccine Regulators Are Set to Depart During a Crucial Period

The announcement that Dr. Marion Gruber and Dr. Philip Krause will leave this fall comes as the agency conducts sensitive reviews of coronavirus vaccines for children and booster shots.


By Noah Weiland and Sharon LaFraniere

Published Aug. 31, 2021 Updated Sept. 22, 2021

WASHINGTON — Two of the Food and Drug Administration's top vaccine regulators will leave the agency this fall, a development that could disrupt its work on deciding whether to recommend coronavirus vaccines for children under 12 and booster shots for the general population.

Dr. Marion Gruber, the director of the F.D.A.'s vaccines office, will retire at the end of October, and her deputy, Dr. Philip Krause, will leave in November, according to an email that Dr. Peter Marks, the agency's top vaccine regulator, sent to staff members on Tuesday morning. One reason is that Dr. Gruber and Dr. Krause were upset about the Biden administration's recent announcement that adults should get a coronavirus booster vaccination eight months after they received their second shot, according to people familiar with their thinking.

Neither believed there was enough data to justify offering booster shots yet, the people said, and both viewed the announcement, amplified by President Biden, as pressure on the F.D.A. to quickly authorize them.

Dr. Marks said he would serve as the acting director of the vaccines office while the agency searched for its next leader. Stephanie Caccomo, a spokeswoman for the agency, said it was "confident in the expertise and ability of our staff to continue our critical public health work."

Some public health experts have said the administration's booster shot announcement, which did include a caveat that the F.D.A. would first have to authorize such shots, undermined the agency's responsibility to make that assessment on its own schedule, led by career scientists. Since Mr. Biden took office in January, the White House has made a point of saying it would not influence the F.D.A.'s work.

Some outside experts have also challenged the booster plan as premature, saying the available data shows that the Pfizer-BioNTech and Moderna vaccines are holding up well against severe disease and hospitalization, including against the Delta variant. Extra shots would be warranted only if the vaccines failed to meet that standard, some have said.

White House officials have stressed that the plan for Americans to start receiving boosters next month was uniformly endorsed by the most senior federal health officials, including Dr. Janet Woodcock, the acting F.D.A. commissioner. They have described the need to develop a booster plan as urgent in light of growing evidence that the vaccines lose potency over time — a trend that they fear suggests the vaccines' protection against severe disease and hospitalization will also soon weaken.

Officials have singled out data from Israel as a particularly worrisome sign, especially for older adults and other vulnerable groups. Data from abroad "actually has led us to be even more concerned about increased risk of vaccine effectiveness waning against hospitalization, severe disease and death," Dr. Rochelle P. Walensky, the director of the Centers for Disease Control and Prevention, said at a White House briefing on the pandemic Tuesday.

Asked about reports that Dr. Gruber and Dr. Krause were unhappy with what they viewed as pressure on the agency, Jeffrey D. Zients, the White House's Covid-19 response coordinator, reiterated that the booster strategy had always been contingent on F.D.A. review.

"As our medical experts laid out, having reviewed all the available data, it is in their clinical judgment that it is time to prepare Americans for a booster shot," he said at the briefing. "We announced our approach in order to stay ahead of the virus, give states and pharmacies time to plan, and to be transparent with the American people."

But some critics have said that explanation falls short, because F.D.A. regulators are in the position of trying to determine whether booster shots are safe and effective after the White House — and their own agency head, Dr. Woodcock — already endorsed administering them.

Dr. Marion Gruber and Dr. Philip Krause viewed the announcement on booster shots, amplified by President Biden, as pressure on the F.D.A. to quickly authorize them, people familiar with their thinking said. Doug Mills/The New York Times

"This process has been the reverse of what we would normally expect in vaccine policy," with the administration announcing plans based on a certain outcome before regulators can complete their review, said Jason L. Schwartz, an associate professor of health policy at the Yale School of Public Health. "That has made it even more complicated and confusing for the public."

The announcement of the departures comes at a critical time for the F.D.A. The agency is in the midst of a marathon push to decide several important questions about the three coronavirus vaccines it authorized on an emergency basis over the past year. It is facing public pressure from some quarters to speed up, and from others to slow down. Mr. Biden still has not nominated someone to permanently lead the agency, a post that requires Senate confirmation.

Only about three weeks remain before the Biden administration wants to begin offering boosters to recipients of the Pfizer-BioNTech and Moderna vaccines, starting with nursing home residents, health care workers and others who were inoculated early in the vaccination campaign.

The F.D.A. is currently trying to schedule a meeting of its panel of independent experts, the Vaccines and Related Biological Products Advisory Committee, to discuss booster shots, according to people familiar with the agency's planning. That meeting would be public, and could potentially reveal concerns among regulators and the F.D.A.'s outside experts about the administration's strategy.

The F.D.A. is also expected soon to tackle the question of whether to authorize coronavirus vaccines on an emergency basis for children under 12.

Last week, the agency fully approved the Pfizer-BioNTech vaccine for people 16 and older, a major decision that spurred a series of vaccine mandates at corporations, universities, hospitals and elsewhere.

That decision and a host of others fell to teams led by Dr. Gruber and Dr. Krause, working under Dr. Marks.

The F.D.A. reviews data from vaccine manufacturers on safety and efficacy, and sometimes makes decisions with input from the outside advisory committee of vaccine experts. The agency's decisions are followed by recommendations from the Centers for Disease Control and Prevention, after it hears from its own outside panel of experts.

Both Dr. Gruber and Dr. Krause have been at the agency for 30 years and have long experience reviewing vaccines, including for Ebola. The office they lead evaluates annual flu vaccines, including which strains each year's version targets, and it had a central role in the F.D.A.'s authorization of three coronavirus vaccines, which also include a single-dose shot from Johnson & Johnson.

Their office also guides manufacturers on what kinds of studies they need to conduct to evaluate new vaccines, then reviews the data on them. The F.D.A. came under enormous pressure last fall by Trump administration officials to water down or scuttle standards it had set for vaccine emergency use authorizations, but prevailed in publishing the guidelines. Dr. Stephen M. Hahn, the F.D.A. commissioner under President Donald J. Trump, said on Tuesday that Dr. Gruber and Dr. Krause "stuck together and marshaled amazing resources and got the authorizations done in record time."

"They set the gold standard" for vaccine reviews, said Dr. Luciana Borio, the former acting chief scientist at the agency under President Barack Obama. During the pandemic, she added, "they put their heads down and organized their team to do this work under tremendous pressure, but do it in a rigorous, expedited and flexible form."

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A version of this article appears in print on , Section A, Page 14 of the New York edition with the headline: Two Top F.D.A. Vaccine Regulators Set to Depart During Crucial Period

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

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 <u>NOT</u> 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

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.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen 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 Janssen 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 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 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

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

Barcode Date: 02/2021

The New York Times https://www.nytimes.com/2021/12/23/health/booster-protection-omicron.html

Coronavirus >

Booster protection wanes against symptomatic Omicron infections, British data suggests.

By Emily Anthes
Dec. 23, 2021

New data from Britain suggests that booster protection against symptomatic Covid caused by the Omicron variant wanes within 10 weeks.

There have not yet been enough severe cases of Omicron to calculate how well boosters protect against severe disease, but experts believe the shots will continue to provide significant protection against hospitalization and death.

“It will be a few weeks before effectiveness against severe disease with Omicron can be estimated,” the new report, from Britain’s Health Security Agency, noted. “However, based on experience with previous variants, this is likely to be substantially higher than the estimates against symptomatic disease.”

In the weeks since Omicron was discovered, multiple studies have suggested that the variant is skilled at evading the antibodies that are produced after vaccination or after infection with the coronavirus.

The new report from Britain, which included data on people who had received the AstraZeneca, Pfizer or Moderna shots, confirmed that the vaccines — both the initial two-shot series and booster doses — were less effective and waned faster against Omicron than against Delta.

Among people who received two doses of the AstraZeneca vaccine, a booster with one of the mRNA vaccines, made by Pfizer and Moderna, was 60 percent effective at preventing symptomatic disease two to four weeks after the shot. After 10 weeks, however, the Pfizer booster was just 35 percent effective. The Moderna booster was 45 percent effective at up to nine weeks. (The AstraZeneca vaccine is not authorized in the United States, but the Johnson & Johnson shot uses a similar technology.)

For people who were given three Pfizer doses, vaccine effectiveness dropped from 70 percent one week after the booster to 45 percent after 10 weeks. Pfizer recipients who received a Moderna booster, on the other hand, seemed to fare better; their vaccine regimen remained up to 75 percent effective at up to nine weeks.

The report, which was based on an analysis of about 148,000 Delta cases and 68,000 Omicron cases, also included recent data suggesting that Omicron infections are less likely to lead to hospitalizations than Delta infections. The findings should be interpreted cautiously, the agency noted, because there have still not been many Omicron cases, relatively speaking, and the people who have contracted the variant may not be representative of the broader population.

The Biden administration has been encouraging all eligible Americans to receive booster shots as Omicron spreads.

In a recent interview on WCBS-AM, a New York radio station, Dr. Anthony S. Fauci, the nation’s leading infectious disease doctor, said that officials were monitoring the effectiveness of mRNA boosters against Omicron.

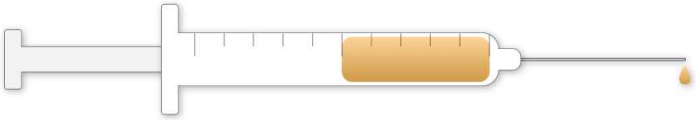
“I do think it’s premature, at least on the part of the United States, to be talking about a fourth dose,” he said. Israel is weighing whether to give a fourth shot to its citizens.

Some scientists have warned against a fourth shot, noting that there is not yet evidence that it is necessary and that some immune cells might eventually stop responding to the shots if too many doses are given.

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

How the Johnson & Johnson Vaccine Works

By Jonathan Corum and Carl Zimmer Updated May 7, 2021

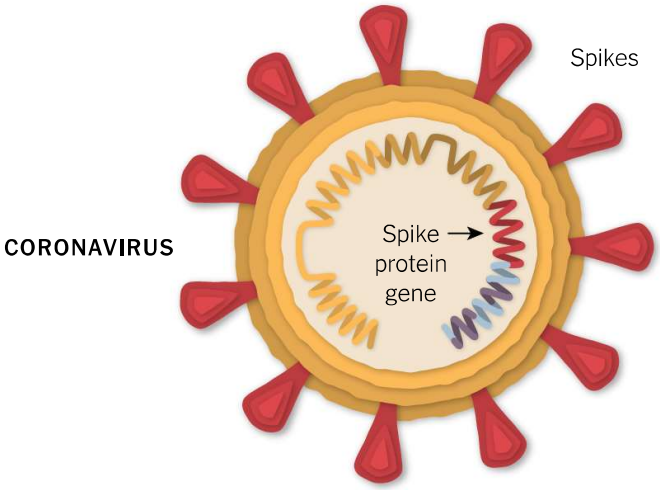


Johnson & Johnson is testing a coronavirus vaccine known as **JNJ-78436735** or **Ad26.COV2.S**. Clinical trials showed that a single dose of the vaccine had an efficacy rate of 72 percent in the United States, and a lower efficacy in countries where more contagious variants are widespread. The vaccine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

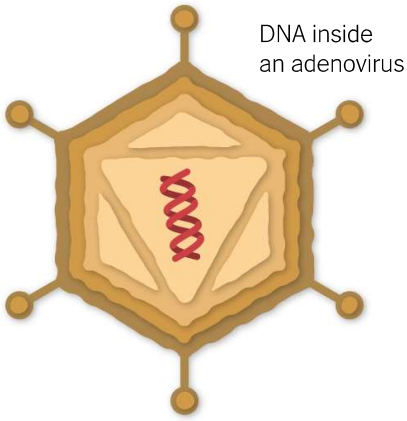
The SARS-CoV-2 virus is studded with proteins that it uses to enter human cells. These so-called spike proteins make a tempting target for potential vaccines and treatments.



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.

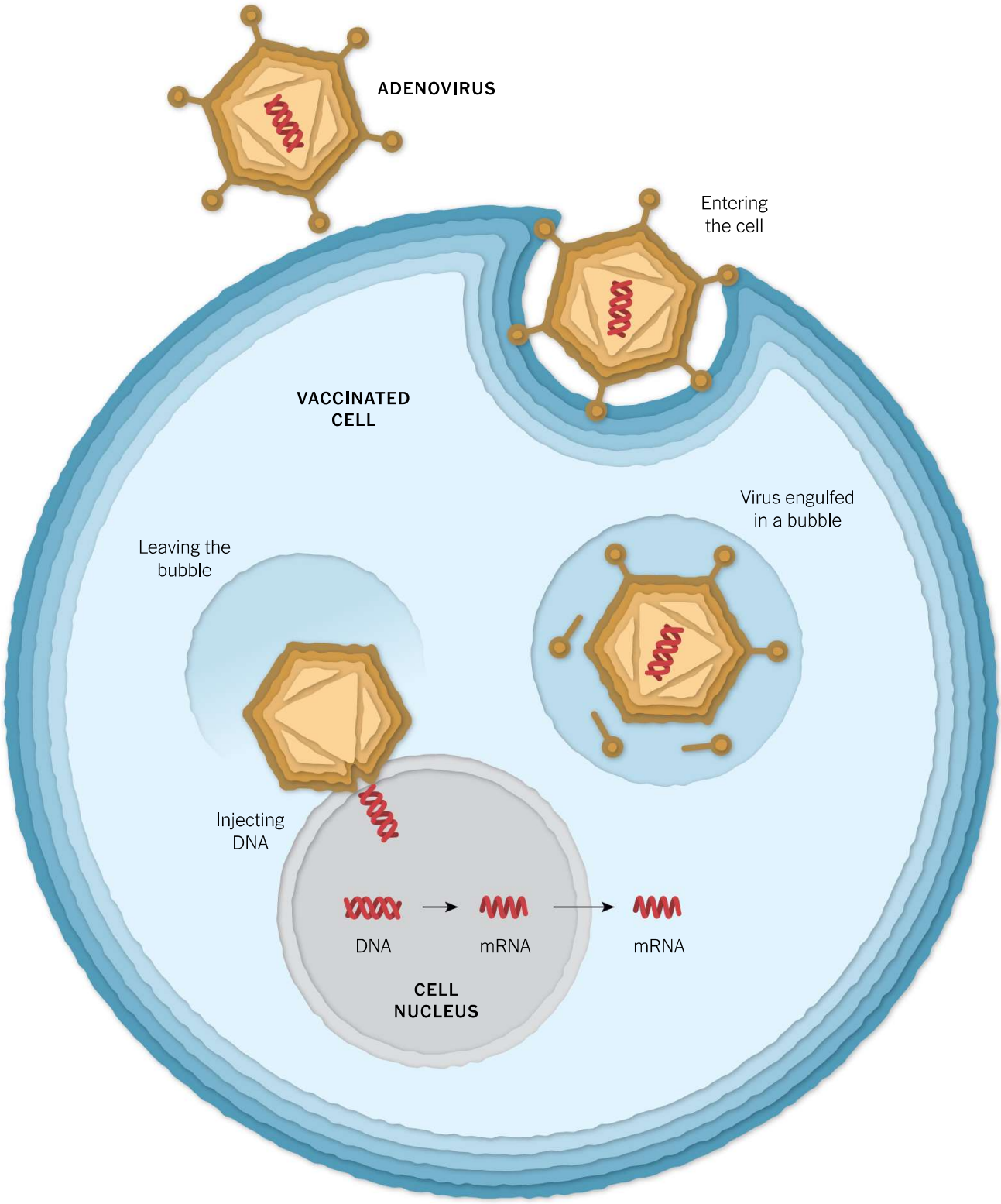


Johnson & Johnson's vaccine comes out of decades of research on adenovirus-based vaccines. In July, the first one was approved for general use — a vaccine for Ebola, also made by Johnson & Johnson. The company is also running trials on adenovirus-based vaccines for other diseases, including H.I.V. and 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

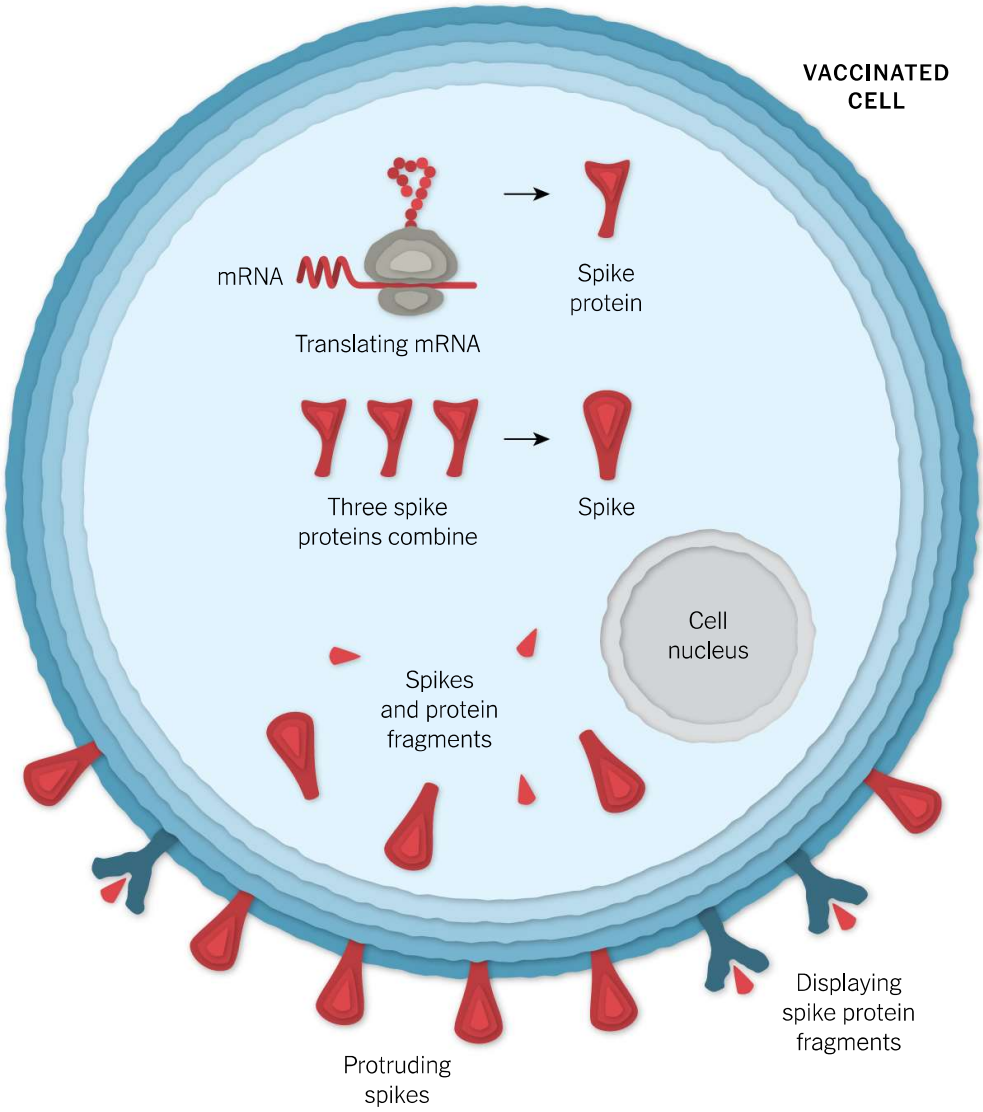
After the vaccine is injected into a person's arm, the adenoviruses bump into cells and latch onto proteins on their surface. The cell engulfs the virus in a bubble and pulls it inside. Once inside, the adenovirus escapes from the bubble and travels to the nucleus, the chamber where the cell's DNA is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

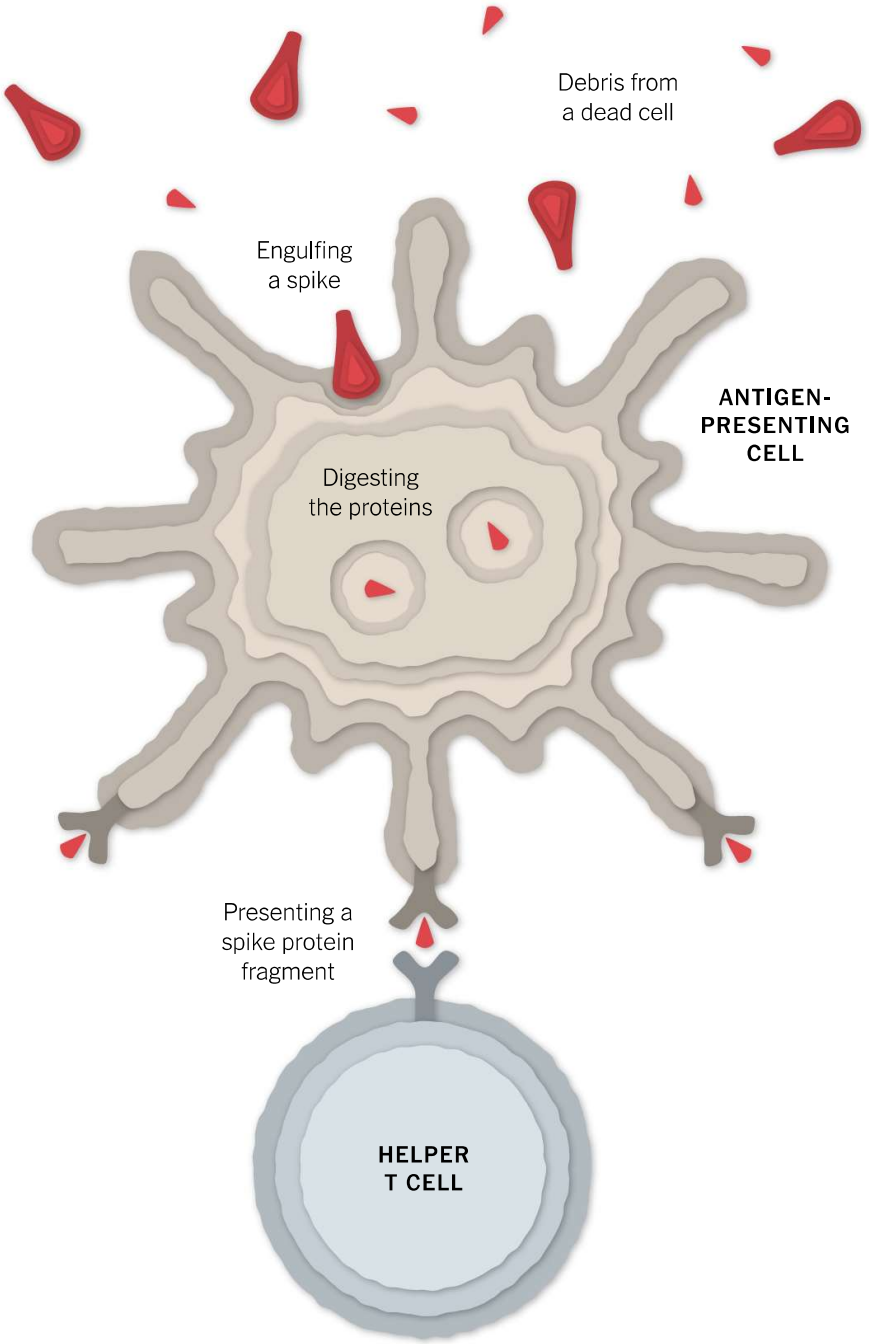


Some of the spike proteins produced by the cell form spikes that migrate to its surface and stick out their tips. The vaccinated cells also break up some of the proteins into fragments, which they present on their surface. These protruding spikes and spike protein fragments can then be recognized by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

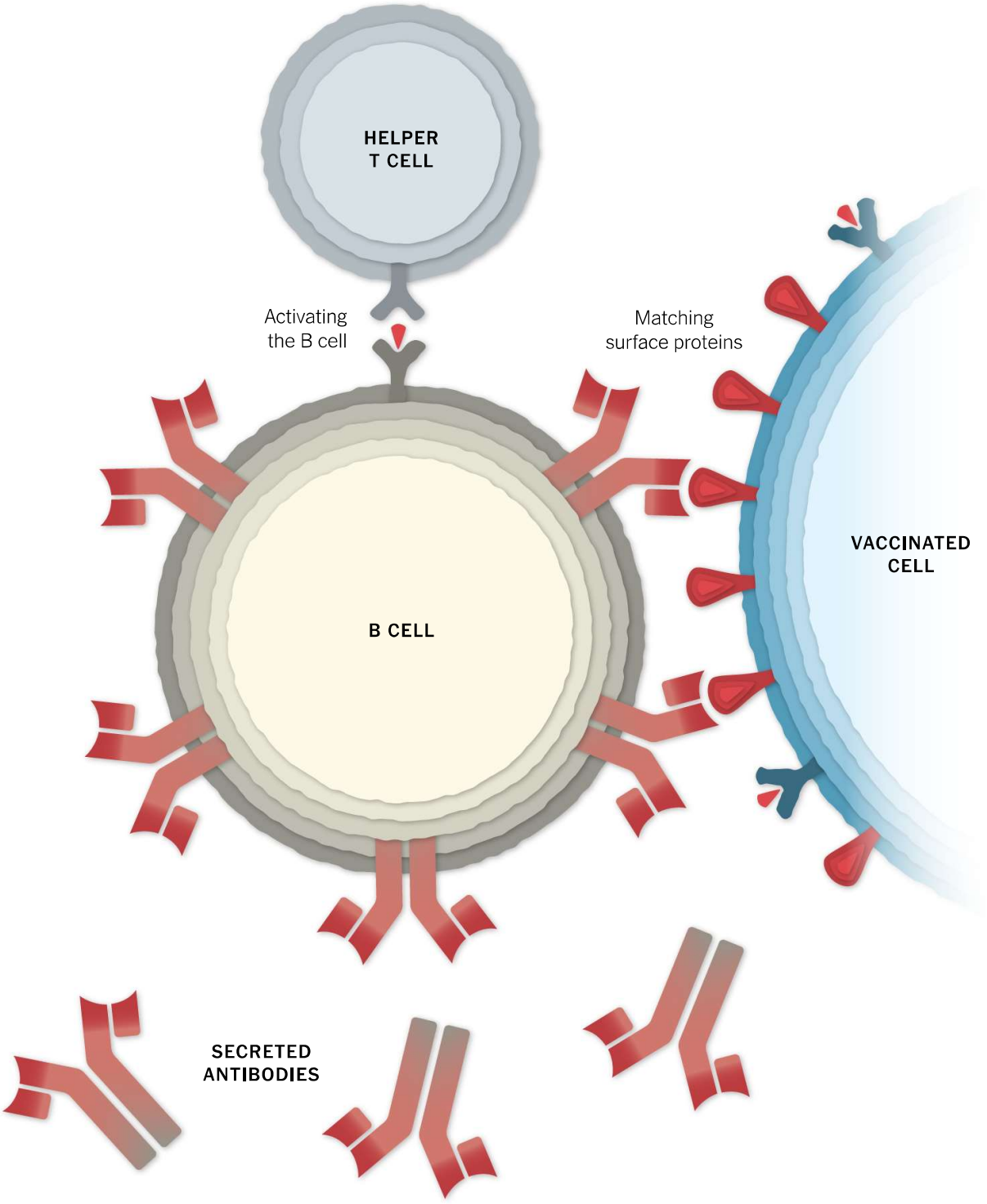
When a vaccinated cell dies, the debris contains spike proteins and protein fragments that can then be taken up by a type of immune cell called an antigen-presenting cell.



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.

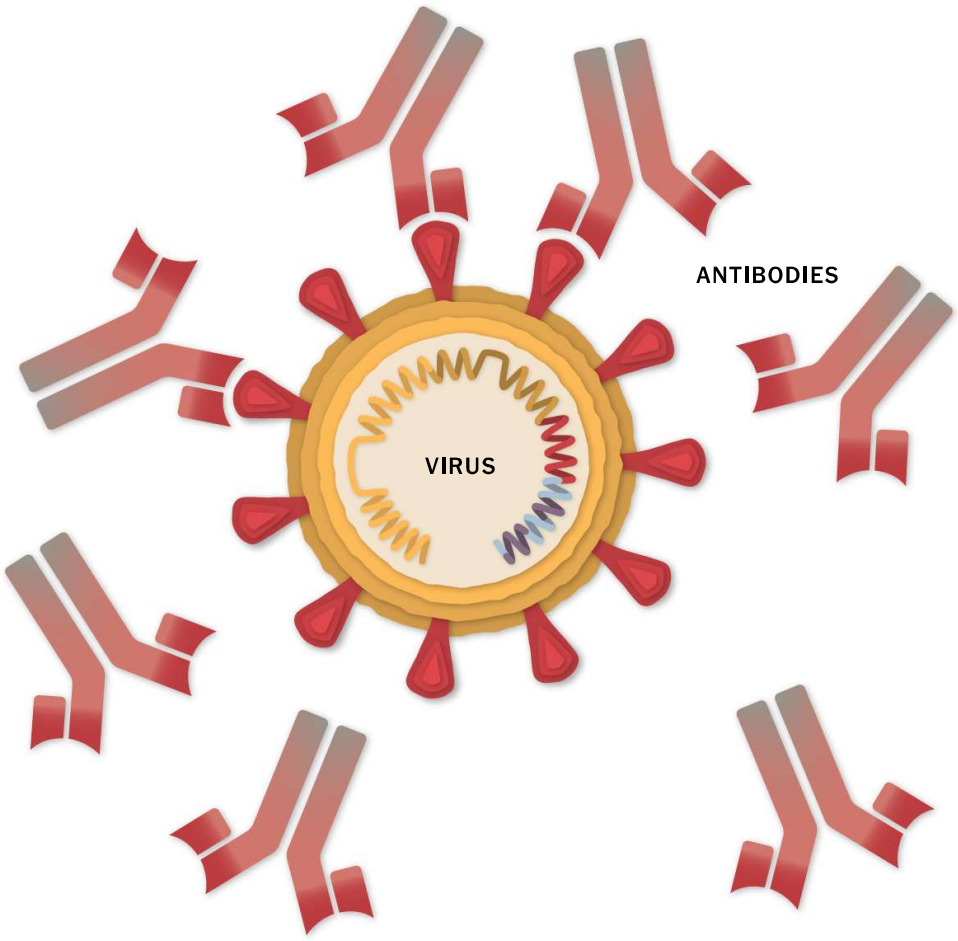
Making Antibodies

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.



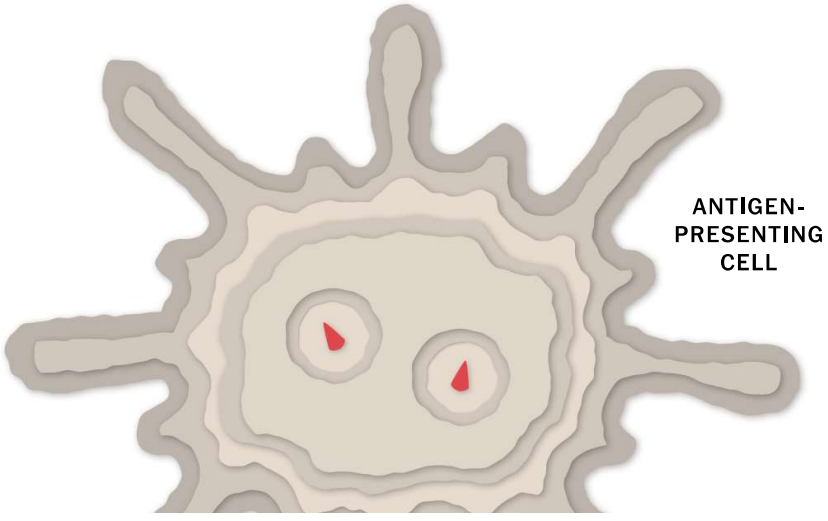
Stopping the Virus

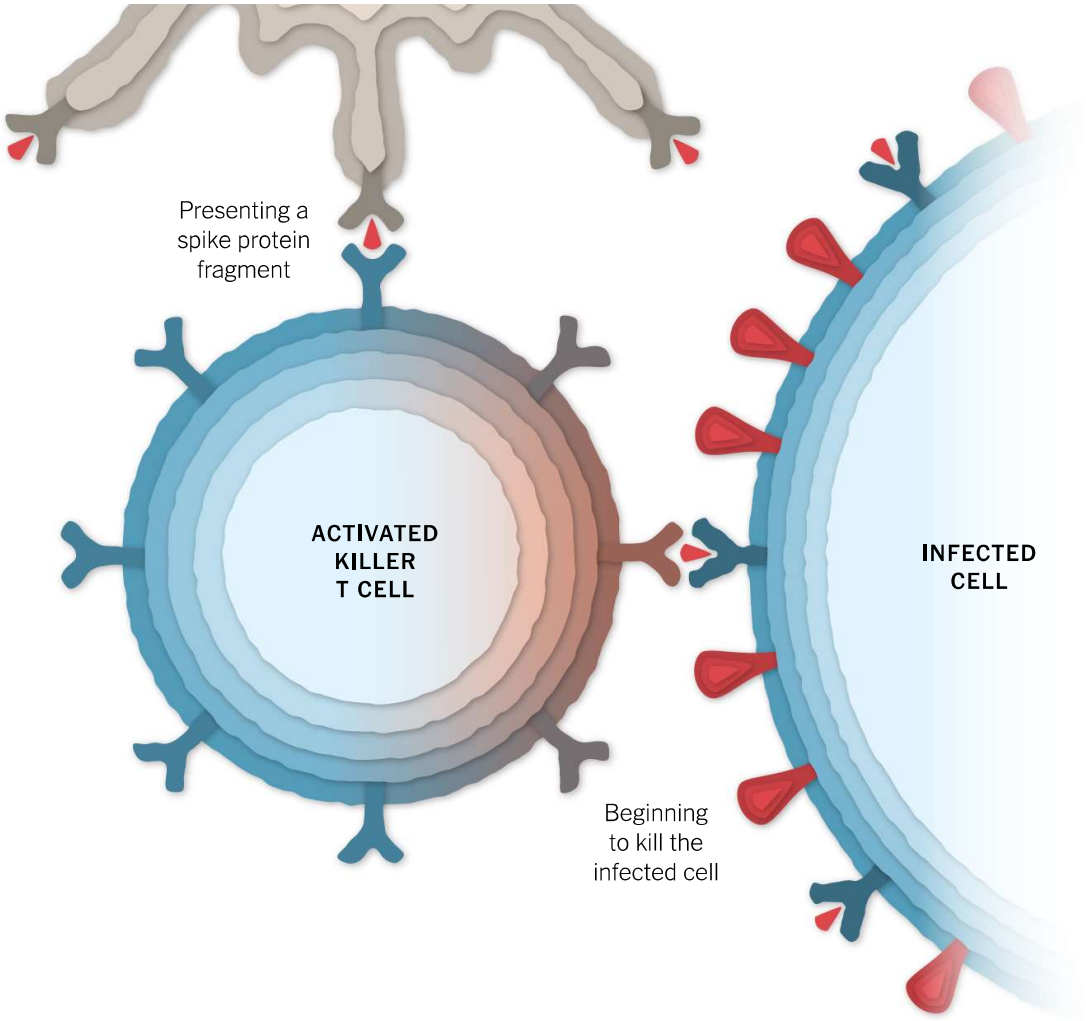
The antibodies can latch onto coronavirus spikes, mark the virus for destruction and prevent infection by blocking the spikes from attaching to other cells.



Killing Infected Cells

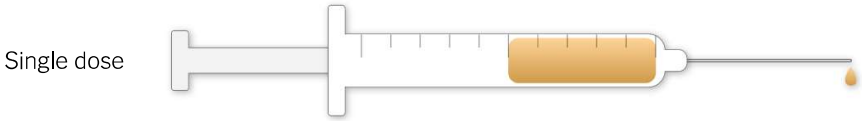
The antigen-presenting cells can also activate another type of immune cell called a killer T cell to seek out and destroy any coronavirus-infected cells that display the spike protein fragments on their surfaces.





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

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

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

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

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

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

THE UNITED STATES DEPARTMENT of JUSTICE
STICE 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

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.

THE UNITED STATES DEPARTMENT of JUSTICE
STICE 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.

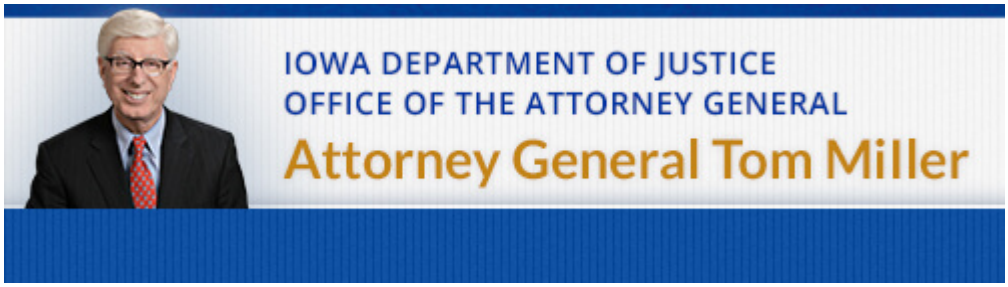
The civil settlements described above resolve multiple lawsuits filed under the qui tam, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the government and to share in any recovery. From the federal government's share of the civil 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



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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THE UNITED STATES DEPARTMENT of JUSTICE
STICE 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

THE UNITED STATES DEPARTMENT of JUSTICE
STICE 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

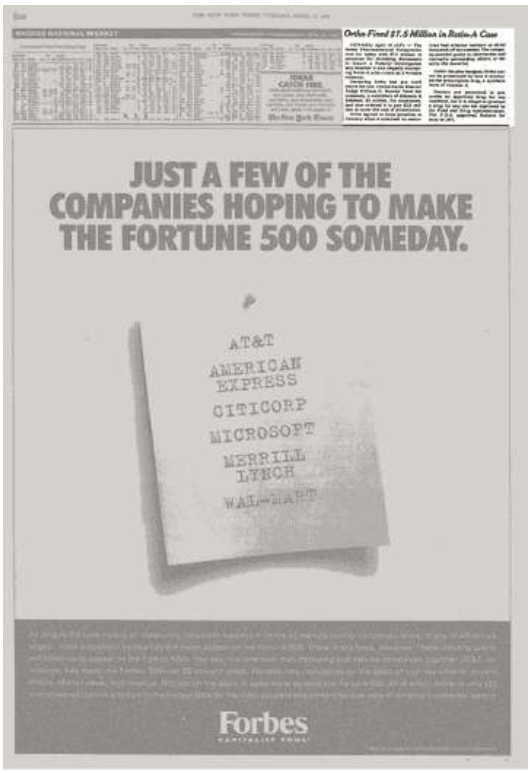
Press Release Number:
15-289

Updated March 10, 2015

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

This is a digitized version of an article from The Times's print archive, before the start of online publication in 1996. To preserve these articles as they originally appeared, The Times does not alter, edit or update them.

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

United States Senate
Committee on Finance

Sen. Chuck Grassley · Iowa
Ranking Member

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Statement of U.S. Senator Chuck Grassley of Iowa
The Adequacy of FDA Efforts to Assure the Safety of the Drug Supply
Subcommittee on Oversight and Investigations
House of Representatives Committee on Energy and Commerce
Tuesday, February 13, 2007

Chairman Dingell, Chairman Stupak, Ranking Members Barton and Whitfield and distinguished colleagues, thank you for holding this important hearing on drug safety and the Food and Drug Administration. Thank you also for inviting me to speak today on this important subject.

During the last three years, I conducted extensive oversight of the Food and Drug Administration while I was Chairman of the Senate Finance Committee, which is responsible for Medicare and Medicaid. I view my role as working to ensure the safety and well-being of the more than 80 million Americans who are beneficiaries of these programs. The Medicare and Medicaid programs spend a lot of money on prescription drugs and medical devices, and that money should be spent on drugs and devices that are safe and effective.

In the course of my oversight of the federal bureaucracy, I have developed many good relationships with whistleblowers. And it was FDA whistleblowers and concerned FDA scientists who first drew my attention to problems at the Food and Drug Administration.

It started in early 2004 with an FDA psychiatrist named Dr. Andrew Mosholder, who realized through his work that there was a serious suicide risk for teenagers taking certain antidepressants. He wanted to make a presentation about his findings to an FDA advisory committee. But for some reason, FDA supervisors didn't want this information to get out. They canceled Dr. Mosholder's presentation and instructed him to write a script approved by his supervisors that he would use if anybody asked him why he was no longer presenting.

That fall, I held a hearing on drug safety in the aftermath of Vioxx - the blockbuster pain medication - being pulled from the market by its manufacturer, rather than the Food and Drug Administration. The testimony at my hearing turned a bright spotlight on problems with the FDA's postmarket surveillance effort. The FDA works tirelessly, as it should, to approve new life-saving and life-enhancing drugs. But it could do a lot better job of keeping track of

developments with these drugs after they're on the market. Reviewing what happened inside the FDA with Vioxx, and in working with a number of whistleblowers who bravely stuck their necks out and came to me after that landmark hearing, I've identified problems at the FDA that consistently fit into a few themes.

First, scientific dissent is discouraged, quashed, and sometimes muzzled inside the Food and Drug Administration. Second, the FDA's relationship with drug makers is too cozy. The FDA worries about smoothing things over with industry much more than it should with its regulatory responsibilities. Third, inside the FDA there's widespread fear of retaliation for speaking up about problems. And fourth, the public safety would be better served if the agency was more transparent and forthcoming about drug safety and drug risks.

These problems involve the culture of the Food and Drug Administration. They're not isolated but systemic. And they can be partly attributed to the organizational structure of the FDA.

My concerns are not isolated either. During the last year, they've been validated by the highly regarded Institute of Medicine, as well as the independent Government Accountability Office and respected medical journals. What's at stake is public safety and public confidence in our nation's world-renowned Food and Drug Administration.

My investigations of FDA issues have also revealed a deeply troubling disregard for Congress' responsibility to conduct oversight of the executive branch of government. The FDA and the Department of Health and Human Services have put up so much resistance to my effort to find out what happened inside the FDA with a relatively new antibiotic called Ketek that I can only wonder what there is to cover up.

Every excuse under the sun has been used to create roadblocks, even in the face of Congressional subpoenas requesting information and access to FDA employees.

In denying access to documents responsive to the subpoenas, the Department and FDA have claimed "prosecutorial deliberative process," "confidential communications," and "agency prerogative to determine who will be interviewed or testify before a jurisdictional committee." Yet, during my years in the Senate, my investigators have obtained access to every single one of these categories of so-called confidential information from HHS as well as other executive branch agencies.

Furthermore, I asked the Congressional Research Service to look into the Department's policies regarding this matter and CRS told me that there is "no legal basis" for the Department's executive branch assertions.

Nevertheless, the Department and FDA not only withheld documents that do not appear to be privileged, but they also won't say what has been withheld and why. The subpoenas compel a privilege log, but the Department and FDA will not provide one.

The Department and FDA say that they have been responsive to the Finance Committee's Ketek investigation because they made available millions of pages of documents to the Committee. But what they provided is quantity, not quality.

They delivered hundreds of pages simply marked, for example, "57 pages removed," or "43 pages removed." (see attachments 1-5) Other documents have whole pages, paragraphs or sentences redacted with no explanation for what has been withheld or redacted and why. In fact, the FDA redacted some of the same documents differently and even redacted one of my own letters to them on a different matter (see attachment 6)

When I point out the absurdities in the Department's responses to my requests for documents and interviews related to Ketek, the Department argues it could not provide access to information and individuals related to open criminal investigations. But I didn't ask for access to open criminal investigations; I don't want to jeopardize a criminal matter. The Department and the FDA know that, yet they keep using that excuse anyway.

Even so, what I've learned about what happened with Ketek troubles me. I've learned that:

- FDA gave its advisory committee questionable data on Ketek and did not tell them about problems with that data. I sent a letter to the FDA in December regarding my findings on this matter and am awaiting a response from the agency.
- FDA approved Ketek without much safety data from the U.S.; the agency relied almost exclusively on foreign, post-marketing safety data; and
- Ketek's sponsor in all likelihood was aware of the fact that it submitted some questionable data to the FDA regarding its large safety study; the sponsor was informed of problems with one of the study sites prior to data submission to the FDA. However, according to FDA reviewers, the sponsor never raised these problems to the FDA. FDA learned about them after its own investigators inspected the site.

I plan to continue my investigation of Ketek and issue more reports. But I am heartened to hear that FDA came to a decision yesterday that mirrors the recommendations of its internal scientists as well as its advisory committees.

During the last three years, I've also tried to work in a productive way with the Commissioners and Acting Commissioners of the FDA. It will take bold leadership to get on top of the FDA's troubles and turn the agency around. So far, the lip service has been fine. The reality a lot less so.

Last month, Senator Chris Dodd and I reintroduced two reform bills that we first proposed in 2005 to get at the safety shortcomings of the FDA. Our first bill would elevate and empower the office with the FDA that is responsible for monitoring FDA-approved drugs after they're on the market. It would make the "postmarket drug safety" function independent within the FDA, instead of under the thumb of the office and center that puts the drugs on the market in the first place, the way it is today.

Chairman Dingell, the Wall Street Journal has reported that you're intrigued by the idea of a drug safety center within the FDA. I appreciate that view. It doesn't make any sense that the FDA officials who are supposed to monitor the safety of a drug on the market serve only as consultants to the FDA officials who approved the drug in the first place. The officials who approved the drug would obviously be conflicted in making a judgment that approval is no longer appropriate or was a mistake in the first place. A separate center for drug safety within the FDA is a vital lynchpin when it comes to meaningful reform and improvement of the agency's postmarket surveillance work.

The second bill that Senator Dodd and I introduced would expand an existing public database by mandating the registry of all clinical trials and the results of those trials. This reform is key to establishing greater transparency regarding clinical trials, the good ones and the bad ones, and to holding drug makers and drug regulators accountable.

Both of these legislative initiatives would make drug information used by doctors and patients more complete and more accessible. American consumers should not have to second guess the safety of the pills in their medicine cabinets.

I appreciate the attention all of you are giving to this important national issue with this hearing. You will hear from some of the heroic whistleblowers who have helped my work, without whom my work wouldn't have been possible. Two of the whistleblowers have left the FDA. It's a tremendous loss for our country when an agency like the Food and Drug Administration gets so dysfunctional that specialists like these whistleblowers are forced to leave the agency to avoid retaliation. I want to work closely with you to make sure FDA whistleblowers can communicate to Congress without fear.

In addition, the existing agreement between the Inspector General for the Department of Health and Human Services and the Food and Drug Administration gives too much power to the FDA when it comes to how allegations of criminal misconduct by FDA employees are investigated. That agreement should be revisited by reform minded leaders in Congress. (see attachment 7)

I look forward to reform opportunities in the year ahead. There's no doubt that the FDA needs additional tools and resources to do its work. The FDA also needs an overhaul to make the agency more transparent, more forthcoming, and more independent-minded.

I look forward to working with this Committee and in particular with you, Chairmen Dingell and Stupak and Ranking Members Barton and Whitfield, as well as my colleagues in the Senate to enact reforms at the FDA. Thank you.

EDMOND J. SAFRA
Center for Ethics

Donald Light

Light received a BA in history from Stanford, an MA in sociology from the University of Chicago, and a PhD in sociology from Brandeis. His research at the Center concerned the historical roots of institutional corruption in the development of prescription drugs and its consequences.

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EDMOND J. SAFRA
Center for Ethics

Risky Drugs: Why The FDA Cannot Be Trusted

July 17, 2013

*by **Donald W. Light***

A **forthcoming article** for the special issue of the *Journal of Law, Medicine and Ethics* (JLME), edited by Marc Rodwin and supported by the Edmond J. Safra Center for Ethics, presents evidence that about 90 percent of all new drugs approved by the FDA over the past 30 years are little or no more effective *for patients* than existing drugs.

All of them may be better than indirect measures or placebos, but most are no better for patients than previous drugs approved as better against these measures. The few superior drugs make important contributions to the growing medicine chest of effective drugs.

The bar for "safe" is equally low, and over the past 30 years, approved drugs have caused an epidemic of harmful side effects, even when properly prescribed. Every week, about 53,000 excess hospitalizations and about 2400 excess deaths occur in the United States among people taking properly prescribed drugs to be healthier. One in every five drugs approved ends up causing serious harm,[1] while one in ten provide substantial benefit compared to existing, established drugs. This is the opposite of what people want or expect from the FDA. Prescription drugs are the 4th leading cause of death. Deaths and hospitalizations from over-dosing, errors, or recreational drug use would increase this total. American patients also suffer from about 80 million mild side effects a year, such as aches and pains, digestive discomforts, sleepiness or mild dizziness.

The forthcoming article in JLME also presents systematic, quantitative evidence that since the industry started making large contributions to the FDA for reviewing its drugs, as it makes large contributions to Congressmen who have promoted this substitution for publicly funded regulation, the FDA has sped up the review process with the result that drugs approved are significantly more likely to cause serious harm, hospitalizations, and deaths. New FDA policies are likely to increase the epidemic of harms. This will increase costs for insurers but increase revenues for providers.

This evidence indicates why we can no longer trust the FDA to carry out its historic mission to protect the public from harmful and ineffective drugs. Strong public demand that government "do something" about periodic drug disasters has played a central role in developing the FDA.[2] Yet close, constant contact by companies with FDA staff and officials has contributed to vague, minimal criteria of what "safe" and "effective" mean. The FDA routinely approves scores of new minor variations each year, with minimal evidence about

risks of harm. Then very effective mass marketing takes over, and the FDA devotes only a small percent of its budget to protect physicians or patients from receiving biased or untruthful information.[3][4] The further corruption of medical knowledge through company-funded teams that craft the published literature to overstate benefits and understate harms, unmonitored by the FDA, leaves good physicians with corrupted knowledge.[5] [6] Patients are the innocent victims.

Although it now embraces the industry rhetoric about “breakthrough” and “life-saving” innovation, the FDA in effect serves as the re-generator of patent-protected high prices for minor drugs in each disease group, as their therapeutic equivalents lose patent protection. The billions spent on promoting them results in the **Inverse Benefit Law**: the more widely most drugs are marketed, the more diluted become their benefits but more widespread become their risks of harm.

The FDA also legitimates industry efforts to lower and widen criteria prescribing drugs, known by critics as “**the selling of sickness.**” Regulations conveniently prohibit the FDA from comparing the effectiveness of new drugs or from assessing their cost-effectiveness. Only the United States allows companies to charge what they like and raise prices annually on last year’s drugs, without regard to their added value.[7]

A New Era?

Now the FDA is going even further. The New England Journal of Medicine has published, without comment, proposals by two senior figures from the FDA to loosen criteria drugs that allege to prevent Alzheimer’s disease by treating it at an early stage.[8] The authors seem unaware of how their views about Alzheimer’s and the role of the FDA incorporate the language and rationale of marketing executives for the industry. First, they use the word “disease” to refer to a hypothetical “early-stage Alzheimer’s disease” that supposedly exists “before the earliest symptoms of Alzheimer’s disease are apparent.” Notice that phrasing assumes that the earliest symptoms will become apparent, when in fact it’s only a hypothetical model for claiming that cognitive lapses like not remembering where you put something or what you were going to say are signs of incipient Altzheimer’s disease. The proposed looser criteria would legitimate drugs as “safe and effective” that have little or no evidence of being effective and expose millions to risks of harmful side effects.

No proven biomarkers or clinical symptoms exist, the FDA officials note, but nevertheless they advocate accelerated approval to allow “drugs that address an unmet medical need.” What “unmet need"? None exists. This market-making language by officials who are charged with protecting the public from unsafe drugs moves us towards the 19-century hucksterism of peddling cures of questionable benefits and hidden risks of harm, only now fully certified by the modern FDA.[9]

The main reason for advocating approvals of drugs for an unproven need with unproven benefits, these FDA officials explain, is that companies cannot find effective drugs for overt Alzheimer’s. Their drug-candidates have failed again and again in trials. The core rationale of the proposed loosening of criteria is that “the focus of drug development has sifted to earlier stages of Alzheimer’s disease…and the regulatory framework under which such therapies are evaluated should evolve accordingly.” Yet they admit there are no “therapies” in this much larger market where (with the help of the industry-funded FDA) companies will not have to

prove their drugs are effective. In fact, these FDA officers propose to approve the drugs without ever knowing if they are therapeutic or not. Their commercialized language presumes the outcome before starting. The job of the FDA, it seems, is to help drug companies open up new markets to increase profits for the FDA's corporate paymasters.

These two FDA officials maintain that "the range of focus must extend to healthy people who are merely at risk for the disease but could benefit from preventive therapies." Yet they admit we do not know who is "at risk," nor whether there is a "disease," nor whether anyone "could benefit," nor whether the drugs constitute "preventive therapies." Similar FDA-encouraged shifts have been made for drugs treating pre-diabetes, pre-psychosis, and pre-bone density loss, with few or no benefits to offset risks of harm. This week, based on policy research at the Edmond J. Safra Center for Ethics, **a letter of concern** was published in the New England Journal of Medicine. The authors write that approval for drugs to treat "early stage Altzheimer's disease" must meet "a much higher bar – evidence of slowed disease progression." But without clinical manifestations or biomarkers for an alleged disease, how will such progression be measured?

Advice to readers: Experienced, independent physicians recommend not to take a new drug approved by the FDA until it is out for 7 years, unless you have to, so that evidence can accumulate about its real harms and benefits.[10]

Disclaimer: The assessment and views expressed here are solely the author's and do not necessarily reflect those of persons or institutions to which he is associated. The comments and suggestions of Gordon Schiff, an expert in prescribing at Brigham and Women's Hospital, and Robert Whitaker are gratefully acknowledged.

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See also: **Public Health**, **Donald Light**

gencer

COVID-19 | UPDATED APR. 1, 2021

CDC Data Suggests Vaccinated Don't Carry, Can't Spread Virus

By Paola Rosa-Aquino

The good news keeps coming. Photo: Grant Hindsley/AFP via Getty Images

After warning for months that vaccinated people should still be cautious in order to not infect others, the Centers for Disease Control and Prevention suggests they may not be at much risk of transmitting the coronavirus.

"Vaccinated people do not carry the virus — they don't get sick," Dr. Rochelle Walensky, director of the CDC, told MSNBC's Rachel Maddow on Tuesday. That's "not just in the clinical trials, but it's also in real-world data."

Walensky was referring to a new CDC study that suggests those fully inoculated with the vaccines produced by Moderna and Pfizer don't transmit the virus. Researchers looked at how the shots protected nearly 4,000 health-care workers, first responders, and other essential workers toiling in eight U.S. locations against the virus and more-contagious variants. Following a single dose of either vaccine, the participants' risk of infection was reduced by 80 percent, and that figure jumped to 90 percent after the second dose. Without infection, people are unable to spread the virus. The results are similar to what scientists saw in clinical trials for the vaccines, which found that two doses of either two-dose vaccine had an efficacy rate of around 95 percent.

The study is the agency's first to analyze how well the vaccines worked among working-age front-line adults, who are at a higher risk of being exposed to the virus and spreading it. "These findings should offer hope to the millions of Americans receiving COVID-19 vaccines each day and to those who will have the opportunity to roll up their sleeves and get vaccinated in the weeks ahead," Dr. Rochelle Walensky, director of the CDC, said in a statement. "The authorized vaccines are the key tool that will help bring an end to this devastating pandemic." Still, the CDC has not issued new guidance on how the vaccinated should behave; its current guidance is that they continue to take precautions such as masking.

Though the study is an impressive piece of evidence of the effectiveness of the Moderna and Pfizer vaccines, some public-health experts pushed back on Walensky's pandemic-changing takeaway. "There cannot be any daylight between what the research shows — really impressive but incomplete protection — and how it is described," Dr. Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center, told the New York *Times* on Thursday. "This opens the door to the skeptics who think the government is sugarcoating the science," Bach added, "and completely undermines any remaining argument why people should keep wearing masks after being vaccinated."

Even the Centers for Disease Control hedged on Walensky's claims. "Dr. Walensky spoke broadly during this interview," a CDC spokesperson told the *Times*. "It's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. We are continuing to evaluate the evidence."

More than 142 million doses of the Moderna and Pfizer vaccines have been administered in the U.S. as of March 30, according to the CDC. The third vaccine currently on the American market is a single-dose shot made by Johnson & Johnson, which was shown to be 66 percent effective in thwarting moderate to severe COVID-19-related illness.

This post has been updated to reflect a statement from the CDC provided to the New York Times.

TAGS: COVID-19 COVID-19 VACCINES CDC

44 COMMENTS

Fact check: Four times Walensky's comments were out of step with CDC guidance

By Holmes Lybrand
Updated 5:20 PM ET, Fri May 21, 2021

Dana Bash presses Walensky on CDC guidance 02:25

Washington (CNN) — Since the early days of her time as Director for the Centers for Disease Control and Prevention, Dr. Rochelle Walensky has made comments and claims over Covid-19 guidance that her own agency, and sometimes the White House, have walked back or toned down.

While some of Walensky's comments might be explained by the gap between more conversational language and official written recommendations, the CDC under President Joe Biden has been criticized for its guidance in the past -- for either being too conservative or too lenient. Thus, the whiplash from Walensky's comments and the subsequent clarifications and revisions might help explain a lack of public confidence that exists among Americans toward the agency.

Vaccinated people spreading Covid

Most recently, Walensky told a Senate committee Wednesday that data now shows fully vaccinated individuals can't pass Covid-19 to other people.

vaccinated people and masks.

The CDC's website, however, continues to say that vaccines only "reduce the risk of people spreading COVID-19" not that people "can't" spread it post-vaccination. The CDC did not respond to CNN's request for clarification.

With the confusion and concern by some over the CDC's new guidance that fully vaccinated people don't need to wear masks in most circumstances, the level of likelihood that a vaccinated person might still be able to spread Covid-19 remains a key question for many Americans. Experts suggest it's incredibly rare, though not entirely impossible. Walensky spoke in more general terms on Wednesday and perhaps created more confusion in doing so.

This is not the first time Walensky has used less precise language than the CDC on whether vaccinated people can spread Covid-19.

On March 29, Walensky told MSNBC that "Our data from the CDC today suggests that vaccinated people do not carry the virus, don't get sick."

"(A)nd that it's not just in the clinical trials," the director added, "but it's also in real world data."

Three days later, on April 1, a CDC spokesperson seemingly walked back the director's comments, telling The New York Times "Dr. Walensky spoke broadly during this interview" adding that "It's possible that some people who are fully vaccinated could get Covid-19. The evidence isn't clear whether they can spread the virus to others. We are continuing to evaluate the evidence."

On April 27 the CDC updated its guidance for people who are fully vaccinated, saying those individuals can now unmask at small outdoor gatherings and when dining outside with friends from multiple households. The agency still says fully vaccinated people should avoid large indoor gatherings and wear a mask at crowded, outdoor events.

Covid vaccine for pregnant people

Another point of contradiction and confusion occurred when Walensky seemed to make a new announcement on CDC guidance for pregnant people during a White House Covid-19 briefing on April 23.

The "CDC recommends that pregnant people receive the Covid-19 vaccine," Walensky said. CDC guidance, however, does not recommend that pregnant people receive the vaccine, instead it says that they "can" get the vaccine and says there is limited data on pregnant people and the vaccines.

The comment came after a study from the CDC found no safety concerns among a group of pregnant people who had received the Pfizer or Moderna Covid-19 vaccine during their third trimester.

"We know that this is a deeply personal decision," Walensky continued, "and I encourage people to talk to their doctors or primary care providers to determine what is best for them and for their baby."

As CNN noted at the time, the CDC guidance had not changed to match Walensky's recommendation. The agency's website currently says those pregnant "can receive a COVID-19 vaccine" but stops short of recommending pregnant people get vaccinated, as Walensky said.

After reaching out to the CDC several times for further clarification, the CDC told CNN in an email on April 27, "pregnant people are eligible and can receive a Covid-19 vaccine, which has always been and remains CDC's recommendation." The agency did not directly address Walensky's comment.

"Additional follow-up is needed, including follow up of those vaccinated in the first and second trimester of pregnancy; however, these preliminary findings are reassuring," the email said.

During the heated debate earlier this year over reopening schools for in-person learning, Walensky made news when she said in a press briefing on February 3 that data suggested schools could reopen safely and do so without teachers needing to be vaccinated.

"I also want to be clear that there is increasing data to suggest that schools can safely reopen," she said, "and that that safe reopening does not suggest that teachers need to be vaccinated in order to reopen safely."

The next day the White House pushed aside the director's comments.

When asked about Walensky's remarks, White House press secretary Jen Psaki told reporters the director "spoke to this in her personal capacity."

"Obviously, she's the head of the CDC, but we're going to wait for the final guidance to come out so we can use that as a guide for schools around the country," Psaki said.

The Biden administration has pushed for teachers to receive the vaccine but has not recommended it as a requirement before returning to in-person learning.

The CDC has faced enormous pressure since the start of the pandemic, both politically and publicly, with each step being scrutinized by people across the political spectrum. As the pandemic has started into its second year, the agency is clearly still struggling to provide clear guidance to battle the virus.

CNN's Jacqueline Howard contributed to this article.