From: Lamary, Mary
Sent: Friday, October 1, 2021 8:04 AM
To: Reed, Tim
Cc: Silk, Anne
Subject: FW: Request to Exercise My Right to Refusal Granted under Title 21 Part E Section 360bbb

Good Morning Mr. Reed:

Your email was sent to me by Anne Silk, our reasonable accommodations coordinator. Thank you for reaching out. While we understand your position, the President- through Executive Order- has required vaccinations for all federal employees as one measure to combat the pandemic. While you may be sincere in your position, it is contrary to a government-wide executive order and does not meet one of the narrow exceptions for a medical or religious accommodation. Please see the NRC SharePoint site for re-entry here: https://usnrc.sharepoint.com/teams/COVID-19Information2

In addition, you can find additional information at the Safer Federal Workforce site, particularly the FAQs on vaccinations here: https://www.saferfederalworkforce.gov/faq/vaccinations/

Regards,
Mary Lamary
Chief Human Capital Officer

From: Silk, Anne <Anne.Silk@nrc.gov>
Sent: Wednesday, September 29, 2021 4:27 PM
To: Reed, Tim <Timothy.Reed@nrc.gov>
Cc: McAllister, Tonishia <Tonishia.McAllister@nrc.gov>; Dixon-Herrity, Jennifer <Jennifer.Dixon-Herrity@nrc.gov>
Subject: RE: Request to Exercise My Right to Refusal Granted under Title 21 Part E Section 360bbb

Hi Tim,

Thank you for this revised request. We are reviewing and will be back in touch with you.

Anne

From: Reed, Tim <Timothy.Reed@nrc.gov>
Sent: Wednesday, September 29, 2021 1:59 PM
To: Silk, Anne <Anne.Silk@nrc.gov>
Cc: McAllister, Tonishia <Tonishia.McAllister@nrc.gov>; Dixon-Herrity, Jennifer <Jennifer.Dixon-Herrity@nrc.gov>
Subject: RE: Request to Exercise My Right to Refusal Granted under Title 21 Part E Section 360bbb

Anne:

Based on this morning's ET chat, I would like to revise my request for two reasons. First there confusion surrounding the Pfizer and Comirnaty injections being legally separate so I added some additional information to address that issue. Also, a number of efforts have been made to

get the Comirnaty injection, and in all cases there is no availability which also confirms the information provided. Secondly, I wanted to add additional language that makes it more explicit regarding what I conclude is the proper and legal implementation of Executive Order 14043. Thanks for your time and patience.

Tim

Here is the revised request:

I am requesting to exercise my right for refusal provided under Title 21 from the Executive Order issued on September 9, 2021 entitled "Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" [https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/] on the following basis.
There are at present only three experimental DNA or mRNA injections available to the American public. All three are authorized for emergency use (EUA) only (i.e., the only FDA-approved injection is an mRNA injection referred to as Comirnaty and it is a separate and distinct legal entity from the existing Pfizer mRNA injection and Comirnaty is not currently available in the United States). Pertinent portions of Executive Order 14043 state the following the following (highlights added):

> **"Sec. 2**. *Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees.* Each agency shall implement, to the extent **consistent with applicable law**, a program to require COVID-19 vaccination for all of its Federal employees, with exceptions only as required by law."
> **"Sec. 4**. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:
>
> (i) the authority granted by law to an executive department or agency, or the head thereof; or
>
> (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
>
> (b) **This order shall be implemented consistent with applicable law** and subject to the availability of appropriations."

In order to implement Executive Order 14043 properly (consistent with applicable law), and in recognition that at present only the experimental injections authorized for emergency use are available, then the applicable law that applies to these EUA vaccines is (pertinent portion quoted in whole):

> "United States Code (USC) Title 21 "Food and Drugs," Part E "General Provisions Related to Drugs and Devices," Section 360bbb-3 "Authorization for medical products for use in emergencies," Section 360bbb-3(e)(1)(A)(ii):
> "(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

In an effort to apply this law and comply with the EO, I have informed myself concerning the known adverse conditions by reviewing the Vaccine Adverse Events Reporting System (VAERS) and by educating myself concerning these experimental injections by listening to experts such as Dr. Luc Montagnier, Dr. Peter McCullough, Dr. Richard Fleming, Dr. Geert Vanden Bossche, Dr. Sucharit Bakdi, Dr. Lee Merritt, Dr. Pierre Kory, Dr. Vladimir Zelenko, Dr. Simone Gold, Professor Francis Boyle, Dr. Michael Yeadon, Dr. Charles Hoffe, and Reiner Fullmich.

Accordingly, based on the understanding I have acquired, I now conclude that I am sufficiently informed to make an informed decision (as required by Title 21 -specifically provision 21 U.S.C Part E Section 360bbb-3(ii)(II)) on whether to participate in the experimental trial. I have concluded that there are clearly devastating side effects associated with these experimental injections (i.e., historic numbers of deaths, greater than the sum total of deaths for all vaccines issued in the US the last 30 years as measured by VAERS). There is no evidence that the longer-term effects have been solved. Trials during the last 20 years led to between 20 and 100 percent death in previous animals for similar novel vaccines (i.e., similar in the design to use mRNA sequences that create the pathogen that then induces antibodies to attack the virus). To be clear these mRNA vaccines have never been successful in the longer term for animals or for humans, and for humans there have been no long terms trials completed to date. The human trials that may give a window into this issue are ongoing.

We are now just beginning to enter the longer term in the ongoing experimental trials on humans. Based on all the available information, and the expert advice from the aforementioned people, several of which are preeminent experts in the world in the fields of immunology, virology, thrombo inflammatory disease, and mircobiology that directly pertain to this matter, I conclude that these injections will continue to result in extensive and devastating effects to all those who receive these injections. In fact very recent data suggests that fully vaccinated people are getting covid and dying (refer to recent UK data, and the data coming out of Israel).

In this field when new medical technology is introduced, the principal applied is “guilty until proven innocent.” In other words, a new drug or vaccine is not presumed to be safe, unless and until it is proven as such. Accordingly, based on the previous animal trials and no additional data to suggest otherwise, there is a strong probability that in the longer term, the already historic level of death and debilitating injuries could significantly increase.

I therefore wish to exercise my legal right to refusal, provided under Title 21 Part E, Section 360bbb-3(e)(1)(A)(ii)(III).

<u>Issue Regarding Comirnaty versus Pfizer</u>

There is confusion as to whether Pfizer and Comirnaty are legally separate entities. To address this I refer you to the FDA approval letter (and license 2229) provided to BioNTech Manufacturing GmbH, Mainz, Germany on August 23, 2021 where it is stated (highlights added):

> “The license authorizes you to **introduce** or deliver for **introduction** into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards. Under this license, you are authorized **to manufacture** the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.”

Clearly this indicates that the approved product was not available at the time of approval and that this entity was now authorized to introduce it. Efforts to obtain this injection have resulted in none being available at this time which confirms that BioNTech has not manufactured and introduced the injection to the US as of September 29, 2021.
In a separate letter issued on September 22, 2021 to Pfizer Inc. (235 East 42nd Street, NY, NY), it is stated:

> "COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series."

There is a footnote (footnote 10) on this statement regarding Comirnaty which states the following (highlights added):

> "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."

It is clear that all available vials or injections that can be taken, today in the US, are Pfizer EUA injections. The Comirnaty product has not yet been introduced. It is also clear, as stated in footnote 10 of the September 22, 2021 letter to Pfizer that these two injections, in the **FDA's own words,** are legally distinct entities.

As additional support for this conclusion I note the following concerning whether these two injections are legally separate entities. First, Pfizer did not get a license. Only BioNTech in Germany was granted a license (to manufacture and introduce Comirnaty). Further, the September 22, 2021 reauthorized the EUA for the Pfizer injections. It did NOT approve it the Pfizer injections (which currently exist) – notwithstanding the purported similarity between the two injections in terms of the ingredients and the anticipated effectiveness. This maintained legal separation. Finally, Orlando based know as Liberty Counsel has reached the same conclusion after a legal analysis of this approval.

Note that copies of these FDA letters are available at FDA.gov (but I can send you a copy of both if you wish)

From: Reed, Tim
Sent: Monday, September 27, 2021 9:04 AM
To: Silk, Anne <Anne.Silk@nrc.gov>
Cc: McAllister, Tonishia <Tonishia.McAllister@nrc.gov>
Subject: Request to Exercise My Right to Refusal Granted under Title 21 Part E Section 360bbb

Anne/Tonisha

I am requesting to exercise my right for refusal provided under Title 21 from the Executive Order issued on September 9, 2021 entitled "Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees" [https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/] on the following basis.

There are at present only three experimental DNA or mRNA injections available to the American public. All three are authorized for emergency use (EUA) only (i.e., the only FDA-approved injection is an mRNA injection referred to as Cominirty and it is a separate and distinct legal entity from the existing Pfizer mRNA injection and Cominirty is not currently available in the United States). Consequently, since these experimental injections are EUA only, they are subject to the following statutory law:

> United States Code (USC) Title 21 "Food and Drugs," Part E "General Provisions Related to Drugs and Devices," Section 360bbb-3 "Authorization for medical products for use in emergencies," Section 360bbb-3(e)(1)(A)(ii):
>
> (ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed
>
> (I) that the Secretary has authorized the emergency use of the product;
>
> (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
>
> > (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

I have availed myself of the known adverse conditions by reviewing the Vaccine Adverse Events Reporting System (VAERS) and by educating myself concerning these experimental injections by listening to experts such as Dr. Luc Montagnier, Dr. Peter McCullough, Dr. Richard Fleming, Dr. Geert Vanden Bossche, Dr. Sucharit Bakdi, Dr. Lee Merritt, Dr. Pierre Kory, Dr. Vladimir Zelenko, Dr. Simone Gold, Professor Francis Boyle, Dr. Michael Yeadon, Dr. Charles Hoffe, and Reiner Fullmich.

Accordingly, based on the understanding I have acquired, I now conclude that I am sufficiently informed to make a decision on whether to participate in the experimental trial. I have concluded that there are clearly devastating side effects associated with these experimental injections. There is no evidence that the longer-term effects which resulted in between 20 and 100 percent death in animals during previous trials of similar experimental injections was solved. We are now just beginning to enter the longer term in the ongoing experimental trials on humans. Based on all the available information, and the expert advice from the aforementioned people, several of which are the preeminent experts in the world in the fields of immunology, virology, , thrombo-inflammatory disease, and biology that directly pertain to this matter, I conclude that these injections will continue to result in extensive and devastating effects to all those who receive these injections. Based on the previous animal trials, there is every indication that these effects could greatly worsen as we head into the longer term. I therefore wish to exercise my legal right to refusal provided under Title 21 Part E, Section 360bbb-3(e)(1)(A)(ii)(III).

Thank you for your attention to this request.

Timothy A Reed
Senior Project Manager
Office of Nuclear Reactor Regulation
Division of Operating Reactor Licensing
Special Projects and Processes Branch
O-12E20/301-415-1462/Timothy.reed@nrc.gov

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From: Lamary, Mary

Created By: Mary.Lamary@nrc.gov

Recipients:
"Silk, Anne" <Anne.Silk@nrc.gov>
Tracking Status: None
"Reed, Tim" <Timothy.Reed@nrc.gov>
Tracking Status: None

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