RFK, Jr. Warned FDA Three Months Ago About Ingredient in Pfizer COVID Vaccine That Likely Caused Life-Threatening Reaction in Two UK Healthcare Workers

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> ***An investigation this week identified polyethylene glycol (PEG) as the likely reason two people in the UK suffered anaphylaxis after receiving Pfizer's COVID vaccine. In September, CHD Chairman RFK, Jr. warned the FDA that PEG in COVID vaccines could lead to severe allergic***

by Lyn Redwood, RN, MSN, *The Defender*, *Children's Health Defense*
December 11, 2020

On Dec. 2, Britain's Medicines and Healthcare Products Regulatory Agency (MHRA) became the first in the world to approve a COVID-19 vaccine developed by Germany's BioNTech and Pfizer.

A mass vaccination campaign that targeted frontline workers to receive the vaccine began on Dec. 8. Within 24 hours of launching the campaign, MHRA acknowledged two reports of anaphylaxis and one report of a possible allergic reaction.

Reuters reported late yesterday afternoon that an investigation into the anaphylactic reactions by MHRA has identified polyethylene glycol, or PEG, as the likely culprit.

Imperial College London's Paul Turner, an expert in allergy and immunology who has been advising the MHRA on its revised guidance, told Reuters: "The ingredients like PEG which we think might be responsible for the reactions are not related to things which can cause food allergy. Likewise, people with a known allergy to just one medicine should not be at risk."

It was also reported that PEG, which helps to stabilize the shot, is not in other types of vaccines.

The statements by Turner that "PEG is not in other types of vaccines" and that people with allergies to "just one medicine should not be at risk" are a failed attempt to provide false assurances and are patently untrue.

Moderna, Pfizer/BioNTech and Arcturus Therapeutics COVID vaccines all utilize a never-before-approved messenger RNA (mRNA) technology, an experimental approach designed to turn the body's cells into viral protein-making factories. This technology involves the use of lipid nanoparticles (LNPs) that encapsulate the mRNA to protect them from degradation and promote cellular uptake.

The LNP formulations in the three COVID-19 mRNA vaccines are "PEGylated," meaning that the vaccine nanoparticles are coated with a synthetic, non-degradable and increasingly controversial PEG.

COVID mRNA vaccines are not the only vehicle for PEG involvement in COVID-19 vaccine production. Researchers at Germany's Max Planck Institute report developing a process for COVID-19 vaccine production to purify virus particles at "high yield." The process involves adding PEG to a virus-containing liquid and passing the liquid through membranes.

On Sept. 25, Robert F. Kennedy, Jr., chairman and chief legal counsel for Children's Health Defense (CHD), notified the Steven Hahn, director of the U.S. Food and Drug Administration (FDA), Dr. Peter Marks director of FDA's Center for Biologics Evaluation and Research and Anthony Fauci, director of the National Institute for Allergy and Infectious Diseases, of the serious and possibly life-threatening anaphylactic potential of PEG.

From: Robert F. Kennedy Jr. <robert.kennedyjr@childrenshealthdefense.org>
Sent: Friday, September 25, 2020 6:02 PM
To: FDA Commissioner <Stephen.Hahn@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Congressman Posey <rockledger@aol.com>; Buchanan, Lisa K (OS) <Lisa.Buchanan@hhs.gov>; senator@kaine.senate.gov; Doepel, Laurie K (NIH) <laurie.doepel@nih.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; hugh.auchincloss@nih.gov; john.mascola@nih.gov; cliff.lane@nih.gov
Subject: Letter from RFK, Jr. on concerns with Moderna's COVID vaccine

Drs. Hahn and Marks,

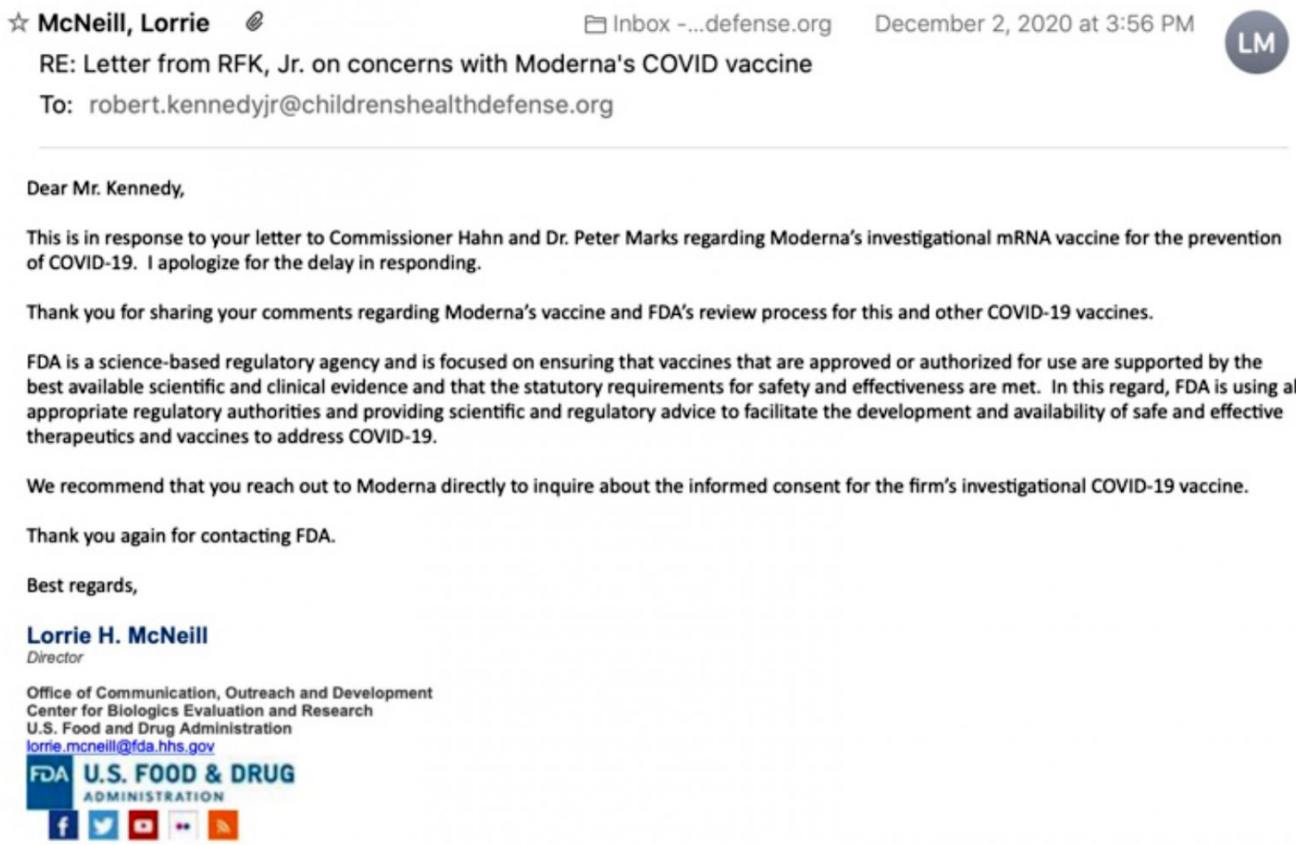
I'm writing to you today regarding Moderna's mRNA vaccine in development that contains polyethylene glycol (PEG). The use of PEG in drugs and vaccines is increasingly controversial due to the well-documented incidence of adverse PEG-related immune reactions, including life-threatening anaphylaxis. Roughly seven in ten Americans may already be sensitized to PEG, which may result in reduced efficacy of the vaccine and an increase in adverse side effects. It is critical that FDA's regulatory scrutiny of Moderna be beyond reproach, since other manufacturers will look to Moderna as a role model for their own safety studies. FDA's review of Moderna's vaccine should be a template for rigorous protocols that unambiguously elevate safety above political or monetary considerations. I urge that you give priority to your agency's duty to protect public health and the rights of trial participants to genuine informed consent regarding the use of PEG in. We ask you to order Moderna to immediately inform all trial participants of the risk for allergic reactions from PEG, and to carefully monitor and publicly disclose allergic reactions potentially associated with PEG.

Please see the attached for more information.

Sincerely,

Robert F. Kennedy, Jr.

CHD received the following response from the FDA, on Dec. 2, but has not yet received a response from Fauci.



☆ **McNeill, Lorrie** Inbox -...defense.org December 2, 2020 at 3:56 PM

RE: Letter from RFK, Jr. on concerns with Moderna's COVID vaccine

To: robert.kennedyjr@childrenshealthdefense.org

LM

Dear Mr. Kennedy,

This is in response to your letter to Commissioner Hahn and Dr. Peter Marks regarding Moderna's investigational mRNA vaccine for the prevention of COVID-19. I apologize for the delay in responding.

Thank you for sharing your comments regarding Moderna's vaccine and FDA's review process for this and other COVID-19 vaccines.

FDA is a science-based regulatory agency and is focused on ensuring that vaccines that are approved or authorized for use are supported by the best available scientific and clinical evidence and that the statutory requirements for safety and effectiveness are met. In this regard, FDA is using all appropriate regulatory authorities and providing scientific and regulatory advice to facilitate the development and availability of safe and effective therapeutics and vaccines to address COVID-19.

We recommend that you reach out to Moderna directly to inquire about the informed consent for the firm's investigational COVID-19 vaccine.

Thank you again for contacting FDA.

Best regards,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

In earlier communications with Moderna scientists regarding the controversial use of PEG in the company's COVID-19 vaccine due to the potential for life-threatening anaphylaxis and need for pre-screening for PEG antibodies prior to vaccine administration, they insisted that the existence of PEG antibodies was purely hypothetical and underserving of concern:

"Pre-screening populations based on hypothesized biomarkers, such as anti-PEG antibodies, is not a strategy currently employed in our clinical trials."

Given the recent evidence of PEG anaphylaxis in Pfizer mRNA vaccine recipients, I wonder if FDA and vaccine manufacturers will now reconsider their position.

An extensive review of PEG therapeutics, published in 2013, documented adverse effects of PEGylation and questioned the wisdom behind the continued use of PEG in drug development. The authors concluded that "the accumulating evidence

documenting the detrimental effects of PEG on drug delivery make it imperative that scientists in this field break their dependence on PEGylation."

The statement by Turner that "people with a known allergy to just one medicine should not be at risk," is also not true.

A 2018 study, "Immediate Hypersensitivity to Polyethylene Glycols and Polysorbates: More Common Than We Have Recognized" reports there are more than 1,000 products, including prescription drugs, that contain PEG. (See chart below for detailed descriptions of PEG containing drugs.)

The decision to allow people with other medication allergies to receive vaccines that utilize PEG in the manufacturing or delivery of the vaccine is a very risky proposition — especially given that Pfizer has said people with a history of severe adverse allergic reactions to vaccines or the candidate's ingredients were excluded from their late stage trials.

We have no idea what the incidence of allergy or anaphylactic reactions will be once Pfizer begins global distribution of the vaccine, without such exclusions.

A 2016 study reported detectable and sometimes high levels of anti-PEG antibodies in approximately 72% of contemporary human samples and about 56% of historical specimens from the 1970s through the 1990s. The population's increased exposure to PEG-containing products since the 1990's makes it natural to assume that anti-PEG antibodies will continue to be widespread.

As approval of PEGylated mRNA vaccines for COVID-19 occurs, the uptick in exposure to injected PEG products will be unprecedented and potentially disastrous.

While four out of five doctors regularly prescribe PEGylated drugs, only one out of five are aware of the potential for

anti-PEG antibody responses. And only a third even know that PEG is in the drugs that they are prescribing.

A Vanderbilt University researcher agrees that there is a widespread lack of recognition that PEG hypersensitivity is possible, much less that it manifests on a regular basis. While it has been recommended to screen patients for anti-PEG antibody levels "prior to administration of therapeutics containing PEG" such testing is currently only available in research settings.

In a declaration effective Feb. 4, the Secretary of Health and Human Services invoked the Public Readiness and Emergency Preparedness Act (PREP Act) and declared Coronavirus Disease 2019 (COVID-19) to be a public health emergency warranting liability protections for covered countermeasures, including vaccines.

The fact that the FDA has abdicated its responsibility for assuring the safety of COVID vaccines to vaccine manufacturers means we are on our own to study the science, and weigh the benefits and risks of all drugs and vaccines.

CHD will continue to monitor this important safety issue in an effort to keep you well informed on the science and public policies surrounding COVID-19 vaccine development.

Descriptions of PEG containing drugs:

Online Table E2 FDA and OTC Polyethylene Glycol 3350 Containing Products

Effective Amount (Strength)	Route of Entry	Product Group *Drug Indication Category* Condition Treated	Product Examples
Grams	Oral	Powder for Solution Bowel evacuant/laxative	Clearlax, CoLyte, EZ2GO, Gavilax, GaviLyte, Glycolax, Golytely, Healthylax, Moviprep, Nulytely, Polyethylene Glycol 3350, TriLyte
Milligrams	Parenteral	Intramuscular Contraceptive Steroid Intra-articular Steroid	 Depo-Provera Depo-Medrol, Methylprednisolone acetate Depo-Medrol, Methylprednisolone acetate
Micrograms/Unknown	Oral	Film Coated Tablet *Cardiovascular* Angina Essential Hypertension Pulmonary Hypertension *Endocrine* Diabetes Fibrate Statin *Gastroenterology* Gallstone Dissolution Primary Biliary Cirrhosis Agent *Infectious Diseases* Antibiotic Antifungal Hepatitis C HIV Malaria *Neurology* Dementia Migraine Pain Seizure *Oncology* Antineoplastic Aromatase Inhibitor *Psychiatry* Antipsychotic Depression Insomnia *Rheumatology* Rheumatoid Arthritis *Urology* Erectile Dysfunction Overactive bladder *Other* Anticoagulation Antihistamine Chelating Agent Cystic Fibrosis Phosphate Binder Tablet *Cardiovascular* Angina Antiplatelet Essential Hypertension Pulmonary Hypertension *Endocrine* Diabetes Fibrate *Neurology* Pain Seizure *Psychiatry* Antipsychotic Depression Stimulant *Other* Antibiotic Antihistamine Antineoplastic Contraceptive Decongestant Gallstone dissolution Leukotriene Antagonist Overactive bladder Capsule Antiplatelet Stool softener Proton Pump Inhibitor Suspension Antitussive	 Ranexa Amlodipine-Atorvastatin, Amlodipine-Olmesartan, Amlodipine-Valsartan, Amlodipine-Valsartan-Hydrochlorothiazide, Avalide, Azor, Byvalson, Irbesartan-Hydrochlorothiazide, Labetalol, Losartan, Losartan-Hydrochlorothiazide, Moexipril-Hydrochlorothiazide, Valsartan, Valsartan-Hydrochlorothiazide Letairis, Sildenafil Glipizide-Metformin, Invokamet, Invokana, Janumet XR, Metformin, Pioglitazone-Metformin, Steglatro Gemfibrozil Amlodipine-Atorvastatin, Fluvastatin, Rosuvastatin, Simvastatin Ursodiol Ocaliva Amoxicillin, Doxycycline, Minocycline, Solodyn Griseofulvin, Noxafil, Voriconazole Epclusa, Harvoni, Mavyret, Moderiba, Ribasphere Ribapak, Ribavirin, Technivie, Viekira Atripla, Descovy, Entecavir, Isentress, Kaletra, Norvir, Prezista, Stribild, Tybost, Zidovudine Chloroquine, Hydroxychloroquine Donepezil Sumatriptan Aleve, Morphine ER, Tramadol, Xartemis XR Briviact, Gralise, Keppra, Keppra XR, Levetiracetam Bosulif, Cotellic, Tagrisso, Zelboraf Letrozole Nuplazid Bupropion, Desvenlafaxine, Fluoxetine, Protriptyline Eszopiclone Xeljanz Sildenafil Trospium Xarelto Cetirizine, Hydroxyzine Ferriprox Kalydeco, Orkambi Sevelamer Metoprolol tartrate, nitroglycerin Clopidogrel Nifedipine, Spironolactone, Teveten, Valsartan Orenitram Glipizide-Metformin, Rosiglitazone Fenofibrate, Gemfibrozil Aleve, Esbriet, Exalgo, Hysingla ER, Ibuprofen, Morphine Divalproex, Keppra Risperidone Phenelzine, Tranylcypromine, Venlafaxine, Wellbutrin SR Benzphetamine, Methylphenidate Amoxicillin, Metronidazole Famotidine Lysodren, Stivarga, Zytiga Dasetta, Elinest, Falessa, Falmina, Juleber, Larin, Larin FE, Levonest, Loryna, Mono-Linyah, Northinodrone, Philith, Setlakin, Sharobel, Sveda, Tri-Linyah, Wera Zephrex-D Ursodiol Montelukast Oxybutynin ER Aspirin-Dipyridamole DOK Omeprazole Delsym, Delsym ER, Tussionex
	Parenteral	Intravenous Hemophilia Antitrypsin Deficiency Subcutaneous Cryopyrin-associated period syndromes	 Recombinate, Hemofil M Aralast NP Arcalyst
	Topical	Ointment Acne Antibacterial Anesthetic Cream Acne Antifungal Steroid Gel Anesthetic Lotion Acne Solution Antibacterial Powder for Reconstitution Hemostatic agent	 Bensal HP Mupirocin Lidocaine Proactiv Clarifying Night Acne Treatment Ting, Tolnaftate Fluocinonide Americaine, Astero, Astra-Dent, Benzocaine, Candee Caine, Comfortcaine, Topex Proactive Gentle Formula Clearifying Night Pre-Scrub II Surgical Hand Scrub Recothrom
	Nasal	Solution Decongestant Steroid	 Oxymetazoline Flunisolide, Triamcinolone acetonide