BILL POSEY
8TH DISTRICT, FLORIDA

COMMITTEES:
SCIENCE, SPACE, AND TECHNOLOGY
SPACE SUBCOMMITTEE

FINANCIAL SERVICES
CONSUMER PROTECTION AND FINANCIAL INSTITUTIONS SUBCOMMITTEE
OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE

CONGRESSIONAL ESTUARY CAUCUS, FOUNDER
HOUSE AEROSPACE CAUCUS, CO-CHAIR
REPUBLICAN STUDY COMMITTEE
CONGRESSIONAL AUTISM CAUCUS
MILITARY VETERANS CAUCUS

Congress of the United States
House of Representatives
Washington, DC 20515

www.posey.house.gov
WASHINGTON OFFICE:
2150 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3671
FAX: (202) 225-3516

MAIN DISTRICT OFFICE:
2725 JUDGE FRAN JAMIESON WAY, BLDG. C
MELBOURNE, FL 32940
(321) 632-1776
FAX: (321) 639-8595

DISTRICT OFFICE:
INDIAN RIVER COUNTY ADMIN. BLDG. A
(772) 226-1701

DISTRICT OFFICE:
BREVARD COUNTY GOVERNMENT OFFICES
IN TITUSVILLE
(321) 383-6090

April 23rd, 2021

Dr. Anthony Fauci, Director
National Institute of Allergy and Infectious Disease
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Fauci,

The COVID-19 pandemic, spreading from Wuhan, China, has ravaged our world but thankfully, we have developed several vaccines for COVID-19. In September of 2020, I wrote to you with concerns about the ingredient Polyethylene Glycol (PEG) in the Moderna mRNA-1273 and the Pfizer-BioNTech BNT162b2 COVID-19 vaccines. This ingredient, a lipid nanoparticle (LNP), encases the mRNA that will cause the production of the spike protein, stimulating the immune response. I was concerned that PEG had the potential to cause allergic reactions since I have seen reports of wide seroprevalence of PEG antibodies.

Prior to the development of the COVID-19 vaccines, PEG was being questioned as a possible source of allergic reactions. After the Pfizer and Moderna vaccines received an Emergency Use Authorization and they were widely distributed, allergic reactions did occur at a rate greater than that of the common flu vaccines. While these are rare events, it is important to understand their mechanism of action so that the risk factors for individuals can be accurately assessed in communication with their doctor. Despite the infrequency of the allergic responses, it is vital to understand the cause of these.

I am pleased that NIAID is currently conducting a study of the allergic reactions to the COVID-19 vaccine in Clinical Trial NCT04761822. This study will hopefully provide important results about the causes of the allergic reactions. Unfortunately, the trial excludes those individuals with a history of allergy to PEG or to Doxil, a lipid nanoparticle formulation.

In a study published in the peer-reviewed journal Clinical and Experimental Allergy, researchers from the University of Cambridge concludes that the allergic reaction of a patient in the United Kingdom was due to a pre-existing allergy to PEG. The allergic reactions to the Pfizer/BioNTech vaccine in the early days of the vaccine administration did major harm to public confidence in the vaccines and have slowed uptake of the COVID-19 vaccines generally. In September of this past year, I wrote to you with questions about the presence of PEG and lipid nanoparticles in the COVID-19 mRNA vaccines and concerns about

possible allergic reactions within the trial population of the mRNA-1273 vaccine trial. The concerns I raised were essentially disregarded and my questions were deflected by the NIAID. These concerns were tragically born out following the authorization and administration of these LNP-containing vaccines.

Has the NIAID identified PEG allergy as a risk for allergic reaction to COVID-19 vaccines, namely the Moderna mRNA-1273 and the Pfizer/BioNTech BNT162b2 vaccines?

Why has Clinical Trial NCT04761822 excluded those individuals with a history of allergy to PEG?

If it is a suspected allergen, then why should it be excluded from the study which is trying to determine the prevalence of allergic reactions to the COVID-19 vaccines?

Has NIAID assessed the cases of the more than 2000 patients who had anaphylactic reactions to the mRNA COVID-19 vaccines?

What is the status of those assessments, if they are being performed?

Has NIAID performed or requested a PEG-allergy test on any of the patients who had an anaphylactic reaction to the mRNA COVID-19 vaccines?

How many of these patients tested positive for a PEG-allergy?

Please relate the results of any assessments or tests, even very early or interim results with your response to this letter, or please provide the reason that such assessments are not being performed. This would be very important data.

I trust that you will see to it that the questions contained within this letter will be properly addressed in a timely manner. I understand that these questions touch on highly technical matters nonetheless, I trust in your ability to expeditiously draft and review a response to this letter. I would appreciate such response by no later than May 7th, 2021.

Sincerely,

Bill Posey
Member of Congress