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Congress of the United States
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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

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IN TITUSVILLE
(321) 383-6090

September 1, 2020

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 world is hopeful that research efforts to develop a safe and effective vaccine for COVID-19 will soon come to fruition. Thank you for the role you are playing in this endeavor.

As we strive to achieve this goal, it is important that we not overlook any aspect of this effort that in hindsight we may wish we had investigated further. I received a copy of the attached letter, which you should have received, that raises some questions that I believe deserve full attention.

The letter raises some significant questions about the presence of polyethylene glycol (PEG) in Moderna's mRNA-1273 vaccine as well as Moderna's proprietary lipid nanoparticles (LNP). The letter raises several issues regarding possible adverse effects on some members of the study population and whether study participants have been properly informed of the risk of these possible adverse reactions. I would appreciate detailed answers to the following questions:

1. Have human subjects participating in the Moderna vaccine trial been informed of the risks of possible adverse events, including a reaction to PEG or Moderna's LNPs? Also, please provide a copy of the informed consent documents that were provided to study participants.
2. Have the study populations for the Moderna study been screened for PEG antibodies?
3. Did Moderna/NIAID specifically investigate adverse reactions in the earlier phase of the trial to determine whether PEG or LNPs may have been a factor in any of the adverse reactions? If so, please provide information on those findings
4. In Phase 3, is Moderna/NIAID specifically screening for PEG antibodies and monitoring for adverse reactions to PEG or LNPs?
5. Are steps being taken to understand the prevalence of PEG antibodies in the United States population, particularly as Moderna's vaccine is a candidate for widespread use across the U.S. population?

6. It has been widely reported that NIAID and NIH employees have partial ownership of the patents on and used in development of Moderna's COVID-19 vaccine. Please provide the details of NIAID's patent ownership, including details of the ownership, the number of and names of NIH employees who own a part of the patent, and details on potential royalties.
7. What measures are being taken, in light of the rapidly advanced development scheme under Operation Warp Speed, to ensure that Moderna and all other developers comply with the Protection of Human Subjects?

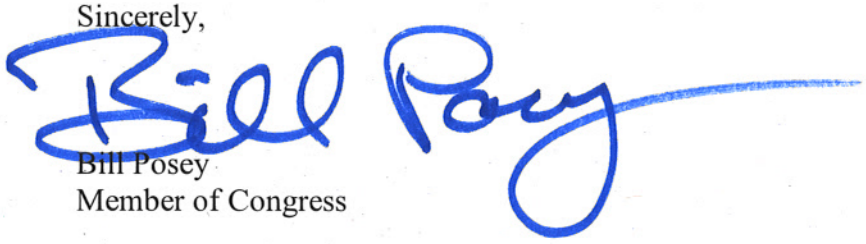
A clear understanding of the impact of PEG and LNP with regard to vaccine safety and efficacy would be an important aspect of the study of a vaccine that public health officials hope to develop and deploy in expedited fashion. There is medical literature indicating that PEG containing medical products may have a lower effectiveness due to PEG antibodies present in a large percentage of Americans. Is this a concern of Moderna or NIAID and if so, what steps have been taken to mitigate this potential impact on effectiveness? Also, as a part of this Phase 3 trial, is an aspect of the study examining the relative effectiveness of the vaccine in participants with PEG antibodies?

In every circumstance, the potential adverse events of any pharmaceutical intervention should be clearly documented and communicated to patients. This is particularly the case in the rapid development of pharmaceuticals, such as through Operation Warp Speed.

We share the goal of a safe and effective vaccine and I look forward to your timely response. Lower effectiveness in a subpopulation as well as documented safety issues would undermine uptake of the vaccine – which directly works against the purposes of the research effort.

I trust that you will see to it that the questions contained within this letter will be properly addressed in a timely manner. I would appreciate a response by no later than September 15, 2020.

Sincerely,



Bill Posey
Member of Congress

cc: Honorable Alex Azar, Secretary of Health and Human Services
Robert F. Kennedy Jr.

Enclosure

Children's Health Defense
1227 North Peachtree Pkwy, Suite 202
Peachtree City, GA 30269
Tel. 202-810-1826

August 26th, 2020

Anthony Fauci, MD, Director
National Institute of Allergy and Infectious Disease

RE: Phase III Moderna mRNA-1273 Vaccine

Dear Dr. Fauci,

We urge you to require Moderna to inform clinical trial participants of the unique risks associated with polyethylene glycol (PEG), an ingredient in the NIAID funded Moderna mRNA-1273 vaccine. As you know, approximately 72% of Americans may have antibodies to PEG with 8% of those individuals having highly elevated levels of antibodies, <500ng/ml.

Injecting a PEG-containing vaccine into individuals with pre-existing PEG antibodies could lead to life-threatening anaphylaxis. The presence of anti-PEG antibodies in approximately 7 out of 10 Americans led to the authors conclusion that "*...sensitive detection and precise quantitation of anti-PEG Ab levels in a clinical setting will be essential to ensuring the safe use of PEGylated drugs in all target patient populations going forward.*"

In its prospectus, Moderna acknowledges the potential for its proprietary lipid nanoparticles and PEG to produce "systemic side effects". The company has nevertheless refused to prescreen individuals participating in the clinical trials for preexisting PEG antibodies, despite FDA's strong recommendations that it do so.

For those participating in the Moderna clinical trials, the uptick in parenteral exposure to PEG will be unprecedented—potentially disastrous and life-threatening. Moderna reported results from the Phase 1 open-label trial in 45 healthy adults acknowledged that over half (23 out of 45) of the participants experienced a vaccine adverse event, including one volunteer who withdrew from the trial due to urticaria (hives), a condition often associated with drug allergies and life-threatening anaphylaxis. We worry that Moderna's failure to inform the trial participants of the PEG allergy risks not only endangers their lives, but also may have caused clinicians and volunteers to dismiss telltale allergic reactions as "unrelated" to the vaccine.

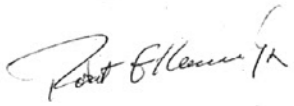
Children's Health Defense has grave safety and efficacy concerns about the use of PEG in vaccines due to the high percentage of the population having preexisting antibodies to PEG.

While it's unlikely that everyone with pre-existing PEG antibodies will have a severe reaction to a vaccine containing PEG, it is criminally reckless to assume that none will. It is our hope that you will make the appropriate public assurances that NIAID will promptly inform the volunteers of this risk.

Moderna answers critics of its dangerous failure to warn trial subjects by dismissing the well-documented fact that a high percentage of people have anti-PEG antibodies as merely "hypothetical". Moderna's justification is disingenuous, at best. There is no serious dispute about PEG's ubiquity across the population. Moderna's refusal to screen for PEG is dangerous to the trial participants and violates 45 CFR 46.116(b)(2). That regulation requires manufacturers to disclose any reasonably foreseeable risks or discomforts to clinical trial subjects. Another provision, 45 CFR 46-111(a) (1) mandates that manufacturers minimize risks to clinical trial participants by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.

The world is aware of NIAID's deep institutional commitment to the Moderna Vaccine. Moderna's novel MRNA vaccine is a career vanity project for certain powerful NIAID officials who have nurtured the platform for years. NIAID apparently owns half of Moderna's patent. At least six NIAID officials also share patent ownership and apparently stand to collect personal royalties of up to $150,000 annually on vaccine sales. NIAID has committed billions of dollars of public monies to the project and placed the Moderna vaccine at the front of the line. As you know, critics have suggested that NIAID's conflicts have engendered a posture, among NIAID regulators, of ignoring emerging safety signals because the Moderna Vaccine is "too big to fail". But, NIAID's peculiar interest in Moderna is no excuse for short cuts. To the contrary, it is critical that NIAID's regulatory scrutiny of Moderna be beyond reproach, since other manufacturers will look to Moderna as a role model for their own safety studies. NIAID's pet vaccine should be a template for rigorous protocols that unambiguously elevate safety above monetary considerations. We urge that you give priority to your agency's duty to protect public health and the rights of trial participants to genuine informed consent. 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.

Sincerely,



Robert F. Kennedy Jr.

cc. President Donald Trump
Jared Kushner