



December 4, 2020

Children's Health Defense
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Peter Marks, MD, PhD
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Food and Drug Administration
10903 New Hampshire Avenue
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cc: Senator Ron Johnson, Chairman, Homeland Security and Governmental Affairs
Congressman Bill Posey

Dear Dr. Marks,

Transparency and accountability are essential ingredients in the public policy process, helping to engender public trust and promote sound decision-making. As you are undoubtedly aware, many Americans are expressing worries about the [lack of transparency](#)¹ and [abbreviated timeline](#)² governing the experimental COVID-19 vaccines currently under development. Children's Health Defense shares the public's concern that the government's single-minded—and perhaps unrealistic—preoccupation with a vaccine as the only way to end the COVID crisis has given the vaccine enterprise a dangerous urgency that could prompt health officials to take reckless steps to speed one or more vaccines to approval. Children's Health Defense is writing to respectfully request that you and the FDA slow down the approval process to meet the public's expectations for deliberations of the utmost rigor and integrity.

Without having to provide “the full data [to back up their claims](#),” executives at Pfizer and Moderna “have made significant amounts of money off their early announcements of [vaccine] success.”³ In addition, through [Operation Warp Speed](#), Pfizer (in partnership with German company BioNTech) has received \$1.95 billion in taxpayer funds for the manufacture and distribution (though not R&D) of 100 million doses of its BNT162b2 mRNA vaccine; Operation Warp Speed has also awarded over \$2.4 billion to support the clinical trials, manufacturing and distribution of 100 million doses of Moderna's mRNA-1273 vaccine developed in partnership with the National Institute of Allergy and Infectious Diseases (NIAID).⁴

Both Pfizer and Moderna have now submitted Emergency Use Authorization (EUA) applications (on November 20 and November 30, respectively) for their vaccines, and Moderna has also directed an application to the European Medicines Agency. News reports indicate that the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet on [December 10](#) to review Pfizer's application and are speculating that FDA could authorize the company's vaccine as soon as mid-December.⁵ VRBPAC is also apparently hurrying to review Moderna's vaccine on [December 17](#).⁶

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At an [October 22](#) meeting of outside experts convened by VRBPAC to discuss COVID-19 vaccines,⁷ one of the attendees [described](#) the difficulty—particularly when making a less stringent EUA decision—of striking the proper “balance between looking at people’s rights to take something where it’s determined that the benefit might exceed the risk, while also making sure that. . . people are not taking vaccines that might actually harm them” (p. 348).⁸ Recognizing the innumerable uncertainties that surround these novel vaccines, Children’s Health Defense believes that, at a minimum, the American public deserves to have the FDA’s thorough and thoughtful answers to the following questions:

- **How will the FDA account for potentially biased conclusions about COVID-19 vaccine efficacy?**

Both Pfizer and Moderna recently issued press releases citing preliminary evidence that their COVID-19 vaccines are 95% effective in preventing symptoms of mild coronavirus infection; they are banking on these early results to obtain the FDA’s emergency use authorization. However, the clinical trials’ reliance on PCR testing to ascertain study participants’ SARS-CoV-2 infection status raises important questions. These prompted world-renowned diagnostics expert Dr. Sin Hang Lee, founder of the Connecticut-based Milford Molecular Diagnostics Laboratory, to file an [Administrative Stay of Action petition](#) with the FDA (Docket No. FDA-2020-P-2225) on November 25.⁹ The petition focuses on the Pfizer study but is just as relevant to the Moderna study. In the petition, Dr. Lee asserts that Pfizer’s study design is “inadequate to accurately assess efficacy” and asks the FDA to conduct a more appropriate efficacy review before proceeding to an EUA determination, stating that PCR testing—prone to generating a high rate of false-positives—should not serve as the primary evidence of SARS-CoV-2 infection in trial participants. As Dr. Lee spells out, “a higher number of false-positive test results in the participants receiving placebo will artificially raise the efficacy of the vaccine.” He argues that it is “absolutely necessary” that all positive test results be verified using gold-standard DNA sequencing.

- **Will the FDA factor into its EUA deliberations the fact that neither clinical trial has a primary objective of assessing whether the vaccines prevent severe outcomes?**

The [pre-specified endpoints](#)¹⁰ forming the basis of Pfizer’s and Moderna’s preliminary conclusions about effectiveness—the endpoints upon which the FDA’s potentially momentous decision to grant EUA rests—focus on a trivial difference in COVID-19 symptomatology between a tiny subset of [164 or fewer](#)¹¹ trial participants in the vaccinated and control groups. In late October, internationally esteemed *British Medical Journal (BMJ)* Associate Editor Dr. Peter Doshi, who is also a University of Maryland professor, [wrote](#) in the *BMJ*, “The world has bet the farm on vaccines as the solution to the pandemic, but the trials are not focused on answering the questions many might assume they are.”¹² Dr. Doshi continued, “None of the trials currently under way are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care, or deaths.” According to Dr. Doshi, Moderna’s chief medical officer is well aware of this design shortcoming, having explained that to capture endpoints such as hospitalization or death, the trials would need to be “[10 times the size](#)” and run for a much longer time frame.¹³ Scientist and former Harvard Medical School professor Dr. William A. Haseltine [agrees](#) that the trials’ narrow focus on mild cold-like symptoms makes the study protocols “far from adequate”; Dr. Haseltine has argued that the trials seem “intended to pass the lowest possible barrier of success,”¹⁴ allowing manufacturers to quickly petition for vaccine approval.

Experts at the late-October VRBPAC meeting made similar remarks about the limitations of using mild infection as the primary endpoint. Noting that there could be “limited and, in some instances, no information about some of the secondary endpoints” (such as more severe illness), one panelist [stated](#) that

“This would be particularly true in the instance of an early EUA” (p. 100).¹⁵ Another attendee [pointed out](#) that a vaccine could be “effective in avoiding mild cases but actually [do] very little to address what we really care about, which is serious disease and deaths” (p. 308).¹⁶ A third participant made the [critical point](#) that “many of the groups at risk for severe disease don’t respond well to vaccines in the first place” (pp. 346-347).¹⁷

- **Messenger RNA technology has previously faced significant safety hurdles; what evidence can the FDA share with the public supporting the short-term and long-term safety of mRNA vaccines?**

Until very recently, concerns about [mRNA instability](#) bedeviled efforts to develop mRNA vaccines.¹⁸ The apparent technological solutions for overcoming these challenges—including nanoparticle carrier systems and, in the case of the Pfizer vaccine, extreme freezing—remain unproven. To our knowledge, Pfizer has not provided detailed information about the reasons for its mRNA vaccine’s unprecedented minus-94-degree [freezing requirements](#),¹⁹ which specify that the cool boxes may only be opened briefly twice a day, must have their dry ice replenished every five days, and that the vaccine can only be stored at refrigerator temperatures for 24 hours. Why are the Pfizer vaccine’s storage conditions so different from those of the Moderna mRNA vaccine, which apparently can be refrigerated for [30 days](#)?²⁰ Many members of the public and scientific community would like to know more about the two vaccines’ real-world stability and safety.

Discussing Pfizer’s vaccine, Professor Allan Cheng, acting chief health officer in the Australian state of Victoria, describes safety as a “key unknown,” characterizing mRNA vaccines as “[pretty reactogenic](#)” and prone to “lots of side effects.”²¹ During the Phase II/III trials, [50%](#) of Pfizer participants aged 18-55 experienced systemic adverse events within a month of their second dose of vaccine,²² as did [100%](#) of those injected with two doses of Moderna’s vaccine.²³

Because mRNA vaccines rely on synthetic RNA, they represent a significant departure from other biologically based vaccine technologies. Virologist, Dr. Luc Montagnier (who won the 2008 Nobel Prize for his discovery of HIV) and other scientists even dispute the label of “vaccine,” arguing that these products represent a new form of [gene therapy](#).²⁴ It is debatable whether a fast-tracked approval schedule is appropriate for an entirely new vaccine technology that, essentially, is intended to turn the body’s cells into viral-protein-making [factories](#).²⁵ Professor Montagnier, who opposes the use of mRNA vaccines in humans, stated in an interview with Children’s Health Defense, “The human genome contains 7% to 9% of endogenous retrovirus sequences. Some of these sequences code for reverse transcription of RNA into DNA. Therefore, it is possible that the spike protein mRNA of the vaccine could be absorbed by human cells, reverse transcribed, and integrated as a human gene in these cells. This could be a beneficial event protecting the human host from further infection by coronavirus or it could induce a long-term deleterious effect such as cancer. Even if animal testing showed protection, nobody could predict long-term pathologic effects in a human population and the precautionary principle should apply.”

Messenger RNA vaccines will not work without an in-built delivery mechanism that enables the mRNA to make its way into a cell’s cytoplasm. [Moderna’s](#)²⁶ and [Pfizer’s](#)²⁷ chosen solution is to use lipid nanoparticle (LNP) carrier systems. The two mRNA vaccine manufacturers are using LNPs to “encapsulate the mRNA constructs to protect them from degradation and promote cellular uptake,” in addition to taking advantage of what vaccine scientists describe as LNPs’ “[inherent adjuvant properties](#).”²⁸ However, the LNP formulations in both COVID-19 vaccines are PEGylated, meaning that the vaccine nanoparticles are coated with the synthetic, nondegradable and [controversial](#) polyethylene glycol (PEG) polymer.²⁹ PEG is a potential [allergen](#)³⁰ as well as a suspected [carcinogen](#).³¹ Moderna’s

2018 [corporate prospectus](#) acknowledges that “there can be no assurance that our LNPs will not have undesired effects,” including reactions that “could lead to significant adverse events.”³²

- **How will the FDA evaluate possible risks of pathogenic priming and antibody-dependent enhancement?**

Although Pfizer and Moderna have conducted some experimental animal trials alongside their clinical trials in humans, neither company has released any data addressing the possibility of pathogenic priming. In individuals vaccinated against the SARS-CoV-2 virus, pathogenic priming could potentially trigger autoimmunity against critical human immune system proteins as a result of molecular similarities between SARS-CoV-2 protein components and human protein components (epitopes). A 2020 paper on [pathogenic priming](#) discusses these risks, pointing out that “All SARS-CoV-2 immunogenic epitopes have similarity to human proteins except one.”³³ The paper’s author [cautions](#), “These epitopes should be excluded from vaccines under development to minimize autoimmunity due to risk of pathogenic priming.”³⁴

Another issue, as yet undiscussed by Pfizer and Moderna, concerns the potential for [antibody-dependent enhancement](#) (ADE),³⁵ a phenomenon documented in [humans](#),³⁶ [non-human primates](#),³⁷ and [ferrets](#)³⁸ in connection with the coronaviruses linked to SARS and MERS. In ADE, vaccines can cause idiopathic antibodies to act like a Trojan horse for wild viruses. In the case of individuals receiving COVID-19 vaccines, ADE could not only end up enhancing disease severity but could also lead to organ damage. Of concern, COVID-19 vaccine trials [are not designed](#) to detect ADE.³⁹ It is not known what proportion of the U.S. population might suffer pathogenic priming or ADE after receiving a COVID-19 vaccine, but the estimated [15 to 24 million Americans](#) who already have an autoimmune disease could be particularly susceptible.⁴⁰ The CDC has indicated that individuals with [high-risk medical conditions](#)—individuals excluded from the Phase I trials—are one of the proposed groups for early vaccination.⁴¹

- **What are the FDA’s plans for ensuring transparency of data describing rates and types of adverse events, including information about susceptible subgroups? And how does the FDA plan to monitor adverse events and long-term health outcomes once the clinical trials are unblinded and vaccines are offered to those in the placebo arm?**

The National Vaccine Injury Compensation Program has awarded over [\\$4.4 billion](#) for vaccine injuries and deaths since 1990.⁴² These awards, along with the scientific literature, the Vaccine Adverse Event Reporting System (VAERS), and the data compiled in vaccine [package inserts](#),⁴³ all illustrate that vaccines cause a multitude of serious injuries, many of which have long diagnostic horizons. Unfortunately, conditions such as allergies, autoimmune diseases, neurodevelopmental problems, and cancers are unlikely to be detectable within the short clinical trial follow-up windows. The appallingly low rate of reporting of vaccine injuries (an estimated [1%](#), according to Harvard researchers)⁴⁴ also suggests that, without fully transparent access to data and information, few vaccine recipients or health care providers are likely to connect the dots between vaccination and subsequent adverse events.

The unpredictable outcomes that may arise from population-wide coronavirus vaccination are a disturbing unknown. Although FDA often requires medicines to continue active monitoring of injuries for up to five years, Pfizer’s approved Phase 3 [protocol](#)⁴⁵ calls for the company to “actively” collect information about adverse events and serious adverse events only through the second month—the point at which the FDA could decide to [award EUA](#).⁴⁶ Although the protocol states that researchers will also collect serious adverse event data “approximately 6 months after the last dose of study intervention,” it implies that it will rely on voluntary rather than “active” reporting of these injuries and illnesses. Moreover, from 24

months on (after the last follow-up visit), Pfizer’s investigators will no longer be “obligated” to pay attention to adverse events.

Following the close of their studies—or even sooner—both Pfizer and Moderna have indicated that they plan to offer their vaccine to every member of the [placebo group](#).⁴⁷ This scheme will have the obvious effect of erasing opportunities for long-term comparisons and making future vaccine injuries invisible and deniable. Industry and health officials argue that they will take this action “for ethical reasons,” stating that it would be unethical to deny placebo group members the advantage of an approved vaccine. It would, however, also be highly unethical to give millions of Americans a vaccine with potential long-term adverse effects that have not been properly researched, characterized, and documented.

- **How will the FDA assess vaccine safety in different age groups, including the elderly and children?**

In a recent [press release](#), Pfizer stated that 45% of the participants in the U.S. portion of its vaccine clinical trials were between the ages of 56 and 85.⁴⁸ This lumping together of working-age adults and seniors will make it difficult to evaluate subsequent claims about COVID-19 vaccine safety and efficacy specifically in the elderly. This is concerning, given that older adults in [assisted living and nursing home populations](#)⁴⁹ are one of the proposed groups for [early phase vaccination](#).⁵⁰ The elderly and the general public have a right to full transparency concerning the number of seniors, broken down by smaller age ranges and underlying health conditions, who participated in the clinical trials and the rates of infection and adverse events experienced by those trial participants. The published data to date in the Phase I and II trials of both vaccines ([Pfizer](#)⁵¹ and [Moderna](#)⁵²) included only 22 healthy, community-living white seniors (the oldest was 74); none of them were representative of the frail elderly populations in long-term care facilities. Almost two out of five [nursing home residents are over age 85](#) (39%), and Pfizer’s Phase III trial excluded people who were over 85. Many comorbidities found in frail seniors would also have excluded them from both of the Phase III trials. The well-known phenomenon of [immunosenescence](#)—the “age-related dysregulation and decline of the immune system”—is linked to poor vaccine responses in older adults. No one, and especially not seniors, will be able to make informed risk-benefit decisions without access to full information and clinical trial data.⁵³

At the October 22 expert meeting convened by VRBPAC, participants expressed [caution](#) about giving COVID-19 vaccines to children, arguing that the risks could well outweigh the benefits.⁵⁴ Leading NIH researcher Dr. Luigi Notarangelo went further, frankly [stating](#) that coronavirus vaccines “should not be considered for use” in children “at this point” and adding that the evidence presented at the meeting had been insufficient to answer pressing questions about safety in children (p. 337).⁵⁵ Although FDA requires institutions that test drugs and biologics in children to have a pediatric plan in place, in early November, the principal investigator leading Pfizer’s vaccine trials in 12-17-year-olds made the scarcely comforting disclosure to [TIME magazine](#) that “The plan can be simply ‘We don’t have a plan,’” stating that the rule “is lenient to the point of being no rule at all.”⁵⁶ Bafflingly, these remarks—which one hopes are a mischaracterization of the FDA’s willingness to exercise pediatric oversight—appear to have been intended to reassure parents pondering whether to sign up their children for the trials.

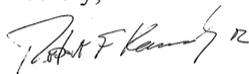
- **How will the FDA earn the public’s trust?**

While all vaccines require due deliberation about safety and efficacy, the candidate vaccines’ accelerated development and the experimental nature of the never-before-approved mRNA technologies upon which they rely clearly raise even more questions than usual. The fact that racial/ethnic minorities are disproportionately represented among the groups targeted for early phase vaccination (including essential

health care workers and individuals with high-risk medical conditions) has also prompted concerns. Focus groups [indicate](#) that communities of color do not want to be “first in line,” are reluctant to be “guinea pigs,” and “want to see some data”; vaccine experts concede that ethnic minority groups’ extremely low levels of trust in the vaccines’ safety are “quite rooted in historical reality.”⁵⁷

There are significant differences between the FDA’s standard drug and biologic approval process and the expedited EUA process; as those familiar with drug development procedures acknowledge, an [EUA](#) “is not an accepted endpoint for product development.”⁵⁸ We urge you, therefore, to take all the time required to carefully assess the full range of unknowns pertaining to the Pfizer and Moderna vaccines. The FDA’s eventual decisions about these vaccines will have major implications not just for 328 million Americans, but potentially for billions worldwide.

Sincerely,



Robert Kennedy, Jr., Chairman
Children’s Health Defense

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