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December 16, 2021

VIA EMAIL

Jay E. Slater, MD  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[Jay.Slater@fda.hhs.gov](mailto:Jay.Slater@fda.hhs.gov)

Re: *Legal Distinction(s) Between the Authorized and Approved Pfizer COVID-19 Vaccines*

Dear Dr. Slater,

We write on behalf of our client, Informed Consent Action Network (“ICAN”), as a follow-up to a question posted at the December 2, 2021 Advisory Committee on Childhood Vaccines (“ACCV”) meeting. At that meeting, you were asked about the stated legal distinction(s) between the authorized Pfizer-BioNTech and the approved Comirnaty COVID-19 mRNA vaccines. You were seemingly unaware of this issue and did not have an answer at the time.

As you are likely now aware, the Fact Sheet for Recipients and Caregivers about Comirnaty and the Pfizer-BioNTech COVID-19 vaccines stated that, “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.**”<sup>1</sup>

The FDA has yet to release a public statement explaining this legal distinction. When you were asked about this at the recent meeting, you responded that you would “have to get back to” the ACCV committee on that issue and later admitted that it was a “good question” that needed to be addressed.

Because the next ACCV meeting is not anticipated to be held until at least March 2022, we ask that you please address the following timely questions forthwith:

- (i) What is the legal distinction(s) referenced by the FDA between the Pfizer-BioNTech emergency use authorized COVID-19 vaccine and the FDA licensed COMIRNATY COVID-19 vaccine?

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<sup>1</sup> <https://heavy.com/wp-content/uploads/2021/08/Screen-Shot-2021-08-26-at-2.37.00-PM.jpg?quality=65&strip=all> (emphasis added) (this is a saved screenshot of the August 23, 2021 Fact Sheet which has since been revised and no longer includes the language regarding the products being “legally distinct”).

- (ii) Is COMIRNATY currently available on the U.S. market?
- (iii) Is COMIRNATY interchangeable with the Pfizer-BioNTech emergency use authorized COVID-19 vaccine in all circumstances?

We look forward to your prompt response.

Sincerely,



Aaron Siri, Esq  
Elizabeth A. Brehm, Esq  
Matthew Menendez, Ph.D.