May 3, 2022

FDA FOIA Officer
Food and Drug Administration
5630 Fishers Lane
Room-1035
Rockville, MD 20857

Re: Freedom of Information Act Request Regarding COVID-19 Vaccine for Children Under 5

To Whom It May Concern:

Pursuant to the Freedom of Information Act ("FOIA"), I hereby request the documents described in the attached requests. I make these requests as a representative of a group of individuals who believe the Food and Drug Administration ("FDA") should move expeditiously to authorize a COVID-19 vaccine for children under 5 years old. The group is called Protect Their Future.

On April 21, 2022, Politico published an article claiming that the Food and Drug Administration ("FDA") was

> leaning toward postponing any action [regarding the potential submission by Moderna, Inc. for Emergency Use Authorization for its COVID-19 vaccine for children ages 5 and under] until the early summer, arguing that it would be simpler and less confusing to simultaneously authorize and promote two vaccines to the public, rather than green-lighting one on a faster timetable and the other down the road.[1]

Since then, Moderna has submitted an Emergency Use Authorization application for its COVID-19 vaccine to be used in children ages 5 and under, but the FDA is not convening a meeting to discuss the application until June 8th, 2022 at earliest.

The purpose of these FOIA Requests is to discover all documents regarding the FDA's decision to wait over a month to discuss Moderna's application, and any other documents relating to the FDA's messaging and decision making regarding the approval and use of COVID-19 vaccines for children under 5 years old. The requests should be read and construed as serving this purpose.

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[1] Politico, *Waiting for a Covid vaccine for your under-5 kid? It may take a bit longer*, https://www.politico.com/news/2022/04/21/biden-kids-vaccine-covid-00026798.

To that end, I hereby request expedited processing pursuant to 21 C.F.R. § 20.44(a)(2). Protect Their Future not only advocates for children under 5 years old, but it also seeks to widely disseminate information regarding the approval process for a COVID-19 vaccine for children under 5 years old. That is one of our primary activities. Further, there is an urgent need for this information as there is just over a month between now and when the FDA might discuss Moderna's Emergency Use Authorization application. These documents are needed now in order for our group to advocate for a speedier process. Receiving the requested documents on a non-expedited timeline will prevent Protect Their Future from effectively disseminating the information and advocating for children under 5 years old.

Furthermore, I hereby request a fee waiver pursuant to 21 CFR § 20.46. Disclosure of this information satisfies both the public interest and commercial interests tests outlined in 21 CFR § 20.46(b)–(c), as described below.

Public Interest Test. Disclosure of this information would contribute significantly to the public's understanding of the FDA's operations and activities. The factors outlined in 21 CFR § 20.46(b) all weigh in favor of a fee waiver:

- First, disclosure of this information pertains to the operations and activities of the Federal Government because it pertains to the operations and activities of the FDA. *See* 21 CFR § 20.46(b)(1).

- Second, disclosure of this information would reveal meaningful information about the FDA's operations that is not already public knowledge. *See id.* § 20.46(b)(2). Over the past several months, the FDA has delayed the submission and approval of any COVID-19 vaccine for children under 5 years old. There has been no meaningful disclosure of the considerations and discussions within the Federal Government and the FDA regarding these delays. Though there have been public statements, they have been vague and contradictory, so no meaning can be parsed.

- Third, disclosure of the requested information will advance the understanding of the general public. *See id.* § 20.46(b)(3). Protect Their Future is in a position to contribute to the public understanding of this information. We are parents, medical professionals, and attorneys, among many other things. Once we receive the requested information, we will use the collective expertise within our group to analyze the information and then disseminate that information to the public.

- Fourth, disclosure of the requested information will significantly contribute to the public's understanding of the FDA's operations. *See id.* § 20.46(b)(4). For many months, the public has been told that a COVID-19 vaccine would be ready for children under 5 years old "soon." But there have been delays at every turn, partly due to the actions of the FDA. Now, the FDA is in a position to swiftly approve a COVID-19 vaccine for children under 5 years old, but—in an unprecedented move during the COVID-19 pandemic—the FDA is waiting over a month to potentially approve a vaccine for the last remaining age group. The messaging regarding this decision has been muddled and contradictory. Disclosure of the requested information will significantly shed light on this misguided decision.

Not in Requester's Commercial Interest. Disclosure of this information would not be in the requester's commercial interests. *See id.* § 20.46(c). The requester has no commercial interests in either COVID-19 vaccine.

To the extent any documents are withheld or redacted, please fully explain the basis for withholding or redacting the document such that I may fully assess the basis.

Sincerely,

Tamara Lea Spira, PhD

Attachment

DEFINITIONS AND INSTRUCTIONS

1. Unless otherwise stated, these FOIA requests seek documents dated from December 1, 2021 to present.

2. The term "communication" means any transmittal of documents or information, of any nature whatsoever, including, without limitation, statements, discussions, conversations, meetings and remarks, whether written or oral. The term "communication" includes, without limitation, communications that are face-to-face and those that are transmitted by media such as intercoms, telephones (including voicemail), hand-held mobile devices, text messages, pagers, electronic mail, instant messaging, computer-based communications systems, or any other system.

3. The term "document" has the broadest meaning accorded to it by Federal Rules of Civil Procedure 26 and 34 and includes, without limitation, originals, masters, all electronic or computer generated information of any kind or nature, and every non-identical copy of writings and printed, typed and other graphic or photographic matter, including electronic and microfilm of any kind or nature, recordings (tape, disc or other) of oral communications, and other data compilations from which information can be obtained, in the possession, custody or control of Plaintiff or any present or former officers, employees or agents thereof, or known by Plaintiff to exist. The term "document" includes, without limiting the generality of the foregoing, all letters, telegrams, teletypes, correspondence, contracts, agreements, notes to the files, notebooks, reports, memoranda, mechanical and electronic sound records or transcripts thereof, blueprints, flow sheets, formal or informal drawings or diagrams, calendar or diary entries, memoranda of telephone or personal conversations or of meetings or conferences, studies, reports, interoffice communications, price lists, bulletins, circulars, statements, manuals, summaries of compilations,

minutes of meetings, maps, charts, graphs, order papers, articles, announcements, books, catalogs, records, tables, books of account, ledgers, vouchers, canceled checks, invoices or bills. A draft or non-identical copy is a separate document within the meaning of this term.

4. The terms "referring to" or "refer to" or "referring or relating to" or "refer or relate to" means comprising, consisting of, referring to, reflecting, discussing, reporting, constituting, disclosing, relating to, pertaining to, concerning and/or regarding.

5. The term "supporting" means comprising, consisting of, referring to, reflecting, discussing, reporting, constituting, disclosing, relating to, pertaining to, concerning and/or regarding.

6. The term "FDA" means the United States' Food and Drug Administration.

7. The term "EUA" means the authorization by the FDA of an unapproved medical product or unapproved uses of an approved medical product pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act.

8. The term "VRBPAC" means the FDA's Vaccines and Related Biological Products Advisory Committee.

9. The term "CDC" means the United States' Centers for Disease Control and Prevention.

10. The term "COVID-19" means the disease caused by SARS-CoV-2.

11. The term "Pfizer" means the company Pfizer, Inc., headquartered at 235 E 42nd Street, New York, NY 10017.

12. The term "Cominarty" means the COVID-19 vaccine manufactured by Pfizer and BioNTech.

13. The term "Moderna" means the company Moderna, Inc., headquartered at 200 Technology Square, Cambridge, MA 02139.

14. The term "SpikeVax" means the COVID-19 vaccine manufactured by Moderna.

REQUESTS

1. Documents referring or relating to the timing of an EUA Request for SpikeVax's use in children ages 5 and under.

2. Documents referring or relating to the timing of an EUA Request for Cominarty's use in children under 5 years old.

3. Communications with Moderna referring or relating to the timing of the submission of an EUA Request for SpikeVax's use in children ages 5 and under.

4. Communications with Pfizer referring or relating to the timing of an EUA Request for Cominarty's use in children under 5 years old.

5. Communications within the FDA referring or relating to the timing of the submission of an EUA Request for SpikeVax's use in children ages 5 and under.

6. Communications within the FDA referring or relating to the timing of an EUA Request for Cominarty's use in children under 5 years old.

7. Communications between the FDA and any other third party, including official or unofficial advisors to the FDA and non-FDA government officials, referring or relating to the timing of the submission of an EUA Request for SpikeVax's use in children ages 5 and under.

8. Communications between the FDA and any other third party, including official or unofficial advisors to the FDA and non-FDA government officials, referring or relating to the timing of an EUA Request for Cominarty's use in children under 5 years old.

9. Communications within the FDA referring or relating to scheduling VRBPAC meetings in June 2022 to discuss EUA Requests for SpikeVax or Cominarty.

10. Documents referring or relating to the perception that granting an EUA to SpikeVax for use in children ages 5 and under prior to granting an EUA to Cominarty for use in children under 5 years old would be "confusing."[2]

11. Documents referring or relating to how parents of children under 5 years old might react to the FDA approving either SpikeVax or Cominarty for use in children under 5 years old at different times.

12. Documents referring or relating to the FDA's request that Pfizer submit for an EUA for Cominarty's use in children under 5 years old in February 2022.

13. Communications within the FDA referring or relating to scheduling VRBPAC meetings in February 2022 to discuss EUA Requests for Cominarty's use in children under 5 years old.

14. Documents referring or relating to the cancellation of the VRBPAC meeting that was scheduled for February 15, 2022.

15. Documents reflecting or relating to the FDA's messaging for COVID-19 vaccines for children ages 5 and under.

[2] Politico, *Waiting for a Covid vaccine for your under-5 kid? It may take a bit longer*, https://www.politico.com/news/2022/04/21/biden-kids-vaccine-covid-00026798.