April 25, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

The undersigned submit this petition pursuant to 21 C.F.R. § 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request that the Commissioner of Food and Drugs (the "Commissioner") immediately and expeditiously review and act on any application for Emergency Use Authorization ("EUA") for a COVID-19 vaccine for children between the ages of six months to under six years, with no delay unrelated to safety or efficacy concerns.

On February 4, 2020, the Secretary of Health and Human Services ("HHS") determined pursuant to his authority under section 564 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, he declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. This public health emergency remains in effect today.

On April 21, 2022, Politico[1] and NBC News[2] reported that the FDA may wait as late as June to review an EUA for a coronavirus vaccine for children under six years old, even if one manufacturer files an application earlier, under the theory 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."[3]

[1] Adam Cancryn, Politico, *Waiting for a Covid vaccine for your under-5 kid? It may take a bit longer*. (Apr. 21, 2022, 4:30 A.M.), https://www.politico.com/news/2022/04/21/biden-kids-vaccine-covid-00026798?fbclid=IwAR3YQEXHRAxCwQudlj8XbMqMfFnehYB7uCDLFX0KY-hEk4RNfyBFBrA1WlQ.

[2] Berkeley Lovelace Jr., NBC News, *FDA could authorize Covid shots for children under 5 in June* (Apr. 21, 2022, 2:17 P.M.), https://www.nbcnews.com/health/health-news/fda-authorize-covid-shots-children-5-june-rcna25386.

[3] Cancryn, *supra* note 1.

The FD&C Act requires the Secretary of the HHS or their delegate, the Commissioner, to base drug approval decisions on evidence of safety and effectiveness, quality of manufacturing and processing, and accuracy of labeling. Theories regarding potential challenges to promotion and messaging are not part of the FDA's role or regulatory charge. And even if they were, parents, pediatricians, and caregivers eager for authorization are not confused about the benefits of vaccination for their children.[4] We know that every day of inaction leads to more preventable suffering, borne disproportionately by the most medically, socially, and economically vulnerable young children. It is immoral and unscientific for our leaders to suggest that they will again delay approval – not because of concerns about safety or efficacy – but because they want to delay review of one vaccine candidate's data for reasons unrelated to the safety or efficacy of the vaccine itself. We also know that if the FDA delays a pediatric vaccine EUA submission for even one day longer than necessary, it will be only the latest – yet most egregious – example of the FDA's inexplicable attempts to delay release of a vaccine for this vulnerable age group.[5] This process is creating the appearance of favoritism of one vaccine candidate over another for reasons that appear wholly unrelated to safety or efficacy, and undermines the credibility of a vital institution while transferring the burden to the lives and health of young children.

I. Action Requested

Petitioners request that the FDA immediately and expeditiously review and act on any EUA application for a COVID-19 vaccine for children between the ages of six months and under six years, without delay.

II. Statement of Grounds

COVID-19 vaccines were initially granted authorization through the EUA process.[6] The Guidance for Industry issued by the FDA on March 31, 2022 for Emergency Use Authorization for Vaccines to Prevent COVID-19[7] explains that the FDA may issue an EUA for a COVID-19 vaccine after determining that four statutory requirements are met, and states:

[4] The FDA has presented no data – nor does it claim to have any – demonstrating that a staggered approval process for the vaccine candidates, as occurred with adult vaccines in winter 2020, would have any adverse effect on vaccine uptake.

[5] For example, in approximately December 2021, the FDA asked Moderna to expand the number of participants in its trial by a few hundred, delaying the results of its trial by months. *See* Ben Jordan, WTMJ-TV Milwaukee, *In-Depth: When kids 6 months and older could become eligible for COVID-19 vaccinations* (Jan. 7, 2022, 7:28 P.M.), https://www.tmj4.com/news/local-news/in-depth-when-kids-6-months-and-older-could-become-eligible-for-covid-19-vaccinations.

[6] FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[7] Emergency Use Authorization for Vaccines to Prevent COVID-19 Guidance for Industry (Mar. 31, 2022),

> When FDA assesses investigational COVID-19 vaccines for use under EUA, FDA's review includes: stringent evaluation of product quality, including a determination that the facilities producing the product meet appropriate standards; evaluation of the conduct of clinical trials; and assessment of trial data integrity.

Notably absent is any discussion of messaging or promotion.[8] More, nothing in section 564 of the FD&C Act provides for the consideration of messaging, promotion, or public confusion when considering an EUA application.

During the course of the COVID-19 pandemic, in the U.S., 468 children under 5 have died[9] and more than 3,600 have been hospitalized[10] from this dangerous virus. A growing number of children suffer from long-COVID and MIS-C. In particular, the Omicron strain that is currently dominant has hit children harder than any previous COVID variant.[11] Especially as state and federal authorities have removed other mitigation measures, the risk to the youngest children is currently greater than at any other time during the pandemic.

Despite this urgency, the FDA has repeatedly delayed approval of a vaccine for children under 5 years old. Both Moderna and Pfizer began studying their COVID-19 vaccine candidates in children as young as 6 months old in March 2021 with the sole objective of finding a vaccine dose and schedule that produces an immune response in children equivalent to that in adults.[12] In July 2021, the FDA asked both Pfizer and Moderna to moderately increase the size of their pediatric trials, ostensibly to identify any rare side effects.[13] At that time, federal officials predicted

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https://www.fda.gov/media/142749/download#:~:text=FDA%20acknowledges%20that%20an%20EUA,meeting%20pre%2D%20specified%20success%20criteria.

[8] Indeed, the distribution of vaccines is outside the purview of the FDA entirely, and in the charge of the CDC.

[9] *See* COVID Data Tracker, Demographic Trends of COVID-19 cases and deaths in the US reported to CDC (last accessed April 23, 2022), https://covid.cdc.gov/covid-data-tracker/#demographics.

[10] *See* COVID-NET: A Weekly Summary of U.S. COVID-19 Hospitalization Data, COVID-19 Associated Hospitalizations by Age (Preliminary data as of April 16, 2022) (last accessed April 23, 2022), https://gis.cdc.gov/grasp/covidnet/covid19_5.html.

[11] Adriel Bettelheim, Axios, *Omicron hit little kids hard* (Mar. 17, 2022), https://www.axios.com/omicron-cases-little-kids-094b7fc0-70c9-462e-a7b9-e64b7789cad6.html.

[12] This trial objective, called immunobridging, is a common method for evaluating pediatric vaccines as an alternative to and proxy for determining efficacy. *See* FDA Briefing Document: Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19 for Use in Pediatric Populations, https://www.fda.gov/media/149935/download.

[13] Laurie McGinley, Carolyn Y. Johnson and Yasmeen Abutaleb, *FDA Asks Pfizer, Moderna to test their vaccines in more children to help rule out safety issues,* The Washington Post (July 26, 2021, 5:49 P.M.), https://www.washingtonpost.com/health/2021/07/26/fda-asks-pfizer-moderna-

approval of at least one vaccine candidate by October or November 2021.[14] This timeline was not met. In December 2021, Pfizer announced that their 2-dose vaccine candidate had met the stated immunobridging goals in children ages 6 months to 23 months, but not in children ages 24 months to under 5 years old.[15] Then, in late January 2022, the FDA requested that Pfizer submit an EUA request for 2 doses while it continued to test a 3rd dose.[16] The FDA scheduled a meeting of the Vaccine and Related Biological Products Advisory Committee (VRBPAC) to review Pfizer's 2-dose EUA application for children under 5 for February 15, 2022. The CDC planned to ship 10 million doses of the vaccines beginning on February 21, 2022, within mere weeks of Pfizer's application and less than one week after an anticipated approval of an EUA application.[17] On February 11, 2022, however, Pfizer suddenly paused the process, announcing that it would wait until data became available on a third dose in early April.[18] As of today, April 25, 2022, there is no update from Pfizer.

Meanwhile, in January 2022, shortly before Moderna had estimated it would be able to release its trial data,[19] the FDA requested that Moderna expand its trial a second time by roughly

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test-their-vaccines-more-children-under-12-help-rule-out-safety-issues/. Although identification of potential myocarditis risk was the stated reason for the expansion, many observers have questioned whether a small expansion of a few thousand trial participants was reasonably calculated to identify a side effect that, among older age cohorts, had an incidence of approximately 13 per every 1 million patients who received the vaccine. *See* Biykem Bozkurt, Ishan Kamat and Peter J. Hotez, *Myocarditis With COVID-19 mRNA Vaccines*, CIRCULATION (July 20, 2021), https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056135.

[14] *Id*.

[15] *Pfizer and BioNTech Provide Update on Ongoing Studies of COVID-19 Vaccine* (Dec. 17, 2021, 8:05 a.m.), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19.

[16] Laurie McGinley, Lena H. Sun and Carolyn Y. Johnson, *Pfizer-BioNTech coronavirus vaccine for children under 5 could be available by the end of February, people with knowledge say*, The Washington Post (Jan. 31, 2022, 7:45 P.M.), https://www.washingtonpost.com/health/2022/01/31/coronavirus-vaccine-children-under-5/.

[17] Advisory Board Daily Briefing, *Inside FDA's plan to review Covid-19 vaccines for young kids* (Feb. 11, 2022), https://www.advisory.com/daily-briefing/2022/02/11/kids-vaccine.

[18] *Pfizer and BioNTech Provide Update on Rolling Submission for Emergency Use Authorization of Their COVID-19 Vaccine in Children 6 Months Through 4 Years of Age* (Feb. 11, 2022, 1:30 p.m.), https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-rolling-submission.

[19] Sarah Jacoby, *When will kids under 5 be able to get a COVID-19 vaccine?*, Today (Dec. 7, 2021, 4:18 p.m.), https://www.today.com/health/health/will-kids-5-able-get-covid-19-vaccine-rcna7761.

200 more children.[20] This second expansion delayed the release of Moderna's data until March 23, 2022, when it announced that its COVID-19 vaccine for children ages 6 months to 6 years was found to be safe and effective.[21] On April 20, 2022, Moderna stated that it planned to file an EUA application by the end of the month. If the FDA were to review and approve this EUA application with the same speed as COVID-19 vaccine EUA applications for other age cohorts, children would begin receiving their first doses by mid-May. In an unusual move, however, unprecedented throughout the COVID-19 pandemic, the FDA almost immediately followed Moderna's announcement with media statements that it intended to delay review of Moderna's application until Pfizer submits its own, scrapping previously proposed VRBPAC meeting dates in May and instead intending to schedule the VRBPAC meeting for June 1 at the earliest to consider both vaccine candidates simultaneously.[22] FDA officials' stated reason for this substantial delay is that parents might be confused by staggered approvals and that such confusion might undermine vaccine confidence.[23] The FDA has presented no data supporting this bizarre theory, and even if it had such data – which, to Petitioners' knowledge, it does not – this would not be a permissible ground upon which to base its decision on whether, or when, to approve a safe and effective vaccine candidate under section 564 of the FD&C Act.

The FDA's unprecedented plan to delay review of Moderna's EUA application until June so that it can review and approve Moderna's and Pfizer's vaccine candidates simultaneously unacceptably extends the dangerous time period when young children remain completely unprotected from COVID-19 infection, and does so *for no scientific reason*. As the BA.2 variant surges throughout the United States and states, cities, and institutions have dropped almost all mask mandates and other forms of protection, parents and physicians are faced with the impossible choice between continuing to isolate their families at great financial, mental health, developmental, and social cost, or likely exposing their children to this dangerous virus. Although all children are at risk of negative outcomes, these choices are particularly fraught for parents of children with disabilities, chronic illnesses, or other high medical needs, who are being denied even compassionate use or off-label access to these life-saving vaccines. Even assuming a June 1 VRBPAC meeting, based on the historic timelines between VRBPAC meetings and the administration of first shots in older age cohorts, this timing would leave children without full

[20] Jordan, *supra* note 5.

[21] *Moderna Announces its COVID-19 Vaccine Phase 2/3 Study in Children 6 Months to Under 6 Years Has Successfully Met Its Primary Endpoint* (Mar. 23, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-its-COVID-19-Vaccine-Phase-23-Study-in-Children-6-Months-to-Under-6-Years-Has-Successfully-Met-Its-Primary-Endpoint/default.aspx.

[22] Cancryn, *supra* note 1; Lovelace, *supra* note 2.

[23] *Id.*

vaccine protection until either approximately July 21 (Moderna) or September 8 (Pfizer).[24] A delay of even two weeks could result in a preventable loss of young lives and additional cases of MISC-C, other complications, and long COVID.

Under the FDA's own guidelines, the agency is directed to move quickly to approve applications from manufacturers as soon as they are ready and the data is sufficient. Waiting to combine applications is preventing progress in fighting this virus, at the cost of children's lives and health. This petition asks the FDA to halt all plans to delay approval and release of a safe and effective pediatric vaccine and to instead follow its regulatory charge to act expeditiously and on a purely scientific basis to approve these life-saving pharmaceuticals.

III. Environmental Impact

Petitioners state that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

IV. Economic Impact

Petitioners state that the relief requested is not anticipated to have any economic impact to the United States government. However, the lack of access to vaccines against COVID-19 for children from 6 months through under 6 years has had significant and irreversible economic impact to their families, and any additional undue delay will continue to adversely impact these families and their ability to contribute to their local economies.

V. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully submitted,

/s/ Fatima Khan
Fatima Khan*
(b) (6)
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**Lead Petitioner, will accept all correspondence*[25]

[24] Moderna's 2-dose vaccine is given at Day 1 and Day 29. Pfizer's 3-dose vaccine is given at Day 1, Day 22, and Day 83. Under both vaccine series, the patient is considered "fully vaccinated" 2 weeks after the final dose.

[25] A full list of undersigned Petitioners is attached.