JW Howard Attorneys

JOHN W. HOWARD*

MICHELLE D. VOLK
ANDREW G. NAGURNEY
ALYSSA P. MALCHIODI**
BRIAN ATTARD

KRISTIN J. WRIGHT
Chief Operating Officer

Also Admitted:
Colorado*
Nevada**

MAIN OFFICE:
701 B STREET, SUITE 1725
SAN DIEGO, CA 92101
TEL (619) 234-2842

LOS ANGELES OFFICE:
201 SOUTH LAKE AVENUE, SUITE 508
PASADENA, CA 91101
TEL (213) 205-2800

OF COUNSEL:
FREDERIC L. GORDON
SCOTT J. STREET
MITCHELL B. STEIN

July 1, 2022

Submitted via overnight delivery (21 C.F.R. § 10.30(b)(2))

Robert M. Califf, M.D.
c/o Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Citizen's petition regarding the FDA's emergency use authorization of COVID-19 vaccines for young children

Dear Dr. Califf:

We are submitting this petition on behalf of our clients, Dr. Naomi Wolf, Daily Clout, Health Freedom Defense Fund, and other concerned citizens regarding the Food and Drug Administration's recent authorization of COVID-19 vaccines made by Pfizer and Moderna for young children. Pursuant to 21 C.F.R. § 10.30 *et seq.* and section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3 *et seq.*, we request that you revoke or suspend the FDA's emergency use authorization of the COVID-19 vaccines for these young children so the FDA can properly consider the potential risks and rewards in injecting young kids with these experimental pharmaceuticals.

A. Action Requested

On June 17, 2022, the FDA authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age. *See* https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children (last visited June 22, 2022).

Specifically, and according to the FDA's own press release: "For the Moderna COVID-19 Vaccine, the FDA amended the emergency use authorization (EUA) to include use of the

vaccine in individuals 6 months through 17 years of age. The vaccine had been authorized for use in adults 18 years of age and older. For the Pfizer-BioNTech COVID-19 Vaccine, the FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age. The vaccine had been authorized for use in individuals 5 years of age and older."

This petition requests that you revoke this authorization, or at least suspend it so the FDA can properly consider the potential risks and rewards in injecting young kids with these experimental pharmaceuticals.

B. Statement of Grounds

During the past two years, we have developed an unprecedented amount of scientific knowledge about COVID-19. We have learned two things about the Pfizer and Moderna COVID vaccines: they do not prevent people from becoming infected with, or transmitting COVID-19, but they are being used to justify unprecedented intrusions on Americans' privacy and bodily autonomy. On this latter point, many American institutions, from employers to schools, have issued vaccine mandates based solely on the FDA's authorization (and implied recommendation) of them. That will almost certainly continue. Preschools could soon be requiring that young children have the COVID shot. Daycares may also mandate the shots. Doctors could mandate the shots for their patients.

Although these actions are unprecedented, they will be justified by one sentence: the FDA authorized and recommended the shots. Thus, it is imperative that the FDA take its time in assessing the safety and efficacy of these shots and that it engages in a reasonable decision-making process in deciding whether to grant them emergency use authorization for young children. Indeed, federal law requires this.

The FDA has not done this. The FDA received 130,795 public comments. Its advisory committee could not possibly have reviewed all those comments, not during the single day it met to discuss the matter. Neither could you and your staff, which approved the shots for emergency use based solely on the advisory committee's vote and just two days later. (The Centers for Disease Control followed suit, recommending the shots for young kids within hours of the FDA's decision.) Indeed, it appears that the FDA did not consider any of the comments it received about this matter as none were posted to Regulations.gov.

That is not proper. "Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational." *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). This focus on the government's decision-making process means that a plaintiff in an administrative law case can show the government acted arbitrarily because it "ignored … evidence altogether or provided reasons for its decisions that were contrary to the evidence presented." *Innova Sols., Inc. v.*

Baran, 338 F. Supp. 3d 1009, 1024 (N.D. Cal. 2018) (discussing cases). We have powerful evidence of that here. Indeed, the FDA's rushed approval process is itself compelling evidence of arbitrariness. *See United States v. NCR Corp.*, 911 F.Supp.2d 767, 773 (E.D. Wis. 2012) ("Capricious means [the agency] rushed through the process or made a sudden, knee-jerk decision without hearing enough evidence."); *TOMAC v. Norton*, 193 F. Supp. 2d 182, 195 (D.D.C. 2002) ("The fact that the Bureau made its decision in an apparently rushed fashion may be an indication of arbitrary and capricious action ....").

The FDA's analysis of the safety and efficacy of the COVID shots for young children is also misleading. Three different Pfizer doses were given: 3 mcg for kids ages 5 through 11, 10 mcg for kids ages 12 through 17, and 30 mcg for those over 18. All Moderna recipients received 100 mcg. This means that a 12-year-old girl weighing 90-pounds got the same dosage as a 17-year-old, 200-pound male athlete, and that an 11-year-old on the last day of this 11th year would get a dose that would more than triple one day later, on his 12th birthday. More than three percent of the subjects died during the trials and there was such a flood of adverse events that Pfizer had to hire 2,400 full-time employees to handle the paperwork. Then there is the known risk of myocarditis, especially in young men, which has been documented by governments across the globe. In fact, several countries, including Denmark, Finland, Norway, and Sweden, suspended use of the Moderna vaccine for young people last fall.

The FDA stated in its press release that the Pfizer vaccine is safe and effective. There is little evidence to support this statement. In fact, Pfizer's own clinical trial data found more COVID-19 cases in children who received the shot than those who received the placebo. Furthermore, 4,526 children enrolled in the Pfizer trial but roughly 3,000 did not finish it. Why? Could it be that those 3,000 children suffered such severe adverse reactions to the shots that their parents removed them from the trial? Did FDA follow up to ascertain the reasons for 3,000 sets of parents removing their children? Could it be that many of these children contracted COVID-19 despite receiving the Pfizer shot? If so, the public should know that, and the FDA should take the evidence into account before granting emergency use authorization and declaring that the shot is effective. Ignoring the data is quintessentially arbitrary and capricious. *See Union of Concerned Scientists v. Nat'l Highway Traffic Safety Comm'n*, No. 19- 1230) 2020 WL 3610284, at *64 (D.C. Cir. June 26, 2020) ("Ignoring evidence that undercuts [the agency's] judgment is quintessentially arbitrary and capricious") (cleaned up).

Moreover, Pfizer's interpretation of its trial data was misleading, if not downright false. For example, Pfizer defined "severe COVID" as being indicated by a slightly raised heart rate or a few extra breaths per minute. Six children between the ages of 2 and 4 in the vaccine group developed these conditions, while only one child in the placebo group developed them, suggesting that the shot does not reduce the chances of developing severe COVID—and may in fact cause it. Similarly, one child in the vaccine group was hospitalized with fever and seizures. And of the 47 children diagnosed with COVID during the three weeks between the first and second doses, 34 were vaccinated. Both Pfizer and the FDA ignored this data. Indeed, Pfizer

disregarded 97 percent of COVID illnesses that occurred during the trial, ultimately concluding that only three children from the vaccinated group contracted COVID-19 compared to seven children in the placebo group. That is grossly misleading, and the FDA has an affirmative obligation to review this data more closely and to reconsider its authorization.

There are similar flaws in the Moderna data. That is why Dr. Buzz Hollander, who is generally pro-vaccine, said the following about the Moderna shot for young kids:

> Efficacy? Middling at best, even in a very short window after the second shot.
>
> How about stopping transmission via reducing asymptomatic infections? Nope.
>
> Helpful in the one high risk group for which the study gathered data, obese infants? Negative efficacy.
>
> And, of course, while we expect at least moderate reduction in Covid-19 hospitalizations, the study was too small and brief to find any severe infections in either placebo or vaccine group. So, no data there.
>
> (Exhibit A at pp. 7-8.)

These findings led Dr. Hollander to conclude that "it's hard to make the case that this vaccine for this cohort makes sense even for a higher risk infant until/unless we had more safety and efficacy data." (*Id.* at p. 8; *see also id.* at p. 7 [concluding that "anyone claiming that the benefits of the Moderna 25mcg vaccine for this age group *clearly* outweighs its risks is not speaking the truth"].)

As Dr. Hollander noted, these safety concerns are real. The number of all-cause hospitalizations in the Moderna trial was higher in the vaccine group (17) than the placebo group (1). The FDA counted only one of the 17 cases from the vaccine group, even though there were numerous febrile seizures and hospitalizations for other issues that could plausibly be linked to the shot. Dr. Hollander said "[t]his sort of potential safety signal should be out in the world, being discussed." (*Id.* at p. 6.) It isn't. Moreover, as concerning as the Moderna research is, there is even less evidence about the potential risks of Pfizer's shot in young kids, given the small size of that trial. We know from the leaked Pfizer Biodistribution studies that the shot's Lipid Nanoparticles accumulate at high levels in the spleen, glands, and ovaries, yet the FDA has not studied or required the study of the injections' impact on reproductive health, even though independent research has already demonstrated concern on that topic with respect to the ovaries/menstruation in females and sperm in males.

Additionally, recent research regarding Moderna's COVID vaccine suggests the injection may actually impair long-term immunity to the virus. While the study specifically evaluated the

Moderna shot, data from around the world show that hospitalizations and deaths are occurring primarily in the vaccinated. Given this alarming information, it is incumbent upon FDA to exercise extreme caution to avoid impairing the immune systems of infants and your children. https://www.israelnationalnews.com/news/328102

Real-world evidence confirms these concerns. Portugal has the highest vaccination rate of any country in Europe aside from the tiny island of Malta. Nearly every adult is vaccinated in the nation of 10.3 million, with 94 percent of all people (including young children) having received at least one dose and 70 percent having received the booster shots. In fact, last year, the *New York Times* said "there is no one left to vaccinate" there. Yet, Portugal now has the highest case rate and COVID death rate per capita in Europe and the second highest COVID fatality rate in the world behind Taiwan, according to Our World in Data.

Thus, there is significant evidence that the COVID-19 shots are ineffective and have serious known and unknown harms. Moreover, we know that COVID-19 poses minimal risk to young people. According to UNICEF, children—which it defines to be people under the age of 20—accounted for fewer than 0.4 percent of global COVID deaths. *See* https://data.unicef.org/topic/child-survival/covid-19/ (last visited June 23, 2022). Even that number may be inflated, as the CDC already reduced its death count in children by 25 percent "because its algorithm was accidentally counting deaths that were not COVID-19-related." Reuters, "CDC reports fewer COVID-19 pediatric deaths after data correction" (Mar. 18, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/cdc-reports-fewer-covid-19-pediatric-deaths-after-data-correction-2022-03-18/ (also noting that while children accounted for 19 percent of COVID infections, they only accounted for 0.26 percent of deaths). This data led UNICEF to find that "the direct impact of COVID-19 on child, adolescent and youth mortality [appears] to be limited." *Id.* Combine this evidence with evidence that most, if not all, children have contracted COVID-19 already and thus have antibodies to the virus that are at least as effective as the COVID shots. There is no reason to rush the authorization process for this group.

Our clients could understand the FDA's rushed process if COVID-19 had a particularly devastating impact on children, or if the government, schools, and health care providers treated the COVID shots as emergency use products that can be declined. But COVID-19 poses minimal risk to children. And, notwithstanding the EUA's plain language, the Department of Justice said it believes the shots can be mandated. Dawn Johnsen, U.S. Department of Justice, Office of Legal Counsel, *Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization* (July 6, 2021), *available at* https://aboutblaw.com/YNR. Although we disagree with this conclusion—and it is not binding—the likelihood that Americans will face more COVID vaccine mandates makes it especially important for the FDA to adequately study the shots' safety and efficacy in this group. It has not done that. Indeed, it is impossible for the FDA to have adequately studied all the risks and rewards of the COVID shots during this short period of time.

The FDA knows how to do this right. In 1976, the agency suspended the use of a swine flu vaccine after it discovered more than 25 deaths and 450 cases of Guillaine-Barré syndrome. It also modified its emergency use authorization of Johnson & Johnson's COVID shot after discovering evidence of potentially serious adverse events linked to that shot. Far more adverse events have been reported with the Pfizer and Moderna shots. The FDA's failure to act consistently provides further evidence of arbitrariness. *See Dongbu Steel Co. v. United States*, 635 F.3d 1363, 1371 (Fed. Cir. 2011) ("We have indicated that an agency action is arbitrary when the agency offers insufficient reasons for treating similar situations differently.").

Lives and liberties hang in the balance. Millions of Americans will soon face the difficult choice of giving their children—their babies—an experimental and ineffective shot that they do not want and whose long-term effects cannot possibly be known. The most vulnerable Americans will feel these effects the worst. They are relying on the FDA to do its job properly, to take the time you know it takes to truly assess the risks and rewards of a new pharmaceutical.

C. Environmental Impact

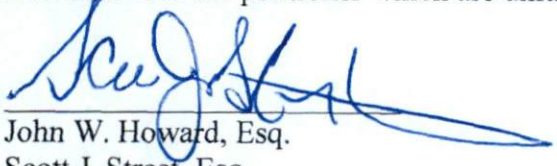
Under 21 C.F.R. §§ 25.30(h) and 25.31, no environmental impact statement is required.

D. Economic Impact

There is no direct economic impact from revoking or suspending the amended emergency use authorization discussed in this petition. We can provide a further analysis if requested.

E. Certification

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



John W. Howard, Esq.
Scott J. Street, Esq.
Attorneys for Dr. Naomi Wolf, Petitioner
701 B. Street, Suite 1725
San Diego, CA 92101
(619) 234-2482