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 electronically (21 C.F.R. § 10.30(b)(1))

Robert M. Califf, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

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

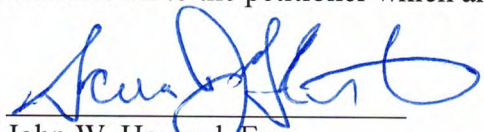
Under 21 C.F.R. §§ 25.30(h) and 25.31, no environmental impact statement is required.

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

EXHIBIT “A”

Buzz About Medicine

The "Safe and Effective" Moderna Covid Vaccine for Infants Might be Neither

The more I look, the less I like their safety data.

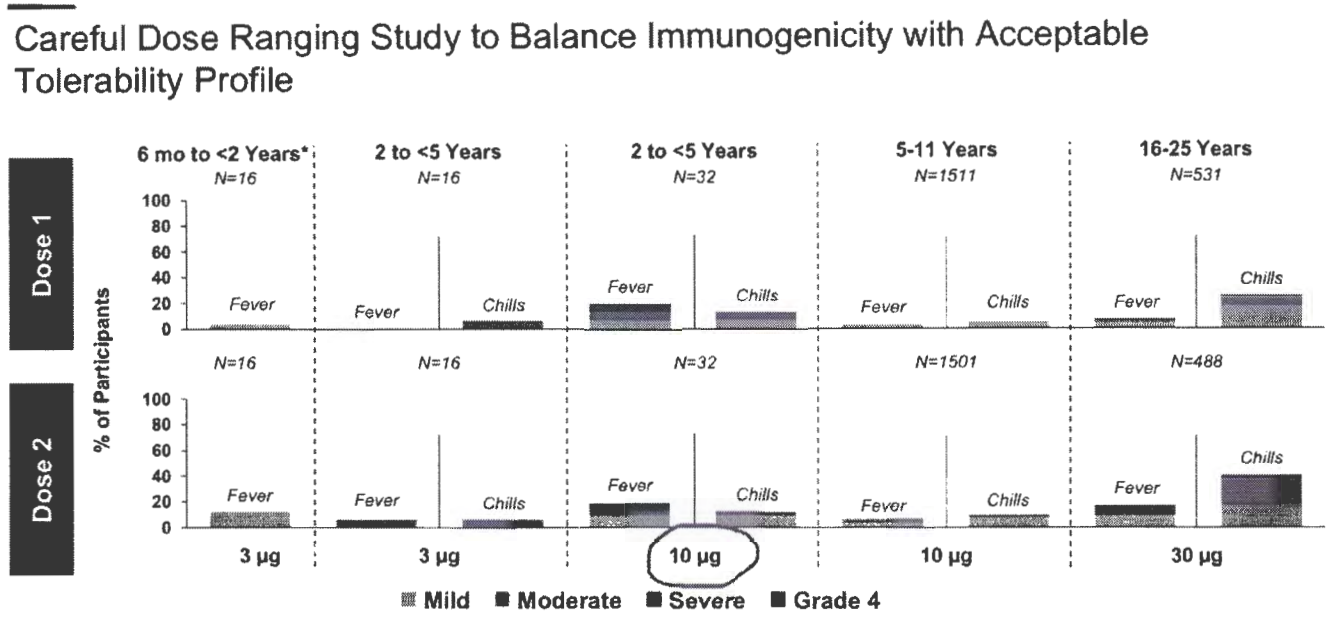
Buzz Hollander MD
23 hr ago

Photo by CDC on Unsplash

I thought I was done writing about the Moderna and Pfizer vaccines for infants and toddlers with my prior piece on the subject. "Safe, not very effective, but let parents desperate to protect their kids have the choice," would be the one line summary. However, one of my readers pointed out the rather awful rate of severe events in the Moderna 6 month to 2 year old group relative to placebo and I investigated. As a physician who prefers boosting vaccines over bashing them, I did not much care for what I found.

The 190 page document the FDA shared with the public from their review process of the Moderna Covid-19 vaccine for children 6 months to 18 years old covered a lot of ground. Skimming it through the first, and second, times, I didn't see anything that looked like a poor safety signal for the youngest cohort. Yes, severe events were unbalanced amongst vaccinated infants, but there were three times as many as in the placebo cohort, and almost nothing looked like the sort of vaccine adverse reaction we might expect. But what *were* we expecting?

To be honest, our pre-trial expectation might have been: *a lot* of adverse reactions. Think again about how Pfizer felt compelled to drop their dosage in this age group to 3mcg, based on the rates of fever with a 10mcg dose in the 2-5 year olds:



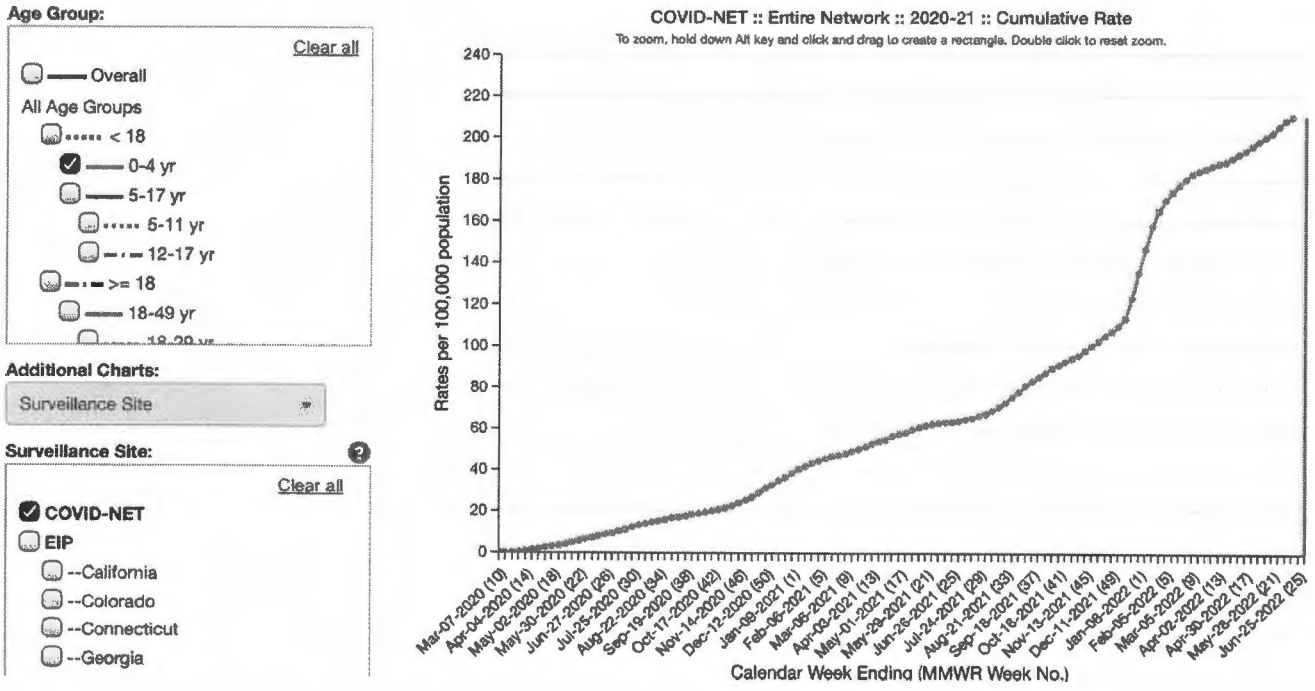
We've been told consistently that Pfizer and Moderna are roughly equal microgram-to-microgram, so if Pfizer was uncomfortable rolling out a **10mcg** dose in children under 5 years old, you can bet I would be nervous about adverse effects with a **25mcg** Moderna dose in 6 month olds!

What the FDA documents reveal, however, is an acceptable safety profile — at first glance. I mean, we *expect* a higher rate of adverse events in a group given an active drug compared to placebo; that's normal. The only concern is if the adverse event is rare but extremely dangerous (i.e., the potentially fatal blood clots from the adenovirus-vector vaccines mostly in younger women) or common enough to possibly outweigh the good they accomplish in disease

prevention (i.e., post-mRNA second shot myocarditis in young, healthy men). Honestly, it's hard to know where to stand with the Moderna 25mcg dose for infants.

On the one hand, there was one "run-of-the-mill" adverse event, attributed both by study investigators and the FDA to the vaccine, in this group: a case of febrile seizure on the day after vaccination. (Febrile seizures are terrifying for parents, sometimes lead to a brief hospitalization, but rarely yield long-term consequences.) Another infant with a family history of diabetes experienced the onset of type 1 diabetes, rather surprisingly linked to the vaccine by study investigators, but not by the FDA. Google "can vaccines cause type 1 diabetes?" if you need convincing this is a hot area of controversy in vaccinology. I'll just say it might be possible, but it's probably more possible that the child was destined to develop diabetes with one immune trigger or another eventually.

One or two infants out of 1800 experiencing a serious medical problem attributable to vaccination could be acceptable. After all, Covid-19 has put about 1 in 450 children under 5 in the hospital since the pandemic began (although the COVID-NET figures include the perhaps 15-30% of hospitalizations "with" Covid rather than "for" Covid, but I allow that distinction is anything but simple):



If these events were the only safety concerns for the 25mcg Moderna dose in this age cohort, parents and physicians would have a nuanced decision to make. Since the minority of American infants with health problems constitute roughly half of hospital admissions, a healthy infant would expect a risk well under 1 in 450, probably 1 in a few thousand. We also

don't know to what degree the Moderna vaccine will prevent hospitalization for SARS-CoV-2 infections; the study had no severe Covid-19 cases in either the vaccine or placebo groups. Certainly, it will be less than 100% effective, most of all in the children with compromised immune systems we most need to help; and whatever initial effect it has will likely wane over time. After all, to keep the comparison fair, the past 6 months were the worst of the pandemic for infant hospitalizations, but the cumulative Covid hospitalization rate over that time period was more like 1 in 1700; this would be the better comparator if the vaccine only protects for 6 months, and is remarkably similar to the 1 in 1800 rate of hospitalization for clear vaccine complications in the trial.

However, concerns for the Moderna dose really don't end there. The all-cause hospitalization rate was profoundly higher in the vaccine group. It's worth a glance:

Table 93. Serious Adverse Events Through Data Cutoff of February 21, 2022, Participants 6 Through 23 Months of Age, Study P204 Blinded Phase Part 2 and Open Label Part 1, Safety Set

Treatment Group	Age*/Sex	SAE Preferred Term	Time to Onset after Most Recent Dose	Risk factors/pertinent details	Resolution	Investigator Assessment	FDA Assessment
Part 2 Blinded							
mRNA-1273 25 µg	17 months/F	Pyrexia Febrile convulsion	Day of Dose 1 1 day after Dose 1	Fever onset 6 hours post-vaccination; unwitnessed febrile convulsion 1 day after; rash developed 3 days after fever (see narrative above)	Resolved Resolved	Related Related	Possibly related Possibly related
mRNA-1273 25 µg	18 months/M	Mastoiditis	3 days after Dose 1	Intermittent fevers 2 months prior to event onset; History of otitis media; Tested positive for adenovirus during hospitalization	Resolved	Not related	Not related
mRNA-1273 25 µg	12 months/F	Metapneumovirus infection	4 days after Dose 1	Hospitalized in intensive care unit for 3 days	Resolved	Not related	Not related
mRNA-1273 25 µg	12 months/F	Electrolyte imbalance	8 days after Dose 1	Hospitalized; concurrent RSV infection with respiratory distress and dehydration	Resolved	Not related	Not related
mRNA-1273 25 µg	12 months/F	Rhinovirus infection	8 days after Dose 1	Hospitalized for 1 day. Reported by mother to have fever of 106° F.	Resolved	Not related	Not related
mRNA-1273 25 µg	23 months/F	Foreign body in respiratory tract	15 days after Dose 1	Unspecified foreign body in respiratory tract, required bronchoscopy assisted removal	Resolved	Not related	Not related
mRNA-1273 25 µg	19 months/F	Bronchiolitis	17 days after Dose 1	Food allergy (nuts), eczema; hospitalized on high-flow nasal cannula; viral panel negative	Resolved	Not related	Not related
mRNA-1273 25 µg	19 months/M	Febrile convulsion	21 days after Dose 1	Medical history of intermittent fevers with rash; Fever for previous 2 days; Infectious disease and rheumatology diagnosed with PFAPA*; Received Dose 2 with no associated AEs	Resolved	Not related	Not related
mRNA-1273 25 µg	11 months/M	Erythema multiforme	35 days after Dose 1	History of eczema and peanut allergy; exposed to peanut butter and amoxicillin (day 8 at onset of symptoms of EM)	Resolved	Not related	Not related

mRNA-1273 25 µg	20 months/M	Adenovirus infection	35 days after Dose 1	Hospitalized due to concern for MIS-C vs Kawasaki Disease (KD). Found to be positive for adenovirus on PCR. SARS-CoV-2 negative; KD diagnosis excluded	Resolved	Not related	Not related
mRNA-1273 25 µg	14 months/M	Asthma	31 days after Dose 2	Prodromal URI symptoms, temperature of 100.3°F, diagnosis of pneumonia at urgent care and started on amoxicillin; hospitalized 4 days later for respiratory distress requiring high-flow nasal cannula. CXR at hospital: viral or reactive airway disease; viral panel negative	Resolved with sequelae: ongoing diagnosis of asthma	Not related	Not related
mRNA-1273 25 µg	15 months/F	Diabetic ketoacidosis Type 1 diabetes mellitus	37 days after Dose 2	Family history of type 1 diabetes (see narrative above)	Resolved Resolved with sequelae: diagnosis of type 1 diabetes	Related Related	Not related Not related
mRNA-1273 25 µg	22 months/F	Croup infectious	43 days after Dose 2	Inflammation of upper respiratory tract after recent adenoidectomy and turbinate reduction	Resolved	Not related	Not related
mRNA-1273 25 µg	18 months/M	Gastroenteritis viral	43 days after Dose 2	Hospitalized (2 days)	Resolved	Not related	Not related
mRNA-1273 25 µg	17 months/F	Febrile convulsion	66 days after Dose 2	Daycare reported possible seizure and tactile fever after a nap; fever 101.5 and normal exam in ED	Resolved	Not related	Not related
Placebo	15 months/M	Bronchiolitis; Rhinovirus infection; Acute respiratory failure	29 days after Dose 1	Hospitalized on high flow nasal cannula	Resolved	Not related	Not related
OL Part 1							
mRNA-1273 25 µg	16 months/M	Febrile convulsion	10 days after Dose 2	Preceding maculo-papular rash and fever suggested associated viral illness	Resolved	Not related	Not related
mRNA-1273 25 µg	7 months/M	Cough; Wheezing; Urticaria	21 days after Dose 2	Hypersensitivity to egg exposure	Resolved	Not related	Not related
mRNA-1273 25 µg	22 months/F	Rhinovirus infection	149 days after Dose 2	Hospitalized (2 days) for respiratory distress, also found to have otitis media, re-admitted 2 days after discharge for continued respiratory distress requiring oxygen (2 days)	Resolved	Not related	Not related

Source: FDA generated table based on case narratives, listings, and dataset submitted to EUA 27073, P204 (6-23 months)

The final tally, kicking out the foreign body which we are not going to try to blame on the vaccine, is 17 severe adverse events after vaccine (nearly 1 in 100 Moderna trial participants) vs 1 hospitalization for viral infection of the 600 placebo recipients. No one was hospitalized for Covid. Of those 17, we had 4 febrile seizures, 9 hospitalizations for infectious diseases, 3 serious autoimmune reactions (the erythema multiforme skin reaction, development of a hypersensitivity reaction to eggs, and the type 1 diabetes onset), and 1 serious case of croup.

Only the febrile seizure soon after vaccination was deemed related to the vaccine by the FDA. I don't fault them for this adjudication. I would not expect this potpourri of adverse reactions many days or even weeks after vaccination to be vaccine induced, either. Possible explanations would include an imbalance in the time that the placebo group was followed versus the vaccine cohort, although that is not mentioned anywhere; also possible would be flaws in data

collection with the placebo cohort (although a pharmaceutical company failing to collect data on adverse effects in the placebo arm of their trial would be strange indeed!). The most likely explanation would be coincidence, the perils of an undersized trial. We also have to allow some possibility, however, that an infant's immune system might be unfavorably altered by a high dose of a novel vaccine, and it might affect their ability to avoid severe infection or make autoimmune reactions more likely for some time.

One of the great benefits of randomized controlled trials is that adverse events should balance out, and not be confounded by the real world issues we are now left to sort through. If hospitalizations are higher in infants who receive the Moderna vaccine than a matched cohort who do not, we can't know whether that's simply due to less healthy infants (rightly) being given this vaccine at a higher rate than healthier infants. We might never know the answer to this rather pressing question.

In a more perfect world, a physician like me would not have to rely on a Substack reader under a *nom de plume* like "Jack McJackers" to even identify a serious safety concern like this. This sort of potential safety signal should be out in the world, being discussed. Curious, I sifted through the 7.5 hour video of the FDA's advisory committee meeting to see if the subject came up; at the 2 hour mark, Dr Ofer Levy shares these comments about the imbalance of serious RSV, croup and pneumonia cases in the Moderna group:

> "I had a question about what appeared to be an imbalance with respect to RSV infections and pneumonia. And my question to you is, I mean, you know, *a priori* we might not think that that's possible but on the other hand vaccines can have off-target effects, effects on the immune memory, but who knows - just looking at the data, is that a statistically significant higher RSV and pneumonia signal in the vaccine group?"

So, the concern was raised. It was parried by other VRBAC speakers noting that the overall rate of viral upper respiratory infections was actually higher in the placebo group since they had a higher rate of Covid-19 infection, 12.2% to 10.3%; and that the high number of reviewed events makes statistical analysis challenging (I think this is a very fair point, especially since we have two age subsets for two vaccine candidates to pick through for problems). Another unnamed speaker stated, "We did not see increased severity of these types of infection in the vaccinated group compared to the placebo group." I am truly unsure what this person *did* "see." Clearly, the overall rate of severe infections was higher in the vaccine group; the only question is whether it was simply failure of the trial to give us representative data.

One thing I can say with certainty: anyone claiming that the benefits of the Moderna 25mcg vaccine for this age group *clearly* outweigh its risks is not speaking the truth. I really don't know what to say when someone who knows much more about the subject than I do, White House COVID-19 Response Coordinator Dr. Ashish Jha, makes a statement like this:

> Now, we know that these vaccines are extraordinarily safe and highly effective. Remember, after an extensive review by career FDA and CDC scientists, they were unanimously approved by an independent group of expert scientists.
>
> Now, I like to remind people it's hard to get a group of independent scientists agree on anything, and yet 21 independent scientists who serve on VRBPAC unanimously voted in agreement that the benefits of these vaccines clearly outweigh the risks. And then, 12 independent scientists that make up the a ACIP agreed, recommending these vaccines for kids six months and above.

Seriously?

Again, I could handle the uncertainty for a frankly borderline safety concern if we knew this vaccine would make a substantial impact on Covid-19 disease burden, like the mRNA vaccines accomplished in the at-risk adult population, where they truly have been life-saving. However, we lack such confidence in the infant cohort.

Efficacy? Middling at best, even in a very short window after the second shot.

Table 84. Incidence of SARS-CoV-2 Infection Starting 14 Days after Dose 2, Participants 6 Through 23 Months of Age, Study P204 Part 2, Per-Protocol Set for Efficacy

Disease/Infection	mRNA-1273 25 µg N=1511 Cases (%) Person-Years[a] Incidence Rate per 1,000 Person-Years[b] (95% CI)	Placebo N=513 Cases (%) Person-Years[a] Incidence Rate per 1,000 Person-Years[b] (95% CI)	Vaccine Efficacy[c] (95% CI)
SARS-CoV-2 infection[d] (regardless of symptoms)	81 (5.4) 363.5 222.8 (177.0, 276.9)	45 (8.8) 120.2 374.4 (273.1, 501.0)	40.5% (12.3%, 59.2%)

How about stopping transmission via reducing asymptomatic infections? Nope.

Asymptomatic SARS-CoV-2 infection[e]	32 (2.1) 363.7 88.0 (60.2, 124.2)	11 (2.1) 120.2 91.5 (45.7, 163.7)	3.8% (-111.5%, 52.8%)

Sources: P204 (6-23 months) Table 14.2.5.1.1 2.1, Table 14.2.6.1.1.2.1.1

Helpful in the one high risk group for which the study gathered data, obese infants? Negative efficacy.

Obesity status	--	--	--
Obese	13/330 (3.9) 160.5 (85.4, 274.4)	4/118 (3.4) 151.9 (41.4, 388.9)	-5.6% (-344.8, 67.4)
Non-obese	38/1179 (3.2) 132.2 (93.6, 181.5)	30/394 (7.6) 316.2 (213.3, 451.4)	58.2% (30.1, 74.8)

Source: P204 (6-23 months) 14.2.8.1.1.3.1

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.

Truly, 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. For a healthy infant, or the majority of infants in the U.S. who have already had Covid? Given annual hospitalization rates probably in the 1 in many 1000s for this group, it seems very unlikely that benefits outweigh risks for this particular vaccine.

I know the FDA, CDC and the White House have enthusiastically endorsed the Moderna Covid-19 vaccine for all infants. I think a system that is capable of such an endorsement is broken, and in dire need of fixing.

support my work.

Type your email... Subscribe

 13 likes

13 11

11 Comments

Write a comment...

Orlando 22 hr ago

I think this might just be your "red pill" moment. I really enjoyed reading your process of re-evaluating the data and updating your opinion

10 Reply Collapse

Jack McJackers Writes McJacker's Newsletter 22 hr ago

"I know the FDA, CDC and the White House have enthusiastically endorsed the Moderna Covid-19 vaccine for all infants. I think a system that is capable of such an endorsement is broken, and in dire need of fixing."

Really well put.

As a lay reader I don't know what to conclude -- other than these trials are tiny and should've been bigger -- but it's easy enough to see that the confident pronouncements from folks like Walensky and Jha bear little resemblance to the actual clinical trial submissions...

Where I live (California) there's a proposed bill to punish doctors for spreading Covid vaccine misinformation. Presumably, adopting the position you've sketched in this article could be enough to get California doctors delicensed! Scary stuff.

Here's to hoping cooler heads will prevail, doctors can advise as they see fit, and we stop rewarding cheerleading and re-focus on evidence as the basis of pharmaceutical regulation.

5 Reply Collapse

3 replies

9 more comments...

Ready for more?

Type your email... Subscribe