



# PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL

August 9, 2022

TO: Christi A. Grimm  
Inspector General  
U.S. Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

David Kessler  
Chief Science Officer for COVID-19 Response  
U.S. Health and Human Services  
330 Independence Ave., S.W.  
Washington, D.C. 20201

Joanne Cono  
Office of Science Chief Science and Medical Advisor  
Center for Disease Control Scientific Integrity Officer  
1600 Clifton Road  
Atlanta, GA 30329

Laurie Lenkel  
Director  
Office of the Ombudsman  
Food and Drug Administration  
10903 New Hampshire Avenue  
WO 1, Room 4204  
Silver Spring, MD 20993  
[ombuds@oc.fda.gov](mailto:ombuds@oc.fda.gov)

**Re: Request for Investigation into Apparent Scientific Integrity Violations by  
Inappropriately Prioritizing Political Considerations When Recommending  
Children Under the Age of 5 Be Vaccinated Against Covid-19**

Dear Ms. Grimm,

Maintaining the trust of the American people is particularly crucial in the midst of a global pandemic, where real time information can have profound personal and societal consequences. Protect the Public's Trust (PPT) is a nonpartisan organization dedicated to promoting ethics in government and restoring the public's trust in government officials. A loss of trust in public health officials can result in citizens ignoring or disregarding even the most logical, scientifically grounded, evidence-based, and well thought out directives. The consequences of a substantial loss of trust can be tragic.



# PROTECT the PUBLIC'S TRUST

As the Centers for Disease Control and Prevention's ("CDC") own reports show, the evidence supporting the efficacy of mRNA vaccines against Covid-19 for children aged 6 months through four years is weak and inconclusive. Nevertheless, the CDC adopted a broad recommendation that all children be vaccinated. This recommendation is unsupported by the scientific data cited by the agency and appears to reflect political considerations, in violation of the agency's own Scientific Integrity policy.

Accordingly, we request an immediate investigation into whether the CDC's recommendation that all children aged six months through four years old receive an mRNA vaccine was properly grounded in the best available science or was improperly influenced by political considerations.

## Background

On June 18, 2022, CDC Director Rochelle Walensky endorsed the Advisory Committee on Immunization Practices' ("ACIP") recommendation that all children aged six months through four years old (herein after "children") be vaccinated against COVID-19.<sup>1</sup>

ACIP made an interim recommendation regarding the use of two COVID-19 vaccines by children: a Moderna vaccine and a Pfizer-BioNTech vaccine.<sup>2</sup> For both vaccines, the "critical benefit of interest was prevention of symptomatic, laboratory-confirmed COVID-19," while the "critical harm of interest was serious adverse events."<sup>3</sup>

For the Moderna vaccine, the ACIP noted "[a] lower risk of symptomatic COVID-19 was observed with vaccination compared with placebo," while "[t]he available data indicates that [severe adverse events] were more common in vaccine recipients, but certainty in the estimate was very low."<sup>4</sup>

---

<sup>1</sup> *CDC Recommends COVID-19 Vaccines for Young Children*, CDC (June 18, 2022), <https://www.cdc.gov/media/releases/2022/s0618-children-vaccine.html#:~:text=Today%2C%20CDC%20Director%20Rochelle%20P,receive%20a%20COVID%2D19%20vaccine>.

<sup>2</sup> *See Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months-5 Years – United States, June 2022*, CDC (Jul. 1, 2022), <https://www.cdc.gov/mmwr/volumes/71/wr/mm7126e2.htm>.

<sup>3</sup> *See Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine for Children Aged 6 Months-5 Years*, CDC (June 27, 2022), <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine-6-months-5-years.html>; *Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine for Children Aged 6 Months-4 Years*, CDC (June 27, 2022), <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html>.

<sup>4</sup> *Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19 Vaccine for Children Aged 6 Months-5 Years*, CDC (June 27, 2022), <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine-6-months-5-years.html>.



# PROTECT the PUBLIC'S TRUST

For Pfizer, the ACIP noted “[a] lower risk of symptomatic COVID-19 was observed with vaccination compared with placebo, but certainty in the estimate was very low,” while “[t]he available data indicated that [severe adverse events] were balanced comparing vaccine and placebo recipients, but certainty in the estimate was low.”<sup>5</sup>

In making its recommendation, ACIP “considered the importance of COVID-19 as a public health problem, as well as parents’ values and preferences, acceptability, feasibility, resource use, and equity regarding use of mRNA COVID-19 vaccines among children aged 6 months-5 years.”<sup>6</sup> ACIP noted:

The pandemic has also had additional indirect effects on children and families, including missed routine childhood immunizations and health care visits; worsening of children’s social, emotional, and mental well-being; and disruptions in early child care and education programs (17–19). In a survey conducted during July 15–August 2, 2021, 39% of parents reported that an adult in their household either left a job or changed work schedules to care for children during the past year; parents of a child aged <5 years, Black and African American parents, Hispanic or Latino parents, and parents with an annual household income of <\$40,000 were most likely to report household job disruptions (20). COVID-19 vaccination in this age group may provide parents with increased confidence to return to prepandemic activities, improving social interactions in young children.<sup>7</sup>

Further, ACIP observed “Based on the National Immunization Survey-Child COVID Module interviews conducted in May 2022, 33.5% of parents said they would definitely vaccinate their child aged 6 months–4 years for COVID-19, once eligible, and 19.6% said they would probably vaccinate their child aged 6 months–4 years.”<sup>8</sup>

These recommendations have been criticized in the press, including in pieces authored by prominent medical doctors.

One report claimed that “this sweeping recommendation was based on extremely weak, inconclusive data provided by Pfizer and Moderna.”<sup>9</sup> With respect to Pfizer, this report noted “Pfizer reported a range of vaccine efficacy so wide that no conclusion could be

---

<sup>5</sup> *Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine for Children Aged 6 Months–4 Years*, CDC (June 27, 2022), <https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html>.

<sup>6</sup> *Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months-5 Years – United States, June 2022*, CDC (Jul. 1, 2022), <https://www.cdc.gov/mmwr/volumes/71/wr/mm7126e2.htm>.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* (citation omitted).

<sup>9</sup> Marty Markary and Tracy Beth Hoeg, *U.S. Public Health Agencies Aren’t ‘Following the Science,’ Officials Say*, Common Sense News (Jul. 14, 2022), <https://www.commonsense.news/p/us-public-health-agencies-arent-following>.



# PROTECT the PUBLIC'S TRUST

inferred,” claimed that “[n]o reputable medical journal would accept such sloppy and incomplete results with such a small sample size,” and quoted a “high-level CDC official – whose expertise is in the evaluation of clinical data” as saying “You can inject [the children] with it or squirt it in their face, and you’ll get the same benefit.”

With respect to Moderna, this report noted that there was a “very weak vaccine efficacy of just 4%” against asymptomatic infections, while noting that the vaccine “did show efficacy that was statistically significant [against symptomatic infections], but the efficacy was low.”

A separate press report criticized the studies underlying the FDA’s authorization of the two vaccines for children on grounds that would likely also apply to the CDC’s recommendation. Specifically, the article criticized the use of antibody tests as a proxy for immunity, the extrapolation of studies done on adults to compensate for a small sample size of children, and the inability of the vaccines to obtain efficacy levels that the FDA previously identified as benchmarks.<sup>10</sup>

This is also not the first instance of the FDA (and the CDC) departing from standard procedures regarding immunization decisions for COVID-19. According to media reports, two senior officials with the FDA resigned their positions in Fall 2021 based on their view that the FDA’s top vaccine official, Peter Marks, “sidelined [them] on major decisions...was jumping the gun [on boosters]”...and relinquishing too much autonomy over traditional FDA immunization decisions to the CDC.<sup>11</sup>

## Scientific Integrity

The CDC’s scientific integrity policy identifies accountability and integrity as “core values,” stating:

Accountability — As diligent stewards of public trust and public funds, we act decisively and compassionately in service to the people’s health. We ensure that our research and our services are based on sound science and meet real public needs to achieve our public health goals.

...

---

<sup>10</sup> James D. Agresti, *FDA Violated Own Safety and Efficacy Standards in Approving Covid-19 Vaccines For Children*, Just the Facts Daily (Jul. 14, 2022), <https://www.justfactsdaily.com/covid-19-vaccines-children-fda-standards-violated>.

<sup>11</sup> Juliegrace Brufke, *Two senior FDA officials resign over Biden administration booster shot plan*, New York Post (September 1, 2021).



# PROTECT the PUBLIC'S TRUST

Integrity — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.<sup>12</sup>

In addition, the scientific integrity policy declares “[c]entral to this process is a commitment to transparency, honesty, and thorough consideration of research outcomes.”<sup>13</sup> Moreover, “CDC has a responsibility to conduct the best science and is committed to disseminating scientific findings and results without being influenced by policy or political issues.”<sup>14</sup>

The Food and Drug Administration (FDA) has a similar policy that seeks to protect against policy or political agendas driving decision-making, recommendations, and deceptive public communications.<sup>15</sup> This includes including important nuances when communicating scientific findings and recommendations to the public: “Protect the integrity of scientific data and ensuring its accurate presentation, including the underlying assumptions and uncertainties.”<sup>16</sup>

In addition to the CDC’s scientific integrity policy, President Biden’s Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking states, “Scientific findings should never be distorted or influenced by political considerations:”

It is the policy of my Administration to make evidence-based decisions guided by the best available science and data. Scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies, and to the delivery of equitable programs, across every area of government. **Scientific findings should never be distorted or influenced by political considerations.** When scientific or technological information is considered in policy decisions, it should be subjected to well-established scientific processes, including peer review where feasible and appropriate, with appropriate protections for privacy.<sup>17</sup>

## Analysis

---

<sup>12</sup> CDC Guidance on Scientific Integrity, v. 2.1 at 2, Office of the Associate Director for Science (ODAS) (April 2016) [https://www.cdc.gov/os/integrity/docs/CDCSIGuide\\_042516.pdf](https://www.cdc.gov/os/integrity/docs/CDCSIGuide_042516.pdf).

<sup>13</sup> *Id.* at 2.

<sup>14</sup> *Id.* at 3.

<sup>15</sup> FDA’s Key Principles of Scientific Integrity (current as of 03/29/2018), found at: <https://www.fda.gov/science-research/about-science-research-fda/fdas-key-principles-scientific-integrity>.

<sup>16</sup> *Id.*

<sup>17</sup> Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, 86 Fed. Reg. 8845 (Jan. 27, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-02-10/pdf/2021-02839.pdf>.



# PROTECT the PUBLIC'S TRUST

The CDC's own data suggests that the agency based its decision to recommend that children receive the COVID-19 vaccine on policy and political, rather than scientific, considerations. This is particularly true with respect to the CDC's recommendation that children receive the Pfizer vaccine.

The CDC's own data provides very little support for the notion that Pfizer vaccine is effective in children. The stated goal of a COVID vaccine is preventing symptomatic infection. Yet, the CDC itself noted that it has "very low confidence" that the Pfizer vaccine actually prevents symptomatic infection. This suggests that other considerations are predominating over scientific concerns in recommending that children receive the Pfizer vaccine. These concerns are amplified by the statements of "high level" CDC officials, who have been quoted in press sources suggesting that the Pfizer vaccine is little better than a placebo.

While the evidence in support of the Moderna vaccine is better, it still falls short of what is to be expected for such a far-reaching recommendation. Moreover, the CDC's data suggests that severe adverse events were more common with the Moderna vaccine than with a placebo, further indicating that the decision to broadly administer the Moderna vaccine may not be costless.<sup>18</sup>

The ACIP recommendation itself suggests that political or policy concerns may have tipped the scales in favor of recommending vaccination. For instance, ACIP noted "COVID-19 vaccination in this age group may provide parents with increased confidence to return to pre-pandemic activities, improving social interactions in young children" and indicated that a majority of parents would either "definitely" or "probably" vaccinate their children if it were recommended by the CDC. The top officials at the Department of Health and Human Services, CDC, FDA and the White House all appear to understand the importance of this point and have factored it into their messaging efforts.

Yet, by papering over or ignoring altogether the important nuances that may cause parents to pause before giving their infants and toddlers what appears to be little better than a placebo, senior government officials have violated these long-standing scientific integrity protections. Some public statements, led by the President himself, exemplify those that raise these concerns:

President Joe Biden:

"These vaccines are safe, highly effective, and will give parents the peace of mind of knowing their child is protected from the worst outcomes of COVID-19. If you are a parent who wants to protect your child, I urge you

---

<sup>18</sup> Tellingly, the confidence level for this conclusion was "very low," the same confidence level for the efficacy of the Pfizer vaccine. There is an apparent internal inconsistency in why a very low confidence level is sufficient to support the critical benefit efficacy of the Pfizer vaccine such that the vaccine is recommended, but not the critical harm of the Moderna vaccine such that it is not.



# PROTECT the PUBLIC'S TRUST

to speak with your child's pediatrician and make a plan to get your child vaccinated as soon as the vaccine becomes available to you."<sup>19</sup>

HHS Secretary Xavier Becerra:

"We are following the data and science as we make sure all Americans are eligible and have access to COVID-19 vaccines and boosters to prevent severe disease and save lives. Based on CDC and FDA actions, we now know that vaccination for our children 6 months through 5 years old is safe and effective and we are ready to get millions of children vaccinated.... COVID-19 vaccines are the best way to protect yourself and your loved ones from severe illness, hospitalizations, and death."<sup>20</sup>

CDC Director Rochelle Walensky:

"COVID-19 vaccines are now available for children under 5. ...[W]e now know based on rigorous scientific review that the vaccines available here in the United States can be used safely and effectively in children under 5. Vaccination young children is a critical opportunity to protect them against hospitalization and death from COVID-19. Parents, I strongly encourage you to get your children vaccinated. ...I hope all parents will take advantage of these life-saving vaccines and protect their children."<sup>21</sup>

FDA Director Robert Califf:

"[W]e expect the vaccines for younger children will provide protection for the most severe outcomes of COVID-19 such as hospitalization and death."<sup>22</sup>

Dr. Peter Marks, Head of FDA's Vaccine Division (June 17, 2022):

"Parents should feel comfortable giving either one of these vaccines to their children...Unless you really want to dive into the subtlety, to a first approximation, the correct answer here is whatever vaccine your health care provider or pediatrician has, that's what I would give my child. If I were to go out right now, to the nearest pharmacy, I would let my child, if they were that age, get whatever vaccine was available."<sup>23</sup>

---

<sup>19</sup> "Statement by President Biden on the First COVID-19 Vaccines for Kids Under 5," Statements and Releases, June 18, 2022, found at: <https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/18/statement-by-president-biden-on-the-first-covid-19-vaccines-for-kids-under-5/>.

<sup>20</sup> "Statement from HHS Secretary Xavier Becerra on COVID-19 Vaccines for Children 6 months through 5 Years Old," June 18, 2022, found at <https://www.hhs.gov/about/news/2022/06/18/statement-from-hhs-secretary-xavier-becerra-on-covid-19-vaccines-for-children-6-months-to-5-years-old.html>.

<sup>21</sup> "CDC Recommends COVID-19 Vaccine for Children Under 5," YouTube video (June 18, 2022) found at: <https://www.nytimes.com/video/us/10000008404432/fda-covid-vaccine-children.html?playlistId=video/coronavirus-news-update>.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*



# PROTECT the PUBLIC'S TRUST

Taken together, along with the paucity of data supporting the efficacy of the vaccines themselves, the unequivocal public messaging by senior officials at the CDC and FDA suggest that the CDC actions may have been driven by policy and political concerns rather than scientific data to improve the health of children.

## Conclusion

The CDC's own data to date suggests that the COVID-19 vaccines for children, and the Pfizer vaccine in particular, can be viewed as little better than a placebo to encourage parents to feel confident returning to normal activity. This is not reflected in the public communications by CDC, FDA, and HHS officials promoting the vaccine and encouraging the public to vaccinate their infants and toddlers to prevent against severe disease, hospitalization or even death.

To be sure, additional studies may ultimately vindicate the efficacy of the Moderna and Pfizer vaccines for children. But, even after using study methodologies that depart from previously stated best practices, the information available at the time of the CDC's recommendation is "extremely weak" and "inconclusive." This leads to inescapable concerns that the CDC's recommendation was based on factors other than the scientific evidence, particularly evidence demonstrating an actual benefit to a child's health or likelihood of avoiding hospitalization or death due to COVID-19.

Accordingly, we call on you to immediately open an investigation into whether the CDC, FDA, or other pertinent scientific integrity policy has been violated by, among other instances identified within this complaint, allowing policy concerns to drive decisions on whether to recommend that children receive the Moderna and/or Pfizer vaccine. Thank you.

Sincerely,

Michael Chamberlain  
Director  
Protect the Public's Trust