PROTECT the PUBLIC'S TRUST

December 10, 2025

Juliet T. Hodgkins
Acting Inspector General
Office of the Inspector General
U.S. Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Michael Kratsios
Director
Office of Science and Technology Policy
Executive Office of the President
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National Institutes of Health
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Director
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Re: Resubmission of complaints alleging violations of scientific integrity regarding COVID-19 vaccines and children

Dear Ms. Hodgkins and other distinguished leaders,

Attached are three separate complaints filed by Protect the Public's Trust between the dates of August 9, 2022, and December 16, 2022, called Attachments A, B, and C, respectively. Each contains serious allegations of violations of scientific integrity principles as they relate to the federal government's COVID-19 vaccinations and children.

The allegations in these complaints are especially relevant in light of recent revelations that link at least 10 childhood deaths to COVID-19 vaccinations. Multiple media reports describe a Food and Drug Administration (FDA) internal memo making this connection and that political considerations may have played a role in the FDA. The reports also detail the FDA's components delaying or refusing to recognize these connections in the past, including while component agencies of the Department of Health and Human

Services (HHS) were recommending COVID-19 vaccinations for children as young as six months. According to one report:

> "This is a profound revelation. For the first time, the US FDA will acknowledge that COVID-19 vaccines have killed American children," [CBER Director Dr. Vinay] Prasad wrote. "Healthy young children who faced tremendously low risk of death were coerced, at the behest of the Biden administration, via school and work mandates, to receive a vaccine that could result in death. In many cases, such mandates were harmful."
>
> Prasad attributed the delayed recognition of pediatric vaccine fatalities to "cultural and systemic" failures inside CBER, suggesting that some safety concerns were dismissed because of internal resistance, politics, or pressure to support mass vaccination.[1]

In consideration of President Trump's Executive Order (EO) 14303, "Restoring Gold Standard Science," and the June 23, 2025 memorandum from Director of the Office of Science and Technology Policy (OSTP) Michael J. Kratsios to the heads of executive departments and agencies, we urge you investigate each of these incidents with an eye toward rectifying the record.

Attachment A

On August 9, 2022, PPT filed Attachment C, a scientific integrity complaint against the Centers for Disease Control and Prevention (CDC) and the FDA. The complaint alleges officials at these agencies may have allowed policy and political considerations to trump data and science when recommending COVID-19 vaccines for children under the age of five. 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.

Attachment B

Documents obtained via the Freedom of Information Act (FOIA) emboldened PPT to file another scientific integrity complaint against the CDC on November 16, 2022. The documents revealed doctors within the CDC using a presentation to declare that COVID-19 is among the top five causes of death for children <1 year through ages 15-19 years. The source for this claim was a non-peer-reviewed preprint study, which also overstated the number of deaths from COVID-19 in children by 32 percent. It appears that the

[1] Ozimek, Tom, *FDA Internal Memo Links Child Deaths to COVID-19 Vaccination*, The Epoch Times, November 29, 2025, https://www.theepochtimes.com/us/fda-internal-memo-links-child-deaths-to-covid-19-vaccination-5951428

study's misstated claim regarding the threat COVID-19 poses to children justified the recommendation for children to be comprehensively vaccinated.

Attachment C

Attachment C, filed on December 16, 2022, reveals another instance of the politicization of science and other possible violations of scientific integrity policies by federal public health agencies. A number of studies clearly established that COVID-19 vaccines presented a special risk of certain severe negative reactions to the vaccines, categorized as adverse events of special interest (AESIs), including myocarditis, pericarditis, and allergic/immune system reactions like anaphylaxis or Guillain-Barré syndrome. Despite the CDC's explicit knowledge of these serious potential side effects from the vaccines, the agency conspicuously failed to explicitly track them, burying them instead in text reports that are difficult to track and aggregate, making it almost impossible to get a full picture of their prevalence.

We are hopeful that new leadership at HHS will bring a revitalized commitment to the principles of scientific integrity. Therefore, we are resubmitting our complaints and calling again for an immediate investigation into the various missteps taken by the previous administration as it relates to COVID-19.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust
michael@protectpublicstrust.org

Attachment A

PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL August 9, 2022

TO: Christi A. Grimm
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David Kessler
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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.

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.[1]

ACIP made an interim recommendation regarding the use of two COVID-19 vaccines by children: a Moderna vaccine and a Pfizer-BioNTech vaccine.[2] 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."[3]

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."[4]

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[1] *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.

[2] *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.

[3] *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.

[4] *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.

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."[5]

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."[6] 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.[7]

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."[8]

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."[9] With respect to Pfizer, this report noted "Pfizer reported a range of vaccine efficacy so wide that no conclusion could be

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[5] *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.

[6] *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.

[7] *Id*.

[8] *Id*. (citation omitted).

[9] 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.

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.[10]

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.[11]

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.
>
> . . .

[10] 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.

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

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

In addition, the scientific integrity policy declares "[c]entral to this process is a commitment to transparency, honesty, and thorough consideration of research outcomes."[13] 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."[14]

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.[15] 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."[16]

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.[17]

Analysis

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[12] 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.
[13] *Id*. at 2.
[14] *Id*. at 3.
[15] 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.
[16] *Id.*
[17] 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.

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.[18]

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

[18] 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.

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."[19]

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."[20]

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."[21]

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."[22]

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."[23]

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[19] "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/.

[20] "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.

[21] "CDC Recommends COVID-19 Vaccine for Children Under 5," YouTube video (June 18, 2022) found at: https://www.nytimes.com/video/us/100000008404432/fda-covid-vaccine-children.html?playlistId=video/coronavirus-news-update.

[22] *Id.*

[23] *Id.*

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

Attachment B

PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL November 16, 2022

TO: Christi A. Grimm
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David Kessler
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Joanne Cono
Office of Science Chief Science and Medical Advisor
Center for Disease Control Scientific Integrity Officer
1600 Clifton Road
Atlanta, GA 30329

Re: Request for Investigation into Apparent Scientific Integrity Violations by Continuing to Cite False or Misleading Data Regarding Childhood Mortality from Covid-19

Dear Ms. Grimm,

The title villain in Ian Fleming's James Bond novel *Goldfinger* declared, "Once is happenstance. Twice is coincidence. Three times is enemy action." If misinformation and mistrust are seen as the enemies of public health officials, the Centers for Disease Control (CDC) may be teetering on the precipice of aid and comfort. We call your attention to yet another instance[1] of senior officials within the CDC prioritizing the Biden Administration's vaccine policy goals[2] above the science.[3] In the face of clear evidence that the CDC's public representation of the science was misleading and inaccurate, senior

[1] Protect the Public's Trust, *Request for Investigation into Whether NIH Director and Other HHS Agency Officials Violated the Agency's Scientific Integrity Policy*, https://protectpublicstrust.org/wp-content/uploads/Request-for-Investigation-HHS-Scientific-Integrity.pdf
[2] Protect the Public's Trust, *Request for Investigation into Apparent Scientific Integrity Violations by Inappropriately Withholding Data About Covid-19 From the Public*, https://protectpublicstrust.org/wp-content/uploads/2022/03/CDC-Scientific-Integrity-Complaint.pdf
[3] Protect the Public's Trust, *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*, https://protectpublicstrust.org/wp-content/uploads/2022/08/CDC-Scientific-Integrity-Complaint.pdf

officials, including Director Rochelle Walensky, perpetuated an intellectually flawed and politically driven conclusion. This type of reckless, politics-above-science approach is dangerous to public health and a violation of basic principles of scientific integrity. We urge your office to investigate this abuse of power before additional harm is brought to American families and children.

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. Unfortunately, recent surveys indicate that less than half of the American public trusts the CDC on coronavirus and a recent incident exemplifies why this may be so. [4]

On June 17, 2022, Dr. Katherine E. Fleming-Dutra and Dr. Sara Oliver, doctors with the Centers for Disease Control (CDC) presented a power point slide deck (the "Presentation") with CDC labeling titled "COVID-19 Epidemiology in Children Ages 6 Months-4 Years."[5] This presentation claimed that "COVID-19 is a leading cause of death among children ages 0-19 years" and claimed that COVID-19 ranked either 4th or 5th among all causes of death for children in age groups ranging from <1 through 15-19 years.

This information was derived from a study (the "Study") that had significant flaws. The Study claimed 1,433 childhood deaths from COVID-19 when the true figure was 1,088 – a 32% overestimation. Worse, Dr. Fleming-Dutra and others at the CDC were informed that the information in the Study was not true no later than June 18, 2022. Since that time, the authors of the Study updated it to "take into account some of this feedback."[6] Neither Drs. Fleming-Dutra and Oliver nor the CDC have made or issued any correction to their statements and policy recommendations that were based on the misinformation in the Study.

Accordingly, we request an immediate investigation into whether the CDC's initial citation to misleading and inaccurate data and/or its continuing failure to correct its misleading and inaccurate data violates the CDC's scientific integrity policies.

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[4] NBC News, *On Covid, Americans can be stingy with their trust*, (January 23, 2022), https://www.nbcnews.com/politics/meet-the-press/who-do-americans-trust-covid-answer-complicated-n1287895

[5] The slide deck remains available here: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf.

[6] *See* Seth Flaxman (June 19, 2022), https://twitter.com/flaxter/status/1538533537355288577.

Background

On June 17, 2022, Drs. Katherine E. Fleming-Dutra and Sara Oliver reportedly presented a power point presentation to the CDC's Advisory Committee on Immunization Practices (the "ACIP").[7] This Presentation deck included claims related to childhood mortality from COVID-19. For example, the slide deck states "COVID-19 is a leading cause of death among children ages 0-19 years" and claims that from March 1, 2020, through April 30, 2022, COVID-19 ranked fourth among causes of death for children aged < 1 year, fifth for children aged 1-4 years, fifth for children aged 5-9 years, fourth for children aged 10-14 years, and fourth for children aged 15-19 years."[8]

The slide deck cited the following study in support of its claims: "Flaxman S, Whittaker C, Semenova E et al. Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States. medRxiv 2022.05.23.22275458; doi: https://doi.org/10.1101/2022.05.23.22275458."

On June 18, 2022, Ms. Kelley Krohnert emailed Dr. Fleming-Dutra to express concern about the June 17 slide deck, stating:

> I am concerned about some very misleading data in the slide deck that you put together for the VRBPAC and ACIP meetings last week. The pre-print from the UK about Covid as a leading cause of death has some serious flaws that seem to have been overlooked, and even exacerbated by the presentation of the rankings in the slide deck. I wanted to give you an opportunity to read my fact check of the data, and see if you had a response.[9]

Ms. Korhnert went on to refer the recipient to the following web page: https://www.covid-georgia.com/pediatric-news/fact-check-covid-is-a-leading-cause-of-death-in-children/.

Email exchanges show that Dr. Fleming-Dutra and other CDC employees discussed Ms. Korhnert's concerns but did not make any changes.

On June 19, 2022, the lead author of the Study, Dr. Seth Flaxman, announced via Twitter "[o]ur preprint on Covid mortality and young people . . . in the US was cited at

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[7] *See* Lena H. Sun and Joel Achenbach, *Coronavirus Vaccines for Kids Under 5 Are Finally Here*, Wash. Post (June 18, 2022), https://www.washingtonpost.com/health/2022/06/18/cdc-coronavirus-vaccine-young-children/.

[8] *See* Katherine E. Fleming-Dutra, MD, *COVID-19 Epidemiology in Children Ages 6 Months – 4 Years* (June 17, 2022), available at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf.

[9] *See* Page 49 of the following email production: https://www.documentcloud.org/documents/23226912-cdc-emails-on-child-covid-19-deaths.

the FDA VRBPAC and CDC ACIP meetings this week. . . . We have received some criticism along several different dimensions. We are planning to update the preprint to take into account some of this feedback."[10]

On June 28, 2022, Dr. Flaxman and his colleagues posted a revised preprint of their article, which showed that Covid-19 ranked eighth of all causes of death for children aged 0-19. The webpage for this version of the preprint (as well as a version published on September 20, 2022) contains the following disclaimer: "This article is a preprint and has not been peer-reviewed... It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice."[11] [12] Yet CDC officials clearly ignored this statement and relied upon the Study to guide the development of policy, recommendations, and public pronouncements.

To the best of our knowledge, neither Dr. Fleming-Dutra nor anyone else at the CDC has corrected the information in the June 17, 2022, presentation to account for Dr. Flaxman, *et al*.'s correction, let alone address the other concerns cited by Ms. Korhnert or others.[13]

Scientific Integrity

a. HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

Under the HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,[14] requirements include CDC-specific guidelines that ensure the integrity of science and policymaking by requiring that information released to the public be objective. The HHS Guidelines also require the use of peer review to ensure the accuracy of the CDC's scientific research and policy recommendations:

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[10] https://twitter.com/repthomasmassie/status/1369629668022902786

[11] Seth Flaxman, *et al*., *Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States*, medRxiv (June 28, 2022), https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v3 (emphasis in original).

[12] Seth Flaxman, et al., Covid-19 is a leading cause of death in children and young people ages 0-19 years in the United States, medRxiv (September 20, 2022), https://www.medrxiv.org/content/10.1101/2022.05.23.22275458v4 (emphasis in original).

[13] *See* Kelley Korhnert, *Fact Check: Covid as a Leading Cause of Death in Children*, COVID-19 in Georgia, https://www.covid-georgia.com/pediatric-news/fact-check-covid-is-a-leading-cause-of-death-in-children/.

[14] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public, Office of the Assistant Secretary for Planning and Evaluation (ASPE) (September 30, 2002) https://aspe.hhs.gov/reports/hhs-guidelines-ensuring-maximizing-quality-objectivity-utility-integrity-information-disseminated.

- "CDC policy is to peer review extramural research and intramural research studies and programs."[15]

- "Intramural research programs will be subject to review and monitoring by external, objective peer review through an advisory committee or board of scientific counselors. Scientific research studies submitted to journals are subject to peer review of methods and findings by the journal prior to publication. ATSDR has a mandated policy for external peer review of all intramural and extramural research study protocols and findings prior to public dissemination."[16]

b. The CDC's Guidance on Scientific Integrity

The CDC's Guidance on Scientific Integrity[17] 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.
>
> . . .
>
> Integrity — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.[18]

In addition, the scientific integrity policy declares "[c]entral to this process is a commitment to transparency, honesty, and thorough consideration of research outcomes"[19] and asserts "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."[20] Thus, the scientific integrity policy requires the following:

- "That all information products authored, published, and released by CDC for public use are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience."[21]

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[15] *Id*. at Part II(D)(V)(A).
[16] *Id*. at Part II(D)(V)(B).
[17] 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.
[18] 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.
[19] *Id*. at 2.
[20] *Id*. at 3.
[21] *Id*. at 3.

- "In accordance with the CDC policy for Peer Review of Research and Scientific Programs, CDC research and science programs will be subject to periodic, independent, external peer reviews, which address quality, integrity, direction, and impact, and help ensure informed decisions and effective public health research and programs."[22]

- "Under the CDC policy for Responding to Allegations of Research Misconduct, CDC employees shall be responsible for reporting observed, suspected, or apparent research misconduct to the Research Integrity Officer. . . . In instances when the observed conduct does not fall under the definition of research misconduct but may lead to loss of integrity, fact-findings should still be undertaken and preemptive measures instituted to prevent loss of integrity."[23]

c. *President Biden's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking*

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, "[s]cientific 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.[24]

Under HHS, CDC, and Administration guidelines, the CDC must 1) make evidence based decisions guided by the best available science, 2) use scientific resources that are "scientifically sound" and "technically accurate," 3) provide information to the public that is "accurate, clear, complete, valid, unbiased, timely, and useful" and peer

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[22] *Id*. at 4.
[23] *Id*.
[24] 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 (emphasis added).

reviewed, and 4) ensure that its reporting of scientific research does not fabricate results through omission, changing facts, misrepresenting the research record.

Analysis

Based on the admitted errors in the Study, the CDC's reliance on the Study for its policy recommendation and the CDC's conduct in refusing to correct its public statements and adjust its policy recommendation after learning of the Study's errors, it appears that the CDC may have violated guidelines that mandate the CDC use the best available science and assess and genuinely respond to well-founded criticism of its process or publications.

The CDC appears to have violated its obligations to maintain its scientific integrity and to avoid research misconduct through its 1) inappropriate reliance upon flawed research to support consequential policy recommendations and 2) failure to correct its own dissemination of misinformation and to adjust its policy recommendations upon learning that the research it relied upon was false.

First, the CDC should not have adopted the vaccine policy recommendations based on Drs. Fleming-Dutra and Oliver's Presentation. Drs. Fleming-Dutra and Oliver relied upon the Study for their major claims about the lethality of COVID-19 to children, but the Study was not peer reviewed and contained factual errors, overestimating the number of deaths for children by 32%. The CDC's failure to discover this 32% error, especially when the CDC intended to rely upon the Study for a massively consequential vaccine policy recommendation affecting the most personal health decisions of 20 million children, is a breach of the CDC's obligation to scientific integrity.

Second, the CDC appears to have violated its obligation to uphold its scientific integrity in its response to learning of the errors in the Study. Drs. Fleming-Dutra and Oliver were informed within days of their Presentation of the errors in the Study.[25] Under the CDC's obligations to maintain the highest standard of quality and credibility in their research and policy recommendations, Drs. Fleming-Dutra and Oliver had a duty to inform the CDC that there was a major error in the Study and therefore a major error with the scientific research supporting their vaccine policy recommendation. If they had fulfilled their obligations, the CDC would have been able to fulfill its obligation to withdraw or amend the policy recommendation it made based upon the flawed research in the Study in a timely manner and correct the misinformation it spread based on the Study's false claims.

[25] Zachary Stieber, *CDC Officials Told They Spread Misinformation but Still Didn't Issue Correction: Emails*, The Epoch Times (Oct. 29, 2022), https://www.theepochtimes.com/exclusive-cdc-officials-told-they-spread-misinformation-but-still-didnt-issue-correction-emails_4826960.html?welcomeuser=1.

If the CDC responded properly to learning of the Study's errors, Drs. Fleming-Dutra and Oliver would have corrected the slide-deck of their Presentation to remove the inaccurate information and the CDC would have corrected its policy recommendations based on the inaccurate Study and would have issued a public correction to avoid misleading the public through scientific misinformation.

Instead, the CDC made no official statement or correction related to the Study's misinformation. The CDC's response was so deficient that even after Drs. Fleming-Dutra and Oliver were informed about the errors in the Study and shared that information with other CDC staff, CDC Director Rochelle Walensky still made a public statement that repeated the Study's false claims regarding COVID as one of the top five causes of childhood death.[26]

Drs. Fleming-Dutra and Oliver's sole response to learning of the Study's errors was to collaborate with the CDC's public relations staff to develop a sophisticated and scientifically irreverent reply that entirely ignored the substantive criticism of the Study. Instead of addressing the Study's 32% overestimation of childhood COVID deaths, which put the lie to Drs. Fleming-Dutra and Oliver's claims in their Presentation that COVID was a top five cause of death for children, they concocted the unscientific and politically tinged response that "even 1 death from COVID that's preventable is too many, regardless of how you count them."[27]

Balancing competing interests and providing sober statistical analysis of mutually exclusive concerns is the core of public health policy and scientific research. The suggestion that a policy is justified if it saves "just 1 one life," without considering harm to others through trade-offs and unintended consequences, is an error that falls well below the sober and non-partisan analysis the American people rightly expect from an institution like the CDC that is obligated under federal regulations and its role in American society to maintain the highest standards of quality and integrity in its scientific research and policy role.

The CDC's own response to criticism of the Study was similarly deficient. In response to an inquiry from a public health professional in June regarding the CDC's reliance on the false statements in the Study, the CDC:

> [N]oted that the ACIP considers a multitude of data points in making their recommendations, so even if this specific pre-print paper was removed from consideration, the data overwhelmingly support COVID-19 as a

[26] Zachary Stieber, *CDC Director Falsely Says COVID-19 One of the Top Five Causes of Death for Children*, The Epoch Times (June 24, 2022), https://www.theepochtimes.com/cdc-director-offers-misinformation-in-promoting-covid-19-vaccination-for-children_4555777.html.
[27] Zachary Stieber, *CDC Officials Told They Spread Misinformation but Still Didn't Issue Correction: Emails*, The Epoch Times (Oct. 29, 2022), https://www.theepochtimes.com/exclusive-cdc-officials-told-they-spread-misinformation-but-still-didnt-issue-correction-emails_4826960.html?welcomeuser=1.

> cause of serious disease and death in young children, and COVID vaccines as an important way to prevent this. These ACIP decision are made after reviewing the totality of the data and it is never one singular data point or analysis used.[28]

The CDC's claim that the ACIP relied upon more data than just the flawed Study is belied by the ACIP's own evidentiary record and Director Walensky's public statement repeating the Study's misinformation. On the webpage containing the evidence for the ACIP's childhood COVID vaccination recommendation, the Study is the *only* source for the claim that COVID-19 was a leading cause of death among children ages 0 to 4 years during the pandemic.[29] Additionally, Director Walensky's public statement on June 23, 2022, repeated the Study's false claim that COVID-19 is among the five leading causes of death for young children and clearly relied on the misinformation in the Study.[30]

By all appearances and evidence, the Study is the only basis for the claim that COVID-19 is as deadly to children as claimed in the Presentation and in Director Walensky's statement, and it is the Study's misstated claim that regarding the threat COVID-19 poses to children that justified the ACIP's recommendation for children to be comprehensively vaccinated.

Thus, the CDC's statement that the ACIP relied upon "a multitude of data points" in making its recommendation appears not to be true and the CDC appears to have violated its obligation to maintain scientific integrity by both its undue overreliance upon a single, inaccurate, not peer reviewed source of data and its active misrepresentation about the number and nature of sources it relied upon for its vaccine policy recommendation.

Conclusion

Accordingly, we call on you to immediately open an investigation into whether the CDC or other pertinent scientific integrity policy has been violated by, among other instances identified within this complaint, relying on flawed information to support a major policy recommendation, failing to correct the record after flaws in the underlying data were brought to the attention of CDC officials, and/or allowing policy concerns to

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[28] *Id*.

[29] ACIP Evidence to Recommendations for Use of Moderna COVID-19 Vaccine in Children Ages 6 months – 5 Years and Pfizer-BioNTech COVID-19 Vaccine in Children Ages 6 Months – 4 Years under an Emergency Use Authorization, Advisory Committee on Immunization Practices (ACIP) (Last Reviewed: June 27, 2022) https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-pfizer-children-vaccine-etr.html.

[30] Zachary Stieber, *CDC Director Falsely Says COVID-19 One of the Top Five Causes of Death for Children*, The Epoch Times (June 24, 2022), https://www.theepochtimes.com/cdc-director-offers-misinformation-in-promoting-covid-19-vaccination-for-children_4555777.html.

drive decisions on whether to recommend that children be vaccinated against COVID-19. Thank you.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust

Attachment C

PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL December 16, 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

Re: Request for Investigation into Apparent Scientific Integrity Violations by Refusal to Monitor Known Severe Vaccine Side Effects

Dear Ms. Grimm,

The CDC has a mandate to use the best science that it can and to provide the public with scientific resources and policy recommendations based upon honest and forthright analysis of the best available data. That is why it is concerning when the CDC appears to not only fail to collect and account for important data on a public health matter, but to actively avoid doing so to further a pre-determined scientific narrative for political purposes. Sadly, disregard of the scientific integrity principles the agency claims to espouse seems to be all too common at the CDC since the beginning of the COVID-19 pandemic,[1] which could lead to potentially tragic consequences. In the instance detailed in this letter, those consequences could be even more direct, more immediate, and more dire than the potential loss of trust in public health officials. The CDC engaged in seemingly intentional indifference to known severe potential side effects of a vaccine the federal government as well as various state and local government entities, private employers,

[1] Protect the Public's Trust, *Science Undermined*, https://protectpublicstrust.org/science-undermined/

and business establishments required people to take in order to preserve their livelihoods and participate in many aspects of normal daily life.

We call your attention to apparent malfeasance in the CDC's administration of its COVID-19 vaccine safety monitoring program, v-safe. The v-safe program has been used by the CDC to collect millions of reports on COVID-19 vaccine patients' health after their vaccination. It is in large part because of v-safe that the CDC boasts that the COVID-19 vaccines "are monitored by the most intense safety monitoring efforts in U.S. history."[2] Yet, despite v-safe's purpose as a vaccine safety monitoring tool to ensure that the best data can be collected to ensure the public's health and safety related to the COVID-19 vaccines, v-safe appears to have been deliberately designed to avoid collecting important data related to known severe potential side effects of the COVID-19 vaccines that the CDC itself has identified as possible "adverse events of special interest" (AESIs).

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. It is imperative in light of the severe health challenges America has suffered in the last several years that institutions responsible for safeguarding public health maintain their credibility with the American people. The consequences of institutions like the CDC losing the trust of the public are dire and should not be risked for the sake of frivolous, short-sighted political gain. Recent surveys indicate that already less than half of the American public trusts the CDC on COVID-19,[3] and the flaws in the CDC's vaccine monitoring program evinces why this is so.

V-safe data is used to encourage the public to receive the COVID-19 vaccines and to recommend policies regarding vaccination.[4] For the CDC to have designed its vaccine safety monitoring tool to avoid collecting data on known potential adverse health effects from the vaccines for the apparent purpose of artificially preserving a narrative that such negative health outcomes do not occur is a clear a breach of the CDC's purpose, its ethical obligations, and its relationship to the public. Accordingly, we request an immediate investigation into whether the CDC's design of its vaccine safety monitoring tool to avoid collecting pertinent negative data about the vaccines' safety violates the CDC's scientific integrity politics.

The V-Safe System

Prior to widespread public availability of the Covid-19 vaccines, the CDC launched its vaccine wellness tracking application, v-safe. The purpose of v-safe is to monitor the health of COVID-19 vaccine patients and collect data on the vaccines' safety. V-safe works by asking

[2] Ensuring COVID-19 Vaccine Safety in the US, Centers for Disease Control and Prevention (Updated July 19, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html.
[3] NBC News, On Covid, Americans can be stingy with their trust, (January 23, 2022), https://www.nbcnews.com/politics/meet-the-press/who-do-americans-trust-covid-answer-complicated-n1287895
[4] *CDC Releases Data Showing Safety of COVID Vaccines*, Adult Vaccine Access Coalition, (Accessed December 7, 2022), https://adultvaccinesnow.org/resources/cdc-releases-data-showing-safety-of-covid-vaccines/.

users to complete health check-ins at regular intervals. For the first week after taking the vaccine, check-ins are daily. After the first week, check-ins are weekly for six weeks, after which there are additional check-ins at the six-month and one-year marks.

The check-ins ask users questions about their health condition, such as: how they are feeling on that day; whether they have symptoms of a fever; their highest temperature recorded on that day; whether they have experienced any symptoms or health conditions they believe to be related to their vaccination; whether any of those symptoms or health conditions caused them to be incapable of work, school, or normal daily activities; or whether their health condition required them to seek medical care and, if so, what type of medical care they sought. For the daily check-ins during the first week after vaccination, v-safe includes a list of checkbox options for users to select from to report symptoms of how they are feeling. The list includes only common flu-like symptoms:

- Chills
- Headache
- Joint pains
- Muscle or body aches
- Fatigue or tiredness
- Nausea
- Vomiting
- Diarrhea
- Abdominal pain
- Rash, not including the immediate area around the injection site
- None

Any symptoms not included on that list can be logged only by writing in a free-text box after the checkbox list.

After the daily check-ins during the first week, the check-ins no longer include the checkbox list of possible symptoms. Users can then only report symptoms and health conditions they believe were caused by their vaccination in a free-text box.

The v-safe system collected a tremendous volume of data — the system has over 10 million registered users, 8.5 million of whom registered between December 2020 when the app launched and April 2021. Over 10 million symptom reports were filed each month between January and April 2021, and v-safe collected millions of reports over the following months after the initial wave of vaccinations.

The CDC Knew of Serious Vaccine Side Effects It Did Not Include in v-safe

Well before the launch of v-safe, the CDC and the broader medical community were aware that mRNA vaccines like the COVID-19 vaccines present certain distinct health risks to

patients. In July 2020, the New England Journal of Medicine published a preliminary study on mRNA vaccines against COVID-19 that highlighted 35 adverse health events related to mRNA vaccination,[5] including eye disorders, gastrointestinal disorders, musculoskeletal and connective tissue disorders, and nervous system disorders. In October 2020, JAMA published an article on safety monitoring for COVID-19 vaccinations after their approval that stated that "AESIs [adverse events of special interest] are likely to include allergic, inflammatory, and immune-mediated reactions, such as anaphylaxis, Guillain-Barré syndrome, transverse myelitis, myocarditis/pericarditis, vaccine-associated enhanced respiratory disease, and multisystem inflammatory syndrome in children."[6] The CDC itself presented on safety monitoring for the COVID-19 vaccines in October 2020[7] and identified a preliminary list of adverse events of special interest related to the vaccines that included acute myocardial infarction, anaphylaxis, convulsions/seizures, encephalitis, Guillain-Barré syndrome, immune thrombocytopenia, MIS-C, myocarditis/pericarditis, and transverse myelitis, among others.

These studies are a sample of the literature that clearly establishes that COVID-19 vaccines presented a special risk of certain severe AESIs like myocarditis, pericarditis and allergic/immune system reactions like anaphylaxis or Guillain-Barré syndrome. The CDC's own protocol for v-safe reflects this. The CDC's v-safe protocol for January 28, 2021[8] identified a list of "Adverse Events of Special Interest" that the CDC determined it needed to track in patients after they received vaccination that included the following "Prespecified Medical Conditions:"

- Acute myocardial infarction
- Anaphylaxis
- Coagulopathy
- Guillain-Barré syndrome
- Kawasaki Disease
- Multisystem Inflammatory Syndrome in children
- Multisystem Inflammatory Syndrome in adults
- Myocarditis/Pericarditis
- Narcolepsy/Cataplexy
- Seizure/Convulsions
- Stroke
- Transverse Myelitis

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[5] Lisa Jackson, et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, N. Engl. J. Med., (July 14, 2020), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377258/#ap2.
[6] Grace Lee, et al., *Post Approval Vaccine Safety Surveillance for COVID-19 Vaccines in the US*, JAMA, (October 16, 2020), available at https://jamanetwork.com/journals/jama/fullarticle/2772137.
[7] Tom Shimabukuro, *CDC Post-Authorization/Post-Licensure Safety Monitoring of COVID-19 Vaccines*, Nation Center for Immunization & Respiratory Diseases, (October 30, 2020), available at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Shimabukuro-508.pdf.
[8] *V-safe Active Surveillance for COVID-19 Vaccine Safety*, Centers for Disease Control, (January 28, 2021), available at https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf.

Despite the CDC's explicit knowledge of these serious potential side effects from the vaccines and resolution to track them in patients post-vaccination, the CDC conspicuously failed to use v-safe to track them at all.

The CDC's Obligations to Use High Quality Science and Uphold Scientific Integrity

The CDC's Guidance on Scientific Integrity[9] 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.
>
> . . .
>
> Integrity — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.[10]

The CDC's commitment to high quality science is fundamental to the agency's mission and runs throughout its policies. The agency's scientific integrity policy declares its "commitment to transparency, honesty and thorough consideration of research outcomes" and that the "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."[11] In furtherance of these commitments, the CDC's scientific integrity policy requires that "all information products authored, published, and released by the CDC for public use are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience."[12]

In addition to the CDC's own scientific integrity policy, President Biden has required the CDC to uphold the highest standards in its research and practices. President Biden's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking states that "[s]cientific finding 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

[9] 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.
[10] *Id*. at 2.
[11] *Id*. at 2-3.
[12] *Id*. at 3.

> 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.[13]

Under CDC and Administration guidelines, the CDC must 1) make evidence-based decisions guided by the best available science, 2) use scientific resources that are "scientifically sound" and "technically accurate," 3) provide information to the public that is "accurate, clear, complete, valid, unbiased, timely, and useful" and peer reviewed, and 4) ensure that its reporting of scientific research does not fabricate results through omission, changing facts, or misrepresenting the research record.

Analysis

The entire purpose of v-safe was to collect data on the safety of the vaccines from its over 10 million users. The CDC could easily have included the serious vaccine side effects it had resolved to track as additional items on the checkbox list of symptoms in v-safe's check-ins. Had it done so, the CDC would then have been positioned to calculate the rate at which patients experienced symptoms indicative of myocarditis, stroke, or Guillain-Barré syndrome. Collecting and publicizing this information would have enabled the public to make informed decisions about choosing vaccination and should have been essential to the CDC's assessment of vaccine safety and its vaccine policy recommendations.

Instead, the CDC purposefully shunted all reporting on symptoms other than the flu-like symptoms in the checkbox list to a free-text box. Even the flu-like symptoms were forced to be entered in the free-text box after the first week of check-ins. Free-text fields are well known to be vastly inferior to checkboxes for gathering information such as symptoms. Users often do not fill out free-text fields, often do not know how to do so properly, and free-text fields are difficult to standardize into usable data.

Belying the CDC's seriousness about using v-safe to monitor vaccine safety is the CDC's overly complex system for dealing with v-safe users who reported experiencing AESIs in the free-text field. When a user reported an AESI in v-safe's free-text field, the CDC's protocol was to have a CDC employee analyze the entry to determine if what was written actually reflected an AESI. Then, a CDC employee was to reach out to the v-safe user by telephone – which may not occur for months or years – and assist the user in completing a VAERS (Vaccine Adverse Event Reporting System) report. Even after these steps, no usable data would be produced for determining the safety of the vaccines because the CDC has held that VAERS reports cannot be used to show that a vaccine causes harm and cannot be used to determine the rate at which any

[13] 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. (emphasis added).

symptom occurs because VAERS receives reports from an unknown population size. Thus, the CDC designed v-safe so that it would not produce relevant, usable data on known AESIs.

There is no supportable reason why the CDC could not or should not have included entries in the checkbox list for the AESIs that the CDC had already identified in its January 28, 2021 v-safe protocol. Similarly, there is no supportable reason why the CDC should not have included this expanded checkbox list in v-safe's check-ins after the first week. Had the CDC included these AESIs as checkbox items, the CDC would have ready access to data from millions of people related to serious adverse side effects it had already identified a need to track. This data on users who experienced AESIs would have been readily usable for calculating incidence rates because the population size of v-safe users is known, unlike with VAERS reports, and the CDC would have a ready denominator for its calculations.

The CDC's apparent intent to avoid a genuine inquiry into the safety of the vaccines is further evinced by the CDC's policy toward the data it did collect through the checkbox items. The CDC does not consider the flu-like symptoms in the checkbox list to be adverse health events but rather evidence of reactogenicity that demonstrates the vaccines are working by provoking immunological responses. Thus, none of the data collected by the CDC in its checkbox list was intended to provide the CDC with any information about potential adverse side effects from the vaccine. The only usable safety data v-safe collected was the "health impact" data reported by users regarding whether they were incapable of performing daily activities, missed work or school, or required medical care as a result of their post-vaccine symptoms. For those who required medical care, v-safe collected data on whether they used telehealth or went to urgent care, the emergency room, or were hospitalized. This data is the only effective vaccine safety data collected by v-safe and the results indicate that the CDC's failure to collect data on AESIs denied the public important information about vaccine side effects.

According to v-safe log data acquired by the Informed Consent Action Network (ICAN) through a Freedom of Information Act request to the CDC, 7.7% of v-safe users reported that they required medical care after receiving the vaccines. Nearly 75% of users above the age of 2 years-old who required medical care had to seek medical care in-person and could not rely on telehealth visits. Nearly half had to go to urgent care and a quarter needed the emergency room or to be hospitalized. Two-thirds of children aged 2 years and younger who required medical care had to go to urgent care and could not rely on telehealth alone. More broadly, 25% of users reported being unable to perform normal activities and/or missing school or work as a result of post-vaccination symptoms.[14]

Given the CDC's awareness of potential serious adverse health events from the COVID-19 vaccines before their release, there is no reason why the CDC's data collection efforts related

[14] Just the News, *CDC knew COVID vax associated with myocarditis but left off post-vax surveys*, (November 28, 2022), https://justthenews.com/government/courts-law/premeditated-cdc-knew-covid-vax-associated-myocarditis-left-post-vax-surveys

to vaccine safety should not have included serious attempts to learn whether v-safe users experienced the AESIs identified in the January 28, 2021 v-safe protocol. The conspicuous absence of any of these AESIs from the checkbox list and the CDC's convoluted process for collecting data on these AESIs through the free-text field, which produced results that the CDC considered unusable for evaluating vaccine safety, shows that the CDC may have deliberately avoided collecting important data on vaccine safety. The CDC appears to have violated its mandate to protect public health, uphold scientific integrity, and use the best quality science by designing its flagship vaccine safety monitoring tool so that it collected almost no relevant data on vaccine safety.

Conclusion

We call on you to immediately open an investigation into whether the CDC's ethics mandates or other pertinent scientific integrity policies have been violated by the agency's apparently deliberate refusal to collect data about serious adverse health effects from the COVID-19 vaccinations that were known to the CDC. The CDC's integrity is of vital importance to the public's trust in its public health institutions and its failure to monitor vaccine safety with integrity is a breach of its mission in service to the American public.

Thank you.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust