



# PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL

November 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  
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Joanne Cono  
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Center for Disease Control Scientific Integrity Officer  
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**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<sup>1</sup> of senior officials within the CDC prioritizing the Biden Administration's vaccine policy goals<sup>2</sup> above the science.<sup>3</sup> In the face of clear evidence that the CDC's public representation of the science was misleading and inaccurate, senior

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<sup>1</sup> 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://protectpublictrust.org/wp-content/uploads/Request-for-Investigation-HHS-Scientific-Integrity.pdf>

<sup>2</sup> Protect the Public's Trust, *Request for Investigation into Apparent Scientific Integrity Violations by Inappropriately Withholding Data About Covid-19 From the Public*, <https://protectpublictrust.org/wp-content/uploads/2022/03/CDC-Scientific-Integrity-Complaint.pdf>

<sup>3</sup> 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://protectpublictrust.org/wp-content/uploads/2022/08/CDC-Scientific-Integrity-Complaint.pdf>



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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.<sup>4</sup>

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."<sup>5</sup> 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 4<sup>th</sup> or 5<sup>th</sup> 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."<sup>6</sup> 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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<sup>4</sup> 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>

<sup>5</sup> 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>.

<sup>6</sup> See Seth Flaxman (June 19, 2022), <https://twitter.com/flaxter/status/1538533537355288577>.



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## 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").<sup>7</sup> 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."<sup>8</sup>

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.<sup>9</sup>

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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<sup>7</sup> 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/>.

<sup>8</sup> 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>.

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



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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.”<sup>10</sup>

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.”<sup>11</sup> <sup>12</sup> 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.<sup>13</sup>

## **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,<sup>14</sup> 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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<sup>10</sup> <https://twitter.com/repthomasmassie/status/1369629668022902786>

<sup>11</sup> 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).

<sup>12</sup> 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).

<sup>13</sup> 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/>.

<sup>14</sup> 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>.



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- “CDC policy is to peer review extramural research and intramural research studies and programs.”<sup>15</sup>
- “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.”<sup>16</sup>

## *b. The CDC’s Guidance on Scientific Integrity*

The CDC’s Guidance on Scientific Integrity<sup>17</sup> 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.<sup>18</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>19</sup> 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.”<sup>20</sup> 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.”<sup>21</sup>

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<sup>15</sup> *Id.* at Part II(D)(V)(A).

<sup>16</sup> *Id.* at Part II(D)(V)(B).

<sup>17</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>18</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>19</sup> *Id.* at 2.

<sup>20</sup> *Id.* at 3.

<sup>21</sup> *Id.* at 3.



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- “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.”<sup>22</sup>
- “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.”<sup>23</sup>

*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.<sup>24</sup>

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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<sup>22</sup> *Id.* at 4.

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

<sup>24</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> (emphasis added).



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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.<sup>25</sup> 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.

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<sup>25</sup> 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](https://www.theepochtimes.com/exclusive-cdc-officials-told-they-spread-misinformation-but-still-didnt-issue-correction-emails_4826960.html?welcomeuser=1).



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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.<sup>26</sup>

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."<sup>27</sup>

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

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<sup>26</sup> 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](https://www.theepochtimes.com/cdc-director-offers-misinformation-in-promoting-covid-19-vaccination-for-children_4555777.html).

<sup>27</sup> 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](https://www.theepochtimes.com/exclusive-cdc-officials-told-they-spread-misinformation-but-still-didnt-issue-correction-emails_4826960.html?welcomeuser=1).



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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.<sup>28</sup>

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.<sup>29</sup> 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.<sup>30</sup>

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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<sup>28</sup> *Id.*

<sup>29</sup> 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-ctr.html>.

<sup>30</sup> 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](https://www.theepochtimes.com/cdc-director-offers-misinformation-in-promoting-covid-19-vaccination-for-children_4555777.html).



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

Sincerely,

Michael Chamberlain  
Director  
Protect the Public's Trust