PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL May 9, 2023

TO: Arati Prabhakar
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Alondra Nelson
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Re: Failure by Ethics Authorities in U.S. Department of Health and Human Services to Investigate Repeated Scientific Integrity Violations by the Department Health and Human Services

Dear Dr. Prabhakar,

We are heartened by the Office of Science and Technology Policy's (OSTP) efforts to provide a framework for agencies to evaluate undue political influence on scientific determinations.

However, we are also concerned by the apparent disconnect between OSTP's focus and the conduct of several federal agencies, particularly those within the Department of Health and Human Services (HHS). Therefore, we write to bring to your attention the repeated failures of HHS and its subagencies, particularly the Centers for Disease Control (CDC), National Institutes of Health (NIH), and Food and Drug Administration (FDA), to live up to their scientific integrity obligations.

Over the last two years, Protect the Public's Trust (PPT), a nonpartisan organization dedicated to promoting ethics in government and restoring the public's trust in government officials, has submitted six scientific integrity complaints to HHS Chief Science Officer for COVID-19 Response, David Kessler, HHS Inspector General, Christi Grimm, and other top department officials. These complaints show how officials at HHS, the CDC, NIH, and the FDA are failing to live up to the Biden Administration's stringent scientific integrity policies.

Despite the thorough documentation and evidence in PPT's complaints, there is no indication that HHS has taken appropriate action to either correct past violations or prevent future violations from occurring.

Accordingly, PPT brings the HHS' years-long refusal to uphold President Biden's scientific integrity mandates to your attention so that the American public can be reassured that these issues will be corrected and that their public institutions will live up to the high standards they profess.

PPT Has Extensively Documented Scientific Integrity Violations by HHS and Its Subagencies

To date, PPT has submitted six complaints dating back to October 2021 detailing repeated scientific integrity violations by HHS and its subagencies, including NIH, the CDC, and the FDA. To date, HHS, NIH, the CDC, and the FDA have neither corrected these apparent scientific integrity violations nor publicly taken action to prevent their recurrence.

The CDC Miscited Research to Falsely Support Claims that COVID-19 Vaccines Are Superior to Natural Immunity

On October 27, 2021, PPT submitted a complaint to Chief Science Officer Kessler, Inspector General Grimm, and others about the CDC and NIH's misrepresentation of a scientific study to support statements about natural immunity to COVID-19 and vaccines that were contradicted by the results of the study.[1]

In August 2021, the CDC issued a press release claiming that vaccination offers higher protection from COVID-19 than previous infection. This claim, as well as several specific claims within the press release, was contradicted by the underlying science in the report cited therein. Most egregiously, the CDC cherry-picked one state out of a fifty-state study, using the minimal rates of infection from Kentucky as evidence that the vaccines were 2.3 times more effective than natural immunity. Furthermore, the cited study only studied individuals with a prior infection, rendering any comparison between those with and without natural immunity gained by previous COVID-19 infection impossible. This constituted a violation of the CDC's stringent scientific integrity rules regarding its communications with the public and its mandate to communicate objectively and honestly with the public based upon the best science. To date, there has not been any retraction or correction of this statement by the CDC.

In addition, NIH Director Francis Collins went even further than the CDC's press release in a Fox News interview with Brett Baier.[2] Baier asked if Collins could "definitively say" that

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[1] *Complaint Alleges Scientific Integrity Violations by Federal Health Officials*, Protect the Public's Trust (October 27, 2021), https://protectpublicstrust.org/press-releases/complaint-alleges-scientific-integrity-violations-by-federal-health-officials/.

[2] *Admiral Brett Giroir explains natural immunity to COVID-19*, Fox News Channel (August 13, 2021), https://www.foxnews.com/video/6267860705001.

"the vaccine provides better protection than the antibodies that you get from actually having had COVID-19."[3] Collins replied unequivocally: "Yes, Bret, I can say that. There was a study published by the CDC just ten days ago in Kentucky . . . . [The protection level] was more than two-fold better from the people who had the vaccine in terms of protection than people who'd had the natural infection."[4] But that's not what the study itself said.

These gross misrepresentations of the Kentucky study drew swift and severe condemnation from members of the scientific community. Particularly notable was the criticism from Johns Hopkins University Surgical Professor Dr. Marty Makary, who described the CDC's decision to highlight the results of a carefully selected two-month period from only a single state from a fifty-state study as "fishing" to find support for a policy position promoted by political appointees at the CDC and by the White House.[5]

The CDC Withheld Information on the Efficacy of COVID-19 Vaccines for 18-49 Year Olds out of "Fear" the Public Could Not Be Trusted with the Information

On March 30, 2022, PPT submitted a complaint to Chief Science Officer Kessler, Inspector General Grimm, and the CDC's Chief Science and Medical Advisor, Joanne Cono, detailing how the CDC withheld data on the efficacy of COVID-19 vaccines for people aged 18-49 years old.[6]

On February 20, 2022, the *New York Times* reported that the CDC refused to publish large portions of data it was collecting related to COVID-19.[7] The article reported that the CDC declined to release data it had collected in three areas: 1) the effectiveness of boosters for the COVID-19 vaccines, particularly on those 18-49 years old; 2) the results of wastewater data collection; and 3) data on hospitalizations, particularly hospitalization data broken down by age, race, and vaccination status.[8] The article reported CDC spokeswoman Kristen Nordlund as citing "fear that the information might be misinterpreted," specifically "misinterpreted as the vaccines being ineffective," as a reason the information was withheld.[9]

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[3] *Id.*
[4] *Id.*
[5] Dr. Marty Makary, *Natural immunity to covid is powerful. Policymakers seem afraid to say so.*, The Washington Post (September 15, 2021), https://www.washingtonpost.com/outlook/2021/09/15/natural-immunity-vaccine-mandate/.
[6] *CDC & NIH to the American People: You Can't Handle the Truth!*, Protect the Public's Trust (March 31, 2022), https://protectpublicstrust.org/press-releases/cdc-nih-to-the-american-people-you-cant-handle-the-truth/.
[7] Apoorva Madavailli, *The C.D.C. Isn't Publishing Large Portions of the Covid Data It Collects*, The New York Times (Feb. 22, 2022), https://www.nytimes.com/2022/02/20/health/covid-cdc-data.html.
[8] *Id.*
[9] *Id.*

PPT's complaint explained how this decision to withhold pertinent information about the vaccines from the public was a violation of the CDC's scientific integrity policies, but also only one of many errors and integrity violations by the CDC – all cutting in the same direction of promoting the vaccines while misreporting, stifling, or ignoring scientific evidence to the contrary.

The CDC Broadly Recommends COVID-19 Vaccination for Small Children Based on Weak and Inconclusive Evidence

On August 9, 2022, PPT submitted a complaint to Chief Science Officer Kessler, Inspector General Grimm, and others revealing how the CDC's decision to adopt a broad recommendation to vaccinate children aged 6 months to 4 years against COVID-19 was based on weak and inconclusive evidence.[10]

On June 18, 2022, CDC Director Rochelle Walensky endorsed the Advisory Committee on Immunization Practices' (ACIP) recommendation that all children aged six months to four years old be vaccinated against COVID-19.[11] ACIP's interim recommendation approved the use of a Moderna vaccine and a Pfizer-BioNTech vaccine for children.[12] For the Moderna vaccine, ACIP supported its recommendation by noting "[a] lower risk of symptomatic COVID-19 was observed with vaccination compared with placebo,"[13] but noted that "the available data indicated that [severe adverse events] were *more common in vaccine recipients*," though the "certainty in the estimate was very low."[14] For the Pfizer vaccine, ACIP noted "a lower risk of symptomatic COVID-19 was observed with vaccination compared with placebo, but certainty in the estimate

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[10] *Complaint: Did Political Considerations Override the Science in the CDC's Recommendations to Vaccinate Young Children?*, Protect the Public's Trust (August 10, 2022), https://protectpublicstrust.org/press-releases/complaint-did-political-considerations-override-the-science-in-the-cdcs-recommendations-to-vaccinate-young-children/.

[11] *CDC Recommends COVID-19 Vaccines for Young Children*, Centers for Disease Control and Prevention (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.

[12] Katherine Fleming-Dutra, et al., *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*, Morbidity and Mortality Weekly Report, July 1, 2022, 71(26); 859-868, https://www.cdc.gov/mmwr/volumes/71/wr/mm7126e2.htm.

[13] Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Moderna COVID-19
Vaccine for Children Aged 6 Months–5 Years, Centers for Disease Control and Prevention, (Last reviewed June 27, 2022), https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine-6-months-5-years.html.

[14] *Id* (emphasis added).

was very low" and "the available data indicated that [severe adverse events] were balanced comparing vaccine and placebo recipients, but certainty in the estimate was low."[15]

ACIP's decision was thoroughly criticized in the press and by prominent medical doctors. One report noted that ACIP's "sweeping recommendation was based on extremely weak, inconclusive data provided by Pfizer and Moderna."[16] With respect to the Pfizer vaccine, "Pfizer reported a range of vaccine efficacy so wide that no conclusion could be inferred," and "[n]o reputable medical journal would accept such sloppy and incomplete results with such a small sample size."[17] The report quoted a "high-level CDC official – whose expertise is in the evaluation of clinical data" for the stunning admission that "[y]ou can inject [children] with it or squirt it in their face, and you'll get the same benefit."[18] With respect to the Moderna vaccine, the report noted there was a "very weak vaccine efficacy of just 4% in children aged six months to two years" against symptomatic infections, and while the vaccine "did show efficacy that was statistically significant [against symptomatic infections, [] the efficacy was low."[19] Further reporting on the vaccine recommendations criticized studies supporting the recommendations for using antibody tests as a proxy for immunity, extrapolating from studies on adults to compensate for the small sample size of children, and the failure of the vaccines to obtain efficacy levels that federal agencies had previously identified as benchmarks.[20]

This weak and inconclusive data on the vaccines suggest that CDC Director Walensky's decision to adopt ACIP's vaccine recommendation for small children was for political, rather than scientific, reasons. The CDC's own data for the vaccine's efficacy provides weak or inconclusive support for the CDC's decision. The goal of a COVID-19 vaccine is to prevent symptomatic infection, yet the CDC itself noted that it had "very low confidence" that the Pfizer vaccine actually prevents such infection, while the Moderna vaccine falls short of the efficacy that would be expected based on the CDC's far-reaching recommendation. Even under the

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[15] *Grading of Recommendations, Assessment, Development, and Evaluation (GRADE): Pfizer-BioNTech COVID-19 Vaccine for Children Aged 6 Months–4 Years*, Centers for Disease Control and Prevention (Last reviewed June 27, 2022), https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html#print.

[16] Marty Markary and Tracy Beth Hoeg, *U.S. Public Health Agencies Aren't 'Following the Science,' Officials Say*, The Free Press (July 14, 2022), https://www.thefp.com/p/us-public-health-agencies-arent-following.

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] James Agresti, *FDA Violated Own Safety and Efficacy Standards in Approving Covid-19 Vaccines For Children*, The Heartland Institute (July 15, 2022), https://heartland.org/opinion/fda-violated-own-safety-and-efficacy-standards-in-approving-covid-19-vaccines-for-children/.

principle that doing something can be better than doing nothing, the data indicate that severe adverse events were more common in patients given the Moderna vaccine than a placebo.

As detailed in PPT's complaint, the Biden Administration's strong public stance and statements insisting that the vaccines are safe and important for children betrays that a strong political pressure was likely behind the CDC's recommendation. This intrusion of politics into the scientific decision-making of the CDC is an absolute violation of the CDC's scientific integrity policies and a betrayal of the trust the American people hold that their public science institutions make objective decisions and recommendations based upon the best data.

The CDC Spread COVID-19 Misinformation Based on False Data and Willfully Refused to Correct Its Error

On November 16, 2022, PPT submitted a complaint to Chief Science Officer Kessler, Inspector General Grimm, Chief Science and Medical Advisor Cono, detailing how the CDC spread promoted, and refused to correct misinformation inflating COVID-19 death rates for children.[21]

On June 17, 2022, Drs. Katherine E. Fleming-Dutra and Sara Oliver, doctors with the CDC, presented a PowerPoint slide deck (the Presentation)[22] titled "COVID-19 Epidemiology in Children Ages 6 Months – 4 Years." In the presentation, they claimed that "COVID-19 is a leading cause of death among children ages 0-19 years" and that COVID-19 is ranked either 4th or 5th among all causes of death for children in age groups ranging from <1 year through 15-19 years.[23] This information was derived from a preprint of a study titled "COVID-19 is a leading cause of death in children and young people ages 0-19 years in the United States,"[24] which had significant flaws. The study reported 1,433 childhood deaths from COVID-19, but the true figure was 1,088.[25] This was an overestimation of 32%.

Though the failure of Drs. Fleming-Dutra and Oliver to catch this error in a study they relied on was already a breach of the CDC's scientific integrity mandate, worse still was that Dr.

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[21] *Watchdog Files Complaint After Yet Another Apparent Scientific Integrity Violation at CDC*, Protect the People's Trust (November 18, 2022), https://protectpublicstrust.org/press-releases/watchdog-files-complaint-after-yet-another-apparent-scientific-integrity-violation-at-cdc/.

[22] Katherine E. Fleming-Dutra, *COVID-19 epidemiology in children ages 6 months – 4* years, Centers for Disease Control and Prevention (June 17, 2022), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-06-17-18/02-COVID-Fleming-Dutra-508.pdf.

[23] *Id.*

[24] 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.

[25] Kelley Krohnert, *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/.

Fleming-Dutra and others at the CDC were informed no later than June 18, 2022, that the study was flawed. On June 18, Ms. Kelley Krohnert emailed Dr. Fleming-Dutra with a fact check of the data in the study revealing its errors. Email exchanges between Dr. Fleming-Dutra and other CDC employees show that Fleming-Dutra and the CDC were aware of the issue but made no corrections.

On June 19, 2022, the lead author of the study, Dr. Seth Flaxman, announced that he was aware of criticism of the study after it was cited by the CDC, FDA, VRBPAC, and ACIP, and that the authors would be updating the preprint to account for the issues.[26] On June 28, 2022, Dr. Flaxman and his colleagues posted a revised preprint of the article which ranked COVID-19 eighth in causes of death for children aged 0-19 years old. The webpage for the preprint contained a disclaimer that the "article is a preprint and has not been peer-reviewed" and that "it reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice."[27]

Under the CDC's scientific integrity policies, Drs. Fleming-Dutra and Oliver had a duty to inform the CDC and the public of the misinformation in their presentation and to correct it. Instead, neither they nor the CDC issued any correction to the false information they perpetuated. Worse yet, Director Walensky made a public statement a week later in which she repeated the false claims from the study that COVID-19 was a top five cause of childhood death.[28]

The response from Drs. Fleming-Dutra and Oliver to the criticism of the study was not to properly correct the record, but rather repeat the political mantra that "even 1 death from COVID that's preventable is too many, regardless of how you count them."[29]

The CDC's use of an inaccurate study, repeated reference to false statistics, and pointed refusal to properly correct the record reflects a disregard for basic principles of scientific integrity and the right of the American people to make informed choices for themselves based on the best available information.

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[26] @flaxter, Twitter (June 19, 2022, 10:45 AM), https://twitter.com/flaxter/status/1538533542543646720.
[27] Flaxman, et al., *supra.*
[28] 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.
[29] 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

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The CDC Refuses to Collect Data on Severe Side-Effects to the COVID-19 Vaccines that the CDC Admitted Needed to Be Tracked

On December 16, 2022, PPT submitted a complaint to Chief Science Officer Kessler, Inspector General Grimm, and Chief Science and Medical Advisor Cono revealing the CDC's willful refusal to collect complete data on adverse reactions to the COVID-19 vaccines through v-safe, the CDC's app ostensibly designed to monitor vaccine safety.[30]

Prior to the widespread availability of the COVID-19 vaccines, the CDC launched v-safe to monitor the safety of the vaccines. V-safe's purpose was to monitor the health of COVID-19 vaccine patients and collect data on the vaccines' safety. V-safe worked by asking users to complete health check-ins at regular intervals. The check-ins asked users questions about their health condition – such as how they were feeling that day, whether they had fever symptoms, their highest temperature that day, whether they experienced symptoms they believed related to their vaccination, and whether those symptoms required them to seek medical care or rendered them incapable of work, school, or normal daily activities.

For the daily check-ins during the first week after vaccination, v-safe provided a list of symptoms that users could select from to report how they were feeling. The options included only common flu-like symptoms. Any symptoms not included on the list had to be written in a text box included below the list. After the daily check-ins during the first week, check-ins no longer included the list of possible symptoms to select from. Users could only report symptoms and health conditions in the text box.

The CDC used an arcane and unwieldy system for handling data on any symptoms reported in the text box. When a user reported an "adverse event of special interest" (AESI) in v-safe's text field, the CDC's protocol was for a CDC employee to analyze the entry to vet whether the entry actually reflected an AESI. If it did, an employee was to reach out to the user by phone – which may not occur for months or years – to assist the user in completing a report in the Vaccine Adverse Even Reporting System (VAERS). Even if these steps were completed, no usable data would be produced because the CDC had already decided that the VAERS's reports could not be used to show that a vaccine causes harm or be used to determine the rate at which any symptom occurs because VAERS receive reports from an unknown population size. Thus, the CDC designed v-safe and its data collection protocols in a manner that would produce no relevant, usable data on AESIs other than the mild flu-like symptoms on v-safe's list of symptoms, which were only tracked for the first week after vaccination.

On its own, this shoddy and incomplete design would constitute a violation of the CDC's scientific integrity policies because it deliberately collected data in a manner that would produce unusable results and omit relevant data about severe AESIs. But the CDC's conduct was made

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[30] *Watchdog Alleges CDC Refused to Track Known Serious Side Effects of Covid Vaccines*, Protect the Public's Trust (December 16, 2022), https://protectpublicstrust.org/press-releases/watchdog-alleges-cdc-refused-to-track-known-serious-side-effects-of-covid-vaccines/.

far worse by the agency's knowledge at the time it designed v-safe of a distinct set of severe AESIs potentially caused by the vaccines that the CDC admitted it needed to track to determine vaccine safety yet omitted from the list patients could select.

Well before the launch of v-safe, the CDC and the broader medical community were aware that mRNA vaccines, like the COVID-19 vaccines, pose certain distinct health risks to patients. Multiple studies from throughout 2020 highlighted AESIs from the COVID-19 vaccines that included various eye, gastrointestinal, musculoskeletal and connective tissue, and nervous system disorders.[31] These studies also identified likely AESIs from the vaccines 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."[32] The CDC itself presented on safety monitoring for the vaccines in October 2020 and identified a preliminary list of AESIS 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.[33]

These studies are only a sample of the literature showing that the vaccines presented a special risk for certain severe AESIs like myocarditis/pericarditis and allergic/immune system reactions such as anaphylaxis or Guillain-Barré syndrome. The CDC's own protocol for v-safe from January 28, 2021, identified a list of AESIs that the CDC determined it needed to track in patients after vaccination, which it referred to as "Prespecified Medical Conditions."[34]

Despite this acknowledgement by the CDC that it needed to track these serious side-effects of the vaccines and the evidence showing that the vaccines carried risk potential for severe and potentially life-threatening AESIs, the CDC deliberately designed its vaccine safety monitoring tool to not collect any usable data on these AESIs. Instead, the CDC designed v-safe to do a token tracking of some flu-like symptoms for a week before fully shifting to data collection through a text-field under a protocol that the CDC had already decided could not produce relevant, usable data for determining vaccine safety.

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[31] Lisa Jackson, et al., *An mRNA Vaccine against SARS-CoV-2 — Preliminary Report*, N. Engl. J. Med., (July 14, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7377258/#ap2.

[32] Grace Lee, et al., *Post Approval Vaccine Safety Surveillance for COVID-19 Vaccines in the US*, JAMA, (October 16, 2020), https://jamanetwork.com/journals/jama/fullarticle/2772137.

[33] Tom Shimabukuro, *CDC Post-Authorization/Post-Licensure Safety Monitoring of COVID-19 Vaccines*, Centers for Disease Control and Prevention (October 30, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Shimabukuro-508.pdf.

[34] *V-safe Active Surveillance for COVID-19 Vaccine Safety*, Centers for Disease Control and Prevention (January 28, 2021), https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf.

The CDC's deliberate decision not to collect vaccine side-effect data it admitted was necessary is a breach of the CDC's scientific integrity policies. Given that the CDC had already acknowledged it had a compelling scientific need to gather such data, its failure to do so raises serious concerns that the CDC's v-safe design choices were improperly influenced by non-scientific factors. The CDC had an obligation to gather the best data on known severe AESIs from the vaccines in its effort to determine the vaccines' safety, and the CDC's refusal to collect all pertinent data was a betrayal of its obligations to the American public.

The FDA Overhypes the Risk of Electronic Nicotine Delivery Systems to Support Preferred Policy Outcomes

On April 26, 2023, PPT submitted a complaint to Inspector General Grimm and FDA Office of Scientific Integrity Director G. Matthew Warren detailing how the FDA and the Center for Tobacco Products repeatedly decried the dangers of vaping while keeping silent about research, including their own, that contradicted their claims and how FDA leadership overruled their own scientists to ban certain vaping products.[35]

On April 3, 2019, the FDA published an article by FDA Commissioner Scott Gottlieb and Principal Deputy Commissioner Amy Abernethy titled "Understanding the Health Impact and Dangers of Smoke and 'Vapor'" that presents the health dangers of vaping as comparable to smoking traditional cigarettes. [36] However, the article's bold declarations about the health risks from vaping are undermined by publicly available research that the FDA acknowledged in other sources.

On March 28, 2019, the FDA published an article titled "Fact or Fiction: What to Know About Smoking Cessation and Medications" that dismissed vapes as a useful alternative to cigarettes for smokers looking to quit.[37] However, these claims too appear to be contradicted by other publicly research that the FDA acknowledged in other sources.

On January 24, 2023, the FDA announced that it issued marketing denial orders ("MDOs") for two menthol-vape products. MDOs forbid regulated products from being marketing or distributed in the United States.[38] To justify its ban on these menthol-vapes, the

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[35] *Whatever Happened to 'Follow the Science?' PPT Documents Another Instance of Scientific Integrity Breach*, Protect the Public's Trust (Apr. 26, 2023), https://protectpublicstrust.org/press-releases/whatever-happened-to-follow-the-science-ppt-documents-another-instance-of-scientific-integrity-breach/.

[36] Scott Gottlieb and Amy Abernethy, *Understanding the Health Impact and Dangers of Smoke and 'Vapor,'* U.S. Food and Drug Administration (April 3, 2019), https://www.fda.gov/news-events/fdavoices/understanding-health-impact-and-dangers-smoke-and-vapor.

[37] *Fact or Fiction: What to Know About Smoking Cessation and Medications,* U.S. Food and Drug Administration (March 28, 2019), https://www.fda.gov/consumers/consumer-updates/fact-or-fiction-whatknow-about-smoking-cessation-and-medications.

[38] FDA Denies Marketing of Two Vuse Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard, U.S. Food and Drug Administration (January 24,

FDA claimed that "[e]xisting evidence demonstrates that non-tobacco-flavored [vapes], including menthol flavored [vapes], have a known and substantial risk with regard to youth appeal, uptake and use" and that this risk was lower with tobacco flavored vapes.[39] The press release announcing these MDOs contains false and misleading statements about the appeal of menthol-vapes to youth that were contradicted by the FDA's own findings in a review of publicly available sources.

Finally, in October 2022, the FDA banned menthol vape products from Logic, a subdivision of Japan Tobacco International.[40] In doing so, the Director of the Center for Tobacco Products Brian King overruled the recommendation of his own science office.[41] Science office scientists were clear that their recommendation for approving menthol-vapes was based on a review of sound scientific research which showed menthol-vapes would help smokers, particularly of menthol tobacco products, reduce or quit their smoking without increased harm to youth. Director King's decision appears to contradict the best available evidence without offering countervailing scientific evidence.

As a result, the FDA appears to have breached its obligation to uphold scientific integrity in its decision-making through 1) knowing dissemination of scientifically unfounded statements about the vaping industry that were contrary to the FDA's own research and 2) overruling its own scientists' recommendations to authorize menthol-vapes without proper scientific justification and in contradiction of the FDA's own research.

Conclusion

President Biden's commitment to scientific integrity is noble and necessary, especially in light of the unprecedented public health crisis of the last several years. The American public deserves to be governed on the basis of the best science and the most objective scientific decision-making. Our nation should be able to trust that institutions like HHS, the CDC, the FDA, and NIH operate and make decisions only according to objective, high-quality scientific evidence.

Despite PPT's well-documented and sourced complaints, there is no indication that HHS or the Administration has taken any action to correct past or prevent future scientific integrity violations.

2023), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-ecigarette-products-following-determination-they-do-not-meet.

[39] *Id.*

[40] *FDA Denies Marketing of Logic's Menthol E-Cigarette Products Following Determination They Do Not Meet Public Health Standard*, U.S. Food and Drug Administration (October 26, 2022), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-logics-menthol-e-cigaretteproducts-following-determination-they-do-not-meet.

[41] Alex Norcia, *Memos Show FDA Overruled Science-Office Call to Ok Menthol Vapes*, Filter Magazine (December 14, 2022), https://filtermag.org/menthol-vapes-fda/.

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Therefore, we request that OSTP look into violations of scientific integrity principles at HHS and its subagencies to ensure that the standards OSTP sets for the Administration are being implemented in practice.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust