PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL April 25, 2023

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

G. Matthew Warren, JD
Director
Office of Scientific Integrity
FDA White Oak Campus, Bldg. 1
Silver Spring, MD 20993

Re: Request for Investigation into FDA's Prioritization of Policy Over Science at the Center for Tobacco Products

Dear Ms. Grimm,

Decisions of the Food and Drug Administration (FDA) touch the lives of every American. Fortunately, the FDA has a mandate to use the best science that it can and to provide the public with scientific resources and policy decisions based upon honest and forthright analysis of the best available data. Whether the product is a vaccine, treatment for a chronic or fatal disease, infant formula, cannabidiol (CBD), or an electronic nicotine delivery systems ("ENDS," also known as vaping), the requirements of objectivity and scientific integrity don't change. In each case maintaining these standards is critical to ensuring that policy agendas aren't overruling scientific findings.

Trust is the most precious commodity for public health officials. A loss of trust can result in disastrous and tragic consequences as members of the public may fail to heed recommendations that can truly improve the quality and length of their lives. Protect the Public's Trust, a watchdog organization focused on ethics in government, has documented a number of potential scientific integrity violations at the Department of Health and Human Services and its component agencies.[1] Our research into the FDA's abuse of this public trust while promoting COVID-19 vaccines has opened up concern that lesser-known centers of the FDA may have also fallen victim to similar misconduct. Based on records detailed below, it appears that the FDA and the Center for Tobacco Products (CTP) have repeatedly publicly decried the dangers of vaping while keeping silent about research, including their own, that contradicts claims about the harms of vaping. In addition, the FDA's own leadership has overruled its scientists in deciding to

[1] https://protectpublicstrust.org/science-undermined/

ban certain vaping products without scientific support and in clear rejection of evidence showing such products help smokers reduce or quit smoking.

This apparent pattern of unscientific conduct is a betrayal of the FDA's mission to the American public to protect them through robust, scientifically grounded decision-making. For Americans looking to the federal government to advise them on ways to reduce harm from cigarette or combustible tobacco addictions, these actions may have resulted in years of damage to the public's health. Accordingly, we believe an investigation is warranted.

Legal Standard

The FDA Has a Regulatory Obligation to Maintain Scientific Integrity and Quality

Under 42 CFR § 93.103, the FDA is prohibited from engaging in research misconduct through "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." In particular, fabrication "is making up data or results and recording or reporting them" and "[f]alsification is . . . changing or omitting data or results such that the research is not accurately represented in the research record."[2]

Under the HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies,[3] there are FDA-specific guidelines that ensure the integrity of science and policymaking by requiring that information released to the public be objective:

1. The [FDA] will use

    a. the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed science and supporting studies when available

    b. data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)

2. In the dissemination of public information about risks, the [FDA] will ensure that the presentation of information about risk effects is comprehensive, informative, and understandable.[4]

[2] 42 CFR § 93.103.
[3] *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.
[4] *Id*. at Part II(F)(VII)(C).

Under these regulations and guidelines, the FDA must 1) represent research and data objectively without changing, omitting, or misrepresenting the research record, 2) use the best available science and supporting studies in its decision-making, and 3) ensure that information the FDA disseminates about health risks is comprehensive and informative.

The FDA's Scientific Integrity Mandate

The FDA's scientific integrity policy is clearly stated in its "Key Principles of Scientific Integrity at FDA."[5] These key principles include:

> "Maintaining a firm commitment to science-based, data-driven decision-making;"[6]
>
> "Shielding the agency's science and its scientific staff from political influence;"[7]
>
> "Protecting the integrity of scientific data and ensuring its accurate presentation, including the underlying assumptions and uncertainties;"[8]
>
> "Requiring a fair and transparent approach to resolving internal scientific disputes, including hearing and carefully considering differing views;"[9]
>
> "Utilizing peer review of data and research used in decision-making, where feasible, appropriate and consistent with the law."[10]

Furthermore, the FDA's scientific integrity policy staff manual states that "an unbiased presentation and full evaluation and analysis of the data, including its uncertainties, is absolutely critical" when the FDA makes its decision.[11] "While there may be differing views with respect to what one can conclude from the data, and while there are often multiple options that can be considered in a policy approach or regulatory decision that is made based on the science, the underlying research data and findings should be obtained and reported with integrity and should be never be altered for any reason."[12]

In addition to the FDA's own scientific integrity policy, President Biden's administration has declared its firm stance that scientific integrity must be at the heart of executive

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[5] *FDA Staff Manual Guides, Volume IV – Agency Program Directives, General or Multidiscipline, Scientific Integrity, Scientific Integrity at FDA*, U.S. Food and Drug Administration (February 3, 2012), https://www.fda.gov/media/82932/download.
[6] *Id*. at 2.
[7] *Id*.
[8] *Id*.
[9] *Id*.
[10] *Id*.
[11] *Id*. at 1.
[12] *Id*.

branch decision-making. 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.[13]

Scientific Background

On March 16, 2023, a national trade organization representing the vaping industry made public an FDA analytical report titled "Interdisciplinary OS State of the Science on Electronic Nicotine Delivery Systems (ENDS)"[14] (hereinafter, the "Report"). The Report "provides an overview of scientific literature pertaining to [vapes] as of March 31, 2020."[15] The goal of the Report was to "help address general questions for [vapes]," "highlight information or testing needed to answer these questions related to [vapes]," and "provide a basis for the comparison of [vapes] to other tobacco products."[16]

The Report primarily analyzed "information presented in the consensus study report 'Public Health Consequences of E-cigarettes' published in 2018 by the National Academies of Sciences, Engineering and Medicine," also known as the "NASEM Report."

Substantively, the Report states that only a subset of the many harmful or potentially harmful compounds ("HPHCs") found in cigarettes are found in vapes as well and "at much lower levels than those measured in combusted cigarette smoke."[17] This "suggest[s] [vaping] may expose users to fewer HPHCs and thereby reduce [biomarkers

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[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.

[14] *Interdisciplinary OS State of the Science on Electronic Nicotine Delivery System (ENDS)*, United States Food and Drug Administration (April 2020) [hereinafter, the "Report"], https://static1.squarespace.com/static/5f6002fa681995196b0b45cc/t/640f47ea32ee6e4f40e6de02/1678723052998/ENDSStateoftheScience_Spring2020_RIF.pdf.

[15] *Id*. at 5.

[16] *Id*.

[17] The Report at 43.

of exposure] for smokers switching to [vaping]."[18] The Report cites two studies to support this finding.[19] The Report also stated "[t]he NASEM report reviewed available studies related to cancer and [vape] use and found them to be very limited in number and relevance and generally lacking methodological rigor."[20] The NASEM Report declared that "there were no available epidemiological studies on the potential association between [vape] use and cancer or intermediate cancer endpoints in humans that would allow for conclusions."[21] Furthermore, the NASEM Report found that it was not clear if the chemicals in vapes that could cause DNA damage "were present at levels that would cause cancer in humans," and "[n]o additional observational studies published after the NASEM Report related to [vape] use and cancer risks were found."[22]

The Report further stated "[s]tudies do not indicate a direct correlation between [vaping] and known respiratory diseases (including EVALI [E-cigarette, or Vaping Product, Use Associated Lung Injury])."[23]

Moreover, the Report found that "[v]ariability of flavors may promote continued [vape] use among smokers" and that "use of two or more flavors at the time of [vape] initiation was associated with higher odds of being a dual user or complete switcher than stopping [vape] use."[24] For example, the Report showed the overwhelming utility of menthol-vapes for appealing to adult smokers and helping them quit cigarettes with a greater efficacy than fruit, candy, or traditional tobacco flavors: "[Some studies] have found the most common or preferred [vape] flavor for adults is mint/menthol or tobacco."[25] For example, "[i]n a 2017 discrete choice experiment among adult smokers who also used [vapes] . . . smokers were not interested in menthol flavored [vapes] unless they already used menthol combusted cigarettes"[26] and "[i]n a longitudinal laboratory study of smokers . . . the largest drop in combusted cigarettes smoked per day after 6 weeks occurred among those assigned menthol [vapes], while the smallest drop in smoking occurred in those assigned chocolate or cherry flavors."[27]

Finally, the Report discovered that "flavored [vapes] have been found to be appealing to all age groups, not only youth."[28] "[T]hose who used non-tobacco and non-menthol [vape] flavors were significantly more likely to reduce combusted cigarette consumption or quit smoking compared to non [vape] users."[29]

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[18] *Id.*
[19] *Id.*
[20] The Report at 146.
[21] *Id.*
[22] *Id.*
[23] The Report at 89.
[24] The Report at 113.
[25] The Report at 120.
[26] *Id.*
[27] The Report at 112.
[28] The Report at 121.
[29] The Report at 112.

Potential Violations

Dissemination of Scientifically Unfounded Statements

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.'"[30] The article presents the health dangers of vaping as comparable to smoking traditional cigarettes because "several of the dangerous chemicals in tobacco smoke are also present in the aerosol of some [vaping] products."[31] The same article further states that research showed substances in vaping aerosol "can pose a risk for . . . vaping-induced inflammatory reactions that can mimic metastatic cancer."[32] The article also warns of vaping's danger to respiratory health: "Flavorings that are safe for use in food may become toxic when these chemicals are heated and inhaled. Some have been shown to be harmful to the lungs."[33]

This article by Commissioner Gottlieb and Deputy Commissioner Abernethy appears to violate the FDA's scientific integrity mandates. The article's bold declarations about the health risks from vaping are undermined by publicly available research that the FDA acknowledged in the Report. Contrary to Drs. Gottlieb and Abernethy, the Report makes clear that the FDA knew or should have known in 2019 that vaping exposes users to far lower levels of harmful or potentially harmful compounds than cigarettes. The article's other claims against vaping, such as it posing a risk for vaping-induced inflammatory reactions that mimic cancer and other respiratory harms are similarly contradicted by the FDA's own findings in the Report based on research in the NASEM Report that was published in January 2018. This scientific data contradicting Drs. Gottlieb and Abernethy's article was published prior to the article's publication and was either known to the FDA before publication or not long after, as evidenced by the Report. Accordingly, the FDA violated its obligation to uphold scientific integrity and only use the best available research and evidence by publishing these claims, which were contradicted by research and failing to correct them after publication.

On March 28, 2019, the FDA published an article titled "Fact or Fiction: What to Know About Smoking Cessation and Medications."[34] This article dismissed vapes as a useful alternative to cigarettes for smokers looking to quit: "E-cigarettes are not approved by the

[30] 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/fda-voices/understanding-health-impact-and-dangers-smoke-and-vapor.
[31] *Id*.
[32] Gottlieb and Abernethy, *supra*.
[33] Gottlieb and Abernethy, *supra*.
[34] *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-what-know-about-smoking-cessation-and-medications.

FDA as an aid to quit smoking and may expose users to some of the same toxic chemicals found in combustible cigarette smoke. There are other proven, safe, and effective methods for quitting smoking."[35]

Contrary to these claims in the article and accompanying video, the Report states that the chemical exposure from vapes is significantly lower than in traditional cigarettes, it is unknown if the amounts are even sufficient to be harmful, and vapes are effective in substituting for traditional cigarettes with smokers looking to quit.[36] Thus, this article and accompanying video do not appear to present the best available scientific information.

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.[37] To justify its ban on these menthol-vapes, the 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.[38]

The press release[39] announcing these MDOs contains false and misleading statements about the appeal of menthol-vapes to youth. As with the rest of the FDA's statements targeting the vape industry, these claims were contradicted by the FDA's own findings in the Report, which found that menthol-vapes were most attractive to existing smokers of menthol cigarettes and were particularly helpful in aiding such smokers in quitting or reducing the number of cigarettes they smoked.[40]

The FDA's decision to engage in a multi-year public relations campaign targeting certain ENDS products based on false and misleading statements about the risks of vaping is a clear violation of its commitment to science and the American public's health. The FDA's conduct makes an investigation necessary to preserve its credibility and the people's trust in the institutions that exist to protect them, not advance special interest policy agendas.

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[35] *Id*.
[36] *Id*. at 29-30.
[37] *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, 2023), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-e-cigarette-products-following-determination-they-do-not-meet.
[38] *Id*.
[39] *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, 2023), https://www.fda.gov/news-events/press-announcements/fda-denies-marketing-two-vuse-menthol-e-cigarette-products-following-determination-they-do-not-meet.
[40] The Report at 112.

Overruling Its Own Scientists' Recommendations

Per the FDA's policy and CTP Director Brian King's public statements, the FDA "conducts a rigorous, scientific review of submitted premarket tobacco product applications, evaluating the data for each product to determine if it meets the public health standard."[41]

In October 2022, the FDA banned menthol vape products from Logic, a subdivision of Japan Tobacco International. Director King justified the MDO of Logic's menthol-vapes based on "the applicant [] not provid[ing] sufficient scientific evidence to show that the potential benefit to adult smokers outweighs the risks to youth."[42]

An internal FDA memorandum from October 25, 2022, states that "OS concluded that the existing literature supports that menthol-flavored cigarette smokers show a preference for menthol-flavored [vapes] relative to tobacco-flavored [vapes.]"[43] Per the OS memo, OS briefed the CTP's previous director in 2021, offering a "preliminary recommendation to authorize the marketing of [Logic's] products." OS's recommendation was based on OS's understanding that "menthol-flavored ENDS could be a direct substitute for [menthol tobacco products], providing a less harmful alternative for menthol-flavored cigarette smokers, who are less likely to successfully quit smoking than smokers of non-menthol flavored cigarettes."[44] OS determined that the appeal of menthol vapes to youth "may not be at the same level as other flavors" and that the documented preferences among menthol cigarette smokers for menthol vapes "suggest a potential benefit" from authorizing menthol vapes.[45]

The OS memo stated that "OS considered that this suggested potential benefit, in the form of increased opportunity for use and transition, coupled with product-specific evidence of some benefit to smokers (even if not greater than that of tobacco-flavored ENDS products), amounted to a likelihood of greater cessation or significant reduction in smoking that would outweigh the known risks to youth from the marketing of the products, sufficient to meet the legal standard for authorization."[46]

Director King's decision to overrule and pressure OS's scientists into withdrawing their approval of menthol-vapes is highly concerning and appears to constitute a violation of scientific integrity principles and policies.

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[41] *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-cigarette-products-following-determination-they-do-not-meet.
[42] *Id*.
[43] Alex Norcia, *Memos Show FDA Overruled Science-Office Call to Ok Menthol Vapes*, Filter Magazine (December 14, 2022), https://filtermag.org/menthol-vapes-fda/.
[44] *Id*.
[45] *Id*.
[46] *Id*.

OS's 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, including statements in an internal OS memo, without offering countervailing scientific evidence. Director King's justifications in the OS memo appear to be pretextual to support what is otherwise an unscientific determination, in apparent contradiction of the FDA's scientific integrity mandate.

Conclusion

Over the last two years, polls have shown rapidly deteriorating trust in America's public health institutions. This concern has been echoed by Directors at the FDA and the Centers for Disease Control and Prevention (CDC), a few of the agencies previously imbued with high public confidence and respect. Unfortunately, it became standard course for policy goals such as promoting vaccine mandates and vaccines for children, defending lockdowns and school closures, and supporting mask mandates to be elevated over objectively reporting what the science concluded (or was unclear on).

In case after case over the last several years, it has become clear why the public's trust in their public health institutions has deteriorated so rapidly. As our several scientific integrity complaints (including this one) have demonstrated, science appears to be regularly taking a backseat to the policy preferences of those leading our most important (and once credible) agencies. While the COVID-19 pandemic reminded Americans that public health agencies were not immune from the influence of teachers' unions and pharmaceutical companies, the records described in this complaint expose the fragility of scientific integrity at the FDA.

Early in his tenure, President Biden made a commitment to following the science. His Administration's commitment must be viewed through the lens of accountability that it imposes on those who violate basic scientific integrity principles. This complaint cites several instances where FDA leadership appears to have violated those principles.

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. Enforcing high standards for scientific integrity should never be compromised, regardless of the products, statutory mission, or policy preferences of those in leadership roles at the agency or Department.

PROTECT the PUBLIC'S TRUST

Accordingly, we call on you to immediately open an investigation into whether the FDA has violated its scientific integrity regulations and policies by allowing partisan, personal, or other non-scientific concerns to drive its decision-making in the above circumstances. Thank you.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust