



PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL

October 27, 2021

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

CC: Rebecca Haffajee
Acting Assistant Secretary
Office of the Assistant Secretary for
Planning and Evaluation
U.S. Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

The Honorable Christi Grimm
Acting Inspector General
Office of the Inspector General
U.S. Health and Human Services
330 Independence Ave., S.W.
Washington, D.C. 20201

Dr. Eric S. Lander
Science Advisor to President Joseph R. Biden Jr.
Director, White House Office of
Science and Technology Policy
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

**Re: Request for Investigation into Whether NIH Director and Other HHS Agency
Officials Violated the Agency's Scientific Integrity Policy**

Dear Mr. Kessler,

Protect the Public's Trust (PPT) operates as a non-profit organization dedicated to promoting integrity in government and restoring the public's trust in government officials. Trust is a precious commodity for health officials and medical professionals. The information and data with which they deal can be exceedingly complex, often not easily understood even by highly trained and educated professionals. Even relatively non-controversial suggestions – such as to avoid attending school or work when exhibiting symptoms of the flu or common cold or to



PROTECT the PUBLIC'S TRUST

immediately visit a health professional when experiencing indicators of severe ailments – can create significant impositions on an individual's or family's lifestyle or livelihood.

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. In pursuit of Protect the Public's Trust's mission, and out of concern for the scientific integrity, credibility, and trust of the government's leading public health agencies, we are requesting that you open an investigation to determine whether certain statements by senior agency officials, including in an official press release, violated the agency's scientific integrity policy.

Background

On August 6, 2021, the Center for Disease Control (CDC) issued a press release titled, "New CDC Study: Vaccination Offers Higher Protection than Previous COVID-19 Infection." The release made several statements, including the headline, that appear to contradict the underlying scientific report being cited, ignored key caveats, and intentionally misrepresented the conclusion to the public. The CDC release of August 6, 2021, and subsequent statements in the media by the NIH Director Francis Collins advanced a scientific conclusion that, at best, misinterpreted the underlying study's results and, at worst, intentionally misrepresented the findings to advance an Administration policy priority. Agency guidelines on scientific integrity require a higher code of conduct in its communications and statements about scientific findings or conclusions.

Potential Violations

The CDC's press release on August 6, 2021, made several statements that appear to be inconsistent with the underlying study cited and either misrepresent or distort the conclusion. As a result, the faulty conclusion was cited by multiple media sources and has yet to be accurately, honestly, and completely corrected or rescinded. The release reads, in part (emphasis added):

New CDC Study: Vaccination Offers Higher Protection than Previous COVID-19 Infection

In today's MMWR, a study of COVID-19 infections in Kentucky among people who were previously infected with SAR-CoV-2 shows that unvaccinated individuals are more than twice as likely to be reinfected with COVID-19 than those who were fully vaccinated after initially contracting the virus. **These data further indicate that COVID-19 vaccines offer better protection than natural immunity alone** and that vaccines, even after prior infection, help prevent reinfections...



PROTECT the PUBLIC'S TRUST

“If you have had COVID-19 before, please still get vaccinated,” said CDC Director Dr. Rochelle Walensky. **“This study shows you are twice as likely to get infected again if you are unvaccinated.”**¹

As a significant number of American news consumers rarely read past the headlines², the misleading headline of the press release could itself represent a possible violation of the CDC’s scientific integrity principles. The unequivocal headline, scientific finding, and the misleading statement by CDC Director Walensky all work to deceive the American public about the body of science underlying the issue of natural immunity versus that achieved by the COVID-19 vaccines currently available. A reference to the study’s underlying assumptions demonstrates the reckless approach taken in the agency’s press release. For instance (emphasis added):

Second, persons who have been vaccinated are possibly less likely to get tested. Therefore, the **association of reinfection and lack of vaccination might be overestimated.** ...

Finally, this is a retrospective study design using data from a single state during a 2-month period; therefore, **these findings cannot be used to infer causation.** Additional prospective studies with larger populations are warranted to support these findings.³

Yet inferring causation is precisely what the agency leadership proceeded to do by citing the study in a press release and subsequent media appearances. In an interview with Fox News, National Institute of Health (NIH) Director Francis Collins was unequivocal in his response (exchange beginning at approximately 0:22):

Bret Baier: “Can you **definitively** say to somebody that **the vaccine provides better protection than the antibodies** that you get from actually having had Covid-19?”

Francis Collins: “**Yes, Bret, I can say that.** There was a study published by CDC just ten days ago in Kentucky. And they looked specifically at people who had had natural infection and people who’d been vaccinated and then ended up getting infected again. So what was the protection level? It 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. **That’s very clear** in that Kentucky study.”⁴

Collins’s reply evoked strong responses from the scientific community for misstating the study’s conclusion. Dr. Martin Kuldorff, another highly respected epidemiologist at Harvard Medical School, critiqued Dr. Collins on this point.

¹ <https://www.cdc.gov/media/releases/2021/s0806-vaccination-protection.html>

² <https://www.washingtonpost.com/news/the-fix/wp/2014/03/19/americans-read-headlines-and-not-much-else/>

³ <https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm>

⁴ <https://www.facebook.com/FoxNewsVideo/videos/549316876113129/>



PROTECT the PUBLIC'S TRUST

On natural immunity, @NIHDirector Francis Collins is misleading the public. Kentucky study shows less reinfections after COVID disease plus vaccine than COVID only (both very low). He falsely claims less reinfections after vaccine than after COVID disease.⁵

The limitations of the study and the challenges with representing it as decisive evidence of a conclusion it does not support, as the press release and agency officials have done since the study's release, go even deeper. One neurosurgeon described some of flaws, questions, and key omissions inherent in the agency's use of the study:

1. It uses a "case-control" methodology that reverses the logic of more intuitive methods, by first identifying cohorts of re-infected individuals and their vaccination rate, and comparing it to a randomly selected, demographically similar control group. Using this method, they queried the Kentucky state's database of COVID individuals, and found only 246 people who again tested positive for the virus in May/June of 2021. Of these people, they found 72.8% were unvaccinated, compared to 57.7% of the control group. This suggests reinfected individuals would have benefited from the vaccine. The problem? In the communication, they **OMIT** the denominator of total COVID recovered patients in KY in 2020, but this independently reported in public databases as ~275,000 cases. This means only 246/275,000 patients got reinfected in May/June, resulting in **0.05%/month re-infection rate**. This is ridiculously small, given the breakthrough rate for vaccines is on the order of 5-10%!

2. While the reinfected patients necessarily had a positive test result, the control group did not have any testing requirements. This is problematic, because asymptomatic individuals will rarely get tested, and vaccinated individuals may still not get tested even if symptomatic. The end result is that the total number of re-infections (symptomatic and asymptomatic) in the vaccinated group are underestimated. To their credit, the authors acknowledge this, but do not qualify its potential impact.

3. The study curiously looked at reinfections that occurred specifically and only in May and June of 2021. Why not look at all reinfections after the vaccine was made available, in January 2021? The authors justify this decision by saying, "because of vaccine supply and eligibility requirement considerations; this period was more likely to reflect resident choice to be vaccinated, rather than eligibility." But it is preposterous to believe that an individual's choice of vaccination impacts the efficacy of vaccination. More likely, perhaps cynically, these months were selected to give the authors a desired result that the full time period did not.⁶

⁵ <https://twitter.com/MartinKulldorff/status/1426607041406251009>

⁶ <https://www.powerlineblog.com/archives/2021/08/more-vooodoo-epidemiology-at-the-cdc.php>



PROTECT the PUBLIC'S TRUST

Furthermore, CDC's highlighting the results of a carefully selected two-month period from a single state (out of a 50 State study) led Dr. Marty Makary, a Johns Hopkins University Surgical Professor, to claim the CDC was "fishing" in order to find support for a policy position promoted by political leadership at the agency and at the White House. While policy positions are wholly within the discretion granted to political leadership, they must not conflict with the applicable scientific integrity policies. It is not clear they cleared this bar. Dr. Makary also noted the exceedingly low infection rate of the subjects, among both vaccinated and unvaccinated, in the Kentucky study.

There are 14 studies that show that natural immunity is effective, it's durable, and it's going strong. And yet there's been this inexplicable denial of it and after a lot of public pressure now from our public health leaders to talk about natural immunity they come up with this study that they essentially jury-rigged in Kentucky showing that maybe it was 2.3 times higher among those with previous infection...The rate of getting a subsequent infection in those with natural immunity was 0.09%. Those who were vaccinated in that time period it was 0.03%. The conclusion is it's extremely rare in both groups. Not that it's higher among those with natural immunity by 2.3-fold...Why did they pick Kentucky? They've got data on all 50 states. They only reported Kentucky because they were using a statistical method called "fishing" where you run the data on all 50 states and the one state that gives you the signal that's consistent with what you want to say is the state you report out.⁷

Dr. Makary later penned an op-ed in the *The Washington Post* referencing a 700,000-person study in Israel, a Cleveland Clinic study, and another from Washington University demonstrating the strength of natural immunity. These are far from the only studies⁸ that provide evidence⁹ of the power of natural immunity, in contrast to the purported results of the Kentucky study. In light of the body of science, Dr. Makary expressed frustration with Dr. Collins's claims about the Kentucky study.

More than 15 studies have demonstrated the power of immunity acquired by previously having the virus. A 700,000-person study from Israel two weeks ago found that those who had experienced prior infections were 27 times less likely to get a second symptomatic covid infection than those who were vaccinated. This affirmed a June Cleveland Clinic study of health-care workers (who are often exposed to the virus), in which none who had previously tested positive for the coronavirus got reinfected. The study authors concluded that "individuals who have had SARS-CoV-2 infection are unlikely to benefit from covid-19

⁷ <https://twitter.com/MartinKulldorff/status/1426607041406251009>

⁸ <https://academic.oup.com/jid/advance-article/doi/10.1093/infdis/jiab295/6293992>

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7919858/>



PROTECT the PUBLIC'S TRUST

vaccination.” And in May, a Washington University study found that even a mild covid infection resulted in long-lasting immunity.

So, the emerging science suggests that natural immunity is as good as or better than vaccine-induced immunity. That’s why it’s so frustrating that the Biden administration has repeatedly argued that immunity conferred by vaccines is preferable to immunity caused by natural infection, as NIH director Francis Collins told Fox News host...Bret Baier a few weeks ago.¹⁰

Far from the Kentucky study being dispositive, as the press release and accompanying statements suggest, more recent statements indicate the CDC has not sufficiently studied the effect of natural versus vaccine immunity. A recent CNN interview with the White House’s chief medical adviser, Dr. Anthony Fauci, by Dr. Sanjay Gupta is indicative.

GUPTA: And just real quickly, there was a study that came out of Israel about natural immunity, and basically, the headline was that natural immunity provides a lot of protection, even better than the vaccines alone.

What do people make of that? So as we talk about vaccine mandates, I get calls all the time, people say, I've already had COVID, I'm protected. And now the study says maybe even more protected than the vaccine alone. Should they also get the vaccine? How do you make the case to them?

FAUCI: You know, that's a really good point, Sanjay. I don't have a really firm answer for you on that. That's something that we're going to have to discuss regarding the durability of the response.

The one thing that paper from Israel didn't tell you is whether or not as high as the protection is with natural infection, what's the durability compared to the durability of a vaccine? So it is conceivable that you got infected, you're protected, but you may not be protected for an indefinite period of time.

So, I think that is something that we need to sit down and discuss seriously, because you very appropriately pointed out, it is an issue, and there could be an argument for saying what you said.¹¹

Even with all of the uncertainty regarding the relative effectiveness of natural versus vaccine immunity among medical professionals and government health officials as well as the outright misrepresentation of the results of the Kentucky study, the CDC has not edited, revised or clarified any of the publicly available documents associated with the study or the press release.

¹⁰ <https://www.washingtonpost.com/outlook/2021/09/15/natural-immunity-vaccine-mandate/>

¹¹ https://www.realclearpolitics.com/video/2021/09/10/fauci_natural_immunity_vs_vaccine_for_covid-19_needs_to_be_discussed_seriously.html



PROTECT the PUBLIC'S TRUST

Scientific Integrity Policies

The Center for Disease Control's scientific integrity policy states in part (emphasis added):

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**. Although CDC may conduct research in areas relevant for making policy decisions, the goal of such research is to provide the best evidence to drive policy in the right direction. **CDC is committed to ensuring 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.

When CDC learns of confusion about a CDC-issued public health message and determines that clarification or additional information should be published, CDC will take reasonable steps, using plain language, to address confusion. In addition, when CDC issues or releases a product in an expedited time frame or based on uncertain or incomplete information and determines additional information should be published to clarify the original public health message, even if there is no evidence of confusion, it will take appropriate steps to publish the additional information.¹²

CDC requires that its media relations employees adhere to a similar code of conduct (emphasis added):

- **Be honest and accurate in all communications**
- Honor publication embargoes
- Respond promptly to media requests and respect media deadlines
- **Act promptly to correct the record or erroneous information, when appropriate**
- Promote the free flow of scientific and technical information
- Protect non-public information

CDC communications are guided by principles such as:

- CDC communication is science-based, timely, accurate, respectful, credible, and consistent (STARCC).
- CDC embraces intellectual honesty and transparency in its release of information to fully empower public decision making.¹³

¹² https://www.cdc.gov/os/integrity/docs/CDCSIGuide_042516.pdf

¹³ https://www.cdc.gov/os/integrity/docs/CDCSIGuide_042516.pdf



PROTECT the PUBLIC'S TRUST

The National Institute of Health's principles are similar in their high standards of integrity and intellectual honesty (emphasis added):

Ensuring the integrity of science and science-based policymaking is at the heart of everything NIH does in fulfilling its mission. NIH strongly supports appropriate degrees of transparency in the preparation and identification of the scientific and technological information that it uses for policymaking. NIH's goal is to maintain integrity in the conduct of the science that the public funds and to **assure the public of the credibility of our scientific findings.**

OIR, the research community, and the public at large rightly expect adherence to **exemplary standards of intellectual honesty in the formulation, conduct, and reporting of scientific research.** Allegations of research misconduct are taken seriously by NIH. The process of investigating allegations must be balanced by equal concern for protecting the integrity of research as well as the careers and reputations of researchers.¹⁴

The Biden Administration has also made a point of highlighting its commitment to robust scientific integrity. In its "Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking," the White House states (emphasis added):

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. Improper **political interference** in the work of Federal scientists or other scientists who support the work of the Federal Government and **in the communication of scientific facts undermines the welfare of the Nation, contributes to systemic inequities and injustices, and violates the trust that the public places in government to best serve its collective interests. ...**

The Task Force's review shall include an analysis of any instances in which existing **scientific-integrity policies have not been followed or enforced,** including whether such deviations from existing policies have resulted in improper political interference in the conduct of scientific research and the collection of scientific or technological data; led to the suppression or **distortion**

¹⁴ <https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf>



PROTECT the PUBLIC'S TRUST

of scientific or technological findings, data, information, conclusions, or technical results.¹⁵

Given the substantive intellectual criticism of the CDC and NIH's public statements, there is an increasing public perception that the agency's credibility has been undermined and its intellectual honesty placed in doubt. To be clear, scientific integrity policies cannot always prevent a violation from occurring; however, they should always be relied on to police those violations that have been identified. This appears to be such an occasion.

Conclusion

To cite a recent letter from Senators Elizabeth Warren, Gary Peters, and Patty Murray on the importance of scientific integrity at HHS:

The CDC and FDA's independence as scientific agencies is crucial to safeguarding the public health and saving lives. These agencies must be able to develop, review, and disseminate public health data, guidelines, and other information that are based on science, facts, and medical principles—and not the political imperatives and moods of a president and his advisors.¹⁶

We agree.

Forcing agency career scientists to report to senior White House advisors can be a recipe for undue influence, stymied debate, and politically-driven science. According to news reports, this may be occurring and possibly the reason for the recent misrepresentations by the CDC and NIH, among others at the agency. A recent Politico article highlighted the degree to which COVID-19 response policy has been commandeered by the White House.¹⁷ According to the article, "They brief him [Secretary Becerra]. But he's not a decider on response activities." Secretary Becerra's removal from what would appear to be his Senate-confirmed duties, have left "HHS' methodological scientific agencies without an intermediary." The article cites this as "contributing to breakdowns in coordination that have hampered the response and fueled accusations of political interference."

The public perception that the President's political advisors are selecting and interpreting scientific studies for the purpose of supporting the White House's policy agenda significantly undermines public trust and can have long-lasting effects on the agency's reputation and tragic consequences for the Nation's health. As the HHS Chief Science Officer for COVID-19 Response, it is your responsibility to uphold the scientific integrity of the agency's communications and enforce the policy against those who have violated it.

¹⁵ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/>

¹⁶ Letter to The Hon. Gene L. Dodaro, Comptroller General of the United States, Government Accountability Office from Senators Warren, Peters, Murray (Oct. 8, 2020).

¹⁷ Politico, "Becerra takes a backseat while others steer Covid response," Adam Cancryn (Sept. 21, 2021).



PROTECT the PUBLIC'S TRUST

We request that you open an investigation into the circumstances surrounding the public communications highlighted in this letter. Part of the inquiry should explore the decisions by agency officials to continue promoting what appears to be a scientifically unsound conclusion given the relevant data and academic literature available, along with the Kentucky study's methodological infirmities. Thank you.

Sincerely,

Michael Chamberlain
Director