PROTECT the PUBLIC'S TRUST

VIA ELECTRONIC MAIL December 16, 2022

TO: Christi A. Grimm
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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 Refusal to Monitor Known Severe Vaccine Side Effects

Dear Ms. Grimm,

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

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

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

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

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

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

The V-Safe System

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The CDC's Guidance on Scientific Integrity[9] identifies accountability and integrity as "core values," stating:

> Accountability — As diligent stewards of public trust and public funds, we act decisively and compassionately in service to the people's health. We ensure that our research and our services are based on sound science and meet real public needs to achieve our public health goals.
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> . . .
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> Integrity — We are honest and ethical in all we do. We will do what we say. We prize scientific integrity and professional excellence.[10]

The CDC's commitment to high quality science is fundamental to the agency's mission and runs throughout its policies. The agency's scientific integrity policy declares its "commitment to transparency, honesty and thorough consideration of research outcomes" and that the "CDC has a responsibility to conduct the best science and is committed to disseminating scientific findings and results without being influenced by policy or political issues."[11] In furtherance of these commitments, the CDC's scientific integrity policy requires that "all information products authored, published, and released by the CDC for public use are of the highest quality and are scientifically sound, technically accurate, and useful to the intended audience."[12]

In addition to the CDC's own scientific integrity policy, President Biden has required the CDC to uphold the highest standards in its research and practices. President Biden's Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking states that "[s]cientific finding should never be distorted or influenced by political considerations:"

> It is the policy of my Administration to make evidence-based decisions guided by **the best available science and data**. Scientific and technological information, data, and evidence are central to the development and iterative improvement of sound policies, and to the delivery of equitable programs, across every area of government. Scientific findings should

[9] CDC Guidance on Scientific Integrity, v. 2.1 at 2, Office of the Associate Director for Science (ODAS) (April 2016) https://www.cdc.gov/os/integrity/docs/CDCSIGuide_042516.pdf.
[10] *Id*. at 2.
[11] *Id*. at 2-3.
[12] *Id*. at 3.

> never be distorted or influenced by political considerations. When scientific or technological information is considered in policy decisions, it should be subjected to well-established scientific processes, including peer review where feasible and appropriate, with appropriate protections for privacy.[13]

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

Analysis

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

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

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

[13] Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking, 86 Fed. Reg. 8845 (Jan. 27, 2021), https://www.govinfo.gov/content/pkg/FR-2021-02-10/pdf/2021-02839.pdf. (emphasis added).

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

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

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

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

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

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

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

Conclusion

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

Thank you.

Sincerely,

Michael Chamberlain
Director
Protect the Public's Trust