

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

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December 21, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

The Honorable Robert Califf
Commissioner
Food and Drug Administration

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

Dear Secretary Becerra, Commissioner Califf, and Director Cohen:

When it comes to responding to my data requests on the adverse events associated with the COVID-19 vaccines, your arrogant lack of transparency has been unprecedented, irresponsible, and completely unacceptable. Over the course of the last 32 months, I have raised questions, sent formal requests, and conducted oversight on the safety and efficacy of the COVID-19 vaccines. Instead of addressing my legitimate questions and requests for information, you and other public health officials continue to promote the COVID-19 vaccines as safe and effective and often use the number of vaccine doses administered as support for that misleading claim.¹

For example, in September 2023, a reporter asked Centers for Disease Control and Prevention (CDC) Director Cohen how she would respond to individuals who have safety concerns about getting the COVID-19 vaccines.² Director Cohen reportedly stated:

Well, I want folks to know that these vaccines have been studied, frankly, more than any vaccine in history. **We've given over 600 million doses of the COVID vaccine.**

¹ CDC director stresses importance of updated COVID booster shot amid rising cases, ABC News, Sept. 13, 2023, <https://abcnews.go.com/US/cdc-director-stresses-importance-updated-covid-booster-shot/story?id=103152553>; Chelsea Cirruzzo, 'On track': 3 percent of Americans have gotten the new Covid shot, but the CDC director remains confident, Politico, Oct. 24, 2023, <https://www.politico.com/news/2023/10/24/covid-flu-vaccine-cdc-director-mandy-cohen-00123268#:~:text=Health%20Care-,%20On%20track%203A%203%20percent%20of%20Americans%20have%20gotten%20the,have%20had%20their%20flu%20shot.&text=The%20Biden%20administration's%20campaign%20to,to%20a%20very%20slow%20start>.

² CDC director stresses importance of updated COVID booster shot amid rising cases, ABC News, Sept. 13, 2023, <https://abcnews.go.com/US/cdc-director-stresses-importance-updated-covid-booster-shot/story?id=103152553>.

So it's been studied in terms of its safety extensively. So I wouldn't recommend anything I wouldn't recommend for my own family. I'm not just the head of the CDC. I'm a mom. I'm a wife. I'm a daughter. So you're going to see my 9- and 11-year-old daughters get vaccinated with COVID and flu this fall, my husband, my parents. So we're hoping that everyone will protect themselves when we get into the fall and winter, get their updated COVID shot, as well as a flu shot.³

Director Cohen's statement above lacks detail, particularly with regards to the number of deaths per dose associated with the COVID-19 vaccines. As is typical, Director Cohen broadly stated, "these vaccines have been studied, frankly, more than any vaccine in history," but did not cite any specific studies federal officials are using to make such sweeping claims.⁴

Although Director Cohen encouraged people to get both the COVID-19 and flu vaccines this fall and winter—implying that both vaccines are equally necessary and safe—the reality is that there appears to be a dramatic difference in the safety profiles of the COVID-19 vaccines compared to the flu vaccine.

My staff reviewed data on the Vaccine Adverse Event Reporting System (VAERS) to determine the number of deaths per million doses associated with the COVID-19 vaccines and the flu vaccines. Although there is no public database on the number of flu doses administered in individuals in the U.S. over the last 10 years, my staff was able to generate this figure by making reasonable assumptions based on publicly-available data on the number of flu vaccine doses distributed each year. With this information, my staff calculated flu vaccine deaths per million doses assuming different percentages of the distributed flu vaccine were, in fact, administered.

The difference in deaths per million doses is so stark and disturbing, that it makes little difference what we assume the percentage of distributed flu vaccines were actually administered. Below are the comparisons of U.S. deaths per one million U.S. doses for COVID-19 vaccines over the last 3 years, and flu vaccines over the last 10 years:⁵

³ *Id.* (emphasis added).

⁴ *Id.*

⁵ COVID-19 deaths based on VAERS data between Dec. 2020 through Apr. 2023. Flu deaths based on VAERS data between June 2009 through May 2019. Flu doses calculated at a certain percent of distribution over ten flu seasons prior to COVID-19 (June 2009 to May 2019).

COVID-19 vaccines:

- 25.5 (deaths per million doses)

Flu vaccines, based on different percentages of distributed vaccines that were administered:

- 100% of distributed flu vaccines administered: 0.32 (deaths per million doses)
- 70% of distributed flu vaccines administered: 0.46 (deaths per million doses)
- 50% of distributed flu vaccines administered: 0.65 (deaths per million doses)

Using the midpoint assumption that 70% of distributed flu vaccines were administered, the 25.5 deaths per million doses of the COVID-19 vaccine represents a **55 fold increase** over the flu vaccine deaths per million doses. This is a shocking difference and only adds to the growing evidence of safety signals that are screaming to be taken seriously.

Researchers recently informed my office of another alarming piece of evidence that raises safety concerns about the COVID-19 vaccines, particularly the Pfizer vaccine. Based on a study recently published in *Nature* by Dr. Thomas Mulrone, it appears that the Pfizer COVID-19 vaccines may produce “off-target” or incorrect proteins.⁶ Independent researcher, Dr. David Wiseman, and his colleagues provided my office with their commentary on Dr. Mulrone’s study and concluded that “[t]he finding that unintended proteins may be produced as a result of vaccination is sufficient cause for regulators to conduct full risk assessments of past or future harms that may have ensued.”⁷

Although Dr. Mulrone’s study noted, “there is no evidence that frameshifted products in humans generated from [Pfizer’s COVID-19] vaccination are associated with adverse outcomes,” Dr. Wiseman argues that “it is unclear how it is possible to make this statement.”⁸ Moreover, it is also unclear the extent to which U.S. public health agencies were or are aware of Pfizer’s COVID-19 vaccines’ potential to produce incorrect proteins and what effect that may have on a vaccinated individual’s immune system.

In light of my above analysis and Dr. Wiseman’s commentary of Dr. Mulrone’s study, I once again, call on your agencies to immediately produce all Proportional Reporting Ratio data analyses and empirical Bayesian data mining relating to the COVID-19 vaccines and provide the following information by no later than January 18, 2024:

⁶ Thomas Mulrone et al., N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting, *Nature*, Dec. 6, 2023, <https://www.nature.com/articles/s41586-023-06800-3>.

⁷ David Wiseman et al., Ribosomal frameshifting and misreading of mRNA in COVID-19 vaccines produces “off-target” proteins and immune responses eliciting safety concerns: Comment on UK study by Mulrone et al., Dec. 6, 2023, <https://osf.io/preprints/osf/nt8jh>.

⁸ Thomas Mulrone et al., N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting, *Nature*, Dec. 6, 2023, <https://www.nature.com/articles/s41586-023-06800-3>; David Wiseman et al., Ribosomal frameshifting and misreading of mRNA in COVID-19 vaccines produces “off-target” proteins and immune responses eliciting safety concerns: Comment on UK study by Mulrone et al., Dec. 6, 2023, <https://osf.io/preprints/osf/nt8jh>.

1. Provide the amount of flu vaccine doses administered in the U.S. from 2009 to the present.
2. Provide the studies Dr. Cohen referred to in her reported statement: “I want folks to know that these [COVID-19] vaccines have been **studied, frankly, more than any vaccine in history.**”⁹
3. The Food and Drug Administration (FDA) issued guidance that stated, “**COVID-19 vaccine development may be accelerated** based on knowledge gained from similar products manufactured with the same well-characterized platform technology, to the extent legally and scientifically permissible.”¹⁰ What aspects of the Pfizer, Moderna, and Johnson and Johnson COVID-19 vaccine development were “accelerated” prior to Emergency Use Authorization? Following FDA approval, did any of those manufacturers retest or review any aspect of their vaccine development that may have been “accelerated”? If so, to what extent did those tests yield similar or different outcomes when compared to the “accelerated” outcomes?
4. Is your agency aware of Dr. Mulrone y et al.’s study titled, “N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting”? If so:
 - a. Does your agency agree with the study’s findings that the Pfizer COVID-19 vaccine could produce “off-target” or incorrect proteins?
 - b. Since the publication of Dr. Mulrone y’s study, has your agency sought information from Pfizer related to the study? If so, what, if anything, has Pfizer provided? If not, why not?
5. Prior to the publication of Dr. Mulrone y’s study, was your agency aware that the Pfizer COVID-19 vaccine could produce “off-target” or incorrect proteins?
 - a. If so, when did your agency become aware?
 - b. Did Pfizer disclose this information to your agency? If so, when? Please produce all records¹¹ referring or relating to this disclosure.
6. What steps, if any, has your agency taken or will take to determine whether the “off-target” or incorrect proteins potentially produced by the Pfizer COVID-19 vaccine pose a safety risk to vaccinated individuals?
 - a. What are the sequences of the “off-target” or incorrect proteins?
 - b. Have toxicological studies been performed using these “off-target” or incorrect proteins?

⁹ CDC director stresses importance of updated COVID booster shot amid rising cases, ABC News, Sept. 13, 2023, <https://abcnews.go.com/US/cdc-director-stresses-importance-updated-covid-booster-shot/story?id=103152553> (emphasis added).

¹⁰ “Development and Licensure of Vaccines to Prevent COVID-19—Guidance for Industry,” Food and Drug Administration, Oct. 2023, <https://www.fda.gov/media/139638/download> at 2 (emphasis added).

¹¹ “Records” include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (e-mails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

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- c. Have your agencies, Pfizer or Moderna provided risk assessments related to “off-target” or incorrect proteins produced from the COVID-19 vaccines?
- d. Please provide all records relating to these analyses.

Thank you for attention to this matter.

Sincerely,



Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services