United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

March 23, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services

Dear Secretary Kennedy:

Based on my office's ongoing review of records from the Department of Health and Human Services ("HHS"), the Permanent Subcommittee on Investigations ("PSI" or "the Subcommittee") has uncovered evidence that appears to show yet another instance of the Biden administration's failure to take immediate action to warn the public about a serious COVID-19 vaccine adverse event.

On August 31, 2022, the Food and Drug Administration ("FDA") authorized the Pfizer-BioNTech COVID-19 bivalent booster.[1] By late October 2022, HHS reported that approximately 14.4 million people 12 years and older had received the booster.[2] In November 2022, federal health officials became aware of a statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster. An ischemic stroke occurs when a blood vessel supplying the brain becomes blocked, preventing blood and oxygen from reaching parts of the brain.[3] Despite the monthslong persistence of this safety signal in multiple vaccine safety surveillance systems, Biden's FDA and Centers for Disease Control and Prevention ("CDC") did not issue any formal health alerts, nor did they advise the public to avoid the vaccine. Instead, federal health officials continued to tell the public the vaccine was safe, but behind closed doors, they initiated multiple studies and statistical analyses—including a so-called "Stroke Project"—to investigate the validity of their assertion. These investigations continued through at least September 2025.

I am sharing my preliminary findings to provide HHS and the public with even more evidence of the Biden administration's unsupported and unyielding devotion to a harmful vaccine at the expense of the public's health. The information and the records discussed below belong in the public domain, but as noted throughout this letter, the full extent of HHS's awareness of the ischemic stroke safety signal remains incomplete and key records are still missing.[4]

---

[1] Morbidity and Mortality Weekly Report, Safety Monitoring of Bivalent COVID-19 mRNA Vaccine Booster Doses Among Persons Aged ≥12 Years — United States, August 31–October 23, 2022, Dep't of Health and Human Services, Nov. 4, 2022, https://pmc.ncbi.nlm.nih.gov/articles/PMC9639436/pdf/mm7144a3.pdf at 1.
[2] *Id.*
[3] U.S. Food & Drug Admin., Stroke, https://www.fda.gov/consumers/health-education-resources/stroke (last updated Jan. 31, 2024).
[4] The Subcommittee applied Bates stamps to the records cited in the letter that were produced by HHS.

I. Timeline: An Overview of the Detection of the Ischemic Stroke Safety Signal Connected to the Pfizer-BioNTech COVID-19 bivalent booster

Below is a brief timeline of events relevant to the detection and investigation of the ischemic stroke safety signal in individuals 65 years and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.

- **August 31, 2022** – FDA amended the emergency use authorization ("EUA") for the Pfizer-BioNTech COVID-19 vaccine to authorize the Pfizer-BioNTech COVID-19 bivalent booster.[5]

- **November 27, 2022** – The Vaccine Safety Datalink ("VSD"), which is run by the CDC and other health care participants, first detected a statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.[6]

- **December 4, 2022** – VSD monitoring detected a continued statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.[7]

- **December 11, 2022** – VSD monitoring again detected a statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.[8]

- **December 15, 2022** – CDC officials discussed the VSD signal for ischemic stroke flagging the "WH [White House] and HHS intense push to increase uptake of the booster" for people 65 years and older.[9]

- **December 18, 2022** – VSD monitoring continued to detect a statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.[10]

---

[5] U.S. Food & Drug Admin., *Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use*, (Sept. 1, 2022), archived at https://web.archive.org/web/20220901002611/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use.
[6] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[7] *Id.*
[8] *Id.*
[9] PSI-HHS-000007852286.
[10] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).

- **December 25, 2022** – VSD monitoring continued to identify a statistically significant safety signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech COVID-19 bivalent booster.[11]

- **December 28-29, 2022** – CDC officials reviewed reports of ischemic stroke after the bivalent mRNA COVID-19 vaccine and apparently found 53 cases in the Vaccine Adverse Event Reporting System ("VAERS").[12] Out of the 53 cases, CDC officials identified three deaths.[13]

- **January 1, 2023** – VSD monitoring again detected a statistically significant safety signal for ischemic stroke among individuals age 65 and older.[14]

- **January 6, 2023** – A senior CDC official identified 39 additional cases in VAERS of ischemic stroke following the bivalent mRNA COVID-19 injection.[15]

- **January 8, 2023** – VSD monitoring continued to detect the statistically significant safety signal for ischemic stroke among individuals age 65 and older.[16]

- **January 10, 2023** – A senior CDC official identified "an additional 22 reports of ischemic stroke" in VAERS following the bivalent mRNA COVID-19 injection.[17]

- **January 11, 2023** – Then-CDC Director Rochelle Walensky received a draft "communications plan" that apparently included edits from the Biden White House regarding CDC's and FDA's plan to release a position statement on the ischemic stroke safety signal.[18] Edits to a portion of the draft plan titled "Tough Questions and Answers" downplayed the intensity of the safety signal, changing a sentence that stated that the "signal is *moderately* elevated" to the "signal is *slightly* elevated."[19] It is unclear who provided this edit.

---

[11] *Id.*
[12] PSI-HHS-000000179305-07.
[13] PSI-HHS-000005399626.
[14] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[15] PSI-HHS-000000191856-57.
[16] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[17] PSI-HHS-000000191855-56.
[18] 000000338581.
[19] 000000338588. (emphasis added).

- **January 13, 2023** – FDA and CDC released a position statement acknowledging detection of the ischemic stroke safety signal while continuing to recommend that individuals over the age of 65 receive the Pfizer-BioNTech bivalent booster.[20]

- **January 15, 2023** – VSD monitoring again detected a statistically significant safety signal for ischemic stroke among individuals age 65 and older.[21]

- **January 24, 2023** – Pfizer submitted a confidential response to FDA which stated, "there is no evidence at this time that thromboembolic events, including ischemic stroke, are a safety signal or risk of Bivalent Comirnaty."[22]

- **January 25, 2023** – CDC officials discussed deaths and ischemic stroke reports in VAERS following COVID-19 bivalent vaccination.[23] According to the email, from August 31, 2022 to January 8, 2023, one CDC official identified 115 deaths. Of those, seven individuals suffered ischemic strokes.[24]

- **January 29, 2023** – VSD monitoring continued to detect the statistically significant safety signal for ischemic stroke among individuals age 65 and older.[25]

- **February 2023** – An empirical Bayesian ("EB") data mining analysis of VAERS data through February 2023 identified a statistically significant signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech bivalent booster.[26]

- **February 7, 2023** – According to an email between CDC officials, one senior official claimed to have identified a total of "226 STROKE cases" from August 31, 2022 to the present based on VAERS data.[27]

---

[20] U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older.
[21] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[22] PSI-HHS-000001393763.
[23] PSI-HHS-000005286666.
[24] *Id.*
[25] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[26] Email exchange between FDA and Commonwealth Informatics regarding Ischemic Stroke Data Mining Runs (Mar. 3 – Mar. 14, 2023) (PSI-HHS-000001154032-36).
[27] PSI-HHS-000005365003-04, 5374525-26.

- **February 8, 2023** – Lukos LLC, an HHS contractor, created a document that provided a status update on the "Stroke Project," which was initiated in response to the detection of the ischemic stroke safety signal.[28] The status update indicated that 67% of the 110 ischemic stroke case reviews had been completed at the time, and that those completed reviews were relied upon to support the January 13, 2023 position statement from FDA and CDC.[29]

- **February 17, 2023** – Following a February 13, 2023 Vaccine Safety Technical Work Group ("VaST") meeting, Lauri Markowitz, a CDC official who co-led the VaST, emailed members and attendees of the work group "draft minutes and report from the VaST call this week."[30] According to the meeting notes, members of the VaST received information about the ischemic stroke safety signal detected on VSD.[31] However, the notes stated that "VaST concluded," in part that, "the statistical signal among persons aged ≥ 65 years for ischemic stroke/TIA following bivalent Pfizer-BioNTech COVID-19 booster vaccination in VSD is based on limited data and has been attenuating over time. A signal has not been observed in two other active vaccine safety monitoring systems in the United States, nor in data from other countries."[32]

- **March 2023** – An EB data mining analysis of VAERS data through March 2023 identified a statistically significant signal for ischemic stroke among individuals age 65 and older following administration of the Pfizer-BioNTech bivalent booster.[33]

- **March 7, 2023** – FDA officials emailed summaries of VAERS reports on three "Notable US Deaths" following the Pfizer-BioNTech bivalent booster that occurred in January and February 2023.[34] The deaths included a 13-year-old female, a 61-year-old male, and another male whose age was unknown.[35] The summaries also included seven "Notable US Reports" including a "healthy 8 year old boy [who] was diagnosed with four occurrences of transient ischemic attacks" following the booster.[36]

---

[28] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (Feb. 8, 2023) (PSI-HHS-000000074043).
[29] *Id.*
[30] PSI-HHS-000001165454-55.
[31] PSI-HHS-000001165456-93.
[32] PSI-HHS-000001165459.
[33] Email exchange between FDA and Commonwealth Informatics regarding Ischemic Stroke Data Mining Runs (Mar. 3 – Mar. 14, 2023) (PSI-HHS-000001154032-36).
[34] PSI-HHS-000001537592-93.
[35] *Id.*
[36] PSI-HHS-000001537593-94.

- **March 27-April 4, 2023** – FDA officials continued to discuss the case of the "healthy 8 year old boy" who suffered the strokes following the booster and noted that the Sender's Comments in the VAERS report associated with this case indicated that "Based on the temporal relationship, the association between the event transient ischemic attack with BNT162B2, BNT162B2 OMI BA.4-5 [the Pfizer-BioNTech bivalent booster] **cannot be fully excluded**."[37]

- **April 4, 2023** – A CDC official identified "59 new ischemic stroke cases" following injection of the Pfizer-BioNTech bivalent booster.[38]

- **April 11, 2023** – HHS contractor Lukos LLC reported that the "Stroke Project" had been completed.[39]

- **May 9, 2023** – Lukos LLC reclassified the "Stroke Project" as an "ongoing project."[40]

- **May 24, 2023** – CDC official Dr. Tom Shimabukuro wrote to another CDC official, "We are continuing to monitor in VSD and assess the signal but most of the assessment we can do has been completed. The key point from VSD surveillance is that the data are insufficient to conclude that a safety problem exists for ischemic stroke following Pfizer bivalent vaccine or when the Pfizer bivalent vaccine is simultaneously administered with high-dose or adjuvanted flu vaccines in people ages 65 years or older, and that there may be other factors besides vaccination (e.g., unmeasured confounding) that contributed to the initial findings."[41]

- **June 6, 2023** – Lukos LLC reported again that the "Stroke Project" had been completed.[42] The results of the project are unknown.

- **July 24, 2023** – FDA officials circulated a quarterly surveillance report for the Pfizer-BioNTech COVID-19 bivalent booster which claimed, "The previously reported signal for ischemic stroke has resolved."[43]

---

[37] PSI-HHS-000001537590 (emphasis added); PSI-HHS-000001537588-92.
[38] PSI-HHS-000005355500-01.
[39] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (Apr. 11, 2023) (PSI-HHS-000000074035-36).
[40] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (May 9, 2023) (PSI-HHS-000000192191-92).
[41] 000000347174.
[42] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (June 6, 2023) (PSI-HHS-000002727766-67).
[43] PSI-HHS-000001187090-105 at PSI-HHS-000001187098.

- **April 25, 2024** – The Morbidity and Mortality Weekly Report ("MMWR"), published by CDC, stated that ongoing efforts to evaluate the ischemic stroke safety signal had not yet identified "clear and consistent evidence of a safety concern for ischemic stroke with bivalent mRNA COVID-19 vaccines."[44]

- **September 19, 2024** – The MMWR stated that "a follow-up VSD study is in progress to further assess the risk for ischemic stroke after mRNA vaccination."[45]

- **September 19, 2025** – A presentation from a CDC official acknowledged the VSD signal for ischemic stroke remained subject to further analysis, despite years of federal health officials deceptively touting the safety of the vaccine.[46]

II. The Biden Administration Failed to Issue a Formal Warning About the Ischemic Stroke Safety Signal, Continued to Promote the Vaccine

HHS records show that as early as October 2022, federal health officials identified a potential connection between the Pfizer-BioNTech COVID-19 bivalent booster and ischemic stroke for individuals over the age of 65.[47] However, after identifying the safety signal, federal health officials did not issue any formal warnings, such as a Health Alert Network ("HAN") message, about their findings, nor did they pause or modify their recommendations for the affected population. Instead, despite the repeated detection of a safety signal for ischemic stroke after their initial public statement, FDA and CDC continued to recommend that individuals over the age of 65 receive the bivalent booster.[48]

According to draft notes from an FDA Vaccines and Related Biological Products Advisory Committee meeting, on October 16, 2022 VSD first detected a signal for ischemic

---

[44] Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of an Additional Updated 2023–2024 COVID-19 Vaccine Dose for Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:377-381, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7316-H.pdf.

[45] Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of COVID-19 Vaccines for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024–2025. MMWR Morb Mortal Wkly Rep 2024;73:819–824, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7337-H.pdf.

[46] John Su, *Vaccine safety signal detection and evaluation* (slides presented at the Advisory Committee on Immunization Practices meeting, Sept. 19, 2025), https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/05-su-covid-508.pdf.

[47] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420); Food and Drug Administration, Draft notes from January 26, 2023 178th Vaccines and Related Biological Products Advisory Committee Meeting, Feb. 7. 2023, PSI-HHS-000002687342 (see 344).

[48] U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older; Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of an Additional Updated 2023–2024 COVID-19 Vaccine Dose for Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:377-381, at 377, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7316-H.pdf.

stroke among individuals aged 65 years or older following receipt of the Pfizer-BioNTech bivalent booster.[49] By November 2022, it appears that the signal had become statistically significant.[50] Specifically, ischemic strokes were observed to occur more frequently within the 1-21 day post-vaccination risk window than during the subsequent 22-42 day comparison period, and this pattern persisted across multiple weeks.[51] Although the exact moment when health officials discovered the statistically significant safety signal remains unclear, CDC touts that the VSD is used "to assess vaccine safety and detect adverse events in **near-real time**."[52]

Over the next two months, VSD continued to signal for ischemic stroke and federal officials were alerted to reports of deaths connected to ischemic stroke.[53] While health officials were monitoring the continued signal, records suggest that they were also cognizant of the potential effects it would have on the then-Biden White House and HHS's focus on ensuring older individuals received the booster.[54] A December 15, 2022 email, written by CDC official Michael Bell and edited earlier that day by Tom Shimabukuro, flagging the safety signal for ischemic stroke for other CDC officials stated, "[w]anting you to be aware given the **WH and HHS intense push to increase uptake of the booster** in [the 65 years and older] age group."[55]

In early January 2023, records show federal health officials were working on a communication plan for the ischemic stroke safety signal.[56] A draft version of the plan which appeared to include edits from the Biden White House, suggest a concerted effort to publicly downplay the intensity of the safety signal.[57] For example, edits to a portion of the draft plan titled "Tough Questions and Answers" downplayed the intensity of the safety signal, changing a sentence that stated that the "signal is *moderately* elevated" to the "signal is *slightly* elevated."[58] It is unclear who provided this edit.

Ultimately, CDC and FDA failed to alert the public of the risk until January 13, 2023, when they posted an informal notice on the FDA's website stating that a safety signal for ischemic stroke had been detected in adults aged 65 years and older following receipt of the Pfizer-BioNTech bivalent booster.[59] The FDA and CDC webpage stated that they would

---

[49] Food and Drug Administration, Draft notes from January 26, 2023 178th Vaccines and Related Biological Products Advisory Committee Meeting, Feb. 7. 2023, PSI-HHS-000002687342 (see 344).
[50] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[51] *Id.*
[52] Centers for Disease Control and Prevention, About the Vaccine Safety Datalink (VSD), (Sept. 12, 2025), https://www.cdc.gov/vaccine-safety-systems/vsd/index.html. (emphasis added).
[53] Tom T. Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420); PSI-HHS-000005399626.
[54] PSI-HHS-000007852286.
[55] *Id.*; PSI-HHS-000003977576 (emphasis added).
[56] 000000338588.
[57] *Id.*
[58] *Id*. (emphasis added).
[59] U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older.

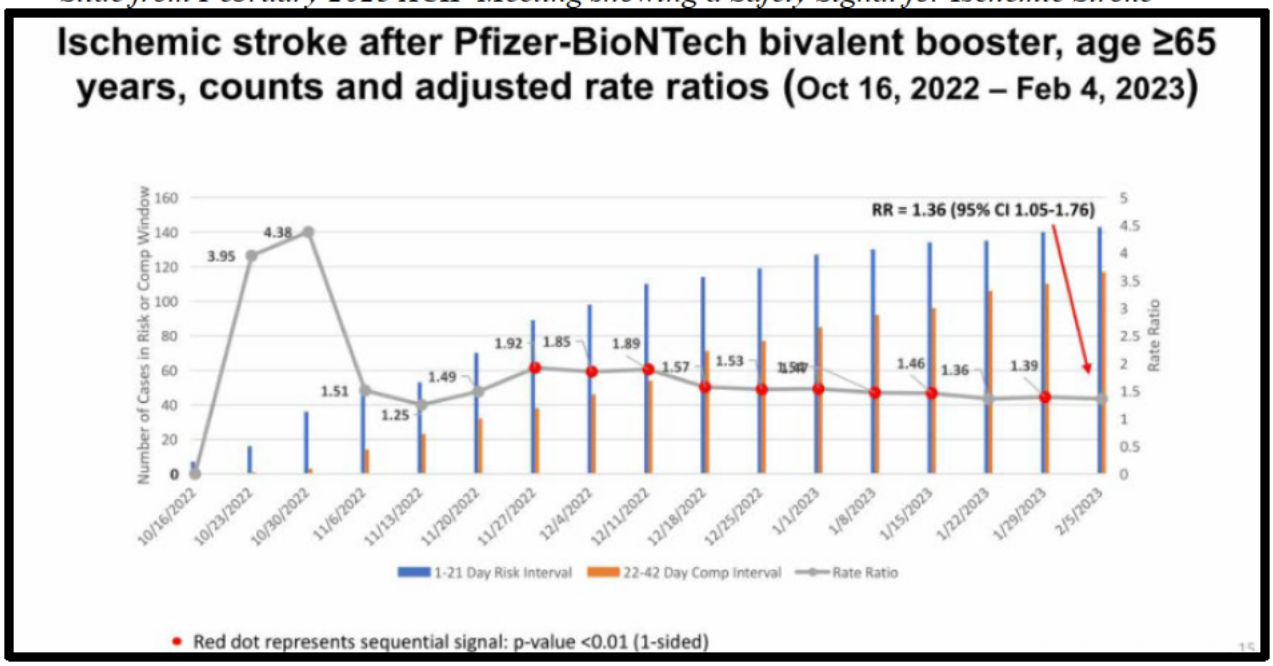
continue to evaluate additional data and monitor the risk.[60] Notably, however, federal health officials did not recommend any pause, age-specific precautions, or modification to existing vaccination recommendations for the population in which the signal had been identified.[61] In fact, federal health officials emphasized twice in bolded font on the website page that, "**no change is recommended in COVID-19 vaccination practice.**"[62]

Documents show that following CDC's and FDA's website posting about ischemic stroke on January 13, 2023, VSD continued to signal for ischemic stroke through at least the end of January.[63] Further, on January 25, 2023, twelve days after federal health officials downplayed the risks of the bivalent booster, records show that CDC officials were aware of seven reported deaths from ischemic stroke following the injection of the booster.[64] By February 7, 2023, the number of reported cases of stroke had risen to 226.[65] In late February 2023, CDC official Tom Shimabukuro presented the slide below at an Advisory Committee on Immunization Practices (ACIP) meeting, marking the statistically significant safety signals with a red dot on the chart.[66]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[60] *Id.*
[61] *Id.*
[62] *Id.* (emphasis in the original record). This was not the first instance when CDC and FDA decided to publish an informal website statement about a potential vaccine safety risk rather than issue a formal health alert, like the HAN. As detailed in the Permanent Subcommittee on Investigations' majority report, in May 2021, following months of reports of myocarditis after COVID-19 vaccination HHS officials decided against issuing a formal HAN and, instead, posted "clinical considerations" on CDC's website about the safety risk. See Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf.
[63] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).
[64] PSI-HHS-000005286666.
[65] PSI-HHS-000005365003-04, 5374525-26.
[66] Tom Shimabukuro, *COVID-19 mRNA Bivalent Booster Vaccine Safety* (slides presented at the Advisory Committee on Immunization Practices meeting, Feb. 22–24, 2023), https://www.cdc.gov/acip/downloads/slides-2023-02-22-24/COVID-02-Shimabukuro-508.pdf (PSI-HHS-000000042420).

Slide from February 2023 ACIP Meeting showing a Safety Signal for Ischemic Stroke[67]



Beginning the same month as Shimabukuro's presentation, a second surveillance system used by federal health officials to monitor adverse events, EB data mining, was also signaling for ischemic stroke.[68] However, despite the continued existence of a safety signal in two separate safety surveillance systems, after the initial January 2023 statement, it does not appear that CDC or FDA issued any further public warnings or statements about the potential risk of ischemic stroke. Federal health officials appeared to have continued identifying new reports of stroke following the bivalent vaccine through at least April 2023, including a "healthy 8 year old boy [who] was diagnosed with four occurrences of transient ischemic attacks" following the booster.[69]

III. Despite Vaccine Safety Assurances, HHS Privately Initiated Studies to Investigate Ischemic Stroke Safety Signal

Publicly, CDC and FDA officials downplayed the risk of ischemic stroke despite the safety signals in VSD.[70] However, behind closed doors, the relationship between ischemic stroke following vaccination of the Pfizer-BioNTech bivalent booster remained an open question. Despite federal health officials continuing to administer the Pfizer-BioNTech bivalent booster to a potentially vulnerable population, internal agency records show that substantive follow-up analyses were already underway and continued through at least September 2025.

---

[67] *Id.*

[68] Email exchange between FDA and Commonwealth Informatics regarding Ischemic Stroke Data Mining Runs (Mar. 3 – Mar. 14, 2023) (PSI-HHS-000001154032-36).

[69] *See* PSI-HHS-000001537593-94; PSI-HHS-000005355500-01.

[70] U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older.

a. The "Stroke Project"

According to a monthly status report generated on February 3, 2023 by Lukos LLC, an HHS contractor, one ongoing evaluation of the risk of ischemic stroke following the Pfizer vaccine was named the "Stroke Project."[71] This document noted that "110 cases [were] assigned in response to enhanced signal for ischemic stroke after Pfizer bivalent vaccine," and that a review of 67% of those cases had been completed.[72] The report suggested that the partially completed case reviews were relied upon to support a "joint FDA/CDC position statement."[73] It appears that this joint position statement may have been the January 13, 2023 statement posted online by FDA and CDC that made no changes to vaccine recommendations.[74]

An April 11, 2023 report from Lukos LLC stated that the "Stroke Project" had been completed, though the results remain unclear.[75] However, a subsequent status report issued on May 9, 2023 reversed that assessment, reclassifying the "Stroke Project" as an "ongoing project" and noted that "59 additional cases [were] assigned to prepare for ACIP meeting."[76] It appears that the final reference to the "Stroke Project" was in a June 6, 2023 monthly status report, which again described the project as "completed," with no new cases assigned.[77] Unfortunately, the Subcommittee has yet to receive many of the underlying documents linked to the "Stroke Project."

b. EB Data Mining Analyses

i. Background

In January 2021, one month after the FDA issued EUAs for the Pfizer-BioNTech and Moderna COVID-19 vaccines, the FDA and CDC published a Standard Operating Procedure ("SOP") document describing how the agencies will perform VAERS surveillance analyses to identify safety concerns for the COVID-19 vaccines.[78] One of the analyses the FDA and CDC

---

[71] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (Feb. 8, 2023) (PSI-HHS-000000074043).
[72] *Id.*
[73] *Id.*; U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older.
[74] *Id.*; U.S. Food & Drug Admin., CDC and FDA Identify Preliminary COVID-19 Vaccine Safety Signal in Persons Aged 65 Years and Older (Jan. 13, 2023), https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cdc-and-fda-identify-preliminary-covid-19-vaccine-safety-signal-persons-aged-65-years-and-older.
[75] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (Apr. 11, 2023) (PSI-HHS-000000074035-36).
[76] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (May 9, 2023) (PSI-HHS-000000192191-92).
[77] Lukos LLC, *Monthly Status Report: Supporting Vaccine Adverse Event Reporting, Clinical Immunization Safety Assessments, and the V-Safe Pregnancy Registry* (June 6, 2023) (PSI-HHS-00000272776-67).
[78] The FDA issued the EUA for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020. Moderna received the EUA for its vaccine on December 18, 2020. COVID-19 Timeline, Centers for Disease Control and Prevention, https://www.cdc.gov/museum/timeline/covid19.html; Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://web.archive.org/web/20210319091240/https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

utilized was EB data mining, a "statistical method for identifying disproportionality (excess of reported [adverse events] for [a] product relative to other products) in large database[s]."[79] FDA oversaw the data mining which was conducted through software developed by Oracle called Empirica.[80] Records show that FDA's threshold for determining a statistically significant safety signal was when the lower bound of the reporting estimate (EB05) exceeded 2.0.[81]

ii. Federal Health Officials Acknowledge EB Data Mining Limitations

Although federal health officials publicly touted the strength of EB data mining as "a more robust technique" for analyzing VAERS reports, the Subcommittee uncovered internal CDC and FDA communications discussing its significant limitations.[82] Privately, federal health officials discussed how EB data mining may not detect safety signals in the vaccines due to a statistical phenomenon called "masking." According to a 2022 article published in the journal *Drug Safety*, masking can occur when "signals for a vaccine of interest are hidden by the presence of other reported vaccines. This masking effect may in turn limit or delay our understanding of the risks associated with new and established vaccines."[83]

Essentially, if the baseline data used by federal health agencies for determining the statistical significance of a safety signal combines the signals of other COVID-19 vaccines, that baseline data will drown out or mask the signals of any single COVID-19 vaccine. To help explain the effects of masking in layman's terms, consider this hypothetical: If 100,000 deaths were reported for Moderna's vaccine, 100,000 deaths were reported for Pfizer's vaccine, and 10,000 deaths were reported for all other vaccines, Moderna's 100,000 deaths may not look significant compared to an inflated baseline of 110,000 deaths that is made up of 100,000 Pfizer deaths combined with the 10,000 deaths from all other vaccines.

---

[79] *Id.* at 16-17. *See also* PSICOVID_00004416; FOIA production: https://www.fda.gov/media/184988/download?attachment at 22.

[80] Letter from Jeff Reezek, Centers for Disease Control and Prevention to Sen. Ron Johnson, Permanent Subcomm. on Investigations, Mar. 14, 2023 (on file with Subcomm.); PSICOVID_00004417; FOIA production: https://www.fda.gov/media/184988/download?attachment at 23.

[81] PSICOVID_00004422; FOIA production: https://www.fda.gov/media/184988/download?attachment at 23. Although FDA officials used 2.0 as their threshold for a statistically significant signal, an FDA official's April 5, 2021 PowerPoint presentation before the Advisory Committee on Immunization Practices appeared to recognize that, "Technically, any [Empirical Bayesian Geometric Mean] value above one indicates disproportional reporting." See PSICOVID_00008744; https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-Supporting-Documents-Failure-to-Warn-Part-08.pdf at 47. As medical researcher Dr. David Wiseman wrote in his September 2025 Preprint article, because health officials used the higher threshold of 2.0, as opposed to 1.0 which would "technically" indicate a signal, "[s]ignals were filtered out by an inappropriately high detection threshold." David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro at 3.

[82] Letter from Rochelle Walensky, Dir., Centers for Disease Control and Prevention to Sen. Ron Johnson, Permanent Subcomm. on Investigations, Sept. 2, 2022 (on file with Subcomm.). See e.g., PSI-HHS-000008268909; PSI-HHS-000008251531; PSI-HHS-000005235281.

[83] Rave Harpaz et al., Signaling COVID-19 Vaccine Adverse Events, Drug Safety (2022), https://link.springer.com/article/10.1007/s40264-022-01186-z.

In this hypothetical, EB data mining would not detect a statistically significant safety signal because the true rate of deaths was masked for one product when compared to a baseline that is inflated by the inclusion of deaths from one or more products with similarly high death rates.

Another simplified way to hypothetically explain the effects of masking would be to test the adverse events of hemlock by comparing them to the adverse events of arsenic. Both may be equally dangerous when each is compared separately against a non-toxic substance such as saline. But, if the effects of hemlock were compared against a baseline that combines the data for the effects of arsenic and saline, the adverse events of hemlock may not result in a significant signal because they have been drowned out or masked by the baseline data which includes the toxic effects of arsenic.

According to a September 2025 preprint article, medical researcher David Wiseman identified several limitations with EB data mining, including masking, that resulted in an underestimation of COVID-19 vaccine adverse events.[84] Wiseman pointed out "FDA's analysis neglected to correct for masking, where signals for one vaccine are concealed by signals from other vaccines."[85] Indeed, documents obtained by the Subcommittee reveal that the officials responsible for monitoring the safety surveillance systems were well aware of the masking problem but apparently failed to "correct" the issue.[86]

For example, in September 2021, FDA official David Menschik raised concerns about masking in an email to CDC official John Su as they discussed whether to include language about EB data mining limitations in an article on the safety of mRNA vaccines.[87] In the email, Menschik proposed that the manuscript include the following language:

> EB data mining has multiple limitations including that an absence of a disproportionality alert does not rule out presence of a safety problem. Additionally, since most reports received during this surveillance period involved COVID-19 vaccines, disproportionately scores (which are adjusted by year to control for time-dependent, potentially confounding, exposure and outcome variables) can be muted by COVID-19 vaccine reports contributing substantially to the comparator group, particularly if both mRNA COVID-19 vaccines are associated with the same adverse event.[88]

Menschik added that he wanted to share this language with Su, who led CDC's VAERS

---

[84] David Wiseman, Signal loss by truancy, masking, and filtering, and underestimation of potential risks and suspected adverse reactions in the Disproportionality Signal Analyses of VAERS data associated with COVID-19 pro-vaccines, ResearchGate, Sept. 2025, https://www.researchgate.net/publication/395382959_Signal_loss_by_truancy_masking_and_filtering_and_underestimation_of_potential_risks_and_suspected_adverse_reactions_in_the_Disproportionality_Signal_Analyses_of_VAERS_data_associated_with_COVID-19_pro.
[85] *Id.* at 3.
[86] *Id.*
[87] PSI-HHS-000008268909; See also PSI-HHS-000008253123, PSI-HHS-000008255441-78.
[88] *Id.*

team, "especially if folks on your end may be placing excess value on data mining alerts (EB05>2) or the absence of specific data mining alerts."[89] In response, Su acknowledged generally that "[s]ignal detection with VAERS data has always been tricky business" and that "[t]hose of us who work with VAERS data frequently are mindful of those limitations," referring to CDC's review of EB data mining.[90]

Based on records uncovered by the Subcommittee, it appears that the limitations of EB data mining confounded other senior CDC officials. For example, documents show that one of the most senior CDC officials working on the COVID-19 vaccine safety team, Tom Shimabukuro, was "perplexed" with the results of the EB data mining analyses.[91] Specifically, in June 2021, as CDC and FDA received increasing reports of myocarditis following mRNA vaccination, the weekly EB data mining reports were apparently not alerting for that adverse event.[92] Shimabukuro wrote to another CDC colleague, "I'm perplexed that myocarditis isn't

---

[89] *Id.*; PSI-HHS-000000302938. The Subcommittee has uncovered several emails regarding the evolution of this excerpt in the manuscript. According to the documents, CDC officials provided edits to FDA officials' proposed language. Eventually, both FDA and CDC officials agreed on the language that appeared in the preprint versions of the article (there are two preprint versions, one dated Oct. 27, 2021, and one dated Oct. 28, 2021). The language in both preprint versions stated:

> "EB data mining has multiple limitations, including that the absence of a disproportionality alert for an event does not rule out a possible corresponding adverse event. A new concern with disproportionality scores, which are adjusted by year to control for time-dependent confounders, is that during the study period most VAERS reports were for COVID-19 vaccinations. As all VAERS reports are used for vaccine-event comparisons in EB data mining, potential associations with mRNA COVID-19 vaccines plausibly could be missed."
>
> See Hannah Rosenblum, et al., Safety Monitoring of mRNA Vaccines Administered During the Initial 6 Months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe, MedRxiv, Oct. 27, 2021, https://www.medrxiv.org/content/10.1101/2021.10.26.21265261v1.full.pdf at 13; Hannah Rosenblum, et al., Safety Monitoring of mRNA Vaccines Administered During the Initial 6 Months of the U.S. COVID-19 Vaccination Program: Reports to Vaccine Adverse Events Reporting System (VAERS) and v-safe, MedRxiv, Oct. 28, 2021, https://www.medrxiv.org/content/10.1101/2021.10.26.21265261v2.full.pdf at 13.

In late Nov. 2021, after the manuscript was sent to the *Lancet* to be considered for the journal, records show that unnamed reviewers for the journal suggested that the authors remove the reference to the EB data mining analysis. In Dec. 2021, the FDA officials that worked on the EB data mining language for the preprint versions of the article agreed to remove the language. Those individuals also recommended that they no longer be listed as authors of the paper because the EB data mining language "was the only aspect of this paper that FDA was involved in[.]" The final version of the paper appeared in the *Lancet* in March 2022 without the reference to EB data mining limitations.

See PSI-HHS-4053406; PSI-HHS-000008261872; PSI-HHS-000008254730; PSI-HHS-000008254738; PSI-HHS-0000040573; PSI-HHS-0000054935; Hannah Rosenblum et al., Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe, The Lancet, https://pmc.ncbi.nlm.nih.gov/articles/PMC8901181/.

[90] PSI-HHS-000008268909.

[91] PSI-HHS-000008251531-32.

[92] *Id.*; In another June 2021 email, Shimabukuro referenced results of EB data mining and wrote to his CDC colleagues, "This stuff is kind of like a foreign language to me. I get it conceptually, but I can't explain the

alerting for either of the mRNA vaccines. I'm wondering if it's getting washout out [sic] in the half million reports."[93]

June 2021 email – CDC officials discuss EB data mining limitation in detecting myocarditis[94]

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[redacted]
Sent: Tuesday, June 22, 2021 12:08 PM
To: Destefano, Frank (CDC/DDID/NCEZID/DHQP) <[redacted]>
Subject: FW: Weekly data mining

I'm perplexed that myocarditis isn't alerting for either of the mRNA vaccines. I'm wondering if it's getting washout out in the half million reports.

Shimabukuro's reference to the absence of a myocarditis alert as a result of "washout" in the half million reports purportedly filed in VAERS, appears to indicate that the lack of the safety signal could have been a result of the "masking" phenomenon.

In September 2021, Menschik described yet another limitation of EB data mining to his colleagues at CDC and FDA. In that email, Menschik appeared to acknowledge that as a result of masking, the threshold for an alert may be too high which could further inhibit detection of a safety signal. Menschik wrote:

> [I]f the comparison group is enriched with so many mRNA COVID-vaccine reports, tha[n] **it becomes very difficult to exceed the EB05>2 alert threshold for an adverse event that may be associated with mRNA vaccines – thus data mining has blind spots** and this is why it's so good to have so many complimentary vaccine safety surveillance systems (e.g., VSD) that can cover different blind spots of other systems…[95]

Even though HHS officials appeared to acknowledge the limitation of their safety surveillance, it remains unclear what, if any, steps those individuals took to address the problems that were hindering their vaccine safety data analyses.

iii. Statistically Significant Signal for Ischemic Stroke Appears Despite Data Limitations

Despite the limitations in EB data mining that obscured actual vaccine safety signals, the signal for ischemic stroke was so prevalent that it apparently overcame these statistical limitations.

---

mathematical details." PSI-HHS-000000693989-90; *See also* Chairman Ron Johnson, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, Permanent Subcomm. on Investigations, May 21, 2025, https://www.hsgac.senate.gov/wp-content/uploads/2025.05.21-PSI-Majority-Staff-Interim-Report-Failure-to-Warn.pdf.

[93] PSI-HHS-000008251531.

[94] *Id.*

[95] PSI-HHS-000008251647 (emphasis added).

In March 2023, another HHS contractor, Commonwealth Informatics, Inc., conducted two data mining runs using FDA's Empirica system to further evaluate whether reports of ischemic stroke were occurring more frequently than expected.[96] The first data mining run that included VAERS data through February 2023 showed that reports of ischemic stroke in individuals 65 years and older following injection of the Pfizer-BioNTech bivalent booster met the FDA's empirical Bayesian threshold for a statistically significant safety signal.[97] The second data mining run that included VAERS data through March 2023 appears to have confirmed the first run and also returned a statistically significant safety signal.[98] Despite these findings, HHS made no changes to booster recommendations during this period.

c. Other Ongoing Evaluations of Ischemic Stroke and the COVID-19 Vaccine

Even after the reported completion of the "Stroke Project" in April 2023, subsequent agency publications indicated that evaluation of the ischemic stroke safety signal continued. The Morbidity and Mortality Weekly Report ("MMWR") published over a year later, on April 25, 2024, noted that "[o]ngoing efforts to evaluate the [ischemic stroke] signal have not identified any clear and consistent evidence of a safety concern for ischemic stroke with bivalent mRNA COVID-19 vaccines."[99] A subsequent MMWR published in September 2024 further stated that "a follow-up Vaccine Safety Datalink study is in progress to further assess the risk for ischemic stroke after mRNA vaccination."[100] According to a September 19, 2025 presentation by CDC official John Su, the VSD signal was subject to "self-controlled case-series ("SCCS") analysis."[101] An SCCS examines whether the introduction of an external factor, such as a vaccine, is associated with an increased risk of a given adverse event compared to a person's baseline risk.[102] However, it is unclear whether this SCCS analysis was ever publicly released while booster recommendations continued.

IV. Outstanding Record Requests

Taken together, the records described above reflect an extended period in which federal health officials continued to evaluate a statistically significant ischemic stroke safety signal while

---

[96] Email exchange between FDA and Commonwealth Informatics regarding Ischemic Stroke Data Mining Runs (Mar. 3 – Mar. 14, 2023) (PSI-HHS-000001154032-36).
[97] *Id.* at PSI-HHS-000001154036.
[98] *Id.*
[99] Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of an Additional Updated 2023–2024 COVID-19 Vaccine Dose for Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. MMWR Morb Mortal Wkly Rep 2024;73:377-381, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7316-H.pdf.
[100] Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of COVID-19 Vaccines for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024–2025. MMWR Morb Mortal Wkly Rep 2024;73:819–824, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7337-H.pdf.
[101] John Su, *Vaccine safety signal detection and evaluation* (slides presented at the Advisory Committee on Immunization Practices meeting, (Sept. 19, 2025), https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/05-su-covid-508.pdf.
[102] Igor Rudan et al., Selecting the Most Informative Positive and Negative Controls for Self-Controlled Case Series (SCCS): Rationale, Approach, and Lessons from Studies Investigating the Safety of COVID-19 Vaccines, 14 J. Glob. Health 03037 (Aug. 6, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11301617/.

leaving booster recommendations for adults aged 65 years and older wholly unchanged. From the initial detection of the safety signal in late 2022, through contractor-led case review, VAERS data-mining analyses, and follow-up VSD studies referenced in MMWR publications through at least September 2024, health officials continued to say the vaccine was safe while simultaneously searching for evidence to support that assertion.[103]

In order to better understand why federal health officials continued to recommend the Pfizer-BioNTech bivalent booster before completing their review of the risk of ischemic stroke, please provide the following records:

1. All communications referring or relating to the decision to inform the public about the ischemic stroke safety signal between November 2022 and January 13, 2023.

2. All records[104] referring or relating to the "Stroke Project" referenced in the April 11, 2023 Lukos LLC report.

3. All records referring or relating to the Vaccine Safety Datalink study referenced in the September 2024 MMWR, including but not limited to all records referring or relating to the self-controlled case-series analysis on ischemic stroke.

4. All records referring or relating to EB data mining or analyses concerning the ischemic stroke safety signal associated with the Pfizer-BioNTech bivalent COVID-19 booster, including, but not limited to, all data mining runs conducted using FDA's Empirica system.

I also request that you make Dr. David Menschik, Dr. Tom Shimabukuro, and Dr. John Su available for an interview with the Subcommittee. Please produce this information as soon as possible, but no later than April 6, 2026. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Chairman
Permanent Subcommittee on Investigations

[103] Panagiotakopoulos L, Moulia DL, Godfrey M, et al. Use of COVID-19 Vaccines for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024–2025. MMWR Morb Mortal Wkly Rep 2024;73:819–824, https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7337-H.pdf.
[104] "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (such as texts, emails, 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).

cc: The Honorable Richard Blumenthal
Ranking Member
Permanent Subcommittee on Investigations

The Honorable Marty Makary
Commissioner
Food and Drug Administration

The Honorable Jay Bhattacharya
Acting Director
Centers for Disease Control and Prevention

Dr. Vinay Prasad
Director
Center for Biologics Evaluation and Research

Dr. Tracey Beth Høeg
Acting Director
Center for Drug Evaluation and Research