

Exhibit 1



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CDC FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL

October 26, 2023

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333

Re: *Records Regarding Ischemic Stroke Safety Signal (IR#1036B)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network (“ICAN”). On behalf of ICAN, we submit this FOIA request to the Centers for Disease Control and Prevention (“CDC”):

I. The Request

Please provide the following records to foia@sirillp.com in electronic form:

All records, including communications,¹ regarding the recently identified safety signal for ischemic stroke in people ages 65 and older who received the Bivalent Pfizer-BioNTech COVID-19 Vaccine,² from December 1, 2022 to the date of search.

II. Expedited Processing Request

We ask that you provide expedited processing for this request. The information requested concerns matters of urgent public concern. ICAN’s request for expedited processing should be granted because it qualifies under the “compelling need” analysis, as defined by FOIA. FOIA provides for “expedited processing of requests for records” upon a showing of a “compelling need.” 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a “compelling need” when it is “primarily engaged in disseminating information,” and there is an “urgency to inform the public concerning

¹ Including email attachments.

² <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>; see also <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/bivalent-boosters.html>.

actual or alleged Federal Government activity.” 5 U.S.C. § 552(a)(6)(E)(v)(II). This request demonstrates both requirements below:

1. The requester is primarily engaged in disseminating information

ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Attachment A.**) In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN’s popular website³ hosts the organization’s largest education program, The HighWire with Del Bigtree.⁴ Utilizing its media teams’ 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 158,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 71,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers. The size of ICAN’s audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN’s mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts and their impact on civil rights.

2. There is an urgency to inform the public concerning actual or alleged Federal Government activity

In determining whether there is an “urgency to inform,” and hence a “compelling need,” courts must consider at least three factors: (i) whether the request concerns a matter of current exigency to the American public; (ii) whether the consequences of delaying a response would compromise a significant recognized interest; and (iii) whether the request concerns federal government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of ICAN’s FOIA request.

(i) ICAN’s request concerns a matter of current exigency to the American public

First, ICAN’s request concerns a matter of current exigency to the American public because Americans are currently faced with vaccine mandates imposed upon federal government

³ <https://www.icandecide.org/>

⁴ <https://thehighwire.com/>

civilians,⁵ healthcare workers,⁶ post-secondary students,⁷ and state employees.⁸ Additionally, CDC added COVID-19 vaccines to the routine childhood immunization schedule,⁹ which opens the door for states or organizations to make access to certain services, such as public school, day care, and pediatric visits, contingent upon a child’s COVID-19 vaccination status. The records requested by ICAN will significantly contribute to the public’s understanding of the potential risks associated with the COVID-19 vaccines, which is paramount to the fundamental right of informed consent.¹⁰ It is critical for decisionmakers to have access to all available safety data when considering establishment of a mandate, and it is equally important for the public to have access to the data in order to make an informed decision regarding mandate compliance.

Second, even without vaccine mandates, based on the recommendations of federal public health agencies, all Americans six months of age and older are recommended to “*stay up to date* with COVID-19 vaccines of their age group”¹¹ (emphasis added). For example, CDC recommends children from 6 months to 4 years of age to receive 3 doses of the Pfizer-BioNTech COVID-19 vaccine.¹² For children ages 5 to 17 years old, CDC recommends 2 doses of the Pfizer-BioNTech COVID-19 vaccine, and COVID-19 booster shots “at least 2 months after 2nd dose or last booster.” Similar, recommendations apply for Moderna’s COVID-19 vaccine. For people 18 years or older, CDC recommends 2 doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccine, and an updated booster “at least 2 months after 2nd primary series dose or last booster.” CDC also states that people are “Up to Date” “immediately after you have received the most recent booster recommended for you.”¹³ The broad application and frequency at which federal health agencies

⁵ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/>

⁶ <https://www.cms.gov/files/document/qs0-23-02-all.pdf>

⁷ <https://policy.usc.edu/covid-19-vaccination-program/>; <https://www.colorado.edu/covid-19-updates/covid-19-vaccination>; <https://covid.uconn.edu/campus-info/vaccinations/>; <https://www.georgetown.edu/coronavirus/covid-19-vaccines/>; <https://www.northwestern.edu/coronavirus-covid-19-updates/resources/frequently-asked-questions/vaccination-requirement-faqs.html>; <https://covid.nd.edu/vaccination/student-vaccination-requirement/>; <https://hr.tulane.edu/content/covid-19-vaccination-policy>; <https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs#gsc.tab=0>; <https://www.washington.edu/coronavirus/vaccination-requirement/>; <https://coronavirus.rutgers.edu/covid-19-vaccine/>; <https://covid19.columbia.edu/vaccine-info>; <https://health.uoregon.edu/immunization-requirements>; <https://healthy.brown.edu/vaccinations>

⁸ <https://www.governor.wa.gov/VaccineMandateFAQ>; <https://www.mass.gov/news/baker-polito-administration-announces-covid-19-vaccine-requirement-for-executive-department-employees>

⁹ <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>

¹⁰ For example, notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a “recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.” Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, “informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . .” 10NYCRR § 405.7 (b)(9).

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

¹² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#children>.

¹³ *Id.*

are recommending Americans to receive COVID-19 vaccines demands immediate transparency regarding any information concerning their safety and efficacy.

Third, transparency regarding the ongoing efficacy and safety studies of the COVID-19 vaccines are essential for restoring trust and confidence in public health agencies. For example, there remains much debate to whether these vaccines offer better protection than natural immunity, as well as whether the safety risks associated with taking the vaccines are worth the level of protection federal health agencies claim they provide.¹⁴ These debates are amplified in situations where vaccine mandates exist, and public and private institutions, including the U.S. Military under the Biden Administration, refused to grant vaccine exemptions to people who could prove they've acquired natural immunity.¹⁵ Americans diminishing confidence in federal health agencies was further embodied when CDC recently admitted its COVID response was a failure¹⁶ and conducted an internal review and reorganization as a result.¹⁷ This *mea culpa* may potentially improve the agency's response to a future pandemic or other emergency, but public trust ultimately determines the effectiveness of government agency programs. A perfectly organized and efficient organization is of no value if the public does not trust it enough to adhere to its recommendations or instructions. Therefore, immediate transparency is critical to restoring the public's trust and confidence in public health institutions.

Lastly, the immediate disclosure of all aspects of the COVID-19 vaccines development, safety and efficacy, licensure, recommendations, distribution, and administration are essential to current and future investigations into the adequacy and legitimacy of the government's response to the COVID-19 pandemic. For example, a grand jury investigation has been launched by Florida Governor Ron DeSantis in order to fully and thoroughly assess "any and all wrongdoing" involved in the creation of the vaccines and any long-term harms that could have potentially been caused by their use.¹⁸ Immediate access to all available data regarding the COVID-19 vaccines is critical to the success of these investigations, and the establishment of remedies created as a result of the investigations may assist in the restoration of public trust in government agencies.

Additionally, at the federal level congressional hearings are currently underway to review the government's COVID-19 pandemic response. At the first hearing, "Republicans accused top Biden administration officials of using faulty science and poor judgement to mandate vaccinations for federal workers...something they said has broken public trust in health officials."¹⁹ Congress is also investigating "whether COVID-19 originated from a lab in Wuhan, China and the Chinese Communist Party covered it up, as well as whether U.S. taxpayer dollars were being sent to the

¹⁴ <https://www.sirillp.com/wp-content/uploads/2023/03/Reply-to-CDC-Re-Natural-Immunity-v-Vaccine-Immunity-4-a6726108455fa82fed8dc9f7f2340b17.pdf>

¹⁵ See e.g. <https://www.military.com/daily-news/2021/09/29/us-troops-go-court-seeking-vaccine-exemption-those-who-had-covid-19.html>.

¹⁶ <https://www.politico.com/news/2022/08/17/cdc-agency-overhaul-covid-19-response-00052384>

¹⁷ <https://www.cdc.gov/about/organization/cdc-moving-forward-summary-report.html>

¹⁸ <https://www.newsweek.com/florida-governor-ron-desantis-criticizes-cdc-over-covid-19-vaccines-1766871>

¹⁹ <https://www.nbcnews.com/politics/congress/house-republicans-take-first-swat-bidens-covid-response-rcna69706>

lab”.²⁰ It is essential that both the public and congressional delegates have access to the safety and monitoring data for the COVID-19 vaccines in order for congressional delegates to meaningfully and accurately assess whether the government’s policies and regulations regarding vaccines and economic restrictions were scientifically justified, as well as to address the public’s safety concerns. Delays in the disclosure of the requested information will negatively impact the reliability of the congressional investigations and the public’s trust in their findings.

For these reasons, ICAN has demonstrated that its request significantly concerns matters of current exigency to the American public. Therefore, the first factor in FOIA’s “compelling need” analysis weighs heavily in favor of granting expedited processing.

(ii) Consequences of delaying a response would compromise significant recognized interests

The American public has a significant recognized interest in informed consent.²¹ Understanding the ongoing studies for the COVID-19 vaccines is a key component of informed consent because it provides consumers insight into the thoroughness of the manufacturers’ data supporting the reported safety and effectiveness. The manufacturers are protected from liability by the Public Readiness and Emergency Preparedness (PREP) Act²², and without the threat of liability for harms caused by products, manufacturers have less incentives to prioritize greater investment into product safety.²³ Therefore, the public must have access to all available safety data in order to fully assess the risks involved in using the vaccines. Delaying a response to ICAN’s request would compromise Americans’ significant recognized interest in informed consent for medical procedures that are recommended, and in the case of COVID-19 vaccines, mandated by the government.

American taxpayers also have a significant recognized interest in the safety data for COVID-19 vaccines, because compensation for COVID-19 vaccine-related injuries and deaths are funded by the Countermeasures Injury Compensation Program (CICP).²⁴ Unlike the compensation provided under the Vaccine Injury Compensation Program (VICP), the burden on taxpayers is not relieved by an excise tax on each vaccine administered; instead, under CICP, the American taxpayers are directly responsible for compensation for those who suffer vaccine-related injuries or deaths via emergency appropriations to the Covered Countermeasures Process Fund.²⁵ Therefore, the American taxpayer has a significant recognized interest in understanding the safety of the COVID-19 vaccines.

²⁰ <https://www.cbsnews.com/news/biden-releases-records-to-gop-led-panel-probing-covid-wuhan-lab-leak-theory/>

²¹ See footnote 8 for examples of informed consent codified.

²² <https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf#:~:text=Public%20Readiness%20and%20Emergency%20Preparedness%20Act%20%28PREP%20Act%29,Declaration%20is%20subject%20to%20amendment%20as%20circumstances%20warrant.>

²³ See generally Restat 3d of Torts: Products Liability, §2.

²⁴ <https://www.hrsa.gov/cicp>

²⁵ <https://crsreports.congress.gov/product/pdf/LSB/LSB10584>.

Moreover, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.²⁶ With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.²⁷ Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

Lastly, as discussed in the prior section, several investigations have been initiated by political leaders into the origin of, and governmental response to COVID-19. Because the findings of these investigations will evaluate the responses of both the Trump and Biden Administrations, as well as top agency personnel, these investigations could have major political ramifications on future elections. As Americans prepare for the 2024 Presidential elections, voters have a significant recognized interest in obtaining the information necessary to guide their decisions behind their democratic involvement. Therefore, it is essential that the public and investigators have access to all the relevant materials regarding the safety of the COVID-19 vaccines, and the related policies and regulations that were imposed based on the assertion they were safe and effective.

For the reasons set forth above, ICAN has demonstrated that delaying a response to its request would compromise significant recognized interests. Thus, the second factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

(iii) ICAN's request concerns federal government activity

ICAN's request concerns federal government activity because the information requested is directly linked to scientific conclusion federal health agencies made regarding the safety of the COVID-19 vaccine booster. As previously described, CDC recommends that everyone over 6 months of age receive an updated (bivalent) booster²⁸, and both CDC and FDA actively promote and effectively advertise the COVID-19 vaccines on social media.²⁹ The propagation of this messaging is further exemplified by the Biden administration's messaging campaign to increase the public's interest in receiving COVID-19 boosters by hosting "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour."³⁰ Therefore, the requested information will assist the public, and the scientific community in evaluating the

²⁶ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

²⁷ *Id.*

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>

²⁹ <https://twitter.com/CDCgov/status/1628484834614976515>;
https://twitter.com/US_FDA/status/1589664190565945345

³⁰ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

appropriateness of these recommendations and outreach efforts carried out by the federal government.

For the reasons set forth above, ICAN has demonstrated that the request concerns federal government activity. Thus, the third and final factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

ICAN has demonstrated (i) the request concerns a matter of current exigency to the American public, (ii) the consequences of delaying a response would compromise a significant recognized interest, and (iii) the request concerns federal government activity. Therefore, ICAN has reasonably established under FOIA a "compelling need" for the expedited processing of its request. 5 U.S.C. § 552(a)(6)(E)(v)(II).

III. Fee Waiver Request

We also ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). As stated above,³¹ ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Attachment B.**) As part of its mission, ICAN actively investigates and disseminates information regarding vaccine safety issues for free, including through its website, a weekly health news and talk show, and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

IV. Estimated Date of Completion Request

Pursuant 5 U.S.C. § 552 (a)(7)(B)(ii), we specifically request that the FDA provide us with an estimated date of completion for this request. The estimated completion date can be emailed foia@sirillp.com when it has been determined.

V. Conclusion

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe

³¹ See page 3.

any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.

Colin M. Farnsworth, Esq.

Marc A. Dudley, Esq.

Attachment A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF HAYS

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022


Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed
said Catharine Layton sign the above statement this 3 day of May, 2022
(month)

Notary Public for 

