

March 6, 2026

VIA EMAIL AND FEDEX

The Honorable Robert F. Kennedy Jr.
Secretary, U.S. Department of Health and
Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
[REDACTED]

The Honorable Martin Makary, MD, MPH
Commissioner, Food and Drug
Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
[REDACTED]

The Honorable Jayanta Bhattacharya, MD, PhD
Director, National Institutes of Health
Acting Director, Centers for Disease Control
and Prevention
9000 Rockville Pike
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[REDACTED]

Re: Recommendations for Task Force for Safer Childhood Vaccines, 42 U.S.C. § 300cc-27

Dear Secretary Kennedy, Dr. Makary, and Dr. Bhattacharya:

I hope this letter finds you all well. We write on behalf of the Informed Consent Action Network (“ICAN”) regarding recommendations for the recently revived Task Force for Safer Childhood Vaccines (“Task Force”).¹

The National Childhood Vaccine Injury Act of 1986 (the “1986 Act”), in section 42 U.S.C. § 300aa-27, titled “Mandate for safer childhood vaccines” (the “Mandate”), requires that “Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.” 42 U.S.C. § 300aa-27(b)(1).

The Mandate requires that “the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).” 42 U.S.C. § 300aa-27(b)(3). In turn, “subsection (a)” provides that:

the Secretary shall—

¹ See <https://www.hhs.gov/press-room/hhs-reinstates-task-force-on-safer-childhood-vaccines.html>.

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

42 U.S.C. § 300aa-27(a).

After ICAN's near-decade-long advocacy and litigation, including regarding the Task Force's disbandment in 1998,² ICAN was pleased to see HHS's announcement of the Task Force's reinstatement.³

With the Task Force reinstated, we respectfully submit that, at a minimum, the following recommendations be made to the Secretary to fulfill the statutory obligations under the Mandate. To the extent the Task Force does not intend to make any of the recommendations listed below, an explanation as to why would be appreciated. Thank you for your timely attention to this important matter.

1. **HHS-Wide Recommendations for the Task Force:**

- a. Release health datasets to permit robust independent vaccine safety studies. The Task Force should require that:
 - i. All health-related datasets accessible by or in possession of the Department that are deidentified or could be deidentified should be posted online by each office and division in deidentified form.
 - ii. This should include, but is not limited to, all data in the Vaccine Safety Datalink, V-Safe, VAERS, Medicaid/Medicare (CMS), Sentinel and FDA's BEST System, the Sudden Unexpected Infant Death (SUID) and Sudden Death in the Young (SDY) Case Registry, BD-STEPS, DOD's VA ECS, and IHS Safety Tracking & Response System.

² In August 2017, ICAN submitted a FOIA request to HHS seeking records related to the reports that the Secretary is to submit to Congress every two years. In April 2018, ICAN sued and, in June 2018, HHS acknowledged it could not locate any such records. <https://icandecide.org/wp-content/uploads/2026/02/STIPULATION-ICAN-v-HHS-2018.pdf>.

Separately, in early 2018, ICAN submitted FOIA requests to NIH, seeking records related to the Task Force. In June 2018, NIH acknowledged it had no Task Force records and disclosed that the Task Force had been disbanded in 1998. <https://icandecide.org/wp-content/uploads/2023/06/Exhibit-274-Task-Force-Safety-Vaccines-Disbanded.pdf>.

In August 2021, ICAN sent a follow up request to NIH, seeking records related to any reports transmitted to Congress pursuant to 42 U.S.C. § 300aa-27(c). In January 2023, NIH acknowledged once again that it had no such records.

³ See note 1.

- b. Release datasets used in vaccine related studies to permit reproducibility, meet basic scientific standards, and increase transparency. The Task Force should require that:
 - i. The datasets used in any vaccine or infectious disease related study (which shall include any article, report, review, or publication of any kind) funded, conducted or published by the Department since 1986 shall be posted online in deidentified form.
 - ii. This section includes, but is not limited to, all studies in the MMWR as well as studies related to vaccination or infectious disease issued by the Department, that include a Department employed author, or which received funding by the Department.
 - iii. The Department shall retract or seek retraction, if outside of its control, of each study where the relevant datasets are not posted as required by this section.
- c. Restore integrity to scientific inquiries. The Task Force should require that:
 - i. Prior to the commencement, in any manner, of any Department funded or conducted study, a detailed study design shall be posted online and be available for review by the public.
 - ii. The results of the study shall be posted online and available to the public on the same webpage. If the study was not completed and therefore the results are not available to be published, an explanation must be provided for why the study was not completed.
 - iii. Any researcher found to violate these requirements shall, if employed by the Department, be subject to termination, and shall otherwise be barred from any future funding from or work with the Department.
- d. Increase transparency and trust with public stakeholders. The Task Force should require that:
 - i. Regarding FOIA:
 - 1. All outstanding FOIA requests (the backlog) shall be processed within 60 days.
 - 2. All active litigations shall be reviewed for timely resolution.
 - 3. All employees shall be promptly retrained on what information is exempt/non-exempt.
 - 4. Individuals who are the subject of a FOIA request (the “target” of the FOIA) shall not be permitted to search their own records for responsive records, and the search must be conducted by another employee.
 - 5. Each office and division shall post online a detailed org chart that clearly identifies each position and employee name, and the chart’s effective date. All obsolete org charts must be posted in a publicly available archive.
 - 6. Any Department employee who intentionally evades FOIA (through the use of private communication channels for official business, code words, deliberate misspellings, disappearing messages, etc.) is subject to termination.

7. To the extent permitted by law, at least 1% or more of the budget of each agency shall be allocated to its FOIA office. In the event any additional funding is needed to abide by FOIA, the agency shall approach Congress and seek additional funding.
- ii. All Department employees may communicate directly with members of the public to respond to inquiries and, time permitting, shall provide fulsome and truthful responses based on high quality data which must also be disclosed as part of any response to a member of the public.
- e. Reduce conflicts of interest.
 - i. Regarding Department employees and committee members:
 1. Request (and only request—not require) that all existing Department employees and committee members sign a pledge that, after leaving federal government employment, they will not receive any remuneration from any company that develops, manufacturers, or sells drugs, biologics, or medical devices (“pharma”).
 2. Restore an online directory of all Department employees (which existed until recently) that, in addition to listing a work phone, email, and address for each employee, also denotes if the employee signed the pledge.
 3. Prohibit the hiring of employees or committee members who have received anything of value from pharma and requires each new hire to sign a pledge to never receive anything of value from pharma.
 - ii. Regarding funds spent by or received by the Department:
 1. Prohibit, to the extent permitted by law, the receipt of any funds, fees, or anything of value by the Department from any person or entity outside the federal government.
 2. Prohibit the Department from providing any funding to any person or entity that has received pharma funds unless required by the President or Congress.
 3. Rescind any publication, recommendation, or action performed within two years of hire by any individual who is employed by pharma after ceasing employment with the Department.
- f. Safeguarding civil and individual rights. The Task Force should require that:
 - i. Within the parameters set by the President and Congress:
 1. all mandates of any medical product or procedure shall be prohibited (including because mandates harm the reputation, legitimacy and trust the Department has with the public); and
 2. for any mandate that cannot be repealed because of Presidential or Congressional decree or because it was enacted by a non-Department government body, the Department shall require where possible (and strongly encourage where not possible) that there be an option for a religious exemption.
 - ii. Provides that shared decision-making between healthcare provider and patient shall not be infringed upon through government action or pressure on the provider or patient.
- g. Engineered pathogens. The Task Force should require that:

- i. Ceases current funding and prohibits future funding to any person or entity developing any self-spreading engineered viruses and bacteria, or any virus- or bacteria-like particles or substance, capable of spreading from person to person.
 - ii. Prohibits any involvement with or funding for gain of function research, in all its forms, by the Department.
 - h. Lifting financial immunity for Covid-19 vaccine injuries. The Task Force should require that:
 - i. Repeals the PREP Act with regard to Covid-19 vaccines.

2. CDC-Wide Recommendations for the Task Force:

- a. Regarding CDC's vaccine schedules:
 - i. The Task Force should require that all vaccine recommendations are "shared clinical decision making," rather than "routine," and make this change for MMR and chicken pox vaccines after all others.
 - ii. Declare that new vaccines may not be added unless licensed per the standards set forth for licensure in the FDA section below.
 - iii. Declare that existing vaccines shall be removed from the schedule if, within the next two years, the pharma company selling each brand of a given vaccine cannot provide safety data of equivalent reliability as required for newly licensed vaccines pursuant to the new standards for FDA licensure.
- b. Regarding VAERS:
 - i. Require that each health care provider and manufacturer report any adverse event or suspected adverse event occurring within 60 days of vaccination to VAERS regardless of a causation analysis. *See* 42 U.S.C. § 300aa-25(b)(C) ("Each health care provider and vaccine manufacturer shall report [to VAERS] ... as the Secretary may by regulation require.")
 - ii. Update VAERS to permit automatic submission from existing electronic medical record systems.
 - iii. Make all VAERS records available to the public in de-identified format, including "deleted" reports, duplicate reports, follow-up or subsequent reports, additional records submitted, etc.
 - iv. Regularly assess for signals and immediately make public all details concerning any signals detected. This should include signals related to reactogenic batches or lots, or any adverse reactions.
- c. Regarding vaccine information statements (VIS):
 - i. Amend each VIS to include:
 - 1. a list of all ingredients,
 - 2. a summary of the clinical trial FDA relied upon to license the vaccine for children (including the duration safety was reviewed after each injection, the number of children in the trial, and the control used in the trial), and
 - 3. the post-marketing adverse events identified by the vaccine's manufacturer for which it has a basis to believe is causally related to its product (meaning, the adverse events listed in Section 6.2 of the package insert for the relevant vaccines).

- ii. *See* 42 U.S.C. § 300aa-25(a) (Each VIS shall include “any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.”)
- d. As provided in the Department-wide section:
 - i. The Task Force should require the release of all datasets for each MMWR report, Vaccine Safety Datalink, V-Safe, VAERS, Medicaid/Medicare (CMS), Sentinel and FDA’s BEST System, the Sudden Unexpected Infant Death (SUID) and Sudden Death in the Young (SDY) Case Registry, BD-STEPS, DOD’s VAECS, and IHS Safety Tracking & Response System to the public in de-identified form (e.g., redact birthday, leaving just month and year, and redact last two digits of each zip code).
 - ii. The Task Force should assure that each study conducted or funded by CDC first has a study design posted publicly prior to any action being taken regarding the study and that the results of the study shall be made public forthwith following the completion of the study. This is particularly important given the CDC’s prior conduct in conducting studies. If a study is not completed and the results of such study are not available for publication, an explanation must be provided explaining why the study was not completed.

3. FDA-Wide Recommendations for the Task Force:

- a. Minimum standards for licensure of vaccines:
 - i. The Task Force should direct the FDA Commissioner to issue industry guidance providing that the clinical trial relied upon to license any vaccine shall, at a minimum:
 - 1. Be randomized and double-blinded so that the researchers and other involved in conducting the study are not aware of which participants received the experimental vaccine and which received the control;
 - 2. Have a safety review period after administration of each dose of at least one year for adults, two years for children, three years preschoolers and toddlers, and four years for infants during which period all adverse events shall be captured and reported to FDA along with underlying medical records (after identifying), with the exception of minor events;
 - 3. Be sufficiently powered to determine that the vaccine prevents more deaths from the target disease than it causes; and
 - 4. Have a control group receiving a placebo or another vaccine for the same proposed indication that was licensed per the foregoing requirements, including that the trial had a placebo control.
 - 5. FDA should conduct numerous, regular, unannounced in-person inspections of all manufacturing and processing facilities for vaccines to oversee manufacturing, processing, and testing.
 - 6. FDA should conduct testing on vaccine vials and make results public.
 - b. For any existing vaccine licensed based on a trial that does not meet the foregoing minimal requirements, the Task Force should require FDA to send a notice to

relevant practitioners informing them of the details of the trial relied upon to license the existing vaccine and that it does not meet FDA's new guidelines. Indicate that the purpose of this notice is to provide practitioners with awareness of the clinical trial relied upon to license products they administer.

- c. The Task Force should require an increase in transparency:
 - i. The Task Force should recommend that the FDA Commissioner amend 21 C.F.R. § 601.51(e) to add the following italicized text: "After a license has been issued *or after emergency use authorization has been granted* the following data and information in the biological product file *or the emergency use authorization file* are immediately available...."
 - ii. The Task Force should conduct its own review of every licensed vaccine label/package insert, including all information concerning warnings and use instructions and make recommended label changes to FDA.
- d. Regarding platform technologies:
 - i. The Task Force should recommend (1) that FDA's draft guidance entitled *Platform Technology Designation Program for Drug Development - Guidance for Industry* regarding the development and review of drug products that use the same "platform" under the PREVENT Pandemics Act is rescinded; and (2) that the FDA Commissioner draft new guidance regarding the preliminary evidence a sponsor requesting platform technology designation must submit to demonstrate the "safety" of the drug or biological product.
- e. Regarding VAERS: Regularly assess for signals and immediately make public all details concerning any signals detected. Regularly assess for signals and immediately make public all details concerning any signals detected.
- f. Regarding direct-to-consumer ads:
 - i. The Task Force should recommend that the FDA Commissioner modify 21 C.F.R. § 202.1, addressing direct to consumer advertising, to repeal changes to same since July 27, 1995, and extend it to biologics and medical devices.

4. CMS-Wide Recommendations for the Task Force:

- a. To the maximum extent permitted by law, restrict all Medicare and Medicaid funding to any state that does not provide for a religious and medical exemption for any state or local mandate that requires the receipt of a medical product to attend school or continue employment.
- b. Require medical facilities to utilize the automated VAERS reporting system within their existing electronic medical management systems to automatically submit VAERS reports for any adverse event or suspected adverse event occurring within 60 days of administration of a vaccine.
- c. Before funding any vaccines for any states, CMS should conduct its own assessment including field surveillance of each state's practices concerning distribution, storage, and administration of vaccines and make any necessary recommendations for improvement.

5. NIH-Wide Recommendations for the Task Force:

- a. Restrict all NIH grants to those that study the root causes of disease, seek to identify non-pharmaceutical preventative health measures, and reproduce prior studies.
- b. Prohibit all NIH employees from receiving anything more than one penny per year from the patent of any technology used or related to vaccines.
- c. Prohibit vaccine development within NIH, either directly or indirectly, and leave those efforts to industry, as in the past NIH involvement has proved to corrupt the later licensure and post-licensure process.

6. Department of Veteran Affairs-Wide Recommendations for the Task Force:

- a. Formally acknowledge that there is a connection between the mandated Covid-19 vaccinations for service members in 2021 and the increase in service members claims for pericarditis, myocarditis, encephalopathy, and encephalitis.
- b. Formally acknowledge a presumption of service connection for pericarditis, myocarditis, encephalopathy, and encephalitis associated with service members mandatory receipt of the Covid-19 vaccinations from January 2021 to December 2023.

7. Health Resources Services Administration-Wide Recommendations for the Task Force:

- a. The Task Force should direct HRSA to approach the VICP in a manner that will actually fulfill its statutory purpose to “establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines.”
- b. Similar to how the Chief Special Master has Staff Attorneys assisting with SPU cases, the Task Force should recommend that each Special Master is permitted to have 2-3 Staff Attorneys to assist with case management and efficiency.
- c. The Task Force should require that a decision on VICP entitlement following an entitlement hearing must be issued within six (6) months after the entitlement hearing or post-hearing briefing if post-hearing briefs were submitted.
- d. The Task Force should require that a decision on a Motion for Interim Attorneys’ Fees and Costs must be issued within two (2) months after the motion is fully submitted.
- e. The Task Force should require that a decision on a Motion for Final Attorneys’ Fees and Costs in a compensated case must be issued within thirty (30) days after the motion is fully submitted.
- f. The Task Force should require that a decision on a Motion for Final Attorneys’ Fees and Costs in a non-compensated case must be issued within two (2) months after the motion is fully submitted.
- g. The Task Force should recommend that each Covid-related CICP request that has been denied to date, including those denied for having missed the 1-year deadline by which to submit, are individually reviewed and reconsidered.

Kindly share this letter with all members of the Task Force and we hope to receive confirmation that all recommendations listed above have been made by the Task Force to the Secretary, and for any recommendation not made, the reason for same. We remain available to

discuss any of the above recommendations and thank you all for your work to make HHS more transparent and accountable, as well as refocusing it to serve the American people.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'EBrehm', is positioned above the typed name.

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