

ONE HUNDRED NINETEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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February 6, 2026

The Honorable Jim O'Neill
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd.
Atlanta, GA 30329

Dear Acting Director O'Neill:

We write regarding recent efforts by the Centers for Disease Control and Prevention (CDC) to finance an ethically disturbing and scientifically unsound study on hepatitis B vaccination in Guinea-Bissau through an award to the University of Southern Denmark (SDU).¹ The proposed study has been met with such backlash from the medical research community that it has been suspended, despite the repeated insistence of Trump Administration officials that it would continue.² This five-year, \$1.6 million award would support a study purporting to test the “overall health impact” of the hepatitis B birth dose by withholding immunization for a subset of 14,000 newborns in Guinea-Bissau, a country where nearly one in five adults is infected with the disease.³ In addition, the fact that CDC is working to channel federal funding to long-time associates of Secretary Robert F. Kennedy Jr. without public solicitation, transparency into the award process, or evidence of meaningful expert review suggests that the agency’s grantmaking process may be seriously degraded in service of an anti-vaccine, ideological agenda.⁴

Since CDC first announced its award on December 18, 2025, the government of Guinea-Bissau has paused the study pending additional review, citing its poorly-reviewed science and the

¹ Centers for Disease Control and Prevention, *Notice of Award of a Single Source Unsolicited Grant to Fund University of Southern Denmark (SDU)*, 90 Fed. Reg. 59124 (Dec. 18, 2025) (notice); *US Plan For \$1.6M Hepatitis B Vaccine Study In Africa Called ‘Highly Unethical’*, The Guardian (Dec. 19, 2025).

² *‘It’s the Sovereignty of the Country’: Guinea-Bissau Says US Vaccine Study Suspended*, The Guardian (Jan. 23, 2026); *Guinea-Bissau Says Plans For Controversial U.S.-Funded Vaccine Study Need Further Review*, STAT (Jan. 22, 2026).

³ Centers for Disease Control and Prevention, *Notice of Award of a Single Source Unsolicited Grant to Fund University of Southern Denmark (SDU)*, 90 Fed. Reg. 59124 (Dec. 18, 2025) (notice); *Controversial CDC Hep B Vaccine Study in Guinea-Bissau May Be Canceled*, University of Minnesota Center for Infectious Disease Research and Policy (Jan. 15, 2026).

⁴ *HHS Gave A \$1.6 Million Grant To A Controversial Vaccine Study. These Emails Show How That Happened*, Rolling Stone (Jan. 16, 2026); *US Awards No-Bid Contract to Denmark Scientists Studying Hepatitis B in African Babies*, Associated Press (Dec. 19, 2025).

lack of prior meaningful coordination with those planning the study to address its concerns.⁵ Nevertheless, CDC has vehemently insisted that the study will move forward as planned.⁶ The agency’s insistence on wasting \$1.6 million of taxpayer funding to finance a scientifically meritless and ethically appalling study demonstrates its serious abuse of taxpayer dollars to the potential detriment of children abroad and Americans at home.⁷ This is particularly disturbing given CDC’s repeated attempts to strip funding from proven, effective health care programs.

According to the World Health Organization, chronic hepatitis B affected 254 million people globally in 2022, and the virus can put infected individuals at high risk of death from cirrhosis and liver cancer.⁸ Fifteen to twenty-five percent of individuals who develop hepatitis B infection will die from the disease, which killed an estimated 1.1 million people in 2022.⁹ Hepatitis B is up to 100 times more infectious than HIV and is most often transmitted from mother to child during birth.¹⁰ About 90 percent of babies exposed to hepatitis B at birth will develop a chronic infection, 25 percent of whom will die of liver cancer or liver failure.¹¹

Though a safe and effective vaccine to prevent hepatitis B has been available for nearly 45 years, elimination of mother-to-child transmission has faced persistent barriers in countries that do not recommend the birth dose.¹² In Guinea-Bissau, which has historically deferred the first dose to six weeks, approximately 11 percent of children younger than 18 months are infected with hepatitis B.¹³ Without the vaccine, as many as nine in ten infants could develop

⁵ See note 2.

⁶ *Id.*

⁷ *HHS Terminates, Then Reinstates, Thousands of Grants for Substance Use, Mental Health*, Politico (Jan. 14, 2025); *Trump Freezes Over \$10 Billion in Childcare, Family Assistance Funds to 5 U.S. States*, Reuters (Jan. 7, 2026).

⁸ World Health Organization, *Hepatitis B* (Jul. 23, 2025) (<https://www.who.int/news-room/fact-sheets/detail/hepatitis-b>).

⁹ *Id.*, Johns Hopkins Bloomberg School of Public Health, *Hepatitis B Vaccination is an Essential Safety Net for Newborns* (Sept. 24, 2025) (<https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth>).

¹⁰ See note 8; World Health Organization, *Hepatitis: Preventing Mother-To-Child Transmission of the Hepatitis B Virus* (Jul. 27, 2020) (<https://www.who.int/news-room/questions-and-answers/item/hepatitis-preventing-mother-to-child-transmission-of-the-hepatitis-b-virus>); Hepatitis B Foundation, *Hepatitis B Facts and Figures* (<https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/facts-and-figures/>) (last accessed Jan. 1, 2026).

¹¹ *Controversial CDC Hep B Vaccine Study in Guinea-Bissau May Be Canceled*, University of Minnesota Center for Infectious Disease Research and Policy (Jan. 15, 2026).

¹² Children’s Hospital of Philadelphia, *Vaccine History: Developments by Year* (Aug. 21, 2023) (<https://www.chop.edu/vaccine-education-center/science-history/vaccine-history/developments-by-year>); *Progress Toward the Elimination of Mother-to-Child Transmission of Hepatitis B Virus – Worldwide, 2016–2021*, CDC Morbidity and Mortality Weekly Report (Jul. 29, 2022).

¹³ Alexander Dutschke et al., *Prevalence of Hepatitis and HIV Infection Among 18-Months Old Children In Guinea-Bissau Before Vaccination*, *Tropical Medicine & International Health* (Oct. 19, 2024).

chronic infection that can lead to liver failure and death.¹⁴ In that context, deliberately withholding a proven vaccine that has saved millions of lives globally for the sole purpose of examining theoretical, non-specific side effects may constitute a major breach of scientific ethics.¹⁵ And using taxpayer dollars in such a study rather than using those dollars to provide proven, life-saving vaccinations to babies is abhorrent.

As numerous scientists have emphasized, this study as designed falls short of widely-accepted scientific and ethical principles governing clinical research.¹⁶ For example, the study focuses on the birth dose’s “overall health effects.”¹⁷ This vague and overbroad scope allows researchers to selectively emphasize outcomes that sow doubt in vaccine safety, while masking the vaccine’s proven effectiveness at preventing hepatitis B in neonates overall.¹⁸ Furthermore, since children often do not experience the long-term, potentially deadly, side effects of hepatitis B until adulthood, this experiment’s five-year time horizon allows investigators to ignore the long-term side effects of withholding immunization from neonates, making it impossible to weigh any risks of vaccination against the long-term benefits in preventing deadly disease.¹⁹

A leaked copy of the study’s research protocol from September 2025 exposed additional glaring ethical concerns, including the failure to test all mothers participating in the experiment for hepatitis B.²⁰ Since an estimated 19 percent of adults in Guinea-Bissau are thought to be hepatitis B carriers, not screening mothers will have the effect of consigning approximately 1,425 infants to almost certain hepatitis B infection by not taking steps to prevent likely transmission.²¹ These ethical failures have led experts to characterize this award as “RFK Jr.’s Tuskegee Experiment,” in reference to the infamous study that, over a period of decades,

¹⁴ Johns Hopkins Bloomberg School of Public Health, *Hepatitis B Vaccination is an Essential Safety Net for Newborns* (Sept. 24, 2025) (<https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth/>).

¹⁵ *Controversial CDC Hep B Vaccine Study in Guinea-Bissau May be Canceled*, University of Minnesota Center for Infectious Disease Research and Policy (Jan. 15, 2026); Substack Dr. Paul Offit, *RFK Jr.’s Tuskegee Experiment* (Jan. 6, 2026) (<https://pauloffit.substack.com/p/rfk-jrs-tuskegee-experiment>); *US Plan for \$1.6m Hepatitis B Vaccine Study in Africa Called ‘Highly Unethical’*, The Guardian (Dec. 19, 2025); Hepatitis B Foundation, *The Hepatitis B Vaccine’s Value and Necessity* (Feb. 4, 2025) (<https://www.hepb.org/news-and-events/the-hepatitis-b-vaccines-value-and-necessity>).

¹⁶ *Controversial CDC Hep B Vaccine Study in Guinea-Bissau May be Canceled*, University of Minnesota Center for Infectious Disease Research and Policy (Jan. 15, 2026); Substack Dr. Paul Offit, *RFK Jr.’s Tuskegee Experiment* (Jan. 6, 2026) (<https://pauloffit.substack.com/p/rfk-jrs-tuskegee-experiment>); *US Plan for \$1.6m Hepatitis B Vaccine Study in Africa Called ‘Highly Unethical’*, The Guardian (Dec. 19, 2025).

¹⁷ See note 1.

¹⁸ *US Plan for \$1.6m Hepatitis B Vaccine Study in Africa Called ‘Highly Unethical’*, The Guardian (Dec. 19, 2025); *New Review Finds No Evidence To Support Delaying Universal Hepatitis B Birth-Dose Vaccination*, University of Minnesota Center for Infectious Disease Research and Policy, (Dec. 2, 2025).

¹⁹ *Controversial CDC Hep B Vaccine Study in Guinea-Bissau May be Canceled*, University of Minnesota Center for Infectious Disease Research and Policy (Jan. 15, 2026).

²⁰ *Scoop: The Leaked Protocol of the CDC-funded Hepatitis B Vaccine Trial in Guinea-Bissau. “This Is Another Tuskegee.”*, Inside Medicine (Jan. 15, 2026).

²¹ *Id.*

withheld proven syphilis antibiotics for hundreds of African American sharecroppers infected with the disease.²²

The absence of any public information about CDC’s review of this award suggests a serious degradation in the agency’s grantmaking process.²³ This grant was issued directly by your office, and there is no indication that the study was meaningfully reviewed by an Institutional Review Board; appropriate scientific divisions within CDC; or CDC grantmaking staff responsible for assessing the scientific, statistical, ethical, and budgetary merits of proposed research.²⁴ Recent reporting demonstrates that the study proposal’s authors, Peter Aaby and Christine Stabell Benn, had been in discussions with Department of Health and Human Services (HHS) staff for several months prior to the award being published.²⁵ Internal HHS emails reveal that Benn first shared details of the proposed study in an October 3, 2025, email to Lyn Redwood, an HHS appointee who previously served as president of the Children’s Health Defense, an anti-vaccine organization founded by now-Secretary Kennedy.²⁶ The process for awarding this grant was reportedly overseen by your Senior Advisor, Stuart Burns, who characterized the award as a “funding priority” for the agency even though the agency had not solicited such a study.²⁷ Secretary Kennedy has previously lionized Aaby as a “hero,” notwithstanding credible concerns that he engaged in questionable research practices and concealed data that did not support his opposition to the Diphtheria, Tetanus, and Pertussis (DTaP) vaccine.²⁸

That CDC announced this award mere days after the agency approved the withdrawal of the hepatitis B birth dose from the national immunization schedule suggests that Secretary Kennedy and the anti-vaccine officials who have been appointed across the agency may be attempting to retroactively find scientific support for their preordained conclusions about the

²² *A Vaccine Trial is Called ‘Unethical’ and a ‘Unique’ Opportunity. What’s its fate?* NPR (Jan. 22, 2026); Substack Dr. Paul Offit, *RFK Jr.’s Tuskegee Experiment* (Jan. 6, 2026) (<https://pauloffit.substack.com/p/rfk-jrs-tuskegee-experiment>); Centers for Disease Control and Prevention, *The Untreated Syphilis Study at Tuskegee Timeline* (Sept. 4, 2024) (https://www.cdc.gov/tuskegee/about/timeline.html?CDC_AAref_Val=https://www.cdc.gov/tuskegee/timeline.htm); Martin J. Tobin, *Fiftieth Anniversary of Uncovering the Tuskegee Syphilis Study: The Story and Timeless Lessons*, *American Journal of Respiratory and Critical Care Medicine* (May 15, 2022).

²³ See note 4.

²⁴ Centers for Disease Control and Prevention, *Notice of Award of a Single Source Unsolicited Grant to Fund University of Southern Denmark (SDU)*, 90 Fed. Reg. 59124 (Dec. 18, 2025) (notice); *HHS Gave A \$1.6 Million Grant To A Controversial Vaccine Study. These Emails Show How That Happened*, *Rolling Stone* (Jan. 16, 2026).

²⁵ *HHS Gave A \$1.6 Million Grant To A Controversial Vaccine Study. These Emails Show How That Happened*, *Rolling Stone* (Jan. 16, 2026)

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

hepatitis B birth dose.²⁹ This would constitute a dangerous politicization of CDC resources by Secretary Kennedy in service of degrading public confidence in vaccines to the detriment of Americans’ health.

To address our concerns about this grant and the current state of CDC’s grantmaking, we request responses to the following questions by February 20, 2026:

1. Please clarify whether the study in question is canceled, suspended, or ongoing.
 - a. If it has been canceled, please specify who decided to cancel the study and whether CDC grant funds have been returned or when they will be returned.
 - b. If it has not been canceled, please explain what the next steps are in determining whether the study will go forward and, if so, under what conditions. Please also explain what role, if any, HHS or CDC has in that process.
2. Please produce the study proposal associated with CDC’s December 18, 2025, award to SDU.
3. Please produce all versions of the study proposal and protocol, including drafts, in CDC’s possession, including drafts created prior to the award date and post-award modifications to the research protocol.
4. Please produce all documents regarding the decision to award the grant and the implementation of this study.
5. Did CDC staff provide any substantive or technical assistance in the drafting or development of this study proposal and any subsequent revisions? If so, please list those staff and detail the scope of their assistance to the grantees.
6. What role, if any, did CDC scientific and research ethics staff play in the review and approval of this study?
7. Did any CDC employees or officials object to or raise concerns about this study before the award was issued? If so, how, if at all, were those concerns addressed?
8. Please provide any documentation regarding the decision to award this grant without a competitive process.

²⁹ Centers for Disease Control and Prevention, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025) (press release).

9. What role did CDC's Office of Grants Management and Office of Financial Resources play in reviewing the financial and budgetary elements of the proposal, including aligning the grant with applicable laws, regulations, and policies?
10. Were the scientific and ethical merits of this study scrutinized by Institutional Review Boards (IRBs)?
11. Which organization(s) commissioned the IRB(s) associated with reviewing this grant (e.g., the CDC, the University of Southern Denmark, and the Ministry of Health of Guinea-Bissau)?
 - a. What are the names and affiliations of the individuals who served on the IRB(s)?
 - b. Please transmit copies of the IRB's analysis and any relevant records relating to the review (e.g., meeting notes, draft proposals, study amendments, slide decks).
 - c. Was the IRB report(s) shared with or approved by, CDC, the University of Southern Denmark, or the Guinea-Bissau Ministry of Health? If so, on which dates?
 - d. What, if any, modifications were made in response to feedback on the IRB(s) analyses.
12. Please describe CDC's communications and coordination with the Ministry of Health of Guinea-Bissau throughout the design, review, and award of this study. Please include:
 - a. A description of all coordination, if any, between CDC and the Guinea-Bissau Ministry of Health prior to issuance of the award (including, if applicable, on a review of the study's Institutional Review Board analysis).
 - b. Whether the Guinea-Bissau Ministry of Health ever granted approval for this study to proceed, and, if so, when that approval happened, and on what basis.
 - c. A description of any issues has the Ministry of Health identified as requiring ongoing coordination or modification before it authorizes the study to proceed.
 - d. A description of how, if at all, the issues identified by the Ministry of Health are being addressed, including who at the agency is responsible for coordinating between CDC and the Ministry. How is CDC addressing the Ministry's underlying ethical concerns?
 - e. Whether enrollment in the study has begun, and, if so, whether enrollment has been paused as the Ministry of Health has stated.

13. Dr. Aaby and Dr. Benn have both been found to have engaged in “questionable research practices,” including concealing the results of an experiment failing to find a link between the DTaP vaccine and female mortality.³⁰ Did CDC independently assess whether Drs. Aaby and Benn’s research meet scientifically defensible standards before awarding this grant? If so, please provide the results of that analysis.
14. An early draft of the study protocol revealed that researchers will perform rapid antigen tests on only 250 mothers to assess the prevalence of hepatitis B in enrollees.³¹ Given that approximately 19 percent of adults in Guinea-Bissau—including women of childbearing age—are believed to be infected with hepatitis B, researchers will inevitably fail to identify hepatitis B-positive mothers, thereby preventing them from intervening to prevent transmission to their children during childbirth.³² How does CDC justify deliberately forgoing maternal screening for a disease that poses a known risk to children, especially when an effective screening is available?
15. Has CDC reviewed and approved the consent protocol related to the implementation of this experiment?
16. Is CDC providing any ongoing monitoring to ensure study participants and their families are fully informed about the risks of the study?
17. How does CDC intend to use the results of this study to inform future vaccine-related policy changes in the United States?

If you have any questions about this request, please contact Committee Democratic staff at (202) 225-2927.

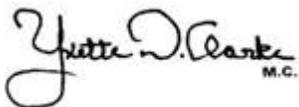
Sincerely,



Frank Pallone, Jr.
Ranking Member



Diana DeGette
Ranking Member, Subcommittee
on Health



Yvette Clarke
Ranking Member, Subcommittee on
Oversight and Investigations

³⁰ See note 25.

³¹ See note 20.

³² *Id.*

The Honorable Jim O'Neill

February 6, 2026

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cc: The Honorable Brett Guthrie
Chairman

The Honorable H. Morgan Griffith
Chairman
Subcommittee on Health

The Honorable John Joyce
Chairman
Subcommittee on Oversight and Investigations