

April 16, 2025

VIA EMAIL

The Honorable Robert F. Kennedy, Jr.
Secretary
The U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Repeal of COVID-19 PREP Act Declarations*

Dear Secretary Kennedy:

The PREP Act authorizes the Secretary of Health and Human Services to terminate any portion of a declaration under the Public Readiness and Emergency Preparedness (“**PREP**”) Act.¹

The declaration regarding medical countermeasures against COVID-19 (85 Fed. Reg. 15198, Mar. 17, 2020) (the “**Declaration**”) should be repealed forthwith as there is no longer even an arguable risk that COVID-19 constitutes such an emergency.² See 42 U.S.C. § 247d-6d(b)(1), (3)-(4). Any such repeal cannot be challenged in court. See 42 U.S.C. § 247d-6d(b)(7) (“No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.”)

Doing what is right at every fork in the road is what has gotten you to your current position. The right thing to do here is a straight repeal of the Declaration and all of its amendments. Attached is a draft publication for the Federal Register to effectuate that moral, ethical, and legitimate common-sense end.

Very truly yours,

s/ 

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

¹ As you know, in full disclosure, we represent Informed Consent Action Network regarding vaccine policy matters.

² Moreover, no company should be able to profit from a product for which it has no economic interest in assuring that product’s safety. Allowing this creates an incredible moral hazard that should not exist. Also, with respect to any concerns about permitting pharmacists to administer certain vaccines, that is an issue that should be left, as it has been traditionally, to the states to regulate; and, in any event, state health departments are empowered to grant such authority to pharmacists, should they choose to do so, outside of any PREP Act declaration.

U.S. Department of Health and Human Services, Office of the Secretary

Repeal of the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of repeal.

SUMMARY: The Secretary issues this repeal of the Declaration pursuant to section 319F-3 of the Public Health Service Act.

DATES: This repeal is effective as of May 30, 2025.

FOR FURTHER INFORMATION CONTACT: [NAME], Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, [ADDRESS]; [PHONE], [EMAIL]

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (PREP) Act authorizes the Secretary of Health and Human Services to issue a declaration to provide liability immunity to certain individuals and entities against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures.

The PREP Act was enacted on December 30, 2005, as Public Law 109-148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d-6e, respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113-5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116-136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

Pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, former Secretary, Alex M. Azar II, declared a public health emergency (PHE) with regard to COVID-19, effective January 31, 2020, and

subsequently issued a Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (the **Declaration**), effective March 17, 2020. The Declaration was renewed effective April 26, 2020, July 25, 2020, October 23, 2020, January 21, 2021, April 21, 2021, July 20, 2021, October 18, 2021, January 16, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 11, 2023. The PHE ended on May 11, 2023.

On December 6, 2024, Former Secretary Xavier Becerra amended the Declaration to extend the time period of PREP Act coverage through December 31, 2029. Upon review, I have not identified a credible risk that COVID-19 constitutes an emergency and am thus repealing the Declaration and all of the Amendments thereto.

I. No Determination of Public Health Emergency - 42 U.S.C. 247d–6d(b)(1)

I have determined that SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 do not constitute a credible risk of a current or future public health emergency.

II. Factors Considered - 42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the covered countermeasures. I have also considered the potential Constitutional issues with the liability immunity and the compensation program created by the PREP Act.

III. Effective Time Period - 42 U.S.C. 247d-6d(b)(2)(B)

The Declaration will be repealed as of April 21, 2025.

Dated: April 1, 2025

Robert F. Jennedy Jr.,

Secretary, U.S. Department of Health and Human Services.