I

118TH CONGRESS
1ST SESSION

H. R. 5773

To amend the Public Health Service Act to remove certain liability protections for certain biological products and other drugs if the sponsor thereof fails to disclose to the public all non-exempt data within the biological product file or drug application, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 2023

Mr. POSEY introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Public Health Service Act to remove certain liability protections for certain biological products and other drugs if the sponsor thereof fails to disclose to the public all non-exempt data within the biological product file or drug application, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Consumer Vaccine Safety and Protection Act of 2023".

SEC. 2. DISCLOSURE OF NON-EXEMPT DATA REQUIRED FOR CERTAIN BIOLOGICAL PRODUCTS AND OTHER DRUGS.

Section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended by adding at the end the following:

''(j) DISCLOSURE OF NON-EXEMPT DATA REQUIRED.—

''(1) COVERED PRODUCTS.—In this subsection, the term 'covered product' means a covered countermeasure that—

''(A) is a biological product or other drug; and

''(B) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act on or after the date of enactment of the Consumer Vaccine Safety and Protection Act of 2023, irrespective of whether the biological product or drug later receives approval or licensure under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act.

''(2) DISCLOSURE BY SPONSORS.—

''(A) IN GENERAL.—Subject to subparagraph (C), the sponsor of a covered product shall disclose to the public, in an easily acces-

sible location on the website of the sponsor of the covered product—

"(i) in the case of a biological product, all data and information available for public disclosure under section 601.51(e) of title 21, Code of Federal Regulations (or successor regulations); and

"(ii) in the case of another drug, all data and information available for public disclosure under section 314.430 of title 21, Code of Federal Regulations (or successor regulations).

"(B) TIMING.—The sponsor of a covered product shall, with respect to any data or information required to be disclosed by subparagraph (A), make the disclosure not later than 10 days after the later of—

"(i) the date on which the Food and Drug Administration authorizes the emergency use of the covered product under section 564 of the Federal Food, Drug, and Cosmetic Act; and

"(ii) the date on which the data or information becomes available to the sponsor.

''(C) EXCEPTIONS.—The disclosure requirement in subparagraph (A) does not apply with respect to—

''(i) a trade secret or confidential commercial or financial information as defined in section 20.61 of title 21, Code of Federal Regulations (or successor regulations); or

''(ii) personally identifiable information.

''(3) DISCLOSURE BY HHS.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Secretary shall—

''(i) not later than 10 days after the Food and Drug Administration authorizes the emergency use of a covered product under section 564 of the Federal Food, Drug, and Cosmetic Act or approves or licenses a covered product under section 505 of such Act or section 351 of this Act, disclose to the public, in an easily accessible location on the website of the Department of Health and Human Services, all data and information required by paragraph (2)

to be disclosed by the sponsor of the product; and

''(ii) not later than 30 days after receiving any additional such data and information, so disclose such data and information.

''(B) EXCEPTION.—The disclosure requirement in subparagraph (A) does not apply with respect to data and information exempted from disclosure by paragraph (2)(C).

''(4) ENFORCEMENT AGAINST SPONSORS FOR FAILURE TO DISCLOSE.—

''(A) EXCLUSION FROM DEFINITION OF 'COVERED COUNTERMEASURE'.—Notwithstanding subsection (i)(1), a covered product is deemed to be excluded from the definition of a 'covered countermeasure' for purposes of the provisions of this section (other than this subsection) and section 319F–4 if—

''(i) the covered product is administered on or after the date of enactment of the Consumer Vaccine Safety and Protection Act of 2023; and

''(ii) the sponsor of the covered product is determined by the Secretary to have

knowingly failed to make a disclosure required by paragraph (2) with respect to the covered product.

"(B) INELIGIBILITY FOR FDA AWARDS, FUNDS, OR OTHER BENEFITS.—If the sponsor of a covered product is determined by the Secretary to have knowingly failed to make a disclosure required by paragraph (2) with respect to the covered product, such sponsor shall be treated as ineligible for the award of any grant, cooperative agreement, or loan or for any new grant of emergency use authorization, expanded access, or approval or licensure of any product under section 351 of this Act or any provision of the Federal Food, Drug, and Cosmetic Act so long as such sponsor continues to be in violation of such requirement.

"(5) ENFORCEMENT AGAINST HHS FOR FAILURE TO DISCLOSE.—A party injured by a covered product with respect to which the Secretary failed to carry out the Secretary's duties under paragraph (3) may bring an action in the appropriate district court of the United States for appropriate relief, including damages.".

○