

117TH CONGRESS
2D SESSION

H. R. 6431

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the alteration, falsification, fabrication, destruction, omission, or removal of records or certain information required to be produced or maintained for a drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 2022

Ms. SCHRIER (for herself and Mr. JOYCE of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the alteration, falsification, fabrication, destruction, omission, or removal of records or certain information required to be produced or maintained for a drug, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Data Transparency
5 and Drug Safety Act of 2022”.

1 **SEC. 2. ENHANCED PENALTIES FOR FALSE INFORMATION**
2 **AND RECORDS DESTRUCTION.**

3 (a) PROHIBITION OF FALSE INFORMATION AND
4 RECORD DESTRUCTION.—Section 301 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
6 ed by adding at the end the following:

7 “(fff) The alteration, falsification, fabrication, de-
8 struction, omission, or removal of the whole or any part
9 of records or information that is—

10 “(1) required under this Act—

11 “(A) to be produced during the develop-
12 ment or manufacture of a drug; or

13 “(B) to be produced or maintained by the
14 sponsor of an application for the approval of a
15 drug under section 505 or the holder of an ap-
16 proved application for a drug under section
17 505; or

18 “(2) subject to inspection under this Act by the
19 Secretary.”.

20 (b) PENALTIES.—Section 303 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 333) is amended by
22 adding at the end the following:

23 “(h) Notwithstanding subsection (a), any person who
24 violates section 301(fff) shall be subject to—

25 “(1) a civil monetary penalty not to exceed—

26 “(A) \$1,000,000 per violation; and

1 “(B) \$10,000,000 for all violations (ex-
2 cluding those described in paragraph (2)) adju-
3 dicated in a single proceeding; and

4 “(2) in the case of a violation that continues
5 after the Secretary provides written notice to such
6 person, if such person does not sufficiently remedy
7 the violation including by producing corrected
8 records or information, additional civil penalties not
9 to exceed—

10 “(A) \$1,000,000 for the first 30-day pe-
11 riod (or any portion thereof) following such no-
12 tice during which such person continues to be
13 in violation;

14 “(B) for each such 30-day period there-
15 after, the amount that is double the amount ac-
16 tually imposed for the preceding 30-day period,
17 not to exceed \$2,000,000 for any 30-day period;
18 and

19 “(C) \$20,000,000 for all violations de-
20 scribed in this paragraph adjudicated in a sin-
21 gle proceeding.”.

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