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(Original Signature of Member)

119TH CONGRESS  
1ST SESSION

# H. R. \_\_\_\_\_

To amend the Federal Food, Drug, and Cosmetic Act to enhance drug manufacturing amount information reporting, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

Ms. MATSUI introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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# A BILL

To amend the Federal Food, Drug, and Cosmetic Act to enhance drug manufacturing amount information reporting, 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 “Drug Origin Trans-  
5 parency Act of 2025”.

1 **SEC. 2. ENHANCED DRUG MANUFACTURING AMOUNT IN-**  
2 **FORMATION REPORTING.**

3 (a) IN GENERAL.—Section 510(j)(3) of the Federal  
4 Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)(3)) is  
5 amended—

6 (1) in subparagraph (A), by adding “or (2)”  
7 after “paragraph (1)”; and

8 (2) by adding at the end the following:

9 “(C) Each report submitted pursuant to sub-  
10 paragraph (A) with respect to a drug shall—

11 “(i) include additional information as may  
12 be specified by the Secretary in regulation or  
13 guidance regarding the supply chain for such  
14 drug, such as—

15 “(I) the identity of the respective sup-  
16 pliers of each active pharmaceutical ingre-  
17 dient, active pharmaceutical ingredient in-  
18 termediate, and in-process material used in  
19 such manufacture, preparation, propaga-  
20 tion, compounding, or processing of the  
21 drug; and

22 “(II) the respective amounts of such  
23 drug that were manufactured, prepared,  
24 propagated, compounded, or processed  
25 using an active pharmaceutical ingredient,  
26 active pharmaceutical ingredient inter-

1 mediate, and in-process material from each  
2 such identified supplier; and

3 “(ii) be submitted more frequently than  
4 annually, in accordance with a reporting sched-  
5 ule as may be specified by the Secretary in such  
6 regulation or guidance, but not more frequently  
7 than 4 times per year.

8 “(D) Any additional information specified in  
9 regulation or guidance pursuant to subparagraph  
10 (C) shall be a required element of reports under this  
11 paragraph not earlier than 6 months after the date  
12 on which such regulation or guidance is issued in  
13 final form (and in no event shall the absence of any  
14 regulation or guidance issued under subparagraph  
15 (C) affect the requirement to report as described in  
16 subparagraph (A)).”

17 (b) CONFORMING AMENDMENT.—Section  
18 510(j)(3)(B) of the Federal Food, Drug, and Cosmetic  
19 Act (21 U.S.C. 510(j)(3)(B)) is amended by striking “sub-  
20 paragraph (A)” and inserting “this paragraph”.

21 **SEC. 3. REQUIRE DRUG LABELING TO INCLUDE ORIGINAL**  
22 **MANUFACTURER AND SUPPLY CHAIN INFOR-**  
23 **MATION.**

24 Section 502 of the Federal Food, Drug, and Cosmetic  
25 Act (21 U.S.C. 352) is amended—

1 (1) in paragraph (b)—

2 (A) by striking “(b) If in a package” and  
3 inserting “(b)(1) If in a package”;

4 (B) by striking “a label containing (1) the  
5 name and place” and inserting “a label con-  
6 taining—

7 “(A) the name and place”;

8 (C) by striking “or distributor; and (2) an  
9 accurate statement” and inserting “or dis-  
10 tributor; and

11 “(B) an accurate statement”;

12 (D) by striking “under clause (2) of this  
13 paragraph” and inserting “under this clause”;  
14 and

15 (E) by inserting at the end the following:

16 “(2)(A) Subject to clause (C), if it is a drug,  
17 including an active pharmaceutical ingredient, unless  
18 it bears a label containing the name and place of  
19 business, and unique facility identifier of the original  
20 manufacturer of such drug or active pharmaceutical  
21 ingredient, except that the Secretary may provide,  
22 by regulation, for reasonable variations in the imple-  
23 mentation of such labeling requirements.

24 “(B) Subject to clause (C), if it is a drug that  
25 is an active pharmaceutical ingredient, unless any

1 accompanying certificate of analysis contains the  
2 name and place of business, and unique facility iden-  
3 tifier of the original manufacturer of the active  
4 pharmaceutical ingredient.

5 “(C) The Secretary may provide, by regulation,  
6 for reasonable variations in the implementation of  
7 labeling requirements specified in this subpara-  
8 graph.”; and

9 (2) by inserting after paragraph (c) the fol-  
10 lowing:

11 “(d)(1) Subject to subparagraph (2), if it is a drug,  
12 including an active pharmaceutical ingredient, unless it  
13 bears labeling containing the name and place of business  
14 of—

15 “(A) the original manufacturer of each active  
16 pharmaceutical ingredient;

17 “(B) each manufacturer, if different from the  
18 original manufacturer; and

19 “(C) the packer or distributor, if any.

20 “(2) The Secretary may provide, by regulation, for  
21 reasonable variations or an alternative placement for the  
22 labeling requirements specified in subparagraph (1), in-  
23 cluding by electronic means.”.