

Union Calendar No. 46

118TH CONGRESS
1ST SESSION

H. R. 501

[Report No. 118–66, Part I]

To amend the Controlled Substances Act to require registrants to decline to fill certain suspicious orders, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 25, 2023

Mrs. HARSHBARGER (for herself and Mrs. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

MAY 17, 2023

Additional sponsors: Mrs. HINSON, Ms. LEE of Nevada, Ms. TOKUDA, Mr. CISCOMANI, Ms. SCHRIER, and Mr. MOLINARO

MAY 17, 2023

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

MAY 17, 2023

Committee on the Judiciary discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on January 25, 2023]

A BILL

To amend the Controlled Substances Act to require registrants to decline to fill certain suspicious orders, 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 “Block, Report, and Sus-*
5 *pend Suspicious Shipments Act”.*

6 **SEC. 2. BLOCK, REPORT, AND SUSPEND SUSPICIOUS OR-**
7 **DERS.**

8 *(a) CLARIFICATION OF PROCESS FOR REGISTRANTS*
9 *TO EXERCISE DUE DILIGENCE UPON DISCOVERING A SUS-*
10 *PICIOUS ORDER.—Section 312(a) of the Controlled Sub-*
11 *stances Act (21 U.S.C. 832(a)) is amended—*

12 *(1) in paragraph (2), by striking “and” at the*
13 *end; and*

14 *(2) by striking paragraph (3) and inserting the*
15 *following paragraphs:*

16 *“(3) determine whether an order or series of or-*
17 *ders is suspicious, taking into consideration—*

18 *“(A) any unusual size, pattern, or fre-*
19 *quency of the order or series of orders; and*

20 *“(B) any customer business model, dis-*
21 *persing patterns, prior orders, or other charac-*
22 *teristics that may indicate the order or series of*
23 *orders is suspicious, despite the particular order*
24 *or series of orders not exhibiting an unusual size,*
25 *pattern, or frequency; and*

1 “(4) upon discovering suspicious circumstances
2 regarding an order or series of orders, and in a man-
3 ner consistent with the other requirements of this sec-
4 tion—

5 “(A) decline to fill the order or series of or-
6 ders, establish and maintain (for not less than a
7 period to be determined by the Administrator of
8 the Drug Enforcement Administration) a record
9 of the order or series of orders, and notify the
10 Administrator of the Drug Enforcement Admin-
11 istration for the purpose of including informa-
12 tion on such order or series of orders in the cen-
13 tralized database established under subsection
14 (b)(1); or

15 “(B) exercise due diligence as appropriate
16 and—

17 “(i)(I) if the due diligence fails to dis-
18 pel all of the indicators that give rise to the
19 suspicion that, if the order or series of or-
20 ders is filled, the drugs that are the subject
21 of the order or series of orders are likely to
22 be diverted, decline to fill the order or series
23 of orders; or

1 “(II) if the due diligence does dispel all
2 such indicators, fill the order or series of or-
3 ders;

4 “(ii) establish and maintain (for not
5 less than a period to be determined by the
6 Administrator of the Drug Enforcement Ad-
7 ministration) a record of the order or series
8 of orders and the due diligence that was
9 performed; and

10 “(iii) notify the Administrator of the
11 Drug Enforcement Administration for the
12 purpose of including information on such
13 order or series of orders in the centralized
14 database established under subsection (b)(1),
15 including any indicators giving rise to the
16 suspicion that, if the order or series of or-
17 ders is filled, the drugs that are the subject
18 of the order or series of orders are likely to
19 be diverted.”.

20 (b) *REGULATIONS*.—Not later than 1 year after the
21 date of enactment of this Act, for purposes of section
22 312(a)(4) of the Controlled Substances Act, as inserted by
23 subsection (a), the Attorney General of the United States
24 shall promulgate a final regulation specifying—

1 (1) *the indicators that give rise to a suspicion*
2 *that, if an order or series of orders is filled, the drugs*
3 *that are the subject of the order or series of orders are*
4 *likely to be diverted;*

5 (2) *a definition of due diligence; and*

6 (3) *in the case of a registrant that dispels all of*
7 *the indicators giving rise to a suspicious order or se-*
8 *ries of orders, the circumstances in which the reg-*
9 *istrant is not required to file the notification under*
10 *such section 312(a)(4).*

11 (c) *PENALTY.*—Section 402(a)(5) of the Controlled
12 *Substances Act (21 U.S.C. 842(a)(5)) is amended by insert-*
13 *ing before the semicolon at the end the following: “, includ-*
14 *ing any such violation of section 312(a)(4)”.*

15 (d) *APPLICABILITY.*—Section 312(a)(4) of the Con-
16 *trolled Substances Act, as inserted by subsection (a), shall*
17 *apply beginning on the day that is 1 year after the date*
18 *of enactment of this Act. Until such day, section 312(a)(3)*
19 *of the Controlled Substances Act shall apply as such section*
20 *312(a)(3) was in effect on the day before the date of enact-*
21 *ment of this Act.*

22 (e) *SENSE OF CONGRESS.*—*It is the sense of Congress*
23 *that—*

24 (1) *medications for opioid use disorder signifi-*
25 *cantly reduce the risk of overdose death; and*

1 (2) *the requirements of this Act are not intended*
2 *to impair access to controlled substances primarily*
3 *used to treat opioid use disorder.*

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