

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 501  
OFFERED BY M . \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Block, Report, and  
3 Suspend Suspicious Shipments Act”.

**4 SEC. 2. BLOCK, REPORT, AND SUSPEND SUSPICIOUS OR-  
5 DERS.**

6 (a) CLARIFICATION OF PROCESS FOR REGISTRANTS  
7 TO EXERCISE DUE DILIGENCE UPON DISCOVERING A  
8 SUSPICIOUS ORDER.—Section 312(a) of the Controlled  
9 Substances Act (21 U.S.C. 832(a)) is amended—

10 (1) in paragraph (2), by striking “and” at the  
11 end; and

12 (2) by striking paragraph (3) and inserting the  
13 following paragraphs:

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

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

1           “(B) any customer business model, dis-  
2           pensing patterns, prior orders, or other charac-  
3           teristics that may indicate the order or series of  
4           orders is suspicious, despite the particular order  
5           or series of orders not exhibiting an unusual  
6           size, pattern, or frequency; and

7           “(4) upon discovering suspicious circumstances  
8           regarding an order or series of orders, and in a  
9           manner consistent with the other requirements of  
10          this section—

11           “(A) decline to fill the order or series of  
12           orders, establish and maintain (for not less  
13           than a period to be determined by the Adminis-  
14           trator of the Drug Enforcement Administra-  
15           tion) a record of the order or series of orders,  
16           and notify the Administrator of the Drug En-  
17           forcement Administration for the purpose of in-  
18           cluding information on such order or series of  
19           orders in the centralized database established  
20           under subsection (b)(1); or

21           “(B) exercise due diligence as appropriate  
22           and—

23           “(i)(I) if the due diligence fails to dis-  
24           pel all of the indicators that give rise to  
25           the suspicion that, if the order or series of

1 orders is filled, the drugs that are the sub-  
2 ject of the order or series of orders are  
3 likely to be diverted, decline to fill the  
4 order or series of orders; or

5 “(II) if the due diligence does dispel  
6 all such indicators, fill the order or series  
7 of orders;

8 “(ii) establish and maintain (for not  
9 less than a period to be determined by the  
10 Administrator of the Drug Enforcement  
11 Administration) a record of the order or  
12 series of orders and the due diligence that  
13 was performed; and

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

24 (b) REGULATIONS.—Not later than 1 year after the  
25 date of enactment of this Act, for purposes of section

1 312(a)(4) of the Controlled Substances Act, as inserted  
2 by subsection (a), the Attorney General of the United  
3 States shall promulgate a final regulation specifying—

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

8 (2) a definition of due diligence; and

9 (3) in the case of a registrant that dispels all  
10 of the indicators giving rise to a suspicious order or  
11 series of orders, the circumstances in which the reg-  
12 istrant is not required to file the notification under  
13 such section 312(a)(4).

14 (c) PENALTY.—Section 402(a)(5) of the Controlled  
15 Substances Act (21 U.S.C. 842(a)(5)) is amended by in-  
16 serting before the semicolon at the end the following: “,  
17 including any such violation of section 312(a)(4)”.

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

1           (e) SENSE OF CONGRESS.—It is the sense of Con-  
2 gress that—

3           (1) medications for opioid use disorder signifi-  
4 cantly reduce the risk of overdose death; and

5           (2) the requirements of this Act are not in-  
6 tended to impair access to controlled substances pri-  
7 marily used to treat opioid use disorder.

