

*B. M. Cassidy M.D.* S.L.C.

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.**

**S. 3794**

To amend the Federal Food, Drug, and Cosmetic Act to further regulate compounding pharmacies and outsourcing facilities, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended  
to be proposed by Mr. BANKS

Viz:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safeguarding Ameri-  
5 cans from Fraudulent and Experimental Drugs Act of  
6 2026” or the “SAFE Drugs Act of 2026”.

7 **SEC. 2. REPORTING REQUIREMENT.**

8 Section 503A of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 353a) is amended—

10 (1) by redesignating subsections (d) and (e) as  
11 subsections (e) and (f), respectively; and

1           (2) by inserting after subsection (c) the fol-  
2       lowing:

3       “(d) REPORTING.—

4           “(1) SERIOUS ADVERSE EVENTS.—Each li-  
5       censed pharmacist or licensed physician who com-  
6       pounds drug products under this section and sends  
7       such drug products, or causes such drug products to  
8       be sent, out of the State in which the compounding  
9       occurs shall submit any report received by such li-  
10      censed pharmacist or licensed physician of a serious  
11      adverse event associated with a compounded drug  
12      product, in accordance with the content and format  
13      requirements established through guidance or under  
14      section 310.305 of title 21, Code of Federal Regula-  
15      tions (or any successor regulations), to—

16           “(A) the Secretary;

17           “(B) the State in which the compounding  
18      occurs; and

19           “(C) each State to which such drugs are  
20      sent.

21       “(2) INTERSTATE DISPENSING.—

22           “(A) IN GENERAL.—Beginning with the  
23      first calendar year that begins after the date of  
24      enactment of the SAFE Drugs Act of 2026, not  
25      later than January 15 of each calendar year,

1 each licensed pharmacist or licensed physician  
2 who compounds drug products under this sec-  
3 tion and sends, or causes to be sent, out of the  
4 State in which the compounding occurs, more  
5 than 5 percent of the total annual amount of  
6 drug products compounded by such licensed  
7 pharmacist or licensed physician shall annually  
8 submit a report containing the information de-  
9 scribed in subparagraph (B) to the Secretary  
10 and the State to which such drug products are  
11 sent.

12 “(B) CONTENTS.—Each report under sub-  
13 paragraph (A) shall identify—

14 “(i) the name, address, license num-  
15 ber, and State of license of the licensed  
16 pharmacist or licensed physician who com-  
17 pounded the drug product; and

18 “(ii) the total number of units of com-  
19 pounded drug products, by type of product,  
20 and by month, sent or caused to be sent to  
21 each applicable State.

22 “(C) FORM AND MANNER.—A licensed  
23 pharmacist or licensed physician shall submit  
24 each report under subparagraph (A) in such

1 form and manner as the Secretary may pre-  
2 scribe.

3 “(D) INFORMATION SHARING.—The Sec-  
4 retary shall use an information sharing system  
5 for purposes of facilitating the transmission of  
6 reports under subparagraph (A) from a licensed  
7 pharmacist or licensed physician to the Sec-  
8 retary and each applicable State in a manner  
9 that reduces unnecessary administrative bur-  
10 den.

11 “(E) EXCLUSION.—This subsection shall  
12 not apply to the compounding of any drug prod-  
13 ucts for hospital patients by a pharmacy located  
14 on the premises of the hospital.

15 “(3) RULE OF CONSTRUCTION.—Nothing in  
16 this section shall be construed to preempt any re-  
17 quirement of a State or political subdivision of a  
18 State that requires additional, more stringent, or  
19 supplementary reporting with respect to a drug  
20 product compounded under this section.”.

21 **SEC. 3. LABELING.**

22 Section 503A(b)(3) of the Federal Food, Drug, and  
23 Cosmetic Act (21 U.S.C. 353a(b)(3)) is amended—

24 (1) in subparagraph (A), by striking “; and”  
25 and inserting a semicolon;

1           (2) in subparagraph (B)(ii), by striking the pe-  
2           riod and inserting “; and”; and

3           (3) by inserting after subparagraph (B) the fol-  
4           lowing:

5                 “(C) the label of such drug product in-  
6           cludes—

7                         “(i) the statement: ‘This medication  
8                         has been compounded for dispensing to an  
9                         individual patients and has not been ap-  
10                        proved by the Food and Drug Administra-  
11                        tion.’;

12                       “(ii) the following information to fa-  
13                       cilitate adverse event reporting:  
14                       www.fda.gov/medwatch, and 1-800-FDA-  
15                       1088 (or any successor website or tele-  
16                       phone number); and

17                       “(iii) such other information as the  
18                       Secretary may prescribe by order, which  
19                       may include information to facilitate ad-  
20                       verse event reporting.”.