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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:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Safeguarding Americans from Fraudulent and Experimental Drugs Act of 2026" or the "SAFE Drugs Act of 2026".

SEC. 2. REPORTING REQUIREMENT.

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

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

(2) by inserting after subsection (c) the following:

"(d) REPORTING.—

"(1) SERIOUS ADVERSE EVENTS.—Each licensed pharmacist or licensed physician who compounds drug products under this section and sends such drug products, or causes such drug products to be sent, out of the State in which the compounding occurs shall submit any report received by such licensed pharmacist or licensed physician of a serious adverse event associated with a compounded drug product, in accordance with the content and format requirements established through guidance or under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations), to—

"(A) the Secretary;

"(B) the State in which the compounding occurs; and

"(C) each State to which such drugs are sent.

"(2) INTERSTATE DISPENSING.—

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

each licensed pharmacist or licensed physician who compounds drug products under this section and sends, or causes to be sent, out of the State in which the compounding occurs, more than 5 percent of the total annual amount of drug products compounded by such licensed pharmacist or licensed physician shall annually submit a report containing the information described in subparagraph (B) to the Secretary and the State to which such drug products are sent.

"(B) CONTENTS.—Each report under subparagraph (A) shall identify—

"(i) the name, address, license number, and State of license of the licensed pharmacist or licensed physician who compounded the drug product; and

"(ii) the total number of units of compounded drug products, by type of product, and by month, sent or caused to be sent to each applicable State.

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

form and manner as the Secretary may prescribe.

"(D) INFORMATION SHARING.—The Secretary shall use an information sharing system for purposes of facilitating the transmission of reports under subparagraph (A) from a licensed pharmacist or licensed physician to the Secretary and each applicable State in a manner that reduces unnecessary administrative burden.

"(E) EXCLUSION.—This subsection shall not apply to the compounding of any drug products for hospital patients by a pharmacy located on the premises of the hospital.

"(3) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preempt any requirement of a State or political subdivision of a State that requires additional, more stringent, or supplementary reporting with respect to a drug product compounded under this section.".

SEC. 3. LABELING.

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

(1) in subparagraph (A), by striking "; and" and inserting a semicolon;

(2) in subparagraph (B)(ii), by striking the period and inserting "; and"; and

(3) by inserting after subparagraph (B) the following:

"(C) the label of such drug product includes—

"(i) the statement: 'This medication has been compounded for dispensing to an individual patients and has not been approved by the Food and Drug Administration.';

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch, and 1–800–FDA–1088 (or any successor website or telephone number); and

"(iii) such other information as the Secretary may prescribe by order, which may include information to facilitate adverse event reporting.".