110TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for safe and appropriate compounding of drugs by licensed pharmacists and physicians.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Drug Compounding Act of 2007''.

SEC. 2. PHARMACY COMPOUNDING.

Section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) is amended to read as follows:

"SEC. 503A. PHARMACY COMPOUNDING.

"(a) DEFINITIONS.—In this section—

"(1) the term 'bulk drug substance' has the meaning given the term in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation);

"(2) the term 'compounding'—

"(A) includes the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a drug tailored to the needs of an individual patient; and

"(B) does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by a product's manufacturer and other manufacturer directions consistent with that labeling;

"(3) the term 'essentially a copy of a drug approved by the Secretary'—

"(A) includes a drug product for which there is no legitimate medical need for any difference in ingredients, dosage form, route of administration, or strength from the comparable drug approved by the Secretary; and

"(B) does not include a drug product in which there is a change, made for an identified

individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable drug approved by the Secretary;

''(4) the term 'sterile drug product' means any drug product—

''(A) to be administered parenterally;

''(B) for topical use on or in the eye;

''(C) that is an aqueous-based solution for inhalation; or

''(D) that the Secretary defines by regulation to be a sterile drug product; and

''(5) the term 'valid prescription order' means a prescription order—

''(A) for an identified patient; and

''(B) completed by a practitioner authorized by State law to prescribe drugs that is within an established relationship with such patient.

''(b) APPLICATION.—

''(1) APPLICABILITY OF ACT TO COMPOUNDED DRUG PRODUCTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), this Act shall apply to compounded drug products.

"(B) EXEMPTION FOR CERTAIN DRUGS.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a compounded drug product if, with respect to such compounded drug product, the requirements of this section are met.

"(C) NO EXEMPTION FOR NON-COMPLIANT DRUGS.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall apply to a compounded drug product if, with respect to such compounded drug product, the requirements of this section are not met.

"(2) APPLICATION OF SECTION.—This section shall not apply to—

"(A) compounded positron emission tomography drugs, as defined in section 201(ii); or

"(B) radiopharmaceuticals.

"(c) COMPOUNDING.—

"(1) IN GENERAL.—Drug products that are compounded shall be compounded only in accordance with this paragraph as follows:

"(A) COMPOUNDING BY LICENSED PHARMACIST OR LICENSED PHYSICIAN.—A drug product shall be compounded by—

"(i) a licensed pharmacist in a State licensed pharmacy or a Federal facility; or

"(ii) a licensed physician.

"(B) COMPOUNDING ON VALID PRESCRIPTION ORDER OR ON HISTORY OF VALID PRESCRIPTION ORDERS.—

"(i) IN GENERAL.—A drug product shall be compounded—

"(I) for an identified individual patient based on—

"(aa) the receipt by the compounding pharmacist or physician of a valid prescription order that indicates that a compounded drug product is needed by the identified individual patient; or

"(bb) a notation, made by the compounding pharmacist or physician based on a conversation between the compounding pharmacist or physician and the pre-

scribing practitioner, on a valid prescription order that the prescribing practitioner has determined that a compounded drug product is needed by the identified individual patient, subject to clause (ii); or

''(II) in limited quantities before the receipt of such valid prescription orders for such individual patients when based on a history of the compounding pharmacist or physician receiving such valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

''(aa) the compounding pharmacist or physician; and

''(bb)(AA) such individual patients for whom such prescription orders will be provided; or

''(BB) the practitioners who will write such prescription orders.

"(ii) NOTATION.—A compounding pharmacist or physician may make a notation as described in clause (i)(I)(bb), if the drug approved by the Secretary that the valid prescription order indicates should be dispensed to the individual patient is not immediately available for dispensing to the patient, either because the drug is not stocked or is in short supply, in which case the compounding pharmacist or physician may dispense a quantity of a compounded drug product only in a quantity necessary to ensure the health and safety of the patient through the time reasonably expected to be required to acquire the drug approved by the Secretary.

"(C) DISPENSING BY COMPOUNDING PHARMACIST OR PHYSICIAN.—A compounded drug product shall be dispensed to the individual patient for which the drug product was prescribed—

"(i) on receipt of the valid prescription order described in subparagraph (B)(i)(I); and

"(ii) by the compounding pharmacist or physician, unless the patient is an inpatient at a health care facility, such as a hospital.

"(D) BULK DRUG SUBSTANCES.—A drug product shall be compounded using bulk drug substances that—

"(i)(I) are drug substances that are components of drugs approved by the Secretary;

"(II) if the drug substance is not a component of a drug approved by the Secretary, comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or

"(III) if the drug substance is not a component of a drug approved by the Secretary and such a monograph does not exist, appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (e);

"(ii) are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(iii) are accompanied by valid certificates of analysis for each bulk drug substance (which certificates shall be maintained for a period of not less than 2 years after the drug product is dispensed or the drug substance is disposed of, whichever is later).

"(E) OTHER INGREDIENTS.—Ingredients (other than bulk drug substances) that are used in the compounding of a drug product shall—

"(i) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists;

"(ii) comply with the standards of the United States Pharmacopoeia chapter on pharmacy compounding; and

"(iii)(I) be listed in the Inactive Ingredient Guide of the Food and Drug Administration as approved in a product with

the same route of administration and within the potency range listed; and

''(II) not be identified as inappropriate for such a drug product on the list published by the Secretary in the Federal Register as provided for in subsection (e)(3).

''(F) STERILE DRUG PRODUCTS.—A sterile drug product shall be compounded—

''(i) solely from ingredients that are—

''(I) sterile; and

''(II) tested and determined by the compounding pharmacist or physician to be free of endotoxins or other filth that may make the drug product injurious to health; and

''(ii) in conformity with—

''(I) standards for sterile compounding established by the Secretary by regulation; or

''(II) if such regulations do not exist, standards of the United States Pharmacopoeia for sterile compounding.

"(G) REQUIRED DISCLOSURES IN LABELING.—

"(i) IN GENERAL.—A compounded drug product shall be dispensed with labeling containing—

"(I) the statement 'This drug was made specifically for you, because your health care provider determined that no FDA-approved product would suit your needs. It must comply with Federal and State pharmacy guidelines for preparing drugs, but is not required to meet the safety, efficacy, or manufacturing standards for FDA-approved drugs. If you have questions about this medication, ask your health care provider.';

"(II) if the drug product is a sterile drug product, the additional statement 'This drug was not prepared using FDA's manufacturing standards for sterile drugs';

"(III) the date on which the drug was compounded;

''(IV) the name of the licensed compounding pharmacist or compounding physician; and

''(V) relevant information from labeling, including from medication guides, required by the Secretary to be provided to patients when a drug approved by the Secretary with an active ingredient used in the compounded drug product is dispensed to patients.

''(ii) NONAPPLICATION.—Clause (i)(II) shall not apply to the labeling of a sterile drug product if the facility in which the sterile drug product is compounded is—

''(I) registered under section 510; and

''(II) found by the Secretary, after an inspection under section 704, to be in compliance with the requirements of section 501(a)(2)(B) for manufacturing sterile drug products.

''(H) REQUIRED DISCLOSURES IN ADVERTISING.—

"(i) REQUIRED STATEMENT FOR DIRECT-TO-CONSUMER ADVERTISING OF A COMPOUNDED DRUG.—Any advertising or promotion directed to consumers of a compounded drug, shall include the following statement that is displayed or stated prominently and conspicuously: 'This drug can be made specifically for you by a pharmacist if your health care provider determines that no FDA-approved product would suit your needs. It must comply with Federal and State pharmacy guidelines for preparing drugs, but is not required to meet safety and efficacy standards for FDA-approved drugs. If you have questions about this medication, ask your health care provider.'.

"(ii) REQUIRED STATEMENT FOR ADVERTISING OF A COMPOUNDED DRUG TO HEALTH CARE PROVIDERS.—Any advertising or promotion directed to health care providers of a compounded drug shall include the following statement that is displayed or stated prominently and conspicuously: 'This drug can be made specifically

for your patient by a pharmacist if you decide that no FDA-approved product would suit that patient's needs. Such compounded drugs must comply with Federal and State pharmacy guidelines but are not required to meet the safety and efficacy standards for FDA-approved drugs.'.

''(iii) REQUIRED STATEMENT FOR ADVERTISING OF COMPOUNDING SERVICES.—Any advertising or promotion of more than 1 compounded drug or of compounding services by a pharmacist or physician, shall include the following statement that is displayed or stated prominently and conspicuously: 'Compounded drugs can be made specifically for a patient when the patient's health care provider determines that no FDA-approved product meets the patient's needs. Such compounded drugs must comply with Federal and State pharmacy guidelines for preparing drugs, but are not required to meet safety and efficacy standards for FDA-approved drugs. Patients with questions about such medications should ask their health care providers.'.

"(iv) REQUIRED STATEMENT WITH RESPECT TO STERILE DRUG PRODUCTS.—Any advertising or promotion of a compounded drug that is, or of compounding services for, a sterile drug product, shall include, in addition to statements otherwise required under this subsection, the following statement that is displayed or stated prominently and conspicuously: 'The sterile drugs or sterile compounding drug services offered in this promotion are not prepared or performed using FDA's manufacturing standards for sterile drugs.'.

"(v) NONAPPLICATION.—Clause (iv) shall not apply to advertising or promotion for a compounded sterile drug product, or for compounding services for sterile drug products, if the facility in which the drug product is compounded, or in which the compounding occurs, is—

"(I) registered under section 510; and

"(II) found by the Secretary, after an inspection under section 704, to be in compliance with the require-

ments of section 501(a)(2)(B) for manufacturing sterile drug products.

"(2) DRUG PRODUCTS THAT SHALL NOT BE COMPOUNDED.—A drug product shall not be compounded if the drug product is—

"(A) essentially a copy of a drug approved by the Secretary, except in a quantity necessary to ensure the health and safety of a patient through the time reasonably expected to be required to acquire the drug approved by the Secretary;

"(B) a drug that appears on the list published by the Secretary in the Federal Register, and published in section 216.24 of title 21, Code of Federal Regulations (or any successor regulation), of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; or

"(C) identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product.

"(d) SEMI-ANNUAL REPORTS FOR DRUGS DISTRIBUTED OUTSIDE STATE IN WHICH COMPOUNDED.—

"(1) IN GENERAL.—A pharmacist or physician who compounds drugs shall submit to the Secretary a semi-annual report providing, for each distinct compounded drug product distributed by the pharmacist or physician outside the State in which such pharmacist or physician compounded the drug product—

"(A) the name of the drug product as ordered on a prescription;

"(B) the generic names of all ingredients, and the chemical names of all ingredients without generic names included in the drug product;

"(C) the number of doses of the drug product distributed by such pharmacist or physician outside such State;

"(D) the States to which the drug product was distributed;

"(E) the number of doses of the drug product distributed by such pharmacist or physician within the State in which such pharmacist or physician compounded the drug product; and

"(F) all known serious adverse events associated with use of the drug product.

"(2) STATE BOARDS OF PHARMACY AND MEDICINE.—The Secretary shall share the reports described under paragraph (1) with State boards of pharmacy and medicine, as appropriate, and work with such boards to—

"(A) discourage the distribution of inordinate amounts of compounded drug products in interstate commerce; and

"(B) encourage appropriate State investigation of complaints relating to compounded drug products distributed outside such State.

"(e) REGULATIONS AND IMPLEMENTATION.—

"(1) IN GENERAL.—The Secretary shall issue regulations to implement subsections (c)(1)(D)(i)(III), (c)(2)(B), and (c)(2)(C). Before issuing regulations to implement such subsections, the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, consumer organizations, and other experts selected by the Secretary.

''(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (c)(1)(D)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

''(3) COMPOUNDING RESTRICTION LIST.—The Secretary, after providing for not less than 6 months of public review and comment, shall publish in the Federal Register a list of active and inactive ingredients and uses of ingredients that may compromise the safety or efficacy of a compounded drug product, including allergens or other substances that must be absent from some or all compounded drug products, chemicals that should not be used in some or all compounding processes, ingredients that should not be combined, or maximum levels of individual ingredients in a compounded drug product. The Secretary

shall update the list not less often than once every 2 years.

''(4) GUIDANCE ON MEDICAL NEED.—The Secretary, in consultation with physicians, other health care providers licensed to prescribe drugs, and compounding pharmacists, shall develop and issue a guidance document that identifies—

''(A) the types of medical needs that justify the use of a compounded drug, such as—

''(i) the need for a drug without a specified inactive ingredient or without an inactive ingredient from a specified source (such as milk or soy) because the patient is allergic to such ingredient or ingredients from such source and the drug approved by the Secretary contains such an ingredient;

''(ii) the need for a drug in a dosage form, route of administration, or strength that differs from drugs approved by the Secretary; and

''(iii) the need for a drug when there is a shortage of the drug approved by the Secretary; and

"(B) the means by which a licensed prescribing physician or other health care provider can notate such a medical need on a prescription form.

"(5) INORDINATE AMOUNTS.—The Secretary may issue a guidance document to describe the term 'inordinate amounts of compounded drug products in interstate commerce'.

"(6) ELECTRONIC PRESCRIBING.—When developing technical standards for electronic prescribing systems, the Secretary shall develop a standard so that a system certified by the Secretary shall allow a licensed prescribing physician or other health care provider to—

"(A) prescribe a compounded drug;

"(B) indicate the nature of the medical need that requires the use of a compounded drug rather than a drug approved by the Secretary; and

"(C) indicate that the prescribing provider has discussed the risks and benefits of using the compounded drug with the patient.

"(7) MEDICAL NEED EXCEPTION.—

"(A) IN GENERAL.—The Secretary shall by regulation identify circumstances in which med-

ical need justifies an exception from compliance with 1 or more requirements of this section, such as when a bulk drug substance that meets the requirements of subsection (c)(1)(D) or an ingredient other than bulk drug substance that meets the requirements of subsection (c)(1)(E) is not available to compound a drug product.

''(B) NOTIFICATION AND CONFIRMATION.—A regulation promulgated pursuant to subparagraph (A) shall require that, to use an exception—

''(i) the compounding pharmacist or physician notify the prescribing practitioner who completed the valid prescription order indicating that a compounded drug product is needed by the identified patient, of the nature of the exception to be used;

''(ii) the prescribing physician confirm the need for the compounded drug product even given the nature of the exception to be used;

''(iii) the compounding pharmacist or physician make a notation of such confirmation on such prescription order; and

''(iv) such patient be informed, both orally when the drug is dispensed or administered and in the drug label, that the compounded drug product was not compounded in compliance with the normal standards for compounding drugs.''.

SEC. 3. CONFORMING AMENDMENTS.

(a) INSPECTION.—Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended by adding at the end the following:

''(4) Notwithstanding any other provision of this subsection, the provisions of the third sentence of paragraph (1) shall apply to a retail pharmacy that compounds drug products or dispenses compounded drug products, to ensure compliance with section 503A.''.

(b) ADVERTISEMENTS.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by striking ''or distributor'' each place it appears and inserting ''distributor, or compounder''.

(c) MODIFICATION OF MEDWATCH FORMS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall modify the Medwatch mandatory and voluntary forms, and other drug safety surveillance systems, to facilitate

the gathering of information on, and correct attribution of, adverse events associated with the use of compounded drug products.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2008 through 2012.