119TH CONGRESS
2D SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to homeopathic drug products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. TUBERVILLE (for himself and Mr. LEE) 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 with respect to homeopathic drug products, and for other purposes.

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 ''Homeopathic Drug Product Safety, Quality, and Transparency Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Homeopathic drug products have a long history of use in the United States and are prepared

according to methods different from other drugs regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) Federal regulatory oversight of homeopathic drug products has been implemented through mechanisms other than premarket approval, reflecting the distinct characteristics, methods of preparation, risk profile, and patterns of use of such products.

(3) A clear statutory framework consistent with the historical regulatory treatment of homeopathic drug products will promote safety, quality, and access, ensure consistent regulation, and reduce uncertainty.

SEC. 3. REGULATION OF HOMEOPATHIC DRUG PRODUCTS.

(a) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) in paragraph (p), by striking ''except a new animal drug or an animal feed bearing or containing a new animal drug'' each place it appears and inserting ''except a new animal drug, an animal feed bearing or containing a new animal drug, or a homeopathic drug product'';

(2) in paragraph (v), by adding at the end the following: ''A homeopathic drug product is not a new animal drug.''; and

(3) by adding at the end the following:

''(tt)(1) The term 'homeopathic drug product' means a drug that—

''(A) contains 1 or more homeopathic ingredients; and

''(B) contains no other active ingredient.

''(2) The term 'homeopathic ingredient' means an ingredient—

''(A) listed in the Homeopathic Pharmacopoeia of the United States or a State homeopathic formulary; or

''(B) prepared pursuant to—

''(i) homeopathic manufacturing methods and safety and quality standards described in the Homeopathic Pharmacopoeia of the United States or any other officially recognized homeopathic pharmacopoeia; and

''(ii) other standards recognized by the Secretary.''.

(b) SAFETY, QUALITY, AND LABELING REQUIREMENTS FOR HOMEOPATHIC DRUG PRODUCTS.—

(1) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 503D (21 U.S.C. 353d) the following:

"SEC. 503E. HOMEOPATHIC DRUG PRODUCTS.

"(a) IN GENERAL.—Homeopathic drug products constitute a distinct category of drugs and shall be regulated by the Secretary in a manner that is appropriate to their characteristics, methods of preparation, distinct risk profile, and patterns of use.

"(b) PROVISIONS APPLICABLE TO HOMEOPATHIC DRUG PRODUCTS.—The only sections of this chapter that shall apply to homeopathic drug products are this section and sections 501, 502, and 510. Homeopathic drug products shall not be subject to section 505 and shall not be required to be the subject of an approved application under such section.

"(c) SAFETY AND QUALITY STANDARDS.—The Secretary shall regulate homeopathic drug products using standards appropriate to such products, taking into account the Homeopathic Pharmacopoeia of the United States and other standards recognized by the Secretary.

"(d) FINAL RULE ESTABLISHING CURRENT GOOD MANUFACTURING PRACTICES AND LABELING REQUIREMENTS.—

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of this section, the Secretary shall issue a final rule that establishes current good manufacturing practices and labeling requirements for homeopathic drug products.

''(2) REQUIREMENT.—In establishing current good manufacturing practices and labeling requirements pursuant to paragraph (1), the Secretary shall ensure that such requirements—

''(A) are appropriate;

''(B) do not conflict with standards established under subsection (c); and

''(C) do not impose standards for which there are no current and generally available analytical methodologies for homeopathic drug products.

''(e) FINAL AND INTERMEDIATE PRODUCT TESTING.—

''(1) FINAL PRODUCT TESTING.—A finished homeopathic drug product shall be exempt from the requirement for a laboratory determination of identity and strength of each active ingredient described in section 211.165(a) of title 21, Code of Federal Regulations (or any successor regulation), but shall continue to be required to meet other final specifications, such as testing for contaminants and defects of the finished product, consistent with this section.

''(2) INTERMEDIATE TESTING FOR CERTAIN STARTING MATERIALS.—

"(A) IN GENERAL.—The manufacturer of a homeopathic drug product made from a starting material containing a substance which may present a substantial risk of illness or injury in its undiluted form shall ensure and document that the quantity of such substance in an intermediate level preparation used to make all further attenuations does not exceed a safe level, as determined by the Secretary.

"(B) SAFE LEVEL DEFINED.—In this paragraph, the term 'safe level' means—

"(i) a level set by nationally recognized standards for safety, [such as] the Homeopathic Pharmacopoeia of the United States or an accredited voluntary consensus standard for homeopathic drug products; or

"(ii) in the absence of a standard described in clause (i), a level below an analytically detectable presence.

"(f) LABELING; INTENDED USE; CLAIMS.—

"(1) LABELING REQUIREMENTS.—Homeopathic drug products shall comply with labeling requirements under this Act, except that dosage units may be expressed in homeopathic attenuations and sub-

stantiation may include traditional homeopathic evidence.

''(2) INTENDED USE.—

''(A) IN GENERAL.—Homeopathic drug products intended for retail sale shall contain—

''(i) 1 or more intended uses for 1 or more self-limiting conditions; and

''(ii) the following statement: 'These intended uses have not been evaluated by the Food and Drug Administration. This product is intended for traditional homeopathic uses.'.

''(B) EXCEPTION.—A homeopathic drug product not intended for retail sale shall not be required to contain 1 or more intended uses.

''(3) CLAIMS.—Any claim made with respect to a homeopathic drug product—

''(A) shall be supported by competent and reliable evidence appropriate to the nature and risk profile of the homeopathic drug product, including traditional homeopathic principles, pharmacopoeial standards, and real-world evidence; and

''(B) that relates to a specific condition shall be preceded by the following: 'Traditionally used for'.

''(4) EFFECT.—A homeopathic drug product that contains an intended use, or for which a claim is made, that is in compliance with this Act may not be considered a false advertisement or an unfair or deceptive act or practice in or affecting commerce for purposes of section 5 or 12 of the Federal Trade Commission Act.

''(g) HOMEOPATHIC DRUG PRODUCT ADVISORY COMMITTEE.—

''(1) ESTABLISHMENT.—The Secretary shall establish a Homeopathic Drug Product Advisory Committee (in this subsection referred to as the 'Committee') to provide advice and recommendations regarding the regulation of homeopathic drug products.

''(2) MEMBERSHIP.—In appointing members of the Committee, the Secretary shall ensure that the membership of the Committee reflects a proper balance of perspectives from the homeopathic practitioner, manufacturer, education, and consumer communities, including large and small domestic manufacturers, licensed and certified health care practi-

tioners with not less than 3 years of active homeopathic practices and representatives of homeopathic standards and consumer organizations.

''(3) DUTIES.—With respect to the regulation of homeopathic drug products under this Act, the Committee—

''(A) shall—

''(i) provide recommendations on safety, quality, and labeling standards;

''(ii) advise on appropriate regulatory approaches;

''(iii) review guidance and rulemaking; and

''(iv) evaluate relevant scientific, traditional, and real-world evidence; and

''(B) may investigate any report of a homeopathic drug product to the Food and Drug Administration Adverse Event Monitoring System to assist in postmarket surveillance.

''(4) TRIGGERED CONSULTATION.—The Secretary shall consult with the Committee prior—

''(A) to issuing or revising guidance regarding homeopathic drug products;

''(B) to initiating or finalizing rulemaking regarding homeopathic drug products;

''(C) to adopting or revising good manufacturing practice requirements applicable to homeopathic drug products; or

''(D) to undertaking any enforcement initiative of general applicability with respect to homeopathic drug products.

''(5) ADMINISTRATIVE RECORD.—The Secretary shall include in the administrative record a written response to significant recommendations of the Committee.

''(6) LIMITATION.—Nothing in this subsection shall require the Secretary to follow a recommendation of the Committee.

''(7) TERMINATION.—Notwithstanding section 1013 of title 5, United States Code, the Committee shall terminate on the date that is 7 years after the date on which the Committee is established.''.

(2) MISBRANDING.—

(A) DIETARY SUPPLEMENTS.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(z) If it is a dietary supplement and its labeling bears the term 'homeopathic', 'homeopathy', 'homeopath', or such similar term as is determined by the Secretary.''.

(B) DRUGS.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(hh) If it is a drug that is not a homeopathic drug product, and its labeling bears the term 'homeopathic', 'homeopathy', 'homeopath', or such similar term as is determined by the Secretary.''.

(C) COSMETICS.—Section 602 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 362) is amended by adding at the end the following:

''(g) If it is a cosmetic and its labeling bears the term 'homeopathic', 'homeopathy', 'homeopath', or such similar term as is determined by the Secretary.''.

(c) CONFORMING AMENDMENTS.—

(1) PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.—Section 581(13) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360eee(13)) is amended by striking ''homeopathic drugs marketed in accordance with applicable guidance under this Act'' and inserting ''homeopathic drug products marketed in accordance with this Act''.

(2) SERIOUS ADVERSE EVENT REPORTING.—Section 760 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa) is amended—

(A) in the section heading, by inserting ''**AND HOMEOPATHIC DRUG PRODUCTS**'' after ''**NONPRESCRIPTION DRUGS**'';

(B) by inserting ''or homeopathic drug product'' after ''nonprescription drug'' each place it appears (other than in subsection (a)(2)); and

(C) by inserting ''or homeopathic drug products'' after ''nonprescription drugs'' each place it appears.

(3) EXEMPTION FROM REGULATION OF BIOLOGICAL PRODUCTS.—Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by adding at the end the following: ''Such term does not include a homeopathic drug product (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act).''.

(d) WITHDRAWAL OF GUIDANCE.—The guidance of the Food and Drug Administration entitled ''Homeopathic Drug Products; Guidance for FDA Staff and Industry'' (87 Fed. Reg. 75054 (December 7, 2022)) shall have no force or effect.