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119TH CONGRESS
2D SESSION

H. R. 7050

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 14, 2026

Mr. SESSIONS (for himself, Mr. KENNEDY of Utah, and Mr. JACKSON of Illinois) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Homeopathic Drug Product Safety, Quality, and Transparency Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. PURPOSE; SENSE OF CONGRESS.

(a) PURPOSE.—The purpose of this Act is to address consumer and practitioner needs for continued access to homeopathic drug products that meet requirements for safety, quality, and transparency.

(b) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) homeopathic medicines are important to millions of American consumers, and continued consumer access to safe homeopathic products is best ensured by enacting a distinct statutory pathway for the regulation of homeopathic drug products; and

(2) while the Federal Government should continue to take appropriate action against products that are adulterated or misbranded, Federal agencies should not impose regulatory barriers that unreasonably limit or prevent consumer and health care provider access to safe products and accurate information.

SEC. 3. 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 inserting before the period at the end the following: '', and that a homeopathic drug product is not a new animal drug''; and

(3) by adding at the end the following:

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

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

''(2) contains no other active ingredient.

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

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

''(2) prepared pursuant to homeopathic safety and quality standards described in—

''(A) the Homeopathic Pharmacopoeia of the United States or any other officially recognized homeopathic pharmacopoeia; or

''(B) any accredited voluntary consensus standard for homeopathic drug products, as determined by the Secretary in compliance with section 12(d) of the National Technology Transfer and Advancement Act of 1995.''.

SEC. 4. SAFETY, QUALITY, AND TRANSPARENCY REQUIREMENTS FOR HOMEOPATHIC DRUG PRODUCTS.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503D (21 U.S.C. 353d) the following:

''SEC. 503E. HOMEOPATHIC DRUG PRODUCTS.

''(a) PROVISIONS APPLICABLE TO HOMEOPATHIC DRUG PRODUCTS.—

''(1) CHAPTER V PROVISIONS.—No section of this chapter shall apply to homeopathic drug products except this section and sections 501, 502, and 510.

''(2) REQUIREMENTS FOR ALL PROVISIONS.—No provision of law, a regulation, or a guidance document (including sections 501, 502, and 510 and any applicable provisions of this Act outside of this chapter) shall apply to homeopathic drug products unless such provision—

''(A) does not conflict with this section; and

''(B) does not impose standards that are in conflict with standards in the Homeopathic Pharmacopoeia of the United States or in an accredited voluntary consensus standard for homeopathic drug products, as determined by the Secretary in compliance with section 12(d) of the National Technology Transfer and Advancement Act of 1995.

''(b) ADULTERATION; GOOD MANUFACTURING PRACTICE STANDARDS.—

''(1) ADULTERATION.—A homeopathic drug product shall be deemed to be adulterated if it does not comply with—

''(A) the safety and quality standards and manufacturing practices described in—

''(i) the Homeopathic Pharmacopoeia of the United States or any other officially recognized homeopathic pharmacopoeia; or

''(ii) an accredited voluntary consensus standard for homeopathic drug products, as determined by the Secretary in compliance with section 12(d) of the

National Technology Transfer and Advancement Act of 1995; or

''(B) in the case that no standard or manufacturing practice described in subparagraph (A) applies to such homeopathic drug product, the regulations described in paragraph (2).

''(2) ALTERNATIVE REGULATIONS.—The regulations described in this paragraph are the following:

''(A) Good manufacturing practice regulations promulgated under section 501(a)(2) or related guidance documents, provided that such regulations or related guidance documents do not conflict with any other provision of this section.

''(B) In the case that no regulation described in subparagraph (A) applies to the homeopathic drug product, a new good manufacturing practice regulation, which shall be promulgated by the Secretary after notice and opportunity for public comment pursuant to chapter 5 of title 5, United States Code—

''(i) that does not conflict with any other provision of this section;

''(ii) that is specific to and appropriate for homeopathic drug products; and

"(iii) with respect to which the Secretary has requested and received a favorable recommendation from the Homeopathic Drug Product Advisory Committee.

"(3) PETITION FOR EXEMPTION, VARIANCE, OR ALTERNATIVE STANDARD OR PRACTICE.—

"(A) PETITION.—A manufacturer of a homeopathic drug product subject to a good manufacturing practice regulation may submit to the Secretary a petition for an exemption, variance, or alternative standard or practice with respect to such product. The Secretary shall refer such petition to the Homeopathic Drug Product Advisory Committee, which shall report its recommendation to the Secretary not later than 60 days after receiving such petition.

"(B) DEADLINE FOR APPROVAL.—The Secretary shall make a decision on a petition submitted under subparagraph (A) not later than 180 days after the submission of the petition. If the Secretary fails to make a decision on such a petition within such 180-day period, the petition shall be deemed approved and the proposed exemption, variance, or alternative standard or practice established.

''(C) STANDARD FOR APPROVAL.—The Secretary may approve a petition submitted under subparagraph (A) and establish the proposed exemption, variance, or alternative standard or practice with respect to the homeopathic drug product only if such exemption, variance, or alternative standard or practice does not affect the safety of the homeopathic drug product.

''(D) JUDICIAL REVIEW.—For the purposes of chapter 7 of title 5, United States Code, a decision of the Secretary on a petition submitted under subparagraph (A) shall be considered final agency action.

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

''(A) 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.

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

''(i) 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 amount 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 under this subparagraph.

''(ii) SAFE LEVEL DEFINED.—In this subparagraph, the term 'safe level' means—

''(I) a level set by nationally recognized standards for safety, including the Homeopathic Pharmacopoeia of the United States or an accredited voluntary consensus standard for homeopathic drug products, as determined by the Secretary in compliance

with section 12(d) of the National Technology Transfer and Advancement Act of 1995; or

''(II) in the absence of a standard described in subclause (I), a level below an analytically detectable presence.

''(iii) PUBLICATION OF SAFE LEVELS.—The Secretary may issue an order, notice of which shall be published in the Federal Register, establishing a safe level, based on appropriate scientific and technical data, for a substance under clause (i). Such notice shall include—

''(I) a statement of the basis for the Secretary's finding that there is a reasonable probability that the substance may present a substantial risk of illness or injury in its undiluted form;

''(II) a statement of the basis for the establishment of the safe level, including any available methods to establish such level; and

"(III) a request for public comments.

"(c) MISBRANDING.—

"(1) IN GENERAL.—A drug shall be deemed to be misbranded if—

"(A) it is not a homeopathic drug product, and its labeling bears the term 'homeopathic', 'homeopathy', 'homeopath', or such similar term as determined by the Secretary; or

"(B) it is a homeopathic drug product, and its labeling does not comply with the requirements described in paragraph (2).

"(2) LABELING REQUIREMENTS.—With respect to the labeling of a homeopathic drug product, the requirements described in this paragraph are the requirements for the labeling of a drug under this Act, subject to the following:

"(A) The labeling need not adhere to any requirement that does not apply to homeopathic drug products under subsection (a).

"(B) The dosage units of the homeopathic ingredients shall be expressed as attenuations particular to homeopathic ingredients (such as '3x' or '6c').

''(C) If the homeopathic drug product is not intended for retail sale, the label of such product need not contain a purpose or indication for use.

''(D) If the homeopathic drug product is intended for retail sale, the label of such product shall contain—

''(i) 1 or more purposes or indications for use for self-limiting conditions that are supported by—

''(I) the Homeopathic Pharmacopoeia of the United States, an official pharmacopeia of another country where the practice of homeopathy is licensed or certified, or an accredited voluntary consensus standard for homeopathic drug products, as determined by the Secretary in compliance with section 12(d) of the National Technology Transfer and Advancement Act of 1995;

''(II) a traditional homeopathic reference, including a homeopathic Materia Medica in general use by licensed medical practitioners who prac-

tice homeopathy or certified homeopaths in the United States or another country;

"(III) a peer-reviewed medical journal, including any homeopathic medical journal;

"(IV) citation to scientific evidence, including clinical data or trials;

"(V) beneficial clinical usage documented by clinical reports from national or international organizations, professionally recognized publications of clinical indications and contraindications, national or international instructional courses providing training in the use of homeopathic drug products, or professional peer review presentations of physicians' usage results with homeopathic drug products at local, county, State, national, or international meetings; or

"(VI) quality real-world data that provides sufficient evidence to support such purposes or indications for use; and

"(ii) adjacent to such purposes or indications for use, the following statement: 'These indications have not been evaluated by the Food and Drug Administration. This product is intended for traditional homeopathic uses.'.

"(E) The labeling shall not be considered false or misleading for the purposes of section 502(a)(1) due to the inclusion of a purpose or indication for use that is supported by any source described in subclauses (I) through (VI) of subparagraph (D)(i).

"(F)(i) Subject to clause (ii), the label shall describe—

"(I) the source relied upon for each purpose or indication for use under subparagraph (D)(i); and

"(II) if applicable, the name and place of business of any parent, subsidiary, or affiliate company of the manufacturer of the homeopathic drug product, if under common ownership or control.

"(ii) If the label has insufficient space for the information required by clause (i), in lieu of such information the label may contain a quick

response code (commonly known as a 'QR code') or similar mechanism that links to a publicly accessible website containing such information.

''(3) APPLICATION OF OTHER MISBRANDING-RELATED PROVISIONS.—

''(A) FTC ACT.—Labeling or marketing claims associated with a homeopathic drug product that are in compliance with this subsection 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.

''(B) OTHER PROVISIONS OF FEDERAL OR STATE LAW.—If a homeopathic drug product's label, labeling, advertising, and marketing materials are in compliance with this subsection, no other substantiation requirement in Federal or State law shall apply to such product.

''(C) PRIVATE RIGHTS OF ACTION.—No private right of action for false or deceptive advertising may be predicated on the lack of clinical trials to substantiate indications for a homeopathic drug product.

''(d) REGISTRATION AND LISTING.—For purposes of drug establishment registration and drug listing under section 510, the Secretary shall—

''(1) designate a homeopathic drug product establishment as a 'homeopathic' establishment; and

''(2) list a homeopathic drug product as 'homeopathic', with no other designation.

''(e) NO PREMARKET APPROVAL.—The Secretary may not require premarket approval of a homeopathic drug product.

''(f) 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 advise the Secretary on the regulation of homeopathic drug products.

''(2) MEMBERSHIP.—

''(A) IN GENERAL.—Subject to subparagraph (B), the Committee shall be composed of 10 members, to be appointed by the Secretary, as follows:

''(i) 1 representative from an organization of homeopathic product consumers that has been operating for a minimum of

3 continuous years with a minimum of 10,000 members, who shall serve as the Chair of the Committee.

''(ii) 1 representative from a domestic homeopathic drug manufacturer that produces at least 50 distinct homeopathic drug products and has no fewer than 50 employees.

''(iii) 1 representative from a domestic homeopathic drug manufacturer that produces at least 50 distinct homeopathic drug products and has no more than 50 employees.

''(iv) 1 representative from the Homeopathic Pharmacopoeia Convention of the United States.

''(v) 1 representative from an accredited voluntary consensus standards body for homeopathic drug products that has been operating for a minimum of 3 continuous years.

''(vi) 1 licensed medical doctor (M.D.) or doctor of osteopathy (D.O.) who holds a Diplomate, American Board of Homeopathic Medicine (DABHM) or Diplomate,

Homeotherapeutics (DHt) and who maintains a homeopathic practice that has been in operation for a minimum of 3 continuous years.

''(vii) 1 licensed naturopathic doctor (N.D.) who holds a Diplomate, American Board of Homeopathic Medicine (DABHM) or Diplomate, Homeopathic Academy of Naturopathic Physicians (DHANP) and who maintains a homeopathic practice that has been in operation for a minimum of 3 continuous years.

''(viii) 1 licensed pharmacist or chemist actively engaged in the preparation of homeopathic drug products for a minimum of 3 continuous years.

''(ix) 1 licensed veterinarian certified by the Academy of Veterinary Homeopathy or accredited by a recognized homeopathy institution who maintains a practice that has been in operation for a minimum of 3 continuous years.

''(x) The Commissioner of Food and Drugs.

"(B) ALTERNATIVE MEMBERS.—If the Secretary is unable to find a suitable individual to serve in the position of a representative described in clauses (i) through (ix), the other members of the Committee may appoint to such position, by majority vote, such other expert in the field of homeopathic drug products as the Committee determines appropriate.

"(C) BALANCE OF MEMBERSHIP.—In making appointments under subparagraph (A), the Secretary shall ensure that the membership of the Committee reflects a proper balance of perspectives from the homeopathic practitioner, manufacturer, and consumer communities.

"(D) NO COMPENSATION.—The members of the Committee shall serve without compensation.

"(3) FREQUENCY OF SESSIONS.—The Secretary shall call the Committee into session at such times and in such places as the Secretary determines appropriate, but in no case less frequently than once every 3 months.

"(4) INVESTIGATIONS.—The Committee may investigate any report of a homeopathic drug prod-

uct to the FDA Adverse Event Reporting System to assist in post-market surveillance.

''(5) TERMINATION.—Section 1013 of chapter 5, United States Code (relating to termination of advisory committees), shall not apply to the Committee.

''(g) INSPECTORS.—All Federal inspectors whose duties or authorities extend to homeopathic drug products shall be familiar with the requirements of this section, including the safety and quality manufacturing standards in the Homeopathic Pharmacopoeia of the United States or an accredited voluntary consensus standard for homeopathic drug products.

''(h) NON-PREEMPTION OF STATE LAW ON PRACTICE OF HOMEOPATHY.—Nothing in this section shall be construed to preempt, limit, or interfere with State jurisdiction concerning the practice of homeopathy and related activities within the scope of the health care professional-patient relationship.

''(i) BURDEN OF PROOF.—The United States shall bear the burden of proof to establish a violation of this section. Any Federal court with jurisdiction shall decide any matter under this section on a de novo basis.''.

SEC. 5. CONFORMING AMENDMENTS.

(a) 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''.

(b) SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.—Section 760(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa(a)(2)) is amended to read as follows:

''(2) NONPRESCRIPTION DRUG.—The term nonprescription drug—

''(A) means a drug that is—

''(i) not subject to section 503(b); and

''(ii) not subject to approval in an application submitted under section 505; and

''(B) includes a homeopathic drug product.''.

(c) 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).''.

SEC. 6. WITHDRAWAL OF GUIDANCE.

The guidance of the Food and Drug Administration titled ''Homeopathic Drug Products; Guidance for Food and Drug Administration Staff and Industry; Availability'' (87 Fed. Reg. 75054; published on December 7, 2022) shall have no force or effect with respect to homeopathic drug products (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), as amended by section 3(3)).

SEC. 7. SEVERABILITY.

If any provision of this Act (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.

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