

119TH CONGRESS
2D SESSION

S. 4692

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

JUNE 4, 2026

Mr. TUBERVILLE (for himself and Mr. LEE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Homeopathic Drug
5 Product Safety, Quality, and Transparency Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Homeopathic drug products have a long his-
9 tory of use in the United States and are prepared

1 according to methods different from other drugs reg-
2 ulated under the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 301 et seq.).

4 (2) Federal regulatory oversight of homeopathic
5 drug products has been implemented through mech-
6 anisms other than premarket approval, reflecting the
7 distinct characteristics, methods of preparation, risk
8 profile, and patterns of use of such products.

9 (3) A clear statutory framework consistent with
10 the historical regulatory treatment of homeopathic
11 drug products will promote safety, quality, and ac-
12 cess, ensure consistent regulation, and reduce uncer-
13 tainty.

14 **SEC. 3. REGULATION OF HOMEOPATHIC DRUG PRODUCTS.**

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

17 (1) in paragraph (p), by striking “except a new
18 animal drug or an animal feed bearing or containing
19 a new animal drug” each place it appears and in-
20 serting “except a new animal drug, an animal feed
21 bearing or containing a new animal drug, or a home-
22 opathic drug product”;

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

1 (3) by adding at the end the following:

2 “(tt)(1) The term ‘homeopathic drug product’ means
3 a drug that—

4 “(A) contains 1 or more homeopathic ingredi-
5 ents; and

6 “(B) contains no other active ingredient.

7 “(2) The term ‘homeopathic ingredient’ means an in-
8 gredient—

9 “(A) listed in the Homeopathic Pharmacopoeia
10 of the United States or a State homeopathic for-
11 mulary; or

12 “(B) prepared pursuant to—

13 “(i) homeopathic manufacturing methods
14 and safety and quality standards described in
15 the Homeopathic Pharmacopoeia of the United
16 States or any other officially recognized homeo-
17 pathic pharmacopoeia; and

18 “(ii) other standards recognized by the
19 Secretary.”.

20 (b) SAFETY, QUALITY, AND LABELING REQUIRE-
21 MENTS FOR HOMEOPATHIC DRUG PRODUCTS.—

22 (1) IN GENERAL.—Subchapter A of chapter V
23 of the Federal Food, Drug, and Cosmetic Act is
24 amended by inserting after section 503D (21 U.S.C.
25 353d) the following:

1 **“SEC. 503E. HOMEOPATHIC DRUG PRODUCTS.**

2 “(a) IN GENERAL.—Homeopathic drug products con-
3 stitute a distinct category of drugs and shall be regulated
4 by the Secretary in a manner that is appropriate to their
5 characteristics, methods of preparation, distinct risk pro-
6 file, and patterns of use.

7 “(b) PROVISIONS APPLICABLE TO HOMEOPATHIC
8 DRUG PRODUCTS.—The only sections of this chapter that
9 shall apply to homeopathic drug products are this section
10 and sections 501, 502, and 510. Homeopathic drug prod-
11 ucts shall not be subject to section 505 and shall not be
12 required to be the subject of an approved application
13 under such section.

14 “(c) SAFETY AND QUALITY STANDARDS.—The Sec-
15 retary shall regulate homeopathic drug products using
16 standards appropriate to such products, taking into ac-
17 count the Homeopathic Pharmacopoeia of the United
18 States and other standards recognized by the Secretary.

19 “(d) FINAL RULE ESTABLISHING CURRENT GOOD
20 MANUFACTURING PRACTICES AND LABELING REQUIRE-
21 MENTS.—

22 “(1) IN GENERAL.—Not later than 3 years
23 after the date of enactment of this section, the Sec-
24 retary shall issue a final rule that establishes cur-
25 rent good manufacturing practices and labeling re-
26 quirements for homeopathic drug products.

1 “(2) REQUIREMENT.—In establishing current
2 good manufacturing practices and labeling require-
3 ments pursuant to paragraph (1), the Secretary
4 shall ensure that such requirements—

5 “(A) are appropriate;

6 “(B) do not conflict with standards estab-
7 lished under subsection (c); and

8 “(C) do not impose standards for which
9 there are no current and generally available an-
10 alytical methodologies for homeopathic drug
11 products.

12 “(e) FINAL AND INTERMEDIATE PRODUCT TEST-
13 ING.—

14 “(1) FINAL PRODUCT TESTING.—A finished ho-
15 meopathic drug product shall be exempt from the re-
16 quirement for a laboratory determination of identity
17 and strength of each active ingredient described in
18 section 211.165(a) of title 21, Code of Federal Reg-
19 ulations (or any successor regulation), but shall con-
20 tinue to be required to meet other final specifica-
21 tions, such as testing for contaminants and defects
22 of the finished product, consistent with this section.

23 “(2) INTERMEDIATE TESTING FOR CERTAIN
24 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-

1 stantiation may include traditional homeopathic evi-
2 dence.

3 “(2) INTENDED USE.—

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

6 “(i) 1 or more intended uses for 1 or
7 more self-limiting conditions; and

8 “(ii) the following statement: ‘These
9 intended uses have not been evaluated by
10 the Food and Drug Administration. This
11 product is intended for traditional homeo-
12 pathic uses.’.

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

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

18 “(A) shall be supported by competent and
19 reliable evidence appropriate to the nature and
20 risk profile of the homeopathic drug product,
21 including traditional homeopathic principles,
22 pharmacopoeial standards, and real-world evi-
23 dence; and

1 “(B) that relates to a specific condition
 2 shall be preceded by the following: ‘Tradition-
 3 ally used for’.

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

11 “(g) HOMEOPATHIC DRUG PRODUCT ADVISORY
 12 COMMITTEE.—

13 “(1) ESTABLISHMENT.—The Secretary shall es-
 14 tablish a Homeopathic Drug Product Advisory Com-
 15 mittee (in this subsection referred to as the ‘Com-
 16 mittee’) to provide advice and recommendations re-
 17 garding the regulation of homeopathic drug prod-
 18 ucts.

19 “(2) MEMBERSHIP.—In appointing members of
 20 the Committee, the Secretary shall ensure that the
 21 membership of the Committee reflects a proper bal-
 22 ance of perspectives from the homeopathic practi-
 23 tioner, manufacturer, education, and consumer com-
 24 munities, including large and small domestic manu-
 25 facturers, 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;

1 “(C) to adopting or revising good manufac-
2 turing practice requirements applicable to ho-
3 meopathic drug products; or

4 “(D) to undertaking any enforcement ini-
5 tiative of general applicability with respect to
6 homeopathic drug products.

7 “(5) ADMINISTRATIVE RECORD.—The Secretary
8 shall include in the administrative record a written
9 response to significant recommendations of the Com-
10 mittee.

11 “(6) LIMITATION.—Nothing in this subsection
12 shall require the Secretary to follow a recommenda-
13 tion of the Committee.

14 “(7) TERMINATION.—Notwithstanding section
15 1013 of title 5, United States Code, the Committee
16 shall terminate on the date that is 7 years after the
17 date on which the Committee is established.”.

18 (2) MISBRANDING.—

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

23 “(z) If it is a dietary supplement and its labeling
24 bears the term ‘homeopathic’, ‘homeopathy’, ‘homeopath’,
25 or such similar term as is determined by the Secretary.”.

1 (B) DRUGS.—Section 502 of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 352)
3 is amended by adding at the end the following:
4 “(hh) If it is a drug that is not a homeopathic drug
5 product, and its labeling bears the term ‘homeopathic’,
6 ‘homeopathy’, ‘homeopath’, or such similar term as is de-
7 termined by the Secretary.”.

8 (C) COSMETICS.—Section 602 of the Fed-
9 eral Food, Drug, and Cosmetic Act (21 U.S.C.
10 362) is amended by adding at the end the fol-
11 lowing:

12 “(g) If it is a cosmetic and its labeling bears the term
13 ‘homeopathic’, ‘homeopathy’, ‘homeopath’, or such similar
14 term as is determined by the Secretary.”.

15 (c) CONFORMING AMENDMENTS.—

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

23 (2) SERIOUS ADVERSE EVENT REPORTING.—
24 Section 760 of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 379aa) is amended—

1 (A) in the section heading, by inserting
 2 **“AND HOMEOPATHIC DRUG PRODUCTS”**
 3 after **“NONPRESCRIPTION DRUGS”**;

4 (B) by inserting “or homeopathic drug
 5 product” after “nonprescription drug” each
 6 place it appears (other than in subsection
 7 (a)(2)); and

8 (C) by inserting “or homeopathic drug
 9 products” after “nonprescription drugs” each
 10 place it appears.

11 (3) EXEMPTION FROM REGULATION OF BIO-
 12 LOGICAL PRODUCTS.—Section 351(i)(1) of the Pub-
 13 lic Health Service Act (42 U.S.C. 262(i)(1)) is
 14 amended by adding at the end the following: “Such
 15 term does not include a homeopathic drug product
 16 (as defined in section 201 of the Federal Food,
 17 Drug, and Cosmetic Act).”.

18 (d) WITHDRAWAL OF GUIDANCE.—The guidance of
 19 the Food and Drug Administration entitled “Homeopathic
 20 Drug Products; Guidance for FDA Staff and Industry”
 21 (87 Fed. Reg. 75054 (December 7, 2022)) shall have no
 22 force or effect.

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