

119TH CONGRESS
1ST SESSION

H. R. 2300

To ensure national uniformity with respect to certain requirements relating to preterm infant formula, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 24, 2025

Mrs. HARSHBARGER (for herself and Mr. SCHNEIDER) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To ensure national uniformity with respect to certain requirements relating to preterm infant formula, 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. PRETERM INFANT FORMULA.**

4 (a) STUDY.—

5 (1) IN GENERAL.—The Secretary of Health and
6 Human Services, acting through the Commissioner
7 of Food and Drugs, shall study—

8 (A) the availability of preterm infant for-
9 mula in the United States;

1 (B) Federal and State laws, regulations,
2 orders, and requirements, including under State
3 common law, that relate to preterm infant for-
4 mula, including with respect to—

5 (i) the design, development, clinical
6 testing or investigation, formulation, man-
7 ufacture, distribution, sale, donation, pur-
8 chase, marketing, promotion, packaging,
9 labeling, licensing, and use of preterm in-
10 fant formula; or

11 (ii) any aspect of the safety of
12 preterm infant formula;

13 (C) whether the Federal Food, Drug, and
14 Cosmetic Act (21 U.S.C. 301 et seq.) should be
15 amended to require a manufacturer of preterm
16 infant formula to obtain premarket approval for
17 such formula from the Food and Drug Admin-
18 istration; and

19 (D) if the Secretary recommends such pre-
20 market approval, a process and corresponding
21 requirements for such premarket approval.

22 (2) RECOMMENDATIONS.—Not later than two
23 years after the date of enactment of this Act, the
24 Secretary of Health and Human Services, acting
25 through the Commissioner of Food and Drugs, shall

1 submit to the Congress a report on the results of the
2 study under paragraph (1).

3 (b) TEMPORARY PREEMPTION.—

4 (1) PERIOD OF APPLICABILITY.—This sub-
5 section applies only during the period—

6 (A) beginning on the date of enactment of
7 this Act; and

8 (B) ending on the date that is two years
9 after the date of enactment of this Act.

10 (2) PREEMPTION.—Except as provided in para-
11 graph (3), no State or political subdivision of a
12 State may establish, implement, or enforce with re-
13 spect to preterm infant formula any requirement, in-
14 cluding under any State statute, regulation, order,
15 or common law—

16 (A) that is different from, or in addition
17 to, any requirement applicable to preterm in-
18 fant formula under the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 301 et seq.), the
20 Poison Prevention Packaging Act of 1970 (15
21 U.S.C. 1471 et seq.), or the Fair Packaging
22 and Labeling Act (15 U.S.C. 1451 et seq.); and

23 (B) that relates to preterm infant formula,
24 including—

1 (i) the design, development, clinical
2 testing or investigation, formulation, man-
3 ufacture, distribution, sale, donation, pur-
4 chase, marketing, promotion, packaging,
5 labeling, licensing, and use of preterm in-
6 fant formula; and

7 (ii) any aspect of the safety of
8 preterm infant formula.

9 (3) EXCEPTION FOR CIVIL AND CRIMINAL AC-
10 TIONS FOR WILLFUL MISCONDUCT.—

11 (A) EXCEPTION.—Paragraph (2) does not
12 preempt civil or criminal actions based on a re-
13 quirement described in paragraph (2) to the ex-
14 tent such actions are against a manufacturer
15 for willful misconduct in the manufacturing or
16 production of preterm infant formula that
17 caused death or serious physical injury.

18 (B) REMOVAL.—In the case of a civil ac-
19 tion brought in a State court against a manu-
20 facturer, if that manufacturer alleges that the
21 law under which the action is brought is pre-
22 empted by paragraph (2), such action may be
23 removed by the manufacturer to the district
24 court of the United States for the district and
25 division embracing the place wherein the civil

1 action is pending. This subparagraph applies to
2 any action pending before, on, or after the date
3 of enactment of this Act, except to the extent
4 that there is a final judgment from which no
5 appeal may be taken and no further review may
6 be sought from a court of last resort, including
7 the Supreme Court of the United States.

8 (C) BURDEN OF PROOF.—In determining
9 whether the exception in subparagraph (A) ap-
10 plies, the plaintiff shall have the burden of
11 proving that the criteria described in subpara-
12 graph (A) are met by clear and convincing evi-
13 dence.

14 (4) DISMISSAL OF PENDING ACTIONS.—A civil
15 or criminal action that is pending as of the date of
16 enactment of this Act shall be dismissed to the ex-
17 tent such action seeks to implement or enforce a re-
18 quirement that is preempted by paragraph (2).

19 (c) DEFINITIONS.—In this section:

20 (1) The term “infant formula” has the meaning
21 given to such term in section 201(z) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)).

23 (2) The term “manufacturer”—

24 (A) means a person who—

1 (i) prepares, reconstitutes, or other-
2 wise changes the physical or chemical char-
3 acteristics of a preterm infant formula; or
4 (ii) packages or labels a preterm in-
5 fant formula in a container for distribu-
6 tion; and

7 (B) does not include a person taking ac-
8 tions described in subparagraph (A) exclusively
9 for an infant under such person's direct care.

10 (3) The term "preterm infant formula" means
11 any infant formula that is exempt under section
12 412(h)(1) of the Federal Food Drug, and Cosmetic
13 Act (21 U.S.C. 350a(h)) and intended to be admin-
14 istered to—

15 (A) an infant born before 37 weeks of ges-
16 tation; or

17 (B) a low-birth-weight infant.

18 (4) The term "willful misconduct" means, ex-
19 cept as such term is further restricted pursuant to
20 subparagraph (B), an act or omission that is
21 taken—

22 (A) intentionally to achieve a wrongful
23 purpose;

24 (B) knowingly without legal or factual jus-
25 tification; and

- 1 (C) in disregard of a known or obvious risk
- 2 that is so great as to make it highly probable
- 3 that the harm will outweigh the benefit.

