

119TH CONGRESS
2D SESSION

S. _____

To set forth requirements for the regulation by the Food and Drug Administration of nitrous oxide products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. WYDEN (for himself, Mr. BLUMENTHAL, and Mr. PADILLA) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To set forth requirements for the regulation by the Food and Drug Administration of nitrous oxide 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Nitrous Oxide Inhalation Prevention Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Purpose.
- Sec. 3. Requirements with respect to nitrous oxide products.
- Sec. 4. Nitrous oxide harm reduction and misuse prevention.

Sec. 5. Rulemaking and interagency coordination.

Sec. 6. Authorization of appropriations.

1 **SEC. 2. PURPOSE.**

2 The purpose of this Act is to prevent misuse of ni-
3 trous oxide while preserving access to such substance for
4 legitimate and essential uses.

5 **SEC. 3. REQUIREMENTS WITH RESPECT TO NITROUS OXIDE**
6 **PRODUCTS.**

7 (a) IN GENERAL.—Subchapter E of chapter V of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb
9 et seq.) is amended by adding at the end the following:
10 **“SEC. 569E. REQUIREMENTS WITH RESPECT TO NITROUS**
11 **OXIDE PRODUCTS.**

12 “(a) IN GENERAL.—The Secretary shall establish re-
13 quirements with respect to nitrous oxide products, con-
14 sistent with this section. No person may introduce or de-
15 liver for introduction into interstate commerce, manufac-
16 ture, sell, or distribute any nitrous oxide product that does
17 not meet the requirements of this section.

18 “(b) NITROUS OXIDE PRODUCT DEFINED.—

19 “(1) IN GENERAL.—For purposes of this sec-
20 tion, the term ‘nitrous oxide product’ means any
21 product containing nitrous oxide, subject to para-
22 graph (2).

23 “(2) EXCEPTIONS.—

1 “(A) EXCLUSION OF TOPPING CAN-
2 ISTERS.—Such term does not include any can-
3 ister of aerosol whipped cream or whipped dairy
4 or non-dairy topping, provided that the product
5 is not marketed, labeled, or distributed in a
6 manner promoting inhalation for the purpose of
7 achieving a euphoric, psychoactive, or intoxi-
8 cating effect.

9 “(B) EXCLUSION FOR CERTAIN REGU-
10 LATED PRODUCTS.—Such term does not include
11 any product regulated by the Food and Drug
12 Administration as a drug for medical or dental
13 purposes.

14 “(c) PACKAGING AND LABELING.—The Secretary
15 shall establish requirements with respect to the packaging
16 and labeling of nitrous oxide products, including—

17 “(1) a prohibition on packaging or labeling of
18 such products that is brightly colored or contains
19 cartoon characters or mascots; and

20 “(2) requiring warning labels on such products,
21 including each individual 8-gram cartridge con-
22 taining nitrous oxide, covering at least 20 percent of
23 the principal display panel, stating the following:
24 ‘WARNING: Inhalation of nitrous oxide for non-
25 medical purposes can cause brain injury, suffocation,

1 and death. If inhaled, call Poison Control at 1-800-
2 222-1222.’.

3 “(d) PRODUCT RESTRICTIONS.—

4 “(1) BAN ON FLAVORING.—No flavored nitrous
5 oxide product may be introduced or delivered for in-
6 troduction in interstate commerce.

7 “(2) SIZE RESTRICTION.—No nitrous oxide
8 product for food use shall contain more than 8
9 grams of nitrous oxide by weight. Nothing in this
10 paragraph shall affect nitrous oxide canisters for
11 any legitimate medical, dental, industrial, or auto-
12 motive use.

13 “(e) SALES RESTRICTIONS.—

14 “(1) AGE AND TIME RESTRICTIONS.—

15 “(A) IN GENERAL.—No person may sell or
16 transfer a nitrous oxide product to any indi-
17 vidual under 21 years of age.

18 “(B) IN-PERSON RETAILER REQUIRE-
19 MENTS.—The Secretary shall promulgate regu-
20 lations regarding the sale of nitrous oxide prod-
21 ucts to consumers in-person, including require-
22 ments that retailers—

23 “(i) verify the age of consumers
24 through government-issued photo identi-
25 fication to ensure that consumers meet the

1 age requirement under subparagraph (A);
2 and

3 “(ii) not sell any nitrous oxide prod-
4 ucts, except for nitrous oxide products in-
5 tended for a legitimate medical, industrial,
6 or automotive use, at retail stores between
7 the hours of 10:00pm and 5:00am.

8 “(C) DELIVERY SELLERS.—

9 “(i) IN GENERAL.—The Secretary
10 shall promulgate regulations regarding the
11 sale of nitrous oxide products in accord-
12 ance with this subparagraph.

13 “(ii) REQUIREMENTS.—A delivery
14 seller who mails or ships nitrous oxide
15 products—

16 “(I) shall not sell, deliver, or
17 cause to be delivered any nitrous
18 oxide products to a person under the
19 minimum age required under subpara-
20 graph (A);

21 “(II) shall use a method of mail-
22 ing or shipping that requires—

23 “(aa) the purchaser placing
24 the delivery sale order, or an
25 adult who is at least the min-

1 imum age required under sub-
2 paragraph (A) for the sale or
3 transfer of nitrous oxide products
4 to sign to accept delivery of the
5 shipping container at the delivery
6 address; and

7 “(bb) the person who signs
8 to accept delivery of the shipping
9 container to provide proof, in the
10 form of a valid, government-
11 issued identification bearing a
12 photograph of the individual, that
13 the person is at least the min-
14 imum age required under sub-
15 paragraph (A) for the legal sale
16 or transfer of nitrous oxide prod-
17 ucts; and

18 “(III) shall not accept a delivery
19 sale order from a person without ob-
20 taining the full name, birth date, and
21 residential address of that person.

22 “(iii) LIMITATION.—No database
23 being used for age and identity verification
24 under clause (ii)(III) shall be in the pos-
25 session or under the control of the delivery

1 seller, or be subject to any changes or sup-
2 plementation by the delivery seller.

3 “(2) SALES LOCATION RESTRICTIONS.—Each
4 retailer of nitrous oxide products shall—

5 “(A) store all such products in a locked or
6 restricted-access area; and

7 “(B) ensure that such products are not
8 visible to the public in any retail stores.

9 “(3) LIMITS ON PURCHASE AMOUNTS.—The
10 Secretary shall establish a limit on the amount of a
11 nitrous oxide product that individual consumers may
12 purchase.

13 “(4) WHOLESALERS.—Wholesalers of nitrous
14 oxide products shall not sell such product to indi-
15 vidual consumers.”.

16 (b) PENALTIES.—Section 303(f) of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 333(f)) is amended—

18 (1) in paragraph (5)—

19 (A) in subparagraph (A)—

20 (i) in the first sentence—

21 (I) by striking “or (9)” and in-
22 serting “(9), or (10)”; and

23 (II) by inserting “or no-nitrous-
24 oxide-product-sale order, as applica-

1 ble,” after “no-tobacco-sale order”;
2 and

3 (ii) in the second sentence, by insert-
4 ing “or no-nitrous-oxide-product-sale
5 order” after “no-tobacco-sale order”;

6 (B) in subparagraph (B), in the second
7 sentence, by inserting “or nitrous oxide prod-
8 ucts, as applicable,” after “tobacco products”;

9 (C) by inserting “or no-nitrous-oxide-prod-
10 uct-sale order” after “no-tobacco-sale order”
11 each place it appears in subparagraphs (B) and
12 (D); and

13 (D) in subparagraph (C), by striking “or
14 (9)” and inserting “(9), or (10)”;

15 (2) in paragraph (6), by inserting “or a no-ni-
16 trous-oxide-product-sale order” after “no-tobacco-
17 sale order” each place it appears; and

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

19 “(10) PENALTIES FOR VIOLATION OF NITROUS
20 OXIDE PRODUCT REQUIREMENTS.—

21 “(A) IN GENERAL.—In the case of a per-
22 son who violates a requirement of section 569E,
23 a civil monetary penalty described in subpara-
24 graph (B) shall be assessed, or a no-nitrous-
25 oxide-product-sale order may be imposed by the

1 Secretary by an order made on the record after
2 opportunity for a hearing provided in accord-
3 ance with subparagraph (C) and section 554 of
4 title 5, United States Code.

5 “(B) CIVIL MONETARY PENALTIES.—

6 “(i) MANUFACTURERS AND DISTRIBUTORS.—In the case of a manufacturer or
7 distributor of a nitrous oxide product who
8 violates a requirement of section 569E
9 with respect to manufacturing, labeling,
10 packaging, distributing, or introducing into
11 interstate commerce such a product, such
12 manufacturer or distributor shall be sub-
13 ject to a civil monetary penalty in an
14 amount not to exceed \$21,348 for each
15 such violation.
16

17 “(ii) RETAILERS AND DELIVERY
18 SELLERS.—In the case of a retailer or de-
19 livery seller of a nitrous oxide product who
20 violates a requirement of section 569E
21 with respect to the sale or offering for sale
22 of such a product, such retailer or delivery
23 seller shall be subject to civil monetary
24 penalties as follows:

1 “(I) In the case of a first such
2 violation, no civil monetary penalty
3 shall apply, and the Secretary shall
4 issue a warning letter.

5 “(II) In the case of a second
6 such violation within any 12-month
7 period, such retailer or delivery seller
8 shall be subject to a civil monetary
9 penalty in an amount not to exceed
10 \$356.

11 “(III) In the case of a third such
12 violation within any 24-month period,
13 such retailer or delivery seller shall be
14 subject to a civil monetary penalty in
15 an amount not to exceed \$709.

16 “(IV) In the case of a fourth
17 such violation within any 36-month
18 period, such retailer or delivery seller
19 shall be subject to a civil monetary
20 penalty in an amount not to exceed
21 \$2,846.

22 “(V) In the case of a fifth or
23 each subsequent such violation within
24 any 48-month period, such retailer or
25 delivery seller shall be subject to a

1 civil monetary penalty in an amount
2 not to exceed \$14,232.

3 “(VI) No such retailer or delivery
4 seller shall be subject to a total
5 amount of civil monetary penalties
6 under this clause that exceeds
7 \$100,000, for all violations of section
8 569E adjudicated in a single pro-
9 ceeding.

10 “(C) NO-NITROUS-OXIDE-PRODUCT-SALE
11 ORDER.—Prior to the entry of a no-nitrous-
12 oxide-product-sale order against a manufac-
13 turer, distributor, retailer, or delivery seller
14 under this paragraph, such manufacturer, dis-
15 tributor, retailer, or delivery seller shall be enti-
16 tled to a hearing pursuant to the procedures es-
17 tablished through regulations of the Food and
18 Drug Administration for assessing civil money
19 penalties, including, at the request of such per-
20 son, a hearing by telephone, or at the nearest
21 regional or field office of the Food and Drug
22 Administration, or at a Federal, State, or coun-
23 ty facility within 100 miles from the location of
24 an establishment of the manufacturer, dis-

1 tributor, retailer, or delivery seller if such a fa-
2 cility is available.”.

3 **SEC. 4. NITROUS OXIDE HARM REDUCTION AND MISUSE**
4 **PREVENTION.**

5 Part P of title III of the Public Health Service Act
6 (42 U.S.C. 280g et seq.) is amended by adding at the end
7 the following:

8 **“SEC. 399V-8. NITROUS OXIDE HARM REDUCTION AND MIS-**
9 **USE PREVENTION.**

10 “(a) IN GENERAL.—The Secretary shall award
11 grants to eligible entities for purposes of carrying out pro-
12 grams to reduce use of nitrous oxide for the purpose of
13 achieving a euphoric, psychoactive, or intoxicating effect.

14 “(b) ELIGIBILITY.—To be eligible to receive a grant
15 under this section, an entity shall—

16 “(1) be a nonprofit organizations, law enforce-
17 ment agency, emergency department, poison control
18 center, school, outreach program, community center,
19 mental health facility, public health department, cur-
20 rent recipient of Drug-Free Communities Program
21 funding under section 1032 of the Anti-Drug Abuse
22 Act of 1988, or other entity, as the Secretary deter-
23 mines appropriate for the purpose of this section;
24 and

1 “(2) submit an application to the Secretary, at
2 such time, in such manner, and containing such in-
3 formation as the Secretary may require.

4 “(c) USE OF FUNDS.—Eligible entities may use
5 funds received under this section to conduct—

6 “(1) targeted education campaigns warning of
7 the dangers of use of nitrous oxide for the purpose
8 of achieving a euphoric, psychoactive, or intoxicating
9 effect;

10 “(2) community-based prevention and youth
11 outreach programs; and

12 “(3) training programs for law enforcement,
13 emergency departments, and poison control centers
14 on identifying and responding to nitrous oxide mis-
15 use.”.

16 **SEC. 5. RULEMAKING AND INTERAGENCY COORDINATION.**

17 (a) REGULATIONS.—Not later than 1 year after the
18 date of enactment of this Act, the Secretary of Health and
19 Human Services, acting through the Commissioner of
20 Food and Drugs, in consultation with the Consumer Prod-
21 uct Safety Commission and the Federal Trade Commis-
22 sion, shall issue regulations to carry out section 569E of
23 the Federal Food, Drug, and Cosmetic Act, as added by
24 section 3.

1 (b) ANNUAL REPORTING.—Not later than October
2 31, 2027, and annually thereafter, the Secretary of Health
3 and Human Services, in consultation with the Commis-
4 sioner of Food and Drugs, shall submit a report on en-
5 forcement actions, public health outcomes, and rec-
6 ommendations for policy updates relating to the regulation
7 of nitrous oxide products, as defined in section 569E of
8 the Federal, Food, Drug, and Cosmetic Act, as added by
9 section 3, including pursuant to section 569E of the Fed-
10 eral Food, Drug, and Cosmetic Act (as added by section
11 3), to—

12 (1) the Committee on Health, Education,
13 Labor, and Pensions, the Committee on Commerce,
14 Science, and Transportation, and the Committee on
15 the Judiciary of the Senate; and

16 (2) the Committee on Energy and Commerce
17 and the Committee on the Judiciary of the House of
18 Representatives.

19 **SEC. 6. AUTHORIZATION OF APPROPRIATIONS.**

20 To carry out this Act, including the amendments
21 made by this Act, there are authorized to be appropriated
22 such sums as may be necessary for each of fiscal years
23 2027 through 2036.