

119TH CONGRESS
1ST SESSION

S. 3134

To amend the Fentanyl Sanctions Act to address trafficking of copy-cat and counterfeit drugs and active pharmaceutical ingredients, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2025

Mr. COTTON (for himself and Mr. RICKETTS) introduced the following bill; which was read twice and referred to the Committee on Banking, Housing, and Urban Affairs

A BILL

To amend the Fentanyl Sanctions Act to address trafficking of copy-cat and counterfeit drugs and active pharmaceutical ingredients, 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 “Combating Counterfeit
5 Pharmaceuticals Act of 2025”.

6 **SEC. 2. DEFINITIONS.**

7 Section 7203 of the Fentanyl Sanctions Act (21
8 U.S.C. 2302) is amended—

1 (1) by redesignating paragraphs (4) through
2 (10) as paragraphs (5) through (11), respectively;

3 (2) by inserting after paragraph (3) the fol-
4 lowing:

5 “(4) COPY-CAT INGREDIENT.—The term ‘copy-
6 cat ingredient’, with respect to a drug, means an in-
7 gredient that is intended, including through the con-
8 tainer or labeling of the ingredient, to mimic,
9 knockoff, or otherwise purports to be a drug sub-
10 stance that is a component of a prescription drug
11 approved under section 505 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355) or licensed
13 under section 351 of the Public Health Service Act
14 (42 U.S.C. 262), and—

15 “(A) the ingredient is manufactured by a
16 different process than specified for the drug
17 substance in the approval or licensure of the
18 drug; or

19 “(B) the purity or quality of the ingredient
20 falls below that of the drug substance that is a
21 component of the approved or licensed drug.

22 “(5) COUNTERFEIT DRUG.—The term ‘counter-
23 feit drug’ has the meaning given that term in section
24 201(g)(2) of the Federal Food, Drug, and Cosmetic
25 Act (21 U.S.C. 321(g)(2)).”;

1 (3) in paragraph (6), as redesignated by para-
 2 graph (1)—

3 (A) in the paragraph heading, by striking
 4 “OPIOID” and inserting “ILLICIT DRUG”; and

5 (B) by striking “opioid” each place it ap-
 6 pears and inserting “illicit drug”; and

7 (4) by striking paragraph (9), as so redesign-
 8 nated—

9 (A) in the paragraph heading, by striking
 10 “OPIOID” and inserting “ILLICIT DRUG”;

11 (B) in the matter preceding subparagraph
 12 (A), by striking “opioid” and inserting “illicit
 13 drug”; and

14 (C) in subparagraph (A)—

15 (i) in clause (i), by striking “; or” and
 16 inserting a semicolon; and

17 (ii) by adding at the end the fol-
 18 lowing:

19 “(iii) counterfeit drugs; or

20 “(iv) copy-cat ingredients;”.

21 **SEC. 3. MODIFICATION OF REQUIREMENTS FOR DIRECTOR**
 22 **OF NATIONAL INTELLIGENCE.**

23 (a) **AUTHORITY TO DELEGATE.—**

24 (1) **IDENTIFICATION OF FOREIGN DRUG TRAF-**
 25 **FICKERS.—**Section 7211 of the Fentanyl Sanctions

1 Act (21 U.S.C. 2311) is amended, in subsections (d)
2 and (e), by inserting “(or a designee of the Direc-
3 tor)” after “Director of National Intelligence” each
4 place it appears.

5 (2) BRIEFINGS ON IMPLEMENTATION.—Section
6 7216 of the Fentanyl Sanctions Act (21 U.S.C.
7 2316) is amended by inserting “(or a designee of the
8 Director)” after “Director of National Intelligence”.

9 (b) PROGRAM ON USE OF INTELLIGENCE RE-
10 SOURCES.—Section 7231 of the Fentanyl Sanctions Act
11 (21 U.S.C. 2331) is amended—

12 (1) in the section heading, by striking
13 “**OPIOID**” and inserting “**ILLICIT DRUG**”;

14 (2) in subsection (a)—

15 (A) in paragraph (1), by striking “, in con-
16 sultation” and all that follows through “Pol-
17 icy,”; and

18 (B) in paragraph (2)(A), by striking “nar-
19 cotics” and inserting “illicit drug”;

20 (3) by striking subsections (b) and (c); and

21 (4) by redesignating subsection (d) as sub-
22 section (b).

1 **SEC. 4. WAIVER FOR ACCESS TO PRESCRIPTION MEDICA-**
 2 **TIONS.**

3 Section 7214(b)(1)(B) of the Fentanyl Sanctions Act
 4 (21 U.S.C. 2314(b)(1)(B)) is amended by inserting after
 5 “medications” the following: “on the current drug short-
 6 age list maintained by the Secretary of Health and
 7 Human Services under section 506E of the Federal Food,
 8 Drug, and Cosmetic Act (21 U.S.C. 356e)”.

9 **SEC. 5. TECHNICAL AND CONFORMING AMENDMENTS.**

10 (a) **FENTANYL SANCTIONS ACT.**—The Fentanyl
 11 Sanctions Act (21 U.S.C. 2301 et seq.) is amended—

12 (1) in section 7202(3) (21 U.S.C. 2301(3)), by
 13 inserting “and other illicit drugs” after “fentanyl”;

14 (2) in the subtitle heading for subtitle A, by
 15 striking “**Opioid**” and inserting “**Illicit Drug**”;

16 (3) in section 7211 (21 U.S.C. 2311), in the
 17 section heading, by striking “**OPIOID**” and inserting
 18 “**ILLICIT DRUG**”;

19 (4) in section 7214 (21 U.S.C. 2314)—

20 (A) in subsection (a)(2)(B)(ii), by striking
 21 “opioids” and inserting “illicit drugs”; and

22 (B) in subsection (b)(2), by striking “illicit
 23 opioids” and inserting “illicit drugs”;

24 (5) in section 7217(a) (Public Law 116–91;
 25 133 Stat. 2269), in the matter preceding paragraph

1 (1), by striking “illicit opioids” and inserting “illicit
2 drugs”;

3 (6) in section 7233 (21 U.S.C. 2333), by strik-
4 ing “section 7203(8)” and inserting “section
5 7203(9)”;

6 (7) by striking “opioid trafficking” each place
7 it appears and inserting “illicit drug trafficking”;

8 (8) by striking “illicit opioids” each place it ap-
9 pears and inserting “illicit drugs”;

10 (9) by striking “foreign opioid traffickers” each
11 place it appears and inserting “foreign illicit drug
12 traffickers”; and

13 (10) by striking “foreign opioid trafficker” each
14 place it appears and inserting “foreign illicit drug
15 trafficker”.

16 (b) INTERNATIONAL NARCOTICS CONTROL STRAT-
17 EGY REPORT.—Section 489(a)(9) of the Foreign Assist-
18 ance Act of 1961 (22 U.S.C. 2291h(a)(9)) is amended—

19 (1) in subparagraph (A), by inserting “(or a
20 designee of the Director)” after “Director of Na-
21 tional Intelligence”; and

22 (2) by striking “illicit opioids” each place it ap-
23 pears and inserting “illicit drugs”.

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