

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 593

To amend the Federal Food, Drug, and Cosmetic Act to authorize the export of new drugs and for other purposes.

---

## IN THE SENATE OF THE UNITED STATES

MARCH 22 (legislative day, MARCH 16), 1995

Mr. HATCH (for himself, Mr. GREGG, Mrs. KASSEBAUM, Mr. ABRAHAM, Mr. FRIST, and Mr. COATS) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

---

## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the export of new drugs 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 “FDA Export Reform  
5        and Enhancement Act of 1995”.

6        **SEC. 2. EXPORT OF NEW DRUGS.**

7        Section 801(e) of the Federal Food, Drug, and Cos-  
8        metic Act (21 U.S.C. 381(e)) is amended—

9                (1) in paragraph (1), by inserting after “under  
10        this Act” the following: “or in violation of section

1 505 or section 351 of the Public Health Service  
2 Act”,

3 (2) in paragraph (1), by striking the last sen-  
4 tence, and

5 (3) by amending paragraph (2) to read as fol-  
6 lows:

7 “(2) Paragraph (1) does not apply to the export of—

8 “(A) any device—

9 “(i) which does not comply with an appli-  
10 cable requirement under section 514 or 515,

11 “(ii) which under section 520(g) is exempt  
12 from either such section, or

13 “(iii) which is a banned device under sec-  
14 tion 516, or

15 “(B) any drug (including a biological product)  
16 which does not comply with an applicable require-  
17 ment under section 505 or 512 or section 351 of the  
18 Public Health Service Act,

19 unless the device or drug is in compliance with the require-  
20 ments of paragraph (1) and if the device or drug is to  
21 be exported to a country which is not a member of the  
22 World Trade Organization, the person exporting it has no-  
23 tified the Secretary of the export at least 30 days before  
24 the export and has included in such notice the name of  
25 the product, the country to which the product is being ex-

1 ported, and a brief description of the medical need for the  
2 device or drug in the country. In the case of a device or  
3 drug for which an export notice is required under this  
4 paragraph, the Secretary may prohibit the export of the  
5 device or drug if the Secretary determines that the possi-  
6 bility of the reimportation of the device or drug into the  
7 United States presents an imminent hazard to the public  
8 health and safety of the United States and the only means  
9 of limiting the hazard is to prohibit the export of the de-  
10 vice or drug.”.

11 **SEC. 3. EXPORT OF CERTAIN UNAPPROVED PRODUCTS.**

12 Section 802 (21 U.S.C. 382) is repealed.

13 **SEC. 4. PARTIALLY PROCESSED BIOLOGICAL PRODUCTS.**

14 Subsection (h) of section 351 of the Public Health  
15 Service Act (42 U.S.C. 262) is amended to read as follows:

16 “(h) A partially-processed biological product which—

17 “(1) is not in a form applicable to the preven-  
18 tion, treatment, or cure of diseases or injuries of  
19 man,

20 “(2) is not intended for sale in the United  
21 States, and

22 “(3) is intended for further manufacture into  
23 final dosage form outside the United States,

1 shall be subject to no restriction on its export under this  
2 Act or the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 321 et seq.).”

○