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104TH CONGRESS
1ST SESSION

H. R. 1300

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 22, 1995

Mr. UPTON (for himself, Mr. GREENWOOD, Mr. BURR, Mr. NORWOOD, Mr. COBURN, Mr. BILBRAY, Mr. HASTERT, Mr. GANSKE, Mr. TOWNS, Mr. COX of California, Mr. GILLMOR, Mr. MOORHEAD, Mr. HALL of Texas, Mr. BRYANT of Tennessee, Mr. KNOLLENBERG, Mr. CHRYSLER, Mr. CAMP, Mr. BARCIA of Michigan, Mr. EHLERS, Mr. MARTINI, Mr. CALVERT, Mr. ROHRABACHER, Mr. MCINTOSH, Mr. CHAMBLISS, Mr. COOLEY, Mr. BREWSTER, Mr. FRELINGHUYSEN, Mr. CHABOT, Mr. TRAFICANT, Mr. SOLOMON, Mr. OXLEY, Mrs. CHENOWETH, and Mr. RAMSTAD) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''FDA Export Reform and Enhancement Act of 1995''.

SEC. 2. EXPORT OF NEW DRUGS.

Section 801(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e) is amended—

(1) in paragraph (1), by inserting after ''under this Act'' the following: ''or in violation of section 505 or section 351 of the Public Health Service Act'',

(2) in paragraph (1), by striking the last sentence, and

(3) by amending paragraph (2) to read as follows:

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

''(A) any device—

''(i) which does not comply with an applicable requirement under section 514 or 515,

''(ii) which under section 520(g) is exempt from either such section, or

''(iii) which is a banned device under section 516, or

''(B) any drug (including a biological product) which does not comply with an applicable requirement under section 505 or 512 or section 351 of the Public Health Service Act,

unless the device or drug is in compliance with the requirements of paragraph (1) and if the device or drug is to be exported to a country which is not a member of the

World Trade Organization, the person exporting it has notified the Secretary of the export at least 30 days before the export and has included in such notice the name of the product, the country to which the product is being exported, and a brief description of the medical need for such device or drug in such country. In the case of a device or drug for which an export notice is required under this paragraph, the Secretary may prohibit the export of such device or drug if the Secretary determines that the possibility of the reimportation of the device or drug into the United States presents an imminent hazard to the public health and safety of the United States and the only means of limiting the hazard is to prohibit the export of the device or drug.''.

SEC. 3. EXPORT OF CERTAIN UNAPPROVED PRODUCTS.

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

SEC. 4. PARTIALLY PROCESSED BIOLOGICAL PRODUCTS.

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

''(h) A partially-processed biological product which—

''(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man,

''(2) is not intended for sale in the United States, and

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

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

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