

105TH CONGRESS  
2D SESSION

# H. R. 4035

To amend the Federal Food, Drug, and Cosmetic Act and title 10, United States Code, with respect to the administration to members of the Armed Forces of certain drugs without the informed consent of the members.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 1998

Mr. SHAYS (for himself, Mr. TOWNS, Mr. SNOWBARGER, Mr. SANDERS, Mr. GILMAN, Ms. NORTON, Mr. BURTON of Indiana, Mr. METCALF, Mr. MCHUGH, Mr. ALLEN, Mr. LANTOS, Mr. BARRETT of Wisconsin, Mr. CONDIT, Mr. MCINTOSH, Ms. STABENOW, Mr. MCGOVERN, Mr. PAPPAS, Mr. SOUDER, Mr. KUCINICH, Mr. KENNEDY of Massachusetts, Mr. DAVIS of Virginia, Mrs. JOHNSON of Connecticut, and Mr. UPTON) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on National Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act and title 10, United States Code, with respect to the administration to members of the Armed Forces of certain drugs without the informed consent of the members.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Drugs and Informed  
3 Consent Armed Forces Protection Act of 1998”.

4 **SEC. 2. PROVISIONS REGARDING WAIVERS OF REQUIRE-**  
5 **MENT OF INFORMED CONSENT FOR ADMINIS-**  
6 **TRATION OF CERTAIN DRUGS TO MEMBERS**  
7 **OF ARMED FORCES.**

8 (a) REQUIREMENT OF CONCURRENCE OF PRESIDENT  
9 IN DETERMINATION OF FOOD AND DRUG ADMINISTRA-  
10 TION TO GRANT WAIVER.—Section 505(i) of the Federal  
11 Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)), as  
12 amended by section 117 of Public Law 105–115 (111  
13 Stat. 2315), is amended by adding at the end the following  
14 paragraph:

15 “(5) With respect to the administration under this  
16 subsection of a drug to members of the Armed Forces for  
17 investigational use, if the Secretary of Defense submits to  
18 the Secretary a request under paragraph (4) that the re-  
19 quirement under such paragraph for prior consent be  
20 waived, any determination under such paragraph by the  
21 Secretary that obtaining consent is not feasible, or is con-  
22 trary to the best interests of the members involved, is not  
23 effective unless the President provides to the Secretary a  
24 written statement providing that the President concurs in  
25 such determination.”.

1 (b) WAIVER OF CONSENT; WRITTEN NOTICE TO AF-  
2 FECTED MEMBERS REGARDING DRUGS INVOLVED.—Sec-  
3 tion 1107 of title 10, United States Code, as added by  
4 section 766(a) of Public Law 105–85 (111 Stat. 1827),  
5 is amended—

6 (1) in subsection (a)(1), by striking “Whenever  
7 the Secretary of Defense requests or requires a  
8 member” and inserting the following: “Whenever the  
9 Secretary of Defense is authorized pursuant to sec-  
10 tion 505(i)(5) of the Federal Food, Drug, and Cos-  
11 metic Act to request or require a member”;

12 (2) in subsection (b), by striking “first adminis-  
13 tered to the member, if practicable” and all that fol-  
14 lows and inserting “first administered to the mem-  
15 ber.”; and

16 (3) in subsection (c), by striking “provided in  
17 writing unless” and all that follows and inserting  
18 “provided in writing.”.

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