

105TH CONGRESS
1ST SESSION

H. R. 1294

To amend title 10, United States Code, to require the Secretary of Defense to provide to members of the Armed Forces who receive an investigational new drug relevant information regarding the drug, including the possible side effects of the drug.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 1997

Mr. KENNEDY of Rhode Island introduced the following bill; which was referred to the Committee on National Security

A BILL

To amend title 10, United States Code, to require the Secretary of Defense to provide to members of the Armed Forces who receive an investigational new drug relevant information regarding the drug, including the possible side effects of the drug.

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. NOTICE OF USE OF INVESTIGATIONAL NEW**
4 **DRUGS.**

5 (a) NOTICE TO MEMBERS RECEIVING DRUGS.—(1)
6 Chapter 55 of title 10, United States Code, is amended
7 by adding at the end the following new section:

1 **“§ 1107. Notice of use of investigational new drugs**

2 “(a) NOTICE REQUIRED.—Whenever the Secretary of
3 Defense requests or requires a member of the armed
4 forces to receive an investigational new drug, the Sec-
5 retary shall provide the member with notice containing the
6 information specified in subsection (c). The notice shall
7 be provided before the investigational new drug is first ad-
8 ministered to the member, if practicable, but in no case
9 later than 30 days after the investigational new drug is
10 first administered to the member.

11 “(b) FORM OF NOTICE.—The notice required under
12 subsection (a) shall be provided in writing unless the Sec-
13 retary of Defense determines that the use of written notice
14 is impractical because of the number of members receiving
15 the investigational new drug, time constraints, or similar
16 reasons. If the Secretary provides notice under subsection
17 (a) in a form other than in writing, the Secretary shall
18 submit to Congress a report describing the notification
19 method used and the reasons for the use of the alternative
20 method.

21 “(c) CONTENT OF NOTICE.—The notice required
22 under subsection (a) shall include the following:

23 “(1) Clear notice that drug being administered
24 is an investigational new drug.

25 “(2) The reasons why the investigational new
26 drug is being administered.

1 “(3) Information regarding the possible side ef-
2 fects of the investigational new drug, including any
3 known side effects possible as a result of the inter-
4 action of the investigational new drug with other
5 drugs or treatments being administered to the mem-
6 bers receiving the investigational new drug.

7 “(4) Such other information that, as a condi-
8 tion of authorizing the use of the investigational new
9 drug, the Secretary of Health and Human Services
10 may require to be disclosed.

11 “(d) DEFINITION.—In this section, the term ‘inves-
12 tigational new drug’ means a drug covered by section
13 505(i) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355(i)).”.

15 (b) CLERICAL AMENDMENT.—The table of sections
16 at the beginning of such chapter is amended by adding
17 at the end the following new item:

“1107. Notice of use of investigational new drugs.”.

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