

106TH CONGRESS  
1ST SESSION

# H. R. 3460

To amend title 10, United States Code, to require the consent of a member of the Armed Forces before administering the member with an investigational new drug or drug unapproved for its applied use.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 1999

Mr. BACHUS (for himself and Mr. JONES of North Carolina) introduced the following bill; which was referred to the Committee on Armed Services

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## A BILL

To amend title 10, United States Code, to require the consent of a member of the Armed Forces before administering the member with an investigational new drug or drug unapproved for its applied use.

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. FINDINGS.**

4       The Congress finds the following:

5           (1) Under current law, the Department of De-  
6       fense may administer drugs that have not obtained  
7       approval by the Food and Drug Administration to  
8       members of the Armed Forces without informing the

1 members of the drug they are receiving or obtaining  
2 consent of the members.

3 (2) In a time when military recruiting is at his-  
4 toric lows, and evidence of failure of the Department  
5 of Defense to properly inform military personnel of  
6 the true nature of medical treatment performed on  
7 members of the Armed Forces in past conflicts, it is  
8 the duty of Congress to ensure that no member of  
9 the Armed Forces will be administered an unap-  
10 proved drug without the informed consent of the  
11 member.

12 (3) While there may be situations in which an  
13 unapproved drug is the best protection for members  
14 of the Armed Forces facing the threat of biological  
15 warfare, such members should have the same con-  
16 stitutional protections as every other United States  
17 citizen and therefore have the right to know about  
18 any drug being administered to them.

19 (4) Every member of the Armed Forces should  
20 be informed of the nature and Food and Drug Ad-  
21 ministration approval status of all drugs that the  
22 Department of Defense seeks to administer.

1 **SEC. 2. CONSENT REQUIRED FOR ADMINISTRATION OF IN-**2 **VESTIGATIONAL NEW DRUG OR DRUG UNAP-**3 **PROVED FOR ITS APPLIED USE.**

4 (a) IN GENERAL.—Section 1107 of title 10, United

5 States Code, is amended—

6 (1) by amending the heading to read as follows:

7 **“§ 1107. Notice and consent required for use of an in-**8 **vestigational new drug or drug unap-**9 **proved for its applied use”;**

10 (2) in subsection (a)—

11 (A) by inserting “AND CONSENT” after

12 “NOTICE”; and

13 (B) in paragraph (1)—

14 (i) by striking “or requires”; and

15 (ii) by adding at the end the following

16 new sentence: “The Secretary may not ad-  
17 minister an investigational new drug or  
18 drug unapproved for its applied use to a  
19 member without obtaining the consent of  
20 the member.”; and

21 (3) by striking subsection (f); and

22 (4) by redesignating subsection (g) as sub-  
23 section (f).

24 (b) CLERICAL AMENDMENT.—The table of sections

25 at the beginning of such chapter is amended to read as

26 follows:

“1107. Notice and consent required for use of an investigational new drug or drug unapproved for its applied use.”.

