

106TH CONGRESS  
2D SESSION

# H. R. 5385

To require the Food and Drug Administration to establish restrictions regarding the qualifications of physicians to prescribe the abortion drug commonly known as RU-486.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 4, 2000

Mr. COBURN (for himself, Mr. ARMEY, Mr. DELAY, Mr. WATTS of Oklahoma, Mr. SMITH of New Jersey, Mr. OBERSTAR, Mr. STUPAK, Mrs. MYRICK, Mr. RAHALL, Mr. ADERHOLT, Mr. BAKER, Mr. SHIMKUS, Mrs. EMERSON, Mr. SCHAFFER, Mr. DEMINT, Mr. DOOLITTLE, Mr. WAMP, Mr. ISTOOK, Mr. HILLEARY, Mr. BURR of North Carolina, Mr. TANCREDO, Mr. VITTER, Mr. PICKERING, Mr. ENGLISH, Mr. HAYES, Mr. PETERSON of Pennsylvania, Mr. BARR of Georgia, Mr. PITTS, Mr. DICKEY, Mr. HOSTETTLER, Mr. HOEKSTRA, Mr. LARGENT, Mr. SOUDER, Mr. TLAHRT, Mr. HAYWORTH, Mrs. CHENOWETH-HAGE, Mr. SAM JOHNSON of Texas, Mr. GOODE, Mr. RYUN of Kansas, Mr. BARTLETT of Maryland, Mr. GREEN of Wisconsin, Mr. JONES of North Carolina, Mr. MANZULLO, and Mr. SHADEGG) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To require the Food and Drug Administration to establish restrictions regarding the qualifications of physicians to prescribe the abortion drug commonly known as RU-486.

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 “RU–486 Patient  
3 Health and Safety Protection Act”.

4 **SEC. 2. ESTABLISHMENT OF RESTRICTIONS REGARDING**  
5 **PRESCRIBING OF CERTAIN ABORTION DRUG.**

6 With respect to the application that was submitted  
7 under section 505(b) of the Federal Food, Drug, and Cos-  
8 metic Act for the drug mifepristone (commonly referred  
9 to as RU–486, to be marketed as MIFEPREX), and that  
10 was approved on September 28, 2000, the Secretary of  
11 Health and Human Services, acting through the Commis-  
12 sioner of Food and Drugs, shall promptly modify the con-  
13 ditions of the approval of such drug to establish the addi-  
14 tional restriction that the drug may not be prescribed by  
15 any person other than a licensed physician who meets the  
16 following requirements:

17 (1) The physician is qualified to handle com-  
18 plications resulting from an incomplete abortion or  
19 ectopic pregnancy.

20 (2) The physician has been trained to perform  
21 surgical abortions and has met all applicable legal  
22 requirements to perform such abortions.

23 (3) The physician is certified for ultrasound  
24 dating of pregnancy and detecting ectopic preg-  
25 nancy.

1           (4) The physician has completed a program re-  
2           garding the prescribing of such drug that uses a  
3           curriculum approved by the Secretary.

4           (5) The physician has admitting privileges at a  
5           hospital to which the physician can travel in one  
6           hour or less, determined on the basis of starting at  
7           the principal medical office of the physician and  
8           traveling to the hospital, using the transportation  
9           means normally used by the physician to travel to  
10          the hospital, and under the average conditions of  
11          travel for the physician.

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