

111TH CONGRESS  
1ST SESSION

# H. R. 3002

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2009

Mr. BOEHNER (for himself and Mr. CANTOR) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

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 “Preserving Access to  
3 Targeted, Individualized, and Effective New Treatments  
4 and Services (PATIENTS) Act of 2009” or the “PA-  
5 TIENTS Act of 2009”.

6 **SEC. 2. PROHIBITION ON CERTAIN USES OF DATA OB-**  
7 **TAINED FROM COMPARATIVE EFFECTIVE-**  
8 **NESS RESEARCH; ACCOUNTING FOR PERSON-**  
9 **ALIZED MEDICINE AND DIFFERENCES IN PA-**  
10 **TIENT TREATMENT RESPONSE.**

11       (a) IN GENERAL.—Notwithstanding any other provi-  
12 sion of law, the Secretary of Health and Human Serv-  
13 ices—

14           (1) shall not use data obtained from the con-  
15 duct of comparative effectiveness research, including  
16 such research that is conducted or supported using  
17 funds appropriated under the American Recovery  
18 and Reinvestment Act of 2009 (Public Law 111–5),  
19 to deny coverage of an item or service under a Fed-  
20 eral health care program (as defined in section  
21 1128B(f) of the Social Security Act (42 U.S.C.  
22 1320a–7b(f))); and

23           (2) shall ensure that comparative effectiveness  
24 research conducted or supported by the Federal  
25 Government accounts for factors contributing to dif-  
26 ferences in the treatment response and treatment

1 preferences of patients, including patient-reported  
2 outcomes, genomics and personalized medicine, the  
3 unique needs of health disparity populations, and in-  
4 direct patient benefits.

5 (b) RULE OF CONSTRUCTION.—Nothing in this sec-  
6 tion shall be construed as affecting the authority of the  
7 Commissioner of Food and Drugs under the Federal  
8 Food, Drug, and Cosmetic Act or the Public Health Serv-  
9 ice Act.

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