

113TH CONGRESS
1ST SESSION

S. _____

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny or delay 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.

IN THE SENATE OF THE UNITED STATES

Mr. ROBERTS introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny or delay 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preserving Access to
5 Targeted, Individualized, and Effective New Treatments

1 and Services (PATIENTS) Act of 2013” or the “PA-
2 TIENTS Act of 2013”.

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

8 (a) IN GENERAL.—Notwithstanding any other provi-
9 sion of law, the Secretary of Health and Human Serv-
10 ices—

11 (1) shall not use data obtained from the con-
12 duct of comparative effectiveness research, including
13 such research that is conducted or supported using
14 funds appropriated under the American Recovery
15 and Reinvestment Act of 2009 (Public Law 111–5)
16 or authorized or appropriated under the Patient
17 Protection and Affordable Care Act (Public Law
18 111–148), to deny or delay coverage of an item or
19 service under a Federal health care program (as de-
20 fined in section 1128B(f) of the Social Security Act
21 (42 U.S.C. 1320a–7b(f))); and

22 (2) shall ensure that comparative effectiveness
23 research conducted or supported by the Federal
24 Government accounts for factors contributing to dif-
25 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.