

AMENDMENT NO. _____ Calendar No. _____

Purpose: 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.

IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.

S. _____

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

1 At the end of title II, add the following:

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

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

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

18 (2) shall ensure that comparative effectiveness
19 research conducted or supported by the Federal
20 Government accounts for factors contributing to dif-
21 ferences in the treatment response and treatment
22 preferences of patients, including patient-reported
23 outcomes, genomics and personalized medicine, the
24 unique needs of health disparity populations, and in-
25 direct patient benefits.

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