

Bob Casey

AMENDMENT NO. _____ Calendar No. _____

Purpose: To support and improve the review of drugs to treat rare diseases and conditions.

IN THE SENATE OF THE UNITED STATES—117th Cong., 2d Sess.

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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 Mr. CASEY

Viz:

1 On page 94, line 10, insert “, including patients and
2 patient groups,” after “stakeholders”.

3 On page 96, line 8, strike “average” and insert “ap-
4 proximate”.

5 On page 96, strike lines 22 through 24 and insert
6 “the Secretary consulted patients and patient groups pur-
7 suant to subsection (a)(1) of section 569 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8) and

1 experts pursuant to subsection (a)(2) of such section 569;
2 and”.