

Bill Cassidy, M.D.

AMENDMENT NO. _____ Calendar No. _____

Purpose: To set forth limitations on exclusivity for orphan drugs.

#1

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 Ms. BALDWIN

Viz:

1 At the appropriate place in title V, insert the fol-
2 lowing:

3 **SEC. 5 ____ . LIMITATIONS ON EXCLUSIVE APPROVAL OR**
4 **LICENSURE OF ORPHAN DRUGS.**

5 (a) IN GENERAL.—Section 527 of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

7 (1) in subsection (a), in the matter following
8 paragraph (2), by striking “same disease or condi-
9 tion” and inserting “same approved use or indica-
10 tion within such rare disease or condition”;

11 (2) in subsection (b)—

1 (A) in the matter preceding paragraph (1),
2 by striking “same rare disease or condition”
3 and inserting “same approved use or indication
4 for which such 7-year period applies to such al-
5 ready approved drug”; and

6 (B) in paragraph (1), by inserting “, relat-
7 ing to the approved use or indication,” after
8 “the needs”;

9 (3) in subsection (c)(1), by striking “same rare
10 disease or condition as the already approved drug”
11 and inserting “same use or indication for which the
12 already approved or licensed drug was approved or
13 licensed”; and

14 (4) by adding at the end the following:

15 “(f) APPROVED USE OR INDICATION DEFINED.—In
16 this section, the term ‘approved use or indication’ means
17 the use or indication approved under section 505 of this
18 Act or licensed under section 351 of the Public Health
19 Service Act for a drug designated under section 526 for
20 a rare disease or condition.”.

21 (b) APPLICATION OF AMENDMENTS.—The amend-
22 ments made by subsection (a) shall apply with respect to
23 any drug designated under section 526 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regard-
25 less of the date on which the drug was so designated, and

1 regardless of the date on which the drug was approved
2 under section 505 of such Act (21 U.S.C. 355) or licensed
3 under section 351 of the Public Health Service Act (42
4 U.S.C. 262), provided that the amendments made by sub-
5 section (a) shall not affect the scope of any 7-year period
6 of exclusivity under section 527(a) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) that is in
8 effect on the date of enactment of this Act unless, on such
9 date of enactment, there is at least one other approved
10 application under section 505 of the Federal Food, Drug,
11 and Cosmetic Act (21 U.S.C. 355) or licensure under sec-
12 tion 351 of the Public Health Service Act (42 U.S.C. 262)
13 for the same drug for the same disease or condition, held
14 by a sponsor other than the sponsor that holds the appli-
15 cation for which such 7-year period of exclusivity was
16 granted.