

Rand Paul

PAUL

AMENDMENT NO. 3 Calendar No. _____

Purpose: To permit the use of data from clinical investigations conducted in the European Union.

IN THE SENATE OF THE UNITED STATES—112th Cong., 2d Sess.

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, 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. PAUL

Viz:

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

2 **SEC. 11__ . EFFECT OF CLINICAL INVESTIGATION DATA**

3 **FROM THE EUROPEAN UNION ON INVESTIGA-**

4 **TIONS CONDUCTED IN THE UNITED STATES.**

5 Subchapter E of chapter V (21 U.S.C. 360bbb et

6 seq.), as amended by this Act, is amended by adding at

7 the end the following:

1 **"SEC. 569B. EFFECT OF CLINICAL INVESTIGATION DATA**
2 **FROM THE EUROPEAN UNION ON INVESTIGA-**
3 **TIONS CONDUCTED IN THE UNITED STATES.**

4 "Notwithstanding any other provision of this Act—

5 "(1) if a drug or device has been approved for
6 marketing in the European Union for at least 1
7 year, the results of the clinical investigations con-
8 ducted in the European Union that correspond to
9 Phase I investigations in the United States may be
10 used in lieu of results from such a Phase I investiga-
11 tion that would otherwise be required in an applica-
12 tion for approval, licensure, or clearance of such
13 drug or device submitted to the Secretary under this
14 chapter;

15 "(2) if a drug or device has been approved for
16 marketing in the European Union for at least 2
17 years, the results of the clinical investigations con-
18 ducted in the European Union that correspond to
19 Phases I and II investigations in the United States
20 may be used in lieu of results from such a Phase I
21 or II investigation that would otherwise be required
22 in an application for approval, licensure, or clear-
23 ance of such drug or device submitted to the Sec-
24 retary under this chapter;

25 "(3) if a drug or device has been approved for
26 marketing in the European Union for at least 3

1 years, the results of the clinical investigations con-
2 ducted in the European Union that correspond to
3 Phases I, II, and III investigations in the United
4 States may be used in lieu of results from such a
5 Phase I, II, or III investigation that would otherwise
6 be required in an application for approval, licensure,
7 or clearance of such drug or device submitted to the
8 Secretary under this chapter; and

9 “(4) if a drug or device has been approved for
10 marketing in the European Union for at least 4
11 years, the results of the clinical investigations con-
12 ducted in the European Union that correspond to
13 Phases I, II, III, and IV investigations in the United
14 States may be used in lieu of results from such a
15 Phase I, II, III, or IV investigation that would oth-
16 erwise be required in an application for approval, li-
17 censure, or clearance of such drug or device sub-
18 mitted to the Secretary under this chapter.”