

112TH CONGRESS
2^D SESSION

H. R. 6342

To allow the importation, distribution, and sale of investigational drugs and devices intended for use by terminally ill patients who execute an informed consent document.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2012

Mr. PAUL (for himself, Mr. BROUN of Georgia, and Mr. HANNA) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To allow the importation, distribution, and sale of investigational drugs and devices intended for use by terminally ill patients who execute an informed consent document.

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 “Compassionate Free-
5 dom of Choice Act of 2012”.

1 **SEC. 2. DRUGS AND DEVICES FOR USE BY TERMINALLY ILL**
2 **PATIENTS.**

3 The Federal Food, Drug, and Cosmetic Act is amend-
4 ed by inserting after section 561 (21 U.S.C. 360bbb) the
5 following:

6 **“SEC. 561A. DRUGS AND DEVICES FOR USE BY TERMINALLY**
7 **ILL PATIENTS.**

8 “(a) IN GENERAL.—Nothing in this Act or section
9 351 of the Public Health Service Act prevents or restricts,
10 and the Food and Drug Administration shall not imple-
11 ment or enforce any provision of law preventing or re-
12 stricting, the importation, distribution, or sale of an inves-
13 tigational drug or device intended for use by a terminally
14 ill patient in accordance with subsection (b).

15 “(b) PATIENT REQUIREMENTS.—In order for an in-
16 vestigational drug or device to be intended for use in ac-
17 cordance with this subsection, such drug or device must
18 be intended for use by a patient who has—

19 “(1) been diagnosed with a terminal illness by
20 a licensed physician;

21 “(2) been informed by a licensed physician that
22 no drug or device that is lawfully marketed in the
23 United States is likely to cure the illness; and

24 “(3) executed a written informed consent docu-
25 ment that states—

1 “(A) the known and potential risks and
2 benefits of such drug or device; and

3 “(B) any indications of the illness for
4 which a drug or device is lawfully marketed, or
5 for which treatment is otherwise available, in
6 the United States.

7 “(c) PROHIBITION ON REQUIRING THE DISCLOSURE,
8 COLLECTION, AND REPORTING OF CERTAIN INFORMA-
9 TION BY FOOD AND DRUG ADMINISTRATION.—

10 “(1) IN GENERAL.—The Commissioner of Food
11 and Drugs may not require the disclosure, collection,
12 or reporting of—

13 “(A) any information related to the deliv-
14 ery, administration, or use of an investigational
15 drug or device pursuant to this section; or

16 “(B) any information related to the clinical
17 outcomes experienced by a terminally ill patient
18 supplied an investigational drug or device pur-
19 suant to this section.

20 “(2) EXCEPTION.—Nothing in this subsection
21 prevents the sponsor of a clinical trial from volun-
22 tarily disclosing, collecting, or reporting information
23 to the Food and Drug Administration.

1 “(d) DEFINITION OF INVESTIGATIONAL DRUG OR
2 DEVICE.—In this section, the term ‘investigational drug
3 or device’ means a drug or device that—

4 “(1) has not yet been approved, licensed, or
5 cleared for commercial distribution under section
6 505, 510(k), or 515 of this Act or section 351 of the
7 Public Health Service Act (42 U.S.C. 262), and can-
8 not otherwise be lawfully marketed in the United
9 States; and

10 “(2) is or has been the subject of one or more
11 clinical trials.”.

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