

113TH CONGRESS
2^D SESSION

H. R. 4475

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2014

Mr. GRIFFITH of Virginia (for himself and Mr. HANNA) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

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

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 2014”.

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 manufacture, importation, distribution, or
13 sale of an investigational drug or device intended for use
14 by a terminally ill patient in accordance with subsection
15 (b).

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

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

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

25 “(3) executed a written informed consent docu-
26 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, and cannot otherwise be
8 lawfully marketed in the United States; and

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

11 **SEC. 3. LIABILITY PROTECTION.**

12 The Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 301 et seq.) is amended by inserting after section
14 561A, as inserted by section 2 of this Act, the following:

15 **“SEC. 561B. LIABILITY PROTECTION.**

16 “Except in the case of gross negligence or willful mis-
17 conduct, any person who manufactures, imports, distrib-
18 utes, prescribes, dispenses, or administers an investiga-
19 tional drug or device in accordance with section 561A shall
20 not be liable in any action under Federal or State law for
21 any loss, damage, or injury arising out of, relating to, or
22 resulting from—

23 “(1) the design, development, clinical testing
24 and investigation, manufacturing, labeling, distribu-

1 tion, sale, purchase, donation, dispensing, prescrip-
2 tion, administration, or use of the drug or device; or
3 “(2) the safety or effectiveness of the drug or
4 device.”.

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