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113TH CONGRESS
2D 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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Compassionate Freedom of Choice Act of 2014''.

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

The Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561 (21 U.S.C. 360bbb) the following:

"SEC. 561A. DRUGS AND DEVICES FOR USE BY TERMINALLY ILL PATIENTS.

''(a) IN GENERAL.—Nothing in this Act or section 351 of the Public Health Service Act prevents or restricts, and the Food and Drug Administration shall not implement or enforce any provision of law preventing or restricting, the manufacture, importation, distribution, or sale of an investigational drug or device intended for use by a terminally ill patient in accordance with subsection (b).

''(b) PATIENT REQUIREMENTS.—In order for an investigational drug or device to be intended for use in accordance with this subsection, such drug or device must be intended for use by a patient who has—

''(1) been diagnosed with a terminal illness by a licensed physician;

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

''(3) executed a written informed consent document that states—

''(A) the known and potential risks and benefits of such drug or device; and

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

''(c) PROHIBITION ON REQUIRING THE DISCLOSURE, COLLECTION, AND REPORTING OF CERTAIN INFORMATION BY FOOD AND DRUG ADMINISTRATION.—

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

''(A) any information related to the delivery, administration, or use of an investigational drug or device pursuant to this section; or

''(B) any information related to the clinical outcomes experienced by a terminally ill patient supplied an investigational drug or device pursuant to this section.

''(2) EXCEPTION.—Nothing in this subsection prevents the sponsor of a clinical trial from voluntarily disclosing, collecting, or reporting information to the Food and Drug Administration.

''(d) DEFINITION OF INVESTIGATIONAL DRUG OR DEVICE.—In this section, the term 'investigational drug or device' means a drug or device that—

''(1) has not yet been approved, licensed, or cleared for commercial distribution under section 505, 510(k), or 515 of this Act or section 351 of the Public Health Service Act, and cannot otherwise be lawfully marketed in the United States; and

''(2) is or has been the subject of one or more clinical trials.''.

SEC. 3. LIABILITY PROTECTION.

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

''SEC. 561B. LIABILITY PROTECTION.

''Except in the case of gross negligence or willful misconduct, any person who manufactures, imports, distributes, prescribes, dispenses, or administers an investigational drug or device in accordance with section 561A shall not be liable in any action under Federal or State law for any loss, damage, or injury arising out of, relating to, or resulting from—

''(1) the design, development, clinical testing and investigation, manufacturing, labeling, distribu-

tion, sale, purchase, donation, dispensing, prescription, administration, or use of the drug or device; or

''(2) the safety or effectiveness of the drug or device.''.

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