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113TH CONGRESS
2D SESSION

H. R. 5854

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

DECEMBER 11, 2014

Mr. GRAYSON introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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

SECTION 1. 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 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) 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 (42 U.S.C. 262), and cannot otherwise be lawfully marketed in the United States; and

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

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