

## 115TH CONGRESS 1ST SESSION H.R. 1020

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

February 13, 2017

Mr. Griffith (for himself and Mr. Brat) 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 2017".

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,
0	and the Food and Drug Administration shall not imple-
1	ment or enforce any provision of law preventing or re-
2	stricting, the manufacture, importation, distribution, or
3	sale of an investigational drug or device intended for use
4	by a terminally ill patient in accordance with subsection
5	(b).
6	"(b) Patient Requirements.—In order for an in-
7	vestigational drug or device to be intended for use in ac-
8	cordance with this subsection, such drug or device must
9	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
- 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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