

---

---

## A BILL FOR AN ACT

RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:**

1           SECTION 1. The legislature finds that the process of  
2 approval for investigational drugs often takes many years. This  
3 process often denies terminally ill patients the benefit of  
4 potentially life-saving treatments. The legislature believes  
5 that terminally ill patients have a right to access these  
6 treatments when fully aware of the potential risks, benefits,  
7 and consequences.

8           The federal Food, Drug, and Cosmetic Act, prohibits a  
9 person from introducing into interstate commerce any new drug  
10 unless the drug has been approved by the United States Food and  
11 Drug Administration (FDA). Clinical trials must be completed to  
12 establish the safety and efficacy of the drug in human  
13 populations prior to FDA approval. Further, HRS §328-17 outlines  
14 the state restrictions on dispensing drugs pending approval  
15 under section 505 of the Federal Act. The intent of this  
16 legislation is to remove all state-barriers to any terminally



1 ill patient seeking the use of potentially life-saving  
2 investigational treatments.

3 SECTION 2. Section 328-17, Hawaii Revised Statutes, is  
4 amended by amending subsection (1) to read as follows:

5 **"§328-17 New drugs, regulation of sale, etc.; exceptions.**

6 (a) No person shall sell, deliver, offer for sale, hold for  
7 sale, or give away any new drug unless (1) an application with  
8 respect thereto has been approved and the approval has not been  
9 withdrawn under section 505 of the Federal Act, or (2) the  
10 patient is terminally ill; a physician recommends use of  
11 investigational treatment, the patient provides informed  
12 consent; and the treatment has completed a "Phase I" clinical  
13 safety/dose limitation trial; or (3) when not subject to the  
14 Federal Act, unless the drug has been tested and has been found  
15 to be safe for use and effective in use under the conditions  
16 prescribed, recommended, or suggested in the labeling thereof,  
17 and prior to selling or offering for sale the drug, there has  
18 been filed with the director of health an application setting  
19 forth (A) full reports of investigations which have been made to  
20 show whether or not the drug is safe for use and whether the  
21 drug is effective in use; (B) a full list of the articles used



1 as components of the drug; (C) a full statement of the  
2 composition of the drug; (D) a full description of the methods  
3 used in, and the facilities and controls used for, the  
4 manufacture, processing, and packing of the drugs; (E) such  
5 samples of the drug and of the articles used as components  
6 thereof as the director may require; and (F) specimens of the  
7 labeling proposed to be used for the drug.

8 (b) An application provided for in subsection (a)(2) shall  
9 become effective on the one hundred eightieth day after the  
10 filing thereof, except that if the director finds, after due  
11 notice to the applicant and giving him an opportunity for a  
12 hearing, (1) that the drug is not safe or not effective for use  
13 under the conditions prescribed, recommended, or suggested in  
14 the proposed labeling thereof; or (2) the methods used in, and  
15 the facilities and controls used for the manufacture,  
16 processing, and packing of such drugs are inadequate to preserve  
17 its identity, strength, quality, and purity; or (3) based on a  
18 fair evaluation of all material facts, such labeling is false or  
19 misleading in any particular, he shall, prior to the effective  
20 date of the application, issue an order refusing to permit the  
21 application to become effective.



1 (c) An order refusing to permit an application under this  
2 section to become effective may be revoked by the director.

3 (d) The director shall promulgate regulations for  
4 exempting from the operation of the foregoing subsections of  
5 this section drugs intended solely for investigational use by  
6 experts qualified by scientific training and experience to  
7 investigate the safety and effectiveness of drugs. Such  
8 regulations may, within the discretion of the director, among  
9 other conditions relating to the protection of the public  
10 health, provide for conditioning such exemption upon: (1) the  
11 submission to the director before any clinical testing of a new  
12 drug is undertaken, of reports, by the manufacturer or the  
13 sponsor of the investigation of such drug, of preclinical tests  
14 (including tests on animals) of such drug adequate to justify  
15 the proposed clinical testing; (2) the manufacturer or the  
16 sponsor of the investigation of a new drug proposed to be  
17 distributed to investigators for clinical testing obtaining a  
18 signed agreement from each of such investigators that patients  
19 to whom the drug is administered will be under his personal  
20 supervision, or under the supervision of investigators  
21 responsible to him, and that he will not supply such drug to any



1 other investigator, or to clinics, for administration to human  
2 beings; and (3) the establishment and maintenance of such  
3 records, and the making of such reports to the director by the  
4 manufacturer or the sponsor of the investigation of such drug,  
5 of data (including but not limited to analytical reports by  
6 investigators) obtained as the result of such investigational  
7 use of such drugs, as the director finds will enable him to  
8 evaluate the safety and effectiveness of such drug in the event  
9 of the filing of an application pursuant to subsection (b).  
10 Such regulations shall provide that such exemption shall be  
11 conditioned upon the manufacturer, or the sponsor of the  
12 investigation, requiring that experts using such drugs for  
13 investigational purposes certify to such manufacturer or sponsor  
14 that they will inform any person to whom such drugs, or any  
15 controls used in connection therewith, are being administered,  
16 or their representatives, that such drugs are being used for  
17 investigational purposes and will obtain the consent of such  
18 person or their representatives, except where they deem it not  
19 feasible or, in their professional judgment, contrary to the  
20 best interests of such person.



1           (e) In the case of any drug for which an approval of an  
2 application filed pursuant to this section is in effect, the  
3 [applicant] shall establish and maintain such records, and make  
4 such reports to the director, of data relating to clinical  
5 experience and other data or information, received or otherwise  
6 obtained by such applicant with respect to such drugs, as the  
7 director may by regulation, or by order with respect to such  
8 application, prescribe; provided that regulations and orders  
9 issued under this subsection and under subsection (d) shall have  
10 due regard for the professional ethics of the medical profession  
11 and the interests of patients and shall provide, where the  
12 director deems it to be appropriate, for the examination, upon  
13 request, by the persons to whom such regulations or orders are  
14 applicable, of similar information received or otherwise  
15 obtained by the director.

16           Every person required under this section to maintain  
17 records, and every person in charge or custody thereof, shall,  
18 upon request of an officer or employee designated by the  
19 director permit such officer or employee at all reasonable times  
20 to have access to and copy and verify such records.



# H.B. NO. 1980

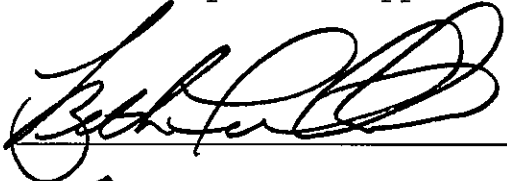
1 (f) The director may, after affording an opportunity for  
 2 hearing, revoke an application approved pursuant to this section  
 3 if he finds that the drug, based on evidence acquired after such  
 4 approval, may not be safe or effective for its intended use, or  
 5 that the facilities or controls used in the manufacture,  
 6 processing, or labeling of such drug may present a hazard to the  
 7 public health."

8 SECTION 3. New statutory material is underscored.

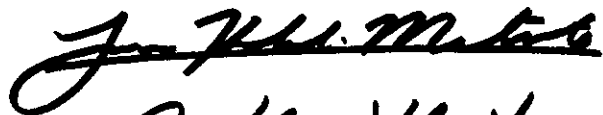
9 SECTION 4. This act shall take effect upon its approval.

10

INTRODUCED BY:



Beth Paul



Jan K. M. M. M.



Gordon Hieken



Greg Ward

JAN 22 2016



# H.B. NO. 1980

**Report Title:**

Patient Protection; Terminal Illness; Investigational Drugs

**Description:**

Grants terminally ill patients access to potentially life-saving investigational drugs, biological products, and devices that are only accessible through clinical trials.

*The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.*

