THE SENATE
TWENTY-EIGHTH LEGISLATURE, 2016
STATE OF HAWAII

S.B. NO. 2713

JAN 22 2016

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:

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

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

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

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

"**§328-17 New drugs, regulation of sale, etc.; exceptions.** (a) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under section 505 of the Federal Act, or (2) the patient is terminally ill; a physician recommends use of investigational treatment, the patient provides informed consent; and the treatment has completed a "Phase I" clinical safety/dose limitation trial; or (3) when not subject to the Federal Act, unless the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale the drug, there has been filed with the director of health an application setting forth (A) full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use; (B) a full list of the articles used

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

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

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

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

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

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

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

S.B. NO. 2713

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

SECTION 3. New statutory material is underscored.

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

INTRODUCED BY:

S.B. NO. 2713

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.

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