LATE

TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
TWENTY-EIGHTH LEGISLATURE, 2016

ON THE FOLLOWING MEASURE:
S.B. NO. 2181, RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS.

BEFORE THE:
SENATE COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH

DATE: Thursday, February 4, 2016 **TIME:** 9:00 a.m.

LOCATION: State Capitol, Room 229

TESTIFIER(S): Douglas S. Chin, Attorney General, or
Wade H. Hargrove III, Deputy Attorney General

Chair Baker and Members of the Committee:

This measure might conflict with existing state law and is inconsistent with the federal law that regulates the sale and distribution of drugs and medical devices. Therefore, we express the following concerns and recommend that, should this measure move forward, any inconsistencies with federal and state law be remedied. We will work with the Committee to address these concerns.

This measure would add a new section to chapter 321, Hawaii Revised Statutes (HRS), to increase access to "investigational drugs, biological products, or devices" (page 2, lines 16-17) for terminally ill patients by allowing a manufacturer of any such drug, biological product, or device to "make available" (page 6, lines 13-14) the product to terminally ill patients in Hawaii where certain preconditions have been met. To become a patient eligible for a drug, biological product, or device, that patient must have (1) a terminal illness attested to by that person's physician, (2) considered all other United States Food and Drug Administration (FDA)-approved treatments, (3) been unable to participate in a clinical trial due to time or geographical constraints, (4) received a recommendation from a physician for a drug, biological product, or device, (5) given informed consent for the drug, product, or device, and (6) documentation from his or her physician that the patient has met all of these requirements (pages 2-3).

Also contained in this measure are provisions for insurance carriers to refuse coverage of any investigational drug, biological product, or device, protections for the heirs of a deceased patient from any debt incurred in relation to the treatment envisioned by this measure, assurances that the license of any health care provider who recommends treatment pursuant to this measure

shall not be revoked, and a prohibition against any state official blocking an eligible patient's access to an investigational drug, biological product, or medical device. Because existing state and federal law expressly prohibit the sale and distribution of drugs or medical devices without FDA approval (see the discussion below), this measure should be reconciled with the conflicting state law governing drugs and devices, and consideration should be given to the possible constitutional challenges that may be presented due to the inconsistency with federal law.

With respect to this measure's relationship to existing state law, section 328-17, HRS, prohibits the sale and distribution of any new drug without that drug having, in effect, complied with section 505 of the Federal Food Drug and Cosmetic Act (FDCA) (codified in title 21, chapter 9 of the United States Code (USC)). This is largely because chapter 328 is based on its federal counterparts in the FDCA and was designed to complement, rather than compete with it. Therefore, if this measure becomes part of chapter 321 as intended, it will conflict with our own chapter 328. While this measure's wording is permissive rather than prescriptive, and only allows manufactures of an investigational drug, biological product, or devices to "make available" their products, it does allow manufacturers to receive compensation (pages 6-7). Regardless of whether there is an actual exchange of money, chapter 328 as written makes the "distribution" of adulterated drugs and devices punishable under section 328-6, and section 328-17 prohibits anyone from even "giv[ing] away" drugs not approved pursuant to the FDCA. The sale or distribution of "unapproved" drugs or devices is historically treated as the sale of adulterated product and, thus, chapter 328, which currently requires FDA approval of both, would need to be reconciled with this measure.

The FDCA regulates the sale and distribution of drugs and medical devices in interstate commerce and has separate provisions for each. Since this measure fails to define exactly what is meant by a "biological product," it is safe to presume that, to the extent a biological product is a "drug" for purposes of the FDCA (which contains a very broad definition of the term in its own section 321), it will be preempted in the same manner as a "drug" as that term is used in this measure. Section 505, which prohibits the sale or distribution of a drug without FDA approval, states that:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application is filed pursuant to [the subsections pertaining to applications for new drugs] is effective with respect to such drug.

21 U.S.C. section 355.

Section 505 makes it illegal under federal law to make available to anyone a new drug (which presumably includes a "biological product") without its first having been approved by the FDA. Whether or not the FDCA preempts this measure pursuant to the Supremacy Clause (Article VI) of the United States Constitution, which commands that the laws of the United State shall be the "supreme law of the land," is unclear because there is no provision that expressly preempts state requirements. This measure does, however, appear to be inconsistent with the FDCA and Congressional intent to require all new drugs and medical devices to obtain approval prior to being marketed. One of the crucial steps in drug marketing is, of course, the safe and successful trials necessary to prove its eligibility for FDA approval.

Section 540 of the FDCA regulates new medical devices and separates them into three distinct classes based upon the risk of their use and indications of use. 21 U.S.C. section 360c. Unlike section 505 relating to drugs, section 521 explicitly preempts state requirements for medical devices. Section 521 states:

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement ---

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. section 360k.

Many of the recent cases that examine drug and medical device preemption concern state tort actions against manufacturers where those manufacturers have been sued for failing to adequately warn consumers despite FDA approval, but predicting when preemption will actually occur is extremely difficult because the outcomes turn on the facts of the particular case. For example, the Supreme Court decided that a plaintiff could pursue a state "failure to warn" claim

based upon a drug being improperly labeled, despite the fact that the drug's label was FDA approved and thereby conformed to the requirements of the FDCA and seemingly counter to earlier precedent. Wyeth v. Levine 555 U.S. 555 (2009) (a patient recovered on the basis that the manufacturer improperly labeled a drug that caused gangrene and amputation where it was improperly administered intravenously). With respect to drugs at least, the current approach appears to be that only where the state requirement is clearly in conflict with (rather than simply in addition to) a federal requirement, will preemption be found. See also Mason v. SmithKline Beecham Corp., 596 F.3d 387 (7th Cir. 2010) (finding that there was no clear evidence the FDA would not have approved an enhanced label and, therefore, there was no preemption of the state tort claim). The Supreme Court views medical devices differently than drugs in light of section 521 of the FDCA and recently decided a plaintiff's state product liabilities action for a defective device was preempted. Riegle v. Medtronic, Inc., 552 U.S. 312 (2008) (a patient's catheter ruptured during heart surgery causing severe injury). So it would appear that the FDCA preempts state requirements that are different with respect to medical devices. The question remains, however, what preemptive effect the FDCA has on state requirements for drugs. Furthermore, it is unclear whether the qualified immunity for manufacturers that this measure intends to create would be preempted at all being that it is not, technically, a "requirement" at all but rather a kind of exemption. Again, the cases examining these preemption questions primarily involve tort cases where state law arguably provides more protection for patients, not less and where the claimant is often relying upon common law principles rather than specific state requirements for either drugs or devices, so it is unclear how useful any analogy drawn from them will be.

While the state law conflicts are unambiguous, and therefore can and should be addressed, it is difficult to make any specific recommendations based upon a prediction about the outcome of potential challenges to the constitutionality of this measure on federal preemption grounds. This difficulty arises from the fact that more recent findings of no preemption in drug cases, which had been the historic trend based on a respect for state police powers, has not been entirely consistent. See Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008) (finding state "failure to warn" tort action preempted because increased risk of suicide was not required by FDA on generic form of Paxil antidepressant). The cases also appear heavily dependent upon

the facts of the case and an analysis of the specific FDA actions, and though preemption where medical devices are at issue has been relatively consistent, these decisions are focused on and possibly dictated by their products liability law backdrop. Because it is also unclear exactly what form a constitutional challenge against this measure may take, we cannot predict likely outcomes. Therefore we have provided these comments for your consideration and recommend that, should this measure move forward, any inconsistencies be remedied.

[redacted]

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, February 03, 2016 5:45 PM
To: CPH Testimony
Cc: joy.yadao@gmail.com
Subject: Submitted testimony for SB2181 on Feb 4, 2016 09:00AM

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SB2181
Submitted on: 2/3/2016
Testimony for CPH on Feb 4, 2016 09:00AM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Joy Yadao	Individual	Support	No

Comments: I am a Registered Nurse with over 15 years of hospice and palliative care experience in Hawaii. I feel that we should do everything we can to allow people living with serious illness to access care aimed at relieving suffering and improving quality of life! Thank you.

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Testimony COMMENTING on SB2181
RELATING TO ACCESS TO TREATMENT FOR TERMINALLY ILL PATIENTS

SENATOR ROSALYN H. BAKER, CHAIR
SENATE COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH

Hearing Date: February 4, 2016 Room Number: 229
Time: 9:00am

Fiscal Implications: None for the Department of Health (DOH).

Department Testimony: The department acknowledges the value of options for terminally ill patients, including access to investigational treatments, but respectfully recommends amendment of chapter 432E, *Patients' Bill of Rights and Responsibilities Act*, instead of chapter 321.

Section 432E-36, for example, currently governs "External review of experimental or investigational treatment adverse determinations."

Offered Amendments: Page 2, Bill Section 2, from line 13:

SECTION 2. Chapter [~~321~~] 432E, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"[~~§321~~]**§432E- Access to investigational drugs, biological products, or devices for terminally ill patients.**