

SB2491

Measure Title:
RELATING TO HEALTH.

Report Title:
Health and Safety Program; Biological Research Laboratory; Biotechnology

Description:
Establishes a health and safety program within the department of health and an oversight committee for biological research laboratories and facilities that study and contain biological agents, human pathogens, or toxins in Hawaii.

Introducer(s):
GABBARD, Chun Oakland, English, Espero, Hanabusa, Inouye, Kim

Current Referral:
HTH, WAM



STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O. Box 3378
HONOLULU, HAWAII 96801-3378

In reply, please refer to:
File:

Committee on Health

SB2491, RELATING TO HEALTH

**Testimony of Chiyome Leinaala Fukino, M.D.
Director of Health**

**Wednesday, February 13, 2008
1:15 p.m.
Conference Room 016**

1 **Department's Position:** The Department of Health appreciates the intent of this measure, but has
2 serious concerns about its expansive scope, the lack of projected funding, and the likely adverse affect
3 on priorities in the executive supplemental budget proposal, so the Department of Health respectfully
4 opposes this bill.

5 **Fiscal Implications:** Unclear, but considerable. Even under a scope that is reduced from that proposed,
6 the program would require a full time staff, operations and travel budget, and compensation for
7 committee members.

8 **Purpose and Justification:** This bill establishes a health and safety program within the Department of
9 Health and a biosafety committee with expansive oversight responsibilities for laboratories and facilities
10 that research or contain biological agents, human pathogens, or toxins.

11 The department appreciates the intent to provide oversight and regulatory control over
12 institutions conducting biological research; however, the bill raises serious concerns.

13 The proposed Health and Safety Program would require significant resources such as permanent
14 staff (e.g., a program manager and administrative staff), along with a travel and operations budget.
15 Compensation should not be limited to the executive director of the biosafety oversight committee.

1 Furthermore, the time of the committee members is valuable. In order to get knowledgeable members,
2 there should be compensation beyond direct expenses. Committees should have industry and non-
3 academic government representatives. There are too many barriers and constraints to participation.
4 Hawaii has a small laboratory science community and success requires networking. It is unrealistic to
5 expect successful recruitment of scientists with the requisite expertise but no affiliation of any kind with
6 actual research work. We should encourage scientific stakeholder participation rather than excluding
7 them. That said, committee members will also have access to sensitive commercial and security
8 information and would require some background clearance at a minimum. Some costs may be offset by
9 fees collected, but the permit fee structure is unclear and has potential to be a burdensome and uneven
10 tax on institutions.

11 For this program to be successful, the scope would need to be limited considerably from the
12 proposal. The responsibility for standards development should be eliminated because standards already
13 exist (e.g., facility location, operation, maintenance, procedures; agent transportation). Remove from
14 the measure restrictive criteria for laboratory location and perceived public hazards that are arbitrary and
15 not supported by evidence. Coordinate a biosafety review into existing construction permit processes
16 rather than setting up a separate process. It is beyond oversight responsibility to “seek how to improve
17 how laboratories and facilities operate, handle biological agents..., and the delivery or transportation of
18 biological agent...”, so these provisions should be eliminated. There should be criteria for selection of
19 quality community representatives to institutional biosafety committees other than very restrictive
20 residence requirements. The annual report requirement for institutions is too burdensome and should be
21 reduced. At least to some extent, the requirement for research pre-approval should be eliminated
22 because the committee will waste time reviewing proposals that do not get funded or started. Some of
23 the proposed equipment certification documentation requirements for the purpose of annual reporting is
24 of little or no value, and should be eliminated. Some of the training requirements detail should be

1 removed from the bill – the emphasis is disproportionate to the need. Oversight committee does not
2 need to approve training or waste management plans.

3 There are technical and clerical errors in the bill that need correction. For example, completion
4 of a training plan is normally not an entry requirement; it's a work process requirement. The proposed
5 statutory prohibition of research projects really needs to be critically refined; the existing prohibitions
6 are too general and subjective.

7 Thank you for the opportunity to testify.

Testimony Presented Before the
Senate Committee on Health

by
James R. Gaines, Vice President for Research
University of Hawaii System

Wednesday, February 13, 2008, 1:15 p.m.
State Capitol, Conference Room 016

SB 2491 Relating to Health (Health and Safety Program for Biological Research Laboratories)

Chair Ige, Vice Chair Fukunaga, and Members of the Committee:

The University of Hawaii strongly opposes SB 2491 which would create an overly complex and redundant regulatory system for building and operating Biosafety Level 2 (BSL-2) and Biosafety Level 3 (BSL-3) laboratories in Hawaii. Federal, State, and University oversight currently exist for these labs. As such, this bill would not enhance public safety but would significantly impede lab operations as well as add cost to both the lab and the oversight agency. Since Hawaii's public health system must rely on these labs for containing and diagnosing pathogens, this bill could actually jeopardize public safety.

The University of Hawaii takes issues of public health and safety very seriously for two reasons. **First**, we conduct a wide range of biological research throughout our system, including extremely important work on infectious diseases, which is vitally important to the State of Hawaii. Our exposure to infectious diseases is significant because we attract travelers from all parts of the world. Unfortunately, our geographic isolation limits our access to labs which diagnose uncommon diseases, particularly exotic emerging diseases from Asia such as SARS. UH's BSL-3 labs are essential assets for Hawaii to effectively respond to an outbreak of infectious disease and prevent it from spreading. Rapid and effective emergency response to a pathogen of unknown etiology can be accomplished only if the pathogen is identified in a timely manner.

Second, it is our University scientists and lab workers, rather than the general public, who face the most risk from research on infectious diseases. The labs are specially designed and equipped to prevent pathogens from escaping into the environment. As a result, there has not been a documented case of a pathogen escaping from any of the more than 1,350 BSL-3 labs in the United States, and endangering the community. Equally important, the lab staff is highly trained to work with infectious disease agents. While laboratory accidents have occurred

elsewhere in the US causing lab workers to become ill, these incidents have not resulted in the spread of an illness into the surrounding community.

The existing Federal and State regulatory framework for BSL-2 and BSL-3 labs is comprehensive and is more than adequate to maximize public health and safety. I would like to comment on the significant differences between BSL-2 and BSL-3 labs.

Biosafety Level 2 Laboratories. BSL-2 labs are common in Hawaii and throughout the nation. UH alone has over 700 BSL-2 labs, and we estimate that Hawaii has a few hundred more in hospitals and clinics, government agencies, private companies, and military installations. There is about a 70-year track record of BSL-2 lab operations in Hawaii, with no known major incidents endangering public health and safety.

BSL-2 labs are characterized by the Federal Centers for Disease Control as suitable for work involving agents (e.g., microbes, viruses, etc.) that can cause severe and fatal disease, but which pose only moderate risk to the community. The agents worked on in BSL-2 labs cannot be transmitted through the air, so there are no specific requirements for ventilation systems. All manipulation of infectious agents is conducted within biosafety cabinets. The primary risks are to the lab workers themselves through cuts or membrane exposures. Lab workers are highly trained and there are OSHA standards to enforce safe worker conditions. UH inspects each of its BSL-2 labs annually, or more frequently if the nature of research warrants greater attention.

Given the historic safety track record, low risk, and large volume of BSL-2 labs, it is neither necessary nor practical for the State to implement the new oversight policy for BSL-2 labs as proposed in SB 2491. Further, it is neither practical nor necessary to require remote siting of BSL-2 labs, as they are integral to larger research and clinical operations and present no significant risks to adjacent uses.

Biosafety Level 3 Laboratories. There is only one functioning BSL-3 lab in Hawaii, a small University of Hawaii BSL-3 lab at Leahi Hospital. The UH has another small suite of new BSL-3 labs at the John A. Burns School of Medicine in Kakaako, which is nearly ready for use. Other BSL-3 labs are in the planning or construction phases.

BSL-3 labs are designed for research on pathogens that can also cause severe and fatal disease, but can be spread through the air. Accordingly, BSL-3 labs are equipped with: (a) extremely sophisticated air circulation systems with HEPA (High Efficiency Particulate Air) filtration that prevent pathogens from escaping from the lab; (b) multiple, redundant systems for containing agents used in research and destroying and sterilizing them when the work is

completed; (c) biosafety cabinets or other containment devices in which manipulation of infectious agents is conducted; and (d) personal protective equipment that must be worn by workers to prevent contact with or inhalation of pathogens. Lab workers receive comprehensive training and must follow rigorous procedures and protocols to ensure the safe handling of pathogens during diagnosis and experiments, and destruction of pathogens upon completion of work. As with the BSL-2 labs, the trained staff is one of the most important safeguards in preventing accidents in the BSL-3 lab. There are also strict protocols for responding to and reporting any lab accidents that may occur.

Each of the University's BSL-3 labs was commissioned by an independent engineering firm and then certified for operation by an independent lab certification firm. Commissioning and certification are conducted according to Federal (CDC, NIH, and USDA) guidelines. The commissioning and certification processes ensure that the labs can be safely operated for the specific work to be done. The USDA also conducts additional inspections to certify our BSL-3 labs for work on specific pathogens that the agency regulates. The FBI also conducts background security checks on any person involved in select agent research.

In addition, the University's Biosafety Officer thoroughly inspects each BSL-3 lab annually. The State Department of Agriculture and/or the State Department of Health also inspect our BSL-3 labs whenever the UH applies for approval to import a new microbe deemed to be of high risk.

Locational concerns for BSL-3 labs can be addressed through the Environmental Assessment process, the Threat Risk Assessment process, and the community outreach process. As previously noted, the location of a BSL-3 lab poses no significant threat to surrounding uses. As such, many BSL-3 labs are located in urbanized areas or on university campuses, and the US Centers for Disease Control in Atlanta even has one of its BSL-3 labs located next to a childcare center.

Based on the health and safety network and regulations already in place, the University of Hawaii strongly opposes this bill which would impede research rather than create a safer environment. Thank you for the opportunity to testify.



SENATE BILL 2491 Relating to Health

DATE: February 13, 2008
1:15 PM., Conference Room 016

TO: Senate Committee on Health
The Honorable David Ige, Chair
The Honorable Carol Fukunaga, Vice Chair

FROM: Lisa H. Gibson
President
Hawaii Science & Technology Council

RE: Testimony in strong opposition to SB2491.

Aloha Chair, Vice Chair, and Members of the Committee:

The Hawaii Science & Technology Council would like to submit this testimony in strong opposition to SB2491 which would create an overly complex and redundant regulatory system for building and operating Biosafety Level 2 (BSL2) and Biosafety Level 3 (BSL3) laboratories in Hawaii. This bill's provisions largely duplicate federal, state, and university oversight for these labs. Thus, SB2491 would not make the public any safer, but would significantly impede lab operations. Since Hawaii's public health system must rely on these labs for containing and diagnosing pathogens, this bill could actually make the public less safe. The existing regulatory framework for BSL2 and BSL3 labs is comprehensive and more than adequate to maximize public health and safety.

The Hawaii Science & Technology Council is a private tax-exempt 501(c)6 industry association with a 28-member board. The council serves Hawaii companies engaged in ocean sciences, agricultural biotechnology, astronomy, defense aerospace, biotech/life sciences, information & communication technology, energy, environmental technologies, and creative media.

Thank you for the opportunity to testify on this important bill.

Lisa H. Gibson
President

testimony

From: Pang, Lorrin W. [lorrin.pang@doh.hawaii.gov]
Sent: Tuesday, February 12, 2008 3:00 PM
To: testimony
Cc: Panghi@hawaii.rr.com
Subject: SB2491 Health and Safety Program

Testimony for SB 2491
Health and Safety Program; Biological Research Laboratory; Biotechnology

To: HTH and WAM

From: Lorrin Pang, MD, MPH
As private citizen
166 River Rd
Wailuku, HI 96793

Aloha Committee Members,

I strongly support SB2491 for the reasons covered in the Bill itself. According to Sean Hao's Advertiser's article this past year regarding the lost documents by the UH Biosafety Committee, the reassurances by the UH for improving the system may be questionable. The UH argument of no harm-no foul is not valid. How can a system (the UH Biosafety Committee) so broken that it loses hundreds of documents over decades argue that no breaches occurred simply because none were detected? Not seeing breaches is only as good as one's surveillance system. I know this first hand as I was the intern diagnosing subtle cases of bio agents (Q fever in humans) from Letterman Army Research Unit. Even the "best" mainland Biosafety measures could not contain the weapons grade anthrax (US Senate and Postal Service) or the recent GE long grain rice contaminants (<http://www.greenpeace.org/international/press/releases/bayer-rice-scandal-could-cost>). The respective Biosafety Committees did not contain nor detect the breaches.

No matter how sound the written rules and assurances are, a Biosafety Committee must have oversight. Who guarantees that rules are enforced? It is very important to find out what happened to the oversight during the decades that UH documents were lost. Whoever was responsible for the past decades cannot be left in charge now. It is not a questions of remedial "education" and computer systems which the UH now promises but one of responsibility and accountability. I am afraid that the lost documents were just the tip of the ice berg of a lax committee. If this is to be fixed a thorough investigation as to how the problem continued for decades needs to be conducted – no matter how embarrassing the findings may be. Finally, where was the NIH oversight during the past decades? Did thy not know or not care about the lost documents?

I also would like to know who determines if an agent should be considered BSL 2 or less? Especially the newer agents. If NIH input is needed the oversight committee, not the Biosafety Committee, should be involved.

Small change: Section 1 of 4th P – should change to "...avian flu, West Nile, dengue virus...."

Thanks for the opportunity to testify.

Sincerely,

Lorrin Pang, MD, MPH

2/12/2008

LINDA LINGLE
Governor



SANDRA LEE KUNIMOTO
Chairperson, Board of Agriculture

DUANE K. OKAMOTO
Deputy to the Chairperson

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TESTIMONY OF SANDRA LEE KUNIMOTO
CHAIRPERSON, BOARD OF AGRICULTURE

BEFORE THE SENATE COMMITTEE ON HEALTH
February 13, 2008
1:15 P.M.

SENATE BILL NO. 2491
RELATING TO HEALTH

Chairperson Ige and Members of the Committee:

Thank you for the opportunity to testify on Senate Bill. No. 2491. The purpose of this bill is to establish a health and safety program and a biosafety committee within the Department of Health to regulate laboratories that utilize microorganisms and infectious parts of microorganisms for biotechnology research. We oppose this bill.

Under this proposed bill, laboratories engaged in biotechnology research will have regulatory oversight by the proposed health and safety program and biosafety committee, as well as federal regulatory oversight by the U.S. Department of Health and Human Services, National Institutes of Health (NIH). Since 1973, the Hawaii Department of Agriculture (HDOA) regulates the importation and possession of all microorganism species introduced into the State. In addition, researchers at the University of Hawaii (UH) are subject to their Institutional Biosafety Committee requirements as mandated by the NIH. Furthermore, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agriculture Bioterrorism and Protection Act of 2002 require federal oversight for the possession, use, and transfer of high-risk microorganisms and toxins, which could pose a severe threat to both humans and animals. The redundancy or overlapping of the proposed program

with existing federal and state regulations meant to protect human, animal and plant health and the environment may actually cause regulatory confusion and may be more harmful to our State.

For clarification, the UH, to date, has not imported the avian influenza virus, which was approved for import in 2006 by the Board of Agriculture. The Board also approved the importation of West Nile virus and dengue virus in 2002 and the permits for these viruses were issued after laboratory inspection and approval by HDOA, UH IBC, and the U.S. Department of Agriculture. The Centers for Disease Control and Prevention (CDC) also issued permits for the West Nile virus and dengue virus.

In reference to laboratories engaged in biotechnology research, it is not clear as to what laboratories may be subject to the proposed program because 'biotechnology research' is not defined. There is concern that laboratories doing recombinant experiments at the high school level could be affected by this proposal. The NIH has done extensive reviews concerning the use of recombinant DNA and has established detailed regulations for its safe use. The NIH has also exempted certain microorganisms and experiments from NIH regulations because they have been shown to be low-risk. High schools are known to use NIH-exempt strains.

As for the concern that major universities are located in large urban centers, laboratories are built with safety in mind. Whether they are built in urban or rural areas, the CDC and the NIH has established guidelines for four laboratory biosafety levels to accommodate the specific microorganisms being used and the type of research being conducted.

We believe that better protection of human, animal and plant health and environment of Hawaii can be achieved through further discussions between the UH, HDOA and Hawaii Department of Health to review existing regulations and addressing coordinated effort to make sure that microorganism research proposals are reviewed adequately and contained in the laboratory under appropriate safeguards.

Senator David Y. Ige, Chairman
Senate Health Committee

SB 2491 - Relating to Health

Wednesday, February 13, 2008
1:15pm, Conference Room 016 - State Capitol Building

Dear Senator Ige,

My name is Leslie Porter. I am a Registered Professional Nurse and a Physician Assistant working in the field of infectious diseases. I am providing testimony in **SUPPORT OF SB2491** – Relating to Health and the establishment of a health and safety program within the Department of Health, to serve as an oversight committee for biological research laboratories and facilities that study and contain biological agents, human pathogens, or toxins in Hawaii.

Research of various biological pathogens is at an all time high due to the threat of bioterrorism and the natural emergence of infectious diseases, most recently in the news being Avian Influenza. Frequently, reports are published describing accidental exposure of lab personnel to various by the micro-organisms of various diseases being studied. There are also reports published of accidental spills, explosions, and other catastrophes in research laboratories that affect people outside of the lab or the environment. With the recent announcement that University of Hawaii at Manoa has been awarded a grant to study and have access to Avian Influenza strains, it is only prudent to put in place steps to protect personnel working with these dangerous pathogens, the general public, and the environment.

Thank you for your time in hearing my testimony in favor of SB 2492.

Leslie Porter, RN, PA-C

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