

# UNIVERSITY OF HAWAI‘I SYSTEM

## LEGISLATIVE TESTIMONY



SB 2491  
RELATING TO HEALTH  
(Health and Safety Program for Biological Research Laboratories)

Testimony Presented Before the  
Senate Committee on Health

Wednesday, February 13, 2008, 1:15 p.m.

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

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**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.