NEIL ABERCROMBIE
GOVERNOR OF HAWAII

GARY L. GILL
ACTING DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
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In reply, please refer to:
File:

Senate Committee on Health

SB2067, RELATING TO HEALTH

Testimony of Gary L. Gill
Acting Director of Health

January 27, 2014
1:30pm

Department's Position: The department respectfully opposes this bill, but sympathetically acknowledges the tragic consequences of 2013 liver toxicity associated with use of a supplement even though the direct cause has yet to be identified. Although the proposal has good intentions, the truth of the matter is that it could not have prevented recent, heart breaking consequences; nor does it improve the ability to prevent future problems.

Fiscal Implications: Additional manpower and training would be required to enforce this measure.

Purpose and Justification: Although this measure is well intended as it attempts to provide additional protection for public health and safety, it will not have the intended impact. Manufacture of products outside Hawaii are not subject to state law/rules, but are subject to FDA interstate commerce standards. Furthermore it duplicates the department current legal authority to remove known adulterated or misbranded dietary supplements, or any other food products from the market through embargo and seizure powers as authorized by Hawaii Revised Statutes, Chapter 328. If a dietary supplement manufactured in the State of Hawaii was found to be adulterated or misbranded, the department can have the product removed from sale. Although the department has no authority outside the State of

Hawaii to ensure dietary supplements were manufactured using good manufacturing practices as stipulated by the U.S. Food and Drug Administration (FDA), the department does coordinate closely with FDA when suspect product is identified and will aggressively pursue manufacturer accountability. Current embargo and seizure powers enable the department to remove product from sale when there is sufficient evidence indicating the product has been adulterated, misbranded or epidemiologically implicated in causing illness, as was the case with Oxy Elite Pro.

Thank you for the opportunity to testify.

THE QUEEN'S HEALTH SYSTEMS

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S.B. 2067
Relating to Health
Senate Committee on Health
January 27, 2014, 1:30 p.m.

On behalf of The Queen's Medical Center, The Queen's Medical Center's Liver Center, and The Queen's Medical Center's Transplant Center, we appreciate the introduction of S.B. 2067. Collectively, Dr Naoky Tsai, Medical Director of QMC Liver Center, Dr. Marina Roytman, Internist with QMC Liver Center, Dr. Timothy Kuo, Hepatologist with QMC Liver Center support this measure which seeks to require that dietary supplements conform to federal good manufacturing practices.

We would like to share our hospital's experience during the recent outbreak of severe hepatitis in the State of Hawaii that has been linked to the weight loss dietary supplement OxyElite Pro.

The Queen's Medical Center's (QMC) Liver Center and QMC Transplant Center were at the epicenter of this (still ongoing) public health emergency. We have experienced an unprecedented number of patients presenting with acute liver failure to our facilities.

All patients who presented to us were young and previously healthy and had been taking the weight loss and performance enhancing dietary supplement, OxyElite Pro, for 2-6 weeks before the onset of symptoms of liver dysfunction. In a 16-week period, we saw 8 patients with severe drug-induced liver injury. Since the initial 8 patients, the numbers continue to grow and we are now aware of 33 patients who suffered from a drug induced liver injury. Two patients required liver transplantation, one patient died, and one is awaiting liver transplant. Most patients are recovering; however we are not certain of their long term prognosis. It is also notable that 70% of the total cohort was at least in part of Pacific Islander ethnicity. This drug induced outbreak has negatively impacted our current liver patients who have had their wait times for treatment and transplantation delayed and/or extended. The evidence for a causal link between the use of OxyElite Pro and the onset of acute hepatitis in our patients is significant.

In April of 2013, OxyElite Pro had been banned by the FDA for the cardiotoxic effects of one of its ingredients, DMAA. Shortly after, a reformulated, DMAA-free, OxyElite Pro was introduced to the market. We confirmed that all of our patients have been taking the new formulation of OxyElite Pro. Many of our patients had used the old formulation of OxyElite Pro in the past without displaying any liver-related symptoms. Alternative causes of liver dysfunction have been systematically ruled out. To put this into perspective, acute hepatic failure accounts for 3-4% of all patients waiting for liver transplant in the US and annually to about 230-250 liver transplantations. Although there are referrals for acute liver failure in Hawaii, many of these are due to reactivation of hepatitis B or acetaminophen toxicity that frequently do not need liver transplantation. In a small state such as Hawaii, only a few cases of fulminant liver failure will require liver transplantation

annually. It is completely unprecedented to see such large numbers of patients with acute liver failure in this short amount of time, in otherwise healthy patients in the absence of acetaminophen or viral hepatitis.

Dietary supplements are not regulated to the same extent as prescribed medications, which allow for easy marketing of potentially dangerous supplements directly to the consumer. While in the past performance-enhancing dietary supplements were mostly used by athletes and bodybuilders, the growing obesity epidemic and increasing reliance of our society on a "quick fix" has led to the widespread use of these unregulated and potentially dangerous compounds by the general public. Our center's recent experience is a tragic demonstration of the risks posed to public health by the poorly regulated dietary supplement industry.

Based on our experience, we advocate for additional safety assessment of dietary supplements such as weight-loss and performance-enhancing products. We have done our utmost to provide and will continue to provide the best possible care for these patients, but your partnership is critical towards preventing a similar health crisis from occurring again in the future.

Thank you for this opportunity to present our important information to you for your consideration.

From: mailinglist@capitol.hawaii.gov
To: HTHTestimony
Cc: lynhowe1946@yahoo.com
Subject: *Submitted testimony for SB2067 on Jan 27, 2014 13:30PM*
Date: Friday, January 24, 2014 7:08:18 PM

SB2067
Submitted on: 1/24/2014
Testimony for HTH on Jan 27, 2014 13:30PM in Conference Room 229

Submitted By	Organization	Testifier Position	Present at Hearing
Lyn Howe	Individual	Oppose	No

Comments:

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