PRESENTATION OF THE BOARD OF NATUROPATHIC MEDICINE

TO THE HOUSE COMMITTEE ON INTRASTATE COMMERCE

TWENTY-NINTH LEGISLATURE Regular Session of 2018

Wednesday, February 14, 2018 9:00 a.m.

TESTIMONY ON HOUSE BILL NO. 1949, H.D. 1, RELATING TO NATUROPATHIC MEDICINE.

TO THE HONORABLE TAKASHI OHNO, CHAIR, AND MEMBERS OF THE COMMITTEE:

My name is Constance Cabral, and I am the Executive Officer of the Board of Naturopathic Medicine ("Board"). Thank you for the opportunity to testify on this measure, which is a companion to S.B. 2299. S.B. 2299 was heard by the Senate Committees on Commerce, Consumer Protection, and Health and Public Safety, Intergovernmental, and Military Affairs and passed with an S.D. 1. While the Board has not had the opportunity to review and discuss H.B. 1949, H.D. 1, it is identical to last year's S.B. 223, S.D.2, H.D.1, which the Board strongly supported.

H.B.1949, H.D. 1 authorizes the Board of Naturopathic medicine to discipline a naturopathic physician for violation of the Uniform Controlled Substances Act.

The Board takes its duties and responsibilities to the people of Hawaii very seriously. Since 1925, licensed naturopathic physicians have been practicing competently. They have solid naturopathic medical education and clinical training, as well as clinical experience with natural hormone therapy. In treating patients with natural hormones, naturopathic physicians do so with safety, appropriate prescribing

House Bill No. 1949, H.D. 1 February 14, 2018 Page 2

and efficacy in mind. As a result, the Board has taken no disciplinary matters since hormones were included in the naturopathic formulary.

Thank you for the opportunity to provide testimony on H.B. 1949, H.D. 1.

HAWAII MEDICAL ASSOCIATION



1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814 Phone (808) 536-7702 Fax (808) 528-2376 www.hawaiimedicalassociation.org

TO: COMMITTEE ON INTRASTATE COMMERCE

Rep. Takashi Ohno, Chair Rep. Issac W. Choy, Vice Chair

DATE: Wednesday, February 14, 2018

TIME: 9:00 AM

PLACE: Conference Room 429

FROM: Hawaii Medical Association

Dr. Christopher Flanders, DO, Executive Director Lauren Zirbel, Community and Government Relations

Re: HB 1949 RELATING TO NATUROPATIC MEDICINE

Position: OPPOSE

Chairs & Committee Members:

The Hawaii Medical Association (HMA) opposes HB 1949.

The HMA believes scheduled drugs should be used judiciously, and only for therapeutic applications demonstrating evidence based, peer reviewed value and safety to patients.

The HMA feels that the use of testosterone, at this time, has not been adequately established for applications related to "anti-aging." The Journal of the American Medical Association has published recent studies in which the therapeutic use of testosterone has demonstrated no significant effect on improving intellectual function in the elderly.

The Endocrine Society has issued guidelines which outline the therapeutic use of testosterone only in instances of "consistent symptoms and signs and unequivocally low serum testosterone levels." A significant amount of evaluation and testing, including serial blood serum testosterone levels, prostate evaluation, blood counts and urinary tract assessment should be conducted prior to instituting testosterone therapy.

Additionally, the use of testosterone is not without significant side effects, including increased incidence of potentially life threatening blood clots, acceleration of prostate cancer growth and development of sleep apnea.

Until the role of testosterone as a therapeutic agent is fully understood, its use should be limited to those specifically trained in the use of hormonal therapy, such as endocrinologists. Thank you for allowing testimony on this issue.

Submitted on: 2/12/2018 9:48:34 PM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
steven Dubey	Hawaii Society of Naturopathic Physicians	Support	No

Comments:

TO: The House Committee on Intrastate Commerce

Regular Session of 2018

Wednesday, February 14th, 9:00 AM

TESTIMONY ON HOUSE BILL 1949 HD1 , RELATING TO NATUROPATHIC

MEDICINE

DEAR HONORABLE COMMITTEE CHAIR, CO-CHAIR AND

MEMBERS:

My name is Dr Steve Dubey, Naturopathic Physician and Licensed

Acupuncturist, practicing on Kauai for the last 36 years. I am the Vice

President of the Hawaii Society of Naturopathic Physicians. Our group is IN FAVOR

OF PASSAGE OF HB1949.

Modern Naturopathic Physicians are primary Care Providers. Besides passing rigorous Board Examinations for licensing, we are required to satisfy Continuing Education Requirements of 35 total hours Biennially,

with 15 of them in Pharmacy.

The Naturopathic Formulary, established in 2010 by our Board, does include many prescription medicines of natural origin such as hormones.

Thus Naturopathic physicians in Hawaii, and well as other states (such as Oregon and Washington, Arizona for example), have the ability to prescribe the majority of medicines commonly prescribed in family practice.

We have excellent rapport and support from Pharmacists and our MD colleagues, and overwhelming support from our patients who appreciate the complementary approach of balancing natural therapies and remedies with more conventional medicines.

AS primary care practitioners, we use standard Physical Examination,
Laboratory and Radiological assessments, as well as special studies to
make a diagnosis. To diagnose a patient deficient in Testosterone and not
be able to prescribe that medicine for them is incongruous with our
practice and philosophy.

I conclude:

Testosterone is listed in the World Health Organization's "Model List of Essential Medicines", 19th edition, published in April of 2015, and should

be included in the Naturopathic Formulary.

Thank you

Steve Dubey ND LAc

Natural Health Clinic

3093 Akahi St

Lihue , Hi 96766

www.nhckauai.com

Submitted on: 2/13/2018 7:51:46 AM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Michael Traub ND	Hawaii Society of Naturopathic Physicians	Support	No

Comments:

Michael Traub, ND

LOKAHI HEALTH CENTER

75-165 Hualalai Rd. Suite 301

Kailua Kona, Hawaii 96740

Phone 808-329-2114

Fax 808-326-2871

mtraubnd@me.com

Testimony in support of HB1949HD1

February 13, 2018

Dear Chair Ohno, Vice Chair Choy, and members of the House Intrastate Commerce Committee:

I am Michael Traub, ND, Past-president of the American Association of Naturopathic Physicians, current Secretary of the Hawaii Society of Naturopathic Physicians. I have practiced in Hawaii for the past 33 years.

As stated in the preamble of this bill, testosterone is an example of a controlled substance that is consistent with the practice of naturopathic medicine, and naturopathic physicians are known for their expertise in bio-identical hormone replacement therapy. It is incongruous that naturopathic physicians cannot prescribe testosterone when medically necessary, simply because it is classified as a controlled substance.

Testosterone is classified as a controlled substance due to its supposed potential for abuse and physical or psychological dependence. Testosterone is implicated for its potential for abuse due to its similarity to anabolic steroids such as DepoTestosterone. In reality, individuals, such as body builders, who abuse anabolic steroids use other drugs, in much high doses (not testosterone) for increasing strength and muscle mass. Testosterone is actually a hormone that has accepted medical use for men and women who have laboratory proven deficiency and clinical symptoms that warrant its use. The doses used in testosterone replacement only achieve physiologic (normal) levels of hormone in the blood.

Testosterone deficiency in both males and females increases risk for obesity, type 2 diabetes, metabolic syndrome, cardiovascular disease, dyslipidemia (abnormal blood cholesterol and fats), inflammation, hypertension, loss of lean body mass, muscle volume and strength, and bone mineral density.

Naturopathic physicians have a clean record regarding prescriptive authority. There have been no disciplinary actions taken by the Board of Naturopathic Medicine, nor any malpractice awards against a naturopathic physician regarding harm or abuse from the prescription of any drug included on the naturopathic formulary.

Testosterone is the only controlled substance that the Board of Naturopathic Medicine would consider adding to the naturopathic formulary at this time.

Naturopathic physicians are acutely aware of the widespread abuse and overuse of narcotic pain medicines and do not seek authority to prescribe these substances.

The overwhelming majority of naturopathic physicians licensed in Hawaii have trained in naturopathic medical schools in Oregon, Washington, and Arizona where controlled substances are within the prescriptive authority of naturopathic physicians, and students receive sufficient classroom education and clinical training for their safe and appropriate use.

This bill was heard in the House Committee on Health & Human Services on January 25, 2018. Hawaii Medical Association testified in opposition, and HMSA provided comments, that led to a Committee report that suggested that "the use of testosterone may not have sufficient evidence to justify applications related to anti-aging," and "the usage of testosterone causes potentially harmful side effects," and asked that the Board of Naturopathic Medicine address these concerns in further testimony on this measure.

Unfortunately, the Board of Naturopathic Medicine is unable to address these concerns due to a lack of sufficient Board members at this time.

However, I have served on the Board of Naturopathic Medicine in the past for 16 years, much of that time as Chair. As such, I believe I can address these concerns to your satisfaction.

First of all, I believe the opposition by HMA is disparaging and distracting. In the 7 or 8 years that this measure has been introduced in the legislature, nowhere will you find "anti-aging" as a suggested application in testimony in support for the prescription of testosterone by naturopathic physicians. On the contrary, a huge amount of evidence in the published medical literature supports the use of testosterone when medically necessary. Medical necessity is defined by insurance companies (such as Noridian) in these terms:

Low serum testosterone alone does not constitute a diagnosis of androgen deficiency or clinical hypogonadism. Diagnosis of a clinical condition requires the presence of certain characteristic symptoms as well as an abnormally low serum testosterone. Many of the symptoms are not specific to, and not directly correlated to specific levels of testosterone. Guidelines from the

Endocrine Society suggest some of the following symptoms may be related to low serum testosterone but may also have many other causes in the elderly population.

More Specific Signs / Symptoms

- Incomplete or delayed sexual development
- Reduced sexual desire (libido) and activity
- Breast discomfort, gynecomastia (enlarged breasts)
- Loss of body (axillary and pubic) hair, reduced shaving
- Very small or shrinking testes
- Inability to father children
- Low-trauma fracture, low bone mineral density (osteoporosis)
- Hot flushes, sweats

Less Specific Signs/Symptoms

- Decreased energy, motivation, initiative and self confidence
- Feeling sad or blue, depressed mood, dysthymia
- Poor concentration and memory
- Sleep disturbance, increased sleepiness
- Mild anemia
- Reduced muscle bulk and strength
- Increased fat or increased body mass index
- Diminished physical or work performance
- Zero sperm count

Evaluation of primary hypogonadism is undertaken with at least 2 separate serum testosterone levels taken on two different days in the morning (when testosterone secretion is highest), and/or two morning levels of "free" or bioavailable testosterone) and Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) levels. Elevated LH/FSH confirms primary hypogonadism and the potential need for replacement hormone. If the two testosterone determinations are low AND the LH/FSH levels are also low, pituitary disease (including a serum prolactin) or chronic diseases must be considered.

Patients with low testosterone associated significant symptoms should be considered for treatment. A comprehensive examination is required to evaluate for medications or chronic diseases known to cause decreased energy, memory problems, impotence and mental health problems.

HMSA's testimony raising concerns about safety is puzzling, as it flies in the face of their decision last year to credential naturopathic physicians as participating primary care providers. It does not make sense that they would question the ability of naturopathic physicians in their network to know how to safely prescribe testosterone. The main concerns with safety involve adverse effects when testosterone is prescribed in excessive doses, or in men who have prostate cancer. Concerns about increased risks of heart attack, stroke and blood clots have not been confirmed in large clinical trials.

Finally, it must be recognized that naturopathic physicians have a higher level of education and training than physician's assistants and advanced practice registered nurses, both of whom have authority to prescribe testosterone.

In summary, the request for adding testosterone to the Naturopathic Formulary is based on conventional guidelines for its medical necessity. Naturopathic physicians have distinguished themselves for their safe prescribing practices. There is no valid reason, and no evidence whatsoever, to exclude this medication from the Naturopathic Formulary.

Thank you for your support of this measure.

Sincerely,

Michael Traub ND

Pamela Seeney

From:

Richards, Raine <rrichards@osteopathic.org>

Sent:

Monday, February 12, 2018 7:29 AM

To: Subject: IACtestimony House Bill 1949

Attachments:

HI HB 1949 Naturopath Prescribing J 2 12 18.pdf

Good Morning -

Please see the attached letter from the American Osteopathic Association and the Hawaii Association of Osteopathic Physicians and Surgeons in opposition to House Bill 1949.

Regards,

Raine Richards, JD
Director | State Government Affairs
AMERICAN OSTEOPATHIC ASSOCIATION
142 E. Ontario St.

Chicago, IL 60611-2864 Phone: (312) 202-8199

Find the AOA at Osteopathic.org and on Facebook, Twitter and LinkedIn

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TO: Members of the Hawaii State House of Representatives Committee on Intrastate

Commerce

FROM: Hawaii Association of Osteopathic Physicians and Surgeons

American Osteopathic Association

DATE: February 12, 2018

SUBJECT: House Bill 1949

The American Osteopathic Association (AOA) and the Hawaii Association of Osteopathic Physicians and Surgeons (HAOPS) are writing in opposition to HB 1949. This bill would expand the scope of practice for naturopaths to allow them to prescribe testosterone, a controlled substance which increases the risk of heart problems in men, without requiring them to attain a level of competency equivalent to a physician. Physicians receive comprehensive education and training to allow them to properly evaluate the risks and benefits of prescribing testosterone, but controlled substance prescribing falls outside of the competencies of naturopathic education, which focuses on alternative and natural therapies. We believe that expansion of naturopaths' scope of practice in this manner is imprudent, and that health professionals' scope of practice must be based on their level of training, education, experience and examination.

The AOA represents 137,000 osteopathic physicians (DOs) and medical students, promotes public health, encourages scientific research, serves as the primary certifying body for DOs and is the accrediting agency for osteopathic medical schools. More information on DOs/osteopathic medicine can be found at www.osteopathic.org. HAOPS is a professional medical organization that represents over 300 DOs providing patient care in Hawaii.

The AOA and HAOPS support the "team" approach to medical care because the physicianled medical model ensures that professionals with complete medical education and training are adequately involved in patient care. While we value the contributions of all health care providers to the health care delivery system, we believe any expansion of naturopaths' authority to provide services to patients without appropriate oversight should be directly related to additional education, training and competency demonstration requirements. Allowing naturopaths to prescribe controlled substances, without reference to additional requirements or supervision by a physician or surgeon, may ultimately be detrimental to the health and safety of patients in the state of Hawaii. Naturopathic education and training lacks the comprehensive and robust requirements needed to safely provide patients with a full range of unsupervised primary care services.

¹ https://www.health.harvard.edu/mens-health/is-testosterone-therapy-safe-take-a-breath-before-you-take-the-plunge.

Members of the Hawaii State House of Representatives Committee on Intrastate Commerce February 12, 2018 Page 2

Osteopathic physicians complete four years of osteopathic medical school, which includes two years of didactic study and two years of clinical rotations. Clinical rotations in the third and fourth years are done in community hospitals, major medical centers and doctors' offices. This is followed by three to seven years of postgraduate medical education, i.e., residencies, where DOs develop advanced knowledge and clinical skills relating to a wide variety of patient conditions. Physicians have both extensive medical education and comprehensive training that prepare them to understand medical treatment of disease, complex case management and safe prescribing practices.

Naturopathic educational curriculum varies by school. There are seven naturopathic programs accredited by the Council on Naturopathic Medical Education (CNME) in the United States. It was only in 2005 that the CNME implemented an approval process for naturopathic residency programs. While opportunities are now available for graduates of naturopathic schools to complete a one or two year residency, this training is still optional. In addition, standard requirements for naturopathic residency curriculum, rotations or experiences do not exist. In terms of program content, the CNME does not provide specific requirements, instead stating that naturopathic residents receive 35 hours a year of didactic instruction, and participate in "scholarly activities that promote a spirit of inquiry, scholarship, and critical thinking such as discussions, rounds, study clubs, presentations, conferences, and local, regional or national professional associations and scientific societies." This level of education, training and certification is not sufficient to prescribe controlled substances, which are regulated by the federal government due to their potential for misuse.

To protect the public's health and safety, health professionals' scope of practice and titles must be based on their level of training, education, experience and examination. We appreciate your consideration of our concerns regarding <u>HB 1949</u>. Should you need any additional information, please feel free to contact Raine Richards, JD, Director of State Government Affairs at rrichards@osteopathic.org or (312)-202-8199.

Sincerely,

Mark A Balan DO

Mark A. Baker, DO President, AOA Spenen a Jun, D.o.

Spencer Lau, DO President, HAOPS

CC: William S. Mayo, DO, President-elect, AOA
Joseph M. Yasso, Jr., DO, Chair, Department of Governmental Affairs, AOA
Thomas L. Ely, DO, Chair, Bureau of State Government Affairs, AOA
Adrienne White-Faines, MPA, Chief Executive Officer, AOA
David Pugach, JD, Senior Vice President, Public Policy, AOA
Raine Richards, JD, Director, State Government Affairs, AOA
Samyuktha Gumidyala, MPH, Affiliate Executive, HAOPS

Dr. Sarah Sarkis, Psy.D., LLC 460 Ena Road, Suite 505 Honolulu Hawaii 96815

Dear Honorable Ohno, Chair, Honorable Choy, Vice Chair, and other members of the House Committee on Intrastate Commerce:

My name is Dr. Sarah Sarkis and I support HB 1949 HD 1. I am a licensed psychologist in Honolulu and am fully supportive of the addition of testosterone to the naturopathic formulary. Both myself, my family, and many of my patients see a naturopathic physician as our primary care provider. I believe it is an unfortunate oversight that naturopathic doctors, who are experts in bio-identical hormone therapy, are unable to utilize testosterone in their role as primary care providers. The passage of this bill will greatly improve the quality of and access to high standard of care my patients have come to expect from their primary care doctors. Please help pass HB 1949 HD 1.

Thank you, Dr. Sarah Sarkis HI Lic No. 1263



438 Hobron Lane, Suite 314, Honolulu, Hawaii 96815 www.SteelsmithHealth.com (808) 943-0330

Testimony in support of HB 1949 HD 1

February 10, 2018

Position: **Support of** HB 1949 HD 1 Relating to Naturopathic Medicine

To the Honorable Takashi Ohno, Chair, the Honorable Isaac Choy, Vice Chair, and other Distinguished Members of the House Committee on Intrastate Commerce:

I am writing in support of HB 1949 HD 1 Relating to Naturopathic Medicine and the addition of testosterone to the naturopathic formulary. Testosterone is a controlled substance that has been the only bio-identical hormone that naturopathic physicians cannot prescribe in the state of Hawaii. Naturopathic physicians are known for their expertise in bio-identical hormone replacement therapy and the overwhelming majority of naturopathic physicians licensed in Hawaii have trained in naturopathic medical schools in Oregon, Washington, and Arizona where controlled substances are within the prescriptive authority of naturopathic physicians.

Naturopathic physicians have a clean record regarding prescriptive authority. There have been no disciplinary actions taken by the Board of Naturopathic Medicine, nor any malpractice awards against a naturopathic physician regarding harm from the prescription of any drug included on the naturopathic formulary.

Thank you for your support,

Kristen Coles, ND, LAc

Submitted on: 2/12/2018 8:53:21 PM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing	
Kim Haine	Individual	Support	No	

Comments:

To the Honorable Takashi Ohno, Chair, the Honorable Isaac Choy, Vice Chair, and other Distinguished Members of the House Committee on Intrastate Commerce:

I am writing in support of HB 1949 HD 1 Relating to Naturopathic Medicine and the addition of testosterone to the naturopathic formulary. They are well qualified and already capable of recommending estrogens and progesterone. It should be no different. Please vote YES on this bill.

Thank you,

kim

Submitted on: 2/12/2018 11:03:28 PM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing	
Miles Greenberg	Individual	Support	No	

Comments:

Dear Honorable Chairman Ohno and members of the ICS Commitee,

Please SUPPORT the authorization for naturopathic physicians to prescibe testosterone as it is consistent with the practice of naturopathic medicine to prescribe natural or equivalent compounds like hormone replacement therapies (HRT) to promote health. Other HRT's have been utilized by ND's who monitor biological values for appropriate indication and evaluation without incident of harm to the public. Testosterone would complement our repertoire of restorative HRT's since it has been omitted from our formulary due to its listing aa a controlled substance. All other controlled substances would be precluded from the naturopathic formulary.

Thank you for your consideration and SUPPORT of this bill.

Miles Greenberg, ND

3093 Akahi St.

Lihue, HI 96766

Submitted on: 2/12/2018 11:21:32 PM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
magdi latif	Individual	Support	No

Comments:

I am Magdi Latif, Registered Pharmacist, owner of North Shore Pharmacy since 1988. My pharmacy has filled Prescriptions for Naturopathic Physicians in our community for several years. Naturopathic Doctors fill a well needed niche for the public, and I support the passage of HB1949 offering Naturopathic Physicians the limited use of Controlled substances, specifically Testosterone.

Submitted on: 2/13/2018 7:27:21 AM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
LISA WILFORD	Individual	Support	No

Comments:

To the Honorable Takashi Ohno Chair, and other Distinguished Members of the House Committee on Intrastate Commerce:

I am writing in support of HB 1949 HD 1 Relating to Naturopathic Medicine and the addition of testosterone to the naturopathic formulary. I am a current patient of a naturopathic physician and have been for many years. My experience been that naturopathic physicians tend to be experts in hormone replacement therapy and I find it unfair that my doctor is unable to prescribe testosteroneif it was necessary. Please suport HB 1949 and bring Hawaii up to date for naturopathic prescription laws.

Thank you, Lisa Wilford

Submitted on: 2/13/2018 7:29:28 AM

Testimony for IAC on 2/14/2018 9:00:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Dr. Kevin R. Gibson	Individual	Support	No

Comments:

As primary care practitioners with an excellent safety record, it would be beneficial to add Testosterone to our prescriptive authority.

Thank you for your consideration.

Dr. Kevin Gibson



LATE TESTIMONY

February 14, 2018

The Honorable Takashi Ohno, Chair The Honorable Isaac W. Choy, Vice Chair House Committee on Intrastate Commerce

Re: HB 1949, HD1 – Relating to Naturopathic Medicine

Dear Chair Ohno, Vice Chair Choy, and Committee Members:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 1949, HD1, which authorizes a naturopathic physician to prescribe testosterone consistent with naturopathic medical practice and clarifies that narcotic drugs shall not be included within the naturopathic formulary. HMSA appreciates this Bills intent, to align a naturopathic physician's prescriptive authority with the practice of naturopathic medicine.

HMSA would ask the Committee to consider clarifying Sections 3 and 4 as follows:

- A naturopathic physician licensed pursuant to Chapter 455 who is licensed and registered, <u>under section 329-32</u> to prescribe and administer testosterone in the course of professional practice in this State
- "Naturopathic formulary" means vitamins, minerals, dietary supplements, botanical medicines, homeopathic medicines, hormones, and those legend drugs and testosterone consistent with naturopathic medical practice; provided that the naturopathic formulary shall not include any narcotic drugs or controlled substances, as defined in section 329-1, except as provided in Chapter 455, Hawaii Revised Statute

Thank you for allowing us to testify on HB 1949, HD1. Your consideration of our comments is appreciated.

Sincerely,

Pono Chong

Vice-President, Government Relations