

# SB2299

**Measure Title:** RELATING TO NATUROPATHIC MEDICINE.

**Report Title:** Naturopathic Physicians; Testosterone; Naturopathic Formulary; Prescriptive Authority

**Description:** Authorizes a naturopathic physician to prescribe and administer testosterone that is consistent with naturopathic medical practice. Clarifies that narcotic drugs shall not be included within the naturopathic formulary.

**Companion:**

**Package:** None

**Current Referral:** CPH/PSM, JDC

**Introducer(s):** BAKER, KEITH-AGARAN, S. Chang, Espero, Gabbard, Galuteria, Ihara, Inouye, Kidani, Kim, Nishihara, Tokuda

**PRESENTATION OF THE  
BOARD OF NATUROPATHIC MEDICINE**

TO THE SENATE COMMITTEES ON  
COMMERCE, CONSUMER PROTECTION, AND HEALTH  
AND  
PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY AFFAIRS

TWENTY-NINTH LEGISLATURE  
Regular Session of 2018

Tuesday, February 6, 2018  
12:45 p.m.

**TESTIMONY ON SENATE BILL NO. 2299, RELATING TO NATUROPATHIC  
MEDICINE.**

TO THE HONORABLE ROSALYN H. BAKER, CHAIR, TO THE HONORABLE  
CLARENCE K. NISHIHARA, CHAIR, AND MEMBERS OF THE COMMITTEES:

My name is Constance Cabral, and I am the Executive Officer of the Board of Naturopathic Medicine ("Board"). Thank you for the opportunity to present testimony on this measure, which is a companion to H.B. 1949. While the Board has not had the opportunity to review this measure, the Board would strongly support it, as it is identical to last year's S.B. 223, S.D.2, H.D.1, which they strongly supported.

S.B. 2299 authorizes a naturopathic physician to prescribe and administer testosterone that is consistent with naturopathic medical practice. It clarifies that narcotic drugs shall not be included within the naturopathic formulary.

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, 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 testify on S.B. 2299.



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February 6, 2018

The Honorable Rosalyn H. Baker, Chair  
The Honorable Jill N. Tokuda, Vice Chair  
Senate Committee on Commerce, Consumer Protection, and Health

The Honorable Clarence K. Nishihara, Chair  
The Honorable Glenn Wakai, Vice Chair  
Senate Committee on Public Safety, Intergovernmental, and Military Affairs

Re: SB 2299 – Relating to Naturopathic Medicine

Dear Chair Baker, Chair Nishihara, Vice Chair Tokuda, Vice Chair Wakai, and Committee Members:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 2299, which authorizes a naturopathic physician to prescribe and administer testosterone that is consistent with naturopathic medical practice and clarifies that narcotic drugs shall not be included within the naturopathic formulary. HMSA appreciates the Committees' 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, under section 329-32 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 SB 2299. Your consideration of our comments is appreciated.

Sincerely,

Pono Chong  
Vice-President, Government Relations



## **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 COMMERCE, CONSUMER PROTECTION, AND HEALTH

Senator Rosalyn H. Baker, Chair

Senator Jill N. Tokuda, Vice Chair

COMMITTEE ON PUBLIC SAFETY, INTERGOVERNMENTAL, AND MILITARY  
AFFAIRS

Senator Clarence K. Nishihara, Chair

Senator Glenn Wakai, Vice Chair

DATE: Tuesday, February 6, 2018

TIME: 12:45 PM

PLACE: Conference Room 229

FROM:

Hawaii Medical Association

Dr. Christopher Flanders, DO, Executive Director

Lauren Zirbel, Community and Government Relations

**Re: SB 2299– RELATING TO NATUROPATHIC MEDICINE**

**Position: OPPOSE**

Chairs & Committee Members:

The Hawaii Medical Association (HMA) opposes SB 2299.

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.

### **HMA OFFICERS**

President – William Wong, Jr., MD President-Elect – Jerry Van Meter, MD Secretary – Thomas Kosasa, MD

Immediate Past President – Bernard Robinson, MD Treasurer – Elizabeth A. Ignacio, MD

Executive Director – Christopher Flanders, DO



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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.

### **HMA OFFICERS**

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Immediate Past President – Bernard Robinson, MD    Treasurer – Elizabeth A. Ignacio, MD  
Executive Director – Christopher Flanders, DO

# Dr. Chandy Lopes, ND



180 Dickenson Street, Suite 218 • Lahaina, HI • Phone: 808-667-9554 • Fax: 877-533-0405  
E-Mail: [DrLopes@Naturopathicaloha.com](mailto:DrLopes@Naturopathicaloha.com) Web: [NaturopathicAloha.com](http://NaturopathicAloha.com)

February 5, 2018

Committee on CPH & PSM

RE: Testimony in support of SB2299

Dear Committee Chairs, Vice Chairs & Members of CPH & PSM,

My name is Dr. Chandy Lopes & I am a Naturopathic Physician from Maui. I support SB2299 to include testosterone within our formulary.

Naturopathic physicians are well versed and trained in prescribing and integrating bio-identical hormones such as testosterone, into safe, effective & comprehensive treatments for our patients. Within my own training and by working with other doctors, MD's, DO's & ND's, I have seen how the appropriate use of testosterone can greatly improve treatment outcomes and the quality of life for men & women. In brief, some positive outcomes in men include maintaining muscle mass, improving metabolism and increasing energy. In women, testosterone therapy is effective in treating peri- and menopausal issues such as hot flashes, sleep disturbance & moodiness.

Our patients are often paying out of pocket for their visits and it is a grave disservice to their health care that we cannot prescribe testosterone when medically necessary. By including testosterone into our formulary this will ensure that our patients have access to comprehensive Naturopathic care. SB2299 allows me to better serve the needs of my patients and community.

Thank you for your consideration.

Sincerely,

Dr. Chandy Lopes  
Naturopathic Physician  
1427495860  
ND-246

**SB-2299**

Submitted on: 2/4/2018 10:17:39 PM

Testimony for CPH on 2/6/2018 12:45:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
David Kern	Hawaii Society of Naturopathic Physicians	Support	No

Comments:

Dear Chair, Vice Chair and members of the Senate Committee on Commerce, Consumer Protection and Health:

I support naturopathic physicians having prescriptive authority of natural testosterone. Testosterone is consistent with naturopathic medical practice and naturopathic physicians are known for their expertise in bio-identical hormone replacement therapy.

As individuals age, testosterone deficiency in both males and females increases the risk for obesity, type 2 diabetes, metabolic syndrome, cardiovascular disease, dyslipidemia, hypertension, loss of lean body mass and bone mineral density.

Naturopathic physicians have an excellent record with regard to their prescriptive authority. There has 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 of this measure.

Sincerely,

David Kern, ND, LAc

**SB-2299**

Submitted on: 2/5/2018 12:15:16 PM

Testimony for CPH on 2/6/2018 12:45:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Dr. Kevin R. Gibson	Pacific Integrative Medicine	Support	No

Comments:

Naturopathic physicians are trained to thoroughly address any physiologic imbalance that may contribute to current or future risk of health deficiencies.

The endocrine system (which includes the hormone testosterone) is like the conductor of an orchestra. Any deficiencies in performance will affect the whole symphony.

As primary care physicians, we often address hormone imbalances, and without the full breadth of hormone prescriptive authority, naturopathic physicians are potentially limited in supporting the complex rhythm of health.

Naturopathic doctors have not had any malpractice claims awarded in the State of Hawaii regarding patient prescriptions and have an excellent safety record in other states where prescriptive authority for testosterone has been granted.

Thank you for considering this measure.

Kevin Gibson ND, LAc, MS





TO: Members of the Hawaii State Senate Committee on Commerce, Consumer Protection, and Health

FROM: Hawaii Association of Osteopathic Physicians and Surgeons  
American Osteopathic Association

DATE: February 5, 2018

SUBJECT: Senate Bill 2299

**The American Osteopathic Association (AOA) and the Hawaii Association of Osteopathic Physicians and Surgeons (HAOPS) are writing in opposition to SB 2299.** 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.<sup>1</sup> 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 osteopathic 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](http://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 physician-led 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.

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

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.

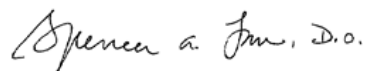
Naturopathic educational curriculum varies by school. There are seven naturopathic programs accredited by the Council on Naturopathic Medical Education (CNME) in the United States. It was only in 2005 that the CNME implemented an approval process for naturopathic residency programs. While opportunities 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 SB 2299.** Should you need any additional information, please feel free to contact Raine Richards, JD, Director of Public Policy at richards@osteopathic.org or (312)-202-8199.

Sincerely,



Mark A. Baker, DO  
President, AOA



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 Gumidyal, MPH, Affiliate Executive, HAOPS



## **Steelsmith Natural Health Center**

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**(808)943-0330**

Testimony in support of SB2299

February 4, 2018

Dear Members of CPH and PSM,

I am writing in support of SB2299 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

Michael Traub, ND  
LOKAMI 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 SB2299

February 4, 2018

Dear Senator Baker, Sen. Tokuda, Sen Nishihara, Sen. Wakai, and members of the Senate Committees on Commerce, Consumer Protection and Health; and Public Safety, Intergovernmental and Military Affairs:

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.

The companion bill to SB2299, HB1949, 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,

A handwritten signature in black ink, appearing to read "Michael Traub", with a long horizontal flourish extending to the right.

Michael Traub ND

**SB-2299**

Submitted on: 2/5/2018 8:32:42 AM

Testimony for CPH on 2/6/2018 12:45:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Landon Oponui		Support	No

Comments:

Testimony in support of SB2299

Dear Senator Baker, Sen. Tokuda, Sen Nishihara, Sen. Wakai, and members of the Senate Committees on Commerce, Consumer Protection and Health; and Public Safety, Intergovernmental and Military Affairs:

I support SB2299, that authorizes a naturopathic physician to prescribe testosterone consistent with naturopathic medical practice.

Mahalo!

Dr. Oponui

**SB-2299**

Submitted on: 2/5/2018 8:32:42 AM

Testimony for CPH on 2/6/2018 12:45:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Present at Hearing</b>
Landon Oponui		Support	No

Comments:

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Mahalo!

Dr. Oponui