



**NATIONAL HEALTH FREEDOM  
ACTION**

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November 6, 2014

State of Hawaii  
Office of the Auditor  
Kekūānāō‘a Building  
465 S. King St., Rm. 500  
Honolulu, HI 96813-2917

**Re: Requesting Jan K. Yamane, Acting State Auditor of Hawaii, to recommend to the Hawaii legislature that:**

- 1. Hawaii citizens would benefit from a law that protects all complementary and alternative unlicensed health care practitioners by the use of a properly designed safe harbor exemption law with certain conditions and disclosures;**
- 2. Licensing of herbal therapists, as proposed by Hawaii Senate Concurrent Resolution 31-14, is not warranted; and**
- 3. Licensing of herbal therapists is not the least restrictive means of regulation available.**

Dear Auditor:

NHFA respectfully requests the Auditor to find that licensing herbal therapists in Hawaii is not warranted, that no other state mandates the exclusive licensing of herbalists, that there are less restrictive models of regulation to cope with the desire to protect the practice of herbal therapy, access, and consumer awareness regarding herbal therapists, and that Hawaii citizens would benefit from a law that protects all complementary and alternative unlicensed health care practitioners by the use of a properly designed safe harbor exemption law with certain conditions and disclosures.

The bill language put forth to license herbal therapists would negatively impact consumer choice and jeopardize access to many wonderful unlicensed herbalists, wellness consultants, health coaches, and homeopaths that utilize herbs, and many other complementary and alternative practitioners practicing in the public domain.

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Hawaii Senate Concurrent Resolution 31-14, requests the Auditor to conduct a sunrise review of the licensure and regulation of herbal therapists as proposed by 2013 Senate Bill No. 195 and 2014 Senate Bill 2439 [hereinafter, the Herbal Therapy Licensing bill] .<sup>1</sup> The Herbal Therapy Licensing bill seeks to license herbal therapists and restrict the practice of herbal therapy to only those individual who hold a license from the Herbal Therapy Board, which the bill creates.<sup>2</sup> The bill imposes civil fines of \$1000 per violation.<sup>3</sup>

Although the Herbal Therapy Licensing bill contains two exemptions, one for unlicensed traditional Hawaiian healers and the other for specialized practices such as naturopathic medicine or traditional Chinese medicine,<sup>4</sup> these exemptions are not broad enough to protect the rights of many practitioners providing natural/herbal health care services in the state of Hawaii.

Instead of licensing herbal therapists, NHFA requests the Auditor recommend Hawaii enact Safe Harbor Exemption legislation, as passed in 8 other states, which would enable all herbalists, and many other complementary and alternative practitioners and healers, to practice their vocation under certain conditions without the need for state professional licensure or the threat of civil violations.

We offer the following information for your consideration.

**I. Introduction**

- a. National Health Freedom Action – a brief description of our work
- b. NHFA’s Health Freedom work in Hawaii (2006 – Present)
- c. Alternative Less Restrictive Model Legislation: Safe Harbor Exemption laws
- d. NHFA’s Response to Hawaii’s Herbal Therapy Licensure bills

**II. Discussion - Licensing Herbal Therapists is Not Warranted**

- a. Licensing herbal therapists is not necessary to protect the health, safety, and welfare of the public and is not consistent with other regulatory policy provisions in Section 26H-2, HRS and in the Auditor’s supplemental review criteria
- b. The probable negative effects of mandatory licensure
- c. Less restrictive forms of regulation exist and are available

**III. Conclusion and Recommendation(s)**

**IV. Appendices**

- a. Hawaii Health Freedom Law (2009)
- b. Table, Excerpts from State Health Freedom laws

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<sup>1</sup> 2013 Hawaii S.B. 195. See also, 2013 Hawaii House Bill 1366, companion bill to SB 195, and 2014 Hawaii SB 2439 and HB 2091, relating to herbal therapy licensing.

<sup>2</sup> See, generally, SB 195.

<sup>3</sup> SB 195, §8(b) Prohibited acts; penalties.

<sup>4</sup> SB 195, §3 Exemptions.

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## I. INTRODUCTION

### a. National Health Freedom Action – a brief description of our work

National Health Freedom Action (NHFA) is a 501(c)4 non-profit corporation working to protect maximum health care options for consumers.<sup>5</sup> NHFA works to protect the right of all people to access their favorite health care practitioners and health care products, as well as to protect the right to access many other healing arts products and services that resonate with people's path to wellness.

NHFA responds to calls year-round from individuals and groups throughout the country who wish to promote legal reform in occupational laws and regulations having to do with complementary and alternative health care on the state level, and with federal and international product laws and regulations having to do with access to desired products.

NHFA works with citizens to empower them to take action to address these concerns. NHFA educates and trains citizens on health freedom principles and on how to develop and pass proactive legislation that will ensure the rights of health care practitioners to offer their services and the rights of consumers to have access to products, practitioners, and information.

NHFA staff works to serve citizens and citizen groups by drafting model legislation, testifying at legislative hearings and public policy meetings, and by providing strategic support and lobbying assistance. NHFA is a Voting Member of the US Health Freedom Assembly and is a founding member of the World Health Freedom Assembly. NHFA staff often assist state leaders in developing local health freedom organizations and are currently working with groups in over 30 states to support health care reform efforts.

Americans are aware and concerned. There is a growing awareness among Americans that personal choice in health care directly impacts how, and whether, a person will gain a full sense of health and wellness. Based upon a July 2009 report from the National Institute of Health's National Center for Complementary and Alternative Medicine (NCCAM), 38 percent of Americans' use complementary and alternative medicine (CAM) based on 2007 survey data. It also found that Americans spent \$33.9 billion in out-of-pocket costs in a 12-month period for CAM. National Health and Nutrition Examination Survey (NHANES) data collected from 2003 to 2006 that covered all types of dietary supplements indicate that 53 percent of American adults took at least one dietary supplement, most commonly multivitamin/multimineral supplements (taken by 39 percent of all adults).<sup>6</sup> Americans have become deeply concerned about infringements on their ability to make choices caused by regulatory systems that do not adequately protect a person's ability to choose.

### b. NHFA's Health Freedom work in Hawaii, 2006 – 2014

#### i. Homeopathy Exemption Legislation introduced in Hawaii

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<sup>5</sup> National Health Freedom Action, [www.nationalhealthfreedom.org](http://www.nationalhealthfreedom.org).

<sup>6</sup> National Center for Complementary and Alternative Medicine, *Using Dietary Supplements Wisely*, available at: <http://nccam.nih.gov/health/supplements/wiseuse.htm>

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In February 2006, NHFA was contacted for help by a homeopath in Hawaii who was investigated for the practice of “naturopathy” without a license. Since homeopathy is within the scope of practice for naturopaths in Hawaii, the homeopath was told that she could not practice without an exemption from naturopathic licensing requirements. In order to prevent the situation from happening to other practitioners like herself, the homeopath found a legislative sponsor and initiated the drafting of a bill to exempt the practice of homeopathy from Hawaii’s naturopathic licensing requirements. The bill, SB 2099, relating to homeopathy, would amend the naturopathic licensing law to provide an exemption that read: “This chapter shall not apply to homeopaths certified by the Council for Homeopathic Certification or other regional or national accrediting body recognized by the United States Department of Education.”<sup>7</sup>

Although NHFA understood that SB. 2099 was introduced in response to an unlicensed homeopath being investigated, NHFA sought to amend the bill to make the exemption broader than allowing only CHC homeopaths to practice. With the agreement of the homeopath initially investigated, NHFA recommended that all unlicensed homeopaths be exempt from licensure as long as they give out proper disclosures and avoid certain prohibited acts, similar to Safe Harbor Exemption laws in other states.<sup>8</sup> The bill, however, never moved out of the Senate Health Committee to which it was originally assigned.<sup>9</sup>

#### ii. Safe Harbor Exemption Legislation introduced in Hawaii

In 2004, Hawaii Representative Cindy Evans contacted NHFA requesting help with drafting Safe Harbor Exemption legislation for Hawaii to protect the practice of complementary and alternative healing modalities such as homeopathy, herbal therapy, energy healing and biofeedback. Representative Evans had heard of NHFA’s work to pass Safe Harbor Exemption laws and understood that the exemption laws applied to all unlicensed natural health practitioners providing services that do not rise to the level of harm requiring mandatory licensing. NHFA collaborated with Representative Evans in 2004, 2006 and 2007 and the Hawaii Health Freedom bills were introduced in the Hawaii Legislature by Representative Evans in 2004, 2007 and 2009.<sup>10</sup> [Click here to view the Hawaii Safe Harbor Exemption bill, as introduced in 2007.](#)

Although a Safe Harbor Exemption bill has not passed in Hawaii yet, NHFA secured the successful passage of this type of Health Freedom legislation in nine states, with differences in language to reflect the unique needs of each state.<sup>11</sup> The Health Freedom states with Safe Harbor Exemption laws are Minnesota, Rhode Island, California, Louisiana, Idaho, Oklahoma, Arizona (for homeopaths), New Mexico, and Colorado. [Click here to view state Safe Harbor Exemption laws.](#)

#### c. **Alternative Less Restrictive Model Legislation: Rationale for Safe Harbor Exemption laws for Complementary and Alternative Health Care Practitioners**

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<sup>7</sup> 2006 HI SB 2099, relating to homeopathy, available at: <http://www.capitol.hawaii.gov/session2006/Bills/SB2099 .htm>

<sup>8</sup> For an overview of Safe Harbor Exemption legislation, see Part I(c) of this comment.

<sup>9</sup> Legislative status history for 2006 HI SB 2099, available here:

<http://www.capitol.hawaii.gov/session2006/status/SB2099.asp>

<sup>10</sup> See, e.g., 2004 HI HB 2036 and 2007 HI HB 631/SB 739.

<sup>11</sup> See Appendix B of this comment for state variations of Safe Harbor Exemption bills.

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In many states, herbalists, homeopaths, and naturopaths who are not licensed health care professionals are successfully providing their services to eager consumers. However these natural health practitioners often live and work in fear because their acts could feasibly be considered by the state to be violations of the medical practice act, the naturopathic practice act, the massage practice act, the acupuncture practice act and/or another health care professional practice act.<sup>12</sup> That is because the practice acts have broad definitions for the practices they regulate and so, if an individual – especially a complementary and alternative health care practitioner – provides a service that falls within a broad practice act definition, he/she could technically be charged for practicing that regulated profession without a license. When natural health practitioners get investigated for unlicensed practice of a health care profession, even when there has been no misrepresentation or harm caused, and the investigation is based on a technical violation of being within the broad definitions of another profession, natural health practitioners practice in fear or refrain from providing services entirely.

The states with Safe Harbor Exemption laws directly address this issue and the chilling effect it has on complementary and alternative health care by exempting natural health practitioners from licensing requirements and creating a list in statute of activities that unlicensed practitioners cannot do, as well as a list of disclosures that they must give to clients before providing services. Under these Safe Harbor Exemption laws, often called “Health Freedom laws” the state retains the power to prohibit the practice of complementary and alternative health care by unlicensed practitioners who do not abide by the Safe Harbor Exemption guidelines for natural health care practitioners.

Safe Harbor Exemption laws do not change the definitions of the various health care practice acts but, rather, they exempt natural health practitioners from the criminal or civil violations of those acts if they provide services within the Safe Harbor Exemption guidelines. This type of exemption legislation is the ideal form of regulation for many diverse complementary and alternative health care practices because as the broad array of natural, non-invasive therapies available to consumers continues to grow and the variety of vocations available to practitioners similarly expands, the exemption law automatically covers these complementary and alternative health modalities without the need for separate practice acts for each type of natural health practitioner. Therefore, practitioners and consumers can work together without fear, as long as practitioners avoid the prohibited acts spelled out by the legislature and provide the consumer with the proper disclosures about themselves and their services. Under Safe Harbor Exemption laws, the state retains the right to stop a practitioner from practicing and consumers retain their legal rights of redress.

#### **d. NHFA’s work to amend or oppose Hawaii’s Herbal Therapy Licensing bills**

In January 2013, Hawaii introduced Herbal Therapy Licensing bills that included mandates for the licensure of persons practicing herbal therapy without proper exemptions for those persons who did not fit within the confines of the bill’s educational requirements:

*“§ -2 Licensure required. Except as otherwise provided by law, a person who practices, offers to practice, or advertises the practice of herbal therapy in the State either gratuitously or for pay*

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<sup>12</sup> For case law examples in which unlicensed natural health practitioners were charged with unlicensed practice of a licensed health care profession, please contact NHFA.

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*shall be required to have a valid license through the board or through a specialized practice such as naturopathic medicine or traditional Chinese medicine.”*

The Herbal Therapy Licensing bills defined herbal therapy very broadly and prohibited the use of the term “herbal therapist” as follows:

*“§ -1 Herbal therapist means a person with knowledge, skills, and experience in the direct personal health care of individuals based on herbal practices, including the utilization of herbal formulas to improve health and wellness, and who has met the standards and requirements pursuant to a license issued under this chapter”*

And

*“§ -8 Prohibited acts; penalties. (a) No person shall: (1) Use in connection with the person's name any designation tending to imply that the person is a licensed herbal therapist unless the person is duly licensed and authorized under this chapter  
(b) Any person who violates this section shall be subject to a fine of not more than \$1,000, and each day's violation shall be deemed a separate offense.”*

NHFA became aware of efforts to mandate the licensure of herbal therapists in Hawaii after the introduction of the Herbal Therapy Licensing bills. NHFA opposed the mandatory licensing knowing that it would negatively impact thousands of Hawaii citizens who consume and practice complementary and alternative therapies that include herbs. Many persons practicing herbal therapies would not meet the criteria for licensure and, even if they did, many had no desire to become licensed herbalists. NHFA immediately began contacting Hawaii citizens to once again discuss the possibility of a Safe Harbor Exemption bill for herbalists and many other therapists and to explain our opposition to the broad herbal therapy licensing. NHFA also communicated our concerns and offered Health Freedom amendments to the primary sponsors of the bill in the House and the Senate, Representative Takumi and Senator Oakland, respectively, and to Representative Evans.

Also in February, 2013, NHFA was contacted by a Constituent of Representative Takumi, House sponsor of the Herbal Therapy Licensing bill. The constituent explained that herbalists are afraid to practice in the state of Hawaii, with the exception of the Traditional Hawaiian Herbalists.<sup>13</sup> The constituent also informed NHFA that Senator Chun Oakland’s office drafted both the House and Senate bills after working with her and other Hawaiian herbal therapists for a number of years but that she and her group members were not interested in shutting-down or excluding certain herbalists from practicing. Rather, she explained, their goal was to expand access to and the practice of herbal therapy in the state.

Senator Oakland’s office elaborated to NHFA that the goal of the Herbal Therapy Licensing bill was to allow the younger generation of herbal practitioners to be recognized through licensing by insurers, who have historically covered services that have gone through a certification or licensing process and to support “a mutual interest in supporting practitioners who are not currently recognized by the medical

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<sup>13</sup> The Hawaii medical practice act provides an exemption for certain traditional natural healers, at Title 25, Chapter 453-2(c), HRS.

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system in our nation, who have incredible value to the health and well-being of people in our community.”<sup>14</sup>

NHFA held conference calls with the constituent group in order to educate them about the concept of a Safe Harbor Exemption bill and its success in other states at protecting the interests they sought to advance. NHFA explained that, despite their best intentions, their Herbal Therapy Licensing bill would have negative consequences for many natural health practitioners, given the language that was presented. The group expressed interest in the concept of Safe Harbor Exemption legislation and NHFA encouraged them to review the previously introduced Hawaii Health Freedom Bills with their group.

In 2014, when the bills were reintroduced and Herbal Therapy Licensing was scheduled for study, NHFA drafted this comment.

## II. DISCUSSION

Regulation is an exercise of the state’s police power and should not be imposed or used lightly. Since regulation is an abridgment of a person’s constitutional right to engage in a lawful profession, trade, or occupation, a state cannot abridge that right unless the abridgment constitutes a reasonable exercise of its police powers. As Hawaii law emphasizes, the state is to regulate professions only if there is a need to protect consumers. §26H-2(1).

Under the Hawaii Regulatory Licensing Reform Act, H.R.S. §26H-6, the Auditor must analyze new regulatory measures that would subject unregulated professions and vocations to licensing or other regulatory controls. The Auditor’s analysis must assess:

- (a) Whether the proposed regulation is necessary to protect the health, safety, and welfare of the public and is consistent with other regulatory policy provisions in §26H-2, HRS;
- (b) The probable effects of the proposed regulation; and
- (c) Alternative forms of regulation.

**a. Licensing herbal therapists is not necessary to protect the health, safety, and welfare of the public and is not consistent with the policy provisions in §26H-2, HRS, because the primary purpose of the Herbal Therapy Licensing bill is not the protection of the public and there is no documented evidence of sufficiently real or serious harm from the unregulated practice of herbal therapy.**

- i. The protection of the vocation of herbal therapy is an improper purpose for regulating a profession.

The policy provisions of §26H-2 state that the primary purpose of regulation is to protect consumers. Concerns outside of consumer protection do not justify the state’s right to regulate a profession because industry promotion and consumer benefits are not the motivating forces behind sunrise review statutes.

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<sup>14</sup> Email from Sen. Oakland to NHFA (February, 16, 2013), on file with author of this comment.

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Because the primary purpose of the Herbal Therapy Licensing bill is the protection of the profession, and not the protection of consumers, the regulation is unwarranted and not necessary.

The stated purpose of the Herbal Therapy Licensing bill is to establish licensing requirements for contemporary herbal healers from all ancestries<sup>15</sup>, to promote the practice of herbal therapy in the State<sup>16</sup>, and to recognize the validity of herbal therapy and the importance of our natural plant resources and knowledge base.”<sup>17</sup>

Further, the bill proposes that the board is to “promote current dialogue, and research, and maintain a basic plant list that includes plant identification, use, preparation, collection and treatment method”<sup>18</sup>, to “work with appropriate agencies to protect ancestral knowledge and natural resources”<sup>19</sup> and to “request coverage by health insurance as with other complementary and alternative medicine such as acupuncture, massage therapy, chiropractic, and naturopathic methods”.<sup>20</sup>

The meaning of the above excerpts is that the Herbal Therapy Licensing bill seeks to specifically allow non-Native Hawaii herbalists (i.e., those who do not fit under the exemption from the medical practice act for Native Hawaiian healers)<sup>21</sup> to provide natural health services too and to generally strive to protect and promote the practice of herbal therapy by documenting uses of and obtaining insurance reimbursement for herbal therapies. While there is nothing inherently wrong with the proponents desire to promote and expand the profession of herbal therapy, this concern does not address the required primary purpose of regulation: the protection of the consumer.

Regardless of the validity of the belief that insurance coverage is a form of validation of a profession, using licensure or regulation as a means to get insurance coverage is an improper legal purpose for regulating a profession. Even if the proponents argue that licensing will lead to insurance reimbursement and thereby provide a benefit to consumers, benefits to consumers are not relevant to a determination of whether regulation is necessary to protect the public.

Aside from a single, unsupported comment that licensing, in and of itself, protects the public and the practitioners, there is nothing in the language of the Herbal Therapy Licensing bill to indicate that the purpose of regulation is the protection of the consumer. Instead, the motivation language clearly reveals that the primary purpose of the bill is the protection of the profession of herbal therapy. NHFA encourages a finding that licensure of herbal therapy is not necessary or warranted.

ii. Documented evidence of sufficiently real or serious harm is absent.

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<sup>15</sup> S.B. 2439 §1, at p. 2, ln. 12-14.

<sup>16</sup> *Id.*, at p.1, ln. 12-15.

<sup>17</sup> *Id.*, at p. 2, ln. 17 - 20.

<sup>18</sup> §6(14)

<sup>19</sup> §(15)

<sup>20</sup> §6 (12) Powers and duties of the Board.

<sup>21</sup> H.R.S. §453-2(c), which states: “Nothing in this chapter shall prohibit healing practices by traditional Hawaiian healers engaged in traditional Native Hawaiian healing practices, both as recognized and certified as such by any kupuna council convened by Papa Ola Lokahi. [...] Nothing in this chapter shall limit, alter, or otherwise adversely affect any rights of practice of traditional Native Hawaiian healing pursuant to the Constitution of the State of Hawaii.”

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Public harm is a required constitutional criterion before an occupation can be regulated. The harm criterion is found in Hawaii policy provisions (2), (3), and (4) of §26H-2, which respectively use the words “jeopardy”, “abuses”, and “danger”, and in the Auditor’s supplemental criteria that the incidence or severity of harm based on documented evidence is sufficiently real or serious to warrant regulation.<sup>22</sup> Further, the Council on Licensure, Enforcement, and Regulation states that the primary guiding principle for legislators is whether an unregulated occupation presents a clear and present danger to the public’s health, safety, or welfare.<sup>23</sup> Finally, in assessing the need for regulation, the burden of proof is on the proponents of the measure to demonstrate the need for regulation.

The Herbal Therapy Licensing bill does not provide any documented evidence of harm from the unregulated practice of herbal therapy, let alone an incidence or severity of harm that is sufficiently real or serious to warrant licensing of the profession. In fact, the proponents claim evidence to the contrary; that herbal therapy is a method for improving the health and wellness of Hawaii citizens. Even the Hawaii Board of Naturopathic medicine admits that it is not aware of any complaints pertaining to patient harm due to prescribing, among other things, herbs and herbal formulas from the naturopathic formulary.<sup>24</sup>

No state currently licenses, registers, or certifies herbal therapists. In Safe Harbor Exemption states, herbalists are free to provide services to consumers without restriction on use of titles or type of educational background. NHFA is not aware of any complaints of harm from herbalists practicing under Safe Harbor Exemption guidelines.

*Herbs are dietary supplements which are regulated as food and are generally recognized as safe.*

Under Federal law, herbs are dietary supplements and, therefore, are regulated as food. The Dietary Supplement Health and Education Act (DSHEA) of 1994, an amendment to the Food, Drug, and Cosmetic Act, defines a dietary supplement as, in part, a product that is ingested by mouth to supplement the diet and contains one or more of the following ingredients:

- a vitamin;
- a mineral;
- *an herb* or other botanical;
- an amino acid;
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- a concentrate, a metabolite, a constituent, or an extract.<sup>25</sup>

An herb is a plant or plant part (such as leaves, flowers, or seeds) that is used for its flavor, scent, and/or potential health-related properties. “Botanical” is often used as a synonym for “herb.” An herbal

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<sup>22</sup> See *Sunrise Reviews: Regulatory Structures and Criteria*, report No. 6 of the Hawaii Legislative Reference Bureau (2002).

<sup>23</sup> See *Questions a Legislator Should Ask*, a publication of the Council on Licensure, Enforcement, and Regulation.

<sup>24</sup> Act 22, Special session 2009, permitted naturopathic physicians to prescribe, administer and dispense substances pursuant to the naturopathic formulary which is established by the board; See also, Testimony from Board of Naturopathic Medicine to the Senate Committee on Health regarding Senate Bill No. 2577, relating to naturopathic physicians (January 27, 2014).

<sup>25</sup> DSHEA, P.L. 103-417 §3 (codified at 21 U.S.C. §321(ff)(1), emphasis added.

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supplement may contain a single herb or mixtures of herbs. The law requires that all of the herbs be listed on the product label.

Foods that make structure/function claims<sup>26</sup> in commerce, such as dietary supplements, are specifically excluded from the definition of “drug” and are regulated as foods. Unlike drugs<sup>27</sup>, which must be proven to be safe and effective prior to entering the market, dietary supplements carry a presumption of safety and are not subject to pre-market drug approval.<sup>28</sup>

Manufacturers of herbs, and other dietary supplements, must follow “current good manufacturing practices” for dietary supplements to ensure that these products are processed, labeled, and packaged consistently and meet quality standards. Once a dietary supplement is on the market, the FDA monitors product information, such as label claims and package inserts. The Federal Trade Commission (FTC) is responsible for regulating product advertising; it requires that all information be truthful and not misleading.

Also, once a dietary supplement is on the market, the FDA evaluates safety by doing research and keeping track of any side effects reported by consumers, health care providers, and supplement companies. If the FDA finds a product to be unsafe, it can take action against the manufacturer and/or distributor, and may issue a warning or require that the product be removed from the marketplace.<sup>29</sup>

Regarding state regulation of herbal therapists, like with Federal regulation of herbs, there is no constitutional endangerment rationale to support the need for pre-market approval of Herbal Therapy practitioners in Hawaii via licensing. The use of herbs to maintain or improve health is the oldest form of natural health care used by men and women. The use of herbs is a non-invasive, natural health care option for thousands of consumers and should not be prohibited by the government nor restricted to a select group of persons with a particular education. NHFA does not support the licensure of herbal therapists and the requirement of all herbalists to have government approved education because the practice of herbal therapy by the use of herbs and dietary supplements that are regulated as foods, does not pose an imminent risk of harm to the public. Herbal therapy is a much better candidate for the legal

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<sup>26</sup> Manufacturers may make three types of claims for dietary supplements: health claims, structure/function claims, and nutrient content claims. Some of these claims describe the link between a food substance and a disease or health-related condition; the intended benefits of using the product; or the amount of a nutrient or dietary substance in a product. Different requirements apply to each type of claim. If a dietary supplement manufacturer makes a claim about a product’s effects, the manufacturer must have data to support the claim. Claims about how a supplement affects the structure or function of the body must be followed by the words “This statement has not been evaluated by the U.S. Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure, or prevent any disease.”

<sup>27</sup> The term “drug” means “(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; [...]”(g)(1)

<sup>28</sup> FD&C Act 201(s)(6), specifically excluding dietary supplement ingredients from the definition of “food additive”, thus releasing them from the requirement of premarket approval under the food additive provisions of the Act.

<sup>29</sup> The Federal Government has taken legal action against dietary supplement promoters or websites that promote or sell dietary supplements for making false or deceptive statements about their products or because marketed products have proven to be unsafe. In 2010, an investigation by the U.S. Government Accountability Office found instances in which written sales materials for herbal dietary supplements sold through online retailers included illegal claims that the products could treat, prevent, or cure diseases such as diabetes, cancer, or cardiovascular disease.

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concept of regulation with a Safe Harbor Exemption because it keeps the non-harmful therapy in the public domain while ensuring that unlicensed natural health care practitioners avoid certain prohibited acts and give out proper disclosures.

**b. Licensing herbal therapists is unwarranted because the probable effects of the proposed regulation are an unreasonable restriction on entry into the profession and an unconstitutional limitation on the First Amendment rights of free speech and religion.**

i. Unnecessary and unfair restriction of individuals to practice their vocation

Licensing herbal therapists would unreasonably restrict entry into professions and vocations by qualified persons in violation of Policy (6) of §26H-2. The Herbal Therapy Licensing bill gives a Board of peers an exclusive rulemaking authority. The Herbal Therapy Board is to create standards for licensure, the definition of the scope of practice, a code of ethics, exam qualifications and apprenticeship. The bill instructs the new board to model the qualifications after those found in Hawaii's Massage Therapy Licensing law, which covers aspects of study including curriculum; length of apprenticeship under a recognized teacher, practitioner, or mentor; degree or certification; hours of practice; and documentation of study and practice and research. This delegation of power to a Board of self-interested individuals where there is no documented evidence of public harm, presents a risk that persons outside of the Board's yet-to-be-determined regulations would not be able to practice. The delegation of authority is overly broad and sweeping and will negatively impact an entire culture, commerce, practice, and use of herbs and herbalist practices.

*Criminalizing Common Behaviors*

Section 2 and Section 8 of the Herbal Therapy Licensing bill are the most onerous sections of the bill impacting the common person using and recommending herbs. It is the police power section of the bill. It mandates that all persons practicing herbal therapy be licensed by the state after having completed state approved educational requirements, and it prohibits the use of the title herbal therapist or using any terms that might imply the person is a licensed herbal therapist. If passed, this would prohibit thousands of persons from doing common behaviors associated with current herbal practices.

No other state has singled out herbal therapy and created these types of restrictions for herbal therapy or herbal therapists. The practice of using herbs, sharing knowledge about herbs, and having cottage industries and vocations in response to herbal knowledge is an ancient common behavior of the human race. Herbalism supports the relationship of humans with plants and is a part of the fabric of being human. To assert that practicing herbalism is a danger to the public or should be removed from the public domain is an affront to the very nature of our relationship with mother earth. Our knowledge of herbs, and all foods, and our relationship with the plants should be forever protected; not given over to police power jurisdiction of a state government or to a special small group of people unless, in a particular instance, there is evidence beyond a reasonable doubt that a governmental action needs to be taken regarding a particular herbalist or a particular herb. Herbalism is a way of life. It is a common behavior. With proper guidance for avoidance of prohibited acts and proper disclosure, such as that

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provided in Safe Harbor Exemption legislation, herbalism can and must remain in the public domain for all humans to experience.

An example of a state protecting these common behaviors is Michigan's recent repeal of its Dietitian Board and licensing laws because they were deemed as not necessary for the protection of the public. All humans make choices regarding foods, plants and herbs, and the plethora of information regarding them should remain accessible to everyone.

ii. Unconstitutional restriction on Freedom of Speech and Religion

The Herbal Therapy Licensing bill states that a person is an herbal therapist if they are “a person with knowledge, skills, and experience in the direct personal health care of individuals based on herbal practices, including the utilization of herbal formulas to improve health and wellness.” This definition includes a large percentage of the population, mothers, fathers, children, grandmothers, farmers, herbalists who are called to the vocation in response to their love of plants, of their neighbors, friends, and of cottage industry shops. The breadth of the Herbal Therapy Licensing bill subjects this diverse range of people to penalties for the unlicensed practice of herbal therapy even if those who do not make their living from sharing information about herbs.<sup>30</sup> It would be unconstitutional for any professional group to define and restrict a subset of free speech about herbs to their group with the attached threat of criminal charges or administrative legal proceedings if one should speak coveted words.

NFHA has no tolerance for banning truthful non-fraudulent speech about herbs and plants or attaching penalties to such speech. There are select examples of laws that restrict speech having to do with fraud, danger, and criminal intent, discrimination, etc. and commercial laws on labeling of products, however to blatantly carve out a section of speech for a particular group of people, speech that is regularly used in the culture for the sustenance of the people and not harmful is onerous. In addition, if there is concern regarding commercial speech, commercial speech about herbs is regulated by the federal government because herbs are dietary supplements, subject to food regulations of the FDA.

*Specifically Restricting Retailer's Freedom of Speech*

The Herbal Therapy Licensing bill offends Hawaii retailers who are currently regulated in their speech about their products by the FDA. Hawaii retailers should not be under the jurisdiction of the state due to their knowledge and recommendation of herbs nor should they have to worry about the state of Hawaii being more stringent than the federal government on commercial speech regarding herbs. It is already legal for them to sell food, food materials, dietary supplements, or other goods containing herbs to consumers so, therefore, a Hawaii Board of Herbal Therapy should not be able to tell them what they can or cannot say when engaged in selling with their customers. The Herbal Therapy Licensing bill attempts to put a broad speech restriction on herbal speech and on people who sell products because it links their freedom of speech to the new definition of “herbal therapist.”

*Absence of religious exemption*

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Licensing laws generally include an exemption for persons practicing according to their religious and philosophical beliefs and this bill contains no such exemption.<sup>31</sup>

**c. Licensing herbal therapists is unwarranted because less restrictive forms of regulation already exist and are available.**

i. Hawaii residents are already protected from risk of harm under Hawaii's Deceptive Trade Practices, Consumer Protection, law

Rather than jumping to the most restrictive form of regulation for herbal therapists in Hawaii, the Auditor should find that Hawaii citizens are already protected from any potential risk of harm from the unregulated practice of herbal therapy by Hawaii's Deceptive Trade Practice law. Hawaii's Deceptive Trade Practice law provides that a person engages in a deceptive trade practice when the person "causes likelihood of confusion or of misunderstanding as to the [...] approval, or certification of services;" or, as to "affiliation, connection, or association with, or certification by, another." §481A-3(a)(2)-(3).

Additionally, the law prohibits a person from using deceptive representations in connection with the services (§481A-3(a)(4)) and from representing that services have "sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have" (§481A-3(a)(5)). Further, the law prohibits representations that services are of a particular standard, quality, or grade, if they are of another. §481A-3(a)(7).

If the proponents are concerned that consumers are being deceived or misled by practitioners of herbal therapy, the Deceptive Trade Practice Act authorizes the state to act to correct or eliminate the source of the confusion. If the proponents are concerned that herbalists or their consumers do not have access to information about herbs, there are already numerous long-term, ongoing and successful efforts to preserve and disseminate information on the identity and uses of diverse plant species.<sup>32</sup>

ii. Introduction of a less restrictive form of regulation for herbal therapists

If the Auditor finds that some form of state regulation for herbal therapists is necessary in Hawaii, then the legislature should be allowed to consider whether a Safe Harbor Exemption bill, and not a strict licensing law, would provide sufficient consumer protection. The use of state licensure, registration, and certification to regulate health care occupations is not the least restrictive means of regulation and can negatively impact consumer options when used as the sole means of regulation. In fact, licensure is

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<sup>31</sup> See e.g., §453-2(b)(1), HRS, providing an exemption to the criminal charges for the unlicensed practice of medicine for Christian Scientists.

<sup>32</sup> For example, the AHPA Botanical Identity References Compendium is maintained by the American Herbal Products Association (AHPA) and was developed by AHPA with the support of many individuals and organizations with a common interest in sharing knowledge and resources relevant to accurate identification of herbal materials; available here: <http://ahpa.org/Default.aspx?tabid=449>; "The AHPA Compendium is a cooperative and centralized source of information on physical characteristics and test methods that can be used by qualified and experienced analysts to determine the identity of plant species and articles of trade obtained from these plants."

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the most restrictive type of regulation, utilizing the broadest sweep of police power possible for occupations. Licensing should not be imposed lightly onto professions with such a low risk of harm.

For that reason, NHFA encourages Hawaii to consider the least restrictive form of regulation necessary for all complementary and alternative health care practitioners who are not licensed. Introducing a Safe Harbor Exemption bill would properly guide practitioners in their practices and provide consumers with important and empowering disclosures for good decision-making.

### **III. CONCLUSION**

No state currently licenses, registers, or certifies herbal therapists and there is no evidence of harm from the unregulated practice of herbal therapy in Hawaii.

A most fundamental freedom of an individual, as well as a tool for staying healthy, is the ability to pursue different avenues and philosophies of care that match the individual's own values and desires, and based on that information, decide which is best for him/her.

NHFA respectfully requests the Auditor to find that licensing herbal therapists in Hawaii is not warranted, that there are less restrictive models of regulation to cope with the desire to protect the practice of herbal therapy, access to, and consumer awareness regarding herbal therapists, and that Hawaii citizens would benefit from a law that protects all complementary and alternative unlicensed health care practitioners by the use of a properly designed Safe Harbor Exemption law with certain prohibited acts and disclosure requirements.

### **IV. APPENDICES**

- a. Hawaii Health Freedom Law (2007)
- b. Table of State Safe Harbor Exemption, "Health Freedom", laws

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