

NOTES

Allies and Adversaries: A Look into the Relationship Between Herbal Medicines and the Environment

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TABLE OF CONTENTS

Introduction	693
I. History and Modern Use	694
A. History	694
B. Modern Use	695
II. Concerns	696
A. Health Effects	696
1. Heavy Metals	696
2. Pesticides	697
3. Supply and Demand	698
B. Environmental Effects	700
1. Climate Change	700
2. Endangered Species and Loss of Biodiversity	701
III. Quality Regulation	701
A. International Regulation	701
B. United States Regulation	703
IV. Environmental Regulation	707
A. International Regulation	707
B. United States Regulation	708
Conclusion	710

INTRODUCTION

The World Health Organization (“WHO”) defines herbal medicines as materials, preparations, and finished products containing plant parts as active ingredients.¹ This broad definition encompasses a variety of foods, dietary supplements,

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1. WORLD HEALTH ORG., GENERAL GUIDELINES FOR METHODOLOGIES ON RESEARCH AND EVALUATION OF TRADITIONAL MEDICINE 4 (2000), <http://apps.who.int/medicinedocs/pdf/whozip42e/whozip42e.pdf>.

and traditional medicines. According to industry analysts, global sales of such herbal products have grown by roughly \$40 billion over the last fifteen years—from close to \$60 billion in 2000 to nearly \$100 billion in 2015—and sales are expected to continue to grow at a rate of three to twelve percent per year.² This increase in consumption has prompted concerns about the safety and efficacy of herbal medicine. Although regulators have taken action against certain potentially harmful herbal products, their efforts have largely ignored the inevitable connection between herbal-product quality and the quality of the natural environment.

This Note explores the relationship between herbal medicines and environmental sustainability. In particular, it examines regulatory efforts relating to each in the United States and abroad. Part I describes the history and current usage of herbal medicines. Part II discusses quality (for example, safety and efficacy) concerns regarding herbal medicines, with particular emphasis on concerns related to ecological factors and the impact of herbal medicine production on the environment. Part III describes current regulations relating to herbal medicine quality, and Part IV discusses environmental regulations relevant to herbal medicine production. Finally, Part V concludes with comments on future prospects for the regulation of herbal medicine quality and environmental sustainability.

I. HISTORY AND MODERN USE

A. HISTORY

Herbs have been used as medicines since the beginning of humankind. Ancient civilizations in Mesopotamia, Greece, Rome, and Egypt began documenting herbal prescriptions on clay tablets as early as 3,000 BC.³ All major indigenous cultures—including Native American, European, South American, Asian, and African cultures—continue to carry extensive knowledge about the medicinal properties of herbs on their respective continents.⁴ Traditional Chinese medicine and Indian Ayurveda, two of the most popular and influential herbal traditions still practiced,⁵ utilize nearly 1,000 different plant species to treat a variety of ailments.⁶

2. See Junhua Zhang et al., *Quality of Herbal Medicines: Challenges and Solutions*, 20 *COMPLEMENTARY THERAPIES IN MEDICINE* 100, 101 (2012) (discussing global usage of herbal medicines); Steven Daniels, *Herbal Supplement Sales to Hit \$93.15 billion by 2015: Report*, *NUTRAINGREDIENTS* (Dec. 10, 2015), <http://www.nutraingredients-usa.com/Markets/Herbal-supplement-sales-to-hit-93.15-billion-by-2015-Report>.

3. See *A Brief History of Herbalism*, *NATURAL HEALTH SCHOOL*, <http://www.naturalhealthschool.com/history-of-herbalism.html> (last visited Sept. 5, 2016).

4. See *id.*

5. See Bhushan Patwardhan et al., *Ayurveda and Traditional Chinese Medicine: A Comparative Overview*, 2 *EVID.-BASED COMP. & ALT. MED.* 465, 465 (2005).

6. *NATURAL HEALTH SCHOOL*, *supra* note 3.

In traditional Chinese medicine, herbs are “ascribed qualities such as ‘cooling’ (yin) or ‘stimulating’ (yang) and are used, often in combination, according to the deficiencies or excesses of these qualities in . . . patient[s].”⁷ Similarly, Ayurvedic practitioners use unique herbal protocols to resolve health imbalances in patients resulting from internal disharmony amongst the five elements of the material world: akasha (ether), vayu (air), teja (fire), aap (water), and prithvi (earth).⁸ Although traditional Chinese Medicine and Ayurveda are rooted in spirituality and superstition, many of the plants these herbal traditions utilize have been scientifically proven to possess curative properties and have served as a basis for the development of orthodox medicines and modern herbal practices.⁹

B. MODERN USE

Today, seventy to eighty percent of the global population relies on herbal medicines as a primary form of healthcare.¹⁰ For millions of people in developing countries, herbal medicinal products continue to be the most accessible and affordable treatment option.¹¹ In developed countries, populations are increasingly using herbal medicine as an alternative to or in combination with conventional medicine to treat many common conditions.¹² According to a 2014 survey by the Council for Responsible Nutrition, more than two thirds of adults in the United States use herbal medicines and other dietary supplements with some frequency.¹³

Although many assume dissatisfaction with mainstream medicine is a primary reason for the increased popularity of herbal medicinal products in the United States and other developed countries, research has found no such statistical relationship.¹⁴ Rather, patients have reported that their use of nonconventional medicine is related to “holistic views of health” and “congruence with personal beliefs.”¹⁵ Due in part to the common assumption that “natural” means “harmless,” individuals view products derived from plant sources as a safe way to improve overall health and well being, alleviate symptoms resulting from chronic

7. Andrew Vickers et al., *Herbal Medicine*, 175 W. J. MED. 125, 125 (2001).

8. Patwardhan et al., *supra* note 5, at 466.

9. See, e.g., H.J.D. Dorman & Stanley G. Deans, *Antimicrobial Agents from Plants: Antibacterial Activity of Plant Volatile Oils*, 88 J. APPLIED MICROBIOLOGY 308, 309 (2000).

10. K. Chan, *Some Aspects of Toxic Contaminants in Herbal Medicines*, 52 CHEMOSPHERE 1361, 1362 (2003).

11. WORLD HEALTH ORG., WHO TRADITIONAL MEDICINE STRATEGY 2014–2023, at 16 (2013), <http://apps.who.int/medicinedocs/documents/s21201en/s21201en.pdf>.

12. Chan, *supra* note 10, at 1362.

13. See COUNCIL FOR RESPONSIBLE NUTRITION, THE DIETARY SUPPLEMENT CONSUMER 1 (2014), <http://www.crnusa.org/CRNconsumersurvey/2014/CRN2014CCsurvey-infographic-pages.pdf>.

14. LUCINDA E. JESSON & STACEY A. TOVINO, COMPLEMENTARY AND ALTERNATIVE MEDICINE AND THE LAW 5 (2010).

15. *Id.*

diseases, and avoid the side effects associated with conventional medicines.¹⁶ Accordingly, close to eighty-four percent of American adults report confidence in the safety and efficacy of herbal medicinal products.¹⁷

II. CONCERNS

A. HEALTH EFFECTS

Recent adverse-event reports and scientific studies indicate that American confidence in the quality of herbal medicinal products may not be fully warranted. The environmental conditions in which herbal plants are grown may pose a threat to consumer health. Recent studies on popular herbal products have revealed the presence of heavy metals, pesticide residues, and other external toxins.¹⁸ While some of this contamination results from poor processing practices, much of it stems from the agricultural inputs involved in herb cultivation.¹⁹ Industrial emissions, toxic waste disposal, and the spraying of pesticides for agriculture and disease control impact the quality of the soil, water, and air used to grow herbal plants, which consequently affect the quality of the herbs themselves. Even “organically grown” herbs are at risk of environmental contamination due to the excessive use and disposal of toxic pollutants.²⁰ In addition to posing safety concerns, environmental contaminants also impact the efficacy of herbal products, especially traditional medicines whose effectiveness is based on precise mixtures of specific herbs.²¹

1. Heavy Metals

Metals occur naturally in the environment and are present in a variety of agricultural products. Some, such as zinc, are intentionally added to foods, medicines, and supplements due to their purported health benefits. However, all metals become toxic at certain levels of exposure and can lead to serious medical conditions in humans, including lung cancer, kidney damage, and neurological disorders.²² Despite laws and regulations designed to protect consumers from

16. See Tainya C. Clarke et al., *Trends in the Use of Complementary Health Approaches Among Adults: United States, 2002–2012*, 79 NAT'L HEALTH STAT. REP. 1 (2015).

17. Press Release, Council for Responsible Nutrition, Annual CRN Consumer Survey Finds Overall Use of Supplements on the Rise 1 (Mar. 13, 2012), <http://www.crnusa.org/prpdfs/CRNPR12-SurveyFindingsUsage031312.pdf>.

18. See, e.g., Zhang et al., *supra* note 2, at 101–03.

19. See María R. Gomez et al., *Determination of Heavy Metals for the Quality Control in Argentinian Herbal Medicines by ETAAS and ICP-OES*, 45 FOOD & CHEMICAL TOXICOLOGY 1060, 1061 (2007).

20. Ivan Kosalec et al., *Contaminants of Medicinal Herbs and Herbal Products*, 60 ARCHIVES OF INDUS. HYGIENE & TOXICOLOGY 485, 485–86 (2009).

21. Patwardhan et al., *supra* note 5, at 467–68.

22. *Toxic Metals*, OCCUPATIONAL SAFETY & HEALTH ADMIN., <https://www.osha.gov/SLTC/metalsheavy/> (last visited Oct. 23, 2016).

exposure to toxic amounts of metals, scientists have found that many herbal medicines contain unsafe levels of mercury, arsenic, lead, cadmium, copper, thallium, and other elements.²³ Aside from the few metals that manufacturers deliberately added to medicines for specific curative purposes, most metals are inadvertently integrated during herb cultivation and processing due to “the accumulation of heavy metals in the environment (e.g., from contaminated soil or atmosphere)” and “inadvertent pollution during the production process” (e.g., from contaminated water inputs).²⁴

Incidences of herbs and herbal products being found to contain illegal and unsafe levels of heavy metals are abundant. To date, there have been more than fifty published reports on heavy metal poisoning from herbal products in a variety of regions including India, North America, the Middle East, Western Europe, and Australia.²⁵ In a 2000–2005 study on 500 different herbal materials produced in China, scientists found that twenty-four percent of samples contained quantities of heavy metals above safe limits.²⁶ In a smaller study of herbal medicines on the Nigerian market, one hundred percent of the products tested were contaminated with heavy metals in amounts that exceeded recommended daily intake.²⁷ Two separate studies conducted on herbal products from the Malaysian market found unsafe levels of lead and mercury in twenty-two percent and twenty-six percent of samples, respectively.²⁸ As a final example, a 2008 study on Ayurvedic medicines manufactured and distributed by American and Indian companies reported that twenty-one percent of the products tested contained unsafe concentrations of lead, mercury, or arsenic.²⁹

2. Pesticides

Although pesticides—including insecticides, fungicides, and herbicides—degrade to some extent, pesticide residues, including metabolites, remain in the natural environment and can accumulate in the food chain.³⁰ These residues, which have harmful effects on the central nervous system,³¹ are now a significant source of herbal-medicine contamination throughout the world. Recent studies of medicinal herbs in Egypt and Brazil found malathion pesticide residues in several Egyptian spices and organochlorine pesticide residues in Brazilian passionflow-

23. Zhang et al., *supra* note 2, at 101.

24. *Id.*

25. Niharika Sahoo et al., *Herbal Drugs: Standards and Regulation*, 81 *FITOTERAPIA* 462, 464 (2010).

26. Zhang et al., *supra* note 2, at 102.

27. *Id.*

28. *Id.*

29. Sahoo et al., *supra* note 25, at 464.

30. *See id.*

31. *Pesticide Residues in Food?*, WORLD HEALTH ORG., <http://www.who.int/features/qa/87/en/#> (last updated May 2016).

ers, at levels well above legal limits.³²

In 2004, the United States government completed testing of sixty-two samples of imported bulk ginseng and eighty-three samples of domestic ginseng for pesticide residues.³³ Testing identified illegal levels of pesticides in sixty percent of the imported ginseng samples and fifty-seven percent of the domestic samples.³⁴ Of these violative products, seventy-six percent of the imported and seventy-one percent of the domestic ginseng samples contained three or more types of harmful pesticide residues, the most common being quintozene, pentachlorine, and pentachlorobenzene.³⁵ More recently, in 2012, the U.S. government identified several herbal import products with pesticide-residue violation rates warranting special attention. Notably, one hundred percent of oolong tea imports, roughly thirty-eight percent of schizandra imports, and twelve percent of ginger-root imports were found to contain levels of pesticide residues in large excess of legal limits.³⁶

3. Supply and Demand

Extended droughts, heavy rain, floods, irregular fluctuations in temperatures, and other climate conditions impact the growing cycles of medicinal plants, and consequently, their yields.³⁷ Moreover, industrialization and urbanism have created “constraints on the availability and accessibility of specific types of plant and animal species used for medicinal purposes.”³⁸ In combination with increases to the world’s population and the overall popularity of herbal products, these factors have caused medicinal-plant demand to outpace available supply.

One obvious consequence of the herbal supply shortage has been an increase in the cost of dry herbs. For example, the price for wild ginseng root has doubled in the last decade.³⁹ The herb can now sell for more than \$1,000 per pound.⁴⁰ A less obvious and potentially more dangerous consequence of the herbal supply

32. See Kosalec et al., *supra* note 20, at 496.

33. *Ginseng Dietary Supplements Special Survey (CFRAN Assignments and Field Regulatory Monitoring for FY 2003 and FY 2004)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm116752.htm> (last updated Sept. 18, 2015).

34. *Id.*

35. *Id.*

36. U.S. FOOD & DRUG ADMIN., PESTICIDE MONITORING PROGRAM: FISCAL YEAR 2012 PESTICIDE REPORT 14 tbl.A (2012), <http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/Pesticides/UCM432758.pdf>.

37. Karen McElroy, *Herbal Medicine Practice: Future Environmental Impacts*, 23 AUSTRALIAN J. MED. HERBALISM 164, 164–65 (2011).

38. Rômulo Alves & Ierecê Rosa, *Biodiversity, Traditional Medicine and Public Health: Where Do They Meet?* 3 J. ETHNOBIOLOGY & ETHNOMEDICINE 14, 17 (2007).

39. Clint Rainey, *The Craze for Wild Ginseng, America’s Alt-Viagra*, NEW YORK MAGAZINE (Aug. 27, 2015), <http://nymag.com/daily/intelligencer/2015/08/ginseng-americas-alt-viagra.html>.

40. Michael S. Rosenwald, *Growing Demand for U.S. Ginseng the Root Cause of Latest Hunting Ban*, GUARDIAN (Jul. 9, 2013), <http://www.theguardian.com/world/2013/jul/09/ginseng-hunting-state-ban-maryland>.

shortage has been the tendency of some herb traders to source cheaper, “fake” herbs that are difficult to distinguish from their medicinal counterparts—many of which are poisonous.⁴¹ Additionally, herbal supply shortages have encouraged the manufacture of pills, capsules, and other products completely deficient of the herbs listed on their labels.⁴²

One of the most widely publicized incidences of herbal substitution was discovered in Belgium after doctors diagnosed a significant number of people with rapidly progressive interstitial nephritis, a rare kidney disorder in which the spaces between the kidney’s tubules become inflamed.⁴³ Government investigation into the cause of the outbreak linked it to the consumption of weight loss supplements and orthodox medicines in which *Aristolochia fangchi*, a poisonous Chinese herb, had been substituted for *Stephania tetrandra*, the Chinese medicinal herb listed on the products’ labels.⁴⁴

More recently, in February 2015, the New York State Office of the Attorney General conducted a study of certain herbal supplements sold at GNC, Target, Walgreens, and Walmart and found that most did not contain any of the herbs listed on their labels.⁴⁵ Instead, they contained cheap fillers such as powdered rice, legumes, peanuts, houseplants, and other substances potentially dangerous to consumers with allergies.⁴⁶ In particular, ginseng pills sold at Walgreens were found to contain only “powdered garlic and rice.”⁴⁷ Ginkgo biloba supplements sold at Walmart contained only powdered radish, houseplants, and wheat (despite a statement on the supplements’ labels claiming them to be gluten-free).⁴⁸ At Target, products advertised as St. John’s wort, valerian root, and ginkgo were found to contain only powdered rice, beans, peas, and wild carrots.⁴⁹ Of the six supplements tested from GNC, only one was found to contain its stated ingredient: garlic.⁵⁰

Additionally, in September 2015, the New York Botanical Garden tested the contents of eighteen different brands of supplements labeled as containing devils

41. Chan, *supra* note 10, at 1366.

42. See Anahad O’Connor, *GNC to Strengthen Supplement Quality Controls*, N.Y. TIMES (Mar. 30, 2015), <http://well.blogs.nytimes.com/2015/03/30/gnc-to-strengthen-supplement-quality-controls>.

43. Chan, *supra* note 10, at 1366.

44. *Id.*

45. Press Release, N.Y. State Office of the Att’y Gen., A.G. Schneiderman Asks Major Retailers to Halt Sales of Certain Herbal Supplements as DNA Tests Fail to Detect Plant Materials Listed on Majority of Products Tested (Feb. 3, 2015), <http://www.ag.ny.gov/press-release/ag-schneiderman-asks-major-retailers-halt-sales-certain-herbal-supplements-dna-tests> [hereinafter Schneiderman Press Release].

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.*

claw, the legal common name for *Harpagophytum procumbens*.⁵¹ According to the test results, sixteen of the eighteen supplements were adulterated or misbranded due to the full or partial replacement of *Harpagophytum procumbens* with *Harpagophytum zeyheri*, a cheaper, less desirable herb.⁵²

B. ENVIRONMENTAL EFFECTS

Though the impact of ecological factors on herbal medicine quality is being increasingly studied, the reverse relationship, specifically, the impact of herbal-medicine production on the environment, has received minimal direct attention. In the face of modern energy and climate issues, “[a] more thorough examination of the [herbal medicine] profession and its impact on the environment now and into the future is warranted.”⁵³

1. Climate Change

Although there is little available data regarding the herbal medicine industry’s specific contribution to climate change, several scholars have acknowledged the likely carbon footprint associated with herbal medicinal practices. Dramatic increases in the sale of herbal remedies over the past few decades have precipitated “large-scale harvesting of medicinal plants” and “factory-like production of herbal drugs.”⁵⁴ As emphasized by Australian herbalist Karen McElroy, this modern style of herbal medicine production is extremely resource-intensive. In addition to the water, soil, fertilizers, and other agricultural inputs required for cultivation, large amounts of energy are needed for the transport of herbs from raw-material wholesalers to manufacturers for processing; from manufacturers to wholesale warehouses for packaging; and from warehouses to practitioners, clinics, and retail outlets for sale and consumption.⁵⁵ Moreover, the processing of herbs for use in medicinal products, which normally involves the “drying, milling, encapsulating, pressing[,] and percolation” of dry herbs, and the use of plastics in the storing and packaging of bulk herbal material and herbal retail products, require large quantities of oil.⁵⁶ An already resource-intensive process, the cultivation and production of medicinal herbs threatens to place even further demands on the environment as the industry continues to grow.

51. Letter from Simon G. Brandler, Senior Advisor & Special Counsel, N.Y. State Office of the Att’y Gen., to Frank W. Gay, CEO, Nutraceutical Int’l Corp. (Sept. 9, 2015), http://www.ag.ny.gov/pdfs/enforcement_letters.pdf.

52. Matthew Hamilton, *Attorney General Launches New Effort to Control Dietary Supplements*, TIMES UNION (Sept. 10, 2015, 7:13 AM), <http://www.timesunion.com/local/article/Attorney-general-launches-new-effort-to-control-6494644.php>.

53. McElroy, *supra* note 37, at 164.

54. Alves, *supra* note 38, at 18.

55. McElroy, *supra* note 37, at 166.

56. *Id.*

2. Endangered Species and Loss of Biodiversity

Increased demand for herbal medicines has also led to the overexploitation of certain plant species, many of which are currently close to extinction. In Africa, several native plant species, particularly pygeum (*Prunus Africana*) and yohimbe (*Pausinystalia yohimbe*), are currently being harvested in “unsustainable and destructive ways in order to feed international markets.”⁵⁷ Similarly, in Brazil, thirty-three of the country’s fifty-four endangered medicinal-plant species are currently being commercialized for international sale.⁵⁸ Internationally, more than 200 cultivated medical herb species have been internationally listed as threatened or endangered. And of the more than 33,000 medicinal plants still harvested from the wild, between 4,000 and 10,000 may now be endangered.⁵⁹

Plants are not the only types of species impacted by herbal medicine production. Many traditional herbal remedies also contain animal-derived ingredients, including rhino, tiger, deer, bear, monkey, and pangolin parts.⁶⁰ Despite international regulations for the protection of endangered animals and national laws against poaching, the large sums of money offered for certain animal parts serve as strong incentives for the illegal trade of several species.⁶¹ As the production of medicinal herbs continues to expand, further reductions in the indigenous flora and fauna should be expected.

III. QUALITY REGULATION

Increased awareness of the potential health and safety risks associated with herbal-medicine consumption has prompted regulatory efforts worldwide. Though varied in the extent of their responses, many countries have enacted laws treating herbal medicines as prescription drugs or subjecting them to good-manufacturing practices. Yet in some countries, most notably the United States, laws friendly to alternative medicine and governmental budgetary constraints have largely prevented the implementation of more-effective procedures for herbal-product quality assurance.

A. INTERNATIONAL REGULATION

Worldwide regulation of herbal medicines varies widely. According to a WHO study, roughly thirty-seven percent of its member states have enacted laws applicable to herbal medicines, forty-two percent of which directly address

57. Alves, *supra* note 38, at 18.

58. *Id.* at 19.

59. *Id.* at 18.

60. *Id.*

61. *Id.*

herbal-medicine quality standards.⁶² Nearly one-third of WHO member states treat herbal medicines as prescription drugs while the overwhelming majority allow for most herbal products to be sold over-the-counter.⁶³ Though relatively few countries have implemented safety-monitoring systems, over half of WHO member states subject herbal-medicine producers to the same good-manufacturing practices that they require conventional pharmaceutical producers to follow.⁶⁴

Among Southeast Asian and Western Pacific countries, Korea, Indonesia, India, Myanmar, Sri Lanka, Thailand, China, Malaysia, and Vietnam have national monographs for herbal drugs, and Bhutan, Nepal, and the Philippines are currently in the process of developing their own monographs.⁶⁵ In India, the Drugs and Cosmetics Act of 1940 governs the production and marketing of herbal medicines, including the implementation of good-manufacturing practices.⁶⁶ However, India does not require herbal medicines to be tested for safety and efficacy before they reach the marketplace.⁶⁷

South America, Brazil, Argentina, and Mexico—the largest producers of herbal products—regulate herbal medicines both as over-the-counter supplements and as prescription drugs.⁶⁸ In Mexico and Argentina, the safety and quality of herbal medicines is assessed based on a history of demonstrated safety and documented scientific research.⁶⁹ In the Eastern Mediterranean region—where countries such as the United Arab Emirates obtain a majority of their herbal medicines from the United States, Europe, and Asia—only a few countries regulate herbal products for safety and efficacy.⁷⁰

Certain regions have also taken steps aimed specifically at reducing heavy metal and pesticide residue contamination of herbal-medicinal products. The European Union, China, and Japan have issued regional and national guidelines designed to ensure that “soil and irrigation water used for herbal material cultivation and propagation are within the limits or free from harmful heavy metals, pesticides,” and other hazardous substances.⁷¹ China, in particular, has taken steps to reduce contamination of herbal materials through the certification of agricultural fields specially designated as being adherent to national good agricultural and collection practices.⁷² However, “lack of scientific standard operating procedures (“SOPs”), normalized management, well-trained farmers,”

62. Sahoo et al., *supra* note 25, at 467.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.* at 468.

67. *Id.*

68. *Id.*

69. *Id.* at 468–69.

70. *Id.* at 469.

71. *Id.* at 466.

72. Zhang, *supra* note 2, at 104.

and other key components continue to limit the overall effectiveness of China's efforts.⁷³

In an attempt to standardize the regulation of herbal medicines globally, the WHO has published guidelines for herbal medicine safety and efficacy assurance, including *Quality Control Methods for Medicinal Plant Materials*,⁷⁴ *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants*,⁷⁵ and *WHO Guidelines for Assessing Quality of Herbal Medicines with Reference to Contaminants and Residues*.⁷⁶ The WHO continues to strive for global standardization of herb classification, cultivation, and processing, in the face of complex and often conflicting national-level regulatory schemes.

B. UNITED STATES REGULATION

In the United States, the Food and Drug Administration ("FDA") is the primary regulatory authority responsible for ensuring the safety and efficacy of herbal medicines.⁷⁷ The FDA, which derives its power from the Federal Food, Drug, and Cosmetic Act ("FDCA"), has the mandate of protecting the public by "assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, [the] nation's food supply, cosmetics, and products that emit radiation."⁷⁸ Additionally, the FDA is "responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health."⁷⁹

With respect to food, the FDA is in charge of four primary tasks: (1) ensuring that foods are processed safely and sanitarily through the enforcement of Current Good Manufacturing Practices ("CGMPs"),⁸⁰ (2) approving certain foods and food additives before they can be marketed;⁸¹ (3) removing "adulterated" foods

73. *Id.*

74. WORLD HEALTH ORG., QUALITY CONTROL METHODS FOR MEDICINAL PLANT MATERIALS (1998), <http://apps.who.int/iris/bitstream/10665/41986/1/9241545100.pdf>.

75. WORLD HEALTH ORG., WHO GUIDELINES ON GOOD AGRICULTURAL AND COLLECTION PRACTICES (GACP) FOR MEDICINAL PLANTS (2003), <http://apps.who.int/medicinedocs/pdf/s4928e/s4928e.pdf>.

76. WORLD HEALTH ORG., WHO GUIDELINES FOR ASSESSING QUALITY OF HERBAL MEDICINES WITH REFERENCE TO CONTAMINANTS AND RESIDUES (2007), <http://apps.who.int/medicinedocs/documents/s14878e/s14878e.pdf>.

77. 21 U.S.C. § 321 (2012) (defining "dietary supplement" to include supplements containing herbs); 21 U.S.C. § 331 (2012) (prohibiting the introduction of a dietary supplement that is unsafe).

78. *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo> (last updated Dec. 7, 2015).

79. *Id.*

80. See 21 C.F.R. § 110.5 (2016). CGMPs prescribe "a broad range of precautions such as material inspection, employee training, storage and transportation standards and cleaning." JESSON & TOVINO, *supra* note 14, at 200.

81. Under §§ 201(s) and 409 of the FDCA, "any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized,

from the market;⁸² and (4) preventing the “misbranding” of food through the enforcement of strict and detailed labeling requirements.⁸³ Drugs are subject to much greater regulation. Before the FDA can approve a drug for marketability, the drug must be demonstrated to be safe and effective through preclinical investigation, laboratory experimentation and testing, and a minimum of three phases of clinical trials.⁸⁴

Prior to the late twentieth century, herbal products could only be regulated as foods or drugs. Accordingly, herbal-medicinal products received different levels of scrutiny based on how they were defined by the FDA. This ad hoc form of regulation presented issues, such as restricting consumers from accessing existing herbal products that had not yet met the approval requirements for marketing as a food or a drug. Consequently—and after much pressure from the dietary-supplement industry and consumers alike—Congress enacted the Dietary Supplement Health and Education Act of 1994 (“DSHEA”), which amended the FDCA to provide “dietary supplements” as a third category under which the FDA can regulate herbal medicines.⁸⁵

Products sold as dietary supplements must not contain adulterated ingredients, including unapproved food additives.⁸⁶ And, since 2008, supplement manufacturers must follow dietary supplement-specific CGMPs.⁸⁷ However, unlike new drugs, dietary supplements need not be tested or pre-approved by the FDA before they can be marketed. Instead, manufacturers are responsible for ensuring the safety and efficacy of the supplement products they introduce into the market. Furthermore, unlike new food ingredients, new dietary ingredients do not have to be “Generally Recognized as Safe” (“GRAS”) before they can be incorporated into products categorized as dietary supplements.⁸⁸ Accordingly, the FDA typically must wait to exercise authority over a dietary supplement until there is reason to believe the product may be unsafe. Although the FDA does have some product-monitoring responsibilities, these obligations are generally limited to the oversight of mandatory adverse-event reporting by manufacturers and voluntary

among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.” *Generally Recognized as Safe (GRAS)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm> (last updated June 4, 2015).

82. 21 U.S.C. § 334 (2012).

83. 21 U.S.C. §§ 341–343 (2015).

84. JESSON & TOVINO, *supra* note 14, at 202–03.

85. Dietary Supplement Health and Education Act, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

86. JESSON & TOVINO, *supra* note 14, at 200.

87. Vasilios H. Frankos et al., *FDA Regulation of Dietary Supplements and Requirements Regarding Adverse Event Reporting*, 87 *CLINICAL PHARMACOLOGY & THERAPEUTICS* 239, 240 (2010); *see also* 21 C.F.R. § 111.1 (2015).

88. Per the FDCA and the FDA’s implementing regulations, a food substance may be determined to be Generally Recognized as Safe “either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.” U.S. FOOD & DRUG ADMIN., *supra* note 81.

adverse-event reporting by consumers.⁸⁹

Since most herbal medicines fit within the FDCA's definition of "dietary supplement,"⁹⁰ the FDA's regulation of external-quality issues has been minimal. Intuitively, heavy metals and pesticide residues seem like they should be classified as adulterated ingredients or new ingredients, but they, like new dietary ingredients, are excluded from the FDCA's definition of "food additive" and are therefore not subject to FDA premarket evaluation.⁹¹ Instead, the U.S. Environmental Protection Agency ("EPA") sets tolerance levels for these contaminants, and the FDA is then responsible for enforcing them.⁹² However, according to the FDA, EPA determines tolerance levels for foods using the "intake method" and therefore those tolerance levels "cannot be strictly applied to dietary supplements."⁹³ Although any product containing the residue of a pesticide for which a tolerance level has not been set "is considered adulterated and its sale is prohibited," many of these products remain on the market due to a lack of information regarding their content—the FDA can only pursue action against products that research or adverse-event reports indicate may pose "a significant or unreasonable risk of illness or injury."⁹⁴

Although the FDA is aware that some herbal medicines and other dietary supplements contain harmful levels of heavy metals and pesticide residues, it has only studied the issue in a few instances and with respect to select products and contaminants.⁹⁵ As explained on the Administration's website, this is primarily due to budgetary constraints:

In that FDA has limited resources to analyze the composition of food products, including dietary supplements, it focuses these resources first on public health emergencies and products that may have caused injury or illness. Enforcement priorities then go to products thought to be unsafe or fraudulent or in violation of the law. The remaining funds are used for routine monitoring of products

89. U.S. FOOD & DRUG ADMIN., FDA 101: DIETARY SUPPLEMENTS 2 (2008), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM050824.pdf>.

90. The FDCA currently defines dietary supplement as "a product (other than tobacco) intended to supplement the diet that 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 total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above." 21 U.S.C. § 321(ff) (2015).

91. See 21 U.S.C. § 321(s) (2015).

92. *Herbal Dietary Supplements—Examples of Deceptive or Questionable Marketing Practices and Potentially Dangerous Advice: Hearing Before the S. Select Comm. on Aging*, 111th Cong. 6–7 (2010) (statement of Gregory D. Kutz, Managing Director of Forensic Audits and Special Investigations, U.S. Gov't Accountability Office), <http://www.gao.gov/assets/130/124769.pdf> [hereinafter *Herbal Dietary Supplements*].

93. *Id.*; see also *Pesticide Q&A*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/ucm114958.htm> (last updated Nov. 2, 2015).

94. U.S. FOOD & DRUG ADMIN., *supra* note 89, at 2.

95. See U.S. FOOD & DRUG ADMIN., *supra* note 33.

pulled from store shelves or collected during inspections of manufacturing firms.⁹⁶

Well aware of the FDA's lack of attention to contaminant levels in herbal medicines, Congress recently asked the U.S. Government Accountability Office ("GAO") to test certain popular herbal medicines, including echinacea and ginkgo biloba, for unsafe levels of heavy metals and pesticides.⁹⁷ Accordingly, the GAO purchased forty herbal supplements marketed in the United States and tested them for contaminants.⁹⁸ Though most of the herbal products tested were found to contain contaminants in amounts well under legal limits, several supplements tested positive for pesticides for which the EPA has not set tolerance levels.⁹⁹ In response to these results, the FDA indicated that nearly half of the supplements tested "would be considered in violation of U.S. pesticide tolerances" if the agency were to confirm the results.¹⁰⁰ The contaminated substances were referred to the FDA for review; however, it is unclear what steps the FDA has taken in response.

For the same reasons that regulation of contaminants in dietary supplements has been minimal, the FDA has done little to ensure that dietary supplements marketed in the United States do not contain fake herbs or other unlabeled ingredients. Accordingly, some states are making efforts to fill the current regulatory void. Most notably, New York Attorney General Eric Schneiderman in February 2015 issued cease-and-desist letters to the CEOs of Walgreens, Target, Walmart, GNC, and thirteen devils-claw supplement manufacturers for the sale of misbranded and adulterated dietary supplements (discussed in Part II, section A.3).¹⁰¹ Additionally, Schneiderman, jointly with Indiana Attorney General Greg Zoeller, sent a letter to Dr. Stephen Ostroff, Acting Commissioner of the FDA, "urging the agency to immediately enhance its oversight of the dietary supplement industry."¹⁰² Among other things, the letter criticizes the FDA, in promulgating its CGMP rules for dietary supplements, for electing not to cover dietary-ingredient suppliers, which are often located overseas and therefore "beyond the reach of enforcement actions."¹⁰³

Though the FDA has not indicated an intent to extend dietary-supplement CGMPs to dietary ingredients, as suggested in Schneiderman and Zoeller's letter,

96. *Questions and Answers on Dietary Supplements*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm480069.htm> (last updated Jan. 13, 2016).

97. *Herbal Dietary Supplements*, *supra* note 92, at 1.

98. *Id.* at 13.

99. *Id.*

100. *Id.*

101. Schneiderman Press Release, *supra* note 45.

102. Press Release, N.Y. State Office of the Att'y Gen., A.G. Schneiderman and A.G. Zoeller Urge Food And Drug Administration to Overhaul Regulation of Dietary Supplement Industry (June 2, 2015), <http://www.ag.ny.gov/press-release/ag-schneiderman-and-ag-zoeller-urge-food-and-drug-administration-overhaul-regulation>.

103. *Id.*

the agency has demonstrated a willingness to regulate dietary ingredients more stringently via other means. Specifically, the agency recently declined to exempt dietary ingredients from certain rules promulgated under the U.S. Food Safety Modernization Act of 2011 (“FSMA”), which made significant amendments to the FDCA and granted the FDA new authorities to regulate food safety. As noted by Jason Sapsin, an attorney in Faegre Baker Daniels LLP’s health care and FDA practice group, there is an irony in the consistency of this agency decision.¹⁰⁴ In 2007, the FDA refused to extend dietary-supplement CGMPs to cover dietary ingredients in part because Congress used the phrase “dietary supplements” in the underlying statute.¹⁰⁵ Now, the FDA is refusing to exempt dietary ingredients from key FSMA provisions—those relating to hazard analysis, internal control measures, and supply-chain verification—because Congress used the phrase “dietary supplement” in the FSMA’s statutory exemptions: “[n]othing in the amendments made by this section shall apply to any facility with regard to the manufacturing, processing, packing, or holding of a dietary supplement;” and “[n]othing in this section shall be construed to affect the regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994.”¹⁰⁶

In addition to stating its intent to subject dietary-ingredient manufacturers to certain FSMA-based rules, the FDA has indicated that it will use new mandatory recall and administrative detention authority to remove unsafe dietary supplements from store shelves.¹⁰⁷ It is important to note, however, that this new authority may only be applied to herbal-medicinal products classified as articles of food and for which a reasonable probability of adulteration or misbranding has been established.¹⁰⁸ Therefore, the impact of this new authority on the integrity of dietary supplements will likely be minimal.

IV. ENVIRONMENTAL REGULATION

A. INTERNATIONAL REGULATION

Internationally, regulatory efforts to address climate change and environmental sustainability range from nonexistent to progressive. In terms of the latter, the European Union (“EU”) has taken specific measures to integrate environmental concerns into its Common Agricultural Policy (“CAP”). Since 1992, the EU’s CAP has been significantly revised to better support environmental protection

104. Jason Sapsin, *FSMA Addresses a Gap Between Dietary Supplements and Dietary Ingredients*, NUTRAINGREDIENTS (Oct. 22, 2015), <http://www.nutraingredients-usa.com/Regulation/FSMA-addresses-a-gap-between-dietary-supplements-and-dietary-ingredients>.

105. *Id.*

106. See FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified at 21 U.S.C. § 301 (2015)).

107. Daniel Fabricant, *FDA Uses New Authorities To Get OxyElite Pro Off the Market*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2013), <http://blogs.fda.gov/fdavoices/index.php/tag/new-dietary-ingredients/>.

108. *Id.*

and sustainability efforts.¹⁰⁹ The EU's agri-environment measures provide payments to farmers who voluntarily implement sustainable farming practices, and its Biodiversity Action Plan for Agriculture, adopted in 2001, prioritizes "the promotion and support of . . . sustainable farming activities in biodiversity-rich areas; the maintenance and enhancement of good ecological infrastructures[;] and the promotion of actions to conserve local or threatened livestock breeds or plant varieties."¹¹⁰ Additionally, the EU has employed a variety of monitoring and management mechanisms in order to minimize the impact of pesticides on soil, air, and water quality.¹¹¹

Though few other regions have enacted agricultural policies as aggressive as the EU's, the WHO has developed sustainability best practices for agricultural producers worldwide, including many that directly address herb cultivation. Specifically, *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants* preferences small-scale cultivation over large-scale cultivation and warns of the impact that introducing nonnative plants into cultivation can have on a region's biodiversity.¹¹² Because a total of 169 countries participate in The Convention on International Trade in Endangered Species of Wild Fauna and Flora ("CITES")¹¹³—an agreement aimed at ensuring the international trade of wild plants and animals does not threaten species' existence—and a greater number of countries regulate wildlife trafficking domestically, the *WHO Guidelines* remind herb cultivators that protected medicinal plants "may be collected only by relevant permission according to national and/or international laws."¹¹⁴ Furthermore, the *Guidelines* warn that any herbal materials obtained from threatened, endangered, or protected medicinal-plant species must be accompanied by certification of their non-wild source.¹¹⁵

B. UNITED STATES REGULATION

The U.S. EPA is the primary government body responsible for environmental-protection policies in the United States. Most of the nation's environmental legislation—including the Clean Air Act,¹¹⁶ the Clean Water Act,¹¹⁷ the Toxic

109. *Integrating Environmental Concerns into the CAP*, EUR. COMM'N, http://ec.europa.eu/agriculture/envir/cap/index_en.htm (last updated April 22, 2015).

110. *Agriculture and Biodiversity*, EUR. COMM'N, http://ec.europa.eu/agriculture/envir/biodiv/index_en.htm (last updated July 6, 2016).

111. *Agriculture and the Environment: Introduction*, EUR. COMM'N, http://ec.europa.eu/agriculture/envir/index_en.htm (last updated April 22, 2015).

112. WORLD HEALTH ORG., *supra* note 75 at 9.

113. *Laws and Regulations to Protect Endangered Plants*, U.S. DEP'T OF AGRIC., http://www.fs.fed.us/wildflowers/Rare_Plants/conservation/lawsandregulations.shtml (last visited Dec. 31, 2015).

114. WORLD HEALTH ORG., *supra* note 75, at 29.

115. *Id.*

116. 42 U.S.C. §§ 7401–7671 (2012).

117. 33 U.S.C. §§ 1251–1387 (2012).

Substances Control Act,¹¹⁸ and the Endangered Species Act¹¹⁹—charge the EPA with establishing standards and regulations for the enforcement of certain statutory provisions. While the EPA has successfully implemented regulations designed to reduce the environmental impact of industrial factory and power plant operations, its regulation of agricultural operations (including medicinal-herb cultivation), has been minimal. Due to the importance of agriculture in the American tradition, most environmental statutes exempt farming practices from regulation.¹²⁰ Instead, the U.S. Department of Agriculture (“USDA”) has historically promoted and supported agricultural production with little view towards the environmental impact of modern cultivation techniques.

Over the last few decades, however, growing concerns about climate change and other ecological issues have prompted both the EPA and USDA to implement standards and programs designed to reduce the environmental impact of agriculture. Due to legal pushback from the agriculture industry, a majority of the EPA’s attempts to apply greenhouse-gas emissions reporting, air and water quality, and fuel and energy standards to farming activities have been unsuccessful.¹²¹ The USDA has had greater success addressing agriculture’s environmental impact through the implementation of programs focused on providing “educational outreach and technical and financial assistance opportunities for producers to implement environmentally sustainable practices,” most likely because these programs are largely voluntary on the part of farmers.¹²²

In light of the fact that many medicinal herbs are grown outside of the United States, domestic agriculture regulations may be less relevant to addressing the environmental impact of herbal medicine production than laws affecting resource and energy use during the transport, processing, packaging, and advertising of plant materials. In addition to regulation through broadly applicable energy, fuel, and other standards, these activities have the potential to be regulated under environmental regulations that generally prohibit the trafficking of endangered plant species.

In the United States, CITES is implemented through the Endangered Species Act (“ESA”), which was the first federal legislation to protect threatened and endangered plants. The ESA makes it unlawful to “import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of a commercial activity” endangered plant and animal species or their parts.¹²³ Similarly, the Lacey Act, which was amended in 2008 to protect a broader range

118. 15 U.S.C. §§ 2601–2697 (2012).

119. 16 U.S.C. §§ 1531–1544 (2012).

120. See generally Elizabeth Stapleton, *Agriculture as Industry: The Failure of Environmental and Agricultural Policy to Adapt to the Modern Agricultural Landscape*, 7 ALB. GOV’T L. REV. 321, 345 (2014).

121. *Id.* at 329–34.

122. Megan Stubbs, *Environmental Regulation and Agriculture*, CONG. RES. SERV. 1 (2014).

123. *Permits: Frequently Asked Questions*, U.S. FISH & WILDLIFE SERV., <http://www.fws.gov/endangered/permits/faq.html> (last updated June 24, 2015).

of plants and plant products, generally prohibits the trafficking of illegally sourced wildlife.¹²⁴ The U.S. Fish and Wildlife Service (“FWS”) is responsible for designating plants as endangered or threatened under the ESA. And the USDA is responsible for enforcing CITES, the ESA, and the Lacey Act as they apply to plant species. Finally, the U.S. Department of Justice’s (“DOJ”) Environment and Natural Resources Division is the primary government authority responsible for prosecuting wildlife-trafficking crimes under the ESA and the Lacey Act.¹²⁵

A recent example of a DOJ prosecution for wildlife trafficking is *United States v. Duncan*, which involved the illegal purchase and sale of wild ginseng by Brett Duncan, owner of Duncan’s Botanical Products, Inc.¹²⁶ On April 4, 2014, Duncan pled guilty to purchasing “approximately \$54,000 worth of illegal ginseng between 2008 and 2010” and later selling the ginseng to an exporter in New York—a scheme that had been uncovered by the FWS during its Operation Native Root, an investigation into illegal herb trafficking in Indiana and Illinois.¹²⁷ Duncan was sentenced to a two-year term of probation and sixty hours of community service.¹²⁸ Additionally, he was forced to forfeit the approximately 1,708 pounds of ginseng that were seized and required to pay a \$15,000 fine and \$55,000 in restitution to the National Fish and Wildlife Fund.¹²⁹ Although Duncan is not the only herb trader to be held liable for the illegal trafficking of wild plant materials, many instances of illegal herb sales and purchases go unnoticed due to a lack of government resources for additional investigations and prosecutions.

CONCLUSION

Increased concerns about herbal-medicine quality and the quality of the natural environment have motivated a consortium of stakeholders to demand regulatory reform. Some of the U.S. Congress’s legislative attempts at improvement have failed outright, such as Senator John McCain’s proposed Dietary Supplement Safety Act of 2010¹³⁰ and Representative Henry Waxman’s proposed American Clean Energy and Security Act of 2009,¹³¹ which did not become law. However, the FDA’s recent commitment to use all available tools to remove unsafe herbs

124. *Lacey Act*, U.S. FISH & WILDLIFE SERV., <http://www.fws.gov/international/laws-treaties-agreements/us-conservation-laws/lacey-act.html> (last visited Dec. 29, 2015).

125. *Wildlife Trafficking*, U.S. DEP’T OF JUST., <http://www.justice.gov/enrd/wildlife-trafficking> (last visited Dec. 31, 2015).

126. *Prosecution of Federal Wildlife Crimes*, U.S. DEP’T OF JUST., <http://www.justice.gov/enrd/prosecution-federal-wildlife-crimes> (last visited Dec. 31, 2015).

127. *Id.*

128. *Id.*

129. *Id.*

130. S. 3002, 111th Cong. (2010).

131. H.R. 2454, 111th Cong. (2009).

from the market and President Obama's 2013 Climate Action Plan¹³² imply progress in the foreseeable future.

There are also opportunities for improvement at the state and local levels. With respect to herbal medicine quality, Jennifer Pomeranz, an assistant professor at New York University College of Global Public Health, notes that "[s]tate attorneys general have the authority to protect consumers in their states [from unsafe herbal supplements] and they need to begin imposing that authority"¹³³ Pomeranz and her colleagues urge state regulators to help ensure the safety and efficacy of herbal products through the implementation of required laboratory testing, safety warnings, educational materials, minimum age purchase limits, taxes, and bans on particularly dangerous products.¹³⁴ Other scholars insist that supplement manufacturers should shoulder the bulk of the burden.¹³⁵ Fortunately, some companies, such as GNC—which agreed to implement new testing procedures for herbal supplements in excess of FDA requirements—are strengthening their efforts.¹³⁶

Regarding environmental sustainability, states can improve their efforts by implementing aggressive sustainability standards and programs such as those already in place in California.¹³⁷ Additionally, states can strengthen their protection of endangered plant species by implementing hunting bans, as Maryland has done with respect to American ginseng.¹³⁸ Herbal-supplement manufacturers can help reduce the environmental impact of their operations by ensuring that herbs used in their products are grown and harvested in an ecologically sustainable manner and by engaging in energy-efficient product manufacturing. Whole World Botanicals, which manufactures a variety of herbal products, has already committed to such practices.¹³⁹ Furthermore, herbalists can increase the environmental sustainability of their practices by home-growing needed herbs, accessing local herbs, and lobbying for industry-wide change, including the elimination of excessive marketing and packaging materials.¹⁴⁰

In addition to implementing change at the national and local levels, the United States should look to coordinate efforts with other countries. As a first step,

132. EXEC. OFFICE OF THE PRESIDENT, THE PRESIDENT'S CLIMATE ACTION PLAN 4 (2013), <https://www.whitehouse.gov/sites/default/files/image/president27climateactionplan.pdf>.

133. Temple University, *States Need to Assume Greater Role in Regulating Dietary Supplements for Weight Loss, Muscle Building, Experts Say*, SCIENCE DAILY (Sept. 24, 2014), www.sciencedaily.com/releases/2014/09/140924113003.htm.

134. *Id.*

135. See, e.g., M. Eric Gershwin et al., *Public Safety and Dietary Supplementation*, 1190 ANNALS OF THE N.Y. ACAD. OF SCI. 104, 112 (2010).

136. O'Connor, *supra* note 42.

137. GREEN CALIFORNIA, <http://www.green.ca.gov/Home.aspx> (last visited Jan. 6, 2016).

138. Rosenwald, *supra* note 40.

139. *WWB Supports & Promotes Bio-Energetic Agriculture*, WORLD WIDE BOTANICALS (June 8, 2015), <http://wholeworldbotanicals.com/wwb-supports-promotes-bio-energetic-agriculture/>.

140. McElroy, *supra* note 37, at 166.

nations can commit to global standardization throughout the herbal-medicine industry. Universal adherence to the WHO's guidelines on good agricultural and collection practices, processing and testing procedures, and classification and labeling systems for herbs will help improve herbal-medicine quality and foster sustainable herb production worldwide. To this end, international participation in herbal-medicine working groups will help ensure that countries are aware of the practices of other nations and that the most relevant information and technology will become more readily available.

To promote the efficiency and effectiveness of all efforts, producers, consumers, and policymakers must be made aware of the interdependence between medicinal-herb quality and the quality of the natural environment. Continued lack of recognition of this connection will only exacerbate associated issues. Once stakeholders learn to fully appreciate that environmental sustainability is critical to sustaining human health, progress with respect to both issues will come with greater support and ease.