Summer 8-11-2023

Health Risks of Herbal Medicine in the US: Recommendations to Improve Awareness and Advance Safety

Darya Sinkevich
University of San Francisco, darya_sinkevich@yahoo.com

Health Risks of Herbal Medicine in the US: Recommendations to Improve Awareness and Advance Safety

Darya Sinkevich

School of Nursing and Health Professions, University of San Francisco

MPH 683 Integrated Learning Experience

August 9, 2023

Table of Contents

Abstract

Adults in the U.S. use herbal medicine as an alternative and in conjunction with conventional healthcare, in many cases because of cultural and economic considerations. With insufficient governmental regulation of the content of herbal supplements, and limited education of healthcare providers on the potential risks and benefits consumers can experience unexpected and potentially harmful health impacts from using herbal medicine.

The health risks associated with these products include but are not limited to, herbal and prescription drug interactions and heavy metal toxicity. For this project, a scoping literature review was conducted using multiple databases to identify the prevalence, health risk, and public health gaps related to herbal medicine usage. The gaps in mitigating the health risks of herbal medicine include inadequate healthcare provider knowledge, scarcity of complementary and alternative medicine courses in medical schools, patient reluctance to disclose the usage of these products to their providers, and limited pre-market governmental regulation.

This project used the social-ecological model to identify and analyze different levels of intervention for the existing gaps found in the primary literature. Recommendations to address the existing gaps include formal herbal medicine education in medical schools, targeted public health campaigns with specific focus on Latino populations, and increased oversight by the U.S. Food and Drug Administration that incorporates mandatory third-party testing of herbal medicine products. The goal of these specific public health interventions is to increase patient and provider knowledge and reduce adverse health outcomes.

Keywords: herbal medicines, heavy metal poisoning, Latino, medical education, social ecological model

Introduction

Herbal Medicine (HM) is popular in the United States and is one of the widely used forms of Complementary and Alternative Medicine (CAM) (Clarke et al., 2015). Consumers use HM due to dissatisfaction with conventional medicine, affordability, ease of access, and cultural beliefs (Barnes et al., 2008; Welz et al., 2018). Yet, there are associated health risks such as herb-drug interactions and heavy metal poisoning (Barnes et al., 2008; Hassen et al., 2022). Healthcare providers play a role in education and disease prevention with HM usage; however, there are no specific requirements for medical curricula. An online study of 130 medical school websites showed that only 44% provided curricula about CAM topics, and 70.9% were available only in an elective format (Cowen & Cyr, 2015). Healthcare providers may not routinely ask patients about their HM usage, and consumers tend not to disclose this voluntarily (Eisenberg et al., 2001). Consequently, patients may be exposed to HM risks without their healthcare provider's knowledge.

This analysis offers specific recommendations to actively reduce the risk of HM through medical education, specific outreach programs for at-risk populations, and reducing gaps in governmental oversight. Healthcare providers should be educated about the risks of HM and trained to recognize possible adverse effects and drug interactions. To reduce risk, the initiation of targeted public health campaigns that will reach specific populations, such as Latinos, can be accomplished through various channels, such as online platforms, community centers, hospitals, and public health organizations. This broad exposure will help consumers make informed choices about these HM products.

Aside from educating the public and healthcare providers, enhanced governmental oversight is necessary to prevent and reduce adverse side effects of HM. Before these products can be sold, Congress must increase FDA oversight authority to implement mandatory third-party testing for contaminants such as heavy metals, pesticides, and microorganisms.

Background

Medicine in the United States is dominated by conventional medicine, a method of treatment that is widely accepted and practiced by most health professionals, which relies heavily on drugs, surgery, and radiation (Cronkleton, 2022). Alternatively, CAM utilizes various other non-traditional methods. According to the National Institutes of Health (NIH), CAM combines a wide range of medical and healthcare practices, systems and products not included in conventional medicine (Ventola, 2010). The five major categories of CAM include mind-body interventions, biological treatments, manipulative treatments, energy therapies, and alternative medical systems (Johns Hopkins Medicine, 2019). Compared to conventional medicine, CAM has a variety of treatment modalities, such as HM, which are not utilized in Western medicine.

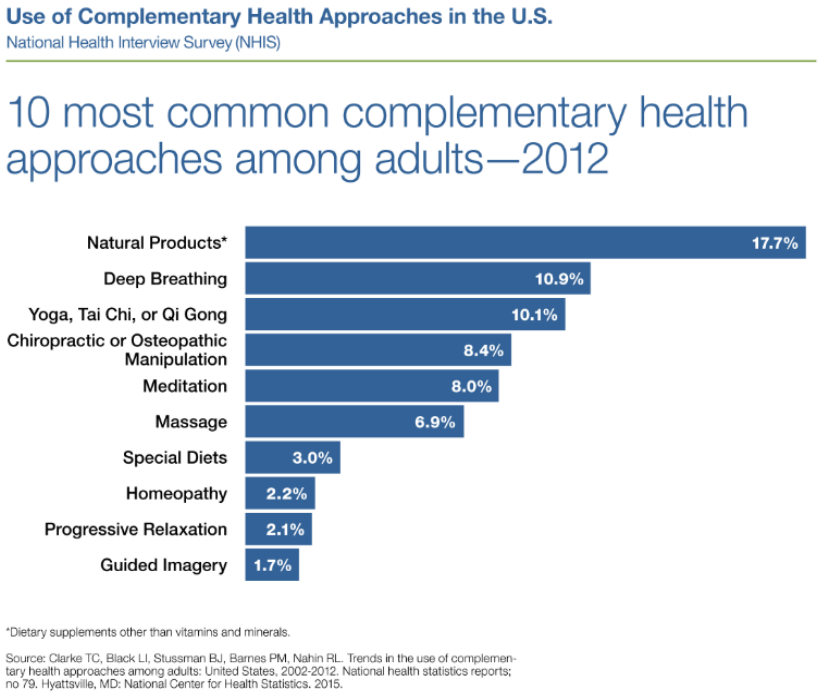


Figure 1: 10 most common complementary health approaches among adults

(Clarke et al., 2015)

HM is one of CAM's most used approaches (Clarke et al., 2015). HM are dietary supplements that contain one or more herbs and can be bought without a prescription (Hassen et al., 2022). Among the most common HM in the U.S. are Ginseng, Ginkgo biloba, Echinacea, St. John's wort, and Kava (Bent, 2008). HM is referred to by many names, including botanicals, herbal products, herbal remedies, and phytotherapy (Tabish, 2008). The consumption of HM, including tablets, capsules, powders, teas, and extracts, is used by consumers with the hope that these products will maintain or improve their health (Hassen et al., 2022). According to

the World Health Organization (WHO), 60% of the total worldwide population is dependent on HM; 80% of populations within developing countries are nearly dependent on their usage (*WHO,* 2023). In contrast, HM usage is lower within the United States but is increasing in popularity.

Prevalence of Herbal Medicine and Motivations Among US Adults

In 2015, the National Consumer Survey on the Medication Experience and Pharmacists' Roles released an online survey designed to collect information regarding consumers' perceptions and views about medications and pharmacies (Rashrash et al., 2017). A study by Rashrash et al. (2017) found that 35% of the 26,157 participants reported using at least one HM. This shows the increasing prevalence of HM in the United States and reflects consumer interests.

In 2008, the National Center for Complementary and Integrative Health (NCCIH) and the National Center for Health Statistics (part of the Centers for Disease Control and Prevention) released data on CAM use by Americans based on the 2007 National Health Interview Survey (NHIS), which examines the experiences of Americans in relation to their health and illness (Barnes et al., 2008). Barnes et al. (2008) analyzed the information collected by NHIS from 23,393 adults for the CAM section. The results of the analysis revealed:

- Most individuals (54.9%) used HM and prescription drugs together.
- HM is commonly used in the treatment of pain syndromes (28.2%), neuropsychiatric conditions (5.8%), arthritis (3.5%), and high cholesterol (2.1%).
- There are multiple reasons why people use HM: 28% thought prescription drugs would not provide adequate treatment, 21% believed it would be interesting to try, 13% believed prescription drugs were too costly, and 8.5% of adults reported taking HM as an alternative to prescription drugs due to adverse side effects or concerns about the safety of prescription drugs (Barnes et al., 2008).

In earlier studies, HM prevalence was shown to vary with gender, age, and ethnicity. Kennedy (2005) analyzed 2002 National Health Interview Survey data and found HM was more commonly used by women than by men (21.0% versus 16.7%). There is a greater prevalence of HM among adults between the ages of 45 and 64, as well as among those of multiple races (32.2%), Asians (24.6%), and American Indians or Alaskan natives (21.9%), compared to whites (19.1%) and African Americans (14.3%) (Kennedy, 2005).

Individuals' cultural and familial ties strongly influence the use of HM. In a study by Welz et al. (2018), 46 individuals participated in focus groups to discuss the factors and reasons for using HM. The study found that culture, tradition, and family history were important factors motivating HM use (Welz et al., 2018). Participants reported that long-standing family traditions and generational knowledge about effective HM influenced usage (Welz et al., 2018). Based on these findings, HM use was influenced by both strong cultural and social influences, contributing to the transmission of knowledge and practice from generation to generation.

The Risks of Herbal Medicine

Herb and Drug Interaction

Although HM might be perceived as a safe and effective treatment, serious health consequences can negatively affect human health. When HM is used alongside prescription drugs, there is a potential for herb-drug interactions, which can result in adverse effects or reduce the effectiveness of the prescribed medications (Hu et al., 2005). Fenugreek, Melatonin, St. John's wort, Ginkgo biloba, Echinacea, and Schisandra are some of the most common HM that interact with prescription drugs (Cupp, 1999). Among the most popular HM used in the U.S. is Ginkgo biloba, which purportedly enhances memory, improves cognition, and reduces the likelihood of blood clots (Hu et al., 2005). However, several drugs have been found to negatively interact with Ginkgo biloba, including sedatives,

anxiety drugs, and antidepressants (Hu et al., 2005). One case report states that a patient taking Warfarin for coronary bypass surgery suffered a left parietal hemorrhage following two months of Ginkgo product use (Matthews, 1998). There are significant health risks for consumers associated with HM interactions with prescription drugs. For a most common summary of HM-drug interactions, refer to Appendix B, Table 1.

Although HM is an integral part of Latino culture as an alternative to conventional medicine, passed down from one generation to the next, many Latino adults are unaware of the potential risks related to drug interactions with HM (Howell et al., 2006). Howell et al. evaluated a qualitative self-administered questionnaire on HM knowledge among 620 Latino individuals in a health center. In the study, 80% of participants reported using HM, with only 35.1% believing that some herbs may interact with prescription medications (Howell et al., 2006). Despite a high rate of HM use among Latinos, their knowledge of potential drug interactions is insufficient; this lack of awareness increases the risk of adverse reactions.

Heavy Metal Poisoning

Besides the fact that HM can interact with prescription drugs, HM can also be contaminated with harmful heavy metals. For example, Indian traditional HMs are found to contain high levels of heavy metals, including lead, mercury, and arsenic, in the United States market (Saper et al., 2008). Patients consuming these products to improve health or treat illness are at risk of heavy metal toxicity.

There are several causes of heavy metal contamination, which include failure to properly detoxify or adulteration with geogenic (naturally occurring in soil) or anthropogenic (influenced by humans) sources of heavy metals (Mukhopadhyay, 2021). A product is adulterated if it contains ingredients that are not listed on the label, contains less of the active ingredient than advertised, or is of inferior quality compared to that described on the label (*FDA,* 2023). In 2008, a research group from the

Boston University School of Medicine analyzed 193 Indian herbal medications from online stores to determine quantitative levels of heavy metals (Saper et al., 2008). Of all the products analyzed, 21% contained detectable levels of heavy metals (Saper et al., 2008). The most common element found was lead, followed by mercury and arsenic (Saper et al., 2008). Furthermore, this study revealed that heavy metals, like lead and mercury, are deliberately added to some preparations by manufacturers based on Indian cultural practices (Saper et al., 2008). This analysis of HM showed that some of the lead levels were 100 to 10,000 times higher than those accepted by the FDA (Saper et al., 2008). According to the FDA, the allowable lead level in bottled water is 5 ppb, the maximum amount of lead considered safe for human consumption (*FDA,* 2023). The amount of lead in these products is significantly higher than FDA standards, threatening the health of HM consumers.

There is evidence that Chinese traditional HM may also contain heavy metal contamination leading to serious health effects. A study conducted by Coghlan et al. (2015) examined 26 Chinese HM purchased from retail stores and CAM practitioners to identify heavy metal contamination from lead, mercury, and arsenic. According to the study, 80% of these products contained one or more contaminants in varying amounts, with some levels exceeding acceptable limits by 10 times (Coghlan et al., 2015). California Department of Health Services, Food, and Drug Branch performed an earlier study in 1998 to screen imported Chinese HM for undeclared ingredients and heavy metal contamination (Ko, 1998). Among 260 Chinese HM collected from California retail ethnic stores, 32% contained active pharmaceutical ingredients or heavy metals (Ko, 1998).

In the last few decades, heavy metal toxicity associated with the consumption of Indian HM has been reported in multiple states across the US. The CDC reported 12 cases of lead poisoning among adults in five states between 2000 and 2003 associated with Indian HM (Araujo, 2004). In each case, adults who consumed these products were admitted to the emergency room with various symptoms (Araujo, 2004). During admission to the hospital, Blood Lead Level (BBL) tests revealed ranges between

80 and 112 mg/dL (Araujo, 2004). The CDC defines normal BLL for adults as below 5 mg/dL (*CDC,* 2023). The patients showed symptoms of fatigue, confusion, abdominal pains, and headaches. Chelation therapy, a procedure that removes heavy metals from the body, was administered to all 12 patients to remove heavy metals (Araujo, 2004). Three of these patients, however, developed chronic kidney disease due to high lead exposure (Araujo, 2004). Moreover, six cases of lead poisoning in pregnant women who consumed Indian HM were inspected by the New York City Department of Health and Mental Hygiene (NYC DOHMH) in 2012 (*CDC,* 2012). Healthcare providers assessed the pregnant women for lead exposure risk during the prenatal visit (*CDC,* 2012). Their BLL tests revealed elevated readings ranging from 16 to 64 mg/dL, which is a clear indication of lead poisoning (*CDC,* 2012). Due to the non-specific symptoms that may occur at low exposures to heavy metals, HM consumers may not know they have been poisoned. This may result in long-term health effects that may not be recognized until severe medication conditions occur.

The health consequences of heavy metal toxicity, particularly lead toxicity, are significant not only for children but also for adults. In adults, symptoms of lead toxicity may appear in levels as low as 40 mg/dL, but in most cases, they are first noticed between 50 and 60 mg/dL (Karri et al., 2008). Adults who experience lead toxicity often have non-specific symptoms, including abdominal pain, fatigue, headaches, vomiting, loss of appetite, and irritability (Araujo, 2004). However, chronic exposure to lead may result in anemia, non-traumatic brain injury, cardiovascular disease, coma, and even death (Lanphear et al., 2018). In addition, lead poisoning has been linked to various serious health problems, including heart attack, kidney damage, and reproductive issues (Kumar et al., 2006). Health conditions associated with lead exposure cause severe and chronic ailments, making it imperative for people exposed to seek early medical interventions. HM containing heavy metals can lead to chronic diseases, which have a significant financial impact on healthcare systems, and products may increase out-of-pocket medical expenses.

Medical Expenditures

Many consumers perceive HM as moderate and balanced over the counter treatments and view them as an inexpensive alternative to prescription drugs. Researchers analyzed data from the 2012 National Health Interview Survey to estimate expenditures on HM (Nahin et al., 2016). According to the report, Americans spent $12.8 billion out-of-pocket on HM that year, approximately one quarter of the amount spent on prescription drugs (Nahin et al., 2016). Between 2007 and 2012, out-of-pocket expenses increased gradually from $261 to $368 per capita (Nahin et al., 2016). This increasing trend of American out-of-pocket expenses for HM may be attributed partially to the inexpensive nature of HMs, relative to prescription drugs.

CURRENT INTERVENTIONS

This project used the Social Ecological Model to identify and analyze different levels of interventions regarding heavy metal toxicity and herb-drug interaction. Figure 2 illustrates the current interventions at five different levels.

Figure 2: Social Ecological Model (SEM)

(B. C. Lee et al., 2017)

Policy Level

The FDA Adverse Event Reporting System (FAERS)

The FDA Adverse Event Reporting System (FAERS) contains reports of adverse events, medication errors, and product quality complaints (*FDA*, 2017). An essential function of the database is to inform the FDA's after-market regulatory surveillance program for prescription drugs and HM. To monitor the safety of products, clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) evaluate the data contained in FAERS (*FDA*, 2017). If FAERS identifies a potential safety concern, further evaluation may include using other large databases (*FDA*, 2017). Additionally, the FDA may take regulatory actions to protect the public's health and improve product safety, including updating product labeling requirements, restricting use, providing updated safety information to the public, and on occasion, withdrawing a product from the market (*FDA*, 2017). Using FAERS helps the FDA identify occasional harms from certain HM and determine if the relative risk-benefit warrants discontinuation of the substance. Also, the FDA may inform the healthcare community about any potential risks associated with HM, helping them prevent adverse effects associated with these products (*FDA*, 2017).

Adult Blood Lead Epidemiology and Surveillance (ABLES)

The National Institute for Occupational Safety and Health (NIOSH) developed the Adult Blood Lead Epidemiology and Surveillance (ABLES) to evaluate and prevent elevated BLL in adults (*CDC,* 2018). As of 2022, 37 states chose to participate in the ABLES (*CDC*, 2018). This program monitors levels of lead exposure in adults. It collects data from healthcare providers and laboratories to track lead exposure in a particular population and provides data to NIOSH (*CDC,* 2018). In addition to monitoring adult BLL, ABLES programs can help identify populations at risk of exposure to heavy metals from Indian and Chinese HM. As a result, NIOSH can implement preventative strategies to limit further exposure to these products. These strategies include education about lead exposure hazards and providing access to medical care for individuals exposed to lead (*CDC*, 2018).

Institutional

National Center for Complementary and Integrative Health

Within the National Institutes of Health (NIH), NCCIH focuses on complementary and integrative health approaches (*NCCIH*, 2021). As part of its mission, the NCCIH conducts and funds research on HM to better understand the benefits, risks, and safety. For example, NCCIH funded studies on the adverse effects and drug interactions associated with St. John's wort, a popular herb used for depression (*NCCIH*, 2021). Gurley et al. (2008) evaluated St. John's wort's impact on digoxin drugs. According to the results, St. John's wort reduced digoxin medication effectiveness (Gurley et al., 2008). NCCIH distributes research results to public health departments, government agencies, and public health organizations (*NCCIH*, 2021).

Organizational

Independent Third-Party Testing Laboratories

Third-party laboratories also play a role in verifying the safety and potency of dietary supplements and HM. HM manufacturers may submit their products for independent third-party testing to ensure the active ingredients are consistent with the labels (*NSF*, 2023). U.S. Pharmacopeia, NSF International, and Consumer Lab are some organizations that offer testing services. The Consumer Lab is committed to providing consumers and healthcare professionals with independent tests and information that helps them identify high-quality health and nutritional products (*Consumer Lab*, n.d.). To be rated as high-quality, products must be free of contaminants such as heavy metals, pesticides, mold, and bacteria and contain ingredients consistent with their labeling (*Consumer Lab*, n.d.). An official stamp from the certification company is typically displayed on the labels of products that have been third-party certified. While testing cannot guarantee efficacy, it does verify that a product's label is accurate and does not contain contaminants. The only retailer in the United States to

sell vitamins and supplements that have been tested by a third party for safety and label accuracy is CVS Pharmacy (Duffy, 2022).

Community

Supplement Your Knowledge – Dietary Supplement Education Initiative

An initiative launched by the FDA in 2022, Supplement Your Knowledge, aims to educate, inform, and broaden consumer understanding of dietary supplements (*FDA,* 2022). This initiative can serve as a trusted source of information about the benefits and risks associated with dietary supplements. On the FDA website, related educational videos and fact sheets are available in English and Spanish (*FDA,* 2022). This makes information accessible to a wide range of audiences, such as the Latino population who may have limited English proficiency.

Label Wise- Campaign

In 2019, the Council for Responsible Nutrition (CRN) launched the Label Wise campaign with the support of the CRN Foundation (*Council for Responsible Nutrition*, n.d.). Label Wise provides easy-to-understand information on the "Supplement Facts" label on dietary supplements, vitamins, and herbal medicines. There are videos, fact sheets, infographics, and interactive instructions for reading Supplement Facts labels available on the campaign's website. Also, the campaign emphasizes the importance of speaking with a healthcare provider prior to taking any supplements (*Council for Responsible Nutrition*, n.d.).

Interpersonal

Online Healthcare Provider Continuing Education Series on CAM

The NCCIH offers the Online Continuing Education Series, which provides a comprehensive overview of the latest research, evidence-based information, emerging trends, and an in-depth overview

of current research in CAM (*NCCIH,* n.d.). This series offers healthcare providers free, comprehensive video lectures regarding complementary health approaches. It covers various topics, including prescription drug and herbal medicine interactions. These lectures are designed for healthcare physicians, nurse practitioners, and other health professionals interested in complementary medicine (*NCCIH,* n.d.). Continuing education credits (CME and CEU) can be earned by accessing recorded videos and passing a test available online (*NCCIH,* n.d.). Healthcare providers can apply the knowledge they acquire from these educational series to their clinical practice.

Herb and Drug Interaction Databases for HealthCare Providers

Several online databases and computerized programs inform healthcare providers about potential drug interactions. These tools aim to ensure that consumers and healthcare providers are well-informed about the potential interactions between prescription drugs and HM, as well as the safety and efficacy of combining both (Hassen et al., 2022). By utilizing these resources, providers can identify adverse side effects and ensure the proper medication is prescribed at the right frequency and dose.

A number of databases contain information regarding herbal and drug interactions, including the UW Drug Interaction Database, Drugs.com, RxList, Lexicomp, and Natural Medicines Database (Hassen et al., 2022). In the UW Drug Interaction Database, physicians can access information from research articles, drug labels, FDA approval review packages, and biologics license applications (Zhang et al., 2021). As of June 2021, a total of 2,539 natural products are included in this program, containing 15,864 drug interaction experiments and studies (Zhang et al., 2021). An essential benefit of herb and drug interaction databases is their ability to provide comprehensive information concerning known drug-herb interactions (Li et al., 2019). It allows healthcare providers to assess the potential risks associated with specific combinations of HM and prescription drugs.

Individual

The HerbList App

The HerbList App, developed by the NCCIH, provides research-based information about herbal products' safety and effectiveness for consumers (*NCCIH*, 2018). According to the NCCIH, the app provides easy-to-find information about safety concerns, side effects, and interactions between herbs and prescription medications (*NCCIH*, 2018). The HerbList App also provides information regarding the herb's common names, history, uses, and what scientific research indicates regarding their effectiveness in treating illnesses (*NCCIH*, 2018). According to David Shurtleff, the acting director of NCCIH, consumers should be provided with information regarding the safety and effectiveness of these products using this tool (*NCCIH*, 2018).

Gaps in Mitigating the Risks of Herbal Medicine

Lack of Knowledge of Herbal Medicine Among Healthcare Providers

Physicians can play a crucial role in ensuring patient safety and mitigating the risks of HM. Although CAM is widely used among US adults, a lack of formal training and evidence-based information for healthcare professionals leads to inadequate knowledge and communication gaps surrounding patient counseling regarding efficacy, safety, and drug interactions (Hassen et al., 2022). Healthcare providers do not have sufficient exposure to HM topics; thus, the adverse health effects are not adequately addressed in conventional medical practice (Hassen et al., 2022). In numerous studies, physicians indicate that they lack necessary training to answer patients' questions regarding HM (Ventola, 2010). In 2008, Xu and Levine surveyed multiple healthcare clinics and hospitals to measure knowledge about HM among healthcare professionals. The survey found that, of the more than 80% of respondents who were general practitioners, 76% perceived themselves as "poorly informed" about HM, while 46.6% perceived themselves as "very poor" or "quite poor" (Xu & Levine, 2008). Another study investigated physicians' knowledge of adverse effects and drug interactions associated with HM

(Suchard et al., 2004). The survey completed by 116 healthcare physicians and 26 medical students found that most healthcare providers and medical students had an insufficient knowledge of herbal health hazards and drug interactions (Suchard et al., 2004). Inadequate knowledge by healthcare providers may result in serious medical complications if patients unknowingly combine HM with prescription drugs.

Most medical schools either do not include CAM courses in their curricula or offer them as electives, contributing to the lack of awareness regarding the dangers of HM among medical students (Hassen et al., 2022). Cowen and Cyr's (2015) study reviewed the course descriptions and content of 130 U.S. medical school websites. The researchers report that fewer than half of the medical schools in the U.S. (44.4%) offer instruction in CAM (Cowen & Cyr, 2015). In addition, 70.9% of the CAM courses offered in medical schools were electives (Cowen & Cyr, 2015). Therefore, many healthcare professionals are not confident discussing HM with patients as they are unfamiliar with these alternative medicines.

Nondisclosure of Herbal Medicine use with the Healthcare Providers

Research reveals that it is common for patients not to inform their primary care physician of their use of CAM for reasons that include fear of judgment, concern about their provider's knowledge, or simply not being asked (Eisenberg et al., 2001; Jou & Johnson, 2016). In 2016, using data from the 2012 National Health Interview Survey, analyzed patterns of HM use in the United States and reasons for non-disclosure to healthcare providers. Based on the analysis, of 7,493 respondents who used these products and had primary care providers, almost half had not disclosed their use of HM to their physician (Jou & Johnson, 2016). Most non-disclosures are due to healthcare providers not asking about HM (57%), not believing that physicians know enough about HM (46%), and past or potential discouragement by providers (2%) (Jou & Johnson, 2016). In 2001, Eisenberg et al. conducted a

nationally representative, random telephone survey across 48 states to assess perceptions of HM use among people who use them in conjunction with conventional medicine. The study found that among 507 respondents who did not disclose their use of CAM to their doctor, respondents reported: "It wasn't important for the doctor to know" (61%), "The doctor did not ask" (60%), "It was none of the doctor's business" (31%), and "The doctor would not understand" (20%) (Eisenberg et al., 2001). According to these findings, there is a communication gap between patients and their healthcare providers regarding HM usage, and the lack of education among providers can have severe consequences for patients at risk of adverse reactions without critical information about potential adverse effects.

Poor Regulation of Herbal Medicine in the United States

The FDA regulates HM as dietary supplements under the Dietary Supplement Health and Education Act of 1994 (*DSHEA*, 1994). The FDA has authority under DSHEA to periodically inspect manufacturing facilities to evaluate whether they meet applicable labeling and manufacturing requirements. In accordance with DSHEA, the FDA must warn manufacturers when they find the products are unsafe or may potentially pose significant or severe risks to consumers (*NCCIH,* 2018). While the FDA regulates products on the market, it lacks pre-market authority (*DSHEA*, 1994). Before their sale to the public, the FDA has no authority to review the safety and effectiveness of HM and their labeling (*DSHEA*, 1994). Manufacturers must certify their products are safe per Current Good Manufacturing Practices (GMP) under FDA oversight (*Code of Federal Regulations Title 21,* 2018). They must also verify that it contains the ingredients and strength that it claims. There are, however, still problems associated with the manufacture of HM.

Despite the limited regulations currently in place, there continue to be issues with the manufacturing and safety of HM. The FDA has recalled numerous products due to microbiological, pesticide, and heavy metal contamination and FDA findings that products do not contain the dietary

ingredients manufacturers claimed on the labeling (*FDA,* 2022). In the study by Saper et al. (2008), which investigated Indian HM bought online, the group discovered that 75% of the products that claimed GMP compliance contained heavy metals (Saper et al., 2008). The study indicates that following GMP regulations does not guarantee product safety after entering the market (Saper et al., 2008). Although GMP is intended to reduce the risk of adulteration it does not guarantee that a product is contamination-free (*FDA,* 2023). GMP guidelines focus more on the production and quality control processes than testing the composition of finished products (*Code of Federal Regulations Title 21,* 2018). Importantly, there is no requirement for manufacturers to prove that their products are free from contaminants before they are released for sale (*FDA*, 2023). Consumers are therefore exposed to the risk of unknowingly consuming contaminated products.

Methods

The literature review for this project analyzed peer-reviewed articles focused on adults (over age 18) using herbal medicines in the US. The review focused on the adverse health effects of herbal medicines such as herb and drug interactions and heavy metal toxicity. Sources for the review included Fusion, PubMed, and Google Scholar articles published between 1998 and 2023. Other databases included the World Health Organization (WHO), US Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and National Center for Complementary and Integrative Health (NCCIH). Keywords for the search included complementary and alternative medicine, traditional medicine, herbal medicine, traditional remedies, traditional medical practice, heavy metal poisoning, heavy metal toxicity, lead poisoning, adverse health effects, health issues, health risks, contamination, and herb and drug interactions and Latinos. Filters narrowed the search, focusing on articles available as full text and in English.

Recommendations

Medical Students and Healthcare Provider Education

Medical schools must include HM courses in their curriculum to educate future healthcare providers about the risks associated with these products. The Liaison Committee on Medical Education (LCME) establishes standards, evaluates medical schools, and guides curriculum design and assessment to medical schools (*LCME,* 2015*)*. In collaboration with the American Medical Association (AMA) and the NCCIH, this committee should develop and implement the CAM curriculum with an emphasis on HM in medical schools. The goal is to provide medical students with a better understanding of the risks of HM, including herb-drug interactions and the dangers of heavy metal toxicity from traditional HM. Furthermore, as future healthcare providers they will be able to advise on the most effective treatment options for individuals who use these products.

US medical schools must establish collaborative relationships with CAM associations, such as the American Traditional Chinese Medicine Association (ATCMA) and the National Ayurvedic Medical Association (NAMA). These entities can help develop educational materials and recruit herbal practitioners to help educate medical students on how to approach each patient individually regarding HM and what risks may be associated with their consumption. As part of this course, medical students will learn about the various cultural and historical contexts that influence HM and how they may influence patient decisions and health outcomes. Through this collaboration, students will become more familiar with HM applications, as well as the risks and benefits associated with them. As a result, future healthcare providers can provide the highest quality care.

Additionally, medical schools need to incorporate cultural humility courses in their curricula because some HM, such as Indian and Chinese, are administered in accordance with culture and traditions. Incorporating cultural humility curricula will educate future healthcare providers on providing culturally sensitive advice to the patients who consume HM. It has been argued in the literature that

cultural humility is an ongoing process of the act of reflecting and critiquing oneself in which an individual learns about another's culture and examine its beliefs and individual identity (Yeager & Bauer-Wu, 2013). Healthcare providers must recognize and respect the individual cultural needs of patients and strive to build trust and collaboration between them. To ensure that their patients are respected and understood, healthcare providers should spend time understanding their patients' backgrounds, values, and experiences. By doing so, patients will be able to communicate more openly with their primary care providers regarding their HM and why they are taking it. Medical schools nationwide receive funding from the National Institutes of Health (NIH) for research up to $1,911,393,279 for schools (*NIH*, 2021). A portion of these funds should be allocated toward developing CAM curricula in medical schools nationwide.

In addition, continuing medical education (CME) programs must include mandatory HM and cultural humility courses. CME is required by many states in the United States for medical professionals to maintain their licenses (*ACCME*, n.d.). The Accreditation Council for Continuing Medical Education (ACCME) regulates continuing medical education for U.S. healthcare providers (*ACCME*, n.d.). Many healthcare providers receive Continuing Medical Education (CME) annual allowances from their employers to cover the costs associated with maintaining licensure, acquiring new skills, and staying up to date with medical advances. CME allowances for physicians have increased over the years, reaching an average of $3,691 in 2022 (*ACCME*, n.d*.).* By offering this allowance, physicians are encouraged to keep up to date with medical knowledge and skills by actively participating in learning activities. As a result, physicians can provide their patients with the highest quality of care possible.

In fulfilling their CME accreditation, healthcare providers select courses based on their specialty areas. There are, however, some courses that healthcare providers are required to complete to maintain their licenses. The Drug Enforcement Administration has mandated that all health providers complete an 8-hour course regarding controlled medication drugs every five years as part of CME (*DEA,* 2019).

State Medical Boards should mandate healthcare providers complete HM courses every few years to keep up with new HM introduced on the market, the prevalence among patients, and research on the risks associated with these products. Healthcare providers need to become familiar with the various types of HM medication and possible adverse effects such as drug interactions and heavy metal toxicity. As a result of gaining knowledge about these effects, providers will make informed decisions when consulting patients, such as screening them for heavy metal toxicity, advising them to stop using HM or suggesting alternatives to enhance their well-being.

Medical students and healthcare providers' education on HM, their risk, as well as herb-drug interactions can lead to a more patient-centered approach to healthcare delivery. Additionally, healthcare providers may make evidence-based recommendations regarding the use of HM, and medical students will be better prepared to address the needs of patients who use HM. Furthermore, this knowledge will improve patient-healthcare provider communication, resulting in greater satisfaction with the care they receive.

Public Health Campaign Reaching the Latino Population

To reach the at-risk Latino population, initiating a public education campaign regarding HM health risks is essential. The CDC could design and develop this campaign with Better World Advertising (BWA). BWA is a social marketing organization that designs, implements, and administers social marketing campaigns (Better World Advertising, n.d.). To raise awareness of the potential risks and dangers of HM and reach Latinos, it is necessary to partner with state and local public health organizations, community centers, churches, and medical facilities serving Latinos to distribute information. As a result of these partnerships, the health campaign can effectively reach the Latino community and educate them about HM risks.

Regarding campaign efficiency, it is critical to consider who is delivering the message. If a campaign is intended to engage the Latino community effectively, the messenger must be viewed as credible and trustworthy by the Latino community. A Latino community health worker (CHW), celebrities, and social media influencers should be messengers for this health campaign. CHWs are effective communicators since they have a common understanding of the linguistic and cultural background of the targeted population (Balcazar et al., 2011). Additionally, they deeply understand the cultural norms, values, and beliefs that shape healthy behavior within the community (Balcazar et al., 2011). It is also possible for celebrities and social media influencers with large Latino followers to serve as powerful messengers. To reach out to popular Latino celebrities, the CDC will offer them incentives for advertising and delivering the message to Latinos.

The campaign would produce various materials, including infographics, posters, flyers, videos, and social media posts in English and Spanish. Information should be disseminated through various media outlets, such as radio, television, and social media, to reach the Latino community. Data shows that the Latino cohort watches approximately 33 hours of television each week, and 6.9 hours of video are viewed monthly (Gandolf, 2022). In addition, about 90 percent of Latino adults listen to the radio every week, spending an average of 12 to 13 hours (Gandolf, 2022). According to these statistics, radio, and television are effective mediums for engaging Hispanic audiences. However, social media can be more effective at expanding reach and engagement.

A variety of social media platforms should be used to disseminate the materials, including Twitter, Facebook, YouTube, and Instagram. According to Shah et al. (2023), the Mejor Vive Sin Duda social marketing intervention had the highest rate of reaching Latino immigrants through Facebook. Approximately 84% of respondents indicated they were exposed to the campaign via Facebook (Shah et al., 2023). In this regard, social media effectively reaches a targeted population segment and can rapidly spread information. To raise awareness about the dangers associated with HM, educational materials

can be shared on these platforms with friends and family members. As a part of the outreach effort, the flyers and posters must be distributed to medical centers, public health organizations, community organizations, and Latino grocery stores.

All materials should be designed to promote the campaign's message, the dangers of HM, effectively and clearly for the Latino population. The materials should include information about the health risks associated with HM, such as herb and drug interaction and heavy metal toxicity from common traditional HM. Also, the materials will include information on the signs of heavy metal toxicity and why disclosing HM consumption to healthcare providers is necessary. Furthermore, the campaign's call to action can encourage patients to ask their healthcare providers about possible interactions between HM and prescription drugs.

The campaign approach must be based on the premise that messaging should be culturally, linguistically, and emotionally relevant to the Latino audience. In this regard, it is essential to tailor messages to the Latino community based on their language, values, and cultural beliefs. Utilizing the right tone, visuals, and other meaningful elements is the key to making the message meaningful to the Latino population. Moreover, the campaign should seek feedback from those within the target culture to ensure that it communicates effectively with them and is respectful of them.

The campaign would aim to increase awareness about safety issues and guide how to find information about HM's safety, side effects, and risk. Resources such as herb and drug interaction apps and databases can assist the Latino population in assessing HM risks. The call to action may encourage consumers to consult their healthcare provider before taking HM and report any adverse reactions they may experience after consuming HM. This public health campaign will significantly impact Latino's perception and influence their behavior toward HM.

To implement this campaign, funds can be allocated towards concept testing and development of the materials, salaries for production staff, development of advertisements on different channels, and the distribution of advertisement materials. In preparing campaign materials for Latino audiences, one of the expenses is the development of high-quality images, graphics, and videos relevant to this audience. Ananthapavan et al. (2022) conducted a cost-effective analysis of the LiveLighter campaign, which promotes healthy behaviors among Australian adults. Approximately 45,000 Australian dollars, equivalent to $31,000 U.S. dollars, are required to develop educational materials (Ananthapavan et al., 2022). An estimated USD 47,000 would be required to advertise and promote the product through social media, television, and radio (Ananthapavan et al., 2022). This campaign would cost approximately $80,000 to be tested, implement, and reach the Latino target audience. However, adverse health risks associated with HM can result in a substantial increase in the cost of treatment and time away from work. Therefore, investing in preventative measures like this campaign will ultimately result in cost savings for the community in the long run.

Congress should provide funding for the public education campaign. CDC's budget request to Congress for Fiscal Year 2023 includes $10.675 billion in discretionary budget authority, evaluation funds, and the Affordable Care Act Prevention and Public Health Fund (PPHF) (*CDC,* 2022). Funds from these sources are an important part of the budget of CDC, which supports programs aimed at improving health outcomes and reducing costs (*CDC,* 2022). This funding source should be allocated toward developing and implementing public health campaigns to reduce HM health risks and provide necessary resources for Latino populations. Appendix D: Figure 3 contains the logic model which shows the relationship between resources, activities, and outcomes of this campaign.

Mandatory Third-Party Testing for Herbal Medicine

Congress should require manufacturers to conduct mandatory third-party testing of dietary supplements, such as HM and vitamins, and increase FDA's authority to oversee compliance with the requirements. The FDA should be authorized to regulate and approve products tested by third parties and require a certified stamp before entering the market. This regulation would help ensure that products on the market do not contain harmful metals and microorganisms. Additionally, it would protect consumers from potentially harmful or contaminated products. Furthermore, the FDA should report to Congress on the effectiveness of the new regulation.

Under this proposal, HM manufacturers will send their products to independent laboratories to test for contaminations such as heavy metals, microorganisms, mold, and bacteria. After that, the laboratories will submit a detailed report to the FDA for approval to put the products on the market. This regulation will reduce the chances that HM consumers are exposed to heavy metals and other contaminants. As well as verifying product quality and safety, it will also verify the accuracy of labeling for HM products. Additionally, this would enhance consumer confidence in the industry and ensure product safety.

Consumers are becoming more aware that third-party testing indicates better quality and safety. In a study by Vento and Wardenaar (2020), 138 university students who consume dietary supplements were interviewed about their attitudes toward the importance of third-party testing of these products before their arrival on the market. As a result of the survey, more than 90% of respondents believed it was imperative to know whether a supplement had been tested by a third party (Vento & Wardenaar, 2020). Based on the study's findings, consumers are concerned about the safety of dietary supplements, and third-party testing is viewed as a critical factor in ensuring product quality.

Currently, multiple independent third-party laboratories test HM products, which are voluntarily sent by manufacturers to ensure their safety and contamination-free status. The U.S. Pharmacopeia,

Consumer Lab, and NSF are accredited laboratories in the US that can detect contaminants such as heavy metals, pesticides, molds, and microbes (Gurib-Fakim, 2006). A certified stamp of approval appears on the label of products that have passed the tests, informing the consumer that the product has been subjected to independent laboratory testing (White, 2020).

Furthermore, third-party testing is vital to avoid conflict of interest since a manufacturer may be biased when testing his or her product. The results of independent laboratories are unbiased and can be trusted by consumers. Such testing can help identify quality issues and potential safety risks before products reach consumers. Establishing stringent regulations specifying required tests and acceptable criteria is essential to ensure high-quality and safe HM on the market. U.S. Congress must ensure that consumers have access to trustworthy and safe products by authorizing FDA to implement mandatory third-party testing to ensure only high-quality, contaminant-free HM is marketed to consumers. As a result, adverse health effects such as heavy metal poisoning will be reduced.

Implications and Discussion

HM's safety is compromised by several factors, including inadequate regulation, lack of knowledge among healthcare providers regarding HM, and patients' non-disclosure of consumption. HM is made from plants, so consumers often perceive them as natural and safe for consumption. However, there is growing evidence that HM can have adverse health effects. These include the toxic effects of heavy metal contamination and interactions with prescription drugs. Unlike prescription drugs, HM is not strictly regulated by the federal government for purity and safety prior to marketing.

Education of health care providers is one critical element in reducing adverse health effects, and prescription drug interactions, associated with consumer use of HM. The recommended changes to medical school curricula are intended to provide future healthcare professionals with enhanced tools and information on how to communicate with patients, offer advice, and raise awareness regarding

potential harm caused by HM. Additionally, by incorporating HM courses into the CME, healthcare providers will better understand how HM interacts with prescription drugs and how some traditional HM can be toxic to patients' health. Healthcare providers will be able to make better recommendations and offer patients alternative treatment options.

Implementing the recommended public health campaign addressing the dangers of HM can significantly impact the Latino population's health behavior towards HM. In addition to learning more about HM dangers, Latinos will be more likely to discuss its use with their healthcare providers. Furthermore, this educational campaign will provide HM users with tools and resources to help them access information regarding herb-drug interactions. In the long run, education about potential risks and side effects associated with HM will assist the general population in weighing risks and benefits and making informed decisions while using these products.

In addition, requiring third-party testing for HM sold in the United States will help minimize the risk of heavy metal poisoning or other adverse effects from contaminated products. To improve the safety of these products, stricter regulations, such as testing them for potency and purity before they are put on the market, are necessary. This policy adjustment will help to reduce the number of emergency room visits, hospitalizations, and treatment costs associated with heavy metal poisoning.

Limitations

One limitation to the recommendation of mandatory third-party testing is the cost that manufacturers of HM will incur to the independent laboratories. Independent testing expenses can be significant when considering the number of products to be tested. As a result, consumers' prices may rise, making HM products less accessible to those who rely on them.

The fact that consumers can import HM from abroad or purchase them via online shipping from other countries is another serious limitation. There is the possibility that these products may be

contaminated. Since they are not manufactured in the United States, they might not be tested for harmful substances. Thus, the public may be at risk and suffer serious health consequences. Even if labeled accurately, a product's purity and safety cannot be guaranteed.

A few limitations apply to incorporating HM courses into the medical school curriculum. As these schools already offer a full course load, LCME may feel that education in HM is not as important as conventional medicine; thus, students can learn HM through electives and other less formal means. Also, adding HM curricula to medical schools will increase tuition costs for students, resulting in a larger student loan debt. Consequently, fewer students may apply to medical schools, resulting in a shortage of physicians.

Regarding public health campaigns reaching Latinos, there are a few limitations. There is a possibility that Latino adults do not have health insurance or do not consult their healthcare provider regularly. As a result, they may not be able to discuss the use of HM with the healthcare profession. Another challenge is that this campaign will compete with advertisements for HM products. Manufacturers will likely seek different ways to mislead the public about the safety and effectiveness of their products.

Future Direction

Going forward, public health officials, policymakers, providers, and consumers need additional research and better information on the effectiveness and safety of HM. Every year, new products are introduced to the market that may pose new consumer risks. Additional research is needed on interactions between herbs and drugs with consideration of age, demographics, gender, and existing medical conditions.

An additional direction in the future is to make HM only available through pharmacies with the consultation of pharmacists. Pharmacy schools and continuing medical education programs will need to

provide pharmacists with extensive training on the potential risks of herb and drug interactions. This way, pharmacists will inform patients about the risks associated with combining HM with prescription drugs and suggest alternative medication options.

Ultimately, increased global collaboration and education can help to reduce the burden of HM health care within the US. Policymakers may wish to consider limiting the importation of the most dangerous HM from abroad or purchasing those products online and require labels that warn consumers that foreign-made products are not subject to US standards. The regulation will also protect consumers from buying products from online retailers who may sell contaminated or incorrectly labeled products.

Conclusion

HM is popular in the United States and is one of the most utilized forms of CAM, used by approximately 35% of adults. Consumers use HM because they are dissatisfied with conventional medicine, affordability, ease of access, and cultural beliefs. However, there are associated health risks, such as herb-drug interactions and heavy metal poisoning. Public health systems and the federal government have implemented several interventions to decrease the risk of HM. However, there are still gaps that need to be addressed in order to reduce the risk of HM, including insufficient knowledge among healthcare providers due to the lack of CAM courses in medical schools and CME programs. Further, there is a reluctance among patients to disclose these products to their healthcare providers, and there are limited pre-market regulations for these products. Education of healthcare professionals and consumers regarding the health risks associated with HM, as well as the implementation of mandatory third-party testing, will reduce the adverse health effects of these products.

References

Accreditation Council for Continuing Medical Education/ ACCME. (2023). *Accreditation Council for Continuing Medical Education.* Retrieved from https://www.accme.org/

Ananthapavan, J., Tran, H. N. Q., Morley, B., Hart, E., Kennington, K., Stevens-Cutler, J., Bowe, S. J., Crosland, P., & Moodie, M. (2022). Cost-effectiveness of LiveLighter® - a mass media public education campaign for obesity prevention. *PLOS ONE*, *17*(9), e0274917. https://doi.org/10.1371/journal.pone.0274917

Araujo, J. (2004, July 7). *Lead Poisoning Associated with Ayurvedic Medications — Five States, 2000-2003*. PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2768057/

Balcazar, H., Alvarado, M., & Ortiz, G. (2011). Salud Para Su Corazon (Health for Your Heart) Community Health Worker Model. *The Journal of Ambulatory Care Managment*, *34*(4), 362–372. https://doi.org/10.1097/jac.0b013e31822cbd0b

Barnes, P. M., Bloom, B., & Nahin, R. L. (2008). Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007 [Dataset]. In *PsycEXTRA Dataset*. https://doi.org/10.1037/e623942009-001

Bent, S. (2008). Herbal Medicine in the United States: Review of Efficacy, Safety, and Regulation. *Journal of General Internal Medicine*, *23*(6), 854–859. https://doi.org/10.1007/s11606-008-0632-y

Better World Advertising. (n.d.). *Home | BWA*. Retrieved from http://www.socialmarketing.com/

Centers for Disease Control and Prevention. (2012). Lead poisoning in pregnant women who used Ayurvedic medications from India--New York City, 2011-2012. *MMWR. Morbidity and Mortality Weekly Report*, *61*(33), 641–646. https://pubmed.ncbi.nlm.nih.gov/22914225

Centers for Disease Control and Prevention. (2022). *Congressional Justifications | Budget* *https://www.cdc.gov/budget/fy2023/congressional-justification.html*

Centers for Disease and Control. (n.d.). *Lead: Adult Blood Lead Epidemiology and Surveillance (ABLES) | NIOSH.* https://www.cdc.gov/niosh/topics/lead/ables.html

Centers for Disease Control and Prevention. (2023, January 6). *Understand Blood Lead Levels | NIOSH | CDC.* Retrieved from https://www.cdc.gov/niosh/topics/lead/referencebloodlevelsforadults.html

CFR - Code of Federal Regulations Title 21. (2018). Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211

Clarke, T. C., Black, L. I., Stussman, B. J., Barnes, P. M., & Nahin, R. L. (2015). Trends in the use of complementary health approaches among adults: United States, 2002-2012. *National health statistics reports*, (79), 1–16. Retrieved from https://www.cdc.gov/nchs/data/nhsr/nhsr079.pdf

Coghlan, M. L., Maker, G. L., Crighton, E., Haile, J., Murray, D. C., White, N., Byard, R. W., Bellgard, M. I., Mullaney, I., Trengove, R. D., Allcock, R. J., Nash, C., Hoban, C. L., Jarrett, K., Edwards, R. L., Musgrave, I. F., & Bunce, M. (2015). Combined DNA, toxicological and heavy metal analyses provides an auditing toolkit to improve pharmacovigilance of traditional Chinese medicine (TCM). *Scientific Reports*, *5*(1). https://doi.org/10.1038/srep17475

ConsumerLab.com. (n.d.). *About ConsumerLab.com.* Retrieved from https://www.consumerlab.com/about/

Cowen, V. S., & Cyr, V. (2015). Complementary and alternative medicine in US medical schools. *Advances in Medical Education and Practice*, 113. https://doi.org/10.2147/amep.s69761

Council for Responsible Nutrition. (n.d.). *Get the facts—and be Label Wise!* Retrieved from https://www.crnusa.org/CRN-supplement-facts

Cronkleton, E. (2022, June 30). *Conventional vs. complementary medicine*. Retrieved from https://www.medicalnewstoday.com/articles/difference-between-bconventional-and-complementary-medicine

Cupp, M. J. (1999, March 1). *Herbal Remedies: Adverse Effects and Drug Interactions*. AAFP. https://www.aafp.org/pubs/afp/issues/1999/0301/p1239.html

Duffy, S. (2022). CVS Pharmacy Introduces Third Party Testing for All Dietary Supplements. *Dermatology Advisor*. https://www.dermatologyadvisor.com/home/topics/general-dermatology/cvs-pharmacy-introduces-third-party-testing-for-all-dietary-supplements/

Eisenberg, D., Kessler, R., Van Rompay, M. I., Kaptchuk, T. J., Wilkey, S., Appel, S., & Davis, R. F. (2001). Perceptions about Complementary Therapies Relative to Conventional Therapies among Adults Who Use Both: Results from a National Survey. *Annals of Internal Medicine*, *135*(5), 344. https://doi.org/10.7326/0003-4819-135-5-200109040-00011

Gandolf, S. (2022, June 16). *Healthcare marketing and medical advertising for doctors, hospitals, healthcare networks & pharmaceuticals*. Healthcare Success. https://healthcaresuccess.com/blog/healthcare-marketing/marketing-hispanics-healthcare-services.html

Gurib-Fakim, A. (2006). Medicinal plants: Traditions of yesterday and drugs of tomorrow. *Molecular Aspects of Medicine*, *27*(1), 1–93. https://doi.org/10.1016/j.mam.2005.07.008

Gurley, B. J., Swain, A., Williams, D., Barone, G. W., & Battu, S. K. (2008). Gauging the clinical significance of P-glycoprotein-mediated herb-drug interactions: Comparative effects of St. John's wort,

Echinacea, clarithromycin, and rifampin on digoxin pharmacokinetics. *Molecular Nutrition & Food Research*, *52*(7), 772–779. https://doi.org/10.1002/mnfr.200700081

Hassen, G., Belete, G., Carrera, K. G., Iriowen, R. O., Araya, H., Alemu, T., Solomon, N., Bam, D. S., Nicola, S. M., Araya, M., Debele, T., Zouetr, M., & Jain, N. (2022). Clinical Implications of Herbal Supplements in Conventional Medical Practice: A US Perspective. *Cureus*. https://doi.org/10.7759/cureus.26893

Howell, L. K., Kochhar, K., Saywell, R. M., Zollinger, T. W., Koehler, J. M., Mandzuk, C., Sutton, B. S., Sevilla-Martir, J., & Allen, D. H. (2006). Use of Herbal Remedies by Hispanic Patients: Do They Inform Their Physician? *Journal of the American Board of Family Medicine*, *19*(6), 566–578. https://doi.org/10.3122/jabfm.19.6.566

Hu, Z., Yang, X., Ho, P. T. P., Chan, S. Y., Heng, P. W. S., Chan, E., Duan, W., Koh, H., & Zhou, S. (2005). Herb-Drug Interactions. *Drugs*, *65*(9), 1239–1282. https://doi.org/10.2165/00003495-200565090-00005

Johns Hopkins Medicine. (2019). *Types of Complementary and Alternative Medicine*. Johns Hopkins Medicine Health Library. https://www.hopkinsmedicine.org/health/wellness-and-prevention/types-of-complementary-and-alternative-medicine

Jou, J., & Johnson, P. T. (2016). Nondisclosure of Complementary and Alternative Medicine Use to Primary Care Physicians. *JAMA Internal Medicine*, *176*(4), 545. https://doi.org/10.1001/jamainternmed.2015.8593

Karri, S. K., Saper, R. B., & Kales, S. N. (2008). Lead Encephalopathy Due to Traditional Medicines. *Current Drug Safety*, *3*(1), 54–59. https://doi.org/10.2174/157488608783333907

Kennedy, J. (2005). Herb and supplement use in the US adult population. *Clinical Therapeutics*, *27*(11), 1847–1858. https://doi.org/10.1016/j.clinthera.2005.11.004

Ko, R. H. (1998). Adulterants in Asian Patent Medicines. *The New England Journal of Medicine*, *339*(12), 847. https://doi.org/10.1056/nejm199809173391214

Lanphear, B. P., Rauch, S., Auinger, P., Allen, R. W., & Hornung, R. W. (2018). Low-level lead exposure and mortality in US adults: a population-based cohort study. *The Lancet. Public Health*, *3*(4), e177–e184. https://doi.org/10.1016/s2468-2667(18)30025-2

LCME | Liaison Committee on Medical Education. (n.d.). Retrieved from https://lcme.org/

Lee, B. C., Bendixsen, C. G., Liebman, A. K., & Gallagher, S. S. (2017). Using the socio-ecological model to frame agricultural safety and health interventions. *Journal of Agromedicine*. https://doi.org/10.1080/1059924x.2017.1356780

Lee, E., Richards, N., Harrison, J., & Barnes, J. (2022). Prevalence of Use of Traditional, Complementary and Alternative Medicine by the General Population: A Systematic Review of National Studies Published from 2010 to 2019. *Drug Safety*, *45*(7), 713–735. https://doi.org/10.1007/s40264-022-01189-w

Li, X., Li, Y., Deng, L., Chen, Q., Fang, L., & Tan, Z. (2019). Evaluating The Completeness and Reliability of Information on Herb-Drug Interactions in Commonly Used Databases. *Journal of Alternative and Complementary Medicine, 23*(10), 845-863. https://doi.org/10.1245/acm.2019.0064

Matthews, M. K. (1998). Association of Ginkgo biloba with intracerebral hemorrhage. *Neurology*, *50*(6), 1933. https://doi.org/10.1212/wnl.50.6.1933

Mukhopadhyay, S., Abraham, S., Holla, B., Ramakrishna, K. K., Gopalakrishna, K. L., Soman, A., Chikkanna, U. C., Bharath, M. M. S., Bhargav, H., Varambally, S., & Gangadhar, B. N. (2021).

Heavy Metals in Indian Traditional Systems of Medicine: A Systematic Scoping Review and Recommendations for Integrative Medicine Practice. *Journal of Alternative and Complementary Medicine*, *27*(11), 915–929. https://doi.org/10.1089/acm.2021.0083

Nahin, R. L., Barnes, P. M., & Stussman, B. J. (2016). Expenditures on Complementary Health Approaches: United States, 2012. *PubMed*, *95*, 1–11. https://pubmed.ncbi.nlm.nih.gov/27352222

National Center for Complementary and Integrative Health. (2018). *HerbList App*. Retrieved from https://www.nccih.nih.gov/health/herblist-app

National Center for Complementary and Integrative Health. (n.d.). *Online Continuing Education Series*. Retrieved from https://www.nccih.nih.gov/training/videolectures

National Center for Complementary and Integrative Health. (n.d.). *Statistics From the National Health Interview Survey*. NCCIH. https://www.nccih.nih.gov/health/statistics-from-the-national-health-interview-survey

National Center for Complementary and Integrative Health. (2018). *Using Dietary Supplements Wisely*. Retrieved from https://www.nccih.nih.gov/health/using-dietary-supplements-wisely#:~:text=The%20U.S.%20Food%20and%20Drug%20Administration%20%28FDA%29%2C%20which,for%20safety%20and%20effectiveness%20before%20they%20are%20marketed

NSF International. (2023, June 6). *The Public Health and Safety Organization*. NSF. https://www.nsf.org/consumer-resources/articles/supplement-vitamin-certification

Rashrash, M., Schommer, J. C., & Brown, L. H. (2017). Prevalence and Predictors of Herbal Medicine Use Among Adults in the United States. *Journal of Patient Experience*, *4*(3), 108–113. https://doi.org/10.1177/2374373517706612

S.784 - 103rd Congress (1993-1994): Dietary Supplement Health and Education Act of 1994. (1994, October 25). https://www.congress.gov/bill/103rd-congress/senate-bill/784

Saper, R. B., Phillips, R. S., Sehgal, A., Khouri, N., Davis, R. J., Paquin, J., Thuppil, V., & Kales, S. N. (2008). Lead, mercury, and arsenic in US- and Indian-Manufactured Ayurvedic medicines sold via the internet. *JAMA*, *300*(8), 915. https://doi.org/10.1001/jama.300.8.915

Shah, H., Miller, A. F., Yang, C., Grieb, S. M., Lipke, M., Bigelow, B. F., Phillips, K. W., Palomino, P., & Page, K. R. (2023). A Community-Engaged social marketing campaign to promote equitable access to COVID-19 services among Latino immigrants. *American Journal of Public Health*, *113*(3), 263–266. https://doi.org/10.2105/ajph.2022.307191

Suchard, J. R., Suchard, M. A., & Steinfeldt, J. (2004). Physician knowledge of herbal toxicities and adverse herb???drug interactions. *European Journal of Emergency Medicine*, *11*(4), 193–197. https://doi.org/10.1097/01.mej.0000134721.72356.f7

Tabish, S. A. (2008, January 1). *Complementary and Alternative Healthcare: Is it Evidence-based?* PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068720/

United States Drug Enforcement Administration. (2019). *Home | DEA*. Retrieved from https://www.dea.gov/

US EPA, O. (2023, February 12). *Heavy Metals in Cultural Products*. Retrieved from https://www.epa.gov/children/heavy-metals-cultural-products#:~:text=This%20website%20provides%20additional%20information%20on%20a%20variety

U.S. Food and Drug Administration. (2022). *Recalls Of Foods & Dietary Supplements*. Retrieved from https://www.fda.gov/food/recalls-outbreaks-emergencies/recalls-foods-dietary-supplements

U.S. Food and Drug Administration. (2017). *FDA Adverse Reporting System (FAERS)*. Retrieved from https://www.fda.gov/drugs/drug-approvals-and-databases/fda-adverse-event-reporting-system-faers

U.S. Food and Drug Administration. (2022). *Supplement your knowledge*. Retrieved from https://www.fda.gov/food/information-consumers-using-dietary-supplements/supplement-your-knowledge

U.S. Food and Drug Administration. (2023). *Lead in Food, Foodwares, and Dietary Supplements*. Retrieved from https://www.fda.gov/food/environmental-contaminants-food/lead-food-foodwares-and-dietary-supplements

U.S. Food and Drug Administration. (2023). *Facts about the current Good Manufacturing Practices (CGMP)*. Retrieved from https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp

Vento, K. A., & Wardenaar, F. C. (2020). Third-Party Testing Nutritional Supplement Knowledge, Attitudes, and Use Among an NCAA I Collegiate Student-Athlete Population. *Frontiers in Sports and Active Living*, *2*. https://doi.org/10.3389/fspor.2020.00115

Ventola, C. L. (2010, August 1). *Current Issues Regarding Complementary and Alternative Medicine (CAM) in the United States: Part 1: The Widespread Use of CAM and the Need for Better-Informed Health Care Professionals to Provide Patient Counseling*. PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2935644/

Welz, A. N., Emberger-Klein, A., & Menrad, K. (2018). Why people use herbal medicine: insights from a focus-group study in Germany. *BMC Complementary and Alternative Medicine*, *18*(1). https://doi.org/10.1186/s12906-018-2160-6

White, C. M. (2020). Dietary Supplements Pose Real Dangers to Patients. *Annals of Pharmacotherapy*, *54*(8), 815–819. https://doi.org/10.1177/1060028019900504

WHO. (2023). *WHO Global Centre for Traditional Medicine*. https://www.who.int/initiatives/who-global-centre-for-traditional-medicine

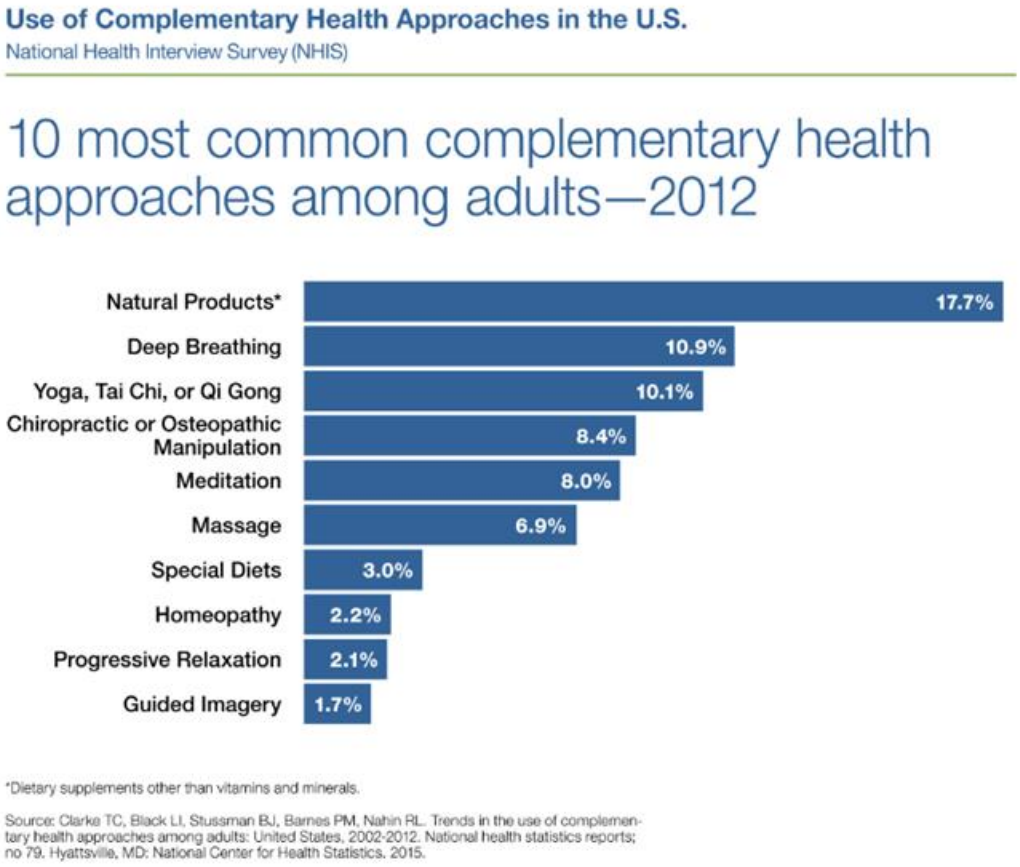
Xu, S., & Levine, M. (2008). Medical residents' and students' attitudes towards herbal medicines: a pilot study. *PubMed*, *15*(1), e1-4. https://pubmed.ncbi.nlm.nih.gov/18184982

Yeager, K. A., & Bauer-Wu, S. (2013). Cultural humility: Essential foundation for clinical researchers. *Applied Nursing Research*, *26*(4), 251–256. https://doi.org/10.1016/j.apnr.2013.06.008

Zhang, Y., Ip, C. Y., Lai, Y. L., & Zuo, Z. (2021, October 25). Overview of Current Herb–Drug Interaction Databases. *Drug Metabolism and Disposition*. https://doi.org/10.1124/dmd.121.000420

Appendices

Appendix A: Figure1: 10 Most Common Complementary Health Approaches Among Adults in US -2012



(Clarke et al., 2015)

Appendix B: Table 1: Potential Herb and Drug Interaction of Common Herbal Medicines

Herb Name (Latin/ Scientific)	**Promoted For**	**Adverse Effect**	**Interacting Drug**	**Effect of Interaction**
Black Cohosh (Actaea racemosa, Cimicifuga racemosa)	hot flashes, other menopausal symptoms	stomach upset, cramping, HA, rash, feeling of heaviness, vaginal spotting or bleeding, weight gain	statins	->reduced effectiveness
Ginkgo (Ginkgo biloba)	anxiety, allergies, dementia, eye problems, PAD, tinnitus	HA, stomach upset, dizziness, N, V, palpitations, constipation, allergic skin reactions, bleeding risk, liver & thyroid cancer (animal study), early labor or extra bleeding during delivery (in pregnancy), ICB	Aspirin Thiazide diuretic Trazodone Warfarin (Coumadin)	->spontaneous hyphemia ->increased BP ->coma ->increased bleeding risk
Ginseng, Asian (Panax ginseng)	to increase resistance to stress (adaptogen), for general well-being (general tonic), to improve physical stamina, concentration & memory; to stimulate immune function; to slow the aging process; to relieve respiratory & cardiovascular disorders, colds and other respiratory tract depression, anxiety,	insomnia, menstrual problems, breast pain, increased HR, high or low BP, HA, loss of appetite, digestive problems, altered blood sugar, birth defects (animal study), questionable safety for infants, children, pregnancy or BF, platelet inhibition, lowering blood glucose	Drugs metabolized by CYP3A4 (Ginseng induces CYP3A4 enzymes) Warfarin	->decrease the effectiveness of drugs such as CCB, some chemotherapeutic & HIV agents, certain antihypertensive & statin medications, some antidepressants -> decreased INR

	menopausal hot flashes, premature ejaculation (topical)		Metformin	-> drop in metformin level
Goldenseal (Hydrastis canadensis)	colds and other respiratory tract infections, allergic rhinitis, ulcers, digestive upsets such as diarrhea and constipation, mouthwash, eyewash	unsafe for pregnancy or breastfeeding, neonatal jaundice	Drugs metabolised by CYP2D6 and CYP3A4 (Goldenseal inhibits both CYP2D6 & CYP3A4)	->increase in the level of many pharmaceutical agents currently in use
SJW (Hypericum perforatum)	depression, menopausal symptoms, ADHD, somatic symptom disorder, OCD, topical use for skin conditions (wounds & bruises) & muscle pain	GI disturbances, allergic reactions, fatigue, dizziness, confusion, dry mouth, photosensitivity/phototoxicity (skin rash, nephropathy), insomnia, anxiety, headache, or sexual dysfunction, unsafe for pregnancy or BF (infantile colic, drowsiness & fussiness)	Drugs with pharmacokinetics involving CYP3A4 and P-gp (SJW is a potent inducer of CYP and intestinal P-g) Certain antidepressants	->reduction in cyclosporine, indinavir, nevirapine, OC, warfarin (reduce INR), digoxin, ivabradine, benzodiazepines, tacrolimus, irinotecan, imatinib theophylline, venlafaxine, statins -> serotonin syndrome

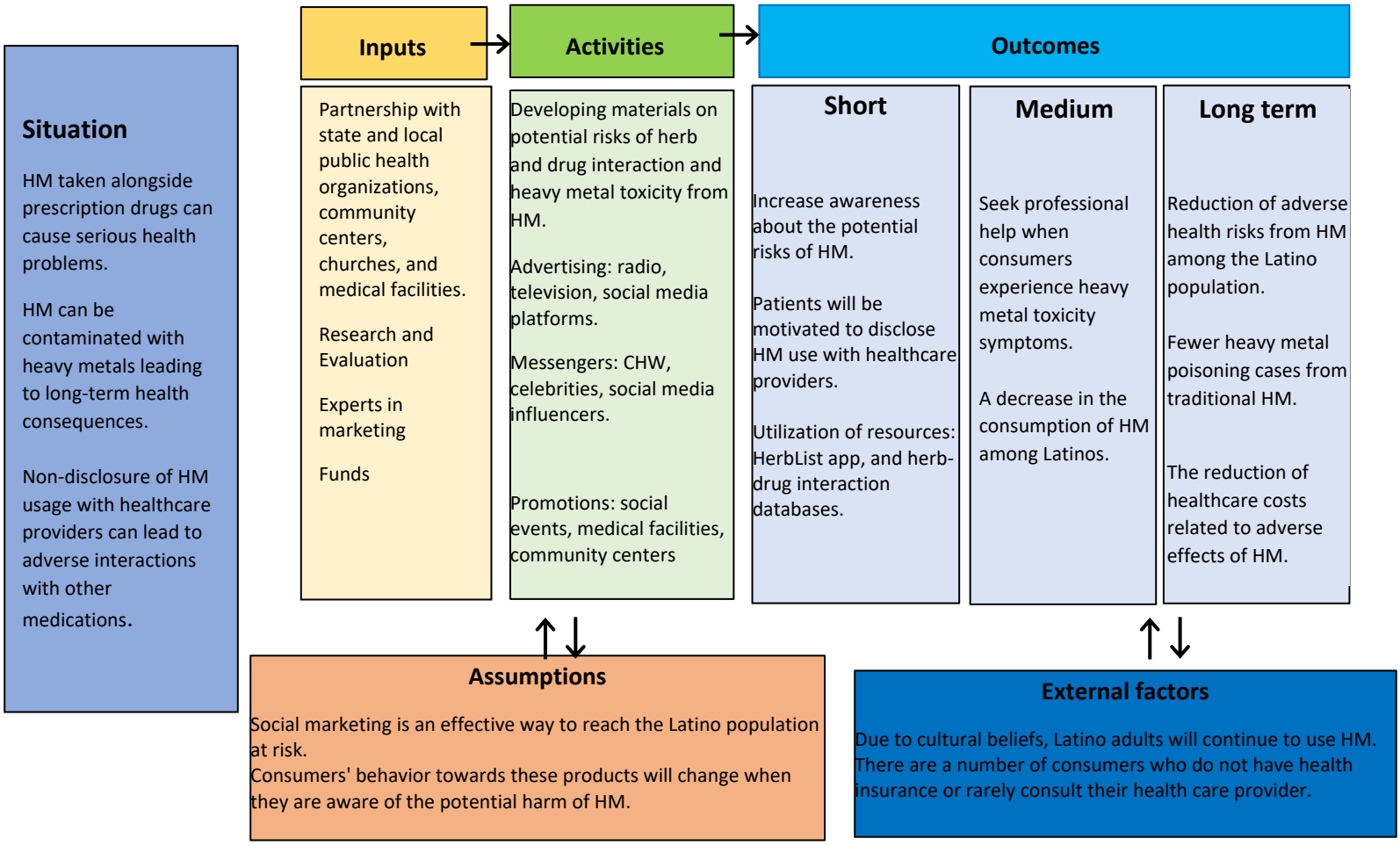
(Hassen et al., 2022)

Appendix C: Figure 2: Social Ecological Model (SEM)

(B. C. Lee et al., 2017)

Appendix D: Figure 3: Logic Model

Public Health Campaign Reaching the Latino Population- Logic Model



Appendix E: MPH Foundational Competencies Applied in this Ilex Paper

Foundational Competency	Description of how used for Capstone
Evidence-based Approaches to Public Health	
2. Select quantitative and qualitative data collection methods appropriate for a given public health context	Conduct a literature review of existing data on herbal medicine prevalence and health risks among the US adult population. This was done using multiple databases such as PubMed, Fusion, and Google Scholar.
4. Interpret results of data analysis for public health research, policy, and practice	Analyzed quantitative and qualitative data regarding herbal medicine health risks, patient nondisclosure, and healthcare provider knowledge about these products. To identify areas for improvement in consumers' and healthcare providers' education, the existing literature was analyzed and interpreted.
Planning & Management to Promote Health	
8. Apply awareness of cultural values and practices to the design or implementation of public health policies or programs	A recommendation has been made to incorporate cultural humility curricula into medical education to give healthcare providers the opportunity to provide culturally sensitive advice to patients who use herbal medicine. Recommended a public health campaign approach based on the principle that messaging should be culturally relevant to Latinos.
9. Design a population-based policy, program, project, or intervention	Analyzed the literature for evidence-based interventions targeting Latinos at risk. Developed recommendations for implementing a public health campaign targeting Latinos at risk.
Communication	
19. Communicate audience-appropriate public health content, both in writing and through oral presentation	Prepared an outline, draft, revised, and finalized literature review, recommendations, and implications for an Ilex paper on herbal medicine health risks. Delivered an oral presentation based on the Ilex paper to an interprofessional audience at Health Professions Day.

Health Policy Leadership Concentration Competencies

Competency	Anticipated FW Activity
3. Formulate efficient health policy change recommendations through the analysis of proposed health policy initiatives that could affect health outcomes of vulnerable populations	Policy analysis of the Dietary Supplement Health and Education Act of 1994. Recommendation to increase FDA authority to mandate third-party testing for herbal medicines.
4. Develop recommendations to improve organizational strategies and capacity to implement health policy	Examined the literature to determine the best practices and gaps in medical education. Provided recommendations for implementing herbal medicine courses in medical schools and continuing medical education programs.