Herbal Medicine: A Path to Self-Medication or Medical Complications?

I Badar, F J Abboud, P A Clark, P George, B McNierney, J Kelly, M Galdo

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Abstract

In recent years, the herbal medicine and dietary supplements sector has grown exponentially with estimates of around 14.7 billion dollars in spending on nonprescription supplements in the U.S. in 2012, according to NCCIH. Worldwide, 37.8% of patients with hypertension (HTN) and anywhere between 2% and 46% of patients with cardiovascular disease (CVD) report using herbal medicines. However, herbal medicines do not fall under FDA premarket-approval regulations, permitting patients with chronic diseases to self-medicate uncontrollably. Furthermore, clinical data has shown that herbal medicine-use in conjunction with use of prescription drugs may pose considerable risks to patients' health, spanning from decreased prescription drugs' activity to hepatotoxicity to even fatal serotonin syndrome in pregnant women. Further exacerbating the uncontrolled use of herbal products is the lack of patient education and poor physician-patient communication about the risks of self-medication. Such perils, however, must not be disregarded. Therefore, this article, in tailoring the arguments to patients with HTN and CVD, addresses this public health dilemma. It underscores the potential risks of unregulated herbal medicine-use, especially in conjunction with prescription medications, and the importance of patients with HTN and CVD maintaining transparency about their self-medication with primary care physicians. Finally, it provides an ethical ground for imposing stricter FDA-regulations on herbal products.

INTRODUCTION

When thinking of medicine today, one may imagine their most recent physical exam, X-ray, or blood lab work. Yet before technological imaging, testing, and industrial pharmaceuticals were the standard for diagnosis and treatment, people were documenting ailments, anatomical observations, and discovering plant-based cures.[1] Throughout medical history, tradition has defined medicine as "the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness".[2] Traditional medical practices have been conserved across human civilizations throughout time. Although these practices vary based on geography, religion, and the environment in which the traditions evolved, "...a common philosophy is a holistic approach to life, equilibrium of the mind, body, and the environment, and an emphasis on health rather than on disease".[2]

Complementary and alternative medicine (CAM), in the broadest sense, refers to multiple traditional medical systems or schools of thought, most of which are known for their long-standing and rich histories. Ancient medical systems such as the Indian-native Ayurveda and traditional Chinese medicine have been practiced for thousands of years and continue to be in the present day. The eastern and western parts of the world, however, differ in their traditional medical practices. The west has come across CAM only recently compared to the eastern part of the world, home to the earliest civilizations. Herbal medicine, either in the form of medications or dietary supplements, is just one of the most prevalent forms of CAM being utilized. It is estimated around one-third of the U.S. population resorts to medicinal herbs for treatment of illnesses or ailments.[3]

Western medicine relies heavily on use of prescription drugs in management of disease. However, there has been increasing public aversion to synthetic drugs, in favor of herbal products. Pharmaceutical medicine advocates and herbal medicine supporters have polarized into two opposing groups, each pushing to promote one approach over the other. A 2016 Pew Research Center survey study showed

that around two-in-ten U.S. adults would opt for alternative medicines, including herbal medicines, over conventional treatment.[4] However, the biggest difference between conventional and herbal medicine is the lenient FDA-regulation, accompanied by minute stipulations on herbal products when introduced into the market. Consequently, unregulated herbal medicine-use may pose a threat to patients' health and life, especially after considering that 37.8% of hypertensive patients and anywhere between 2% and 46% of patients with different forms of cardiovascular disease internationally report self-medicating using herbal medicines;[5,6] these percentages are as high or even higher among arthritis (43.0%), cancer (43.1%), and stroke (48.7%) patients in the United States,[7] but this article will limit its scope to hypertension (HTN) and cardiovascular disease (CVD).

As a corollary to non-regulation, patients are often unaware of the potential health risks and complications (allergic reactions, asthma, organ damage, and seizures) arising from unregulated doses of herbal medicines.[8] In fact, in 2004, the FDA prohibited the sale of ephedra-alkaloid-containing herbal dietary supplements, declaring them as adulterated and requesting users to immediately stop their consumption following more than 18,000 reports of adverse-events, including deaths.[9,10] This is further exacerbated as evidence suggests a prominent patient preference to not disclose their use of traditional forms of medicine, including herbal products, to their primary care physician. Globally, traditional medicine disclosure rates vary between 7.6% and 48.2%,[11] and the 2002 National Health Interview Survey showed that only 33% of herbal medicine users in the United States disclose their self-medications to their primary care physicians.[12] Hence, the current surge in uncontrolled use of herbal medicines in the U.S., particularly among patients with HTN and CVD, is a public health issue falling within the realms of patient autonomy, physician beneficence and physician-patient relationship.

The purpose of this paper is threefold: to (1) underline the motivations behind taking herbal-medicines as well as some perils associated with their use for the treatment of HTN and CVD, (2) raise awareness, especially among patients suffering from HTN and CVD, on the importance of disclosure of intentions/current acts of self-medication to primary care physicians, and (3) provide an ethical basis to impose stricter regulations on herbal medicines/dietary supplements.

SOCIAL TRENDS

Historically, different cultural groups, including Native Americans, across the United States have resorted to herbal medicine as a front-line treatment of illnesses or for dietary supplementation.[13] Herbal medicine-use is also prominent among members of the African American community. As part of an extensive medical folklore arising from a decades-long mistrust in healthcare institutions, African Americans turned to different forms of CAM, notably herb and plant-based recipes for the treatment of ailments and illnesses such as high blood pressure, headaches, and stomach disorders.[14] Furthermore, a 2013 study showed that around 30% of both the Asian and the Hispanic communities, geographically distributed across the United States, use herb-based medicine.[15] Notably, a 2017 study showed that people of older age, higher than high-school-educated, users of over the counter medications, prescription medications, and/or mail-pharmacy were more likely than the other study participants to resort to use of herbal medicine in conjunction with their current medications.[7] Moreover, a 2016 survey study showed that around 18% of respondents who had never taken over-the-counter medications, potentially out of fear of pharmaceuticals, preferred trying alternative medicine before conventional medicine while 27% preferred alternative medicine in conjunction with conventional medical approaches.[4]

The motivation underlying patients' decisions to opt for herbal medicine, disregard prescription medication, and even discredit physicians' advice is multifactorial. A major factor is public skepticism fueled by social media attacks and negative publicity on pharmaceutical companies' activities, deals, and marketing strategies. Pharmaceutical companies have repeatedly made headlines because of deadly clinical trials, drugs proven ineffective and withdrawn from market after FDA-approval, and scandals.[16] A 2023 study by Gallup estimates that 60% of Americans have a negative view on pharmaceutical companies.[17]

Another prevalent belief is that "natural means safe".[16] The term "natural" appeals to people better than "man-made" or "synthetic" does; this is further exacerbated by data showing that drug-related morbidities account for 15.4% of hospital admissions worldwide.[18] Public fear, thus, plays a role also in pushing people towards herbal medicine. By the same token, people tend to associate "natural" with "affordable" or "cheap" compared to the more expensive pharmaceutical drugs.[16]

A third reason is people's inclination to falsely assume a causal relationship instead of a correlational one. Anecdotal evidence seems implicated in the arguments of many herbal medicine advocates and CAM users, in general.[16] Many of these "success stories" may please listeners; however, observational studies and case reports/testimonies do not provide sufficient evidence to infer a cause and effect. It's easily misleading to ascribe a successful treatment and recovery to one factor that may have interacted with many other confounds.[19] Regardless, case reports seem to be sufficient evidence to garner people's support of herbal regimens or treatments.

In addition, dissatisfaction with past conventional medical treatments and sustaining family tradition are two leading causes for the use of herbal medicine.[20,21] Across various societies, family and community traditions, including herbal recipes for treating illnesses and ailments, are upheld across generations as symbols of cultural identity. On the other hand, choosing herbal medicines because of dissatisfaction with past treatments ties into a desire for self-control over treatment and may explain the large percentage of chronically ill patients reporting using herbal medicines.[22]

HISTORY OF HERBAL MEDICINE

Herbal medicine appears to date back as early as the lower and middle Paleolithic age.[23] Analysis of the oral cavity of a Homo erectus, who lived 1.7 million years ago, suggests the early use of antibacterial plants. Evidence also suggests that medicinal plant-use extended well into the Neanderthal period, from about 300,000 to 40,000 years ago.[24,25]

The earliest human civilizations heavily relied on herbal medicines. An Indian-originated clay tablet dating to 3,000 B.C. references more than 250 plants used in drug preparations at the time.[26] Likewise, a 20.23-meter-long Egyptian papyrus called "Ebers Papyrus" dating to approximately 1536 B.C. enumerates over 700 plant-based drugs, including gargles, infusions, and ointments.[27,28] By the start of the first millennium A.D., historical records were more prominent and so were records of popular contemporary herbal medicines. Dioscorides, a first century Greek physician and pharmacist in the Roman Army, wrote the first pharmacopeia, a catalog of drug descriptions and preparation procedures, called "De Materia Medica" in 65 A.D.[29,30] Notably, 657 of the 944 drugs mentioned in the pharmacopeia were derived from plants, with the majority possessing mild and few others proving strong therapeutic effects.[29]

Hundreds of years later, Li Shi-Zhen, a traditional Chinese Medicine practitioner and writer during the Ming dynasty, published the most renowned Chinese traditional medicine pharmacopeia, The Compendium of Materia Medica, in 1596. The book, later earning the distinction of "China's 16th century encyclopedia" included 1,892 different kinds of herbal medicines and a corresponding 11,096 herbal formulae.[31] In the meantime, monasteries in the western world became centers for herbal treatments; the monks and hermits grew and cultivated medicinal plants, hence assisting the sick and herb-seeking apothecaries.[30]

By the late 18th and early 19th century, herbal medicine began to accrue popularity in America, and herbal medicinal schools of thought began to flourish.[29] The mid-19th century witnessed a breakthrough in therapeutic herbal extracts, particularly with the advent in study of alkaloids though use of alkaloid-containing plants dates back to 2000 B.C. in ancient Mesopotamia.[32]

In 1906, the United States' President Theodore Roosevelt signed into effect the Pure Food and Drugs Act. This Act imposed the strictest regulations at the time on marketed botanical products. Nonetheless, botanical products, mainly concentrated extracts and tinctures, remained popular for the next 30 years until they fell out of favor with the onset of synthetic drugs. Fully synthetic products at the time were under patent protection and easier to standardize. Thus, they were more appealing to manufacturers than botanical products. By 1960, almost all medicine sold in pharmacies in the U.S. was synthetic.[33]

Herbal medicines soon regained popularity in the U.S. as European studies in the 70s and 80s supported the therapeutic effect of some herbal products, including echinacea and saw palmetto. Companies, however, invested minimally in herbal products because of their lack of patentability. As a result, the FDA did not have necessary evidence to support the efficacy of herbal products. Fearful of uncontrolled claims of herbal products' effectiveness in treating diseases, the U.S. Congress passed the Dietary Supplement Health and Education Act (DSHEA) of 1994. The DSHEA did not ban herbal products but prohibited issuing claims of therapeutic effects of herbal medicines.[33] Still, herbal medicines were and are to this day considered dietary supplements and thus do not need the same clearances as pharmaceutical drugs do.[34] The FDA allowed for statements on herbal products' effects on the human body and function, only if accompanied with a statement on

that the product is not FDA-tested and not purposed for diagnosing, treating, preventing, or curing a disease. Despite the FDA's subsequent suggestion to change the definition of disease to include any deviation from normal metabolism to ultimately expand its regulation of herbal medicines, the attempt failed, and herbal products have persisted in the market.[33]

MEDICAL, PHARMACOLOGICAL, AND FINANCIAL PERSPECTIVES

Patient Strive to Autonomy

Conventional medicine is the backbone of modern medicine. It relies on treatments rigorously developed through research and clinical trials, ensuring that medications have well-defined mechanisms of action, standardized dosages, and documented side effect profiles. In the management of HTN and CVD, first-line agents like chlorthalidone, lisinopril, losartan, and amlodipine have been extensively studied for their efficacy in reducing blood pressure, managing cholesterol levels, and preventing heart attacks, providing a reliable and evidence-based approach to current popular treatments. The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) is one study that influenced the development of current hypertension treatments; it evaluated the effectiveness of three commonly used blood pressure-lowering medications– amlodipine (a calcium channel blocker), lisinopril (an angiotensin converting enzyme inhibitor), and chlorthalidone (a thiazide-type diuretic)– and concluded that thiazide-type diuretics are better at preventing various forms of cardiovascular disease and are more affordable than angiotensin-converting enzyme inhibitors and calcium channel blockers.[34] Despite such studies, clinicians have seen the increasing use of CAM, especially in the treatment of HTN and CVD.

According to the 2017 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines, over 50% of US adults who are taking antihypertensive medications are not achieving blood pressure (BP) goals.[36] This may be due to patient non-adherence, or a general lack of understanding of their medications. Therefore, some patients might prefer utilizing adjunctive treatment strategies to cope with their underlying disease(s); this leads to significant challenges for clinicians as these patients believe the herbal medicines being used are natural and thus safe. In a review study done by Chrysant, S analyzing the complementary medicines and food supplements used by patients for management of their hypertension, it was noted that patients that used CAM desired greater autonomy in the control of their disease(s).[36]

Risks of Herbal Medicine-Use and the Discrepancies Between Herbal Medicines and Pharmaceuticals

Herbal medicines come with a plethora of side effects. As these medications are labeled as food supplements, they do not pass through the rigorous testing required by the Food and Drug Administration (FDA). These medications are largely marketed as safe, and attractive advertisements by manufacturing companies promote their use. With an increasing patient burden on clinicians, adequate information is sometimes not provided to patients. Therefore, some patients may not fully understand the need for conventional medical management. In a recent report, it was noted that nearly 25% of U.S. adults reported taking a dietary supplement along with their prescription medication(s) for the control of their underlying disease(s) without sufficiently understanding the herb-medication interactions.[37] This is even more concerning when patients take these supplements without informing their healthcare providers, increasing the risks of harmful side effects.[38]

Dietary supplements, defined as "a product (other than tobacco) intended to supplement the diet", provide nutrients that may be missing or insufficient in a person's regular food intake.[34] These encompass vitamins, minerals, herbs, botanicals, amino acids, and enzymes. The rise in popularity of herbal medicines continues to raise critical questions on their safety and efficacy. More importantly, their increase in favor necessitates examination of their role in medical treatment given the eased FDA-regulations governing herb-based products and dietary supplements. Although the FDA reviews New Dietary Ingredient (NDI) applications for potential safety concerns, manufacturers are not required, under DSHEA, to submit efficacy or safety data with their NDI applications.[39] Consequently, herb-based dietary-supplement manufacturers do not have to prove their products' effectiveness or safety. Instead, the DSHEA places the burden on the FDA to demonstrate that consuming a certain herb-based dietary supplement product or ingredient is unsafe.[39]

Additionally, the DSHEA classifies these products as goods "intended to supplement the diet", rather than drugs, eliminating the requirement of effective clinical trials assessing the safety and efficacy of these products.[39] While some alternative treatments have demonstrated efficacy in

clinical trials, certain pharmacodynamic factors like their mechanisms of action are often not as well understood. For example, herbal supplements, such as St. John's Wort, vary in active ingredient concentrations and quality,[40] rendering standardizing dosages and reliably predicting long-term outcomes challenging.

Some dietary supplements commonly used for the treatment of HTN include American ginseng (AG), St. John's Wort, and Ginkgo, among others. In a study done by Mucalo et al., the use of AG reduced the BP in patients with HTN compared with placebo.[41] However, it has been noted that AG has significant drug interactions especially with high-risk medications, decreasing the activity levels of some drugs like warfarin.[42] Gingko has long been used for the control of BP and CVD, which has been supported by two systematic reviews showing a decrease in BP.[43,44] However, it, too, has been implicated in severe drug interactions with certain medications, such as warfarin and nifedipine, already being used by patients with HTN or CVD.[45]

Unregulated use of herbal medicines in conjunction with prescription medications may harm patients through in-vivo herb-drug interactions. Simultaneous use of both herbal medicines and synthetic drugs may not be for the intent of treating the same disease; a patient may be self-medicating one condition using over-the-counter herbal supplements while taking prescription medications to manage another condition. For example, a patient living with HTN and depression may be taking prescription medications for either condition and herbal medicines for the other. However, clinical data suggests that select herbal supplements may interfere with a drug's metabolic activity; Saint John's wort (SJW) is only one of those supplements.

Despite its indicated anti-depressive effects,[46,47] SJW-containing products are banned in France and limited to prescription use in several countries, including Germany and Ireland.[48] SJW's drug-interactions are alarming, especially when taken with prescription medications. For instance, SJW's main mechanism of interaction is the induction of cytochrome P450 isoenzymes and P-glycoprotein transporters. Thus, when simultaneously taken with medications relying on cytochrome P450 and P-glycoprotein for their metabolism, SJW may impair the medications' effectiveness. For example, SJW has been shown to decrease the serum concentration of rivaroxaban— a blood thinner prescribed for reducing the risk of recurrence of deep vein thrombosis (DVT) and pulmonary embolism (PE)— when taken in conjunction with one another.[49] The reduced therapeutic effects of rivaroxaban risks patients suffering from a recurrent DVT or PE. The latter is a prime example of how unregulated access to over-the-counter herb-based supplements may prove harmful to patients' health, potentially threatening their lives.

Furthermore, with the increasing use of herbal medicines and dietary supplements, there has been a proportional increase in herbal medicine- and dietary supplement-induced liver injury, accounting for as much as 20% of reported cases of hepatotoxicity in the U.S.[50] Clinicians are already managing an increasing number of cases of liver disease in the form of Non-Alcoholic Steatohepatitis (NASH) and alcohol-induced cirrhotic liver disease; hepatotoxicity secondary to use of herbal medicines further exacerbates this burden.

Costs of Herbal Medicines & Pharmaceuticals

Despite the associated risks, the per-year out of pocket spending on complementary and alternative medicine continues to rise, accounting for 9.2% of out-of-pocket healthcare spending in 2012.[51] The total spend on complementary and alternative medicine at that time was $14.7 billion on visits to providers and $12.8 billion on nonprescription supplements.[52] Since then, use of complementary and alternative medicine has only increased.[53]

As herbal medicine has become an increasingly popular approach to treating chronic diseases, commonly used supplements by HTN and CVD patients include American ginseng (AG), St. John's Wort, Ginkgo, and fish oil. These herbal remedies are highly affordable and easily accessible, making them an appealing option for those whose only other recourse is expensive, brand name pharmaceuticals. Table 1 shows the cost per dose of these herbal medicines.

Table 1

Cost per Dose of Herbal Medicines Used in the Management of Cardiovascular Disease[1]

Medication	Cost/Dose ($)
American Ginseng	0.26[54]
St. John's Wort	0.06[55]
Ginkgo	0.05[56]
Fish oil	0.86[57]

[1] Cost per dose of herbal supplements varies widely depending on the brand and the strength of the dose. The costs represented in the table are for the lowest dose available.

Unlike FDA approved pharmaceuticals, these natural remedies are often not covered by private insurance and are never covered by Medicare which only provides coverage for prescription drugs.[62] First-line management of hypertension includes either an angiotensin converting enzyme inhibitor (ACE-I), non-dihydropyridine calcium channel blocker (CCB), or a thiazide diuretic.[36] First line management of cardiovascular disease includes therapy with a statin such as atorvastatin.[63] The cost per dose of lisinopril (an ACE-I), amlodipine (a CCB), chlorthalidone (a thiazide diuretic), and atorvastatin is found in Table 2. While the costs for the pills themselves may be comparable, obtaining these medications requires a prescription and therefore a visit to a healthcare provider. The need for an office visit can be a significant barrier, especially for those who are uninsured.

Table 2

Cost per Dose of First-line Antihypertensives and Lipid Lowering Agents[2]

Medication	Cost/dose ($)
Lisinopril	0.12[58]
Amlodipine	0.16[59]
Chlorthalidone	0.26[60]
Atorvastatin	0.61[61]

[2] Cost per dose of herbal supplements varies widely depending on the brand and the strength of the dose. The costs represented in the table are for the lowest dose available.

Exemplary Uncertainty About Herb-Based Products

Though some dietary supplements get backlash because of the lack of safety and efficacious data reported through clinical trials, omega-3 fatty acid-containing products are one of the most studied dietary supplements used for the treatment of CVD, specifically coronary heart disease (CHD), and its lipid-lowering effects. Omega-3 fatty acids are polyunsaturated fatty acids found naturally in some plants, fish and other marine life.[64] Omega-3 supplements contain three primary types of fatty acids:

1. Alphalinolenic acid (ALA)
2. Eicosapentaenoic acid (EPA)
3. Docosahexaenoic acid (DHA)

These polyunsaturated fatty acids play a crucial role in maintaining various functions within the body. They are termed "crucial" because the body cannot synthesize them on its own, so they must be obtained through diet or supplements. Currently, the American Heart Association (AHA), recommends "patients with documented CHD take ~1g of EPA and DHA" obtained from either oily fish or omega-3 fatty acid capsules, only after consultation with a physician.[65] Despite the AHA's position, however, there is no conclusive data confirming fish oil treatments' effectiveness in managing CHD. The Diet and Reinfarction Trail (DART), a randomized controlled clinical trial to investigate diet's influence on secondary prevention of myocardial infarction, is currently the strongest piece of evidence for fish oil's therapeutic potential. It yields that "men who were instructed to eat fish after myocardial infarction (MI) had a 29% decline in all-cause mortality as compared with those in the placebo group; however, no significant reduction in cholesterol levels was observed".[66]

Importance of Consulting Health Care Professionals

The SPORT trial is a single-center, randomized, controlled study designed to compare a low-dose statin (rosuvastatin) with placebo and common supplements for reducing LDL-C ("bad cholesterol") and inflammatory markers.[67] Participants with an increased risk of CVD but no history of it, and an LDL-C level between 70-189 mg/dL were recruited.[67] They were randomized to receive 5mg daily rosuvastatin, placebo, or supplements like fish oil, cinnamon, garlic, turmeric, plant sterols, or red yeast rice for 28 days. The primary endpoint, a change in LDL-C levels compared to baseline, was significantly greater in the rosuvastatin group compared to the supplements and placebo groups, emphasizing the importance of HTN and CVD patients consulting with healthcare professionals before taking over-the-counter supplements.

Though dietary supplements play a role in helping individuals manage nutrient deficiencies, health conditions, and promote general wellness, their role is best seen as a complement, not a replacement, to a healthy lifestyle. Unlike conventional medications that undergo rigorous testing and have well-established effects, supplement regulations are less strict, and scientific evidence for many advertised benefits is lacking.

ETHICAL PERSPECTIVE

Proponents of scientific investigation have long disregarded herbal medicines and dietary supplements (for which clinical data is minimal or nonexistent) as a viable form of medicine, maintaining that "there is only scientifically proven, evidence-based medicine supported by solid data, or unproven medicine for which scientific evidence is lacking".[68] However, with at least 12% of U.S. citizens, anywhere between 1% and 73% of the foreign-born U.S. population, and around 4 billion people worldwide, having resorted to its use,[7,15,69] herbal medicine has certainly attracted people's attention, whether because of financial motives, customs and traditions, patient dissatisfaction with former treatments, or even herbal medicine's appeal to patients as "natural" and thus safe.

Therefore, per the article's purpose of raising patient and physician awareness of the dangerous trends of patients self-medicating using herbal medicines, the following ethical argument will briefly assess the current status of herbal medicines through the scope of the basic bioethical principles of autonomy, beneficence, non-maleficence, and justice. It will also underline the need for stricter FDA regulations and mandating physician inquiry into patients' use of non-prescription-medications or herbal products during clinical visits.

Principle of Autonomy

By the principle of autonomy, a person has the right to exercise self-determination, and, when applied to the medical field, it guarantees a patient the right to make choices that resonate with their values and beliefs. Therefore, patients living with HTN and/or CVD have the right to autonomously use herbal medicines for self-medication, especially if motivated by frustration from a personal history of ineffective medical treatments. However, proper exercise of autonomy stipulates that patients act out of informed consent, which requires professional disclosure, comprehension of information, voluntariness, and competence to consent. Therefore, patients making informed decisions must be sufficiently and reliably informed about the benefits, risks, and side effects of using certain herbal medicines, especially if taken in conjunction with prescription medications. However, 9 out of 10 American adults face trouble understanding, interpreting, or even finding medical information.70 In other words, patients who conceal self-medicating using herbal medicines and settle for information available online often misinterpret medical information and potentially fall into a trap of confirmation bias. Therefore, physicians have the ethical obligation to address patients' self-medication habits in a non-judgmental manner. Physicians must be frank about the current scientific data on the safety and efficacy of the used herbal medicines.

As of July 2024, relatively little scientific data on the various herbal medicines is available and strides for scientific investigation are limited considering the FDA's eased regulation of herbal products– requiring printed information stating the product is not FDA approved and not intended for the treatment or prevention of diseases.[71] However, FDA-permitted nuanced language, suggesting the herbal product at hand may enhance physiological processes, promote recovery, and potentially yield other health-benefits, can certainly lead patients to believe these products have proven medical uses. Is such language a form of deception? Do the words "promote" and "enhance" not propel consumers into believing herbal medicines are safe and effective? Also, the mere over-the-counter availability of herbal products may reassure consumers of the appropriateness of their unregulated use. Consequently, the prevalent "status quo, best described as 'don't ask and don't tell', among physicians must be abandoned".[72] The current lack of clinical trials and scientific data available can no longer serve as an excuse for physicians' failure to discuss the potential perils of self-medication with their patients. In fact, patients have the right to full physician disclosure of all available treatment options, including herbal medicines if scientifically proven, and the associated side effects. However, until FDA-regulation of herbal medicines is tightened, adequate scientific data on the safety, efficacy, side-effects, and in-vivo drug interactions of herbal medicines will probably remain out-of-reach, thus exacerbating physicians' unfamiliarity with these products. In turn, patients' informed decision-making will be difficult at best and hazardous at worst.

Principles of Beneficence & Non-Maleficence

In medical ethics, the principle of beneficence mandates the prevention, removal, or minimization of harm and risk,

alongside promotion and enhancement of the patient's good. The principle of beneficence is often coupled with the principle of non-maleficence, which prohibits the infliction of harm, injury, and death onto others. By both principles, physicians have an ethical duty to act in the patients' best interest, having the latter take precedence over the physicians' own interest.

Adverse in-vivo drug interactions are responsible for around 100,000 American deaths every year;[73] such interactions may be compounded with unmonitored herbal-medicine-use. Although the FDA has established MedWatch, a program for consumers and healthcare professionals to report adverse drug interactions, such a program is ineffective in addressing patients' failure to disclose their self-medication habits. As per the principle of beneficence, medical professionals must advocate for clinical studies, at least on the more prevalent herbal medicines. Federal policies on herbal medicines must also be reviewed to encourage federally authorized clinical trials while accommodating for the FDA's budget deficits.[74]

Aside from the aforementioned, the status quo of herbal medicine violates the principle of non-maleficence. In light of the eased federal regulations, the little knowledge of some herbal medicines' in-vivo drug interactions, and the poor physician-patient communication over self-medication, physicians may be indirectly endangering their patients' health, exposing them to preventable injury, harm, and/or even death.

Principle of Justice

According to the principle of justice, all people deserve to be treated fairly and equitably. "Fairness suggests that patients have fair access to alternative medicine therapies as well as conventional therapies that are known to be safe, effective, and appropriate for their conditions. Nevertheless, because little clinical research has evaluated alternative medicine, few data support claims for fair access to these therapies."[75] Provided that some herbal medicines, such as Sinecatechins and Crofelemer, have proven to be medically effective, it's unjust to settle for potentially therapeutic products remaining untested and not investigated for their medical uses. Furthermore, by identifying which herbal medicines have therapeutic potential, clinical investigations may help minimize unnecessary spending on non-prescription supplements, aligning with the principle of justice.

RECOMMENDATIONS

From the healthcare providers' standpoint, the undeniable risks of self-medication using herbal medicines call for a set of regulatory, clinical and educational reforms to minimize possible harm to patients:

Routine physician inquiry into patients' use of herbal medicines and dietary supplements must be mandated during patients' clinical visits.

Patient education, both in clinical and non-clinical settings, is essential to increase the users' and non-users' awareness of potential risks associated with misusing or overdosing on herbal medicines. While a growing culture of individualism has motivated many to seek greater autonomy over medical treatments through self-medication, patients are often unaware of the side effects and the recommended/safe doses when consuming specific medicinal herbs, which are still not thoroughly studied and understood. Thus, it is imperative for medical professionals to allocate time to impartially address patients' use of minimally investigated herbal products while respecting patient autonomy— offering both benefits and drawbacks on a case-by-case basis. Likewise, raising consumer awareness must be initiated in pharmacies, herbal markets and shops.

In-depth pharmacological and clinical tests must be conducted to validate beliefs or claims on the effectiveness of popular herbal and other botanical medicines in treating certain prevalent/common diseases. Guidelines on safe doses per body weight and frequency/duration of consumption of these products must be established to mitigate long-term damage caused from repeated intake of harmful doses.

Considering the uncontrolled financial growth of the herbal medicine sector and the thousands of annual ER visits and subsequent hospitalizations because of dietary supplements and phytotherapeutic product misuse,[76] laws designating herbal products as dietary supplements and thus exempting them from pre-market approval and FDA-assessment of product's compliance with Good Manufacturing Practices (GMP) guidelines must be altered so that the herbal medicines are subject to stricter regulations that may, in turn, help advance the medical field and ameliorate patients' treatment experience. For instance, as of November 2023, Sinecatechins and Crofelemer are two FDA-approved herbal products, now marketed as Veregen® (for treatment of warts outside of genitals and perianal area) and Mytesi® (for treatment of diarrhea), respectively.[77]

Continued medical education (CME) opportunities must underscore, or even revolve around current trends in herbal-

medicine-use, educating physicians on the origins, common uses, potential benefits, and reported side effects of consuming certain botanical products. Similarly, medical, physician assistant, and nursing schools' curricula must account for the rapidly diversifying field of herbal medicine by educating future health professionals on these products.

CONCLUSION

Use of herbal medicine and/or dietary supplements in the U.S., especially among patients suffering from chronic diseases such as HTN and CVDs, has surged uncontrollably in light of the lack of FDA regulation. Therefore, this article sought to address the alarming trends of patients self-medicating using herbal medicines, offering insights into herbal-medicine-use from medical, pharmacological, financial, and ethical perspectives.

Herbal medicine users fall into two categories: those who use herbal products in conjunction with prescribed medications, and those who resort to herbal medicine instead of conventional treatments for chronic diseases. Although allegedly effective in managing or even treating some medical conditions,[78] herbal medicines and supplements may cause patients considerable medical complications ranging from decreased drug metabolic activity in those simultaneously consuming other drugs to hepatotoxicity because of unregulated dose intake.

Therefore, in accordance with the basic bioethical principles of autonomy, beneficence, non-maleficence, and justice, a series of national clinical and federal reforms, ranging from healthcare providers initiating conversations about herbal-medicine-use to the FDA imposing stricter regulations on herbal medicines, must be considered to address patients self-medicating and avoiding professional medical supervision.

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Author Information

Irtza Badar, M.D.
PGY-3, IM Residency Program, Mercy Fitzgerald Hospital
Darby, Pennsylvania, USA

Fredy J. Abboud
Research Fellow, Institute of Clinical Bioethics, Saint Joseph's University
Philadelphia, Pennsylvania, USA

Peter A. Clark, S.J., Ph.D.
Director of Institute of Clinical Bioethics, Saint Joseph's University
Philadelphia, Pennsylvania, USA

Prenin George, PGY-3, PharmD. Candidate
Saint Joseph's School of Pharmacy, Saint Joseph's University
Philadelphia, Pennsylvania, USA

Bridget McNierney
Graduate Research Fellow, Institute of Clinical Bioethics, Saint Joseph's University
Philadelphia, Pennsylvania, USA

Joseph Kelly
Senior Research Fellow, Institute of Clinical Bioethics, Saint Joseph's University
Philadelphia, Pennsylvania, USA

Maria-Lainie Galdo
Research Fellow, Institute of Clinical Bioethics, Saint Joseph's University
Philadelphia, Pennsylvania, USA