Roundtable Discussion:

Women's Health—Menopause and Related Conditions

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Participants: Ellen Kamhi, PhD, RN, AHG, AHN-BC, Fredi Kronenberg, PhD, Tieraona Low Dog, MD, Amanda McQuade Crawford, DipPhyt, RH (AHG), and David Sollars, LAc

Catherine Ulbricht: We are here today with a multidisciplinary group of clinicians and scientists to discuss women's health—specifically, issues concerning menopause. During this roundtable discussion, we will address a range of topics related to perimenopause and menopause, such as hot flashes, sleep disorders, dysmenorrhea, mood disorders, and osteoporosis—all of which may be indications for medical intervention. Other issues we will touch upon include the changes in memory, libido, and lifestyle that are associated with menopause.

To cope with the changes that occur with menopause, many women use a number of complementary and alternative therapies—also known as integrative therapies—which are often used along with conventional therapies, in addition to special diets and changes in lifestyle, to help ease this natural transition.

I represent the Natural Standard Research Collaboration, which conducts evidence-based systematic reviews of the safety and efficacy of natural agents, such as sage and rose hips, for the treatment or prevention of various health conditions. Our research produces a “report card,” so to speak, that is based on a validated, reproducible scale developed from an analysis of the world literature done by the U.S. Preventive Services Task Force.

On our report card, the following agents get a grade “B” for treating these respective conditions: calcium for premenstrual syndrome (PMS); rosehips for dysmenorrhea; and black cohosh for menopausal symptoms. A grade of “B” indicates that the therapies have good scientific evidence that supports their utility in treating these conditions. Calcium could even be considered part of conventional medicine because it has Food and Drug Administration [FDA]–approved health claims for osteoporosis, which is relevant to menopause. Have any of you had clinical or research experience with any of these treatments in terms of their effectiveness, safety, potential interactions, and other factors?

Tieraona Low Dog: Although I think that many of us do not use a single approach to premenstrual syndrome, if a woman comes in with PMS, calcium and chasteberry would be fairly high on my list of treatments, probably with some magnesium to counteract the constipating effects of calcium.

Some formulations for hot flashes and night sweats use sage, particularly for excessive sweating. Sage is also used to dry up breast milk. The only thing I would be concerned about with sage is to make sure that women understand the difference between dried sage, sage tincture, and essential oil of sage. That distinction is important, because sage contains thujone, which can act as an abortifacient and cause seizures and is concentrated in the essential oil, with small amounts in tincture and very little in sage tea. Because excessive or long-term exposure to thujone can be toxic, the best way to use sage is as a tea or in capsule form.

Ellen Kamhi: I think that issues of women's health are one area in which natural interventions really shine. Since 1964, I have had wonderful results with it clinically, especially in treating infertility, which is admittedly at the other end of the spectrum from menopause, and I think one reason for this success is that a holistic approach can be made very specific for the individual client.

The people who are worried about infertility are usually couples who are often younger and who usually have very happy lives other than having been unable to conceive. As far as their health is concerned, they may not have eaten one single nutritious meal in their lives, and many of today's generation of 30-year-olds have been raised almost totally on junk food. Even a bit of a transition to healthy eating helps them, which I think is important for every stage in the female life cycle.

With regard to improving fertility, I would use some other supplements before calcium. They include magnesium, particularly through foods that have high magnesium content, such as kale, Swiss chard, collard greens, and almonds. I also like to have my patients who seek fertility start taking snacks wher-

ever they go, such as organic rice cakes, almond butter, or an avocado in their cars. Avocado—which in Mexican culture is the symbol for fertility—seems particularly effective for infertility, with a high content of a lot of the nutrients that are deficient in couples with infertility. Pomegranate, also known as the love apple, is another fruit whose chemistry is good for fertility. When you use such whole foods, you don't have to worry as much about dosages and possible interactions as when you use isolated nutrients, although some nutrients in foods can be problematic in this respect.

And as Dr. Low Dog mentioned, I would look at the chaste tree, *Vitex agnus-castus*, although we would certainly recommend stopping its use once pregnancy begins. Vitex can also be useful during perimenopause and menopause.

CU: In a natural therapist's world, calcium, sage, chasteberry, and some other integrative therapies are not necessarily backed by the formal clinical testing that supports conventional treatments. Therefore, according to the Natural Standards Research Collaboration grading scale, they might, for example, get a grade of C instead of B. However, that doesn't mean that inte-

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grative therapies don't work. Evidence gathered from historical use and daily practice—from observing and monitoring patients—is sometimes just as strong and important as scientific evidence, and I think that that balance is really important.

Sometimes, the published medical literature does not necessarily reflect what we see in day-to-day practice, especially in the case of some complementary modalities such as acupuncture or acupressure and *shiatsu* for the treatment of infertility and perimenopausal symptoms. The absence of a randomized controlled trial [RCT] does not mean that a treatment isn't providing benefits that can be relatively cost-effective. Some integrative therapies may have fewer and milder side-effects than conventional medical therapies.

David Sollars: Thank you. I can say that acupuncture, *qigong*, nutrition, and Chinese medicine have shown consistent clinical outcomes for improving a number of conditions in women's health care, [which has been] long and extensively used in managing both infertility and the effects of menopause. There is a growing body of literature, which guides my judgment as a practitioner, and patient education for assisting a woman's health on her journey through the natural phases of her life.

With regard to infertility, I have found, as Dr. Kamhi has, that the people seeking treatment for this issue are generally thoughtful couples who choose to have children and are willing to go through a gauntlet of challenges to achieve the desired results. The couples are very commonly using assisted fertil-

ity, especially acupuncture, for which studies have provided us with an expanding body of literature.

The past 5 years has yielded both studies and empirical data from acupuncture providers and assisted-fertility centers. The therapeutic effect of acupuncture as an antispasmodic, anti-inflammatory, circulatory catalyst and hormone regulator, continues to show promising outcomes for individuals seeking assistance with fertility challenges.

We consistently hear from our patients who are being closely monitored by assisted fertility centers, while undergoing procedures such as intrauterine insemination [IUI] as well as in vitro fertilization [IVF], that acupuncture treatments have helped to create a more favorable uterine lining. This is optimal for egg implantation but is often an obstacle for these individuals. Many of them have undergone multiple procedures, so they are able to compare results from previous cycles before electing to add acupuncture as an adjunctive therapy.

I recently saw a patient who had just had her nineteenth IVF transfer, and she said that acupuncture had helped her feel calmer and more comfortable by greatly reducing her abdominal spasm, which had consistently marred her previous experiences. The current literature points to a 25%–45% increase in successful pregnancy when using acupuncture before and after IVF transfer procedures.

IUI and IVF are probably among the most stressful experiences that a couple can go through in their marriage, and acupuncture is a therapy that will help promote the release of serotonin and endorphins. While the exact mechanism for acupuncture is not understood, the therapeutic effects have been well-documented in many areas, including antispasmodic, circulatory, hormone-regulating and strong analgesic effects—all of which acupuncturists use clinically to assist couples coping with fertility concerns to create the best total environment for a healthy pregnancy to take place.

We are also often able to use acupuncture or Chinese herbs to help patients with preexisting medical conditions, such as polycystic ovarian syndrome, dysmenorrhea, endometriosis, and many other women's health challenges. I often see patients who have come off birth-control pills, which many of the women have been taking since they started menstruating. They often remark that they feel like they did when they were first beginning menstruating, in that their painful periods or PMS are still as bad as these women remember. Nothing has changed. It was just covered up.

Our therapeutic role is to assist a patient with appropriate diagnostic referrals and develop a treatment plan outlining options for care with us. A woman's use of assisted fertility may determine timetables and the availability of therapeutic agents, such as Chinese herbal medicine.

Considerations in using complementary or integrative medical methods need to be made when patients are also collaborating with assisted-fertility centers. Patients are often given intricate medication and examination regimens. While the feedback and information learned from the continual observation of patients are extremely valuable, they are often counseled not to use any herbal supplements. I certainly understand the reasoning behind this request.

Collaborative studies have not been done to show the effect of medications, herbals, and acupuncture on this population of patients. The physical and emotional stakes are high, making it even more challenging to do something outside of the current recommendations. We always comply when a medication regimen begins and limit our therapeutic involvement to acupuncture, which still provides significant benefits to the patient.

Beyond that, we encounter women who have a variety of medical histories that can often be managed with a complex Chinese herbal prescription. Many of these combinations have not been tested for interactions with prescription medications, supplements or foods, which can become a hurdle with couples that are making important choices in considering the use of natural methods for improving fertility. If you want to use such regimens, you should, at the minimum, find a company that tests for heavy metals and pesticides and make sure that your quality control is established and reliable.

The flexibility within a Chinese prescription is enviable when treating the symptoms associated with menopause. This full-system therapeutic approach gives the prescriber a highly adjustable customized tool that can address multiple layers of a patient's needs. Here's an example of what I see in the clinic when we discuss menopause. It is symptom driven, so most patients will present to the clinic for management of symptoms, such as hot flashes, night sweats, or insomnia. There is a point at which the disruption of their daily home or business life is now intolerable and they are seeking opinions and options. This is a highly educated and motivated patient population.

The presenting complaint may be hot flashes or night sweats. The next layer of issues may be past medical complaints that have been aggravated by menopause, such as anxiety or a symptom that is new to the patient since menopausal symptoms began. Again, anxiety and sleep disturbance are common in my experience. Another layer of experiences follow, which may include fatigue, headaches, increased thirst, decreased libido, and dryness throughout the tissues of the body.

Prescribing Chinese herbs involves reviewing all the layers of a patient's complaints and selecting herbs that fulfill multiple roles for a customized prescription. The herb *Xuan Shen*, *Radix Scrophularine Ningpoensis*, would be indicated for use when hot flashes, night sweats, feelings of being overheated, thirst, and overall dryness were predominant. The herb *Ye Jiao Teng*, *Polygoni Multiflori Caulis* would become predominant in a complex herbal prescription when fatigue, mild hot flashes, anxiety, and sleep disturbance were the main complaints.

I commonly have about twelve to fifteen herbal ingredients of various proportions in an herbal prescription. Each prescription is chosen for its multiple therapeutic effects on the patient's complaints, with the entire prescription having the flexibility to be completely modified based on the outcome. The individual and flexible prescribing makes the Chinese herbal system patient-friendly but is one of the challenges when studying the effects of these custom prescriptions.

Evidence for complex Chinese herbals is lacking, partly because different practitioners use a variety of methods and history-taking, while prescribing based on findings that these

practitioners consider important. I await more clarity regarding research methods and continue to help alleviate menopausal symptoms for my patients using acupuncture and individual customized Chinese herbal prescriptions. Our patient population has found these integrative approaches to be immensely useful and practically valuable.

TLD: There is a growing body of evidence for the utility of acupuncture in a wide variety of areas, and a couple of very well-done trials of its use in men undergoing androgen deprivation therapy for prostate cancer and experiencing hot flashes have shown that acupuncture has worked extremely well.

In addition, a very recent trial that compared acupuncture with the antidepressant venlafaxine for women who were having hot flashes from adjuvant treatment of breast cancer found that acupuncture was equivalent in effectiveness to venlafaxine in reducing hot flashes. When the patients were followed for 1 year after their 12-week treatment period, those that had taken venlafaxine began to have their symptoms return within

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2 weeks, whereas the group that had received acupuncture continued to have relief from hot flashes and night sweats, as well as showing improvement in their libido, sexual function, and in their quality of life.¹

I also want to go back to what Dr. Sollars said, to note that we use both Chinese herbal medicine and Western herbal medicine for symptoms of perimenopause and menopause. I have found, for example, that a lot of herbs can help patients with insomnia in menopause, but that hops might be more appropriate than valerian, and that you might include skullcap if you are looking for a nervine. There is a rich body of traditional evidence for the efficacy of herbs in these settings.

So I just want to reiterate what my colleagues have said, to the effect that integrative approaches have a lot to offer to help women feel better and improve the quality of their lives. I think all of us would agree that an integrative approach—with nutrition and, when appropriate, acupuncture, mind-body therapy, guided imagery, massage therapy, and herbal medicines, as well as needed medications—is really the approach that makes the best sense in any kind of situation, and particularly in women's health care.

Amanda McQuade Crawford: That is a good point. As Dr. Ulbricht pointed out earlier, evidence-based medicine isn't necessarily the same as good medicine, and when we look at grades of A, B, C for distinct agents, we're often missing the point that Dr. Ulbricht, Dr. Sollars, and others of our group here today have described very well.

For reasons that all of us could describe at length, symptoms related to menopause, beyond hot flashes and night sweats, have been on the increase for several generations, probably because of increasing stress, imbalances in sugar intake and metabolism, and various other factors affecting women. When we look at herbs, we find that many will reduce the symptoms associated with menopause, although these herbs would never really stand up to scrutiny for reducing hot flashes, for instance, in a placebo-controlled trial.

Sage is a good example of an herb that covers many different points here. It has traditionally been used foremost as a digestive remedy and improves the digestion of various foods. It is also an antispasmodic and reduces gastrointestinal gas and flatulence.

There are many reasons why sage has been of potent help in menopause. Besides helping digestion, sage helps liver function and is an astringent diaphoretic. This means, paradoxically, that sage reduces hot flashes and sweating though it moves body fluids more easily to the skin for evaporation. The net result is a more comfortable “insensible perspiration.” The herb’s astringent effect on drying excess body fluids is well-known to mothers using sage tea to decrease breast-milk production during weaning.

Sage is also a mild antimicrobial agent, which is why it is used to ease sore throats and for drying breast milk. As Dr. Low Dog noted, it is important to be careful about using the extracted essential oil of sage, which is not for internal use, and tinctures and capsules of sage, which have a generally reasonable safety profile in a dose of about 2–3 g a day.

An Italian study showed very good safety and very good response to sage in women with menopausal hot flashes,² and a Swiss study done in 2001 of a product that contained sage as well as alfalfa found improvement in a wide variety of symptoms, including hot flashes, in 75% of the women in the treatment group versus 47% who showed some improvement with a placebo.³ In the case of night sweats as a specific symptom, there was some worsening in the placebo group, whereas the group treated with the sage-containing product showed improvement.

Sage has also been used to improve memory among older people. An Iranian study done in 2003 showed that sage blocks the enzyme acetylcholinesterase, which breaks down acetylcholine and has a mild-to-moderate benefit for patients with Alzheimer’s disease.⁴

When we look at these effects together, we see that sage is a food-grade herb that is easily obtained. It has a long human history of use in a number of body systems, is affordable, does not have to be used as a standardized extract, does not have to be taken in a doctor’s office, and is not a danger to the rainforest.

As Dr. Sollars pointed out, sage is almost always used in the context of stress modification and not as a single agent, in which it would surely cause some side-effects, but rather with other herbs and supplements in the context of a woman’s unique constellation of symptoms—whether they be hot flashes, depression, arthritis, or changes in memory—addressed on a case-by-case basis. That is something that is amenable to reasonable research modalities but is just not the so-called “gold standard” of the past, when we were looking at a single agent.

CU: Just as Ms. Crawford said about sage—that it is being used for multiple menopause-related conditions—it is often used concomitantly with other herbs and natural products, and dosing and frequency are often tailored to specific patient profiles. Moreover, modalities, such as acupuncture, chiropractic, and spinal manipulative techniques have been studied for PMS, chronic pelvic pain, and dysmenorrhea, and it is very interesting to see that some of these complementary modalities can assist people who might be taking multiple medications or might be diabetic or have other needs that require careful monitoring for potential interactions.

In the case of insomnia, for example, there is strong evidence supporting the use of melatonin for jet lag and other forms of insomnia. Music therapy and *t’ai chi* are very cost-effective practices with few or no side-effects, and patients can practice these modalities in their own homes. Moreover, some of these modalities have growing scientific evidence supporting their use. It is exciting to see that the scientific evidence is starting to support the clinical experience with some of these therapies. Who might have guessed, for example, that music therapy could yield results equal to those with melatonin, an endogenous hormone, for aiding sleep?

Fredi Kronenberg: I would like to talk about obtaining clinical evidence for the efficacy of such integrative therapies, because it is challenging to do, particularly in the case of menopause. And even if there were the substantial funding necessary for all the studies we’d like to see done, clinical trials are not necessarily the only way to obtain data or reach the

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conclusions that we want. When studying soy for the treatment of hot flashes, for example, there have been many clinical trials, but it is difficult to compare among them because they are so mixed in terms of the populations studied and products being studied. These range from soy-based extracts to whole soy foods, and this diversity raises challenges in terms of comparability of results.

And in their peri- and postmenopausal years, women may have primarily one bothersome symptom (such as hot flashes), or they may have different constellations of symptoms. Moreover, different studies use different outcome scales. I don’t think that you can find more than a handful of studies that use exactly the same scale for measuring menopausal symptoms, be they multiple symptom indices or even hot flash intensity scales. And when a broad composite symptom measure is the primary outcome, it’s difficult to know what exactly, the particular remedy is good for or how it is acting.

And, in addition, there are issues such as the culture of the population being studied, the diet of that culture, and the country in which the study is done. We are just learning, for example, with new and increasing attention to the human microbiome—the bacteria in the human body—that the different intestinal flora in people from different countries influences how they metabolize various foods and drugs. A randomized controlled trial, although it can provide valuable information, tries (often not totally successfully) to involve a more homogeneous population than the real-life, more diverse populations who are affected by a symptom.

I think it's possible to get a handle on many of these variables and design better controlled studies, but it is very challenging to obtain, in a timely fashion, the kinds of results that physicians would like to see before prescribing an herb or other complementary and alternative medicine [CAM] therapy. That's why an integrative approach to therapy is so valuable. It is going to be a long time before we put together the data from multiple human, food, drug, and products that could be involved in the treatment of a particular symptom so as to be able to comprehensively understand it from a scientific point of view. In the meantime, an integrative medicine approach allows for the use of various remedies (in combination or sequentially) and can help to shed light on factors involved in the successful treatment of various symptoms, and perhaps even provide insight into mechanisms of action.

CU: Those are excellent points. For many decades, conjugated estrogens were promoted by conventional practitioners as effective treatments for patients with menopausal symptoms. Then a landmark study⁵ told practitioners they were all wrong and recommended that they not use this therapy any longer. That tells us that no matter how many studies and FDA-mandated phase examinations have been conducted, the recommendations or standards of care can change dramatically even for a product that has been used for a long time.

I'd like to move ahead and discuss cardiovascular health—particularly the statin drugs or coenzyme Q10. Statins are a class of drugs that have been on the market for a very long time, and they definitely have benefits for health and life. However, they have some potentially adverse effects and interactions, and some clinicians recommend that statins should be avoided in perimenopause and menopause. At the same time, some natural products for addressing menstrual symptoms, such as *dong quai*, evening primrose oil, and wild yam, have hormonal properties that, like traditional hormone replacement therapies, make them very controversial. Would anybody like to comment on this?

FK: I think that a double standard has been applied to the study of herbal remedies to treat hot flashes. People often say that we don't know how these remedies work and we should find out before we use them clinically. Estrogen has been used for more than 50 years to treat hot flashes, to mention but one symptom of menopause for which women find estrogen beneficial, and it does get rid of hot flashes in most people.

Yet in all these years, we have as yet not discovered how estrogen works to achieve that relief. We do not know the mechanism responsible for hot flashes, nor do we have any understanding of the mechanism by which estrogen eases them. It is therefore, a bit hypocritical for people to say: "We need to understand the mechanism of these herbal or other integrative approaches before we can use any of them." Certainly, we should do clinical studies and assess safety and efficacy; and an understanding of mechanism of action is valuable and can enhance clinical information. But, especially when we have safety and efficacy data, demanding mechanistic understanding prior to supporting clinical use is not reasonable.

TLD: I'm glad you said that, because I don't think that we want to give the impression that conjugated equine estrogen doesn't work for treating menopausal problems. It does work for hot flashes. But when I was in my residency and a woman was admitted to the hospital for chest pain, the cardiologist would come and evaluate her and leave a note on her chart saying, "before discharge, prescribe Premarin," or, if she had a uterus, "Premarin and Provera." The patient might have been a woman who was 66 years old and 16 years beyond menopause, yet she was put on hormones. And hormone therapy was not an FDA-approved treatment for heart disease, but was approved only for hot flashes, night sweats, and vaginal dryness.

AMcQC: The issue of traditional scientific evidence also raises the question of moving away from the traditional understanding of natural medicines. *Angelica sinensis*, or *dong quai*, for instance, isn't really a women's hormonal herb per se, but because it's been marketed that way, there are many misconceptions about *dong quai* that have led to its misuse.

Yet, the misconception persists that *dong quai* contains phytoestrogens or has a phytoestrogenic effect, whereas *dong quai* is in fact a blood-moving herb. My experience in China and in the United States with women who have been self-medicating with *dong quai* shows that it is really an herb that needs to be used for women with a specific constitution.

DS: Thank you for speaking up about that, because I think you are right on target about many herbs getting heralded commercially for a single particular use and then getting attention only for that particular use. Yet, typically, herbal formulas are set up so as to have many different uses, depending on the other substances with which they are combined. Some products typically use a single synthesized version of an herbal component for a single purpose. But there are typically many other choices that you can use for a particular need, and that is what is usually not explored.

Thus, if you are looking at *dong quai* and decide that the patient presents a concern for its use, you can almost always turn to something else. I will often substitute *Shu Di Huang*, *Radix Rehmanniae* or *Bai Shao*, *Radix Albus Paeoniae* for *dong quai* if I have any reservations. And that is why I think a provider-based health care system* makes sense, especially in integrative medi-

*This is a system in which providers guide treatment instead of patients engaging in self-treatment.

cine. I also think that, in order to have compliance with a treatment, you have to have effective communication. We typically explain the formulas used for treating a particular symptom or condition, what is in them, and why we have chosen these herbal ingredients. We invest in patient education so that our patients understand the process and our expectations for their participation and help set appropriate expectations and timelines. The *dong quai* root, like many other herbs, has many different parts of the plant that can be used therapeutically. As an herbalist, you choose which part of the plant to use and the quality grade of the herb as well as the way the herb is to be processed, because these factors have individual therapeutic properties.

A selection may be made from the *dong quai* root or the root endings, commonly called “hairs,” depending on the desired therapeutic action. *Shu Di Huang* may be processed by being steamed in water or put in some kind of alcohol such as wine. Your choice as a prescriber will be based on the desired effect. There are so many different characteristics of a plant that typically do not get studied, or the part of the plant being studied might not be a medicinally important part of it, and the plant and its beneficial use does not get into the popular press. A qualified herbalist will know the difference and be able to explain the options.

TLD: I think we have to approach the role of phytoestrogens with care. Debate continues about whether women can eat soy if they have had breast cancer, because soy contains phytoestrogens, even though three large epidemiologic studies have shown that soy actually appears to improve the survival of women who have had a diagnosis of breast cancer, even if they are also being treated with tamoxifen.

I am not saying that women should go out and eat lots of soy, but when you begin to reduce the concept of an herb or plant to a single component or single action, you may bias your view of its utility. Soy does lots of things, including inhibiting angiogenesis and affecting cell replication, including tumor-cell division, and to say that soy acts merely as a phytoestrogen is no more accurate than to say that black cohosh is a menopause herb, when it also has antidepressant, anti-inflammatory, and antispasmodic effects as well. It works very well for menstrual cramps and menstrual pain, and to declare black cohosh ineffective for treating menopause allows these other uses to fall off the charts.

So it is sad that some plants that have a wide range of activity and can be used therapeutically in a variety of situations have been reduced to a single use, and if it fails in a clinical trial, it is written off the books. Looking at isolated components and trying to generalize their effects to the whole plant or to an entire population provides a very limited model of clinical efficacy.

CU: I'd like to ask all of you about your experiences with the safety parameters surrounding the therapies that we've discussed today. For instance, we have talked about soy, for which there is the chance of cross-sensitivity in people who are allergic to other nuts and legumes. As a pharmacist, I'm concerned about such interactions or adverse effects in

patients in perimenopause or menopause. Many of these women practice polypharmacy on themselves—in other words, they self-medicate without medical guidance.

By the time a woman is in her menopausal years, for example, she's likely to have been exposed to penicillin or peanut butter or bee stings, and to know if any of them might elicit an allergic response in her or even cause anaphylaxis. But patients in perimenopause or menopause are often trying certain herbs and supplements for the first time. This poses a risk of cross-sensitivities, interactions, and adverse effects, both allergic and nonallergic. How do you address these issues with your patients?

TLD: In 30 years of giving people herbs, I have not had any of them experience an anaphylactic reaction. But I myself am allergic to mushrooms, and can have an anaphylactic reaction, so I'm very aware that we have to be very careful to avoid this. Our Dietary Supplements and Botanicals Expert Information Panel at the United States Pharmacopoeia [USP] examined the evidence for adverse effects for many herbal preparations, including allergic reactions, and we have not seen a great frequency of allergic reactions to herbal products in the literature.

In my own opinion, the greater potential risk is for potential adverse drug interactions with herbal products. Those are hard to predict, because we do not really understand how many herbs are metabolized in the body, and because humans have such variability in their metabolism of drugs as a result of genetic polymorphisms.

I advise a patient that, if she or he is taking a medication that has a very narrow safety window or therapeutic index (TI), that patient is going to be in big trouble if she or he goes outside that window. Patients should not start taking different herbs at the same time. I tell them that patients need to try herbs slowly and in small initial doses, and should have someone knowledgeable to help them monitor for adverse effects.

However, I would hope that we don't reach a point where people are afraid to drink a traditional medicinal calming tea because they read that it has chamomile, lemon balm, and passion flower in it, and they're are frightened that the tea may have adverse effects. We don't want people to be afraid of eating healthy foods and drinking flavorful medicinal teas. Education is the key and the onus is really on clinicians to counsel patients about what they should avoid when taking certain medications.

CU: When I'm addressing a group of clinicians on potential interactions of herbs and other natural products with one another or with foods or drugs, or with laboratory assays or diagnostic tests, I point to possible alterations in blood sugar, hormone levels, and the coagulation cascade as chief areas of concern beyond interactions. Fortunately, patients are often well-aware of their conditions and the things they have to look out for. If patients are taking warfarin, they should always have to check with their health care providers if they change their diets or do anything that might affect their International Normalized Ratio [INR] for their risk of hemorrhage, for example. I also think that collecting postmarket surveillance data is very helpful and will help guide future practice in terms of the

comparative effectiveness and safety risks of herbal and other natural products.

I'd like to conclude our roundtable discussion today with an experience of my own relating to the safety and efficacy of herbal products. Because many women experience anxiety and stress as effects of their menopause, and because there is strong scientific and clinical evidence that kava is effective for reducing anxiety, I remember the report on kava and its correlation with hepatotoxicity that the Natural Standard Research Collaboration prepared for WHO.⁶ There were many reports in the media that kava was killing people's livers, but, when we aggregated the data and looked at the actual scientific data from all of the case reports that had been gathered on this, we found that many of them were duplicates, and that many patients had preexisting liver conditions or were concomitantly taking prescription drugs or other natural products that might exacerbate liver dysfunction. Therefore kava perhaps did not deserve all of the bad press that it got, and its potential benefits might be reconsidered.

I thank all of you very much for your time today and your very valuable contributions to our discussion. ■

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