Many women, concerned about the health risks of the synthetic hormones used in conventional hormone therapy, are looking for natural alternatives. It’s important to know that these products are not necessarily safe just because they’re natural. The same questions we ask about drugs need to be asked of alternative therapies too: what is the specific reason to take it? Are there studies demonstrating its effectiveness for the recommended purpose? What are the risks associated with it?

Manufacturers of herbs and other dietary supplements are not required to provide evidence of safety or effectiveness the way they must for drugs. Moreover, alternative products are less likely to have been studied than conventional drugs because many of them cannot be patented and therefore have lower profit potential. Even so, it is still important to learn what is known about natural products, taking into account any safety concerns in order to be able to make an informed decision. Particularly when it comes to relieving specific symptoms, as opposed to generally improving health, women may reasonably choose to try an alternative product with less evidence than they would demand for a pharmaceutical product. It’s important to examine promotional claims for these alternatives with a critical eye. Just as pharmaceutical companies promote drugs, there is a large industry heavily invested in producing and selling alternative health care products. Alternative health care practitioners are influenced by marketing from these companies similar to the influence of drug companies on other doctors. Whether they are recommended by a doctor, a nurse practitioner, a naturopath or the cashier at the health food store, women should be skeptical of products that claim they will extend life, reverse aging, restore youth or prevent disease without causing any adverse effects.

For the same reasons that we question the use of hormone therapy, the Network approaches herbs and phytoestrogens by looking for reliable information on effectiveness and safety. It is good news that women have alternatives to hormone therapy for the relief of menopausal symptoms, but the field of alternative medicine is cloaked in uncertainty due to a lack of long term research. Many clinical trials on alternative biological treatments are small in scale and short in duration, and often have mixed or conflicting results. Thankfully, the National Center for Complementary and Alternative Medicine (NCCAM) is increasing funding for long term studies into the effectiveness and safety of natural botanicals. If these botanicals work by exerting a hormone-like influence, we should exercise caution about long term use, which could have estrogen-like effects on the uterus and breast, until
we learn more from these studies. This fact sheet provides a brief overview of the National Women’s Health Network’s perspective and some guidance on two types of alternative products promoted for women at menopause: phytoestrogens and herbs.

**Phytoestrogens**

Phytoestrogens are estrogens that occur in some plants. Foods containing phytoestrogens include beans, soy products, peas, lentils, and whole grains and seeds, especially flaxseed, rye and millet. Lignans, isoflavones and coumestans have been the most carefully studied. Isoflavone supplements, such as daidzein and genistein, are widely available.

Health benefits attributed to a diet rich in phytoestrogens include relief from menopausal symptoms and lowered risk of osteoporosis, heart disease and breast cancer. Phytoestrogens exert their beneficial effects through several mechanisms that slow cell growth and prevent inflammation. In addition, when acting on estrogen receptors, phytoestrogens behave differently from estrogen and more like Selective Estrogen Receptor Modulators (SERMs). An example of a well known SERM is the breast cancer treatment drug tamoxifen, which stimulates estrogen receptors in the uterus and bone, but suppresses them in the breast.

Asian women have lower bone density and lower calcium intake than Caucasian women and yet have stronger bones and fewer osteoporotic fractures during menopause. They also have a lower risk of developing cancer and heart disease. A diet rich in phytoestrogens is believed to be a contributing factor, as evidenced by numerous studies.¹,²

However, data from studies that have attempted to show that phytoestrogens are the cause of the lower incidence of fracture and heart disease are inconsistent. One study showed that ingestion of isoflavone-rich soy milk for two years increases lumbar bone density by 2.4 percent³, while another study found no improvement in bone density.⁴ Similarly, the phytoestrogen effect on risk of breast cancer remains unknown.⁵ It is likely that the effect varies with exposure during different stages of human development. While eating foods rich in phytoestrogen has helped menopausal women in reducing hot flashes and vaginal dryness, data is insufficient and inconsistent to recommend a particular dose or duration of phytoestrogen intake. Phytoestrogen levels and effects in the body are contingent upon individual intake, absorption, metabolism and time of initiation, which can explain the variation in response and benefit between individuals. For instance, the bone-sparing benefits of phytoestrogen are mediated by phytoestrogen conversion to equol, which approximately a third to half of the population are capable of doing.⁶,⁷ Such metabolic differences might explain the apparent inconsistencies in the health effects of phytoestrogens.

Phytoestrogens also occur in medicinal herbs and are widely available as supplements. The dose in supplements is often far higher than those in dietary sources. In terms of safety and effectiveness, supplements should be thought of differently from a diet rich in phytoestrogens. For instance, in one study, the removal of soy isoflavones from soy protein did not decrease soy’s LDL cholesterol-lowering potential.⁸ While a randomized clinical trial of isoflavone tablets had no meaningful clinical effect on hot flashes.⁹

Although there is not a lot of evidence about health risks from clinical trials, thousands of years of dietary experience indicates that eating foods containing phytoestrogens is safe. Unlike pharmaceutical estrogens, the phytoestrogens in food do not appear to increase the risk of endometrial cancer. The risks of long-term use of non-food phytoestrogens, like phytoestrogen supplements or red clover pills, however, are not known, and the Network discourages their use. Moderation is key. Since phytoestrogens act on hormone receptors within the reproductive system, they can behave like endocrine disruptors, with the potential for adverse effects. There have been case reports of women who developed abnormal uterine bleeding that subsided on ceasing their intake of phytoestrogens.¹⁰ Timing of phytoestrogen exposure seems important for endocrine disruption, with exposure during puberty and during the reproductive ages likely more significant than at menopause.

A recent review of the pros and cons of phytoestrogens concluded that the issue of whether
phytoestrogens are beneficial or harmful depends on age, dietary status, health status as well as presence of certain helpful bacteria in the gut. As with beneficial effects, adverse effects may differ from individual to individual. The Network believes that moderately supplementing one’s diet with foods rich in phytoestrogen is not harmful. A diet containing legumes, beans and soy has high nutritive value and we do not think postmenopausal women with breast cancer should actively avoid them. However, the safety of supplemental phytoestrogens in these women has not been clearly established yet.

**HERBS**

Black cohosh, red clover, chaste-tree berry, dong quai, evening primrose, ginkgo, ginseng and licorice are among the most popular herbs for women experiencing problems with menopause. Some of these herbs have powerful hormone-like effects, and women should not assume herbs are harmless. There are very few clinical studies on their efficacy and safety.

Black cohosh has traditionally been used by North American Indians for rheumatism and kidney disorders. An official drug in the US Pharmacopoeia from 1820-1926, it has been used in the past for the treatment of gynecological problems, including painful, heavy or absent periods, infertility, and threatened miscarriage and labor pains. In Europe, black cohosh has been a widely prescribed alternative to hormones for the management of hot flashes. In the United States it is available as a dietary supplement (20mg tablet preparation) called Remifemin. Evidence from clinical reports and observational studies on its effectiveness for relieving hot flashes has been encouraging, but again, results of studies have been mixed. It has been used safely in studies lasting up to six months that examined relief from menopausal symptoms such as hot flashes and profuse sweating. However, recent studies have shown no significant effect compared to a placebo. A recent NCCAM-funded study found that black cohosh, whether used alone or in conjunction with other botanicals, failed to relieve hot flashes and night sweats in postmenopausal women or those approaching menopause. It may be possible that black cohosh has a very mild effect, reducing the number of hot flashes by one or two a day, but women who are considering using black cohosh should be aware that they’re exposing themselves to possible risks for little or no benefit in return.

Another point of controversy has to do with whether or not black cohosh has hormone-like action. Some argue that it relieves hot flashes by working on estrogen receptors, while others suggest it has an estrogen-blocking activity. It is also unclear whether it contains phytoestrogens. Better understanding of its mode of action will help clarify whether or not black cohosh has harmful effects on the uterus and breast. Clinical trials have not shown it to have relieve vaginal atrophy or dryness during menopause. As of yet, it is unclear whether it is safe for women who have had hormone-sensitive conditions, such as breast and endometrial cancer. As such, women with breast cancer should avoid it until there is more information.

There have been some case reports of hepatitis and liver failure developing as an adverse reaction to black cohosh in some women. While clinical trials lasting over one year have not found serious side effects, it is recommended that women discontinue the use of black cohosh and consult their health care provider if they have a liver disorder or develop symptoms of liver problems, such as jaundice, abdominal pain or dark urine. Other side effects include headache, stomach discomfort, rash, dizziness, and slow heart rate.

Red clover is similar to soy in that it is a legume and that contains phytoestrogens. It is marketed as a dietary supplement under the brand name Promensil. There are some case reports indicating that it helps reduce hot flashes and anxiety during menopause, but several clinical trials have found no meaningful effects as compared to the placebo. It has been found to have cardiovascular benefit of lowering blood triglycerides and raising HDL. Any potential estrogenic effects on the vagina, uterus and breast remain unknown, as are the potential consequences of long term use.

Research on other herbs, such as ginseng (Panax species), dong quai (Angelica sinensis, a
Chinese herb), and evening primrose oil has also not shown them to be better than a placebo in reducing hot flashes. Ginseng has been associated with uterine bleeding in postmenopausal women, and dong quai may increase the risk of bleeding in those taking anticoagulant medications, such as warfarin. Most of these trials are small, and for effects to be significant, larger and longer trials are needed. Moreover, dong quai, ginseng and other herb usage is traditionally individualized and combined with other ingredients. It may be difficult to replicate what may be the traditional beneficial effects of these herbs using isolated extractions in standardized portions in clinical trials. However, we’ve learned from well-conducted trials that even women whose hot flashes are bad enough to volunteer for a trial get relief from an inactive placebo nearly 30% of the time. Maybe those traditional beliefs about the effectiveness of herbs were based in large part on the placebo effect. We don’t know for sure. But we do know that even herbs used in traditional cultures can have harmful effects, and that consumers can be harmed by contaminants in herbs obtained from unregulated sources.

Conclusion
There is no magic bullet that will safely treat the varied health concerns of women at menopause. Women who want to try non-hormonal alternatives should look at the available evidence and test out their options, starting with those that carry the least known risk, in order to find what works for them, engaging their health care practitioner in the decision making process. Foods containing phytoestrogens have been consumed by people over thousands of years and are not by themselves harmful. However, the Network recommends against using isolated, often high-dose, isoflavones and other herbal supplements sold over the counter, until their safety and effectiveness is shown in well-designed clinical trials.

Contact Us
The National Women’s Health Network is committed to ensuring that women have access to accurate, balanced information. For more information, email us at healthquestions@nwhn.org or call the Women’s Health Voice at (202) 682-2646. Stay informed, connect with us on Facebook and Twitter.

References

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