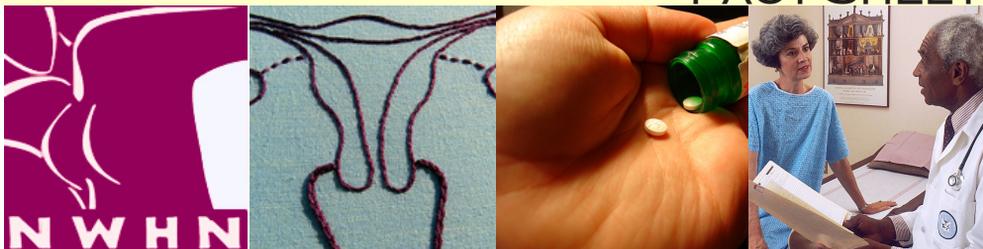


THE NATIONAL WOMEN'S HEALTH NETWORK

Natural Hormones at Menopause

FACT SHEET



As women learn about the proven health risks of [conventional hormone therapy drugs](#), many are looking for natural alternatives, such as herbs and dietary supplements, to address menopausal symptoms like hot flashes.

One alternative therapy — products known as “natural hormones,” or “bio-identical hormones” — has attracted substantial new interest now that conventional hormone therapy products’ health risks have been made clear. This interest has been driven, in large part, by unsubstantiated claims promoted by companies and pharmacies that make and distribute these products, that “natural hormones” are safer than conventional hormone therapy drugs.

It is very important for women to know that these products are not necessarily safe just because they are “natural.” And, just because they’re prescribed by a doctor and sold in a pharmacy, it doesn’t mean they’re effective, either. The same questions we ask about menopause hormone therapy drugs’ safety and effectiveness need to be asked and answered for alternative therapies, too.

NATURAL HORMONES ARE POWERFUL CHEMICALS

Just like hormones synthesized in a lab, hormones made from natural substances are powerful chemicals that affect many parts of the body. The natural

hormones most commonly recommended for women going through the menopausal transition are:

ESTRIOL

Estriol is a weak estrogen that is produced during pregnancy. High doses of estriol relieve hot flashes and other menopausal symptoms.¹ It may also be beneficial in maintaining bone mineral density.² Estriol is promoted as an estrogen that does not cause cancer; some proponents even claim that it prevents breast cancer. There is no reasonable scientific evidence that estriol has anti-cancer effects or is any safer than other estrogens, however.³ Additionally, the Food and Drug Administration (FDA) has not approved any drug containing estriol, thus its safety and effectiveness are still unknown.⁴ Estriol is included in the tri-estrogen (or “Tri-Est”) mixture, which contains estrone, estradiol, and estriol. It is prescribed by health care providers and sold at special pharmacies (called compounding pharmacies), which mix the hormone into pills or topical creams.

PROGESTERONE

Progesterone is a hormone involved in menstruation and pregnancy. Its proponents claim that it prevents hot flashes, osteoporosis, and even breast cancer. The only claim previously supported by

evidence was that progesterone helped reduce hot flashes. A recent study has yielded different results about progesterone's impact on hot flashes, however, calling this claim into question.⁵ And, there is no credible evidence that progesterone improves bone density or prevents cancer. Progesterone proponents say it has different effects than synthetic progestins and is safe, but this is unproven. Estrogen-plus-progestin has been shown to increase the risk of breast cancer, as well as increase the number of deaths from breast and lung cancers. Estrogen alone does not have these effects.^{6,7,8} Topical progesterone creams are available over-the-counter in creams and under-the-tongue formats.

DHEA

Dehydroepiandrosterone (DHEA) is a hormone involved in regulating sex steroids, neurosteroids, and other bodily functions. Its use is promoted to prevent aging, cancer, and cardiovascular disease, as well as to relieve vaginal dryness and increase bone mineral density. Despite animal evidence to support these claims, current studies on post-menopausal women are largely inconclusive.⁹ DHEA may help reduce the vaginal thinning that occurs after menopause,¹⁰ and may maintain or even increase bone mineral density.^{11,12} Yet, some research indicates that taking DHEA may actually increase women's risks for cancer. In women, DHEA can cause acne and increase facial and body hair. DHEA is available over-the-counter.

MELATONIN

Melatonin is a hormone that regulates the wake-sleep cycle and has been shown to help improve sleep.¹³ Some scientists think that nightly surges in melatonin may reduce the risk of breast cancer, but this has not been proven.¹⁴ There is no evidence that melatonin slows down aging, a promotional claim that is made to promote its use by menopausal women. There is also no information available about the long-term effects of taking melatonin on a nightly basis.¹⁵ Melatonin is available over-the-counter.

MAKING AN INFORMED CHOICE FOR AN ALTERNATIVE

A large industry produces and sells these alternative health care products, in much the same way that pharmaceutical companies promote the drugs they make. Alternative health care practitioners are subject to influence by these companies, just as conventional doctors are influenced by drug companies.

Regardless of whether they are recommended by a doctor, a nurse practitioner, a naturopath, or the cashier at a health food store, women should be skeptical of products that claim to extend life, reverse aging, restore youth, or prevent disease without any adverse effects. In too many cases, these products not only don't do what proponents claim, but also have dangerous health effects.

THE FDA TAKES ACTION AGAINST UNFOUNDED CLAIMS, BUT IS IT ENOUGH?

The National Women's Health Network (NWHN) has long urged the FDA to exercise better oversight of alternative hormone products, petitioning the agency throughout the years 14 to do more to ensure that women get reliable and accurate information about these products.

In January 2008, the [FDA took action](#) against misleading marketing claims about natural hormones sold by compounding pharmacies, instructing these pharmacies that the safety and effectiveness claims they were making about bio-identical hormone products "are unsupported by medical evidence, and are considered false and misleading by the agency."¹⁶

The FDA identified several specific misleading claims, including statements that natural hormones are "better" or "safer" than conventional hormone therapy and that natural hormones can treat or prevent Alzheimer's disease, stroke, and cancer.

The FDA also said that the use of the term "bio-identical" implies "a benefit for the drug, for which there is no medical or scientific basis." The agency also warned that selling products containing estriol is a violation of Federal law because the FDA has never approved this product. While the NWHN was encouraged by these actions, we remain concerned that they are insufficient to protect women's health. We urge the FDA to

do more, including to publish regulations about the appropriate labeling and advertising of pharmacy-compounded hormone therapy products.

We also urge the FDA to require that all labeling and advertisements for natural hormones provided to patients and health care professionals specifically note that:

- these products have not been approved by the FDA
- because the products are compounded in pharmacies, they may not be subject to FDA standards for good manufacturing practices¹⁷
- the products have not been demonstrated to be safe or effective in clinical trials.

For more information on hormone therapy and alternative treatments, read the Network's book [The Truth About Hormone Replacement Therapy](#) and our fact sheets on the topic: [Menopause Hormone Therapy Overview](#), [Menopause Hormone Therapy and Breast Cancer](#), [Menopause Hormone Therapy and Cardiovascular Protection](#), [Menopause Hormone Therapy and Heart Disease](#), [Menopause Hormone Therapy and Ovarian Cancer](#), [Menopause Hormone Therapy: Timing Doesn't Matter](#), [Herbs and Phytoestrogens](#), and [Hot Flashes](#).

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.

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17. The FDA expresses these concerns on their website in addition to highlighting that certain bioidentical hormones have never been approved. However this still has not stopped their manufacturing and promotion.