

Endocrine Society encourages clinicians to avoid prescribing compounded hormones

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A new Scientific Statement issued today by the Endocrine Society advises clinicians to avoid using compounded hormone medications to treat menopausal symptoms, female sexual dysfunction and other hormone conditions.

Sometimes called bioidentical compounded hormones, these products are typically a mixture of hormones. Compounded hormone medications are prepared by licensed professionals or facilities specifically for an individual's use. Compounded medications are meant to be an alternative when an individual does not have access to or has an adverse reaction to a medication approved by the U.S. Food & Drug Administration.

Compounded hormone medications can be unsafe when inappropriate practices are used. More than 60 people died from cases of fungal meningitis attributed to compounded medications in a 2010 case.

"In extreme cases, advertisers have marketed compounded products as being able to prevent the ravages of aging and implied they are risk free," said Nanette Santoro, MD, and the chair of the Society task force that developed the statement. "Few, if any, of these claims are supported by science."

Widely available hormone treatments that are 100 percent chemically identical to the native hormones found in the body and that are approved by the U.S. Food & Drug Administration (FDA) offer effective and safe options for people with hormone disorders, and those approved

treatments should be prescribed whenever possible, Santoro said.

Despite limited oversight of quality and dosage, bioidentical compounded hormones are used by millions of women to treat [menopausal symptoms](#) such as hot flashes and night sweats. Several market surveys indicate that custom-compounded menopausal hormone therapies earn \$1 billion dollars in annual sales - enough to treat 2 million to 3 million women. The sales are equivalent to a quarter to a third of sales of menopausal hormone therapies approved by the U.S. Food & Drug Administration.

Although a large 2002 government study called the Women's Health Initiative (WHI) raised concerns about menopausal hormone therapy raising the risks of blood clots, stroke, breast cancer and heart attacks in postmenopausal women, additional research conducted in the ensuing years has found that the level of risk depends on the individual woman's health history, age and other factors. Experts have formed a consensus that the benefits of menopausal hormone therapy exceed the risks for most healthy women seeking relief from menopausal symptoms.

Some women turned to custom-compounded menopausal hormone therapy (MHT) because of a misconception that it was safer than FDA-approved treatments. No large-scale, long-term studies have been conducted to examine the effectiveness and safety of custom-compounded MHT. When women use a customized preparation of estrogen and/or progestin, there are concerns that it could be harmful due to an overdose of the hormones or ineffective due to under-dosing. There is no scientific or medical reason to use a custom-compounded treatment that could have an unknown effect on the body when there are numerous FDA-approved options for treating menopausal symptoms, according to the statement.

The statement also examined compounded hormone treatments used to

boost testosterone levels in women experiencing sexual dysfunction. There are no FDA-approved testosterone or dehydroepiandrosterone (DHEA) therapies for women, and scientific studies, while indicating some effectiveness for testosterone in specific circumstances, do not support the use of DHEA for sexual dysfunction. There are also concerns about under- or overdosing as well as side effects from these treatments.

Compounded medications also are used to treat thyroid disorders. FDA-approved thyroid medications to supplement the body's naturally produced thyroid hormone remain the treatment of choice because they are highly effective and safe, according to the statement. However, some patients may benefit from compounded thyroid medications or desiccated thyroid [hormone](#) exacted from animals. Patients prescribed these alternatives need to have their Thyroid-Stimulating Hormone (TSH) levels and symptoms monitored carefully.

New regulations being developed by the FDA may lead to improved safety and quality control for compounded medications, Santoro said. In the meantime, compounded therapies should be used in limited situations due to concerns about the risks of under-dosing, overdosing or contamination.

"Custom-compounded hormones should be reserved for situations in which a patient is allergic to or does not tolerate any of the FDA-approved therapies, and treatment is necessary for his or her health," Santoro said.

More information: Nanette Santoro et al. Compounded Bioidentical Hormones in Endocrinology Practice: An Endocrine Society Scientific Statement, *The Journal of Clinical Endocrinology & Metabolism* (2016). [DOI: 10.1210/jc.2016-1271](https://doi.org/10.1210/jc.2016-1271)

Provided by The Endocrine Society

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