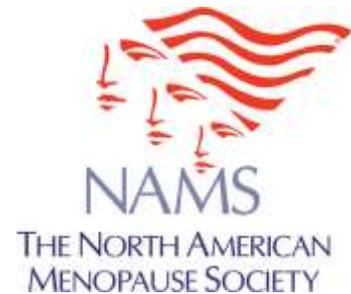


**EMBARGOED UNTIL  
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**Contact:**

The North American Menopause Society  
Eileen Petridis  
Phone: (216) 696-0229  
epetridis@fallscommunications.com



**One Third of Hormone Users at Menopause Take Unapproved, Untested  
Compounded Drugs**

*Cases of uterine cancer reported among users of compounded hormones*

CLEVELAND, Ohio (September 30, 2015)—A third of US women who take hormones at menopause are using compounded hormones, shows a new national survey. These women commonly—and mistakenly—think these hormones are safer and offer more benefits than FDA-approved therapies. But the four reports of endometrial cancer among the women who took compounded hormones point to how risky they may be. The results of the survey were published online today in *Menopause*, the journal of The North American Menopause Society (NAMS), and will be presented at the NAMS Annual Meeting on Saturday, October 3, in Las Vegas.

Some 3,700 women age 40 to 84 took part in the survey that asked about their hormone use at menopause, what they thought the benefits would be, what benefits they got, what side effects and health problems they experienced, and more.

About 1,000 of the respondents had used or were using hormone therapy at menopause. Thirty-one percent of hormone therapy users were taking or had taken compounded hormones, and 34% were taking them at the time of the survey.

Some 42% of the women who took compounded hormones thought that “natural” or “bioidentical” hormones are safer than other types of hormones, even though there are more than 30 tested and FDA-approved hormones for menopause, including many that are similar to human hormones.

“The term ‘bioidentical’ has no basis in science and should be dropped from medical jargon. These are simply compounded hormones, period,” says NAMS Executive Director Wulf H. Utian, MD, PhD, DSc(Med).

Although side effects of hormone therapy were not common among the survey respondents, the women who used compounded hormone therapy reported higher rates of vaginal bleeding and acne than women who used FDA-approved hormones, and four women who used compounded hormones reported they had endometrial cancer (cancer of the uterine lining), whereas none who used approved hormones reported a case.

Most women who used either compounded or FDA-approved hormones (about 70% of each group) took them for hot flashes—the major, FDA-approved indication for menopausal hormone therapy. But women who took compounded hormones more often expected unproven benefits that are not FDA-approved hormone therapy indications, such as to improve moodiness or irritability, sleep, low energy, depression, muscle mass, memory/concentration, sexual desire, and overall appearance as well as to prevent aging and to lose weight.

“Clinical trial, prescribing, and postmarketing data are all available to tell us how safe and effective the FDA-approved hormone therapies are, but none of that is available for compounded hormone therapy,” says NAMS Executive Director Emeritus Margery Gass, MD, NCMP, who led the survey study.

“Because so many women are using these untested therapies with unknown risks, we need to find out what those risks are.

“Federally mandated, centralized reporting of prescriptions filled by compounding pharmacies would be a better approach, and the benefits and risks can be determined only by randomized clinical trials.”

The survey was supported by a grant from TherapeuticsMD.

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Founded in 1989, The North American Menopause Society (NAMS) is North America’s leading nonprofit organization dedicated to promoting the health and quality of life of all women during midlife and beyond through an understanding of menopause and healthy aging. Its multidisciplinary membership of 2,000 leaders in the field—including clinical and basic science experts from medicine, nursing, sociology, psychology, nutrition, anthropology, epidemiology, pharmacy, and education—makes NAMS uniquely qualified to serve as the definitive resource for health professionals and the public for accurate, unbiased information about menopause and healthy aging. To learn more about NAMS, visit [www.menopause.org](http://www.menopause.org).