

Women Are Demanding, and Receiving, Compounded Hormones

Kate Johnson | October 08, 2015

LAS VEGAS — There has been a tsunami-like surge in the use of compounded hormones by newly perimenopausal women, according to a survey conducted by the North American Menopause Society (NAMS).

In fact, 41% of hormone users reported choosing compounded products — often referred to as bioidenticals — over those approved by the US Food and Drug Administration (FDA).

NAMS officials and a panel of discussants spent an hour decrying the practice of prescribing "unsafe and unapproved" compounded hormones during a plenary, supported by a grant from Pfizer, here at the 2015 Annual Meeting.

Survey results were first published online September 25 in *Menopause*.

There appears to be a disconnect between policy and practice; patients are rejecting traditional hormone therapy and insisting on compounded hormones, clinicians in the audience reported.

"We have a large population of women really insisting that they want compounded hormone replacement therapy," said Judith Hersh, an Ob/Gyn from Bedminster, New Jersey.

That experience was echoed by Ricki Polycove, MD, from San Francisco. "After the 2009 appearance of Suzanne Somers on Oprah, the number of my patients who got into this was astounding," she said.

Even "good doctors are capitulating and signing these prescriptions," said Julia Files, MD, from the Mayo Clinic in Scottsdale, Arizona.

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"I'd like the panel's opinion as to where we can intervene, beyond not just capitulating and writing the prescriptions," said James Simon, MD, from Washington, DC, who is past-president of NAMS.

"It's too late; the cat's out of the bag," said panelist Lauren Streicher, MD, from Northwestern University Feinberg School of Medicine in Chicago. "We can all sit here and talk and talk about it, but until the FDA comes out with regulations, I don't think it's going to make any difference."

The survey respondents ranged in age from 40 to 84 years. Of these, 9% reported currently using some form of hormone replacement, 34% of whom reported using compounded hormone therapy.

The top two reasons for the use of compounded hormones were hot flashes, cited by 71% of respondents, and vaginal dryness, cited by 23%. These are the same top two reasons cited by users of FDA-approved hormone therapy (70% and 28%, respectively), reported NAMS Executive Director Emeritus Margery Gass, MD.

Compounded hormones were considered to be safer than FDA-approved therapies by 42% of compounded hormone users who responded to the survey and by 25% of FDA-approved hormone users.

This is a "fantasy" that NAMS is trying hard to debunk, said Wulf Utian, PhD, professor emeritus at Case Western Reserve University in Cleveland, who is outgoing executive director of NAMS.

"Compounded drugs lack an FDA finding of safety, efficacy, and manufacturing quality (identity, potency, purity and sterility)," Dr Utian explained.

"Bioidentical is not a scientific term; there's no uniform definition in the medical dictionary," he pointed out. "The term bioidentical is an anachronism that should be removed from our lexicon. The FDA has said this is not an acceptable term."

And dosing is an issue with compounded products, said Dr Utian. He was involved in a study of compounded estrogen-progesterone pills from 12 compounding pharmacies across the United States, which was conducted in conjunction with *MORE* magazine. The analysis revealed superpotent doses of estrogen combined with subpotent doses of progesterone — a risky combination that increases the risk for endometrial hyperplasia.

"Do I think for one minute that the pharmacies were trying deliberately to create bad products?" he asked. "I most certainly do not," he answered. "I think they were trying their best to make a good product. What this identifies is the extreme difficulty in compounding specific levels of estrogen and progesterone."

Of the 92 survey respondents who experienced adverse effects related to compounded hormone therapy, four women reported uterine cancer. In contrast, there were no cases of uterine cancer among the 191 users of FDA-approved hormone therapy.

Uterine Cancer Risk

A show of hands from the audience suggested that at least 10 practitioners had seen similar cases of uterine cancer in their patients who were taking compounded hormones.

But the fact is, doctors across the United States are enabling the burgeoning business by prescribing compounded hormones for their patients.

"Pharmacy compounding of hormone therapy is now a multibillion dollar a year industry, and compounded drugs are prescription drugs, not over-the-counter drugs," said Dr Utian. "Without active medical profession participation, this industry could not prosper or function the way it has."

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Gynecologists prescribe 47% of compounded hormone therapies, and family practitioners prescribe another 25%, according to the survey. Other prescriptions come from less-reputable sources, such as "antiaging doctors," who prescribe 2% of compounded hormone therapies, and "internet doctors," who prescribe 1%. And respondents reported the source of 9% of prescriptions as "other," and of 5% as "not sure."

Dr Utian urged physicians to reconsider prescribing these products.

"If you get sued, there are a lot of position statements that can be used against you," he warned, listing those issued by the American Medical Association, the International Menopause Society, the American College of Clinical Pharmacy, the American College of Obstetricians and Gynecologists, and, of course, NAMS.

A clinician in the audience reported that compounded estradiol cream costs her Medicare patients a fraction of FDA-approved equivalents.

"I fully sympathize," said Dr Utian. "I am shocked by the price increments in the brand products over the past 5 years. There is absolutely no excuse to the extent those prices have gone up."

But when there is an appropriate FDA-approved product, physicians are legally bound to prescribe that product, he said.

According to the survey, 65% of compounded hormones are prescribed as tablets and 19% are prescribed as transdermal creams, lotions, and gels. FDA-approved hormone therapy is available in all these formats.

Between a Rock and a Hard Place

Refusing to prescribe what a patient demands could mean the loss of that patient, some clinicians in the audience pointed out. Prescribing a compounded hormone for a few months could at least provide an opportunity to educate the patient. But the panelists did not waiver on that point.

"Your prescription is your seal of approval. If you sign it, you approve it — and that's really the wrong message," said panelist Jan Schifrin, MD, from the Harvard Medical School in Boston.

"I tell those patients to go back to whoever filled the prescription last time," said Dr Streicher. "I'll continue to see you and be your gynecologist, and do your endometrial biopsies and take care of your hyperplasia, but if you want to go back to Dr Chip in the Hip, be my guest, but I'm not going to write the prescription."

"The preliminary data from the NAMS survey on compounded hormones indicates that almost one-third of the survey participants received a customized combination of hormones that their physician determined was the most appropriate treatment for them," said David Miller, RPh, executive vice president and chief executive officer of the International Academy of Compounding Pharmacists.

"Having a broad range of treatment options, including compounded therapies prepared by pharmacists on their doctor's prescription, empowers women to have full control of their bodies and their use of hormones," he added.

"The decision to use hormone therapy for peri- and postmenopausal symptoms is one that requires a thorough and open dialogue between a woman and her doctor."

The plenary session was supported by a grant from Pfizer. Dr Gass and Dr Larkin have disclosed no relevant financial relationships. Dr Utian reports consultant/advisory board or review panel work with Pharmavite LLC and PulseNMore. Dr Streicher reports being on the speakers bureau for Noven Pharmaceuticals and Shionogi, and owning stock in InControl Medical.

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