Pharmacist survey shows huge growth in compounded menopausal hormone therapy

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Among prescriptions filled for menopausal hormone therapy (HT) in the U.S., almost half now are custom-compounded "bioidentical" hormones, according to analysis of a recent survey of nearly 500 pharmacists. The study results will be presented Friday March 6th at the Endocrine Society's 97th annual meeting in San Diego.

Custom-compounded prescriptions, which are mixed for an individual according to a doctor's prescription, are not well-regulated or monitored by the U.S. Food and Drug Administration (FDA).

"Despite the increased quality risks and the lack of safety and efficacy data for non-FDA regulated custom-compounded bioidentical hormones, their use by menopausal women is higher than expected and appears to be continuing to grow," said lead researcher JoAnn Pinkerton, MD, a professor of obstetrics and gynecology at the University of Virginia Health System, Charlottesville.

Pinkerton cited statistics from Symphony Health Solutions that there were 36 million FDA-approved prescriptions filled for HT in 2012. That number is down 61 percent from the 93 million HT prescriptions filled in 2002.

Some postmenopausal women have been seeking alternatives to traditional hormone therapy since the Women's Health Initiative study in 2002 linked it to certain increased health risks. Since then, customized bioidentical hormones have often been marketed as natural, safer

alternatives to FDA-approved HT, with purported fewer side effects. However, according to the Endocrine Society, there is no scientific evidence supporting the safety or effectiveness of compounded bioidentical hormones.

Pinkerton and her colleagues analyzed results of a survey conducted last October on behalf of the *International Journal of Pharmaceutical Compounding and inThought Research*, and sent to 12,250 pharmacists who provide compounding services. From 904 pharmacists who reported working at independent community pharmacies or independent compounding pharmacies, the number of completed survey responses totaled 483 (365 responses from community pharmacies and 118 from compounding pharmacies).

Based on the pharmacists' responses of how many custom-compounded HT prescriptions they fill and the average percentage of compounding reported by the National Community Pharmacists Association and industry market research firm IBISWorld, the researchers estimated that 26 to 36 million total prescriptions custom-compounded HT were filled last year.

Of the responding pharmacists, 69 percent reported that they expected their HT compounding business to grow over the next two years. A greater proportion of compounding pharmacists anticipated growth than did community pharmacists: 75 percent versus 52 percent, respectively. Most pharmacists projected 5 to 25 percent growth of HT compounding by 2016, Pinkerton said.

In November of 2013, Congress passed the Drug Quality and Security Act (DQSA),14,15 which clarifies the FDA's authority to enforce provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) that apply to pharmacy compounding. However, health providers and their patients should understand the differences in and the risks associated

with less-regulated treatments of compounded menopausal hormone therapy," she stated.

Possible risks of compounded HT, according to Pinkerton, include the lack of safety and efficacy data along with possible presence of contaminants and concerns of overdosing or underdosing.

Provided by The Endocrine Society