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Untested, Unapproved Compounded Hormone Prescriptions Reach 26 to 33 Million a Year

Despite the risks, the number approaches that for FDA-approved hormone therapies

CLEVELAND, Ohio (December 18, 2015)—The number of prescriptions for mostly unregulated compounded hormone therapy for women at menopause has reached an estimated 26 to 33 million a year. That approaches the 36 million prescriptions per year for well-regulated and tested FDA-approved hormone therapy, shows an analysis of the market compounded hormone therapy market, published online this month in *Menopause*, the journal of the North American Menopause Society (NAMS).

Sales of these compounded hormones have not only grown to some $1.3 to $1.6 billion but are also expected to continue to grow, despite the potential risks. Pharmacists providing these medications predicted 5% to 25% growth in the next 2 years.

The sales of FDA-approved medications are tracked, but those of compounded medications are not, so the authors analyzed data from a Rose Research online survey of US pharmacists at compounding and independent community pharmacies. Nearly 500 pharmacists (118 compounding and 365 independent community pharmacists) completed the survey, which asked about the number of compounded hormone therapy prescriptions filled, the percentage of total volume, the percentages of different types of compounded hormone therapy sold, and what growth the pharmacists expected for these medications in the next 2 years. The analysts then estimated the size of the market based on the responses and the average percentage of compounding reported by the national Community Pharmacists Association and the industry market research firm IBISWorld.

The authors highlighted concerns over the lack of clinical data about the safety of compounded hormones as well as fears over the quality of these products. In fact, an investigative report published in *MORE* magazine showed that none of the 12 compounding pharmacy formulations tested contained the quantities of hormones prescribed. Ten contained too much of the prescribed estrogens and 11 too little progesterone, an imbalance that can allow overgrowth of the uterine lining and lead to cancer.

“Despite the increased quality risks and the lack of safety and efficacy data for non-FDA regulated compounded hormone therapy formulations, their use by menopausal women is higher than expected and

appears to be continuing to grow," says NAMS Executive Director Emeritus Wulf H. Utian , MD, PhD, DSc(Med).

Driving the growth of that market may be a perception that compounded formulations are safer than FDA-approved therapies, noted the authors. After 2002 when the Women's Health Initiative trial identified health risks with one type of estrogen-progestogen therapy, prescriptions of all FDA-approved menopausal hormone therapies dropped precipitously. Also in 2002, a Supreme Court decision allowed pharmacies to market compounded products that were not FDA approved, allowing that market to grow. And most pharmacists surveyed reported that their compounding business had indeed grown.

The formulations are often marketed as "bioidentical" and individualized, implying greater safety and flexibility, even though FDA-approved hormones essentially the same as natural human ones are available in a wide range of doses and options including pills, patches, gels, sprays, pumps, and lotions. Contributing to a perception of low risk from compounded hormone therapies may be that package inserts with boxed warnings and contraindications are not included with the compounded formulations, even though the warnings on FDA-approved menopausal hormone therapy products apply to all of them, "bioidentical" or not and no matter what dosage.

Women should know, and their healthcare providers need to counsel them, that without FDA approval or monitoring, compounded hormone therapies carry risks and unknowns, said the authors. Because of the risks, NAMS and many other medical professional organizations urge providers to advise women to use FDA-approved products whenever possible instead of compounded hormone therapies.

The study, "Compounded non-FDA—approved menopausal hormone therapy prescriptions have increased: results of a pharmacy survey," was funded by TherapeuticsMD and will be published in the April print edition of *Menopause*.

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