Menopausal Hormone Therapy (MHT) Usage: FDA-Approved MHT Has Decreased While Compounded Non-FDA-Approved MHT Has Increased

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Introduction

Data over the last decade show a 51% decrease in prescriptions for FDA-approved formulations of menopausal hormone therapy (MHT), from 1.65 billion in 2003 to 2555 million in 2013. At the same time, the use of custom-compounded hormone therapy (CHT) or bioidentical hormone formulations continued to grow. Recent surveys indicate that consumers are unaware that these formulations are not FDA approved and many websites for CHT are claiming greater safety than for FDA-approved products. To date, little reliable data can be found on the extent of prescribing of CHT by US pharmacies and their expected future trends.

Objectives

- Determine the number, volume, and overall costs of prescriptions for CHT sold by US pharmacies
- Determine the quantity and types of CHT provided by US compounding pharmacies

Methods

- A representative sample of 12,820 pharmacists who provide compounding services in the US were invited to participate in an online survey conducted by Rosene Research, a market research firm.
- Pharmacists responded in October-November 2014.
- Represented independent community pharmacies (ICPs), small chains with <5 stores, and independent compounding pharmacies (CPs).
- Non-stealth compounding had to represent >1% of total revenue and volume.
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- Independent community pharmacies (ICPs), small chains with <5 stores, and independent compounding pharmacies (CPs).
- Pharmacists were invited to participate in the survey if they had knowledge of the annual revenue and volume of both compounded and non-compounded prescriptions at their pharmacy locations.
- The survey included questions on various compounding activities, including:
  - Percentage of non-stealth compounding volume that is CHT
  - Percentage of monthly prescriptions for each type of CHT
  - Likelihood of change in MHT prescribing over the next 2 years
- Industry data were used to determine overall numbers of US ICPs and CPs and average percentages of the types of pharmacies they compounded to determine national volume and cost.

Results

- A total of 2,902 pharmacists (24%) answered the online survey screening questions
- Of these pharmacists, 2,892 (98%) completed the survey
- Of these respondents, 483 (17%) completed the full survey
- Of these respondents, 685 (23%) performed compounding
- Of these respondents, 717 (24%) were used to determine overall numbers of US ICPs and CPs and average percentages of the types of pharmacies they compounded to determine national volume and cost.

Conclusions

- Based on the survey data, a large proportion of the US market for MHT consists of CHT prescriptions
- Based on survey data and extrapolated industry data, an estimated 35 to 32 million CHT prescriptions are written annually at community and compounding pharmacies
- Extrapolations from the survey data show that 54 to 47 million women use compounded non-FDA-approved CHT formulations.
- Extrapolations of the survey data show current total sales volume of CHT may approach $13.5 to $11.7 billion, which is also consistent with the consumer survey reporting $1 to $3 billion spent annually on CHT.

References

1. Symphony Health Solutions PHAST Prescription Data.
4. Presenting at the Annual Meeting of the Endocrine Society, March 5-8, 2015, San Diego, CA
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