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 61% decrease in prescriptions for FDA-approved formulations of menopausal hormone therapy (MHT), from 93 million to 36 million.1
- At the same time, the use of custom-compounded hormone therapy (CHT; or bioidentical hormone therapy) by consumers has increased.
- Recent survey data indicate that consumers are unaware that these formulations are not FDA approved, and many websites for CHT are claiming better safety than for FDA-approved products.2
- 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 from US compounding pharmacies.

Methods
- A representative sample of 12,250 pharmacists who provide compounding services in the US were invited to participate in an online survey conducted by Rose Research, a market research firm.
- Pharmacists responded in October-November 2014.
- Represented independent community pharmacies (ICPs, small chains with <50 stores) and independent compounding pharmacies (CPs)
- Non-compounding had to represent >1% of total revenue and volume.
- Eligible for survey had to be knowledgeable 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-sterile compounding volume that is CHT
  - Percentage of monthly prescriptions for each type of CHT
  - Likelihood of changes 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 pharmacists they compounded to determine nationwide volume and cost.

Results
- A total of 2002 pharmacists (24%) answered the online survey screening questions.
  - Based on the survey, 685 pharmacies perform compounding services. Surveys were completed by 483 of these pharmacies (71%), including 365 ICPs and 118 CPs (Figure 1).
  - Based on survey responses (Table 1) and extrapolated industry data, an estimated 26 to 33 million CHT prescriptions are written annually at community and compounding pharmacies.
    - CPs (versus ICPs) accounted for a higher proportion of CHT prescriptions.

Conclusions
- Based on the survey data, a large proportion of the US market for MHT consists of CHT prescriptions.
- Annual sales volume for CHT may approach $1.3 to $1.7 billion, which is also consistent with the consumer survey10 reporting $1 to $2 billion spent.
- According to the survey, pharmacies expect continuing growth during the next few years.
- Given nearly equivalent prescribing of CHT and HRT and the expected growth of CHT, physicians and consumers need to be educated on the differences between FDA-approved and untested CHT formulations.

References

Disclosures
TherapeuticMD funded this study and medical writing assistance provided by Laura Hugenholtz, B.S. All authors report no conflicts of interest.

Figure 1. Flow of participants into the study

Figure 2. Estimated compounded hormone therapy based on overall annual prescribing

Figure 3. Number of prescriptions filled per month by specific type of compounded hormone therapy (CHT) from pharmacy survey

Figure 4: Estimated compounded hormone therapy based on annual prescriptions for individual products

Figure 5. Expected trends in the compounding business over the next 2 years

Table 1. Compounded hormone therapy (CHT) prescriptions per week and per year

Table 2. Estimated number of prescriptions per pharmacy type

Table 3. Estimated number of prescriptions per pharmacy type