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,[2] and many websites for CHT are claiming better safety than for FDA-approved products.[3]
- 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

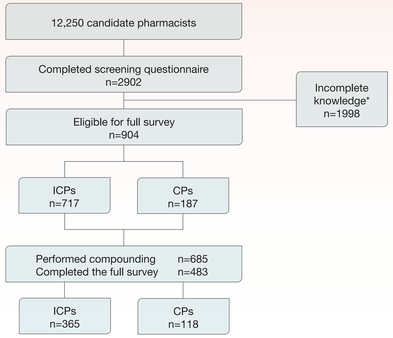
Methods

- 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-sterile compounding had to represent ≥1% of total revenue and volume
- Pharmacists 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 change in MHT prescribing over the next 2 years
- Industry data[4-6] were used to determine overall numbers of US ICPs and CPs and average percentages of the types of pharmaceuticals they compounded to determine nationwide volume and cost

Results

- A total of 2902 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 filled annually
  - CPs (versus ICPs) accounted for a higher proportion of CHT prescriptions whether expressed in relation to overall annual prescribing (26% vs 16%; Figure 2) or sum of annual prescriptions for all individual products (3555 vs 915; Figure 4)
  - CPs (versus ICPs) accounted for more prescriptions of all specific CHT types (Figure 3)
  - Total sales volume, based on an average compounded price of $50, is estimated to reach $1.3 to $1.7 billion (Figures 2 and 4)
- More than half of ICPs (52%) and CPs (75%) expect continued growth of the compounding business, with most predicting 5% to 25% growth over the next 2 years (Figure 5)

Figure 1. Flow of participants into the study



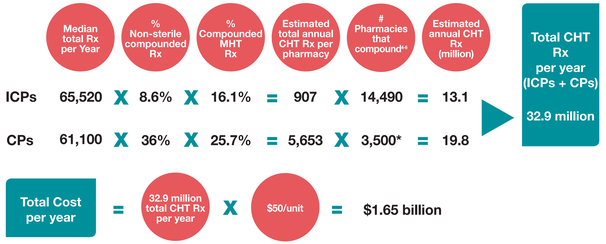
*Incomplete knowledge about their pharmacy's compounding volume and revenue.
ICPs = independent community pharmacies; CPs = compounding pharmacies

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

	Independent community pharmacy		Compounding pharmacy	
	Weekly	Yearly	Weekly	Yearly
Mean total prescriptions	2,081	108,212	1,510	78,520
Median total prescriptions	1,260	65,520	1,175	61,100

Calculated per year based on weekly report of CHT.

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



*Rounded number based on estimated 2013 value.[6]
CHT = compounded hormone therapy; CPs = compounding pharmacies; ICP independent community pharmacies;
MHT = menopausal hormone therapy; Rx = prescriptions

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

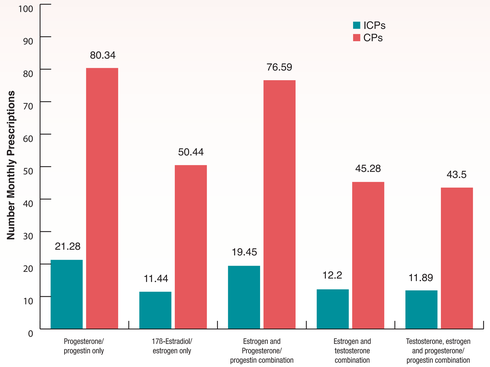
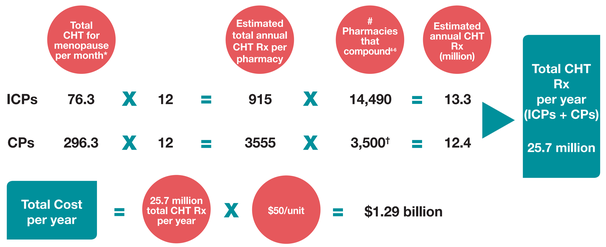


Figure 4: Estimated compounded hormone therapy based on annual prescriptions for individual products



*Sum of CHT prescription numbers per month for CHT types shown in Figure 3.
†Rounded number based on estmated 2013 value.[6]
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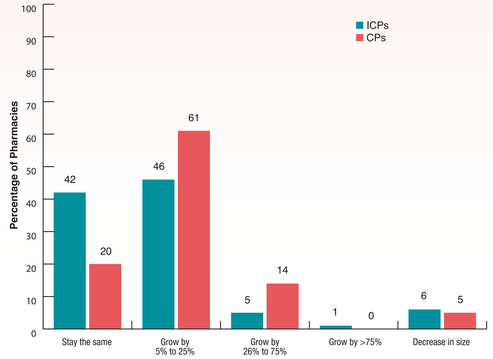
Figure 5. Expected trends in the compounding business over the next 2 years



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,[4-6] an estimated 26 to 33 million CHT prescriptions are written annually at community and compounding pharmacies
- This number of prescriptions supports data from an earlier consumer survey indicating 1.0 to 2.5 million women use CHT with extrapolated data of 21 to 39 million CHT prescriptions which parallels the number written for FDA-approved MHT[2]
- Extrapolations of the survey data show current total sales volume of CHT may approach $1.3 to $1.7 billion, which is also consistent with the consumer survey[2] reporting $1 to $2 billion spent
- According to the survey, pharmacies expect continuing growth during the next 2 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

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