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Patient Experiences with Small-Scale Pharmacy Compounding

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By

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ABSTRACT

MORGAN ALEXIS CAWTHON: Patient Experiences with Small-Scale Pharmacy Compounding

Investigators examined patients' use, knowledge and perceptions of pharmacy compounding at an independent compounding pharmacy in Mandeville, Louisiana. Data were collected using a self-administered survey that patients could complete in hard-copy in the pharmacy or at home, or online using Qualtrics. Investigators found that, in some instances, patients who use compounded medications, or have a member of their household who uses compounded medications, may be more knowledgeable or have more positive perceptions of compounded medications. However, patients who did not have experience with compounds were not unknowledgeable about the practice and did not report any negative perceptions of compounding. These overall positive perceptions and high level of knowledge about compounded medications may be a product of this specific pharmacy, and the culture that the compounding pharmacist has created there, but further, in-depth, longitudinal, quantitative, and qualitative research is needed to confirm these findings. Furthermore, research is needed to determine if this trend is seen in other compounding pharmacies, and for other pharmacy services. Future confirmation of these findings has significant implications for pharmacists, and how

the culture they create in their pharmacy can lead to enhanced knowledge, positive perceptions, and increased satisfaction among patients.

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LIST OF ABBREVIATIONS

FDA	Food and Drug Administration
BHRT	Bioidentical Hormone Replacement Therapy
NECC	New England Compounding Center
ASHP	American Society of Health-System Pharmacists
FDAMA	Food and Drug Administration Modernization Act
USP	United States Pharmacopeia
USPC	United States Pharmacopeial Convention
FDCA	Food, Drug and Cosmetic Act
TPN	Total Parenteral Nutrition
CPG	Compliance Policy Guide
ACOG	American College of Obstetricians and Gynecologists
PPI	Patient Package Insert
DQSA	Drug Quality and Security Act
IRB	Institutional Review Board
MTM	Medication Therapy Management

INTRODUCTION

According to the Food and Drug Administration (FDA), prescription compounding is defined as "a practice in which a licensed pharmacist, or…a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient" (Food and Drug Administration, 2013). The Drug Quality and Security Act defines compounding as "the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug" (Pharmaceutical Compounding Quality and Accountability Act, 2013). Darrell Pesta, a pharmacist in the Boston area describes it as "making stuff that doesn't exist," and Scott Vallee, a pharmacist in southern Louisiana described it as "the art and science of creating personalized medication based on prescriptions from practitioners" (personal communications, December 16, 2014, March 20, 2015). Prescription compounding is a wide and varied field that has grown in popularity in recent years, and many of its aspects are not as concrete and well known as more traditional prescription dispensing, as shown by the multiple definitions that can be used to describe the practice of compounding.

In the 1800s, compounding was common practice for a pharmacist, if not the main portion of his job. Then, in the early 1900s, the industrial revolution hit, and medications began to be produced in large quantities in multiple strengths and

doses (Peterson, 2014). This left the pharmacist with little compounding to do, as there was not much need for individual medicine preparations for individual patients. As a result, prescription compounding decreased in popularity and prevalence until about the 1990s. At that point, interest in compounding was rekindled with the growing demand for veterinary preparations as well as "Bioidentical Hormone Replacement Therapy," also known as BHRT, for the treatment of menopause in women. Both of these have remained as major markets for compounded medications to this day, with "upwards of two million women in the US [using compounded hormones] on a daily basis for relief of symptoms associated with menopause and perimenopause" (Benda, 2006). As women, along with many other demographic groups, and pets benefitted for years from the fact that their medications could be tailored to their needs, misfortune struck the compounding industry in 2012 with the fungal meningitis outbreak from the New England Compounding Center (NECC). Between May and October of that year, vials of compounded methylprednisolone injections were inadvertently contaminated with the fungus and distributed to other states (Peterson, 2014). This was not the first contamination event to occur in the field of compounding, but it certainly got the most press and media attention. As a result, the reaction to compounding by the public was not a good one. Even today, more than two years after the cases occurred, many patients are wary of compounding and compounded medications.

In order to explore patient perspectives of compounded medications, searches were done in an effort to identify previous studies of patients' experiences with compounding—specifically small-scale compounding done for individual

patients in community pharmacies. No studies were identified from the patient's perspective, so the literature reviewed for this study focused on the history of compounding and the compounding regulations that have been levied over the years. The objectives of this study are:

1. To describe the **prevalence** of compounded medication use by respondents in a local community pharmacy.
2. To determine the **types of compounds** respondents use, as well as **why** respondents use compounds.
3. To examine patient **knowledge and familiarity** of small-scale, personal compounding done in a local community pharmacy.
4. To examine patient **satisfaction and perceptions** of small-scale, personal compounding done in a local community pharmacy.

BACKGROUND

Defining Compounding

Compounding is a field that is not very well understood, much less easy to define. There appears to be a fine line between compounding and manufacturing of prescriptions, as well as questions about whether something as simple as reconstituting a retail antibiotic suspension is considered to be "compounding." According to the American Society of Health-System Pharmacists (ASHP), compounding is a process where "a medicine has to be created because the strength, concentration, or dosage form that is needed for a specific patient is not commercially available," and is under the supervision of state boards of pharmacy, rather than the federal government (Flaker, 2012). With this definition, simple processes like reconstituting an antibiotic or mixing a Magic Mouthwash are not a form of compounding because the medications are commercially available preparations. Manufacturing, as termed by ASHP, is "the preparation of large quantities of medication with a process that is approved and regulated by the U.S. Food and Drug Administration (FDA). Under this process, manufacturers must comply with federal quality and safety standards" (Flaker, 2012).

Even when making a medication specific for a patient, there are certain criteria that must be met. The compound must be made for an ethical, approved use, only approved ingredients may be used, and only certain amounts may be made in a

single sitting (Allen, 2003). Medications can only be compounded for a patient if the medication that the patient requires is not already commercially available, or if what is commercially available is not suitable for the patient. Allergies or adverse reactions to inactive ingredients like dyes, preservatives, or fillers are acceptable uses for compounding. It can also be used if a specific dosage strength or dosage route is not commercially available, or if the physician prescribes a medication in which multiple commercially available products are combined into a single capsule or cream, to be administered together (personal communication, March 20, 2015). There are also medications that have multiple clinical uses, but only one use is FDA approved as an indication. In this case, a compound can only be made for the indicated use. For example, domperidone has a FDA-approved use is as a gastrointestinal aid to increase GI movement and prevent nausea and vomiting, but there are studies that show that it can be used to increase lactation in women. This however was found to cause dangerous heart problems in nursing women, so the FDA removed it as an acceptable medication for women who are nursing (Food and Drug Administration, 2013). As a result, only prescriptions for domperidone from gastroenterologists are accepted as an appropriate order to compound the medication. Compounds must also consist entirely of approved ingredients. The FDA Modernization Act of 1997 (FDAMA) legislated that "compounding must be done using ingredients that had US Pharmacopeia/National Formulary (USP/NF) monographs, were components of commercial products, or appeared on a list of approved bulk drug substances that was to be developed by the FDA" (Allen, 2003). Estriol, an estrogen product used in the treatment of menopause, is an ingredient

affected by this law. The FDA states that only pharmacies with valid investigational new drug applications may compound medications containing the estrogen substance (2013). Ingredients that prove to be difficult or potentially dangerous to compound are also not approved. Compounding pharmacists are also limited to the amount of a compound they can make at one time. Legally, the quantity of the compounded medication made is only to be sufficient for the individual patient prescription for which the physician wrote. These restrictions are also outlined by the FDAMA, stating that a pharmacist could not compound drug products that were, for intents and purposes, copies of commercially available products, drugs that could present "demonstrable difficulties for compounding," and may not use an ingredient that is on a list of ingredients that has been removed from the market for efficacy or safety reasons (Allen, 2003). For this reason, compounds must be made in small, patient-specific batches, with no excess to be saved for use at a later date.

History of Compounding Regulation

The history of compounding regulation is much more extensive than determining appropriate ingredients, uses, and quantities. The practice of compounding has been around since the medieval times, when medications were made of fats and herbs in individual doses, only when requested by a doctor, for a single patient. The late 1700s and early 1800s brought with it the Industrial Revolution, which put compounding largely on hold. The Industrial Revolution saw the rise of drug manufacturing companies, churning out copious amounts of drugs offered in only one or two strengths, making the process of providing medication more standardized and economical than preparing individualized compounds

(Petersen, 2014). In 1820, the United States Pharmacopoeia (USP) was established with the intent of setting "standards (for quality, strength, purity) for drug products that were prescribed by physicians and prepared (compounded) by pharmacists" (Allen, 2003). The USP was used until the early 1900s as the standard for pharmaceutical compounding in the United States, mainly with regard to natural ingredients. An official set of quality and purity standards was set for the United States in 1906 with the US Pharmacopeial Convention (USPC), and is still in effect today, supplemented by more recent legislation. Chapters 795, 797, 1075, and 1160 of the USPC pertain directly to compounding ingredients and practices for sterile and non-sterile compounding (Allen, 2003). The Pure Food and Drug Act was also passed in 1906, and was designed to regulate the shift that the pharmaceutical industry was experiencing from small-scale compounding of medications to large scale manufacturing practices (Petersen, 2014).

In 1938, the Pure Food and Drug Act was replaced by the Food, Drug and Cosmetic Act (FDCA), which played a large role in setting up the current US Food and Drug Administration, or FDA (Pergolizzi et. al, 2013). This allowed compounding to be used as a way for doctors to "special order" medications that were not commercially available for a patient, in order for the patient to receive optimal dosing. Pergolizzi states that this is when pediatric medication increased in popularity, because doctors were no longer tied to the pill-form dosages that were too strong for infants (2013). They could have the dosages cut, or the medication made into a liquid, in order to facilitate the needs of the child. The FDCA also stated that compounding pharmacies, unlike drug manufacturers, were not under the

regulations of the FDA, because they were not actually manufacturing drugs, due to the small batch sizes. Instead, compounding pharmacies were deemed to be regulated by state boards of pharmacy, unless a manufacturing-type offense were committed, which would allow the FDA to intervene (Pergolizzi et. al, 2013).

The 1960s and 70s opened up doors to new types of compounding. As technology advanced, the possibility for medications to be offered in single-dose vials and syringes arose and became very popular. By only using a syringe or vial once, the sterility of the drug could be better guaranteed than that of a multi-use vial. This idea won favor among doctors, nurses, and patients, and the compounding of TPNs, and repackaging of medication into single-use administrations became more of a common practice (Pergolizzi et. al, 2013). In the 1990s, veterinary compounds and Bioidentical Hormone Replacement Therapies (BHRT) became a hot new topic in the compounding industry. Veterinarians had the ability to write prescriptions for an animal, using human medications with altered dosages, fillers, or flavorings. Studies show that the 1990s are also when people began to spend more money on their pets with fancy outfits and toys, specialty veterinarians, as well as medications better tailored to their animals (Petersen, 2014). Petersen also shares that compounded hormone therapy also became more popular in the 90s, as it offered women, as well as men, many more hormone options than the select few that were commercially available, and physicians could more specifically target the causes or symptoms of the patient's hormone imbalances (2014).

1992 brought the next round of compounding regulations, with the FDA publishing its first Compliance Policy Guide, or CPG. Because it was published by the

FDA, who legally did not have jurisdiction over compounding pharmacies, the guide was not enforceable, but provided very detailed guidelines on expected procedures and practices in a compounding pharmacy (Allen, 2003). Allen states that the CPG explained the criteria that would classify a pharmacy as a manufacturer versus a compounding pharmacy, and would therefore make the establishment subject to regulation by the FDA, rather than the state board of pharmacy (2003). In 1997, official legislation, by the name of the Food and Drug Administration Modernization Act (FDAMA), was passed and allowed the FDA to have a bigger role in the regulation of compounding, declaring it the official regulatory board, rather than the state boards of pharmacy (Petersen, 2014). With their new authority, the FDA began to investigate pharmacies that they felt were "manufacturing under the guise of compounding" (Allen, 2003). This was a major change for compounding pharmacies, and many of them challenged the restrictions, with a few cases making it to the US Supreme Court (Petersen, 2014). The passage of the FDAMA was helpful to compounding pharmacies with regard to New Drug Applications, however. The Act declared that if the new prescription is being compounded based off of a physician's orders, for a single patient, then the new drug requirements do not apply to that drug (Allen, 2003).

The practice of compounding has dealt with more than the passage of a few laws over the years and has had its share of outbreaks and media attention as well. The first was in 2002, with a fungal meningitis outbreak following the administration of injections that were found to be contaminated with Exophiala dermatitidis from a compounding pharmacy in North Carolina, killing 6 patients

(Pergolizzi et. al, 2013). The FDA has also dealt with complaints from the drug manufacturers, in regards to compounding. Wyeth Pharmaceuticals, the manufacturers of the commercially available hormone replacement drugs Premarin and Prempro, put pressure on the FDA to delve deeper into the regulations in place regarding pharmacists making BHRT drugs. The manufacturer argued that was stealing a significant portion of their FDA-regulated business, partly because those pharmacies did not have to answer to FDA regulation (Benda, 2008). At the center of the dispute was the term "bioidentical," which compounding pharmacies used to describe their hormone replacement therapies. The Endocrine Society defines "bioidentical" pertaining to hormone compounds as "compounds that have exactly the same chemical and molecular structure as hormones that are produced in the human body" (Files et. al, 2011). Similarly, the American College of Obstetricians and Gynecologists (ACOG) states that:

> Bioidentical hormones are plant-derived hormones that are chemically similar or structurally identical to those produced by the body. Bioidentical hormones include commercially available products approved by the U.S. Food and Drug Administration (FDA), such as micron-ized progesterone and estradiol, as well as compounded preparations that are not regulated by the FDA (2012).

Wyeth was arguing that compounding pharmacies that were offering or advertising "bioidentical" hormone therapies were taking a large portion of their business, falsely advertising the benefits of compounded hormones versus manufactured ones, and because they were not regulated by the FDA, were getting away with it

(Benda, 2008). In October of 2005, Wyeth Pharmaceuticals submitted a citizen's petition to the FDA, asking the FDA, among other things, to classify compounded BHRT products as "new drugs," making them subject to all of the same FDA criteria that Wyeth was subject to (Benda, 2008). In his article, William Benda states that the petition asked for enforcement against pharmacists that were compounding or advertising BHRT products and were in violation of the FDCA, for investigation into whether compounding pharmacies were dispensing PPIs and facts and risk information with their compounds, for compounding pharmacists to be required to disclose certain things on their BHRT labels, and for another CPG to be issued discussing the concerns associated with BHRT medications (2008). The petition made it all the way to the Supreme Court, where all of the requests made by Wyeth Pharmaceuticals were denied, particularly the one requesting that compounded BHRTs be subject to new drug testing. The court's ruling was that "it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the testing required for the new drug approval process…requiring such testing would force pharmacists to stop providing compounded drugs" (Benda, 2008). Furthermore, Benda states that many patients and physicians were documented as being on the side of the compounded BHRT prescriptions, rather than the commercially available ones, like those manufactured by Wyeth, among others (2008).

The compounding industry remained outbreak-free until 2011, when multiple cases of Serratia, caused by the bacteria Serratia marcescens, were determined to have been linked to contaminated total parenteral nutrition (TPN)

bags that were compounded by a pharmacy in Alabama and distributed in the surrounding areas (Pergolizzi et. al, 2013). In 2012, there was a multi-state outbreak of endopthalmitis, traced back to contaminated vials of intraocular injections of bevacizumab, along with the well-known fungal meningitis outbreak traced back to the New England Compounding Center (NECC) (Pergolizzi et. al, 2013). The NECC contamination event is the most influential of these outbreaks, due to the large amount of media attention that it got, and the vast area that the infections covered. Because the NECC is a manufacturer of compounded medications, like the methylprednisolone vials that were affected, its products were shipped outside the states borders, putting more than just the customers of Massachusetts at risk of infection. The NECC outbreak received such a significant amount of media attention due to the large number of deaths and hospitalizations caused. The injections, contaminated with the Exserohilium rostratum fungi, were administered in the spinal cords of patients, giving the fungus access to the meninges, causing fungal meningitis, which is very difficult to treat (Centers for Disease Control, 2013). Because of the geographical spread of the infected vials, and the prolonged, intense media exposure that the situation received, havoc broke out in the United States for multiple months as new cases popped up across the nation.

In response to the chaos and worry that was caused by the NECC event, the FDA issued the Drug Quality and Security Act (DQSA) in 2013. The legislation distinguishes between a compounding pharmacy and compounding manufacturers, "which make sterile products without or in advance of a prescription and sell those products across state lines" (Food and Drug Administration, 2013). The Act is

divided into two sections. The first section, the Compounding Quality Act sets up a compliance system in which compounding pharmacies can voluntarily deem themselves as "outsourcing facilities" and be subject to the same supervision by the FDA as pharmaceutical manufacturers (Looser, 2013). Once registered as an outsourcing facility, the compounding pharmacy must pay fees to the FDA, ensure that the labels on their compounded medications clearly indicate that the drug is compounded, along with many other pieces of information for the patient, and be subject to risk-based inspections, initiated by the contents of the adverse event reports that the outsourcing facilities are required to submit (McGuire-Woods, 2013). The Act also states that the FDA was in the process of developing a new list of drugs that may not be used in compounds, as well as bulk ingredients that will be permitted. The second section of the DQSA is the Drug Supply Chain Security Act, which requires that all manufacturers put barcodes on their products from the very beginning of manufacturing. The barcode can be used to track products through every step of the manufacturing process, as well as through the distributing and dispensing steps (Food and Drug Administration, 2013).

Because of all of the events that have occurred recently, there is an understandable possibility that consumer and public opinions of compounding have been affected. Between the news coverage and the talk of new legislation as a result of a widespread compounding manufacturing contamination error, the general public, along with any healthcare professional not familiar with compounding practices, received a very biased and dramatized representation of the

compounding industry. The lasting effect of this representation has yet to be studied.

METHODS

Design

This study was conducted using an observational, cross-sectional, descriptive, non-experimental survey design. A cross-sectional study is a method of data collection, in which all data are gathered at one point in time, rather than multiple times over an extended period of time.

Sample

The sample frame for this study consisted of any patients, age 18 or older, of *C and C Drugs Vital Care*, an independent retail pharmacy in Mandeville, Louisiana. This setting was chosen for this study because, unlike the other chain or independent pharmacies in the area, it offers compounded medications. A variety of patients use these compounded medications, including children, animals, men, women, and elderly patients. A total of 175 paper surveys and 1300 links to the electronic version of the survey were made available to patients of the pharmacy.

Data Collection

Before any surveys were administered, an application for exempt status was submitted to the University of Mississippi Institutional Review Board (IRB). The University of Mississippi IRB indeed designated the study as exempt, and surveys were then allowed to be distributed and data to be collected. The study offered two ways in which to complete the survey: a paper copy that could be filled out while in

the pharmacy or taken home and brought back at the patient's convenience, and a website address that linked to the survey, generated using Qualtrics. Refer to Appendix A for the survey questions that were administered. Each form of the survey given included a cover letter explaining the study, and instructions on how to complete it. Refer to Appendices B and C for these letters.

The first few questions in the survey were basic demographic questions, such as gender, age, ethnicity, education, employment status, and household income. The survey also contained questions about patients' use, knowledge and perceptions of the small-scale pharmacy compounding that was done at *C and C Drugs Vital Care*, the pharmacy where they get their medications filled. Patients who had received compounded medications, either for themselves, a relative, a child, or pet were prompted to answer more detailed questions about the kinds of compounds they received, what they understood compounded medications to be for, and their opinions on the compounded medications they had received. The survey then asked all participants about their perceptions of the kind of small-scale pharmacy compounding done at *C and C Drugs Vital Care*, and of the New England Compounding Center fungal meningitis outbreak. Levels of agreement were used in multiple questions to describe levels of familiarity

Data Management

After closing data collection, surveys completed in Qualtrics were downloaded to an Excel 2013 spreadsheet. On this spreadsheet, investigators entered data from the paper surveys. An additional field was added to the spreadsheet to indicate survey numbers. Numbers on the spreadsheet matched

numbers that were placed on the paper survey in order to allow the investigators to cross-reference papers surveys with the dataset as necessary. After all paper survey data were entered, the data was uploaded into IBM SPSS Statistics 22 for data analysis.

Analysis

Sample Description. A sample description was generated by calculating means, frequencies and percentages as appropriate for each demographic characteristic measured among participants.

Prevalence of Compound Use. Frequencies and percentages were used to describe the prevalence of compound use among respondents.

Types of Compounds Used/Reasons for Use. Frequencies and percentages were used to describe the types of compounds used among respondents as well as why respondents use compounds. A Chi-Square test of Independence was conducted to determine if the type of compound used varied according to patient age.

Knowledge and Familiarity. Patient knowledge and familiarity were analyzed using frequencies, percentages, and Pearson Chi Square tests of Independence. Frequencies and percentages were used to analyze questions about awareness of availability of compounding at C and C Drugs Vital Care, legal uses for compounding, and familiarity with compounding in general, as well as the New England Compounding Center (NECC) event. Chi Square analyses were conducted to test for differences in knowledge between respondents who received compounds and those who did not receive compounds to determine whether the differences in their knowledge were statistically significant.

Satisfaction and Perceptions. Patient perceptions were analyzed using frequencies and means, along with Chi Square tests to determine statistically significant differences between groups. Means were calculated to establish an average satisfaction or agreement score on questions regarding receipt of a compound and patient-pharmacist relationships related to compounding. Chi Square analysis was used to examine statistically significant differences between those who did and did not receive compounds with regard to how supportive they were of pharmacy compounding.

RESULTS

Response Rate

Although the number of paper surveys and survey links available is known (175 and 1300, respectively), it is possible that individual patients may have received the survey or link multiple times as a result of multiple visits to the pharmacy. Therefore, a response rate was not able to be calculated. At the conclusion of data collection, 81 electronic and 60 paper surveys were received. Of the 141 total surveys received, 7 were not included in data analysis due to the surveys being incomplete. Therefore, a resulting 134 total surveys were used for data analysis.

Sample Description

In order to better understand some of the characteristics of respondents, multiple demographic questions were asked. Of the 134 completed surveys, 27 (20.1%) were completed by males, and 107 (79.9%) were completed by females. The minimum age to complete the survey was 18 years old. Participant ages ranged from 18 to 80 years of age, with a mean age of about 50 (49.59) years. The majority of respondents reported their race as Caucasian, with 129 of 134 (96.3%) respondents designating it as their nationality. Respondents' highest levels of education were more varied, with Bachelor's degree and some college completed being the most common responses at 32.1% and 23.9%, respectively. In terms of

employment status, 47.8% of respondents had full-time jobs. When asked about their total household income, only 129 of the 134 respondents chose to answer the question. Most of the respondents reported a total household income of $80,000 per year or more. Additional sample characteristics can be found in Table 1.

Table 1: Demographic Characteristics

Nationality	**Number of Respondents (%)**
African-America	2 (1.5)
American Indian/Alaska Native	0 (0)
Asian/Asian Indian	1 (0.7)
Caucasian (white)	129 (96.3)
Hispanic	2 (1.5)
Native Hawaiian/Pacific Islander	0 (0)
Other	0 (0)
Highest Level of Education	**Number of Respondents (%)**
Some grade school	0 (0)
Some high school	3 (2.2)
High school diploma or GED	26 (19.4)
Some college	32 (23.9)
Vocational degree	4 (3.0)
Associate's degree	5 (3.7)
Bachelor's degree	43 (32.1)
Master's degree	11 (8.2)
Doctoral degree	5 (3.7)
Professional degree (MD, etc.)	5 (3.7)
Employment Status	**Number of Respondents (%)**
Full-time	64 (47.8)
Part-time	20 (14.9)
Unemployed	11 (8.2)
Student	9 (6.7)
Retired	24 (17.9)
Disabled	6 (4.5)
Total Household Income*	**Number of Respondents (%)**
Less than $10,000	4 (3.0)
$10,000 to $19,999	9 (6.7)

$20,000 to $29,999	6 (4.5)
$30,000 to $39,999	7 (5.2)
$40,000 to $49,999	7 (5.2)
$50,000 to $59,999	6 (4.5)
$60,000 to $69,999	9 (6.7)
$70,000 to $79,999	5 (3.7)
$80,000 to $89,999	11 (8.2)
$90,000 to $99,999	10 (7.5)
$100,000 to $149,999	30 (22.4)
$150,000 or more	25 (18.7)

*Total number of respondents = 129

Prevalence of Compound Use

Respondents were asked to indicate if they themselves, a spouse or significant other, a child, a pet, or no one in their household had ever received a compounded medication. Respondents were asked to select all answers that applied. The most common responses were "myself" and "no one," with frequencies of 60 and 50 responses, respectively. There were a total of 83 surveys that indicated that they either received a compound themselves, or had a household member that got one, and 51 respondents indicated no one in their household had ever received a compounded medication. Other data pertaining to the distribution of association with compounds can be found in Table 2.

The respondents that reported having a household association with compounded medications were then asked to complete an additional set of questions. The sample size for these questions was 83 (representing the number of respondents indicating that someone in their household has used a compound), rather than 134, used in previous questions. They were asked to write in the

number of different compounds received in the last year, not including refills. Responses varied from zero to ten. A response of zero indicated that they had gotten compounds before, just not in the last year. The majority of participants received one or two compounds in the last year, with those percentages being 24.6% and 17.9% of the 83-respondent sample size, respectively. Additional data on the number or prescriptions picked up in the last year by those patients that got compounded medications can be found in Table 3.

Table 2: Recipients of Compounds

Compound Recipient	Number of Respondents (%)
Myself	60 (44.8)
Spouse or significant other	17 (12.7)
Child	15 (11.2)
Pet	17 (12.7)
No one	50 (37.3)

Table 3: Number of Compounds Received in the Past Year

Number of Compounds	Number of Respondents (%)
0	15 (18.1)
1	33 (39.8)
2	24 (28.9)
3	6 (7.2)
4	3 (3.6)
5	1 (1.2)
6	0 (0)
7	0 (0)
8	0 (0)
9	0 (0)
10	1 (1.2)

Patients who used compounds in their household were also asked to indicate how many of their compounded medications are covered by insurance (in other words, not run for a "cash price"). Ten compound users (12%) indicated that they did not have insurance while 37 (46%) indicated that none of their compounds were covered by insurance. Twenty-one respondents (26%) indicated that all of their compounds were covered by insurance. A small number of respondents (13) indicated that some of their compounds are covered by insurance.

Types of Compounds Used/Reasons for Use

Question 12 asked those participants that got compounds in their household, what kinds of compounds they get, or what the indications are for them. Of the 83 who got compounds, 33.7% indicated that they or someone in their household got a compound that was a bioidentical hormone cream or gel, followed by 21.7% respondents having bought a compounded medication for their pet. Other dermatologic or anesthetic creams were also common, with 16.9 and 15.7%, respondents reporting use, respectively. Additional data on what kinds of compounds respondents reported receiving can be found in Table 4.

Further analysis, using the Chi Square test of Independence was performed to determine for each type of compound listed in Table 4, if there was a difference in frequency of usage based on age. To conduct the analysis, age ranges were used. Based on their reported age, respondents were categorized into four age groups as utilized by the Census Bureau (18-24, 24-44, 45-64, and 65+). Not surprisingly,

respondents in the 45-64 age group reported using more bioidentical hormone creams than respondents in any other age group, X^2 (3, N = 134) = 18.4, p < .05.

Table 4: Types of Compounds Received

Kinds of Compounds Received	Number of Respondents (%)
Bioidentical hormone capsules	11 (13.3)
Bioidentical hormone creams/gels	28 (33.7)
Nasal sprays or irrigations	5 (6)
Infusible antibiotics or TPNs	4 (4.8)
Anesthetic (pain relief/numbing)	13 (15.7)
Lip balms (cold sores)	4 (4.8)
Dermatologic creams	14 (16.9)
Gastroenterological (domperidone)	5 (6)
Magic Mouthwash	5 (6)
Pet medications	18 (21.7)
Trimix	1 (1.2)
Vancomycin	2 (2.4)
Troches or lollipops	0 (0)
Suppositories	2 (2.4)
Eye or ear drops	3 (3.6)

Those patients who had received compounded medications themselves or in their household were asked to indicate why they received a compounded medication. As indicated by the information above, the most common reasons for using compounds were "individualized hormone combinations" and "drug not available for pharmacy to order," with 34.9% and 30.1% of respondents indicating those as their reasons for getting compounds, respectively. Another common reason was to get the drug product in the right dosage form, chosen by 26.5% of respondents. More than one reason could be chosen, and some may be related to the

same compounded medication used by the patient. Additional data can be found in Table 5.

Table 5: Respondent Reasons for Using Compounds

Reasons for Using Compounds	Number of Respondents (%)
Individualized hormone combinations	29 (34.9)
Individualized dosages for a child	10 (12.0)
Individualized dosages for a pet	17 (20.5)
Drug not available for pharmacy to order	25 (30.1)
Proper dosage/strength not available to order	12 (14.5)
More personal patient-pharmacist relationship	5 (6.0)
Allergies to commercially available drugs	4 (4.8)
Combine multiple medications into a single dose	16 (19.3)
Avoid unwanted ingredients	13 (15.7)
Dosage form needs (cream vs tablet)	22 (26.5)
Personal preference	9 (10.8)
Insurance reasons	2 (2.4)
Addition of flavoring	4 (4.8)

Knowledge and Familiarity

Participants were asked if they were aware that C and C Drugs Vital Care offered compounded medications. Of the 134 respondents, 118 respondents, or 88.1% were aware that compounded prescriptions were an option. Of these 118 respondents aware of compounded prescriptions at the pharmacy, 81 of those respondents, or 68.6%, had used compounds in their household. This was significantly higher than respondents who did not use compounds in their household to be aware of compounds being made at the pharmacy, X^2 (1, N = 134) = 15.0, $p < .05$.

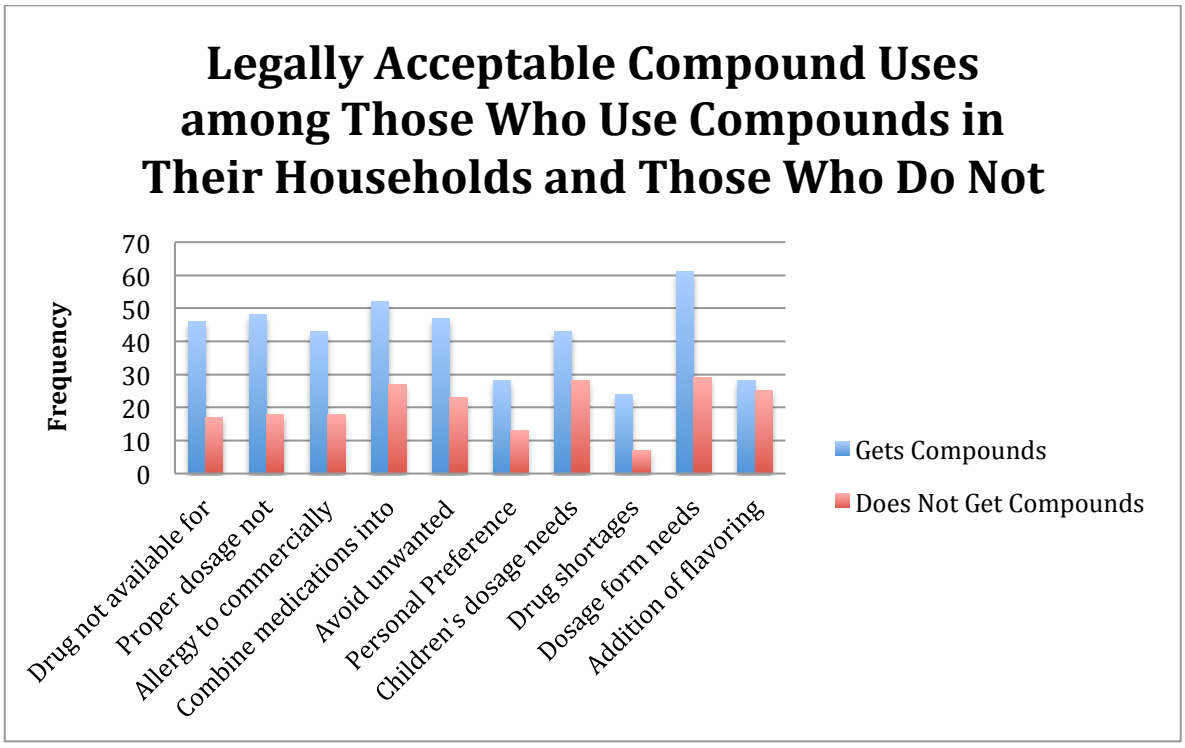
All respondents were asked to indicate, from a list of options, what they thought were legally acceptable uses for compounded medications. Participants could select as many of the ten options that they thought were legally acceptable reasons for getting medications compounded. The most commonly selected reasons were "dosage form needs" and to "combine medications into a single dose," with 90 and 79 people choosing the options, respectively. Further information on frequencies for each of the options can be found in Table 6. Additionally, Table 6 outlines which of the uses are legally acceptable, and which are not.

The frequencies for each option were then split into those who reported themselves, or someone else in their house getting a compounded medication, and those who had no one in their household receive a compounded medication. The frequency breakdown of the ten options between those who got compounds, and those who did not can be found in Figure 1. There was a statistically significant difference between those who received compounds and those who did not for "drug not available for pharmacy to order" (X^2 (1, N = 134) = 5.4, $p < .05$) and "proper dosage not available for pharmacy to order" (X^2 (1, N = 134) = 5.6, $p < .05$). Among these, those who used compounded medications in their household thought the reasons mentioned above were legally acceptable uses more frequently than those who had not gotten a compound.

Table 6: Legally Acceptable Uses for Compounded Medications

Potential Uses	Number of Respondents (%)	Legal Use?
Drug not available for pharmacy to order	63 (47)	No
Proper dosage not available to order	66 (49.3)	Yes
Allergy to commercially available version	61 (45.5)	Yes
Combine medications into a single dose	79 (59)	Yes
Avoid unwanted ingredients	70 (52.2)	Yes
Personal preference	41 (30.6)	No
Children's dosing needs	71 (53)	Yes
Drug shortages	31 (23.1)	Yes
Dosage form needs (cream vs. tablet)	90 (67.2)	Yes
Addition of flavoring	53 (39.6)	Yes

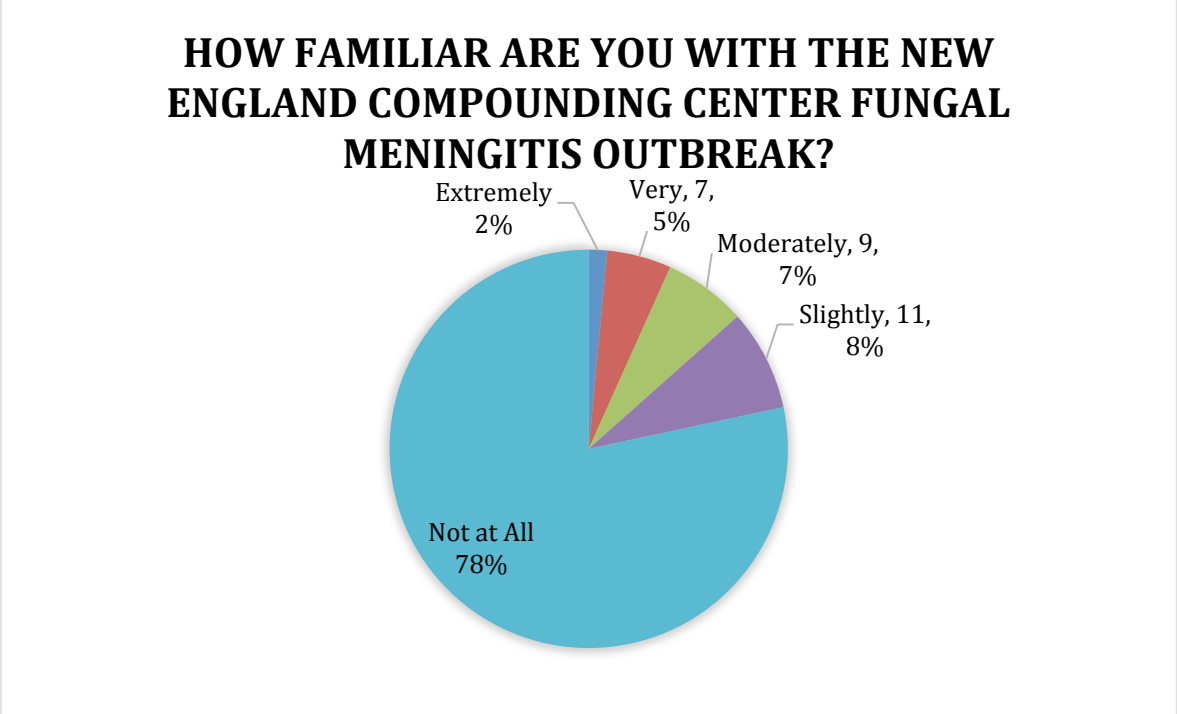
Figure 1: Legally Acceptable Compound Use Perceptions



All respondents were to indicate their level of knowledge about the outbreak of fungal meningitis that was traced back to the New England Compounding Center

(NECC). The answer choices ranged from “extremely familiar” to “not at all familiar.” The majority of respondents reported being “not at all familiar,” with 78% choosing this option. A summary of responses can be found in Figure 2.

Figure 2: Familiarity with NECC Outbreak



All respondents were asked about their familiarity with pharmacy compounding, from “extremely familiar” to “not at all familiar.” While C and C Drugs Vital Care dispenses a large amount of compounded medications, about 37% of respondents reported being moderately familiar and almost 30% reported being only slightly familiar with compounding. A summary of responses can be found in Figure 3.

Additional analysis was done to determine if the familiarity with compounded medications changed with the personal or household use of a compound, and then further to determine if the relation to the person that received the compound changed peoples' familiarity with the topic. When respondents were divided into only two groups, one having not received a compounded medication within their household and the other including all respondents that either had a household member receive a compounded medication, or they personally had gotten a compound, a Pearson Chi Square test of Independence was performed to examine whether or not there was a difference in familiarity between the two groups. There was found to be a statistical significant difference between the two groups, with the group who had at least received a household compounds being more familiar with compounded medications, X^2 (4, N = 134) = 35.3, $p < .05$. Of the "receives compounds" group, 70% of those included in the group were "moderately familiar" or more with compounded medications. In the group that did not get compounds, 76% of respondents reported being "not at all," or only "slightly" familiar with compounding. Additional data can be found in Figures 4 and 5.

A third analysis was done to examine whether familiarity changed depending on the particular person that received the compound. Respondents were split into three groups: those who claimed no contact with compounded prescriptions, those who said they had a household member who received a compounded medication, and those who personally received compounded medications, and may have an additional household member receive them as well. A Pearson Chi Square test of Independence was performed on the three groups and a statistically significant

difference in familiarity was found between the three groups, X^2 (8, N = 134) = 39.8, $p < .05$. Higher levels of familiarity were more often found in the group with personal receipt of a compound, and lowest familiarity in those who had no connection to compounded medications.

Figure 3: Familiarity with Pharmacy Compounding

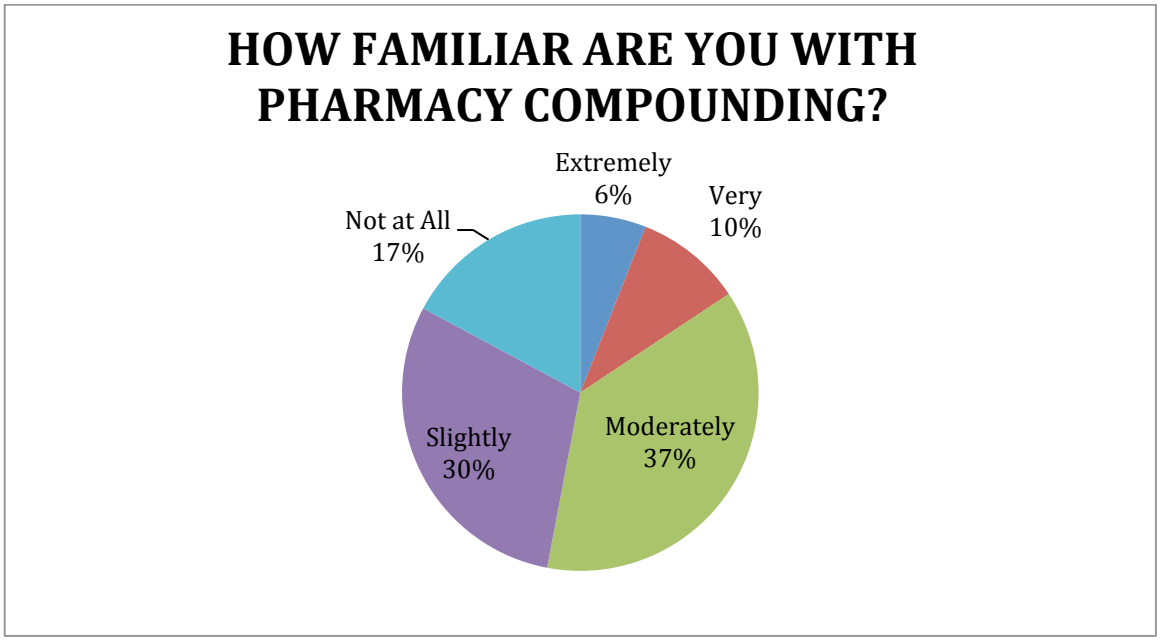


Figure 4: Familiarity with Pharmacy Compounding among Compound Users

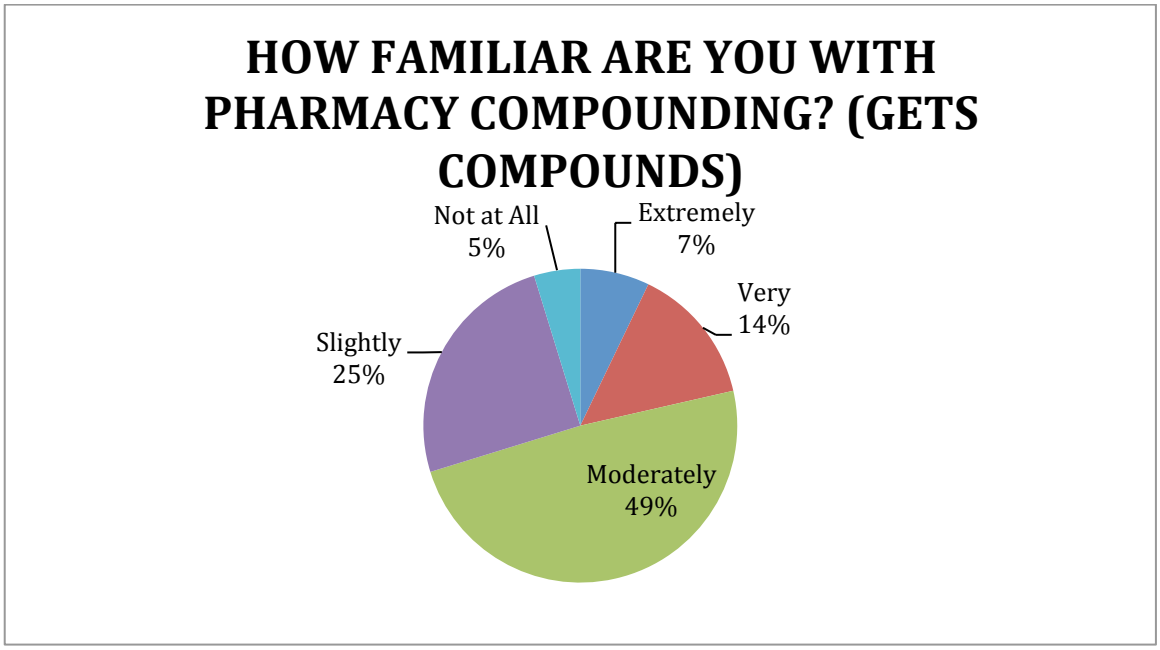
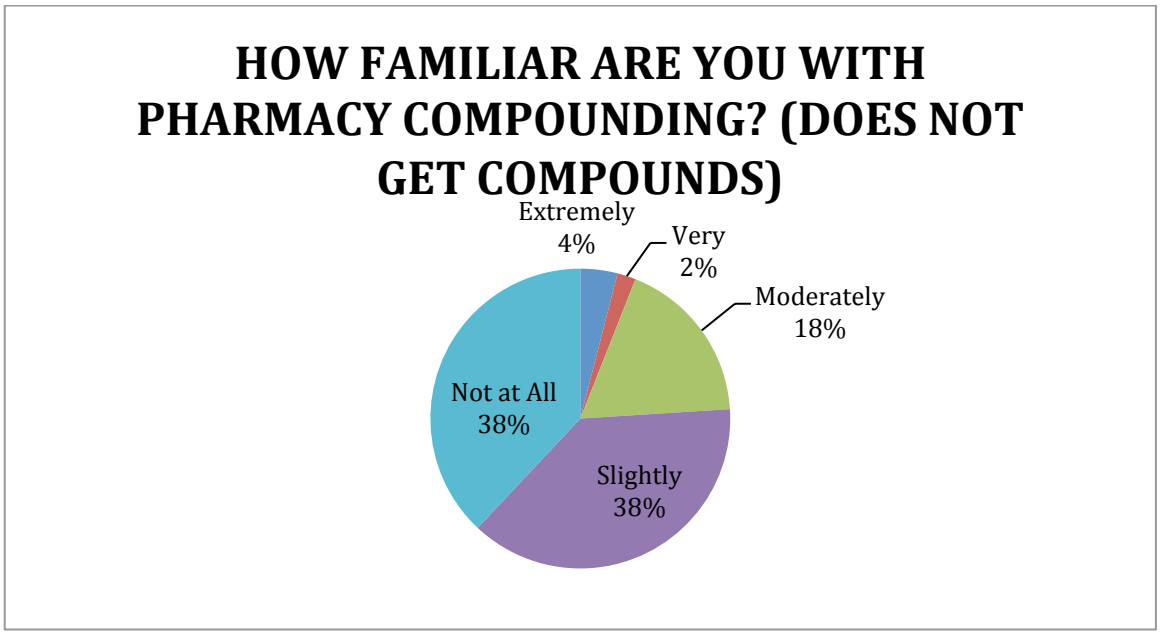


Figure 5: Familiarity with Pharmacy Compounding among Compound Non-Users



Satisfaction and Perceptions

Respondents who received compounds were asked a series of questions regarding their satisfaction with compounded medications. This first set of questions was product-focused. They were asked to rate their satisfaction on a linear numeric scale, with "1" being "not at all satisfied," and "5" being "very satisfied." The average answers to the questions were high, with the highest being 4.68 out of 5 for the safety and quality, and the lowest being 4.10 out of a possible 5 for the cost of the compounds. Additional data on patient satisfaction with compounds can be found in Table 7.

Other questions were asked to assess how respondents that received compounded medications felt about more subjective matters, like relationships with their pharmacist. These questions used a Likert scale with "1" being "strongly disagree," and a score of "5" being "strongly agree." Average scores were not as high as the satisfaction questions asked in the section before, but still comparatively high, ranging from 3.53 to 3.90, out of a possible 5. Additional data can be found in Table 8.

Table 7: Respondent Satisfaction with Compounded Medications*

	Frequency (%)					Average (SD)
	1	**2**	**3**	**4**	**5**	
How satisfied are you, in general, with your compound?	2 (2.5)	0 (0)	3 (3.8)	13 (16.5)	61 (77.2)	4.66 (0.783)
How satisfied are you with the cost of your compound?	3 (3.8)	4 (5.1)	13 (16.5)	21 (26.6)	38 (48.1)	4.10 (1.093)
How satisfied are you with the quality of your compound?	1 (1.3)	2 (0)	4 (5.1)	13 (16.5)	61 (77.2)	4.68 (0.690)
How satisfied are you with the ease of use of your compound?	0 (0)	2 (2.5)	6 (7.6)	13 (16.5)	58 (73.4)	4.61 (0.741)
How satisfied are you with the safety of your compound?	0 (0)	1 (1.3)	4 (5.1)	14 (17.9)	59 (75.6)	4.68 (0.634)
How satisfied are you with the appearance of your compound?	1 (1.3)	0 (0)	4 (5.1)	14 (17.7)	60 (75.9)	4.67 (0.693)
How satisfied are you with the packaging of your compound?	0 (0)	0 (0)	4 (5.1)	19 (24.1)	56 (70.9)	4.66 (0.575)
How satisfied are you with the convenience of having a compound?	1 (1.3)	0 (0)	6 (7.6)	13 (16.5)	59 (74.7)	4.63 (0.737)
How satisfied are you with the performance of your compound?	1 (1.3)	0 (0)	6 (7.6)	13 (16.5)	59 (74.7)	4.63 (0.737)

* 1 = not at all satisfied and 5 = very satisfied

Table 8: Respondent Agreement with Statements*

	Frequency (%)					Average (SD)
	1	**2**	**3**	**4**	**5**	
I prefer compounded medications over manufactured, commercially available medications	0 (0)	6 (7.2)	46 (55.4)	12 (14.5)	19 (22.9)	3.53 (0.928)
Getting compounded medications leads to a deeper and more personal relationship with my pharmacist	3 (3.6)	5 (6.0)	32 (38.6)	25 (30.1)	18 (21.7)	3.60 (1.011)
Getting compounded medications leads to a more patient-centered, rather than drug-centered relationship with my pharmacist.	1 (1.7)	4 (4.8)	25 (30.1)	25 (30.1)	28 (33.7)	3.90 (0.970)

* 1 = strongly disagree and 5 = strongly agree

Respondents were also asked about their support for compounded medications. Answer choices were the same as the question before it that asked about familiarity, ranging from "extremely supportive" to "not at all supportive." There was also a sixth option, "I don't know; I have never heard about pharmacy compounding before taking this survey." The majority of respondents were supportive of compounds, with 36% of respondents being "very supportive," and 34% being "extremely supportive." Additional data can be found in Figure 6.

Additional analysis was done to determine if those who had received a compound within the family were more supportive of compounded medications

than those who had not. The respondents were split into two groups: those who had compound use in the household, and those who had no connection to compounded medications. A statistically significant difference was found between the two groups, with those having a household connection to compounded medications being more supportive of compounded medications, X^2 (4, N = 134) = 34.4, p < .05 The group that did not get compounds reported more "I don't know" and "moderately supportive" answers than the group that received compounds. No participant in either group reported being unsupportive of compounded medications. Further data on the differences in answers between the two groups can be found in Figures 7 and 8.

Figure 6: Support for Pharmacy Compounds (All Respondents)

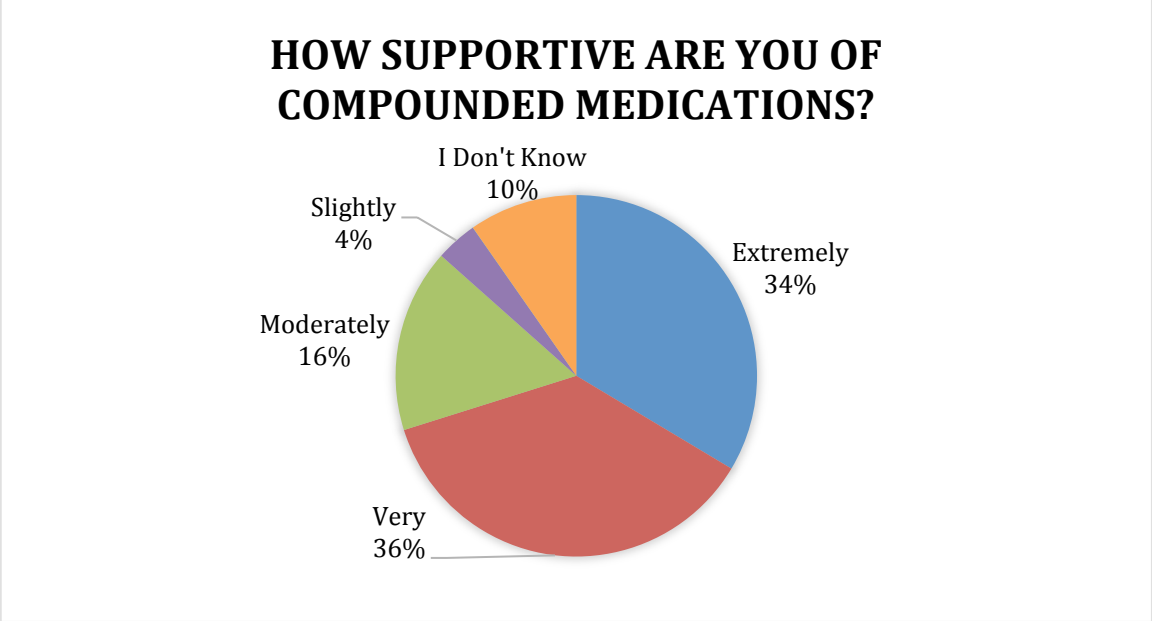


Figure 7: Support for Pharmacy Compounds by Compound Users

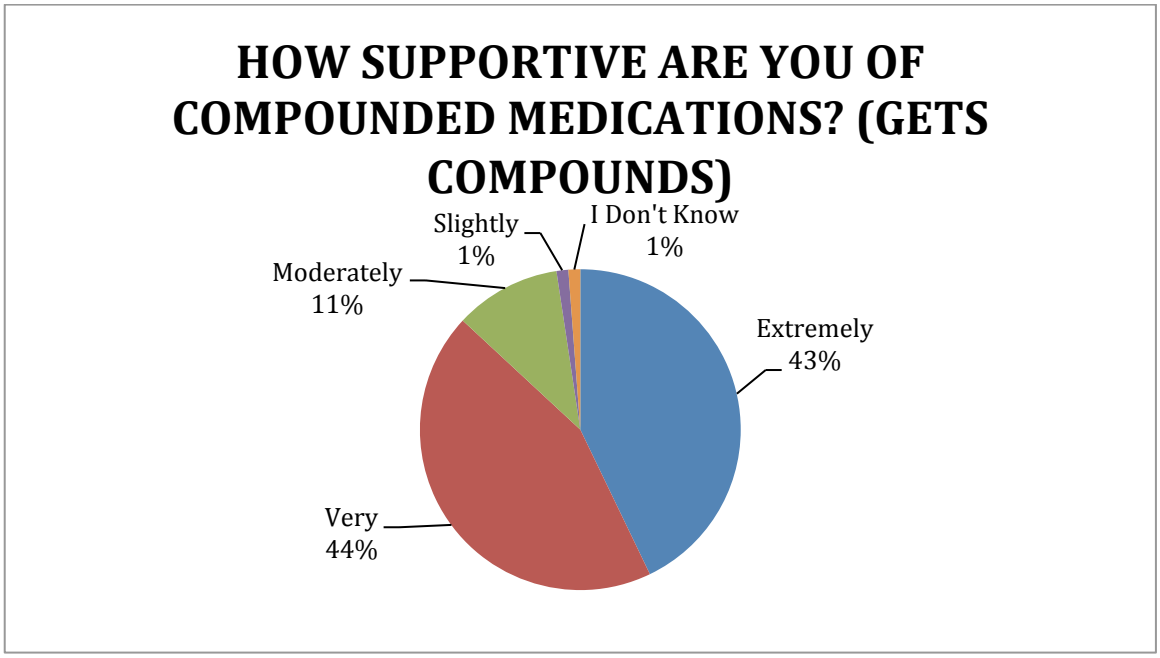
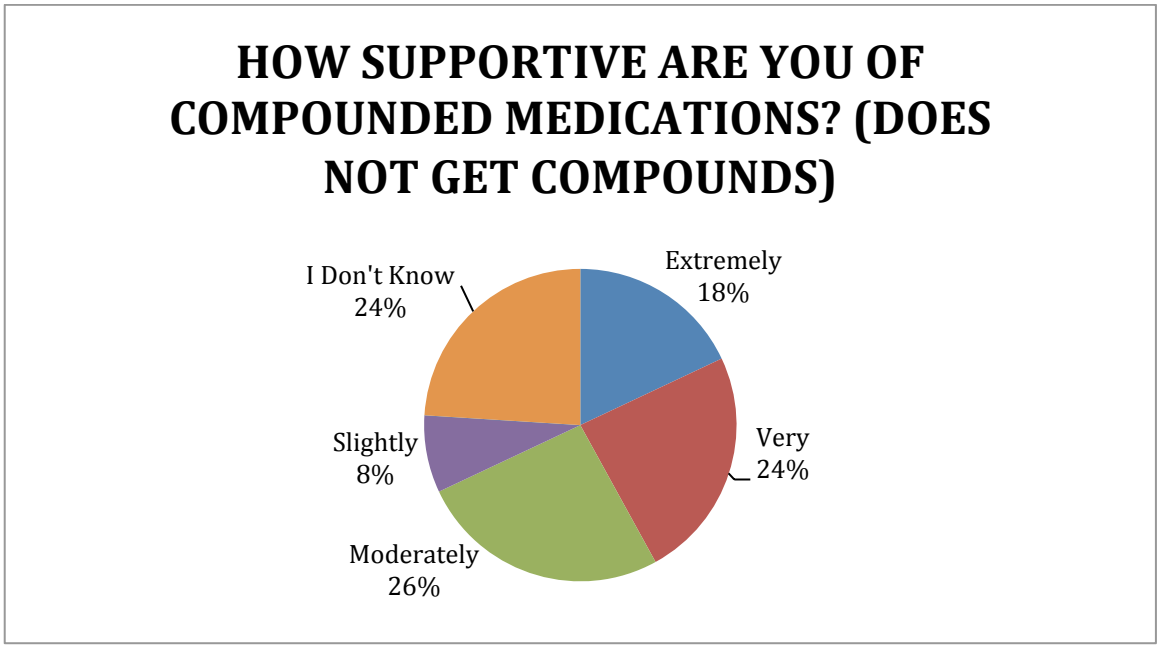


Figure 8: Support for Pharmacy Compounds by Compound Non-Users



DISCUSSION

Discussion of Findings

This study aimed to measure patients' use, knowledge and perceptions of small-scale pharmacy compounding at an independent compounding pharmacy in Mandeville, Louisiana, *C and C Drugs Vital Care*. About 20%, of the pharmacy's business is comprised of compounded medications, and therefore they are widely used in the store's patient population, with some patients using more than one unique compound. Anecdotally, many of the patients have gotten to know the compounding pharmacist and tend to be very supportive of him, whether they get compounds or not. Specifically, positive word-of-mouth, is thought to be a reason that new patients come to *C and C Drugs Vital Care*. Many of the findings in this study may be explained by the support for the compounding pharmacist and his practice, but further, in-depth, longitudinal, quantitative, and qualitative research is needed to confirm these findings.

For example, all respondents were asked to report their familiarity with, and supportiveness of, pharmacy compounding. While there were significant differences in familiarity and support between those who did and did not have a connection to compounded medications, even those who did not get compounded medications were still familiar with or supportive of the practice. Indeed, comments provided by

some of the respondents at the end of the survey reiterated these findings. For example, one respondent noted:

> "My 38 year daughter has many medical problems, and compounding meds is extremely valuable to her due to many allergies to many ingredients that are used, although in small amounts, in many drugs, causing terrible side effects. Can get just an effective med thru compounding."

Another respondent less familiar with compounding noted:

> "I know very little about pharmaceutical compounding. I assume that it was more common prior to the mass production of medications in recent times. Depending on the circumstances, I would think that there is still and will continue to be a need to pharmaceutical to better serve patients."

In light of these findings, the characteristics of the study sample should not be ignored. The vast majority of the respondents described themselves as Caucasian, highly educated, and making high incomes. Perhaps this sample is a reflection of the local population, or it could be a self-selection phenomenon. In other words, this pharmacy may attract this type of patient population because it does make compounds that may be more expensive and sometimes not covered by insurance, or this type of population may be more desiring of compounded

products. That said, there was still concern expressed by a respondent in her comment about the cost of compounded medications:

> "Why is it so expensive? I used to get my compounding cream for $35 and now it's over $200, therefore I no longer get it because I can't afford it, although it is like "magic" cream for my pain. It really helps my pain condition greatly."

Indeed, nearly 56% of the 83 respondents reported not having insurance or insurance not covering any of their medications.

Interestingly, those that reported using a compounded medication in their household more often reported that a "drug not available for the pharmacy to order" and "proper dosage not available for the pharmacy to order" were legally acceptable reasons to make a compounded medications. While a proper dosage not being available is a legitimate reason to compound a medication, a medication not being available for the pharmacy to order is not. Additionally, 41 of the 134 total respondents (approximately 31%) indicated that they believed personal preference was a legally acceptable use for a compounded medication. While not statistically significant, it was found that more respondents who did not use compounds in their household thought personal preference was legally acceptable than did respondents who did use compounded medications in their household. In general, this suggests that patient education on appropriate reasons for making compounded medications

may be worthwhile. However, respondents' interpretation of the questions should be taking into consideration when exploring these findings.

Another interesting finding was the lack of knowledge of the NECC event that happened only a few years ago. The reported outcome may have been a function of how the question was asked. Many patients may have remembered hearing about the many cases of deadly fungal meningitis that were contracted from an injection, but they may not have known that the NECC was the organization responsible for compounding those tainted medications.

Limitations

The topic of pharmaceutical compounds and their perception by the surrounding patient population can be greatly affected by the setting, which is the main limitation of this study. The survey was only administered at a single pharmacy, making it a convenience sample, rather than one that is truly representative of the whole state or country. Community perceptions may differ in New England, as the NECC outbreak was a closer threat and may have turned many patients off of compounding, or in a city that does not have a pharmacy that offers compounded medications, in which case there is a lack of knowledge of them. By using only one community to draw data from, and by choosing a pharmacy that was very involved in the practice of pharmacy compounding, the study is not generalizable to the rest of the United States or all patient populations.

The motivation of patients within the sample may also affect the generalizability. Participation was voluntary, so it can be expected that self-selection bias may result in a much higher ratio of patients who get compounded medications

participating. The results were not adversely swayed in this study, but there was a very large percentage of responses that were from patients with a connection to compounded medications. Pharmacy patients may have also felt more inclined to complete the survey when they saw that their participation would benefit one of the employees, someone they knew personally, rather than a survey that was conducted by someone they did not know.

Conclusions and Implications

Overall, both groups of participants, those who got compounds themselves or had a household member who received a compound, and those who had no ties to compounds, had positive perceptions of compounded medications, and were familiar with the practice. Even those who did not have any connection to compounded medications appeared familiar with the practice of compounding medications. Again, this may be due to the culture of *C and C Drugs Vital Care* and the efforts by the compounding pharmacist to create an atmosphere and business that promotes pharmacy compounding and positive perceptions of it by the patients. However, further, in-depth, longitudinal, quantitative, and qualitative research is needed to confirm these findings. Future confirmation of these findings has significant implications for pharmacists, and how the culture they create in their pharmacy can lead to enhanced knowledge, positive perceptions, and increased satisfaction among patients. This type of work could be translated to other compounding practices or any other patient-oriented pharmacy service such as medication therapy management (MTM).

REFERENCES

Allen, L. J. (2003). Contemporary pharmaceutical compounding. *The Annals of Pharmacotherapy*, *37*(10), 1526-1528. Doi: 10.1345/aph.1C508.

Benda, W. (2008, May 1). Compound Fractures: The Battle between Wyeth Pharmaceuticals and the Compounding Industry over Bioidentical Hormones. (Guest Editorial). *Townsend Letter*, 100-102.

Committee on Gynecologic Practice and the American Society for Reproductive Medicine Practice Committee. (2012, August). Compounded Bioidentical Menopausal Hormone Therapy. Committee Opinion No. 532. American College of Obstetricians and Gynecologists. Retrieved February 7, 2015. http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Compounded-Bioidentical-Menopausal-Hormone-Therapy.

Files, J., Ko, M. G., Pruthi, S. (2011, July). Bioidentical Hormone Therapy. *Mayo Clinic Proceedings, 86*(7), 673-680. Doi: 10.4065/mcp.2010.0714.

Flaker, S. (2012, December 1). Why Do Patients Need Access to Compounded Medicines. Retrieved July 19, 2015. http://www.safemedication.com/safemed/PharmacistsJournal/Access-to-Compounded-Medicines.

Food and Drug Administration. (2013, December 16). Compounded Menopausal Hormone Therapy Questions and Answers. Retrieved November 13, 2014. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm183088.htm.

Looser, B.J., Kennan, S. A. (2013, December 4). Drug Quality and Security Act: What You Need to Know. McGuire-Woods. Retrieved November 12, 2014. https://www.mcguirewoods.com/Client-Resources/Alerts/2013/12/Drug-Quality-and-Security-Act.aspx.

Pergolizzi, J. V., Labhsetwar, S., & LeQuang, J. A. (2013). Compounding Pharmacies: Who is in Charge? *Pain Practice*, *13*(3), 253-257. Doi:10.1111/papr.12033.

Petersen, C. (2014, August 1). The Art and Science of Compounding: Where We Are Now, and How Did We Get Here? *Townsend Letter*, 18-22.

Pharmaceutical Compounding Quality and Accountability Act: Summary of the Bipartisan Senate Legislation. (n.d.). 1-3. Retrieved July 19, 2015, from http://www.help.senate.gov/imo/media/Section-by-Section_PCQA.pdf.

APPENDICES

Appendix A: Survey Questions

Appendix B: Cover Letter for Paper Survey

Appendix C: Cover Letter for Electronic Survey

Appendix A: Survey Questions

PART A: Please tell us a little about yourself.

1. How old are you? _____

2. Are you: ❒ Male ❒ Female

3. Are you:

❒ African-American
❒ American Indian/Alaska native
❒ Asian/Asian Indian
❒ Caucasian (white)
❒ Hispanic
❒ Native Hawaiian/Pacific Islander
❒ Other (specify) _____

4. Which of the following describes the ***highest level*** of schooling you have completed?

❒ Some grade school
❒ Some high school
❒ High school diploma or GED
❒ Some college
❒ Vocational degree
❒ Associate's degree
❒ Bachelor's degree
❒ Master's degree
❒ Doctoral degree
❒ Professional degree (MD, etc.)

5. Employment status:

❒ Full-time
❒ Part-time
❒ Unemployed
❒ Student
❒ Retired
❒ Disabled

6. What is your total household income?

❒ Less than $10,000
❒ $10,000 to $19,999
❒ $20,000 to $29,999
❒ $30,000 to $39,999
❒ $40,000 to $49,999
❒ $50,000 to $59,999
❒ $60,000 to $69,999
❒ $70,000 to $79,999
❒ $80,000 to $89,999
❒ $90,000 to $99,999
❒ $100,000 to $149,999
❒ $150,000 or more

PART B: Please answer the following questions about pharmacy compounding.

7. Are you aware that this pharmacy offers compounded medications? ❒ Yes ❒ No

8. Which of the following are legally acceptable uses for compounded medications? ***(Check all that apply)***

❒ drug not available for pharmacy to order
❒ proper dosage not available for pharmacy to order
❒ allergy to commercially available version
❒ combine medications into a single dose
❒ avoid unwanted ingredients
❒ personal preference
❒ children's dosing needs
❒ drug shortages
❒ dosage form needs (cream vs pill)
❒ addition of flavoring

9. Who in your household has used a pharmacy compound? ***(Check all that apply)***

- ❒ Myself
- ❒ Spouse or significant other
- ❒ Child
- ❒ Pet
- ❒ No one ➡ ***PLEASE SKIP TO QUESTION #16***

10. How many ***different*** pharmacy compounds have you gotten in the past year, not including refills? _____

11. What kinds of compounded prescriptions have you gotten? ***(Check all that apply)***

- ❒ Bioidentical hormone capsules
- ❒ Bioidentical hormone creams/gels
- ❒ Nasal sprays or irrigations
- ❒ Infusable antibiotics or TPNs
- ❒ Anesthetic (pain relief/numbing)
- ❒ Lip balms (cold sores)
- ❒ Dermatologic creams
- ❒ Gastroenterological (domperidone)
- ❒ Magic Mouthwash
- ❒ Pet medications
- ❒ Trimix
- ❒ Vancomycin
- ❒ Troches or lollipops
- ❒ Suppositories
- ❒ Eye or ear drops
- ❒ Other: _____

12. Please rate the following statements based on your experience with compounded medications from this pharmacy, with "1" being "not at all satisfied," and "5" being "very satisfied."

	Not at all				Very
How satisfied are you, in general, with your compound(s)?	1	2	3	4	5
How satisfied are you with the cost of your compound(s)?	1	2	3	4	5
How satisfied are you with the quality of your compound(s)?	1	2	3	4	5
How satisfied are you with the ease of use of your compound(s)?	1	2	3	4	5
How satisfied are you with the safety of your compound(s)?	1	2	3	4	5
How satisfied are you with the appearance of your compound(s)?	1	2	3	4	5
How satisfied are you with the packaging of your compound(s)?	1	2	3	4	5
How satisfied are you with the convenience of having a compound?	1	2	3	4	5
How satisfied are you with the performance of your compound(s)?	1	2	3	4	5

13. Please rate the following statements with "1" being "strongly disagree," and "5" being "strongly agree."

	Strongly Disagree				Strongly Agree
I prefer compounded medications over manufactured, commercially available medications.	1	2	3	4	5
Getting compounded medications leads to a deeper and more personal relationship with my pharmacist.	1	2	3	4	5
Getting compounded medications leads to a more patient-centered, rather than drug-centered relationship with my pharmacist.	1	2	3	4	5

14. Why do you or members of your household use compounded medication(s)? ***(Check all that apply)***

- ❒ Individualized hormone combinations
- ❒ Individualized dosages for a child
- ❒ Individualized dosages for a pet
- ❒ Drug not available for pharmacy to order
- ❒ Proper dosage or strength not available for pharmacy to order
- ❒ More personal patient-pharmacist relationship
- ❒ Allergies to commercially available drugs
- ❒ To combine multiple medications into a single dose
- ❒ To avoid unwanted ingredients
- ❒ Dosage form needs (cream vs tablet)
- ❒ Personal preference
- ❒ Insurance reasons
- ❒ Addition of flavoring
- ❒ Other: _____

15. How many of your compounded medication(s) are accepted by your insurance (not run for a "cash price")? ***(Please select the closest percentage)***

- ❒ Not applicable; I do not have insurance
- ❒ 0%; my insurance does not accept compounds
- ❒ 25%
- ❒ 50%
- ❒ 75%
- ❒ 100%; my insurance includes compounds in their formulary

16. How familiar are you with pharmacy compounding?

❒ Extremely ❒ Very ❒ Moderately ❒ Slightly ❒ Not at all

17. How supportive are you of compounded medications?

❒ Extremely ❒ Very ❒ Moderately ❒ Slightly ❒ Not at all
❒ I don't know; I have never heard about pharmacy compounding before taking this survey

18. How familiar are you with the New England Compounding Center fungal meningitis outbreak?

❒ Extremely ❒ Very ❒ Moderately ❒ Slightly ❒ Not at all

19. If you have never received a compounded medication, would you ever get one, if your doctor recommended it or wrote a prescription for it?

❒ Yes ❒ No ❒ Does not apply; I have received compounded medications

If not, please explain:

20. Do you have any other thoughts, opinions, or concerns about pharmaceutical compounding?

Appendix B: Cover Letter for Paper Survey

Dear Patient,

My name is Alix Cawthon, and I am a pharmacy student at Ole Miss. This summer and fall, I am conducting a research survey through the Sally McDonnell Barksdale Honors College, and I am asking for your participation. This survey should take no more than 7 or 8 minutes of your time. It includes various demographic questions, but mainly focuses on your knowledge and perceptions of pharmacy compounding, such as the kind done at C and C Drugs Vital Care. We are inviting all customers to participate, whether you get compounded medications or not. Your willingness to participate in this research will help me better understand patients' understanding and attitude toward small-scale pharmaceutical compounding.

Please keep in mind that your participation in this survey is entirely voluntary. Your completion of this survey does not affect your patronage at this pharmacy, or with any of its employees. Your responses will remain completely anonymous and will be examined along with other respondents' surveys.

This study has been reviewed by the University of Mississippi's Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections obligations required by the state and federal law and University policies. If you have any questions, please contact the IRB at (662) 915-7482.

If you have any questions about the research project specifically, feel free to contact me at macawtho@go.olemiss.edu, or my advisor, Dr. Erin Holmes, at erholmes@olemiss.edu, or (662) 915-5914.

Thank you in advance for your participation.

Sincerely,
Alix Cawthon

Appendix C: Cover Letter for Electronic Survey

Dear Patient,

My name is Alix Cawthon, and I am a pharmacy student at Ole Miss. This summer and fall, I am conducting a research survey through the Sally McDonnell Barksdale Honors College, and I am asking for your participation. This survey should take no more than 7 or 8 minutes of your time. It includes various demographic questions, but mainly focuses on your knowledge and perceptions of pharmacy compounding, such as the kind done at C and C Drugs Vital Care. We are inviting all customers to participate, whether you get compounded medications or not. Your willingness to participate in this research will help me better understand patients' understanding and attitude toward small-scale pharmaceutical compounding. You can access the survey by typing the link below into your internet browser:

http://tinyurl.com/n7nj89l

Please keep in mind that your participation in this survey is entirely voluntary. Your completion of this survey does not affect your patronage at this pharmacy, or with any of its employees. Your responses will remain completely anonymous and will be examined along with other respondents' surveys.

This study has been reviewed by the University of Mississippi's Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections obligations required by the state and federal law and University policies. If you have any questions, please contact the IRB at (662) 915-7482.

If you have any questions about the research project specifically, feel free to contact me at macawtho@go.olemiss.edu, or my advisor, Dr. Erin Holmes, at erholmes@olemiss.edu, or (662) 915-5914.

Thank you in advance for your participation.

Sincerely,
Alix Cawthon