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Community Pharmacists' Attitudes Toward An Expanded Class Of Nonprescription Drugs

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COMMUNITY PHARMACISTS' ATTITUDES TOWARD AN EXPANDED CLASS OF NONPRESCRIPTION DRUGS

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ABSTRACT

Objectives: There has been considerable discussion about creating a third class of drugs which would not require a prescription, but require a pharmacist's consultation upon purchase. Very recently the Food and Drug Administration (FDA) held a hearing which repositioned a third class as an expanded nonprescription drug class termed as the "new paradigm" using certain innovative technologies. The specific objectives of this study were to: 1) Measure community pharmacists' attitudes toward an expanded nonprescription drug class under the FDA's proposed "new paradigm"; 2) determine if attitudes of community pharmacists toward an expanded nonprescription drug class under the FDA's proposed "new paradigm" differ by type of practice setting, location of community pharmacy, region in which the practice is located, degrees earned, years actively practicing pharmacy, position in the pharmacy, perceived workload, and pharmacy association affiliation; and 3) determine which drugs community pharmacists believe would be acceptable additions to an expanded definition of nonprescription drugs under the FDA's proposed "new paradigm".

Methods: This cross-sectional study was conducted using a self-report, web-based survey. 462 completed responses from a national convenience sample of community pharmacists were obtained. The survey items were either obtained from the existing scales in the literature or developed based on the FDA's proposed guidelines for the new paradigm. A principal components analysis (PCA) with VARIMAX rotation and reliability analyses were conducted to determine the factors affecting community pharmacists' attitudes toward the new paradigm.

Multivariate Analysis of Variance (MANOVA) was used to determine whether attitudes toward the new paradigm differed based on aforementioned respondent characteristics.

Results and Conclusions: Respondents were generally positive about the provision of patient care under the proposed new paradigm. The results from the PCA suggested that community pharmacists' attitudes toward the new paradigm is comprised of six factors including patient care, workflow, patient safety, non-pharmacist providers, pharmacist burden and access. Respondent attitudes differed based on certain practice and demographic variables. Not surprisingly, the majority of respondents indicated that Plavix® and Ambien® should still be dispensed as prescription drugs even upon implementation of the "new paradigm" while Lipitor®, Glucophage®, Viagra® could be switched to the "new paradigm".

DEDICATION

This thesis is dedicated to my Appa, Amma, parents and brother who have supported me in all my academic and non-academic endeavors.

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I would like to thank my advisor and friend Dr. Erin Holmes. She has worked as hard as me on this thesis and without her I would have never completed this project. I have learned a lot from her. Although I still have a long way to go, I have definitely come a long way since the time I started off with her a year back because of her efforts. She has been an excellent guide and an outstanding friend who always supported me at every crucial stage of this project.

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INTRODUCTION

Access to prescription medications continues to be a significant public health concern (Food and Drug Administration, 2012a) and is thought to lead to undertreatment of disease and other effects on the healthcare system (Karst, 2012). Limited access to prescription medications can be attributed to several factors, such as cost, perceived need, and access to a community pharmacy (Ried et al., 2011). Additionally, limited access to prescription medications can also be attributed to cost or time required to visit a physician for a prescription or prescription refill (Food and Drug Administration, 2012a). Making prescription drugs accessible as over-the-counter (OTC) medications, particularly through prescription-to-OTC switches, may resolve some of these access issues. However, for some drugs, the risk associated with use or potential for abuse or misuse of the drug may make it impractical to switch a drug from prescription status to OTC status (Food and Drug Administration, 2012b).

It is for these reasons that the debate about creating a third class of drugs, also referred to as a "behind-the-counter", "BTC", "pharmacist only", or "pharmacist controlled" class of drugs has been sparked and reignited by various stakeholders (Karst, 2012). Such a class of medications would include those drugs that do not require a prescription, but require a pharmacist's consultation upon purchase (Sood et al., 2008). This class is purported to provide patients with better access to certain drugs while still being monitored by a pharmacist (Cranor, 2003). In addition to improving access to certain drugs, a third class of drugs may alleviate safety concerns about drugs that might otherwise be available OTC. Pharmacist monitoring under the third class would minimize the risk of patients misdiagnosing their condition and

reduce the potential for abuse or misuse that make certain drugs unsafe to market as over-the-counter (OTC) products (Oster et al., 1990).

While these deliberations have never brought such a class to fruition, some medications have been classified as BTC drugs on a case-by-case basis. Pseudoephedrine was re-classified from an OTC to BTC class as a result of the Combat Methamphetamine Act because of a documented history of abuse as an OTC drug (Drug Enforcement Administration, 2005). Levonorgestrel (Plan B) was formerly a prescription-only product and is now dual-labeled to be dispensed as a OTC drug to patients 17 years of age and older and as a prescription to patients younger than 17 years of age (Food and Drug Administration, 2006). Recently, Plan B was switched to OTC status for females 15 years of age or older. However, the Obama administration has appealed this decision of the FDA and thus the matter is under further review (American Pharmacists Association, 2013).

Very recently, the third class debate was sparked again with a February 28, 2012 Federal Register notice announcing a late March public hearing for the FDA to gather input about how to address the issue of such a class of drugs (Karst, 2012). Unlike previous public hearings about expanding a BTC class of drugs, the 2012 public hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription" repositions a third class of drugs not as a BTC class, "but rather as a 'new paradigm' under which FDA "would approve certain drugs that would otherwise require a prescription for nonprescription use . . . under conditions of safe use"(Karst, 2012). These "conditions of safe use," says the FDA, "would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy" (Karst, 2012).

Therefore, the FDA is exploring the expansion of the current definition of nonprescription drugs as currently defined by the Durham Humphrey Amendment (Fink et al., 2006).

In concept, the idea of expanding the current definition of nonprescription drugs does not appear to markedly differ from previous proposals outlining a third class of drugs. However, several aspects of the new paradigm such as establishing conditions of safe use and using innovative technologies as one of the potential ways to dispense of these types of drugs does appear novel. The "new paradigm" will be discussed in detail in the forthcoming literature review.

Study Significance

Following the March 2012 public hearing on the new paradigm, the FDA seeks to elicit comments, opinions and suggestions about the proposed new paradigm from the key stakeholders in the field of healthcare. Arguably, the community pharmacist is one of the most significant stakeholders in expanding the definition of nonprescription drugs. In response to the FDAs need for feedback on the "new paradigm", this study measures community pharmacists' attitudes toward the expansion of the definition of nonprescription drugs in the United States.

Study Objectives

The specific objectives of this study are to:

1) Measure community pharmacists' attitudes toward an expanded nonprescription drug class under the FDA's proposed "new paradigm".

2) Determine if attitudes of community pharmacists toward an expanded nonprescription drug class under the FDA's proposed "new paradigm" differ by type of practice setting, location of community pharmacy, region in which the practice is located, degrees earned, years actively practicing pharmacy, position in the pharmacy, perceived workload, and pharmacy association affiliation.

3) Determine which drugs community pharmacists believe would be acceptable additions to an expanded definition of nonprescription drugs under the FDA's proposed "new paradigm".

LITERATURE REVIEW

History of the Third Class Debate

The idea of a third class of drugs has been debated ever since the passage of the Durham-Humphrey Amendment to the Food, Drug and Cosmetic Act in 1951 (Fink et al., 2006). The Durham Humphrey Amendment created two classes of drugs (prescription and non-prescription) in the United States (Fink et al., 2006). In 1964, due to concerns over safety of non-prescription sale of drugs such as albuterol, epinephrine and ibuprofen, the American Pharmaceutical Association (now the American Pharmacists Association) (APhA) House of Delegates recommended the creation of a third class of medications which would not require a prescription. However the clinical necessity and appropriateness of the drug would be determined by the pharmacist (Martin, 1991). Following this, in 1967, the APhA House of Delegates suggested that the sale of all codeine-containing cough and cold products and anti-diarrheal medications should be controlled by pharmacists. Support from the APhA and the National Community Pharmacists Association (NCPA), for an intermediate "transition" class of drugs which would be dispensed without a prescription by pharmacists, grew stronger after the first Rx-to-OTC switch was made in 1975 (Marshall, 1992). Several state pharmacy associations (such as the California and Florida Pharmacy Associations) have sponsored legislative resolutions that gave prescribing authority to pharmacists for drugs that are potential candidates for a prescription to non-prescription switch. In doing so, these states successfully created a "transition" category of drugs (Marshall, 1992).

Although some BTC drugs currently exist in the United States, the FDA has always vetoed the expansion of a third class of drugs on the grounds that it is not "necessary" (Sega & Sullivan, 2011). In 1995 the Government Accountability Office (GAO) issued a report evaluating the need for a BTC class of drugs. The GAO report analyzed similar systems in ten other countries such as the United Kingdom, Canada, and Australia. The report's main focus was on the effect of a third class of drugs on drug use/misuse, access and cost to patients. The GAO concluded that there was not enough evidence to add another class of drugs to the United States healthcare system (Marshall, 1992). In 2007, this topic reemerged in a FDA public hearing. The GAO was asked to revise its 1995 report. However, the GAO, after reviewing 86 drugs from 5 countries, concluded that the need for a third class of drugs in the United States was "still unclear" (Government Accountability Office, 2009) and that the FDA would need more evidence from key stakeholders before such a drug class could be operationalized and expanded. The third class debate was reignited again in 2011 when Research Director of the Center for Drug Evaluation and Research, Dr. Janet Woodcock, sought to revive the discussion at the Food and Drug Law Institutes annual conference (Karst, 2012).

Very recently, the third class debate was sparked again with a February 28, 2012 Federal Register notice announcing a late March public hearing for the FDA to gather input about how to address the issue of such a class of drugs (Karst, 2012). Unlike previous public hearings about expanding a BTC class of drugs, the March 2012 public hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription" repositions a third class of drugs not as a BTC class, "but rather as a 'new paradigm' under which FDA "would approve certain drugs that would otherwise require a prescription for nonprescription use . . . under conditions of safe use" (Karst,

2012). These “conditions of safe use,” says the FDA, “would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy” (Karst, 2012). Thus, the FDA is exploring the expansion of the current definition of nonprescription drugs as currently defined by the Durham Humphrey Amendment (Fink et al., 2006).

To ensure the safe and appropriate use of these nonprescription drugs, the FDA would have to establish the conditions for safe use for all such drugs on a case-by-case basis. For example, the patient might be required to talk to a pharmacist, or need to have a diagnostic test performed or visit a physician for the first prescription of the drug, but the subsequent refills could be obtained without a prescription. The FDA is also considering awarding dual status (i.e., both prescription and nonprescription) to certain drugs after determining the conditions for their safe use (Karst, 2012).

The FDA stated that in order for such a system of patient-directed self-care to work efficiently, various technologies such as kiosks at pharmacies, computer algorithms or questionnaires on the Internet, which would help the patient to self-diagnose correctly, could be used. Such technologies would be able to suggest appropriate medications to the patient for the particular condition. Additionally, the patient would be informed about the conditions for the safe use of the specific drug and the foods/drugs with which that drug might be contraindicated. Alternatively pharmacists would recommend the appropriate drug based on the patient’s medical records and inform the patient about the conditions for the safe use of the drug (Food and Drug Administration, 2012c).

Benefits and Limitations of an Expanded Definition of Nonprescription Drugs

There are several potential benefits to establishing an expanded definition of nonprescription drugs. Doing so would ensure better access to certain medications especially in

rural areas and at odd times (i.e. weekends, holidays, late evenings) when procuring a prescription might be difficult (Ried et al., 2011). Accessing an expanded nonprescription drug without a prescription could arguably save a patient both the time and money involved with a physician visit (Ried et al., 2011). Patient medication monitoring by the pharmacist through Medication Therapy Management (MTM) has shown to improve adherence and health outcomes (Bunting, Smith, & Sutherland, 2008) and thus there is a potential to see similar outcomes under the new paradigm. An expanded nonprescription drug class could arguably extend the pharmacist's role in healthcare; therefore further enhancing the value of the pharmacy profession by elevating pharmacists' involvement in patient treatment decision-making (Ried et al., 2011).

Such a drug class can also impact strategies, which pharmaceutical companies adopt, for their drugs nearing patent expiration. The existence of a well-developed expanded nonprescription drug class would add to the drug life-cycle extension avenues available to pharmaceutical manufacturers because now a drug nearing the end of its patent term could be approved for dispensing as part of the expanded nonprescription drug class. Additionally, after the FDA hearing of March 2012, the FDA might consider dual availability of a drug as both prescription and nonprescription under the new paradigm (Food and Drug Administration, 2012c). Such a move might be beneficial for manufacturers as they would be able to market an on-patent prescription drug as nonprescription as well.

Such a class of drugs has the potential to foster better patient-pharmacist as well as physician-pharmacist relationships. This is predicated on the idea that qualified healthcare professionals would work collaboratively with patients to appropriate decisions about the patients' medication regimen (Ried et al., 2011). However, if physicians are not comfortable

with the idea of pharmacists recommending and monitoring patients' medications, or ordering diagnostic tests, then pharmacist-physician relationships could be negatively affected.

There are certain limitations associated with expanding the definition of a nonprescription drug class. These drugs could have a greater abuse/misuse potential than prescription drugs as patients may "shop" (i.e., acquire multiple fills and refills) for these drugs from one pharmacy to the other (Ried et al., 2011) unless controlled for by the FDAs "conditions for safe use" (Food and Drug Administration, 2012c). Implementing an expansion of nonprescription drugs would require a greater investment of time on the part of the pharmacist for patient counseling and documenting patients' medical records (Ried et al., 2011). Reimbursing pharmacists for the additional time spent on providing these services by third party payers is another concern (Ried et al., 2011). An expanded nonprescription definition could also result in increased pharmacist liability (Department of Health and Human Services, 2012).

Finally, infrastructure changes would have to be made in pharmacies to provide additional private patient counseling rooms as well space to store these drugs (Ried et al., 2011). Another important factor that must be considered is patient cost. It is anticipated that initially expanded nonprescription drugs will increase out of pocket expenses for patients as they may not be covered by insurance. However, overall costs in the long run will depend upon third party coverage of drugs as well as mortality and morbidity rates as a result of pharmacists' interventions (Ried et al., 2011).

Drug Candidates for an Expanded Definition of Nonprescription Drugs

Organizations such as APhA and the Academy of Managed Care Pharmacy have suggested that only those medicines that are used for ailments that involve limited physical assessment (i.e., easy self-diagnosis) and whose lab results can be easily interpreted could

potentially be dispensed under an expanded definition of nonprescription drugs (Ried et al., 2011). Prescription drugs having a good benefit-to-risk ratio could be included in such a drug class (Ried et al., 2011). The pharmacist must be able to order and access lab tests when needed and electronic health information records must be kept up to date for such a switch to work. These drugs should have a manageable side effect profile and they should not put the patient at risk for microbial resistance (Ried et al., 2011). For certain drugs, the patient may need to consult the physician initially, but the pharmacist may be consulted for subsequent refills (Department of Health and Human Services, 2012).

With these considerations in mind, the discussion as to which drugs would make ideal candidates for an expanded definition of nonprescription drugs begins. Prospective candidates for this class of drugs include medications for treating hypertension, hyperlipidemia, asthma, gastrointestinal reflux, allergies, pain, migraines, and obesity (Ried et al., 2011). Recently, there has been significant attention paid to the inclusion of statins in either a traditional or expanded nonprescription class. Statins have a history of being well tolerated and effective reducing cholesterol (Nag, Pearson, Ma, et al., 2005). However, it has been estimated that over 60% of patients do not receive adequate statin treatment (Nag, Pearson, Ma, et al., 2005). Therefore, there have been several attempts to switch statin drugs to a nonprescription class.

Merck made unsuccessful efforts to switch Mevacor, its blockbuster cholesterol lowering drug, to a nonprescription before its patent expired in 2001 (Wechsler, 2000). There have been endeavors to switch cholesterol-lowering pravastatin and lovastatin to a nonprescription category (Sood et al., 2012). However, these efforts have been rendered null by the FDA due to concerns such as inappropriate self-selection, side-effects like rhabdoamyolosis, and the necessity to screen liver enzymes (Tinetti, 2008). Perhaps in the “new paradigm” of an expanded

nonprescription drug class, statins may find their fit. The Federal Register of February 2012 (Department of Health and Human Services, 2012) states that certain chronic medications may be sold under an expanded nonprescription class of drugs after the conditions for its safe use are determined. These conditions of safe use could be established after evidence has been established through post marketing surveillance, adverse events reports or epidemiological studies which could be sponsored by the manufacturer while they would be carried by pharmacists (Marshall, 1992).

Stakeholder Perspectives on an Expanded Definition of Nonprescription Drugs

Consumer groups. Generally, consumer groups have voiced support for an expanded class of nonprescription drugs. The National Consumers League and the Consumers Union have advocated the creation of a class that will increase patient access to safe drugs, after consulting a pharmacist, for self-diagnosable conditions (Ried et al., 2011). These groups have held the opinion that such a class of drugs would increase the range of self-diagnosable conditions for the patient. This has the potential to save time and money that would have otherwise been spent on a physician visit and would go a long way in alleviating patients' access problems.

In September 1991, the National Consumers League sponsored a symposium "Transition Class of Drugs: Prescription for Change – Global Perspectives" which illustrated the effectiveness of such a class of drugs in countries such as United Kingdom, Australia and Canada, where such an expanded nonprescription class already exists (Marshall, 1992). However, these groups are concerned about the lack of insurance coverage for these drugs as well as patient privacy and comfort level in discussing medication issues at length with the pharmacist (Branding & Narula, 2011). Thus, these organizations have suggested a test phase for an expanded nonprescription class of drugs before its eventual implementation.

On the other hand, the Consumer Healthcare Products Association (CHPA), formerly known as the Nonprescription Drug Manufacturer's Association (NDMA), believes that the current two drug class system in the United States is sufficient and provides enough flexibility to the consumer (Ried et al., 2011). Indeed, it has been argued that an expanded nonprescription class of drugs would reduce patient empowerment and increase FDA control over patient medication choice and access (Ried et al., 2011). CHPA estimated that creating a third class would reduce the number of available non-prescription options from 750,000 to 55,000 (Government Accountability Office, 1995). The CHPA also stated that the number of retail establishments, which currently sell OTC medications, would decrease by as much as 80% if a majority of OTC drugs were moved behind the pharmacy counter. Because the CHPA lobbies for OTC manufacturers, it fears that an expanded nonprescription class would severely curtail the sale of OTC drugs, as seen in the case of pseudoephedrine. They believe that the current two class system "works" and pharmacists want such a move to be implemented for their own "economic benefits" (Martin, 1991).

Professional pharmacy organizations. Most professional pharmacy organizations such as the American Pharmacists Association, American Society of Health System Pharmacists, National Association of Boards of Pharmacy, and the National Community Pharmacists Association advocate for the implementation of an expanded nonprescription class of drugs (Ried et al., 2011).

The justification provided by them in favor of an expanded class of drugs is that such a category will be useful in reducing the side effects of certain OTC drugs, especially in high risk patients with asthma, diabetes, bleeding disorders, and effective intervention will ensure appropriate drug use (Ried et al., 2011). They also believe that an expanded category of drugs

will increase patient access to essential medications, enhance patient safety and improve the quality of patient care (Ried et al., 2011). They note that pharmacists have the clinical training required for reliable monitoring and management of chronic and self-diagnosable conditions (Ried et al., 2011). Pharmacists expect such a class of drugs to decrease healthcare costs in the long run as well as promote better collaboration among healthcare teams (Martin, 1991).

However, certain potential barriers cited by pharmacist organizations to the implementation of an expanded nonprescription class are unavailability of specialized training in patient diagnosis and follow-up, increased liability, an unacceptable legal and insurance framework which will reimburse the pharmacist for the time spent in patient diagnosis and counseling (Hunt, 2010), and insufficient space for private patient counseling rooms (Sega & Sullivan, 2011). Although it has been argued that the funding for pharmacists' reimbursement could come from various sources such as Medicare Part D (in a manner similar to how pharmacists are reimbursed for MTM), state Medicaid and out-of-pocket from the patient (Levy, 2008), reimbursement mechanism will likely be unclear until the class is actually expanded.

A recent statement by the president of the APhA, Thomas Menighan, sums up the above arguments very well. Menighan commented, "While many details of this potential drug paradigm need to be worked out through future collaborations, none of them are significant enough to stop this important initiative from being enacted. America's pharmacists view this proposal as 'Yes... if,' rather than 'No... but.' We look forward to working with FDA and other healthcare providers and stakeholders to answer the 'if' questions and make this concept a reality for the benefit of patients and the healthcare system" (American Pharmacists Association, 2012). The American Society of Health System Pharmacists (American Society of Health System

Pharmacists, 2012) and the APhA have supported the creation of this new drug paradigm though released statements after the March 2012 hearing.

Professional physician organizations. The American Medical Association (AMA) argues that the FDA does not have enough evidence to establish an expanded nonprescription class without new legislation and that such a class may actually hamper access to medications (i.e. OTC drugs) while increasing cost and risk (American Medical Association, 2010). The AMA argues that pharmacists' clinical training may not be sufficient to diagnose patients (especially in chronic cases) correctly and hence an expanded nonprescription class may be inappropriate. Physicians also worry that patients may not feel the need to see their doctor for routine check-ups or they might delay care in case of acute conditions (Zwillich, 2007). Other medical professions have also expressed concern over an expanded class of nonprescription drug. Nutritionists have noted that "fewer patients would pursue preventative measures like diet and exercise if they can easily buy a pill" (Zwillich, 2007).

Pharmaceutical manufacturer organizations. The Pharmaceutical Research and Manufacturers of America (PhRMA), formerly known as Pharmaceutical Manufacturers Association (PMA) has not taken a stand on the issue of an expanded nonprescription class (Marshall, 1992). However, it has been largely estimated that the industry would be skeptical about the addition of a transition class of drugs (Marshall, 1992). It is argued that indecisiveness in their opinion exists because pharmacy organizations have not fully defined what should constitute of such a class of drugs (Marshall, 1992).

Current Research in Community Pharmacist Attitudes

There are certain studies in the current literature which have reported on community pharmacists' attitudes and perceptions toward a potential expanded nonprescription drug class in

the United States. Sega and Sullivan (2011), Hunt et al. (2010) and Prince and Pharo (2008) measured attitudes of community pharmacists' toward the establishment of a permanent BTC category of drugs, in the states of Ohio, Idaho and Alabama respectively. These studies examined various issues related to a potential expanded nonprescription drug class in the United States such as pharmacist knowledge about an expanded nonprescription drug class, pharmacists' readiness for the establishment of such a class in the United States, reimbursement issues, and social and legal aspects surrounding the implementation of such a drug class. These studies also considered pharmacist opinions about pharmacy related factors (staffing, structural changes which might be essential), and patient related factors (access, time, monetary concerns). The results of these studies suggested that pharmacists agree that there is a need for a BTC drug class in the United States. Pharmacist readiness for the implementation of a third class of drugs appeared to be based on the belief that patients would benefit from having increased access and time savings. However, pharmacists also agreed that certain changes would need to be made in the pharmacy and that pharmacists would need some amount of training before a BTC drug class is established

A study by Taylor et al. (2000) explored community pharmacists' readiness to assess the OTC selections of their customers in a Canadian province using the Transtheoretical Model of Change. This study assessed the benefits and limitations of establishing a pharmacist-only class of drugs and pharmacists' level of agreement with the legislative status that had been given to such a class of drugs. The results of this study showed that community pharmacists differed considerably in their degree of readiness to acknowledge the establishment of pharmacist-only class of drug products. A majority of the respondents were not ready to accept the responsibility of assessing patients' OTC selections (57.6% of the respondents were in pre-contemplation

stage). Precontemplators were expectedly less supportive of keeping pharmacist-only agents behind the counter.

Madhavan (1993) examined the conditions preferred by United States community pharmacists' for the sale of Rx-to-OTC switch drugs. He also assessed if these conditions varied significantly with regard to demographics and practice characteristics of the pharmacists. This study suggested community pharmacists' preferred a permanent pharmacist supervised class (i.e. BTC drug class) of drugs over a general unsupervised drug class. Overall, for switch drugs, pharmacists preferred conditions of sale that involved pharmacist supervision rather than conditions that did not, although some pharmacists were governed by safety concerns and economic issues.

The current study seeks to make significant contributions to the literature evaluating pharmacists' attitudes toward an expanded nonprescription drug class. First, this study employs a theoretical framework to describe pharmacists' attitudes toward an expanded nonprescription class of drugs. Second, a national sample is employed to ensure greater generalizability of findings and allow for regional comparisons in attitudes. Most importantly, this study examined pharmacists' attitudes toward an expanded nonprescription class of drugs specifically under the FDA's recently proposed "new paradigm".

Theoretical framework

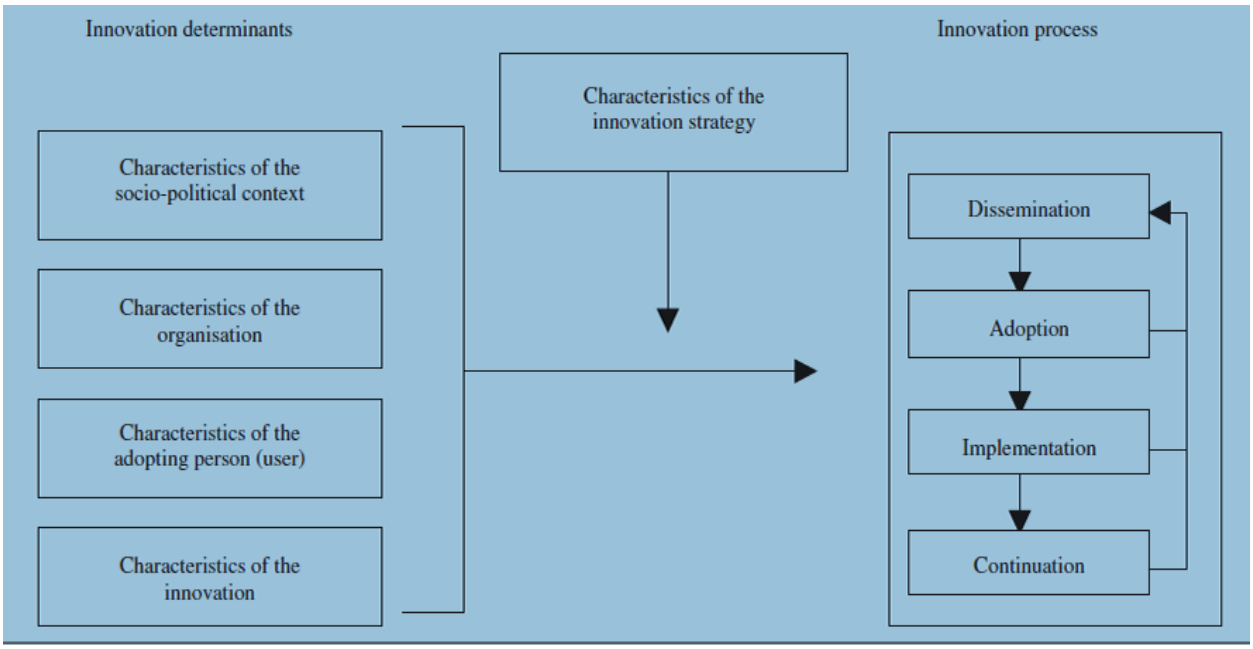
With respect to this study, it was considered that an expanded nonprescription class under the "new paradigm", if implemented, would be a new innovation in healthcare because currently, only a de-facto BTC class of drugs exists in the United States, with certain drugs added to it on a case by case basis. In fact, the FDA's March 2012 public hearing was entitled "using *innovative*

technologies and other conditions of safe use to expand which products can be considered nonprescription."

Rogers defines an innovation as "an idea, practice or object that is perceived as new by an individual or other unit of adoption" (Rogers, 2003). Whenever a new innovation or a major policy change is introduced into any field (healthcare in this case) it is essential to understand the determinants or the factors that facilitate or impede the adoption and implementation of that innovation by the key stakeholders. An understanding of these determinants is essential for the successful implementation of the new innovation because there may be several positive or negative factors in addition to the attitude and characteristics of the adopting healthcare professional as well as the adequacy of financial resources which can affect the optimum adoption and implementation of an innovation.

Therefore, a theoretical framework based on the determinants of innovation within healthcare organizations was adapted from Fleuren, Wiefferink and Paulussen (2004) for use in this study. In this framework, the main stages in the process of incorporating an innovation into practice and the related categories of determinants have been structured such that the adopter of a new innovation can identify the various determinants that can affect the process of incorporating an innovation into practice. The framework can be found in Figure 1 below.

Figure 1: Determinants of Innovation Framework.



Fleuren, Wiefferink & Paulussen (2004)

The various determinants that impact the process of incorporating an innovation into practice can be divided into four broad categories: (i) *characteristics of the socio-political context* refers to rules, legislation and patient characteristics; (ii) *characteristics of the adopting organization* refers to issues such as staff-turnover or involvement in decision-making; (iii) *characteristics of the adopting person* refers to the knowledge, skills, and colleague support which the user of the innovation might need; (iv) *characteristics of the innovation* refers to matters such as the ease/complexity of the implementation and use of the innovation, and relative advantage the innovation offers over current counterparts (Fleuren, Wiefferink, & Paulussen, 2004).

The four innovation determinants described above were adapted as needed to provide theoretical framework for identifying the dimensions of community pharmacists' attitudes toward an expanded definition of nonprescription drugs. Characteristics of the socio-political context were used to describe legal and patient factors related to an expanded nonprescription class of drugs under the FDA's proposed new paradigm. Characteristics of the organization were adapted to characteristics of the pharmacy to describe characteristics of pharmacies that would be ultimately implement the expanded nonprescription class of drugs under the FDA's proposed new paradigm. Characteristics of the adopting person (user) were adapted to characteristics of the pharmacists who would adopt the expanded nonprescription class of drugs under the FDA's proposed new paradigm. Characteristics of the innovation were used to describe complexity and relative advantage of the expanded nonprescription class of drugs under the FDA's proposed new paradigm over the current two drug class system.

METHODS

Design

This study was conducted with a cross-sectional non-experimental descriptive design by means of a self-administered web-based survey which was distributed to a national sample of community pharmacists.

Sample

Sample description. A national convenience sample of community pharmacists was used in this study. Using a national sample facilitated investigating regional differences that might exist in community pharmacists' attitudes toward an expanded nonprescription drug class in the United States while also facilitating the generalizability of results. Community pharmacists provide the sample frame for this study because they are major stakeholders and would be essential to the successful establishment of an expanded nonprescription class of drugs. The sample contained community pharmacists from independent pharmacies, traditional chain pharmacies, grocery stores and mass merchandisers.

Sample source. The sample of community pharmacists was drawn from a national panel of community pharmacists obtained from Delta Marketing Dynamics, a data services company. Out of the database maintained by the company, a list of 2800 community pharmacists was selected and this served as the respondent sample for the study.

Sample size. Two estimates were used for calculating the sample size for the study. In the first approach, sample size was determined using the formula mentioned below

$$N_s = (N_p)(p)(1 - p)/((N_p - 1)(B/C)^2+(p)(1 - p))$$

Where N_s is the sample size needed for the size of the survey population and N_p is the number of units in the survey population from which the sample is to be drawn which has been estimated to be 184,700 community pharmacists. This estimate was determined by combining the National Community Pharmacists Association's (NCPAs) estimate of 66,700 independent pharmacists in the United States (National Community Pharmacists Association, 2012) and the National Association of Chain Drug Stores' (NACDSs) estimate of 118,000 chain pharmacists in the United States (National Association of Chain Drug Stores, 2012). The term (p)(1-p) is a measure of the expected variation in answers to the question of interest (i.e. set at 50% which is the most conservative value possible for the population). The term B represents the margin of error which is taken as 0.05. Finally, C is the corresponding Z score associated with the amount of statistical confidence one desires to have in the estimate (commonly set at 95% and thus 1.96 would be the corresponding Z score). The estimated sample size was determined to be 383 respondents when the population variance is 0.5, the margin for sampling error is set at 5% and a 95% confidence interval is used (Dillman, Smyth & Christian, 2009).

In the second estimate, the sample size was determined using G*Power, a power analysis program (Buchner et al., 1997). The estimate of sample size for a fixed-effects, one-way Analysis of Variance (ANOVA) using a medium effect size (0.25), $\alpha = 0.05$ at power = 0.95 and five groups was 305. Taking both sample size calculations into consideration, it was determined that the conservative estimate of 383 respondents would be needed.

Attempts were made to determine the response rate of a community pharmacist sample completing a self-administered web-based survey. A study conducted by Barnard (2012) using a sample of community pharmacists yielded a usable response rate of 2.4%. However, it is possible that the sensitivity of Barnard's survey topic (interpersonal violence) resulted in the low

response rate. Other web-based surveys conducted in a national sample of community pharmacists yield slightly higher response rates. For example, a response rate of 10.8% was obtained by McKenny and his colleagues in a study to determine the beliefs and attitudes of pharmacists about the significance of heart disease and its treatments (McKenny et al., 2004). Given these varying response rates, it was determined that the self-administered web-based survey would be administered to the entire available panel of community pharmacists provided by Delta Marketing Dynamics (n=2800).

Measures

Objective 1. To meet the first study objective, determinants of innovation within healthcare organizations were adapted from Fleuren, Wiefferink and Paulussen (2004). Using this framework, it was proposed that characteristics of the socio-political context, characteristics of the adopting pharmacist, characteristics of the pharmacy, and characteristics of the innovation would comprise community pharmacists' attitudes toward expansion of the nonprescription class of drugs.

To generate a pool of items for each construct, items were adapted from scales developed in previous literature by Hunt et al. (2010), Sega and Sullivan (2011), Prince and Pharo (2008), Karst (2012) and the Department of Health and Human Services February 2012 Federal Register Notice. Additionally, items were developed by the investigator. The pool of items was categorized by the investigator into each framework component (socio-political, pharmacy, pharmacist, and innovation). The initial pool contained 36 items (Appendix 1). The attitudes of community pharmacists toward an expanded nonprescription class of drugs were assessed using a 7-point linear numeric scale.

In-depth cognitive interviews were conducted with six local pharmacists with community practice experience. They were asked to provide feedback about each item's relevance, clarity, and conciseness. Also, they were asked to identify any other items that might be needed for the measure, in order to ensure comprehensiveness. Following in-depth cognitive interviews, the items (and the survey in its entirety) were assessed for content validity by pharmacy administration graduate students at the University of Mississippi. The graduate students were asked to note the time taken to complete the survey. Any necessary refinements to the survey were made. The survey was also pre-tested among community pharmacists in the state of Mississippi and Doctor of Pharmacy students at the University of Mississippi Medical Center in Jackson, Mississippi.

Objective 2. To meet the second objective, data was collected for twelve demographic and practice variables which included: 1) type of practice setting, 2) location of community pharmacy (rural or urban), 3) state in which the practice is located, 4) daily prescription volume for the pharmacy, 5) degrees earned, 6) years actively practicing pharmacy, 7) position in the pharmacy (staff, manager, etc.), 8) age, 9) gender, 10) race/ethnicity, 11) daily prescription volume for the individual pharmacist, and 12) pharmacy association affiliation. Perceived workload was measured using a perceived role overload scale that was previously used in a sample of retail chain pharmacists with a Cronbach's alpha of 0.92 (Holmes, 2008).

Objective 3. To meet the third objective, the survey contained a list of current "prescription-only" drugs which may be potential candidates for an expanded nonprescription class of drugs based on criteria outlined in the February 2012 Federal Register, "Using innovative technologies and other conditions of safe use to expand which drug products can be considered nonprescription" (Department of Health and Human Services, 2012). The

respondents were asked to indicate whether the particular drug should be marketed as a prescription drug, nonprescription drug or dual marketed as both prescription and nonprescription under the new paradigm. Input was obtained from the literature (Sega & Sullivan, 2011) and content experts (two pharmacists and a pharmacy student) to develop this drug list.

Data Collection

The data collection instrument proposed for this study was a web-based self-administered survey. The survey was programmed and distributed using *Qualtrics*, a web-based tool used for survey design and distribution. The modified Dillman tailored design method was adapted for use in this study to reduce survey error (Dillman, Smyth & Christian, 2009).

IRB approval was obtained before the data collection process was started. To send the final survey (Appendix 2) to the full study sample, the URL link to the survey was emailed to 2800 pharmacists via Qualtrics. The same email also contained a cover letter (Appendix 3) which provided details about the nature and purpose of the study. All respondents were notified that their participation in the survey was voluntary and that their responses as well as private demographic information would be kept confidential. Respondents were not forced to answer any question on the survey. A screener question was included at the start of the survey to ensure that only community pharmacists answered the survey. An email expressing appreciation was sent out to all the responders at the end of the data collection period. Respondents were incentivized by offering them an executive summary of the results and implications of the study. A similar procedure was also followed for the pre-test.

Data Management

Data for responses from community pharmacists were obtained in the form of Microsoft Excel® file (*.xls). Responses to the survey were automatically recorded electronically as the respondents completed their survey. Data were cleaned in Microsoft Excel® before being analyzed using Statistical Package for Social Sciences IBM (SPSS®) version 20.0 for Windows®. Observations with 15% or more data missing were excluded from analysis to avoid omitted data bias (Hair et al., 1998).

Data Analysis

Sample description. The description of the sample was provided using the twelve demographic variables previously discussed by calculating appropriate means, frequencies and percentages as appropriate.

Objective 1. Initially, a principal component analysis (PCA) using VARIMAX rotation was performed for all pharmacist attitude items in order to define a set of underlying dimensions or factors, of pharmacist attitudes, despite the theoretical framework used to develop the items. To examine reliability, item-total correlations and Cronbach's alpha were calculated for each of these subscales. Means, standard deviations, and per item means were calculated for each subscale to meet the first objective of determining community pharmacists' attitudes toward a nonprescription drug class as a "new paradigm".

Objective 2. Multivariate Analysis of Variance (MANOVA) (depending on whether variables contained two or more levels for comparison) were carried out to assess significant differences between and among levels of demographic variables (i.e. type of practice setting, location of community pharmacy, region in which the practice is located, degrees earned, position in the pharmacy, pharmacy association affiliation) for each of the four attitude subscales. Before conducting analyses, assumptions of homogeneity of variance-covariance

matrices, independence, linearity and existence were tested. The level of significance used for these tests was $\alpha = 0.05$.

Correlation coefficients were calculated to test the degree of correlation between the perceptions of workload scale and the four attitude subscales. This procedure was repeated for testing the degree of correlation between years of actively practicing pharmacy and the four attitude subscales.

Objective 3. Frequencies were calculated in order to determine the number of pharmacists that appropriated the sale of a particular drug under each of the three categories (i.e. prescription-only, nonprescription, and both prescription and nonprescription).

Nonresponse bias. A time-trends extrapolation method was used to determine the nonresponse bias by comparing the responses of the first and last 20% of survey respondents on demographics and practice characteristics. The assumption underlying this test is that individuals who respond later to a questionnaire are similar to those who do not respond at all (Armstrong & Overton, 1977). Independent sample t-tests and chi-square tests were conducted to determine if differences in demographic and practice variables existed between these two groups.

RESULTS

Sample Description

Participant Response. A total of 462 completed, useable responses were obtained. Participants were eligible for the study only if they were community pharmacists (potential respondents were screened at the start of the survey). Initially, 616 responses were obtained. However, participants who were missing more than 15% (Hair et al., 1998) (i.e. more than four questions) of their responses on the attitude scale were excluded from analysis.

Respondent Demographics. The average age of the respondents was 49 years. The sample consisted of 272 males (61.4%) and 171 females (38.6%). The sample was predominantly Caucasian (87.2%). Just over 66% of respondents had a Bachelor of Pharmacy (BPharm; practice degree) while almost 28% had a Doctor of Pharmacy (PharmD). 297 (64.28%) respondents were affiliated with a national, state, or local professional pharmacy organization while 165 (35.72%) did not report membership with a pharmacy organization. A full description of respondents' demographic characteristics is provided in Tables 1 and 2.

Table 1. Characteristics of Respondents

Characteristics	*No. Respondents (%)**
Gender	
Men	272 (61.4)
Women	171 (38.6)
Race/Ethnicity	
White/Caucasian	381 (87.2)
Asian/ Asian Indian	32 (7.3)
Hispanic	4 (0.9)
African American/Black	9 (2.1)
American Indian/Alaska Native	3 (0.7)
Other	8 (1.8)
*Pharmacy Training***	
Bachelor of Pharmacy (practice degree)	320 (66.12)
Doctor of Pharmacy	133 (27.48)
Master of Science	6 (1.24)
Doctor of Philosophy	3 (0.62)
Other	22 (4.54)
*Membership of Professional Pharmacy Organization***	
American Pharmacists Association	118 (22.01)
National Community Pharmacists Association	81 (15.14)
American Society of Health-System Pharmacists	9 (1.68)
National Pharmaceutical Association	10 (1.87)
State Pharmacy Association	226 (42.24)
Other	91 (17.01)

**Categories may not add to the total of 462 useable responses due to missing demographic data.*
*****Respondents could check all responses that applied.***

Table 2. Characteristics of Respondents and their Practices

Characteristics	*Mean (Standard Deviation)*	*Range*
Age	48.76 (11.27)	25-82
Years of actively practicing pharmacy	23.59 (11.50)	1.5-60
Number of hours practiced in a typical week	41.51 (7.81)	10-80
Number of prescriptions store fills on an average weekday	449.93 (554.26)	50-4500

Respondent Practice Characteristics. Most of the respondents were pharmacy managers/ pharmacists-in-charge (54.3%) and worked in an independent pharmacy (37.8%) in a self-reported urban location (57.9%). The sample was representative of all four census regions in the United States (Census Bureau, 2013). On average, respondents reported to have been actively practicing pharmacy for nearly 24 years. In a typical week respondents worked an average of almost 42 hours. Respondents reported that their stores fill an average of 450 prescriptions on a typical weekday. A full description of respondents' practice characteristics is provided in Tables 2 and 3.

Table 3. Characteristics of Respondents' Practices

Characteristics	*No. Respondents (%)**
Type of Pharmacy	
Independent	168 (37.8)
Franchise	23 (5.2)
Traditional Chain	72 (16.2)
Supermarket with a pharmacy	130 (29.3)
Mass merchandiser with a pharmacy	41 (9.2)
Other	10 (2.3)
Position in the Pharmacy	
Staff/Floater/Relief pharmacist	128 (29.0)
Manager/Pharmacist in-charge	240 (54.3)
Owner	70 (15.8)
District manager	3 (0.7)
Regional manger	0 (0.0)
Other	1 (0.2)
Location of Pharmacy	
Urban	256 (57.9)
Rural	186 (42.1)
Geographic Region of practice	
South	152 (34.1)
Mid-West	104 (23.3)
North East	108 (24.2)
West	82 (18.4)

**Categories may not add to the total of 462 useable responses due to missing practice characteristic data.*

Estimation of Nonresponse Bias

Nonresponse bias was estimated using the time trends extrapolation technique (Armstrong & Overton, 1977). T-tests and chi-square tests were conducted to determine if significant differences in demographic and other variables existed between the first and last 10% of respondents. T-tests indicated significant differences between early and late responders' age and years practicing (Table 4). Chi-square tests did not indicate significant differences in nonparametric data between early and late responders (Table 5).

Table 4. Estimation of Nonresponse Bias: Time Trends Extrapolation of Parametric Data

Variable	*Mean and Std Error*	*First 10% (n=46)*	*Last 10% (n=46)*	*t-value*	*p-value*
Patient care	mean std error	5.11 0.19	5.16 0.19	-0.198	0.843
Workflow	mean std error	5.30 0.15	5.27 0.16	0.133	0.894
Patient safety	mean std error	6.33 0.13	6.39 0.11	-0.329	0.743
Non-pharmacist providers	mean std error	4.62 0.26	4.48 0.20	0.420	0.675
Pharmacist burden	mean std error	6.61 0.10	6.63 0.14	-0.124	0.901
Access	mean std error	5.09 0.15	4.81 0.18	1.212	0.229
Age*	mean std error	44.47 1.65	49.52 1.68	-2.153	0.034
Number of years practicing*	mean std error	18.04 1.52	23.82 1.73	-2.153	0.034
Number of hours practiced in a typical week	mean std error	43.00 1.36	40.89 1.37	1.097	0.276
Number of prescriptions store fills on an average weekday	mean std error	423.52 74.74	457.5 83.53	-0.303	0.763
Perceptions of workload	mean std error	3.03 0.14	3.22 0.15	-0.913	0.364

*****Significant at $\alpha = 0.05$

Table 5. Estimation of Nonresponse Bias: Time Trends Extrapolation of Nonparametric Data

Variable	*Category*	*First 10% (n=50)*	*Last 10% (n=50)*	χ^2	*p-value*
Work location	Urban Rural	27 (61.4%) 17 (38.6%)	29 (65.9%) 15 (34.1%)	0.196	0.906
Store category	Independent Chain	14 (33.3%) 28 (66.7%)	15 (34.9%) 28 (65.1%)	0.177	0.915
Position	Staff/relief/floater PIC/manager Owner	15 (34.9%) 22 (51.2%) 6 (13.9%)	19 (44.2%) 18 (41.9%) 6(13.9%)	0.871	0.833
Geographic region of the country	Northeast Midwest South West	13(29.5%) 9 (20.5%) 11 (25%) 11(25%)	14 (31.8%) 10 (22.7%) 11 (25%) 9 (20.5%)	0.290	0.990
Gender	Male Female	22 (50%) 22 (50%)	25 (56.8%) 19 (43.2%)	0.411	0.521
Professional Organization Affiliation	Yes No	27 (%) 16 (%)	31 (%) 12 (%)	0.847	0.655
Race	American Indian Asian African American Hispanic Native Hawaiian White Other	0 (0%) 3 (7%) 0 (0%) 1 (2.3%) 0 (0 %) 36 (83.7%) 3 (7%)	0 (0%) 5 (11.4%) 2 (4.5%) 0 (0%) 0 (0%) 37 (84.1%) 0 (0%)	6.503	0.165

Objective 1

The first objective for this study was to measure community pharmacists' attitudes toward an expanded nonprescription drug class under the FDA's proposed "new paradigm".

Principal Components Analysis. The scale used to measure community pharmacists' attitude toward an expanded nonprescription drug class established under the "new paradigm" consisted of 37 items. The scale was a 7-point linear numeric scale where 1 = "Strongly Disagree" and 7 = "Strongly Agree". These items were based on a thorough search of the literature and the theoretical framework for the study (Determinants of Innovation Framework) (Fleuren, Wiefferink, & Paulussen, 2004) but not from any established scale. Therefore a principal components analysis (PCA) with VARIMAX rotation was performed in order to identify the dimensions of community pharmacists' attitudes toward the "new paradigm".

Although the scale initially had 37 items, eight items were removed after assessing factor loadings, cross loadings and communalities (as well as Cronbach's alpha if deleted and item-to-total correlations examined in the reliability analysis described below). Thus the final scale had only 29 items. The items which were deleted were:

"Assuming the implementation of an expanded nonprescription drug class under the FDA's proposed 'new paradigm'……"

1. Pharmacist intervention would still be needed if innovative technologies that help patients self-assess their drug choices are instituted under the "new paradigm".
2. Patients would seek medical help more quickly than they do now.
3. Additional pharmacist training would have to be provided by pharmacies if the "new paradigm" were instituted.
4. The "new paradigm" would foster better physician-pharmacist relationships.

5. The "new paradigm" would foster better patient-pharmacist relationships.
6. Patients would be capable of gauging their own health status using kiosks and online questionnaires.
7. Adopting the "new paradigm" should be mandatory for all pharmacies.
8. The profitability of a pharmacy would increase.

As a result of this analysis, six components (i.e., underlying dimensions) were identified from the scale: *patient care* (9 components), *workflow* (6 items), *patient safety* (5 items), *non-pharmacist providers* (3 items), *pharmacist burden* (3 items) and *access* (3 items). Standardized coefficients from the rotated factor matrix representing the loading of each item to the component to which it was assigned is shown in Table 6.

Reliability. Reliabilities of the six components obtained from the PCA were calculated using Cronbach's alpha. Table 6 lists all six components and their associated items along with their Cronbach's alpha coefficients, the summated means and standard deviations of the scale scores, and the per-item means for each scale. Cronbach's alpha of the overall scale was 0.786 with summated mean and standard deviation of 157.907 ± 16.21 after the deletion of the above-mentioned eight items.

Table 6. Principal Component Analysis and Reliability Results

Items*	Number of Items	Standardized Coefficients		Cronbach's Alpha	Means ± SD	Per-Item Mean
Component 1 – Patient Care	**9**			**0.888**	**46.539 ± 10.62**	**5.17**
Pharmacists would have time to assist patients in selecting the most appropriate "new paradigm" drug		0.696				3.91
Pharmacist-authorized refills following a physician's initial prescription should be permitted under the new paradigm		0.740				5.35
Pharmacists would be comfortable enough to order diagnostic/lab tests before dispensing certain "new paradigm" medications		0.740				4.65
Pharmacists are capable enough to order diagnostic/lab tests before dispensing certain "new paradigm" medications		0.704				5.11
Pharmacists have the ability to make appropriate treatment recommendations		0.660				6.50
The "new paradigm" would allow for more patient-directed care		0.533				6.10
I support the institution of the "new paradigm" in pharmacy practice.		0.853				5.33
Patient medication adherence would improve		0.600				4.85
Patients would be accepting of pharmacists monitoring their treatment		0.588				5.35
Component 2 – Workflow	**6**			**0.816**	**31.088 ± 6.90**	**5.18**
Significant structural changes would have to be made in pharmacies to incorporate extra space for patient consulting rooms		0.767				5.64
Significant structural changes would have to be made in pharmacies to incorporate extra space for an expanded nonprescription drug section under the "new paradigm"		0.788				5.03
The number of personnel in pharmacies would have to be increased if the "new paradigm" were instituted		0.780				5.67
Significant changes in workflow of the pharmacy would have to be made		0.749				5.79
It would be difficult to implement the "new paradigm" in a typical community pharmacy setting		0.580				4.17
The installation of innovative technologies such as kiosks and online questionnaires in pharmacies would be problematic		0.457				4.80

Items*	Number of Items	Standardized Coefficients		Cronbach's Alpha	Means ± SD	Per-Item Mean
Component 3 – Patient safety	**5**			**0.769**	**32.163 ± 3.97**	**6.43**
When in doubt, pharmacists should refer patients to a physician before dispensing a "new paradigm" medication		0.682				6.44
Pharmacists should alert a physician if there are problems with "new paradigm" medications that a patient is taking		0.750				6.62
Patient counseling by pharmacists for "new paradigm" medications should be mandatory		0.683				6.32
Pharmacists should document the "new paradigm" medication history of a patient		0.738				6.50
Pharmacists should have access to patient medical records to dispense "new paradigm" medications		0.665				6.29
Component 4 – Non-pharmacist providers	**3**			**0.809**	**13.463 ± 4.39**	**4.49**
Physician workload would be reduced		0.796				4.84
Primary care physician shortages would be reduced		0.802				4.28
The burden on emergency rooms would be reduced		0.762				4.34

*All items were preceded by the statement, "Assuming the implementation of an expanded nonprescription drug class under the FDA's proposed 'new paradigm'……" Items were measured on a 7-point linear numeric scale where 1 = Strongly Disagree and 7 = Strongly Agree.

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Items*	Number of Items	Standardized Coefficients		Cronbach's Alpha	Means ± SD	Per-Item Mean
Component 5 – Pharmacist burden	**3**			**0.705**	**19.920 ± 1.87**	**6.64**
Pharmacists should be reimbursed for the time they spend diagnosing and counseling a patient for "new paradigm" medications		0.463				6.76
The professional liability of a pharmacist would increase		0.844				6.55
Pharmacist workload would increase		0.794				6.62
Component 6 – Access	**3**			**0.472**	**14.734 ± 3.32**	**4.91**
Pharmacy shopping among patients would increase		0.640				4.36
Patients would have increased access to medications		0.555				5.72
There would be an increase in out-of-pocket drug expenditures for insured patients under the "new paradigm"		0.704				4.65

*All items on the scale start off as "Assuming the implementation of an expanded nonprescription drug class under the FDA's proposed 'new paradigm'……" Items were measured on a 7-point linear numeric scale where 1 = Strongly Disagree and 7 = Strongly Agree.

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Objective 2

Overview. The second objective of this study was to determine if attitudes of community pharmacists toward an expanded nonprescription drug class under the FDA's proposed "new paradigm" differed by 1) type of practice setting, 2) location of community pharmacy, 3) geographic region, 4) degrees earned, 5) years actively practicing pharmacy, 6) position in the pharmacy, 7) perceived workload, and 8) pharmacy association affiliation.

Multivariate analysis of variance (MANOVA) was conducted to test the six categorical independent variables (type of practice setting, location of community pharmacy, geographic region, degrees earned, position in the pharmacy, and pharmacy association affiliation). Correlations were conducted to test the two continuous independent variables (years actively practicing pharmacy and perceived workload). The dependent variables for each of the models were the six components of community pharmacists' attitudes toward an expanded nonprescription drug class established under the "new paradigm". These components were previously identified using a PCA with VARIMAX rotation. The scores on these components for each community pharmacist were calculated as average scores for all the survey items which loaded under that particular component (See Table 6, above) (Hair et al., 1998).

Three assumptions of the MANOVA design which were essential for the MANOVA procedure to be valid were (Hair et al., 1998):

- Independence of the observations – This assumption requires that the dependent measures for each respondent be totally uncorrelated with the responses from other respondents in the sample. A lack of independence affects the statistical validity of the MANOVA and this is the most important assumption that must be met.

- Homogeneity of the variance-covariance matrices – This assumption is the multivariate equivalent of the assumption of homogeneity of variance in the ANOVA design. Meeting this assumption ensures that there are no substantial differences in the amount of variance for one group versus another for the dependent variable of interest. In the null form this assumption can be stated as

  H_0: $\sum_1 = \sum_2 = \sum_3 = \ldots = \sum_k$

  This assumption was tested using the Box's M test. Although this assumption is prone to violations, MANOVA is robust to the violations of this assumption as long as the group sizes are roughly equal.
- Multivariate Normality - Multivariate normality holds when, and only when, any linear combination of the individual variables involved is univariate normal (i.e., testing for multivariate normality per se is not practically possible, since it involves infinitely many tests). This assumption must be met for the computation of hypothesis tests.

Type of Practice Setting. The independent variable of interest for the first MANOVA was the type of pharmacy in which the community pharmacist worked. This variable was dichotomized into 1) independent pharmacy and 2) chain pharmacy. The initial six categories for this variable were collapsed into two due to the small number of respondents in some levels of this variable. Independent and franchise pharmacies were combined to create an *independent pharmacy* level, while traditional chain, supermarket with a pharmacy and mass merchandiser with a pharmacy were combined to create a *chain pharmacy* level. The results for this MANOVA are shown in Table 7.

Results of this analysis indicated that there were significant differences in attitudes toward an expanded nonprescription drug class under the "new paradigm", between pharmacists from independent and chain pharmacy settings with respect to *patient care* and *workflow*. Pharmacists working in independent pharmacies more strongly agreed with *patient care* statements (means: 5.32 versus 5.05) and pharmacists working in chain pharmacies more strongly agreed with *workflow* statements (means: 5.39 versus 4.96). Table 8 provides the means for the two groups on each component of attitude (i.e., each DV).

Table 7. MANOVA Results for Objective 2
Independent Variable: Type of Pharmacy

		Sum of Squares	df	Mean Square	F	Sig.
Patient care*	Between Groups	7.541	1	7.541	5.404	0.021
	Within Groups	605.602	434	1.395		
	Total	613.143	435			
Workflow*	Between Groups	20.627	1	20.627	16.223	<0.0005
	Within Groups	551.829	434	1.271		
	Total	572.456	435			
Patient safety	Between Groups	0.045	1	0.045	0.080	0.777
	Within Groups	244.751	434	0.564		
	Total	244.796	435			
Non-pharmacist providers	Between Groups	0.505	1	0.505	0.239	0.625
	Within Groups	917.851	434	2.115		
	Total	918.356	435			
Pharmacist burden	Between Groups	1.011	1	1.011	2.577	0.109
	Within Groups	170.189	434	0.392		
	Total	171.2	435			
Access	Between Groups	1.274	1	1.274	1.056	0.305
	Within Groups	523.294	434	1.206		
	Total	524.568	435			

*Significant at $\alpha = 0.05$

Table 8. Means of Attitudes Based on Respondents' Practice Type

Factors*	Group 1 Independent Pharmacy		Group 2 Chain Pharmacy		Total	
	N = 193		N = 243		N = 436	
	MEAN	SD	MEAN	SD	MEAN	SD
Patient care	5.32	1.14	5.05	1.22	5.17	1.19
Workflow	4.96	1.15	5.39	1.11	5.20	1.15
Patient safety	6.45	0.76	6.47	0.75	6.46	0.75
Non-pharmacist providers	4.44	1.41	4.51	1.49	4.48	1.45
Pharmacist burden	6.59	0.56	6.69	0.68	6.64	0.63
Access	4.86	0.98	4.96	1.18	4.91	1.10

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Affiliation with a Professional Organization. The independent variable of interest for the second MANOVA was affiliation to a professional pharmacy organization. The independent variable had two levels: member of professional pharmacy organization or not a member of professional pharmacy organization. The results for this MANOVA are shown in Table 9. It should be noted that there were significant differences in attitudes toward an expanded nonprescription drug class between the members of a pharmacy organization and nonmembers with respect to *patient care* and *workflow*. Pharmacists affiliated with a professional organization more strongly agreed with *patient care* statements (means: 5.32 versus 4.90) and pharmacists not affiliated with a professional organization more strongly agreed with *workflow* statements (means: 5.35 versus 5.09). Table 10 displays the means for the two groups on each component of attitude (i.e., each dependent variable).

Table 9. MANOVA Results for Objective 2
Independent Variable: Affiliation to a Professional Organization

		Sum of Squares	df	Mean Square	F	Sig.
Patient care*	Between Groups	18.616	1	18.616	13.751	<0.0005
	Within Groups	622.727	460	1.354		
	Total	641.343	461			
Workflow*	Between Groups	7.397	1	7.397	5.655	0.018
	Within Groups	601.685	460	1.308		
	Total	609.082	461			
Patient safety	Between Groups	1.672	1	1.672	2.663	0.103
	Within Groups	288.811	460	0.628		
	Total	290.483	461			
Non-pharmacist providers	Between Groups	2.258	1	2.258	1.055	.0.305
	Within Groups	984.506	460	2.140		
	Total	986.764	461			
Pharmacist burden	Between Groups	0.428	1	0.428	1.099	0.295
	Within Groups	179.132	460	0.389		
	Total	179.56	461			
Access	Between Groups	3.914	1	3.914	3.207	0.074
	Within Groups	561.381	460	1.220		
	Total	565.295	461			

*Significant at $\alpha = 0.05$

Table 10. Means of Attitudes Based on Affiliation with a Professional Organization

Factors*	Group 1 No affiliation		Group 2 Affiliated to at least one organization		Total	
	N = 165		N = 297		N = 462	
	MEAN	SD	MEAN	SD	MEAN	SD
Patient Care	4.90	1.126	5.32	1.18	5.17	1.18
Workflow	5.35	1.07	5.09	1.18	5.18	1.15
Patient safety	6.35	0.80	6.48	0.79	6.43	0.79
Non-pharmacist providers	4.39	1.35	4.54	1.52	4.49	1.46
Pharmacist burden	6.68	0.53	6.62	0.67	6.64	0.62
Access	5.03	1.08	4.84	1.12	4.91	1.11

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Location of Community Pharmacy. The independent variable of interest for the third MANOVA was the location of the community pharmacy. The independent variable had two levels: rural and urban (self-reported by the respondents). The results for this MANOVA are shown in Table 11. There were no significant differences between the two groups.

Table 11. MANOVA Results for Objective 2
Independent Variable: Location of Pharmacy

		Sum of Squares	df	Mean Square	F	Sig.
Patient care	Between Groups	0.499	1	0.499	.356	0.551
	Within Groups	615.561	440	1.399		
	Total	641.343	441			
Workflow	Between Groups	3.282	1	3.282	2.514	0.114
	Within Groups	574.471	440	1.306		
	Total	609.082	441			
Patient safety	Between Groups	0.511	1	0.511	0.901	0.343
	Within Groups	249.640	440	0.567		
	Total	290.483	441			
Non-pharmacist providers	Between Groups	0.797	1	0.797	0.382	0.537
	Within Groups	917.492	440	2.085		
	Total	986.764	441			
Pharmacist burden	Between Groups	0.112	1	0.112	0.282	0.596
	Within Groups	174.988	440	0.398		
	Total	179.56	441			
Access	Between Groups	3.798	1	3.798	3.072	0.080
	Within Groups	543.971	440	1.236		
	Total	565.295	441			

*Significant at $\alpha = 0.05$

Table 12. Means of Attitudes Based on Location of Pharmacy

Factors*	Group 1 Rural		Group 2 Urban		Total	
	N = 186		N = 256		N = 442	
	MEAN	SD	MEAN	SD	MEAN	SD
Patient Care	5.15	1.21	5.21	1.14	5.18	1.18
Workflow	5.26	1.13	5.09	1.17	5.19	1.14
Patient safety	6.48	0.79	6.41	0.70	6.45	0.75
Non-pharmacist providers	4.51	1.47	4.43	1.41	4.48	1.44
Pharmacist burden	6.65	0.61	6.62	0.66	6.64	0.63
Access	4.98	1.11	4.80	1.12	4.90	1.11

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Region of Practice. The independent variable of interest for the fourth MANOVA was region of practice which was determined based on the state of practice of the respondent as indicated on the survey. The independent variable had four levels which were the four regions of the United States based on Census Bureau designations. These regions were Northeast, Midwest, South and West. The results for this MANOVA are shown in Table 13.

The results from the MANOVA suggested that significant differences existed between the groups with respect to *patient care*. Pharmacists from western states more strongly agreed with *patient care* statements than pharmacists from northeastern states. In order to more specifically examine these differences, post-hoc tests were conducted using Tukey's post-hoc tests. The results from the post-hoc analysis suggest that significant differences existed between the northeast (4.90 ± 1.22) and the west (5.38 ± 1.14) with respect to patient care under the new paradigm ($p = 0.028$). Means of the attitude components are provided in Table 14. No other significant differences existed among the four regions of the country.

Table 13. MANOVA Results for Objective 2
Independent variable: Region of Practice

		Sum of Squares	Df	Mean Square	F	Sig.
Patient care*	Between Groups	12.829	1	12.829	3.118	0.026
	Within Groups	606.120	442	1.371		
	Total	618.949	443			
Workflow	Between Groups	3.143	1	3.143	0.803	0.493
	Within Groups	576.793	442	1.305		
	Total	579.936	443			
Patient safety	Between Groups	3.037	1	3.037	1.807	0.145
	Within Groups	247.625	442	0.560		
	Total	250.662	443			
Non-pharmacist providers	Between Groups	8.532	1	8.532	1.353	0.257
	Within Groups	928.904	442	2.102		
	Total	937.436	443			
Pharmacist burden	Between Groups	2.404	1	2.404	2.045	0.107
	Within Groups	173.213	442	0.392		
	Total	175.617	443			
Access	Between Groups	3.536	1	3.536	0.949	0.417
	Within Groups	548.811	442	1.242		
	Total	552.347	443			

*Significant at $\alpha = 0.05$

Table 14. Means of Attitudes Based on Region of Practice

Factors*	Group 1 Northeast		Group 2 Midwest		Group 3 South		Group 4 West		Total	
	N = 108		N = 104		N = 152		N = 82		N = 462	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
Patient care	4.90	1.22	5.22	1.08	5.26	1.21	5.38	1.14	5.18	1.18
Workflow	5.31	1.16	5.25	1.06	5.13	1.23	5.10	1.04	5.19	1.14
Patient safety	6.36	0.93	6.52	0.53	6.41	0.80	6.58	0.60	6.45	0.75
Non-pharmacist providers	4.34	1.48	4.34	1.46	4.62	1.44	4.61	1.41	4.49	1.45
Pharmacist burden	6.72	0.63	6.66	0.50	6.54	0.80	6.69	0.44	6.64	0.63
Access	5.07	1.05	4.86	1.13	4.86	1.14	4.85	1.11	4.91	1.11

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Pharmacy Position. The IV of interest for the fifth MANOVA was position in the pharmacy. The independent variable had three levels for analysis which were staff/relief/floater pharmacist, pharmacy manager/pharmacist-in-charge and pharmacy owner. The categories of district manager, regional manager and other were excluded from the analysis due to the small number of respondents in these categories. The results for this MANOVA are shown in Table 15.

The results from the MANOVA suggested that significant differences existed between the groups with respect to *patient care* and *workflow*. Pharmacy owners (5.48 ± 1.19) and managers (5.23 ± 1.12) more strongly agreed with *patient care* statements then staff pharmacists (4.91 ± 1.21). Staff pharmacists (5.39 ± 1.02) and pharmacy managers (5.22 ± 1.14) more strongly agreed with *workflow* statements than pharmacy owners (4.76 ± 1.26). To more specifically examine these differences, post-hoc tests were conducted using Tukey's post-hoc tests. With respect to *patient care*, significant differences were observed between staff/relief/floater pharmacists and pharmacy managers/pharmacists-in-charge ($p = 0.033$), and staff/relief/floater pharmacists and pharmacy owners ($p = 0.004$). With respect to *workflow*, significant differences were observed between staff/relief/floater pharmacists and pharmacy owners ($p = 0.007$), and pharmacy managers/pharmacists-in-charge and pharmacy owners ($p = 0.001$). Means of the attitude scale components are provided in Table 16.

Table 15. MANOVA Results for Objective 2
Independent Variable: Pharmacy Position

		Sum of Squares	Df	Mean Square	F	Sig.
Patient care*	Between Groups	15.841	2	7.921	5.878	0.003
	Within Groups	586.203	435	1.348		
	Total	602.044	437			
Workflow*	Between Groups	18.222	2	9.111	7.169	0.001
	Within Groups	552.820	435	1.271		
	Total	571.042	437			
Patient safety	Between Groups	1.500	2	0.750	1.341	0.263
	Within Groups	243.392	435	0.560		
	Total	244.892	437			
Non-pharmacist providers	Between Groups	4.287	2	2.143	1.032	0.357
	Within Groups	903.533	435	2.077		
	Total	907.82	437			
Pharmacist burden	Between Groups	1.116	2	0.558	1.418	0.243
	Within Groups	171.163	435	0.393		
	Total	172.279	437			
Access	Between Groups	6.284	2	3.142	2.530	0.081
	Within Groups	540.236	435	1.242		
	Total	546.52	437			

*Significant at $\alpha = 0.05$

Table 16. Means of Attitudes Based on Pharmacy Position

Factors*	Group 1 Staff/Relief/Floater Pharmacist		Group 2 Pharmacy Manager/Pharmacist in-charge		Group 3 Pharmacy Owner		Total	
	N = 128		N = 240		N = 70		N = 438	
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD
Patient care	4.91	1.21	5.23	1.12	5.48	1.19	5.18	1.17
Workflow	5.39	1.02	5.22	1.14	4.76	1.26	5.19	1.14
Patient safety	6.44	0.81	6.43	0.75	6.59	0.66	6.45	0.75
Non-pharmacist providers	4.39	1.37	4.56	1.43	4.32	1.62	4.47	1.44
Pharmacist burden	6.64	0.74	6.68	0.57	6.53	0.58	6.64	0.63
Access	5.05	1.17	4.91	1.11	4.68	1.03	4.91	1.12

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Highest Pharmacy Degree Earned. The independent variable of interest for the sixth MANOVA was highest pharmacy degree earned. The independent variable had two levels; Bachelor of Pharmacy (BPharm) and Doctor in Pharmacy (PharmD). The other three categories Master of Science (MS), Doctor of Philosophy (PhD) and other were not included in the analysis due to the small number of respondents in these categories. For the purposes of this analysis, community pharmacists who had both a BPharm and PharmD were only included in the PharmD category. The results for this MANOVA are shown in Table 17. It should be noted from the table below that there were significant differences in patient care and non-pharmacist provider attitudes between community pharmacists who had BPharm only compared to community pharmacists who had a PharmD. Pharmacists with a PharmD more strongly agreed with *patient care* (means: 5.41 versus 5.07) and *non-pharmacist* provider (means: 4.84 versus 4.32) statements. Means of attitude components may be found in Table 18.

Table 17. MANOVA Results for Objective 2
Independent Variable: Highest Pharmacy Degree Earned

		Sum of Squares	Df	Mean Square	F	Sig.
Patient care*	Between Groups	10.612	1	10.612	7.686	0.006
	Within Groups	603.324	437	1.381		
	Total	613.936	438			
Workflow	Between Groups	0.018	1	0.018	0.014	0.906
	Within Groups	575.154	437	1.316		
	Total	575.172	438			
Patient safety	Between Groups	0.294	1	0.294	0.515	0.473
	Within Groups	249.158	437	0.57		
	Total	249.452	438			
Non-pharmacist providers*	Between Groups	25.563	1	25.563	12.657	<0.0005
	Within Groups	882.603	437	2.020		
	Total	908.166	438			
Pharmacist burden	Between Groups	0.371	1	0.371	0.939	0.333
	Within Groups	172.763	437	0.395		
	Total	173.134	438			
Access	Between Groups	2.090	1	2.090	1.681	0.195
	Within Groups	543.487	437	1.244		
	Total	545.577	438			

*Significant at $\alpha = 0.05$

Table 18. Means of Attitudes Based on Highest Pharmacy Degree Earned

Factors*	Group 1 B.S. Pharm.		Group 2 Pharm.D.		Total	
	N = 306		N = 133		N = 439	
	MEAN	SD	MEAN	SD	MEAN	SD
Patient care	5.07	1.19	5.41	1.14	5.17	1.18
Workflow	5.20	1.15	5.18	1.13	5.19	1.15
Patient safety	6.43	0.76	6.49	0.74	6.45	0.75
Non-pharmacist providers	4.32	1.43	4.84	1.40	4.48	1.44
Pharmacist burden	6.62	0.65	6.68	0.59	6.64	0.63
Access	4.86	1.11	5.01	1.13	4.91	1.12

*Measured on a 7-point linear numeric scale where 1=Strongly Disagree and 7=Strongly Agree.

Years of Practice and Workload. In order to assess whether attitudes of community pharmacists' toward the new paradigm differed based on the *number of years of practice* or *perceptions of their own workload*, correlations between attitude components and each of these dependent variables were computed. These correlations can be found in the correlation matrix of variables in Table 19.

Number of years of practicing pharmacy was found to be significantly and negatively correlated with non-pharmacist providers ($r = -0.139$, $p = 0.004$) and access ($r = -0.104$, $p = 0.029$). The greater the number of years that respondents practiced pharmacy, the more likely they were to disagree with *non-pharmacist* provider statements and access statements. *Perceptions of pharmacists' workload* were found to be significantly and positively correlated with workflow ($r = 0.255$, $p < 0.0005$). The greater the respondents' perceived workload, the more likely they were to agree with *workflow* statements.

Table 19. Correlation Matrix of Variables

Variables	Mean	S.D.	1	2	3	4	5	6	7	8	9	10
1. Patient care	5.17	1.18	1	-.380**	.326**	.522**	-.018	-.017	-.016	.134**	-.111*	.170**
2. Workflow	5.18	1.15	-.380**	1	.045	-.169**	.339**	.309**	-.079	-.072	.190**	-.110*
3. Patient safety	6.43	0.79	.326**	.045	1	.151**	.354**	.157**	.026	.067	.014	.076
4. Non-pharmacist providers	4.49	1.46	.522**	-.169**	.151**	1	.008	.026	-.139**	.084	.023	.048
5. Pharmacist burden	6.64	0.62	-.018	.339**	.354**	.008	1	.291**	-.089	-.053	.077	-.049
6. Access	4.91	1.1	-.017	.309**	.157**	.026	.291**	1	-.104*	-.065	.049	-.083
7. Number of years of practice	23.72	11.47	-.016	-.079	.026	-.139**	-.089	-.104*	1	-.068	-.130**	.156**
8. Region of practice	-	-	.134**	-.072	.067	.084	-.053	-.065	-.068	1	-.009	-.048
9. Type of pharmacy	-	-	-.111*	.190**	.014	.023	.077	.049	-.130**	-.009	1	-.306**
10. Membership of pharmacy organization	-	-	.170**	-.110*	.076	.048	-.049	-.083	.156**	-.048	-.306**	1
11. Gender	-	-	-.112*	.210**	.035	.030	.108*	.179**	-.288**	-.059	.137**	-.135**
12. Age	48.76	11.27	.011	-.101*	.039	-.117*	-.102*	-.128**	.938**	-.017	-.124**	.143**
13. Highest pharmacy degree earned	-	-	.131**	-.006	.034	.168**	.046	.062	-.638**	.182**	.122*	-.085
14. Location of pharmacy	-	-	.028	-.075	-.045	-.029	-.025	-.083	-.076	.084	-.212**	.057
15. Number of hours practiced in a typical week	41.51	7.81	.153**	-.154**	-.036	.010	-.048	-.055	-.081	.017	-.206**	.187**
16. Number of prescriptions store fills on an average weekday	449.93	554.26	.027	.016	-.004	.030	.053	-.032	-.061	.025	.084	.031
17. Position in the pharmacy	-	-	.161**	-.167**	.054	.001	-.037	-.105*	.249**	-.035	-.432**	.277**
18. Perceptions of workload	3.22	0.97	-.064	.255**	.006	-.062	.049	.038	.031	.012	.108*	-.044

**Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed).

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Variables	Mean	S.D.	11	12	13	14	15	16	17	18
1. Patient care	5.17	1.18	-.112*	.011	.131**	.028	.153**	.027	.161**	-.064
2. Workflow	5.18	1.15	.210**	-.101*	-.006	-.075	-.154**	.016	-.167**	.255**
3. Patient safety	6.43	0.79	.035	.039	.034	-.045	-.036	-.004	.054	.006
4. Non-pharmacist providers	4.49	1.46	.030	-.117*	.168**	-.029	.010	.030	.001	-.062
5. Pharmacist burden	6.64	0.62	.108*	-.102*	.046	-.025	-.048	.053	-.037	.049
6. Access	4.91	1.1	.179**	-.128**	.062	-.083	-.055	-.032	-.105*	.038
7. Number of years of practice	23.72	11.47	-.288**	.938**	-.638**	-.076	-.081	-.061	.249**	.031
8. Region of practice	-	-	-.059	-.017	.182**	.084	.017	.025	-.035	.012
9. Type of pharmacy	-	-	.137**	-.124**	.122*	-.212**	-.206**	.084	-.432**	.108*
10. Membership of pharmacy organization	-	-	-.135**	.143**	-.085	.057	.187**	.031	.277**	-.044
11. Gender	-	-	1	-.290**	.137**	-.067	-.243**	-.035	-.251**	-.063
12. Age	48.76	11.27	-.290**	1	-.584**	-.059	-.072	.023	.260**	.022
13. Highest pharmacy degree earned	-	-	.137**	-.584**	1	-.065	.057	.020	-.204**	-.014
14. Location of pharmacy	-	-	-.067	-.059	-.065	1	.025	-.010	.150**	-.050
15. Number of hours practiced in a typical week	41.51	7.81	-.243**	-.072	.057	.025	1	.014	.377**	.043
16. Number of prescriptions store fills on an average weekday	449.93	554.26	-.035	.023	.020	-.010	.014	1	-.081	.127**
17. Position in the pharmacy	-	-	-.251**	.260**	-.204**	.150**	.377**	-.081	1	-.033
18. Perceptions of workload	3.22	0.97	-.063	.022	-.014	-.050	.043	.127**	-.033	1

**Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed).

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Objective 3

The third objective for this study was to determine which drugs community pharmacists believed would be acceptable additions to an expanded definition of nonprescription drugs under the FDA's proposed "new paradigm". A list of twenty five current "prescription-only" drugs was included in the survey and respondents were asked to determine whether a particular drug, assuming the establishment of an expanded nonprescription drug class under the FDA's proposed new paradigm, should be dispensed as a prescription drug, new paradigm drug or sold over-the-counter. Definitions for the three response categories, "Dispensed as Prescription Only", "Dispensed as a New Paradigm medication" and "Sold as Nonprescription Only" were provided to the respondents. Table 20 displays the results for objective 3. To summarize:

The majority of respondents believed that the following drugs should be dispensed as prescription only:

- Plavix® (clopidogrel bisulfate)
- Ambien ® (zolpidem)
- Medrol Dosepak ® (methyl prednisolone)
- Imitrex ® (sumatriptan)

The majority of respondents suggested that the following prescription-only drugs should be dispensed as "new paradigm" medications if established:

- Lipitor® (atorvastatin)
- Glucophage® (metformin)
- HydroDIURIL® (hydrochlorothiazide)
- Zestril® (lisinopril)
- Viagra® (sildenafil)
- Propecia® (finasteride)
- Valtrex® oral (valacyclovir hydrochloride)
- Benzaclin® (clindamycin benzoyl peroxide)
- Zyban® (bupropion SR)
- Vaniqa® (eflornithine)
- Singulair® (montelukast sodium)
- Proventil® inhaler (albuterol)

- Flonase® (flurticasone)
- Tamiflu® (oseltamivir)
- Diprolene® cream (betamethasone)
- Zofran® (ondansetron)
- Epipen® (epinephrine)
- Phenergan® oral (promethazine)

The majority of the respondents were of the opinion that the following prescription-only drugs should be sold as nonprescription or over-the-counter (i.e., without pharmacist intervention):

- Prescription pre-natal vitamins
- Clarinex® (desloratadine)

Table 20. Respondents' Classification of Drugs into Dispensing Categories

Drug Name	Category under which the Drug should be Dispensed						Total	
	Dispensed as Prescription Only		Dispensed as a "New Paradigm" Medication		Sold as Nonprescription Only			
	N	%	N	%	N	%	N	%
Lipitor® (atorvastatin)	175	39.0	266	59.2	8	1.8	449	100
Glucophage® (metformin)	201	44.8	242	53.9	6	1.3	449	100
Plavix® (clopidogrel bisulfate)	383	85.3	63	14.0	3	0.7	449	100
HydroDIURIL® (hydrochlorothiazide)	106	23.6	316	70.4	27	6.0	449	100
Zestril® (lisinopril)	152	33.9	288	64.1	9	2.0	449	100
Viagra® (sildenafil)	122	27.2	298	66.5	22	6.3	448	100
Propecia® (finasteride)	154	34.4	259	57.8	35	7.8	448	100
Valtrex® oral (valacyclovir hydrochloride)	142	31.7	279	62.3	27	6.0	448	100
Ambien® (zolpidem)	388	86.6	56	12.5	4	0.9	448	100
Benzaclin® (clindamycin benzoyl peroxide)	22	4.9	277	61.8	149	33.3	448	100
Zyban® (bupropion SR)	210	47.0	221	49.4	16	3.6	447	100
Prescription pre-natal vitamins	18	4.0	205	45.8	225	50.2	448	100
Vaniqa® (eflornithine)	101	22.5	231	51.6	116	25.9	448	100
Singulair® (montelukast sodium)	159	35.7	248	55.6	39	8.7	446	100
Proventil® inhaler (albuterol)	97	21.7	315	70.6	34	7.6	446	100
Clarinex® (desloratadine)	9	2.0	149	33.4	288	64.6	446	100
Flonase® (fluticasone)	42	9.4	298	66.8	106	23.8	446	100
Tamiflu® (oseltamivir)	177	39.7	255	57.2	14	3.1	446	100

Diprolene® cream (betamethasone)	110	24.7	287	64.3	49	3.1	446	100
Medrol Dosepak® (methyl prednisolone)	243	54.5	199	44.6	4	0.9	446	100
Zofran® (ondansetron)	149	33.4	271	60.8	26	5.8	446	100
Imitrex® (sumatriptan)	278	62.3	160	35.9	8	1.8	446	100
Epipen® (epinephrine)	117	26.2	288	64.6	41	9.2	446	100
Phenergan® (promethazine)	124	27.8	276	61.9	46	10.3	446	100

DISCUSSION

The FDA has been contemplating the implementation of a permanent third class of drugs in order to resolve some of the issues related to patient medication access. Initially, a "third class" or a "behind-the-counter" class of drugs was conceptualized as one under which medications could be dispensed without a physician's prescription; however, pharmacist appropriation would be necessary. Despite the fact that the idea of a third class of drugs has been debated since the 1960's, FDA deliberations and hearings did not bring about the creation and establishment of such a drug class. Very recently, the third class debate was sparked again with a FDA hearing in March, 2012. Unlike previous public hearings about expanding a BTC class of drugs, the 2012 public hearing entitled "Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription" repositioned a third class of drugs not as a BTC class, "but rather as a 'new paradigm' under which FDA "would approve certain drugs that would otherwise require a prescription for nonprescription use . . . under conditions of safe use" (Karst, 2012). Although in concept, the idea of expanding the current definition of nonprescription drugs, under the new paradigm, may appear to be similar to that of a third class of drugs but there are certain differences with respect to the drug specific conditions of safe use, and implementation of new technologies to help patients better self-assess their condition.

Community pharmacists are the most important stakeholders for the implementation of the new paradigm and thus the FDA is seeking feedback on the new paradigm from community pharmacists at large. This study assessed attitudes of community pharmacists toward the new

paradigm with the help of a self-administered Internet survey. Community pharmacists' attitudes were measured using a 7-point linear numeric scale with 1 = "Strongly Disagree" and 7 = "Strongly Agree". Other specific objectives included evaluating differences in community pharmacists' attitudes toward the new paradigm based on their demographic and practice characteristics and determining which drugs community pharmacists believe are be suitable additions to the new paradigm.

Objective 1

A principal components analysis (PCA) was conducted in order to identify the factors that comprise community pharmacists' attitudes toward the new paradigm. Results from this analysis (Table 6) suggest that community pharmacists' attitudes toward the new paradigm is comprised of six factors including patient care, workflow, patient safety, non-pharmacist providers, pharmacist burden and access.

Respondents generally agreed with attitudinal statements regarding the "new paradigm" (per-item mean: 5.45 ± 0.86). Respondents were generally positive about the provision of patient care under the proposed new paradigm and indicated there should be patient safety mechanisms in place. Respondents felt significant workflow changes would have to be made to pharmacies, felt their own liability and workload would increase, and felt they should be reimbursed for services related to "new paradigm" drugs. Respondents were largely ambivalent about the effect of the "new paradigm" on patients' access to medications and how the workload of other health providers would be affected. Workflow change, liability and workload are issues the FDA will have to consider prior to the implementation of the new paradigm. Most importantly, the FDA must recognize that pharmacists desire to be adequately reimbursed for the

increased liability and workload associated with providing patient directed services under the new paradigm.

Objective 2

The second objective of this study was to assess differences in community pharmacists' attitudes toward the new paradigm based on demographic and practice characteristics. The first variable explored was pharmacy type. Inherently, independent and chain pharmacies tend to be different with respect to their structure, workflow, prescriptions filled, and staff size. Results (Table 7 and 8) suggest that independent pharmacists more strongly agreed with statements regarding *patient care* then chain pharmacists. Pharmacists working in independent pharmacies were more likely to agree that pharmacists have the ability to provide patient care under the new paradigm and recognize the potential advantages of the new paradigm over the current system, specifically for the patient. Perhaps it is the structural differences described above that make independent pharmacists more sensitive to the patient care issues related to the "new paradigm". Also, a search of the existing literature reveals that independent pharmacists have been known to provide better pharmaceutical care and/or Medication Therapy Management (MTM) for patients with chronic diseases such as asthma (Mclean and MacKeigan, 2005). Thus independent pharmacists may be more confident about providing patient care under the new paradigm. On the other hand, chain pharmacists were more likely to agree with *workflow* statements than independent pharmacists. This may suggest that chain pharmacists are more sensitive to the significant structural changes that would have to take place in the entire chain for which they work, not just their own store. If and when the nonprescription drug class is expanded under the new paradigm, considerable structural changes will have to be made in the pharmacy to

incorporate extra space for drugs, patient counseling rooms and self-assessment kiosks for patients.

The second demographic variable of interest was affiliation with a professional pharmacy organization (Table 9 and 10). Unlike pharmacists who are not associated with any professional organization, pharmacists who are affiliated to some professional pharmacy organization usually tend to be more progressive and ready for changes which would potentially further the value of the profession in providing patient directed care. Following the FDA's March 2012 hearing, a large number of pharmacy organizations at the national, state and local level provided comments/suggestions with regard to the implementation of the new paradigm. Most professional pharmacy organizations such as the American Pharmacists Association, American Society of Health System Pharmacists, National Association of Boards of Pharmacy, and the National Community Pharmacists Association advocate for the implementation of an expanded nonprescription class of drugs. They believe that this would increase the involvement of the community pharmacy in patient treatment decisions and therefore further enhancing the value of the pharmacy profession. Respondents who were affiliated to at least one professional pharmacy organization more strongly agreed with *patient care* statements than pharmacists who were not affiliated with a professional pharmacy organization. This finding is not surprising because pharmacists who are members of professional organizations are likely to be more progressive with respect to enhancing and achieving the goal of the profession to provide better patient care. They were also less likely to agree than respondents who were not members of a pharmacy organization that there would be significant workflow-related issues. This could be indicative of the fact that pharmacists affiliated with a professional pharmacy association are more progressive and accepting of shifts in current settings which would result in the improvement of the role of

the pharmacist in patient care. Thus they would be less sensitive to making changes in their current workflow settings for a step that would further the value of the profession. In fact, they may already be working toward achieving this goal.

The third variable of interest was the location of the community pharmacy (i.e. rural or urban). One might expect that pharmacies in urban settings might be more progressive and thus more easily transition to changes like the "new paradigm." However, no significant differences in attitudes toward the new paradigm were found between pharmacists who practiced in a rural versus ones who practiced in an urban setting (Table 11 and 12). The lack of significant differences may be indicative of the fact that there are many progressive pharmacies in rural areas as well.

The fourth practice variable of interest was the region of the country where the respondent practiced (i.e. Northeast, Midwest, South and West). Respondents from the West more strongly agreed with *patient care* statements compared to those in the Northeast (Table 13 and 14). To more clearly understand these findings, respondents' comments and suggestions about the new paradigm were examined. One of the comments from a respondent practicing in Washington State suggested that about twenty five community pharmacists from Washington and California were in fact interested in implementing and experimenting with a system similar to the new paradigm as part of a collaborative practice model. Although limited in nature, this comment may, in part, suggest that respondents from the western regions of the country are more positive about implementing the "new paradigm" as compared to respondents from the Northeast.

The fifth practice variable of interest was respondents' positions in the community pharmacy (i.e., staff/relief/floater pharmacist, pharmacy manager/pharmacist-in-charge,

pharmacy owner). The responsibilities, liabilities, workload of a pharmacist in a community practice setting tend to vary based on his/her position in the pharmacy (Perepelkin et al., 2008). Considering this, it was expected that the views of community pharmacists toward the new paradigm would vary based on their role and position in their current pharmacy. The results from the analyses (Table 15 and 16) suggested that pharmacy owners and managers more strongly agreed with *patient care* statements then staff pharmacists. Staff pharmacists and pharmacy managers more strongly agreed with *workflow* statements than pharmacy owners.

Perhaps pharmacy owners and managers more strongly agreed with patient care statements because they have more practice experience, more advanced qualifications, or both. Also, perhaps inherently pharmacy owners and managers tend to be more entrepreneurial in nature than staff pharmacists. Therefore, it might be expected that pharmacy owners and managers would rate the patient care factor higher than staff pharmacists.

Another interesting finding in this study was that pharmacy owners were significantly less likely to agree with workflow statements compared to both pharmacy managers and staff pharmacists. When examining the workflow items, it appears that pharmacy owners did not think that workflow changes would be as significant or challenging as pharmacy managers and staff pharmacists did. While this finding appears counterintuitive, perhaps this is explained by the fact that owners are more adept at designing and making workflow changes. Staff pharmacists may typically not be responsible for such workflow changes. Pharmacy managers, assuming they are in the chain pharmacy setting would not typically be responsible for workflow changes either, as workflow changes in the chain setting are typically left to corporate decisions.

Based on highest pharmacy degree earned (BPharm or PharmD), community pharmacists' attitudes toward the new paradigm differed on *patient care* and *non-pharmacist*

provider statements. Respondents who had PharmDs as their highest degree more strongly agreed with *patient care* statements than respondents with a BPharm as their highest degree earned. This finding is not surprising because The PharmD curriculum across the United States generally tends to be more practice oriented as compared to the former BS in pharmacy program. The PharmD is a professional degree in pharmacy practice and individuals with this degree do tend to be more confident about practicing pharmacy, as compared to pharmacists with only a Bachelor's in pharmacy, due to the 1-2 years of additional training that they have to undertake in school (Cox et al., 1988).

Respondents with a PharmD also more strongly agreed with *non-pharmacist provider* statements than those with a BPharm as their highest degree. These statements reflected the idea that implementing the new paradigm would reduce burden and workload from other healthcare providers and services. PharmDs tend to be more oriented toward advancing the goal of the profession of providing better and more involved patient care than individuals who have a BPharm only and therefore they would generally be more receptive toward any initiative taken to that effect. Also, the nature of the PharmD curriculum tends to be more interdisciplinary in nature and thus PharmDs may be more familiar with the role of other healthcare professionals and therefore more acutely recognize the potential effect of the new paradigm on these other healthcare professionals as opposed to pharmacists with BPharm as their highest degree.

In order to assess whether there were differences in community pharmacists' attitudes toward the new paradigm based on number of years they actively practiced pharmacy, simple correlations were computed for the variable of interest (i.e. number of years of practice) with the various factors (or components) of respondent attitudes obtained from the PCA (Table 6). The number of years of actively practicing pharmacy was significantly and negatively correlated with

non-pharmacist providers and *access*. Specifically, pharmacists with greater number of years of experience were less positive about the belief that the new paradigm would reduce the workload on other healthcare providers and facilities. Also, later career pharmacists were less likely to buy into the role of the new paradigm in improving patient medication access. These findings align with the thought that pharmacists nearing the end of their professional career would have more negative attitudes toward the new paradigm as compared to pharmacists who are at the beginning of their career. Community pharmacists who are near the end of their career may not prefer any changes that would involve a major shift from the current practice system (such as the new paradigm) because such a transition might involve rigorous training and additional time commitments. While pharmacists who are at earlier stages of their professional career may be excited by thought of such a change because it would involve more involvement in patient treatment decisions and learning new skills overall which would help them at later stages of their career. Also, such pharmacists would have completed their education more recently and thus are more likely to have been trained in such paradigm shifts in the community practice model. However, the findings related to patient medication access related issues must be interpreted with caution because of low scale reliability (Cronbach's alpha = 0.472) between the three items which loaded onto the factor.

The last variable of interest was community pharmacists' perceptions of their workload. Simple correlations were computed for this variable of interest with the various factors (or components) of respondent attitudes obtained from the PCA (Table 6). Respondent perceptions of their workload were significantly and positively correlated with workflow related issues surrounding the implementation of the new paradigm. This finding is intuitive because pharmacists who perceive that they already have a high workload would be more aware of the

significance in workflow related changes to their practice setting in order to implement the new paradigm. Respondents with greater perceived workload would be more sensitive to taking up any new responsibilities which would further increase their workload.

Objective 3

The third and final objective of this study was to assess what drugs community pharmacists believe would be potential additions to an expanded nonprescription drug class under the new paradigm if implemented. A list of twenty five current prescription-only drugs was created by referencing FDA guidelines on new paradigm drugs. Respondents were asked to indicate whether a particular drug on the list should remain prescription-only, be dispensed as a "new paradigm" medication or whether it should be sold over-the-counter (Table 17). Respondents indicated that the majority of drugs on the list would be acceptable to dispense under the "new paradigm".

However, there were certain drugs on the list that respondents indicated should be dispensed as prescription-only drug even if the new paradigm was implemented. One such drug was Plavix® (clopidogrel). Typically, Plavix® is indicated to prevent clotting of blood in the heart or any other blood vessels. However, side effects of Plavix® include internal bleeding such as in the stomach or intestines even if the patient has a minor injury. This drug is contraindicated for use with common drugs such as aspirin or other NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Thus it is in the best interest of the patient if Plavix® is prescribed after thorough examination by a physician rather than being dispensed as a new paradigm drug by the pharmacist.

Another drug which community pharmacists believed should remain prescription-only was Ambien® (zolpidem). Ambien® is a sedative and is used to treat insomnia. It is habit-

forming schedule IV controlled substance and therefore has a potential for abuse. Additionally, the use of this drug may lead to severe allergic reactions in certain patients. Therefore community pharmacists indicated that Ambien® should remain prescription-only in the best interest of the patients.

On the other hand, there were two prescription-only drugs (Clarinex® (desloratadine) and prescription pre-natal vitamins) on the list that community pharmacists suggested should be switched to over-the-counter (OTC) status. This indicates that respondents believed that there is little or no need to monitor the usage of these drugs in the form of a prescription or pharmacist appropriation under the new paradigm. Clarinex® is indicated for allergic rhinitis and it does not have a severe adverse events profile unlike some of the above mentioned drugs. Additionally, other allergy medications such as Zyrtec® (cetirizine) (which were formerly prescription-only) are now available OTC. Therefore it is not surprising that respondents advocated the OTC sale of the drug.

Limitations

A national community pharmacist panel was used to collect data for this study and no monetary honorarium was provided to the respondents (although an executive summary of the findings was provided to the participants). Despite our recruitment letter statement that this study was being conducted for academic purposes, there is a strong potential of self-selection bias in this study. It is very likely that only respondents who were interested in the concept of the new paradigm (and in the final study results) may have participated in the study. However, because this study did not employ a factorial design, unequal group sizes did not appear problematic.

A further analysis using the time trends extrapolation technique whereby the responses of first 10% and last 10% of the respondents are compared was conducted in order to test for the

presence of non-response bias (Tables 4 and 5). This technique is based on the assumption that late responders are very similar to individuals who did not respond at all. The results from this analysis suggested the presence of some non-response bias because early and late responders significantly differed in terms of age and number of years of practice. Late responders tended to be older (49.52 ± 1.68 versus 44.47 ± 1.65) and have a greater number of years of practice experience (23.82 ± 1.73 versus 18.04 ± 1.52) as compared to early responders.

Generalizability of this study to all pharmacists across the United States may be questionable because this study employed a national convenience sample of community pharmacists. However, the sample was stratified by region of the country where the respondents practiced in order to ensure that the distribution of the respondents was representative of the distribution of community pharmacists nationally based on the region of practice (i.e. northeast, south, mid-west and west). This study employed a cross sectional design and therefore causal relationships among the variables cannot be drawn. Future studies should employ alternative designs such as longitudinal data collection to more fully understand causal relationships among variables.

Lastly, future researchers should consider the low scale reliability ($\alpha = 0.472$) obtained for the sixth factor identified from the PCA of using these items for future studies.

Directions for future research

This study was preliminary in nature. It would be interesting for future researchers to assess whether or not the attitudes of community pharmacists, toward the new paradigm, measured in this study translate into willingness to adopt the new paradigm if it was implemented by the FDA. Future researchers should also try to measure the predictors of community pharmacists' attitudes toward an expanded nonprescription drug class under the new

paradigm. A detailed evaluation of these predictors would provide great insight in understanding why community pharmacists have a particular outlook toward a specific aspect of the new paradigm. Also, with the help of the results of such a study the FDA would be able to pinpoint the type of community pharmacists and/or pharmacies who might be early adopters of the new paradigm when it is implemented.

Also, it is important to know the opinions and perceptions of other healthcare professionals (i.e. physicians, nurse practitioners etc.) about the new paradigm because, although community pharmacists may be the most important stakeholders for implementing the new paradigm, such a move by the FDA would affect all healthcare practitioners and patients alike. Such a study would be relevant in providing feedback to the agency and help in determining if and how the new paradigm should be implemented.

Conclusions

Respondents were generally positive about the provision of patient care under the proposed new paradigm and indicated there should be patient safety mechanisms in place. Respondents felt significant workflow changes would have to be made to pharmacies, felt their own liability and workload would increase, and felt they should be reimbursed for services related to “new paradigm” drugs. Respondents were largely ambivalent about the effect of the “new paradigm” on patients’ access to medications and how the workload of other health providers would be affected. Finally, respondents indicated, with some exceptions that most of the 25 drugs they were provided could be considered “new paradigm drugs”, suggesting that pharmacists do see opportunity for such a drug class.

At the end of the survey, respondents were given the opportunity to provide their thoughts about the new paradigm. There comments appeared to mirror their quantitative

assessments. Most of the respondents suggested that it was an interesting concept and that the implementation of such a system would definitely be fruitful in increasing the role of community pharmacists in providing patient care. However, time constraints seemed to be a detractor for most pharmacists and the general consensus suggested that if the new paradigm was implemented then pharmacists should be reimbursed for the additional time spent on dispensing these to patients.

The results of this study have several implications for the pharmaceutical industry, health care providers, and patients. Such a drug class can impact strategies that pharmaceutical companies adopt for drugs nearing patent expiration. Specifically, drug life-cycle extension avenues may be available to pharmaceutical manufacturers if a drug nearing the end of its patent term was approved for dispensing as a "non-paradigm" drug. Additionally the FDA may consider dual availability of a drug as both prescription and nonprescription under the "new paradigm", a policy that could be potentially beneficial for manufacturers. However, changes to labeling, packaging, marketing, and promotion (especially direct-to-consumer advertising) requirements for "new paradigm" drugs would have to be considered.

The "new paradigm" may affect the pricing and reimbursement of drugs entering this class. Additionally, pharmacist adoption of this third class may largely depend on reimbursement issues when considering the time required for them to appropriately dispense "new paradigm drugs" and investment required to potentially modify pharmacy workflow. However, it could be argued that the role of the pharmacist in providing patient-directed care would increase, while at the same time reducing physician workload.

Finally, for the patient, there is potential in increased medication access. However, patient safety may also be a concern if a new third class of drugs is not properly implemented.

While it is still unclear as to whether the “new paradigm” will come to fruition as proposed, it is important that stakeholder perspectives be considered by the FDA as they embark on this debate.

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LIST OF APPENDICES

APPENDIX 1: SURVEY ITEMS

A) Characteristics of the Socio-Political context

1. The new paradigm would increase the problem of "pharmacy shopping" among patients.
2. Patients would have increased access to medications under the new paradigm.
3. Patient medication adherence would improve under the new paradigm.
4. For a given drug, the new paradigm would increase the out-of-pocket drug expenditures for insured patients.
5. With the implementation of the new paradigm, patients would seek medical help more quickly than they do now.
6. Patients would be accepting of pharmacists monitoring their treatment.
7. Patients would be able to gauge their own health status using kiosks and online questionnaires.

B) Characteristics of the Innovation

1. The new paradigm would allow for more pharmacist-directed patient care.
2. The new paradigm would foster better physician-pharmacist relationships.
3. The new paradigm would reduce physician workload.
4. The new paradigm would alleviate primary care physician shortages.
5. The new paradigm would foster better patient-pharmacist relationships.
6. The new paradigm would reduce the burden on emergency rooms.
7. The new paradigm would increase the professional liability of a pharmacist.
8. The new paradigm would increase pharmacists' workload.

C) Characteristics of the Pharmacy

1. Pharmacies would be willing to make significant structural changes to incorporate extra space for patient counseling rooms for the new paradigm.
2. Pharmacies would be willing to make significant structural changes to incorporate extra space for an expanded nonprescription drug section for the new paradigm.
3. Pharmacies would have to increase the number of personnel if the new paradigm were instituted.
4. Pharmacies would be willing to train pharmacists for the new paradigm.
5. Pharmacies would be willing to install innovative technologies such as diagnostic tests, kiosks, and computer algorithms under the new paradigm.
6. Adopting the new paradigm would require a significant change in workflow for pharmacies.
7. Adopting the new paradigm, if instituted, should be mandatory for all pharmacies.
8. The new paradigm could increase the profitability of a pharmacy.
9. It would be difficult to implement the new paradigm in the current community pharmacy setting.

D) Characteristics of the Adopting Pharmacist

1. Pharmacists would have time to assist patients in selecting the most appropriate nonprescription medication under the new paradigm.
2. Pharmacist-authorized refills upon a physician's initial prescription should be permitted under the new paradigm.
3. When in doubt, pharmacists should refer patients to a physician before dispensing a nonprescription medication under the new paradigm.
4. Pharmacists should alert the physician if there are problems with the nonprescription medications that the patient is taking under the new paradigm.
5. Pharmacists should be reimbursed for the time they spend diagnosing and counseling a patient under the new paradigm.
6. Patient counseling by pharmacists for new paradigm drugs should be mandatory.
7. Under the new paradigm, pharmacists would be comfortable ordering diagnostic/lab tests before dispensing certain nonprescription drugs.
8. Under the new paradigm, pharmacists should document the nonprescription medication history of a patient.
9. Pharmacists have the skills to make appropriate treatment recommendations under the new paradigm.
10. Pharmacists should have access to patient medical records to dispense nonprescription drugs under the new paradigm.
11. Pharmacist intervention would still be needed if innovative technologies that help patients self-assess their drug choices are instituted under the new paradigm.
12. I am a proponent of instituting the new paradigm in pharmacy practice.

APPENDIX 2: SURVEY

Thesis Questionnaire

Are you a community pharmacist?

- Yes
- No

The FDA recently held a public hearing to consider a "new paradigm" whereby it would expand the current nonprescription drug class. Under this "new paradigm", the FDA would allow pharmacists to dispense certain medications that are currently prescription only, as nonprescription drugs, but only after confirming the patient's diagnosis.

To confirm a patient's diagnosis, the pharmacist might have to order and/or verify diagnostic tests, verify a physician's diagnosis, or verify and fill a physician's initial prescription but then subsequently refill the prescription without physician authorization.

The pharmacist would dispense the drug only after educating the patient about safe use of the medications.

Assuming the implementation of an expanded nonprescription drug class under the FDA's proposed "new paradigm", please indicate your level of agreement with each statement using a scale from 1-7 where 1 = "strongly disagree" and 7 = "strongly agree".

As previously described a new paradigm medication is a medication dispensed under the expanded nonprescription drug class which would require a confirmation of diagnosis by the pharmacist.

	1 = Strongly Disagree	2	3	4	5	6	7 = Strongly Agree
Pharmacists would have time to assist patients in selecting the most appropriate "new paradigm" medication.	○	○	○	○	○	○	○
Pharmacist-authorized refills following a physician's initial prescription should be permitted.	○	○	○	○	○	○	○
When in doubt, pharmacists should refer patients to a physician before dispensing a "new paradigm" medication.	○	○	○	○	○	○	○
Pharmacists should alert a physician if there are problems with a "new paradigm" medication that a patient is taking.	○	○	○	○	○	○	○
Pharmacists would be comfortable enough to order diagnostic/lab tests before dispensing certain "new paradigm" medications.	○	○	○	○	○	○	○
Pharmacists should be reimbursed for the time they spend diagnosing and counseling a patient for [illegible]	○	○	○	○	○	○	○

APPENDIX 3: COVER LETTER

Dear Pharmacist,

A few months ago, the FDA held a public hearing to obtain input on a ***new paradigm*** it is considering. Under this ***new paradigm***, the FDA would approve certain prescription drugs for nonprescription use, but only under certain conditions to assure safe use of the drug by patients.

The FDA is eliciting public comment on this proposed ***new paradigm***. Arguably community pharmacists are the most important stakeholders for implementing the new paradigm. As a part of my thesis requirements, I am conducting a survey to obtain input from community pharmacists and assess their views about the ***new paradigm***. Your response is important as we want to make sure that we have an accurate estimate of pharmacists' attitudes toward the ***new paradigm***. The completion of the survey should not take more than fifteen minutes of your time. Please consider completing your survey today.

The responses to this survey will be kept confidential. This study has been reviewed by The University of Mississippi's Institutional Review Board (IRB). Our IRB has determined that this study fulfills the human research subject protections obligations required by state and federal law and University policies. If you have any questions, concerns, or reports regarding your rights as a participant of research, please contact the IRB at **662-915-7482**. If you have any questions about this project, please contact Dr. Erin Holmes, faculty in the department of Pharmacy Administration at the University of Mississippi at **662-915-5914**.

Follow This Link to the Survey:
Or Copy and Paste the following Link in your internet browser:

Thanks you in advance for your thoughtful consideration of this request.

Respectfully,
Ruchit Shah
Graduate Student
The University of Mississippi
Department of Pharmacy Administration

VITA

Ruchit Shah was born in Mumbai, India. He is the son of Mukesh Shah (Chartered Accountant) and Swati Shah (B.Sc Chemistry and Biochemistry, Optometry). Currently, Ruchit Shah is a third year doctoral student at the University of Mississippi. He has a BS in Pharmacy from Mumbai, India. He is currently pursuing a PhD in Pharmaceutical Marketing and Health Outcomes Research.

His primary research interests include studying pharmacist behavior, pharmaceutical pricing and reimbursement, positioning of products on the market and issues related to drug therapy compliance/adherence. He am also interested in conducting research related to health policy, health outcomes and pharmacoepidemiology. He has a good understanding of qualitative and quantitative primary research, dministrative claims data management and analysis using SAS and understanding and applying appropriate statistical techniques to research.

Ruchit likes to play tennis and table tennis in his spare time. His hobbies include travelling, watching football and playing soccer games online.