THE POTENTIAL SUCCESS OF THE F.D.A.'S NEW PARADIGM BASED ON COMMUNITY PHARMACISTS' OPINONS

by
Anna Blair Brown

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Approved by

_____
Advisor: Dr. Donna West-Strum

_____
Reader: Dr. Rahul Khanna

_____
Reader: Dr. Erin Holmes

ABSTRACT

ANNA BLAIR BROWN: The Potential Success of the F.D.A.'s New Paradigm Based on Community Pharmacists' Opinions
(Under the direction of Dr. Donna West-Strum)

For the past 40 years the F. D. A. (Food and Drug Administration) has considered creating a third class of drugs in the United States of America that would be a pharmacist-only class which could only be sold with the approval of a pharmacist. Several things have inhibited its creation, the main one being the Durham-Humphrey Amendment which states that there are only two classes of drugs: prescription and over-the-counter. This has culminated into the development of the F.D.A.'s new paradigm, which is an expansion of the over-the-counter class of drugs to create and O.T.C.+ category. Community Pharmacists were interviewed in order to learn more about their knowledge and opinions of the new paradigm in order to measure the potential success of an O.T.C.+ class of drugs. Though many barriers were seen facing the implementation of the new paradigm, the majority of those interviewed believed it would be beneficial.

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INTRODUCTION

Currently, the United States of America has two official classes of drugs. They are over-the-counter and prescription medications. For the past 40 years there has been an interest in creating a third class of drugs. The third class of drugs that has been considered by the Food and Drug Administration is one that is used in many other countries around the world. It is the pharmacist-only class of drugs, also known as behind-the-counter drugs (B.T.C.). Countries with systems that include a class of drugs where the pharmacist must be present to make a sale which have been studied in detail by the United States Government Accountability office include Australia, the Netherlands, Italy, and the United Kingdom. The European Union has been studied as well (GAO, 2009).

In order to define the pharmacist-only class of drugs, it is important to first understand the other two classes of drugs. Prescription drugs require a prescription from a prescriber such as physician and are filled by the pharmacist. The pharmacist then gives the drug to the patient. Over-the-counter drugs can be purchased anywhere and require no supervision.

Pharmacist-only drugs are similar to over-the-counter drugs in that they do not require a prescription. However, they cannot be sold in any retail setting. They are only available in a health care setting, most likely a pharmacy. This is because in order to purchase a pharmacist-only drug, a recommendation is needed from a pharmacist.

One key barrier standing in the path of adopting the proposed third class of drugs is the legality of it. The Durham-Humphrey Amendment states that there are two classes of drugs. The F.D.A. has stood behind this law (Karst, 2013). All of this has cumulated into the possible establishment of what the F.D.A. is calling its new paradigm, also known as the NSURE initiative, which stands for Nonprescription Drug Safe Use Regulatory Expansion. Rather than a third class of drugs, the F.D.A. is expanding the over-the-counter class of drugs by creating an O.T.C.+ category with conditions of safe use.

LITERATURE ANALYSIS

The Food and Drug Administration has considered creating a third class of drugs several times over the last 40 years, yet it has never come to fruition. In December 2012, *U.S. Pharmacist* said, "the likelihood of a third class of drugs becoming a reality is perhaps greater than ever." However, in present times, the F.D.A. has taken the idea of a third class of drugs to create an O.T.C.+ category, which is simply an expansion of the over-the-counter class of drugs. Because the O.T.C.+ idea is so recent, much of the literature discussing the issues of the new paradigm or ways to increase drug availability refers to a third class or B.T.C. class of drugs. The question is, "Why has the idea of a pharmacist-only class of drugs been considered so many times, but never put into action?" What makes the F.D.A. reconsider it and why do they keep deciding against it?

One of the main reasons the American Pharmacist Association, also known as the APhA, and many others have supported the creation of a pharmacist-only or behind-the-counter class of drugs is "to address the public health problem of under treatment of common conditions such as high cholesterol, high blood pressure, migraine, headaches, and asthma (Yap, 2012)". Untreated chronic conditions such as these often lead to emergency room visits. If the public were given easier access to treatment, the number of emergency room visits could also go down. If medicines to treat these conditions no longer required a trip to the physician's office and the bill that comes along with it, maybe Americans would be more inclined to treat them.

The APhA says that the goal is to help people who may not be seeing a healthcare professional at all, not to make the pharmacist a substitute for a physician. The F.D.A. has also stated that a third class of drugs could free physicians' time by removing prescription refill tasks. The possibility of lowered drug costs from being switched from prescription class has also come up as another way people would benefit from a third class.

Several other countries around the world use two main criteria to switch a drug from prescription to non-prescription. The first is that the reasons for taking the drug are proper for self-diagnosis and self-medication with the involvement of a pharmacist. The second is that the drug only has a small possibility for side effects and over dosage. The United States has four conditions for this. They include their benefits outweighing their risks, ability to be used with self-diagnosis, labeled for easy self-medication, and a prescription is not needed for the drug to be used safely and effectively for self-limiting conditions. The foreign countries seem to have less strict criteria. This is because the third class of drugs does not require a prescription, but does still involve the consideration of a pharmacist (GAO, 2009).

Table 1:

Highest Recommended Drugs for American B.T.C. Category		
Prescription prenatal vitamins	Triamcinolone cream	Silver sulfadiazine cream
Mometasone nasal inhalation	Fluconazole	Epinephrine injection
Promethazine	Mebendazole	

There are also many concerns about adopting a pharmacy-only class of drugs. One of the main ones is monetary. Those who do not support the third class suggest that insurance companies would not provide coverage for the B.T.C. drugs, and so the consumer would have to pay more. Those who do support it suggest that they may cover them like they do immunizations. These questions about insurance coverage still apply to the new O.T.C.+ category. There is also the question as to whether pharmacists would charge a fee for any counseling provided.

Opponents have said that a third class of drugs will be a default for drugs that could be changed from prescription to O.T.C. Even if drugs could be placed directly into O.T.C., they will be put in the B.T.C. category first and require pharmacist approval. This can easily be applied to drugs switching from prescription to O.T.C.+. Another hesitation stems from the fact that many question whether or not a pharmacist has the knowledge or preparation to provide counseling services that may be necessary for the sale these drugs.

Most medical societies have been against the introduction of a pharmacy-only class of drugs. The pharmacist does not have access to medical records. Many of the chronic conditions whose medication has been suggested for B.T.C. have other problems associated with them that the pharmacist may not be aware of in order to administer the best medication.

One of the qualifications of a drug in the O.T.C. drug class is that it is safe for self-diagnosis. One of the arguments against a pharmacy-only class of drugs has been that pharmacists are not trained in diagnosis. However, there are technologies in development to challenge this. These technologies are computer algorithms that

could be available either online or at a kiosk and other diagnostic tests that could be available in a pharmacy. Consumers could be lead through this algorithm to determine if a drug is right for them. An example of a diagnostic test would be blood tests for cholesterol levels (F.D.A., 2013).

There seems to be several reasons why adopting either a third class of drugs or the F.D.A.'s new paradigm would be beneficial, yet the reasons people are against it can not be overlooked. They are why it has not yet been adopted. However, the fact that the idea repeatedly comes to the forefront of the F.D.A.'s attention suggests that the benefits might be enough to one day adopt the expansion of the O.T.C. class of drugs under the F.D.A.'s new paradigm which has stemmed from the idea of a pharmacy-only class of drugs regardless of the possible problems that may come along with it.

Benefits

Those who have supported the addition of a behind the counter, B.T.C., class of drugs in the United States have several reasons that they believe creating this class will overall improve our healthcare system. Supporters believe that a B.T.C. class of drugs could improve overall public health through an increase in the availability of nonprescription drugs. The logic behind this is that public will be more inclined to treat conditions that they may not consider serious enough for a physicians visit because of the cost of seeing a physician and a prescription medication. This leads to the next point of advocates of the O.T.C.+ category, which is that it will reduce costs by reducing the number of physician visits. It will also lower the number of physicians visit that could be deemed inappropriate by making

medications that treat less severe conditions but may have more side effects available. The price of the drug may also be lowered since it is not a prescription drug, saving the consumer more money. There are also several ideas as to how this would affect third-party payers. Advocates say that if third-party payers did not cover B.T.C. drugs, it would obviously lower their expenses. Also, a reduction in the number of physician visits would lower the costs for third-party payers.

Money is a top concern in the idea of adding a B.T.C. class of drugs as it is in all things, but advocates have other arguments to support the new class. Adding this class of drugs controlled by the pharmacist would make greater use of the pharmacist's expertise. Increasing interaction with the pharmacist could also give the pharmacist a chance to intervene with the patients' self-treatment and recommend seeing a physician when appropriate. The B.T.C. class would also allow easier treatment of chronic ailments. Those who are medicated for hypertension, diabetes, or other common chronic illnesses would have easier access to refills. This could also apply to getting an epinephrine injection for those with allergies. Those with chronic illnesses who have to have medication refilled regularly may also increase their adherence to their drug regimen if they know that obtaining refills will be easier. The B.T.C. class could play a big role in increasing access to the healthcare system. Those who live in rural areas or cannot afford a trip to the physician would have more medications available to them at a lower cost.

If implemented, the B.T.C. class could allow a safer transition of medication from prescription to nonprescription. Still having control on the drug could allow its usage to be studied to better determine wither it should go into the O.T.C. class,

stay in the B.T.C. class, or perhaps go back to being a prescription drug. The O.T.C.+ category would offer this same control.

Barriers

Many of the opponents play devil's advocate to the benefits that supporters say a B.T.C. class of drugs will introduce. Opponents have said that access will be reduced because drugs will enter the B.T.C. category by default rather than going straight to O.T.C. They also have said the cost of a B.T.C. class drug will more expensive than an O.T.C. class drug, so the consumer will opt to buy the O.T.C. When an O.T.C. drug to treat the same condition is not available, the consumer will have to buy the B.T.C. drug. If third-party payers do not cover B.T.C. drugs, costs to the consumer will increase. The consumer may opt to go to the physician and get a prescription if third-party payers do not cover B.T.C. drugs (now referred to as the O.T.C.+ category drugs). This increases the costs for third-party payers because consumers are taking advantage of them when they have another option of treatment.

Another effect on cost is what the pharmacist will charge for any consultation that is required when purchasing a B.T.C. drug. Pharmacies may also be tempted to raise the price of B.T.C. drugs because there is less competition in the sale of these drugs. They cannot be sold in retail outlets like O.T.C. drugs.

Many opponents are concerned about the pharmacists ability to consult patients on these medications. They question whether the pharmacist has enough training to correctly consult the patient and help them treat their illness. They bring up the fact that pharmacists are not trained in clinical diagnosis. Pharmacists may

also lack access to other relevant information, such as lab results, that could be important in treating a patient. They worry that treatment from a pharmacist may only include treatment of the symptoms of the illness rather than the actual illness. Patients may simply find remedies for their problems rather than changing their lifestyle to treat or cure them. Opponents also question if pharmacists have enough time to provide these services. Lack of time along with other things may lead to a poor quality of service.

Uncoordinated care has also been a concern of those that oppose the B.T.C. class of drugs. The physician may not know what B.T.C. drugs the patient is on, and depending on whether or not the patient goes to his or her usual pharmacy to get a B.T.C., the pharmacist may not know what other prescription drugs the patient is on.

One big question is whether or not pharmacists are willing to provide this service and take on the extra liability that comes with it. As the F.D.A. continues to consider what they are calling the new paradigm, they continue to offer more solutions to the considered barriers making the adoption of the paradigm more probable. This new paradigm could have a large impact on community pharmacists. Community pharmacists are on the front lines of healthcare because of their high level of accessibility. Therefore, it is important to consider their opinions and whether they think that the infrastructure of pharmacy could adjust to the new paradigm.

OBJECTIVES

The purpose of this research is to describe community pharmacists' awareness and attitudes towards the F.D.A.'s proposed new paradigm (i.e. NSURE initiative). Specifically, the objectives of the study are to

- 1) Describe the pharmacists' awareness and current knowledge of the new paradigm
- 2) Identify benefits and challenges of the new paradigm costs
- 3) Describe pharmacists' attitudes toward the implementation a new paradigm
- 4) Identify drugs that should be included in the new paradigm from the pharmacist perspective

METHODS

In-depth interviews were conducted with 10 pharmacists practicing in community retail pharmacies in the state of Mississippi. The initial interviews were chosen from a convenience sample, and snowballing was relied upon to find more pharmacists to interview. Those interviewed included both urban and rural pharmacists. Retail pharmacists were selected because the addition of a third class of drugs would have a prominent effect on them over all other practicing pharmacists. University of Mississippi Institutional Review Board approval was obtained for the interviews, and pharmacists were asked to sign a consent form prior to the interview. The consent form provided information about the study, that the study was voluntary, and that the interview was being audio taped. All data was kept confidential.

The purpose of the interviews was to gain understanding of the pharmacists' knowledge and opinions of the proposed third class of drugs: the new paradigm. An interview guide was developed and can be found in Appendix A. The interview was planned to take approximately 30 minutes, and each interview was audio taped. Notes were taken during each interview and from the recordings. Interview notes were analyzed in order to gain an idea on what the general attitudes of Mississippi pharmacists is toward the adoption of this new paradigm. The interview guide included questions that address four main areas.

- Pharmacists' awareness and current knowledge of the new paradigm

- Pharmacists' opinion on the benefits and costs of the new paradigm
- Pharmacists' attitudes toward the implementation a new paradigm, specifically training of the pharmacists to perform consultations, impact on the pharmacists' time, financial implications of the new paradigm, workflow/infrastructure issues related to the new paradigm, and consumer acceptance
- Pharmacists' views of the drugs that should be included in the new paradigm

ANALYSIS

Thematic analysis of the interview notes was performed (Miles and Huberman) by two investigators independently. Themes were formed from the data on pharmacists' awareness, benefits and costs of the new paradigm, and pharmacists' attitudes toward implementation. Quotes from participants were used as evidence for the themes. The investigators compared the findings of recurrent themes to reach consensus on the major themes identified. Descriptive analysis was used to provide frequencies for the drugs proposed for the new paradigm.

RESULTS

Ten pharmacists were interviewed on the topic of the F.D.A.'s new paradigm. Topics covered include their current knowledge of the new paradigm and their attitudes and opinions towards an O.T.C+ category of drugs. The pharmacists interviewed varied in age and in practice experience. They have all practiced in either chain or independent community pharmacy.

Pharmacists were first asked about any knowledge they might have of an O.T.C.+ category of drugs and if they had heard of the F.D.A.'s new paradigm. Nine out of the ten pharmacists interviewed had minimal, if any, knowledge of the possible new category of drugs. The pharmacists were then given a brief background of the F.D.A.'s new paradigm and a general idea of what an O.T.C.+ category of drugs would be like. Many related the topic to the current status of the plan B emergency contraceptive drug. The pharmacists were also asked questions about their background including the year they graduated pharmacy school, how long they had practiced community pharmacy, and whether most of their background was in independent or chain drug store settings.

Benefits

The pharmacists interviewed were able to see many possible benefits that would stem from an O.T.C.+ category of drugs. Several of these benefits were on the behalf of the patient. They were increased access to medication, increased time savings, and increased money savings. Increased access to medication is a clear

benefit of the paradigm because patients have access to more medications without the need to visit a doctor. One of the pharmacists mentioned that, along with not having to see a doctor, the pharmacy is open more hours of the day, which also contributes to increased access. Both time and money savings would mostly stem from not having to see a doctor. It was also pointed out that the drugs moved from prescription from to O.T.C.+ classification may decrease in price, therefore leading to more money savings. It was also mentioned that the O.T.C.+ category of drugs would improve the role of pharmacists in providing patient care. This may lead to more respect for the pharmacists as caregivers.

The new paradigm could also be seen as a benefit to physicians. It could decrease the physician workload and allow them to spend more time treating more serious conditions or new cases of disease. One additional benefit to the patient that could be seen as a benefit to physicians and even insurance providers would be increased patient compliance. The pharmacist-patient relationship may develop enough that we see increased patient compliance. If patients are more compliant, they are less likely to have to visit a physician for an illness related to non-compliance. This saves the patient time and money. Patients not having to see the doctor again for the same condition would increase the efficiency of the doctor. The insurance companies will save money by not having to pay for additional doctor visits or prescriptions.

Barriers

There are also barriers related to the new paradigm. Some of these barriers contradict the benefits. These contradictions relate to the details of the

implementation of the new paradigm. One of the barriers of the new paradigm could be increased monetary costs to patients. If insurance companies do not cover these drugs, the patients will have to pay for a drug out-of-pocket when they could have gone to the doctor and gotten a prescription, so that insurance would cover the cost of the drug. Other questions that must be asked are "Should insurance pay for anyone who asks to be on a drug?" and "Does Medicaid pay for it?" Pharmacists also worried that patients may misuse this system. They may approach the pharmacist and make irrational demands for medication. There is also the chance that the patients misuse the medication though the pharmacists instructed them on how to use it correctly. Another barrier not mentioned in the answering of this particular question, but mentioned at other times throughout the interviews would be buy in from the medical institutions. Physicians may not agree with pharmacists ultimately taking some of their business.

The rest of the mentioned barriers relate to the pharmacist. The biggest barrier by far was time. Lack of time was mentioned repeatedly throughout the interviews with each pharmacist. Pharmacists, especially in those who work in pharmacies with high prescription volumes, will, most likely, not have time to manage the additional service of an O.T.C.+ category of drugs. Whether or not pharmacists have adequate training and/or knowledge to manage the O.T.C.+ category of drugs was also questioned. This relates not to how to use the medication, but how to accurately judge whether a patient is in need of a certain medication and monitoring a patient with chronic conditions. The last barrier to the F.D.A's paradigm would be the implementation of a reimbursement system for the care and

time that a pharmacist would provide to a patient using the O.T.C.+ category of drugs. "There would have to be a really good plan in place as far as how to it implement it."

Attitudes

Pharmacists were then asked whether the benefits of the new paradigm outweighed the barriers. There was an absolute majority of those saying that it would be beneficial overall. Those who said that the benefits did outweigh the barriers said so with the reasoning that it would of benefit to the patient due to increased access. Most of these pharmacists still mentioned the barriers but one included, "I would lean toward the benefit for the patient because that is why we are all in this business." Those with the opposing opinion believed that troubles with logistics of the implementation would be hard to overcome. Two pharmacists said they would like to know more information about the logistics before they could say whether or not the benefits outweighed the barriers of the new paradigm. They were concerned with each of the aforementioned barriers, but also would have like to know the extent of the new drug category. The number of drugs included in the category along with what types of drugs they are affects how much time pharmacists would spend in managing this class.

The following questions addressed many of the topics thought of as barriers to the implementation of an O.T.C.+ category. The first problem addressed is whether or not pharmacist would need any type of extra training in order to adequately perform the counseling that the sale of these O.T.C.+ drugs would require. The majority of the pharmacists stated that extra training would be needed

and could be completed in the form of continuing education, live seminars, or a combination of both. One pharmacist said, "Our memories would need to be refreshed, and we need guidelines to go by." This matches and summarizes the sentiments of many of the other pharmacists. It was also mentioned that pharmacists would need to be trained on how to work any machines that may start to be used in the pharmacy such as the machines that check blood work. Only one thought that pharmacists would not require any extra training, but another said it would depend one what drugs were included in the category and the severity of their adverse reactions.

The most repeated barrier to the success of an O.T.C.+ class of drugs is time. The pharmacists were asked how they thought time would affect the ability to perform an increased number of consultations related to the new paradigm. Every pharmacist agreed that any time to add this to his or her current schedule was limited. There would be a need for more staff in order to meet the extra demands this would place on the pharmacy, and that most pharmacies are understaffed as it is. The addition of the O.T.C.+ category may only be easy for pharmacies that have adequate staff to meet their current prescription load. This all leads to an economic decision because economics drive pharmacists to spend more time on dispensing and will keep companies from wanting to hire more staff to help with the increased workload. One pharmacist said, "Conversations can end up taking a lot of time. It is hard to effectively do both (fill prescriptions and counsel patients)." This pharmacist continued by stating concern over whether the pharmacists may neglect the consultation and still give the medicine to the patient.

Our world is driven by money, so the financial implications will have a considerable effect on the implementation and success of an O.T.C.+ category. Specifically, insurance coverage or lack there of will have a large effect on the success of the category along with any payment to the pharmacist for these services because this will affect the pharmacies willingness to perform these services. Pharmacists had mixed opinions on insurance involvement in the new paradigm. Some pharmacists skipped thinking about whether they could or should be involved and jumped straight to saying that insurance would not cover anything related to the new paradigm. One said, "Insurance takes any excuse to not pay for something." Another pharmacist took a more cautionary approach and said that "The insurance companies will put up a fuss, but their goal is financial. They may have to see if they are spending less money doing it this way rather than with the physician's visits and refills." The pharmacist who said that insurance should cover these products related it to being the same as if a physician or nurse practitioner prescribed a medication to a patient.

The majority of the pharmacists interviewed were also supportive of a consultation fee for the pharmacist. They believe that they should be reimbursed for the time they spend consulting the patient. The problem will be giving a dollar value to the time, but there are models out there from other professions that can be followed. Those who believed that pharmacists would not be reimbursed said that they give consultations now and are not being paid for it, so they also do not see patients or insurance companies being willing to pay for it under the new paradigm.

The F.D.A.'s new paradigm would lead to a lot of change in the healthcare system. The patients would need to be informed of this change in order to make proper use of the O.T.C.+ category of drugs. Pharmacists unanimously agreed that Direct-to-consumer advertising (D.T.C.A.) should be used to make patients aware of these products. Only half of the pharmacists mentioned that the pharmacy should take any sort of action or responsibility to advertise these products. Some other ways to inform consumers of these products that were mentioned were physicians and insurance. Doctors may be making initial recommendations for drugs that will be used for a long period of time and, therefore, should tell patients about the new category of drugs. Also, if insurance sees this as a money saving opportunity, they should promote it as much as possible to those that they insure. This means insurance could promote these products through direct-to-consumer advertising, as well. One pharmacist said, " The current D.T.C.A. structure is a good one, and these (products) should follow this structure."

Implementation of this new paradigm would lead to several changes within a pharmacy. One thing to be considered is if the actual structure of the pharmacy is going to be able to meet the needs of the new paradigm. For starters, many of the pharmacists mentioned they would need a new area or work space. The pharmacy may have to be rearranged in order to create a special place for these medications. Privacy must also be considered due the consultations that will come with the sale of an O.T.C.+ drug. Most of the pharmacists agreed that the current "private" consulting area was inadequate and that it should be improved upon. One pharmacist said that it would "make the patient more comfortable." However,

others said they did not see the privacy area as a concern saying, “The topics we have mentioned are not sensitive enough to invest money in changing the structure of a pharmacy. You will never get adoption if you have to invest money.”

The last change within a pharmacy would be a workflow change. Many pharmacists mentioned additional staff would be needed to accommodate this change in workflow. Those who mentioned the need of more staff had varying ideas of the job of the new staff member. Most agreed the additional staff would have to be a licensed pharmacist, but opinions varied on whether the additional pharmacist would work full time, certain hours of the day, or certain days of the week.

Appropriate Drugs for O.T.C+

One of the biggest things to consider about the new O.T.C.+ category of drugs is what drugs would be included in this category. Throughout the interviews, many of the pharmacists qualified their answers by saying “it depends on what drugs would be included.” The table below represents what each pharmacist would choose to include in an O.T.C.+ category of drugs. Drugs or categories of drugs that were mentioned by only one of the pharmacists interviewed were not included. No themes were found when considering the age of the pharmacist or the type of community pharmacy they had experience in.

Table 2:

Drug	Number of Pharmacists
Cholesterol	7
Steroid Cream	3
Corticosteroids	1
Higher Power Steroids	1
Bactroban	4
Antifungals	2
Diflucan	2
Eye Infections	6
Non-controlled Cough and Cold	6
Blood Pressure	7
Ear Drops	3

DISCUSSION

Other than those regarding the pharmacists age or background, the first question asked was whether or not the pharmacist had ever heard or new of a possible O.T.C.+ category of drugs. The answer to this question is "no." Most of the pharmacists had not heard of the over-the-counter plus category of drugs. If the Food and Drug Administration along with all of the national pharmacy organizations hope to ever make the new paradigm a reality, they need to be more proactive about reaching out to community pharmacists. This initiative will be most successful if they increase communication with pharmacists all around the nation and invite feedback on how to make the transition into the new paradigm as smooth as possible and how to make the O.T.C.+ category as successful as possible. As one pharmacist said, there will need "to be a really good plan in place as far as how to implement it."

There are many barriers to the adoption of the new paradigm, but most agree that it would be beneficial in the end. All the barriers seem to do with the implementation of the new paradigm because it is going to take more than just labeling some of what are now prescription drugs as O.T.C.+. It will call for other changes within the pharmacy system and other systems as well. A list to summarize the barriers:

1) Pharmacists' lack of time (need for more staff pharmacists)
2) O.T.C.+ drug coverage by the insurance companies

3) Reimbursement to the pharmacist for consultation time
4) Need for changes of current structure of the pharmacy
5) Buy-in from other practitioners

Time

The first, and largest issue facing the new paradigm is whether pharmacists have time to manage the O.T.C.+ drug category. How much of an impact this will make will certainly vary based on the pharmacy and even the extent and success of the O.T.C.+ drugs. Pharmacies that fill low numbers of prescriptions will not view time as quite as large of an issue. According to the pharmacists interviewed, it is more common to consult patients at an independent pharmacy now than it is a chain pharmacy, so it may not be as much of an adjustment for these pharmacists to add more consultations to their daily workload. The same cannot be said for higher volume pharmacies. Interviewed pharmacists thought they were commonly already understaffed for the number of prescriptions they fill, and many already have vaccinations as another demand for their time. Many of the pharmacists referenced how they already get behind on verifying prescriptions when they need to give someone a vaccine.

One solution to this problem would be to add another pharmacists to the staff, but this can be done in many different ways. This pharmacist may just come to the pharmacy on certain days of the week or certain hours of the day. This seems to have been looked upon as a good solution because it would keep companies from having to pay another fulltime pharmacist. One of the pharmacists interviewed did specifically mention that this was not a good solution and that the pharmacist or the

availability of the O.T.C.+ drugs would need to be fulltime because it would be too confusing for the patients if there were only certain times when they could come get the drugs. Having limited times when these drugs are available also hurts the whole idea of increased access to care for the patients.

The single pharmacist that had heard of the O.T.C.+ category of drugs prior to the interview had another opinion. No demand for increased staff was seen. The O.T.C.+ category of drugs would not include any medications that had common extremely dangerous side effects. The drugs included should not be complicated. The patient could fill out a survey about their condition while the pharmacist does other things. The pharmacist could check the survey and then give a short consultation. The consultation should not take 30 minutes for these medications. The changes each pharmacy makes regarding staff will most likely reflect the popularity of the O.T.C.+ drugs in the individual pharmacy, yet a degree of uniformity is necessary to keep from confusing patients.

Finances

The second biggest barrier dealt with the financial details of the new paradigm. Will insurance cover these products? Although it was stated that insurance companies would refuse because they keep from spending any money they can keep from spending, the possibility that insurance companies may view this as an opportunity to save money was also mentioned. There are several different reasons the new paradigm could be viewed as a way to save money.

One reason an O.T.C.+ category of drugs could save insurance companies money that was not mentioned in the interviews is looking at it under the lens of

preventative care. Patients that may usually wait to go to the doctor because of the expense and the hassle as their condition becomes more severe may go to the pharmacy sooner than they would go to the doctor and save money by treating a less severe condition. The insurance companies may also view it as a way to reduce the number of doctors' visits they pay for. Even if pharmacists are reimbursed for their counseling services, the overall expense is likely to be much less than a visit to the doctor. Also, if the price of the drugs moved into the O.T.C.+ category goes down from the price of the drug in the prescription class, the insurance companies may prefer and promote the use of these drugs to save them money.

In order for this new paradigm to truly be successful, it needs to have the support of pharmacists. Pharmacists are not going to be willing to add more pressure, stress, and time constraints upon themselves unless they see some kind of reimbursement for it. Many questions come along with the simple idea of reimbursing the pharmacist. Will it be a flat rate or be according to the amount of time the pharmacist spends with the patient? Could it even be according to which medication is given to the patient? Should the insurance cover this consultation fee or should the patient pay for it? The pharmacist that believed that the insurance companies should pay for the drug also believed that they should pay the consultation fee. This will be a large adjustment because pharmacists have never been paid for consultations before. There is not system valuing pharmacists' time and knowledge with a dollar amount in place. It was mentioned in the interviews that there are many other models that could be followed. Accountants, lawyers, and many others are paid by the amount of time they work. One of the pharmacists

thought that managed care companies should cover these costs. Managed care companies care about the outcome and have a dollar amount for everything. They will see the value of the patient having a drug and the value of being adherent to that drug. This pharmacist also mentioned that patients do not know enough to properly value the consultation. If patients are left to pay for the consultation, they will not properly see the value because they will view it as a service that used to be free.

Logistics

Another question that must be asked is what it will actually look like inside of the pharmacy when the O.T.C.+ category of drugs is introduced. Where will the drugs be located and where will the consultations be performed? This beckons the question of whether the structure of the pharmacy is adequate to meet these needs. While some pharmacists did mention that they may need a new computer or new workspace, it was mentioned that these needs could be met by simply rearranging the pharmacy. There will need to be an area where these drugs are kept behind the counter. A computer should be put in this space so that the pharmacist can easily look up information for the sale of these drugs. The bigger question is whether the current structure of each pharmacy has an adequately private area to perform consultations for these drugs. While some of the pharmacists did believe that current privacy partitions were adequate, many thought that the privacy areas should be improved upon. Those who believed current conditions were adequate supported their opinion by saying it will be harder to implement the new paradigm if pharmacies have to invest money in structural changes to their pharmacy. Some

pharmacies have very good privacy areas and others have plastic screens. Privacy is a concern, but would most likely be dealt with differently by different pharmacies. Some may want to create a more private setting in order to promote success of the program, and others may not see the need to make a more private area for the consultations. As one of the pharmacists said, most of the drugs mentioned do not deal with very sensitive topics.

The last big barrier to the new paradigm will be buy-in from the medical institutions. Physicians may not promote the new paradigm. The new paradigm is a large change to America's traditional healthcare system. Physicians or nurse practitioners diagnose a condition and write a prescription. Pharmacists simply give you the medication, try to prevent any interactions, and warn you against any adverse effects of drugs. Physicians make their money because the patients come to see them in hopes being given medications that will make them better. Physicians will see this as competition to their job.

Despite what may seem like a great deal of barriers, there would be very beneficial outcomes from the new paradigm. The greatest benefit of the new paradigm that was mentioned by most of the pharmacists is increased accessed to the healthcare system. The literature pointed out some of the benefits of this increased access. It could lead to improved general health of the public. People may treat conditions they would have tried to ignore if it required a visit to the doctor. Not visiting the doctor will also reduce the costs of treating a condition, which reinforces the patient's incentive to make use of the O.T.C.+ category. This increased access is not merely due to a decrease in costs. The new paradigm will be beneficial

for people who live in rural areas and do not have easy access to primary health care providers.

Benefits

One of the targets of the new paradigm is chronic condition medications. People who have conditions such as diabetes, hyperlipidemia, and hypertension can access refills to their medications via the O.T.C.+ category of drugs. The benefits of this are reduced costs for the patients because they will not have to go see the doctor just to obtain a prescription for a refill, and doctors will not have to spend their time on these simple appointments. They can put their time towards more severe situations. Several pharmacists also mentioned increased compliance. This could stem from reduced costs of acquiring the drug, so patients may not skip taking their medication some days to make it last longer. It could also be because every time a patient gets the drug they are consulted on how to properly take the medication and improve patient-pharmacist relationships.

Though it is the driving reason behind the new paradigm, patients are not the only ones that may experience benefits from the new paradigm. The public view of pharmacists may improve. This is also a great way for pharmacists to expand their scope of practice.

One very important question about the new paradigm is what drugs would be included in the O.T.C.+ category. One notable thing to report from the interviews is that none of the pharmacists mentioned concern that this would be a category that drugs would automatically go into during a transition from prescription to over-the-counter. The pharmacists interviewed mentioned most of the categories

of drugs that are amongst the highest recommended for the new category. Those that are on the list of highest recommended but were not mentioned by the pharmacists interviewed include prescription prenatal vitamins and mebendazole, which is an anti-worm medication. Epinephrine injection was not included in the chart of medications mentioned more than once in the interviews because it was used as an example medication, but every pharmacist agreed with this medication. It is inevitable that there will be conflicting opinions on what drugs to place into the O.T.C.+ category. Success will most likely be found in starting of small and, hopefully, growing.

CONCLUSION

Overall, the majority of pharmacists interviewed were in support of the new paradigm. All of the pharmacists interviewed saw numerous barriers facing the implementation of an O.T.C.+ category. However, mentioning the barriers did not come without ideas to overcome the barriers. The new paradigm is recognized as a benefit to patients and the health of people in America. Change often comes with barriers simply because people are not inclined to change. The new paradigm is a change that would affect many different people from the patients, the pharmacists, pharmacy corporations, insurance companies, and the medical doctors. It will take all of these people working together under the recognition of the benefit to the people of the United States, but according to the community pharmacists interviewed, the new paradigm has the potential to be successful.

Appendix A

Interview Guide

1. When did you graduate from pharmacy school?
2. How long have you been practicing community pharmacy?
3. Is most of your experience in independent or chain pharmacies?
4. What is your current knowledge of the possible O.T.C.+ category of drugs?
5. Are you aware of that the F.D.A. has proposed a "new paradigm?" If yes, please tell me what you know about it.

So for the rest of the interview, I am going to be interested in your thoughts about this new paradigm proposed by the F.D.A.. This new paradigm is defined…. Conditions of use which might be ….

6. What do you think are the benefits of this new paradigm or expansion of the over-the-counter class of drugs?
7. What do you think are the challenges associated with this new paradigm? Please expand, tell me more.
8. Do you think the pros of a new paradigm outweigh the cons? Why?
9. Tell me what types of extra training, if any, might pharmacists need to adequately counsel patients on drugs approved for this new paradigm?
10. How do you think time will affect the ability of pharmacists to perform an increased number of consultations related to the new paradigm?
11. What are the financial implications of a new paradigm of drugs? (probe: insurance cover these products, should there be a pharmacist consultation fee

and who should pay this?)

12. How do you think the consumer could or should be made aware of the drugs that fall into this category and how to properly make use of them?
13. What structural or workflow changes do you think a pharmacy would have to make to implement this new paradigm/third class of drugs? (probe: consumer privacy)
14. What types of drugs would you choose to make to include in this class.?- LIST DRUGS OR DRUG CLASSES

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