Debate on Behind-the-Counter Medication Continues

For many years, medication in the United States has been placed into two categories for distribution to the public. Either a drug is available as an over-the-counter (OTC) product, or a prescription is required. There are instances of a drug changing between these classes, usually a prescription drug becoming OTC; this is a process called switching. Examples of medications switching classes include now widely used OTC products such as diphenhydramine, ranitidine, loperamide, ibuprofen, naproxen and omeprazole.\(^1\) Recently, medications such as pseudoephedrine-containing products, that do not require a prescription, have been removed from front-end pharmacy shelves and placed behind the pharmacy counter. Though there are certain age and quantity restrictions to be met, a typical adult customer can still buy the product as they wish. There is also a current example of a prescription medication, Plan B, being changed to a non-prescription product for those over the age of eighteen. This product is also available behind the pharmacy counter where access can be restricted, again, to those over the age of eighteen. Having an OTC product available with restricted access, such as with Plan B and pseudoephedrine, is a departure from the norm for non-prescription products. These two examples illustrate a possible need for a third class of drugs to be established, one that places a medication behind the pharmacy counter but available upon request, without a prescription from the doctor. Many terms have been thrown around to describe this type of drug class, including behind-the-counter (BTC), pharmacist only, transition class, and pharmacist legend.\(^2\)

Recognizing that there may be a need to establish a third legal class of drugs, the FDA scheduled a public hearing in November to discuss public opinion on this topic.
Creating a new class of medication will impact the practice of pharmacy. Additional workload may be placed on pharmacy personnel by having to keep track of additional stock, paperwork, and medication storage. The pharmacist workload may increase as well if they are required to evaluate every request for medication, but this may also create an opportunity for pharmacists to be reimbursed for their counseling. The ethics of pharmacy practice will be tested as well as patient’s access to medication increased. To examine the impact of behind-the-counter medication on the practice of pharmacy and pharmacy ethics thoroughly, the general history of drug regulation will be discussed. In addition, the pros and cons of creating a BTC class, the characteristics of a BTC medication, the role of the pharmacist in dispensing BTC medication, and the ethical implications for pharmacists and their patients will be considered.

Thanks to the Interstate Commerce Act of 1887, the federal government of the United States was able to regulate commerce that crossed state lines. This became important for the regulation of drugs in this country in 1906 when the Food and Drug Act was passed. This was the first federal law designed to regulate drug products manufactured domestically and placed into interstate commerce. Drugs that were marketed were required to comply with claims of strength, purity, and quality. In 1938, the government’s regulatory role expanded with the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration (FDA) was created and given the power to grant or deny permission for new drugs to be placed on the market; it also required products to be safe for human use. The Durham-Humphrey Amendment in 1951 provided some criteria for deciding if a drug should be prescription or OTC. If a drug is safe enough for use by the layman, it is categorized as non-prescription. If the drug is habit forming or “can be used safely only under the supervision of a licensed healthcare practitioner” because it requires “expert diagnosis” and laboratory monitoring, it is a prescription medication.
important step in the regulatory process occurred when the FDA was required to evaluate not only the safety of new drugs but also the efficacy of prescription and over-the-counter medication. This was due to the Kefauver-Harris Amendment of 1962.

To summarize, the federal government, through acts of Congress, regulates drug policy. The FDA approves drugs entering the market and categorizes them by prescription or non-prescription. They also are required to determine if a drug is both safe and effective for use. These standards would continue to apply if a new class of medication is introduced. Though “it would take an act of Congress to establish a new drug class in the United States,” the FDA has debated this issue several times since the 1970’s, most recently in the 1990’s.\textsuperscript{5,6}

In the early 1990’s, the FDA considered making either a permanent behind-the-counter third drug class or what they called a transitional class. The transitional class would have allowed a medication to be available without a prescription, under pharmacist supervision for a few years before becoming an OTC medication. This would have allowed time for the FDA to study the medication’s use and decide if it would be safe for full OTC status. The permanent class would place a medication behind-the-counter indefinitely. Other terminology considered for this permanent class has been ‘pharmacist only’, a name borrowed from other countries, such as Britain, who have a three drug class system. As an aid for debate on this topic, one of Michigan’s Representatives to the House, John Dingell, requested the General Accounting Office (GAO) to submit a report about creating another class of drugs. The GAO published a document in 1995 entitled Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to be Demonstrated.

As apparent by the title of the report, the GAO was rather negative in its findings. This may have stifled debate for some time, but the FDA hearing in November this year reopened
discussion once again. Several groups made statements either for or against a third class of drugs, which closely reflected the pros and cons documented by the GAO. The American Pharmacist Association (APhA), as a representative of pharmacists in the country, supported the idea of BTC medication. The American Medical Association (AMA) opposed the idea, as did a group called the Consumer Healthcare Products Association (CHPA), who represents manufacturers who sell medications to all outlets, both to pharmacies and other retail settings.

The advantages of having BTC medication include increased healthcare access, making use of a pharmacist’s drug expertise, enhancing safe and appropriate use of medication, reducing healthcare costs, and reducing the abuse potential of some medication. Opponents of BTC medication use similar arguments to support their claims, just from the opposite side of the coin. They tend to believe that access to medication will be decreased by the creation of a third class of drugs, that physicians alone have diagnostic skills necessary to evaluate disease states, that prescription counseling by pharmacists is infrequent, that medication costs may actually be driven higher, and that a third class of drugs will not prevent abuse of medication.

Michael Mone of the APhA submitted a statement for the FDA’s public meeting. In it, he provided a number of reasons why behind-the-counter medication would be a beneficial public health initiative. Their first point was that pharmacists are already the most accessible healthcare providers, and they are “the only health care provider available to interact and communicate with patients at the point-of-sale for prescription and over-the-counter medications.” Since they are also medication experts, they have unique qualifications to instruct patients on the proper use of BTC medication. The APhA suggests that if a BTC class is approved, it should make use of pharmacists’ clinical knowledge and facilitate communication between pharmacists and patients in order to improve public health, enhance patient access to
medications, and facilitate safe and appropriate use of medications. Many of these points are reflected in a list made by the GAO. One main point is the increased access consumers would have to medication with a BTC system. “BTC availability could facilitate patient access to medications especially by people without health insurance because these medications would otherwise be available only with a prescription.”⁸ Patients who are not able to afford expensive visits to a prescriber’s office would still be able to get medication to treat chronic disease states, depending on the type of medication approved for BTC use. The GAO also generally assumed that non-prescription versions of medication would be cheaper than the prescription versions, so healthcare costs would be decreased, not only by saving money on office visits, but by cutting medication costs.⁶ Though physicians may protest to this, by decreasing the number of office visits for easier to manage needs, perhaps such as osteoporosis or acne, the physician would have more time to treat patients with serious illnesses. The GAO report also agrees with the APhA in that a benefit of BTC medication is consumers’ ability to use pharmacist expertise as a drug resource and the pharmacist being able to teach consumers proper medication use. Having a pharmacist available to monitor access to medication may also decrease the abuse of certain drugs. The FDA may find it beneficial to officially place pseudoephedrine in the behind-the-counter class, since it is already regulated because of its use in illicit drug manufacturing.

The Consumer Healthcare Products Association is a group that lobbies for over-the-counter drug manufacturers. They were called the Nonprescription Drug Manufacturers Association (NDMA) when the GAO report was published, but nonetheless, they argued that access to nonprescription products would be decreased if sales were limited to pharmacies, mostly because they cited 750,000 stores that sell non-prescription products to consumers but only about 54,000 community pharmacies.² Their fear was that current OTC medication would
be reclassified as BTC, a fear that may be legitimized with current restrictions on pseudoephedrine.

The AMA opposes a change in the present two-class system for a variety of reasons. As Joseph Cranston, head of science and research at the AMA, points out, physicians are trained to perform a history and physical examination and to consider all disease states when prescribing a medication.\(^9\) Physicians have enjoyed exclusivity in diagnosing patients and do not want to share this clinical aspect with other practitioners. Physicians are also worried that patients will avoid office visits and skip regular checkups if they do not need to see a doctor to get a prescription for medication. This may have a negative impact on a patient’s health if they do not go in for regular screenings and chronic diseases are allowed to continue unimpeded. One nutritionist from New York was also concerned that “fewer patients would pursue preventative measures like diet and exercise if they can easily buy a pill.”\(^6\)

The pharmacy tends to be a very busy place. Counseling takes place at a less than ideal frequency already, as pharmacists must deal with staffing issues, high prescription volumes, and other duties. Adding more to the pharmacist workload in terms of stocking BTC medication, maintaining paperwork and being torn from other duties to assess a patient’s condition does not make counseling for BTC medication more likely. The NDMA also points out that another class of medication does not need to be created for pharmacists to counsel patients.\(^2\)

Another argument is that medication costs would actually increase if more products were nonprescription. A pharmacy selling BTC medication may raise the price of the drug to make up for the pharmacist’s time in dispensing it or for extra pay to the support staff. Also, insurance plans may not cover a product once it has become BTC, so a five dollar copay for a month might become twenty or thirty dollars. The argument that having some medication behind the counter
would reduce its abuse potential has been waylaid, again, because many opponents believe pharmacists do not have the time to pay the proper attention to analyzing a patient’s need when dispensing the product.

In the statement of the APhA, their support was based on four key principles: a pharmacist-patient clinical intervention is essential, the FDA must base its BTC categorization decisions on science, the processes for drug availability without a prescription must be uniform, and pharmacists must be able to bill and be paid for the clinical services provided. The second point, that decisions for BTC categorization must be based on science, is especially important when considering what characteristics a drug should have to fit well into an intermediate class. In general, the drug should be safe, be easy to use, have a high benefit to risk ratio, and be labeled appropriately for self-medication. Luckily, some switching criteria has been developed by Peck and DeLap that can be used as a basis for scientific decision making.

In 1989, the CHPA asked the FDA to make a list of criteria that the manufacturing industry could use as a guide for selecting products that would make a good candidate to switch from prescription to OTC. A year later, the CDER director Carl Peck delivered a list of thirteen switch principles. These are shown in Table 1. Many of the principles on this list could also be used to consider what would make a good BTC medication. Some of the abbreviated principles include: does the switch candidate have special toxicity in its class, is there a large margin of safety, has the safety profile been defined,
has the product been on the prescription market long enough to establish a safe profile, and have drug interactions been fully characterized. Notice that these switching criteria mainly focus on the characteristics of the drug itself. This is important because another set of switch criteria was developed in 1998 that focused more on the consumer's use of a product and the condition it is used for, as seen in Table 2. These are called DeLap’s Principles after Robert DeLap, the director of the Office of Drug Evaluation at the time.

A few modifications could be made to these principles in table 2 to make them applicable to BTC medication. For example, rather than asking if the condition can be adequately self-diagnosed, the first point could ask if the condition can be recognized and diagnosed by collaboration of the patient and pharmacist. Under points to consider, perhaps the pharmacist may be needed for evaluation rather than the physician. Using the DeLap and Peck principles together, and perhaps modifying them to consider an expanded patient and pharmacist role in choosing medication, would be a good place to start making official criteria for a BTC medication.

A number of medication classes have been mentioned as possible candidates for being moved behind the counter, such as topical acne medication, asthma inhalers, birth control pills, or statins. Any proposed medication will have to be debated individually as to its value for being maintained as a BTC medication. Of these, some of the statins may be the quickest medications
to move BTC if such a class is ever developed, as there have already been proposals by Merck to move Mevacor OTC.\textsuperscript{11} Mevacor (Lovastatin) has been available as a prescription product for at least twenty years; in this time, its safety and efficacy data has been well established and the switch criteria of Peck would seem to have been met. The Consumer Use Study of Over-the-Counter Lovastatin (CUSTOM) was published in 2004. The study’s purpose was to evaluate the ability of subjects to self-manage high levels of cholesterol.\textsuperscript{12} This study addresses many DeLap Principles.

Mevacor OTC (MOTC) is intended to be used by patients in an intermediate risk category for heart disease according to the Framingham risk stratification, a population of about 23 million Americans. CUSTOM study participants were observed over 26 weeks in a simulated store-front setting where patients could evaluate their need for lovastatin and purchase the product. A nurse was available to give finger stick cholesterol tests and help evaluate a patient’s risk factors, but only if requested to do so. A total of 3,316 people evaluated the product; 2,111 did not purchase the product, citing things such as not being interested or not being eligible according to the labeling. There were 1205 purchasers, but only 1061 users of the product. Overall, 84\% of evaluators appropriately decided to use MOTC or not purchase the product. This shows that most users were able to read, understand, and follow the proposed label directions. The average reduction in LDL was 25\%, although the study’s primary focus was not on efficacy. Neither was the study totally focused on safety, but only 23 users (or 2\%) ignored safety concerns on the label. These people ignored the label advice about such things as not taking the medication if on a prescription statin or having liver disease. A promising safety point was that no users reported being diagnosed by a physician with myopathy or rhabdomyolysis.
when they purchased the drug and only 1 serious adverse event occurred, an allergic reaction to lovastatin.

The CUSTOM study intended to demonstrate how consumers would use lovastatin in an OTC setting, and the results were promising. However, the results would probably be improved if a pharmacist were introduced to the picture. If Mevacor were BTC and the pharmacist was required to evaluate the patient’s Framingham risk category and counsel the patient on the medication’s use, the rate of appropriate use would exceed 84%, the drug efficacy in the population would increase, and risk for adverse events would be even further diminished. This may be an idea for future study, to include pharmacist intervention in a BTC setting.

It will be important for the role of a pharmacist to be defined in relation to BTC medication. One issue will be preparedness. Are pharmacists ready for the responsibility of expanding their healthcare role? In addition to assuring proper medication use, they will be helping patients diagnose a chronic health condition. This is a new role, as previously pharmacists were involved in helping patients assess minor, acute health issues. Not only will their role as a healthcare provider be expanded, but so will time spent on clinical services. With the prescription volumes many community pharmacists face, will they have the necessary time to spend with patients without compromising the safety of fulfilling their primary duties of verifying prescriptions? In order to fulfill these new obligations, pharmacists may need to receive continuing education to make sure their skills are up to speed. In the case of statins, the pharmacist will need to be very familiar with the Framingham Cardiovascular Study and the application of its components.

In Britain, simvastatin has been available without a prescription from pharmacists for a few years, and a survey of community pharmacists’ experience with the product has been
completed. The manufacturer provided an educational package for pharmacists and the Royal Pharmaceutical Society of Great Britain also developed practice guidelines for utilization of pharmacist-only simvastatin. Questionnaires were returned from community pharmacists that indicated 93.9% had received continuing education. The pharmacists had “confidence in making appropriate cardiovascular risk assessment” and were confident in selling OTC simvastatin. Another interesting point was that there were very few requests for OTC simvastatin. Of 1,156 respondents, 956 (or 82.7%) had no sales within a fourteen-day period. This may allay some of the fears about the time commitment for pharmacists, as it might not take up that much time if there are only a few requests. Only 19% of pharmacies performed a cholesterol test, though many of the pharmacists thought a test should be available and were concerned they did not have access to all the necessary lab values. Even now, pharmacies are beginning to offer more blood pressure and cholesterol screenings. As this service expands, BTC seems more plausible since pharmacists will have the ability to perform the tests they need to initially screen patients and to do follow up monitoring.

Pharmacists may need to make changes to their practice if a third class of drugs is created. They may need to spend more time outside of work educating themselves on current practice guidelines for the use of a medication placed BTC. They may need to offer blood pressure monitoring, cholesterol tests, or glucose monitoring on a regular basis rather than on predetermined screening days. They may need to demand more staffing to keep the pharmacy running smoothly, maybe even have two pharmacists on duty at once. The pharmacist will be obligated to interact with patients who request BTC medication and provide counseling not only about the medication but also the disease state.
These new duties and obligations place a burden on pharmacists that they must be willing to take in order to provide the best service to their patients. As a professional, they also have a responsibility to maintain a code of ethics. BTC medication creates a new aspect of pharmacy practice that the APhA’s Code of Ethics will need to be applied to. Concepts of autonomy and just distribution of health resources may be two very important aspects of the Code that BTC medication may impact, but we can look at each part of the Code and see how it relates to a third class of drugs.

The first two points of the APhA Code of Ethics is that the pharmacist respects the covenantal relationship they have with patients, and that they promote the good of every patient. The pharmacist has obtained a great deal of trust from society at large, and they should be willing to take on new time commitments and responsibilities if BTC medication becomes a reality. They would be using a new standard in healthcare and health science to help their patients benefit from medication.

The third point of the Code of Ethics is that a pharmacist respects the autonomy of each patient. Each person has the right to determine their own healthcare needs and make their own health decisions, with a little guidance from a knowledgeable health professional. “Social trends have led to increased interest among patients in self-care and in control over their medical treatments,” says Brass in the New England Journal of Medicine. He goes on to say that having drugs available OTC allow this trend to continue. This idea can be expanded to BTC medication just as easily, since medication now only available by prescription will be easier to obtain. With the internet and all the information technology available, patients have access to a lot of information about disease states and medication. They can use this information, along with advice from their doctors, to expand their knowledge about their disease, and when they have
learned the importance of treating the disease, they can walk into the pharmacy at their own convenience, talk to the pharmacist, and receive the medication with more complete information about how to use it.

An important point to consider if BTC medication becomes a reality is that the pharmacist should act honestly when maintaining professional relationships. This will be important for maintaining a healthy relationship between their patients and the doctors in the community. It will be important for the pharmacist to be honest about which patients need BTC medication and not make sales of this medication for the sake of profit or just to get a patient out the door. It will also be important to refer the patient to their doctor under certain situations, realizing that the physician spends a long time learning about diagnosing and evaluating patients and their expertise can never be replaced. With Mevacor OTC, for example, it is meant for people with an intermediate coronary heart disease risk category. If the pharmacist classifies the patient into a low risk category, they shouldn’t sell the product, even if the patient insists. Also, if the patient’s risk category is high, they should be referred to a physician because the patient will need to be managed closely in a primary healthcare setting.

To keep up with the skills necessary to dispense BTC medication, the pharmacist will have to maintain professional competence. This is part five of the Code of Ethics. The pharmacist will already know about the use of the medication sold BTC, since these drug entities will not be new, they will just be reclassified from prescription status. They will know about pharmacokinetics, drug interactions, and side effects; yet, to aid the patient in selecting a BTC medication, the pharmacist will need to keep up with changes in information on disease states, practice guidelines and counseling techniques.
When Soller talks about labeling on OTC products, he describes it as “the intermediary between the consumer and the drug,” since the person doesn’t have to talk to anyone to purchase that product. BTC medication will be labeled so the patient can follow the directions, but the pharmacist would act as the primary intermediary. Again, the physician is not part of the picture. This makes part six of the Code of Ethics important: that pharmacists respect the value and abilities of other health professionals. Everyone recognizes that physicians are important healthcare providers that have diagnostic skills. As previously mentioned, even the GAO report assures that a pharmacist cannot replace a physician. The pharmacist will be responsible for assuring physicians that their role will not be usurped just because more medication is available BTC. The pharmacist will still need to refer patients to the physician in a number of cases, and the Asheville project has already shown that physician referrals increase when the pharmacist is active in making clinical interventions.

The next point in the Code of Ethics is that a pharmacist needs to serve the needs of society and the community. Heart disease is a leading cause of death in the United States and it is established that statins are important to use for primary and secondary prevention. Unfortunately, as much as 62% of the intermediate risk population is untreated. Pharmacists can help fill a need to improve the cardiovascular health of this nation by dispensing BTC statins leading, hopefully, to a decrease in the treatment gap. If other medications used in the treatment of chronic diseases become available BTC, they should also be evaluated to see if their use could positively impact the overall health of the nation.

The final point of the APhA Code of Ethics is another very important concept with regard to BTC medication: A pharmacist seeks justice in the distribution of health resources. As a New York Times editorial pointed out in August, “the United States ranks dead last on almost all
measures of equity because we have the greatest disparity in the quality of care given to richer and poorer citizens.” The rate of uninsured individuals in this country is high, and the cost of healthcare is a barrier to many. “The need to visit a healthcare professional represents a substantial barrier to care for many patients because of financial, transportation, or scheduling limitations,” according to Brass. By increasing access to medications through a BTC system, we can help distribute needed medication fairly.

Currently, there are a lot of questions about BTC medication, but there is insufficient data to answer these questions. What type of drugs could be used safely and effectively in a BTC situation where patients and pharmacists collaborate? We have some idea of general characteristics these drugs should have through Peck’s and DeLap’s Principles, but these principles were developed to characterize OTC, and not BTC, drugs. Studies modeled after CUSTOM could be done to include pharmacist intervention and help validate switch principles for BTC medication. How do different drug distribution systems compare? There are models available in other countries, such as Britain, that the United States can use as an example, but there are no studies that evaluate the two drug or three drug distribution systems as to their impact on health or costs, neither are there studies to compare these systems to each other. There are many issues surrounding behind-the-counter medication that need to be discussed before a third regulated class of drugs becomes available in the United States. The FDA may not have the authority to create such a class on their own, but legislation passed by Congress could bring a pharmacist-only class into existence. Pharmacy practice needs to be prepared for change if pharmacists become responsible for dispensing BTC medication. Pharmacists will also need to adhere to all parts of the Code of Ethics, as it will help define their role in dispensing BTC medication and will act as a guide for their actions. Pharmacists need to find ways to utilize their
clinical skills and make their role as a healthcare provider more visible to their patients and other professionals; expanding their services through behind-the-counter medication, if available in the future, is an excellent way to do this.
References


