Abstract

Objective: To examine the issues surrounding the development and implementation of a behind-the-counter (BTC) category of medications.

Data sources: Testimony from organizations submitting comments to the Food and Drug Administration (FDA) panel hearings in November 2007, the 2009 final report of the U.S. General Accounting Office regarding a BTC drug category, literature review of research that has been conducted, experiences from other countries, and publicly available information from agencies in charge of regulating medications similar to BTC.

Summary: Based on evidence attained from the current work, the following six recommendations regarding a BTC category of medications are provided. (1) Demonstration needs to occur that the risks and/or costs of BTC are outweighed by benefits, positive measurable outcomes, and financial savings to society. (2) Sufficient resources, including personnel, equipment, and facilities, need to be available for the appropriate provision of BTC services and to ensure ongoing monitoring and controls. (3) An appropriate compensation structure needs to be developed. (4) Encounters and outcomes should be documented in an electronic record, the information should be shared with other health care providers involved in patients' care, and interprofessional collaboration and communication should occur. (5) Criteria for designating candidates for transition, ongoing review for safety, and reverse transition must be developed. (6) Applicable lessons learned from other countries should be incorporated into BTC strategies. In addition to implementation recommendations, we also summarize additional evidence that needs to be gathered to optimize the BTC model.

Conclusion: Based on the accumulated evidence, comments to FDA's request, and information from other countries, implementation of a BTC model probably is feasible in the United States. However, the optimal model remains uncertain and various aspects of a program need to be prioritized and rigorously tested.

Keywords: Pharmacy-access drug products, nonprescription medications, legend medications, quality of care, medication access.
In October 2007, the Food and Drug Administration (FDA) announced a public meeting and request for comments on "behind the counter availability of certain drugs." The public hearing and comments were requested to examine the evidence regarding behind-the-counter (BTC) availability of certain human drugs.

"BTC availability could make certain drugs available behind the counter at the pharmacy without a prescription and require the intervention of a pharmacist before dispensing. Some groups have asserted that pharmacist interaction with the consumer could ensure safe and effective use of a drug product that otherwise might require a prescription. Because pharmacists have the training and knowledge to provide certain interventions, they may be able to ensure that patients meet the conditions for use and educate patients on appropriate use of the drug product. These groups have suggested that the availability of certain drugs BTC could increase patient access to medications that may be underutilized, particularly by patients without health insurance, because these medications otherwise would be available only with a prescription."1

Numerous organizations and health care providers attended the meeting and submitted comments. Based on those comments and evidence in the literature, the current work examines the benefits, risks, and logistics of establishing a BTC medication category in the United States.

**At a Glance**

**Synopsis:** Issues surrounding the development and implementation of a behind-the-counter (BTC) category of medications are examined, including increased medication access and adherence, safety concerns, professional training, risks and benefits, and experience with similar categories of drugs in other countries. Based on available evidence, response to a Food and Drug Administration public meeting and request for comments, and information from other countries, implementation of a BTC model is feasible in the United States. However, the optimal model remains uncertain and various aspects of a BTC program need to be prioritized and tested rigorously.

**Analysis:** Establishing a BTC category of medications would likely fulfill a medical need, improve access to care for patients and their caregivers, and allow more efficient use of drugs and health care personnel. Insurance coverage, payment for consultation and monitoring, marketing decisions, and improved clinical outcomes are among the factors likely to play a key role in the final outcome of developing a BTC category. Providing higher quality and safer care at a reduced cost to patients, payers, and society is a goal of BTC, and process and terminal outcomes have to be measured to show that these goals are being met. Agreement needs to be reached on evidence-based clinical goals, and the BTC health care team must be responsible for meeting those goals.

**Objective**

This report provides a definition of BTC medications, current BTC opportunities and concerns, BTC regulations and structure in countries other than the United States, and clinical and policy recommendations surrounding BTC medications.

**Definition of BTC**

BTC medications are defined in the current report as pharmaceutical products that have expanded access to patients by being available from authorized health professionals in the community setting without a prescription. BTC medications are deemed sufficiently safe and effective for patients to use without a prescription but require supervision by a health professional. Professional supervision ensures that patients have enough information to use these products safely and ensures that the products are appropriate for applicable medical conditions. For the purposes of this report, the term “BTC” is interchangeable with other terms such as “third category of drugs,” “expanded-access medications,” “pharmacist only,” and “pharmacist-controlled medications.”

BTC medications would have the following characteristics:

- Used for conditions diagnosed by a physician or another health practitioner or for conditions that can be reliably self-diagnosed by the patient
- Dispensed with appropriate verbal and written information and oversight by a qualified health professional to promote safe and optimal use
- Monitored and managed by the patient and qualified health care practitioner
- Enhancing patient outcomes
- Saving patients time and money
- Improving access to medications that would otherwise require a prescription
- Designated as BTC by FDA, with the benefit-to-risk profiles of these medications considered when used in accordance with a qualified professional’s recommendation

**Roles of health professionals**

Patients would be able to obtain BTC medications on the recommendation of qualified health professionals based on evidence-based guidelines. Qualified professionals would perform initial assessments, perform screenings, perform medication reviews, counsel, monitor, document services, bill insurance, and communicate with and refer patients to other health professionals as appropriate. Some of the medications most frequently mentioned as potential BTC candidates have a history of safety and are used for common long-term chronic conditions that require professional monitoring. Potential candidates include medications for high blood pressure, high cholesterol, asthma, gastrointestinal reflux, allergies, and pain, as well as dietary supplements, that could be managed by a qualified professional. Statins are frequently mentioned because they are well tolerated and effectively lower cholesterol. Under the current system, an estimated 60% of those who could benefit from statin treatment do not receive it.2 Statins have been rejected for over-the-counter (OTC) status because of concerns such as
inappropriate self-selection, potential for rhabdomyolysis adverse effects, and the need to monitor liver enzymes. BTC status could ease at least some of these concerns while increasing availability and access to medication therapy and potentially improving adherence.

Triptans, which are used to prevent painful migraines and cluster headaches, are a potential BTC candidate drug category with an excellent safety profile. Migraines are a debilitating symptomatic condition that patients can adequately identify and, if treated in time, can be prevented, potentially reducing the need for additional physician visits and opioid pain medications.

Qualified health professionals would work collaboratively with patients to make informed decisions about the appropriateness of the medication(s) for the condition. For example, consider the case of OTC vaginal antifungal products. Clotrimazole became available as an OTC product in 1990. A 13% decline in the number of visits to physicians coded for vaginitis also occurred between 1990 and 1994, possibly because of the OTC availability of clotrimazole. Fewer vaginitis-related visits resulted in direct cost savings of $45 million. The savings may be even greater than reported in the study because antifungal sales doubled during the period, suggesting that a previously unfulfilled need was satisfied by creating greater access through OTC status. Of note, visits to obstetricians and gynecologists (OBGYNs) by women between 1990 (48.3/100 women) and 1994 (48.5/100) did not decline. Why the overall number of obstetrician/gynecologist visits did not decline is unclear, but one possibility is that fewer visits for vaginitis improved access for women with other complaints. This case shows that it cannot be assumed that physician visits will decrease if a prescription product is switched to BTC status. It also suggests that a learned intermediary other than a physician may have a role in reducing unnecessary or inappropriate use of products switched to BTC status. A qualified health professional may decide that the medication is inappropriate and refuse to dispense the product. Establishing a BTC category of medications would likely fulfill a medical need, improve access to care for patients and their caregivers, and allow more efficient use of drugs and health care personnel.

**Overview of stakeholder comments to FDA**

In 2007, FDA received comments regarding the need for a BTC category/classification of medications. The following overview summarizes the positions and central arguments of key stakeholders with respect to developing a BTC category, potential impact on patient access to medications, and potential cost implications. Following the overview, we will provide a more detailed examination of key stakeholder comments to FDA.

Stakeholders voiced considerable differences of opinion regarding the safety and effectiveness of a BTC category of medications. Organizations such as the Consumers Union and the National Consumers League traditionally have supported the concept but opine that the evidence for or against a BTC category is equivocal. They are advocates for rigorous regional testing before implementing a BTC category nationally. On the other hand, the Consumers Healthcare Products Association (CHPA), a not-for-profit association representing the consumers and makers of OTC medications and nutritional supplements, is opposed to a BTC category. CHPA opposes a BTC category because it believes the current two-category system works and has enough flexibility to meet consumer needs. CHPA also opposes giving FDA additional authority. CHPA’s testimony opines that a BTC category of medications would reduce patient empowerment.

In general, physician organizations have serious doubts regarding a BTC category. They opine that the current system works well, no evidence supports the creation of a BTC category, and a BTC category would actually decrease access to medications for patients while increasing risk and cost. Some physician organizations have singled out pharmacists and claim that their training to provide clinical services related to BTC medications is inadequate. They also assert that a BTC category will interfere with the physician–patient relationship. Most of the statements expressed by these organizations are opinion based with little or no evidentiary support.

Most pharmacy organizations, such as the American Pharmacists Association, American Society of Health-System Pharmacists, Academy of Managed Care Pharmacy, and American College of Clinical Pharmacy support a BTC medication category. These organizations uniformly expressed the belief that BTC medications linked to appropriate clinical care and safeguards will increase patient access to medications that would otherwise be available only by prescription. These pharmacy organizations maintain that pharmacists are well trained, with a rigorous minimum 6-year didactic and experiential curriculum. The curriculum includes clinical training in physical assessment and medication therapy management (MTM) and culminates in a doctor of pharmacy degree. The National Association of Chain Drug Stores and Food Marketing Institute appear neutral, calling for discussion and rigorous studies of BTC structural and implementation issues.

Most health organizations did not express an opinion. However, the Asthma and Allergy Foundation (AAF) did not favor BTC because it would not happen quickly enough to address the metered-dose inhaler situation. However, the situation has changed substantially since the time of the testimony. Although one or two products have disappeared from the market, many inhalers were relaunched with hydrofluoroalkane (HFA) propellants or given “essential use” designation or longer time lines to manufacture an HFA version. AAF’s comments agreed with physician groups that BTC could interfere with the physicians’ role and increase costs to patients if BTC medications were not covered by third-party payers.

Finally, the 1995 Government Accountability Office (GAO) report advised against establishing a BTC category. The report advised against a BTC category not because it might be dangerous or ineffective but because evidence to support it was insufficient. The GAO follow-up report was released in February 2009. The new report did not recommend initiating a BTC category but carefully examined arguments for and against a BTC drug category in the United States.
changes in drug availability in five specific studies since 1995, and (3) identified issues important to establishing a BTC category. The primary arguments promulgated by various groups for or against a BTC category did not change significantly between 1995 and 2009. Consequently, the primary focus of the 2009 report was on drug availability across the five countries in the 1995 GAO report (Australia, Italy, the Netherlands, the United Kingdom, and the United States).

Opportunities and concerns
More than 250 million people visit pharmacies each week. Moreover, pharmacies often have longer open hours, including evenings, weekends, and some 24-hour locations. Access to eligible medications is predicted to expand because of the relatively larger number of pharmacies in a wider variety of locations compared with physician offices. However, expansion of access is based on the assumption that pharmacists will be included among the qualified health professionals authorized to prescribe medications included in the new BTC category. Access may be even better if other qualified health professionals are authorized to prescribe these medications. A BTC category may reduce societal costs if these services substitute using emergency departments for primary care and obtaining authorization to refill prescriptions.

The food and convenience store segment of the pharmacy industry is concerned that access would decline at nonpharmacy sites. However, this concern is directed at the relatively smaller portion of products that may move from OTC to BTC because they are deemed unsafe for OTC use. Little would change for items that are currently prescription only because they are not available in this market segment currently. The net impact on these outlets ultimately would depend on the medications that are deemed unsafe for OTC use and transitioned to BTC.

In addition to accessibility, whether a sufficient number of BTC products would be available to have a discernible effect remains unclear. Between 2007 and 2009, GAO compared the availability of 86 different medications between the United States and four different countries: Australia and the United Kingdom, which have a BTC category, and Italy and the Netherlands, which do not have a BTC category. If availability is defined as the number of medications available without a prescription (BTC or OTC), then the United States had fewer drugs available than Australia and the United Kingdom and was similar to Italy and the Netherlands. However, if availability is defined as having a larger number of medications in the OTC category, then the United States was the clear leader. Unfortunately, the GAO report does not address the key question of whether medications are appropriately available and accessible, with the proper degree of counseling and monitoring needed for safe and effective use.

Impact on patient adherence
Most organizations’ testimony agreed with the notion that increased interactions with qualified health care practitioners could improve adherence. Patient medication adherence is a multifaceted problem including patient (e.g., socioeconomic status, age, mental status) and system (e.g., number of physicians, drug costs, treatment complexity) factors. A paucity of evidence describes the relationship between the BTC category of medications and patient adherence in the United States. However, studies have shown that increased patient interaction with a health care provider may improve medication adherence. Therefore, if the availability of BTC drugs and the number of interactions between pharmacists and patients increase, then an increase in medication adherence may result.

Alternatively, adherence could decrease if patients’ out-of-pocket costs increase. In one study, increased copayments for prescription medications resulted in adverse selection among Medicare enrollees. This same scenario may result with a total absence or reduction in coverage for medications that were previously prescription only in non-Medicare programs. Moreover, based on British Columbia’s experience, cost containment strategies focused on shifting medication expenses to patients may increase net expenditures for the overall treatment of some diseases.

Direct experience is not available in the United States regarding use of medications that move to BTC and variable insurance coverage levels. However, the prescription copayment literature may inform policy discussions. In general, higher copayments result in decisions to delay or sacrifice medication purchases. Even more important, patients may be required to make difficult decisions regarding which medications to purchase when faced with the dilemma of choosing among essential medications. For example, higher copayments consistently affected medication adherence adversely, including lipid-lowering and oral diabetes medications. As a result, lower adherence was associated with higher health care costs.

Plans to shift medication costs to the patient should be well thought out. Any plan should encourage patients to take the medications they need for chronic diseases through targeted financial incentives. For example, higher tiered copayments reduce overall expenditures and the number of prescriptions purchased by Medicare beneficiaries. However, beneficiaries are less responsive to cost-sharing incentives for medications used to treat chronic conditions. In other words, essential medications for chronic diseases are more likely to be purchased and nonessential medications (e.g., cough and cold) are less likely to be purchased with higher tiered copayments. Although increasing copayments may reduce total medication spending, the impact on essential medications is likely to be less striking. In summary, health plans should design their benefit programs to take advantage of policy changes and financial incentives targeted to maintain or improve adherence and lower overall health plan expenditures.

Criteria for prescription-to-BTC switch
Careful definition, selection, and operationalization of criteria to guide consistent decision making are necessary before finalizing a BTC medication category. Organizations have suggested that BTC classification is well suited for medications to treat medical conditions that require limited physical assessment and have easily interpreted lab tests and/or reliable self-diagnosis. Multiple health professional disciplines receive training and are competent in physical assessment and inter-
interpreting lab tests. The murkiest issue at this time is ordering and accessing lab test results. Expanding and improving health information technology with greater access to electronic medical and pharmacy records and lab test results will ameliorate some of these concerns. For example, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 authorizes Medicare and Medicaid payments to physicians and hospitals to help defray the cost of electronic health records systems. Starting in 2015, health care providers will be subject to financial penalties under Medicare if they are not using electronic health records.34

Medications with prescription status for several years and a good benefit-to-risk ratio are suitable candidates for BTC status.9,14 However, conditions for safe use are not defined currently and need to be determined before implementation. For example, some medications may be safe under conditions involving an initial screening, laboratory tests, or limited monitoring but unsafe for unsupervised use.

BTC status should be reserved for medications used safely in conjunction with appropriate guidelines. BTC services should follow those guidelines. Most of the testimony regarding BTC urges FDA to require screening, lab tests, monitoring, and supervision. This model differs from other countries’ models (e.g., the United Kingdom). The U.K. model allows BTC medications to have an “acceptable” margin of safety during unsupervised use with regard to overdose or accidental misdiagnosis.23 As in the United Kingdom, medications with “manageable” adverse effects could be considered for classification as BTC in the United States according to the Consumers Union.8 In addition to being manageable, adverse effects should be recognizable by the health professional or patient and should be reversible, medications at risk of microbial resistance should not be considered for switch, and BTC should not be used simply to enforce “age limits” for products (e.g., emergency contraception).9

Temporary or permanent BTC status

Opinions varied regarding whether BTC should be a transition or permanent category, as well as the procedures that should be used for determining transition candidates. A transition category has been seldom used internationally.23,24 A BTC transition category was proposed for medications ultimately destined for OTC status and should be decided on a case-by-case basis, depending on the nature of the medication.8,9,14,15

Candidate medications should receive serious study and reverse transition (e.g., OTC to BTC) when warranted. For example, FDA recently informed patients and health professionals that it had finished reviewing information regarding the safety of OTC cough and cold medications in children younger than 2 years. FDA recommends avoiding these medications when treating children in this age group because of serious and potentially life-threatening adverse effects.25 The Agency also reported concerns about use of acetaminophen because of the numerous reports of liver damage associated with overdose or misuse. Unsupervised use has been implicated in at least 56,000 emergency department cases and concerns about use of concentrated drops in infants and children.26 These types of actions support concerns about permanently assigning a medication to a status, whether prescription only, BTC, or OTC, without ongoing safety review. If a BTC category of medications becomes a reality, it would be appropriate and important to include postmarketing surveillance rules and regulations for safety purposes, similar to those for prescription-only medications. Both the 1995 and 2009 GAO reports noted a transition period’s usefulness for collecting data regarding safety and abuse potential.22,24 However, the information would have limited usefulness unless demonstration projects included a control group.25

Suggestions for transition criteria

As part of any transition process, regularly scheduled and/or ad hoc advisory committees should be convened in response to outside-group petitions.8,9 Evidence used to determine whether a medication would be safe within a BTC category should include information gathered from postmarketing surveillance, adverse event reports, and epidemiological studies.8,9 Standards should be based on whether (1) a medication is safe and effective, (2) benefits outweigh risks, and (3) patients’ labeling is effective. No guidelines were proposed regarding the thresholds to meet these criteria. Adverse effect profiles are well established before a medication is moved into the BTC category in most countries.23 Reliable and valid medication-specific standards are needed. For example, an initial low-density lipoprotein cholesterol assessment and ongoing monitoring under proposed BTC use conditions should be performed with statins to determine effectiveness before approval.27

Reverse transition

Most organizations with a position on BTC medications did not distinguish between transition and reverse transition criteria. However, it is a legitimate concern, and the transition criteria should be driven by clinical findings and weighing benefits against risk.15 Issues identified with reverse transition include decreased access, abuse reduction,26 and the fact that locations without pharmacies would be unable to sell medications reversed from OTC to BTC status.21 On the surface, looking at reverse transition purely as a movement from OTC to BTC status might appear to decrease access.26 The implicit assumption is that the medication would remain OTC permanently. However, if a medication is deemed unsafe for OTC use, it would likely be moved to prescription status if a BTC category was not available. Again, the focus should be on the appropriate level of availability, provision of optimal access, and risk versus benefit. Ultimately, access would be better for OTC medications switched to BTC versus switched back to prescription only for the largest number of people.23

Cost to patients

A short-term increase in patients’ out-of-pocket cost is anticipated to occur if a BTC category of medications is created. In the long term, however, whether overall costs increase or decrease will depend on third-party coverage and changes in mortality and morbidity resulting from health professionals’ interventions. The most important factor in determining whether
patients’ out-of-pocket costs would increase or decrease is third-party payments for BTC medications and consultations. Patients’ out-of-pocket costs would be essentially the same if consultations were covered by third-party payers and copayments for pharmacist visits were comparable with physician visits. If the copayment was lower for nonphysician providers, out-of-pocket costs would be lower. Conversely, costs would be higher for medications with OTC status at present because a consultation would be an added cost. However, if a medication is deemed unsafe as an OTC product, prescription status would be the only other option if the BTC option did not exist. In that situation, patients’ out-of-pocket costs would remain the same or lower. In the worst case scenario, if third parties chose not to cover BTC medications, patients and physicians could be shifted to medications that are covered by insurance. In this case, medications could be more expensive in the long term. Patients would undoubtedly choose the option they found most cost effective. By shifting the cost into more expensive prescription categories, the overall cost of not covering BTC medications would probably result in a net increase for medications to the third-party payer. If the BTC category operates as intended, although medication costs could increase, overall costs (e.g., physician, emergency department, hospital) would decline and provide a cost-saving incentive.

In addition to pharmacist services costs, medications would cost more if competition was restricted, especially if patients found it difficult to comparison shop in the case of an OTC-to-BTC switch. This argument assumes that “competition” would be restricted to pharmacies and that patients could not obtain price information. However, even if access was limited to pharmacies, patients still would have multiple local and nationwide competitive outlets to purchase medications and consult with pharmacists. Even if the restriction of competition notion was proven to be correct, only a small number of medications deemed unsafe or inappropriate for OTC use would be switched to BTC.

Rationale for predicting overall cost decline
Some forecast that third-party insurers would not pay for BTC medications based on previous experience with prescription-to-OTC switches. The 2009 GAO report notes that patients often oppose prescription-to-BTC switch for medications in other countries if uncovered by third parties.

However, evidence suggests that some percentage of patients would be willing to pay out of pocket. The GAO report cited evidence that 52.5% of patients in a 1990 study would be willing to pay for pharmacist consultation/MTM services, although the dollar amount was not high. Approximately one-third of those willing to pay were willing to pay more than $5.00 for the described service, but that report was written more than a decade ago. In a more recent study, 47% of the sampled consumers were willing to pay 100% out-of-pocket for pharmacist cognitive services. 70% were willing to pay a coinsurance of 20%, and 85% were willing to use these services if insurance paid 100% of the cost.

Patients may benefit from pharmacists’ counseling and monitoring if insurers reimburse pharmacists who reduce potential adverse effects. Further, the indirect saving associated with eliminating higher cost physician visits could benefit third parties and reduce patients’ out-of-pocket costs even further. Third-party payers that are aware of the cost savings with prevention might be willing to provide BTC service coverage.

Overall, patients’ cost savings would depend on insurance coverage levels. If potential savings were realized, BTC might actually have a downward effect on premiums. Access to medications also could be enhanced or reduced based on the copayment levels of third-party formularies and plans. The 1995 GAO report predicted that BTC medications would likely cost less because consultations by providers other than physicians would cost less. Therefore, patients may save even if other providers charge for their visits, depending on the amount of their fees. Even if additional costs for physical pharmacy modifications and pharmacist training or certification result, it is believed that these costs will be offset by lower pharmacists’ fees compared with physician fees. Moreover, patient costs could actually decline if increased demand led to an increased number of professionals providing consulting and education services. The net result would be more access and competition in the service market. However, evidence is lacking and further study is needed.

The 1995 GAO report posited that BTC medications could cost less than prescription medications because OTC medications historically have been priced lower upon release. OTC medications generally were less expensive because (1) access was less restrictive compared with prescription medications, (2) product sales generally increase upon switch, (3) development costs were already recovered, and (4) patent protection usually had expired. More recently, however, newer prescription products switched to OTC have been relatively expensive. Cost to patients should be lower if multiple medications in a therapeutic category are changed to BTC status and are available in generic formulations (e.g., statins). For example, vaginal antifungal medications resulted in direct and indirect savings of at least $64 million after vaginal antifungal medications were switched to OTC between 1990 and 1994. Switching nicotine replacement products to OTC has proven safe, with approximately 450,000 extra attempts to quit smoking. Conservative estimates place the savings between $1.8 and $2 billion. Physician visits were reduced by approximately 100,000 visits per year between 1976 and 1989 when nasal antihistamines and decongestants were switched to OTC, with approximately $700 million in savings. Patient prices might not decrease substantially if a product is still on patent or is the only medication within a therapeutic category.

In addition, prices have historically declined in countries that switched medications from prescription to pharmacist controlled. However, in most cases, those countries had price controls in place at the time of the switch, which the United States does not have at the present time.

Finally, if medication misuse and misadventures decline with BTC status, costs to patients would decline. Monitoring by qualified health care personnel should prevent and reduce adverse drug events. On the other hand, if access is increased,
the absolute number of drug exposures could increase. An increase in the absolute number of exposures could result in an increase in the cost of medication misadventures without supervision. It is hypothesized that because the anticipated additional exposures would be supervised and controlled, the expected cost savings may be offset by limiting adverse effects. The end result is that more patients would receive the medication with fewer adverse events. Rigorous study is needed to confirm this hypothesis. More questions than answers arise in the discussion of whether BTC would be more costly for individual patients and reduce health care costs overall. Factors such as insurance coverage, payment for consultation and monitoring, marketing decisions, and improved clinical outcomes will play a major role in the final outcome of developing a BTC category.

Impact on safety
Opinions regarding a BTC category’s impact on safety were offered with little or no evidence as support. Opinions varied according to underlying assumptions about BTC’s format, the medications selected for BTC status, efficacy, safety, associated costs, and interests and goals of the commenting organization. Mandatory counseling and intervention by a health professional would likely reduce drug misuse, abuse, and improve safety. Mandatory patient counseling should include discussion of key issues. Patients should sign a simple easy-to-read statement acknowledging their awareness of highlighted adverse effects and other information essential to optimal medication use. Special section 905 postapproval safety research and analysis should be completed to ensure medication safety and effectiveness before being moved to BTC status. Next, postmarketing surveillance and medication recalls should be a priority with BTC medications. In comparison, if the alternative to BTC is legend status, then facilitation of recall should be marginally more difficult because only medications proven safe during an initial prescription-only period are likely to be accorded BTC status. Medications continuing in prescriptions depend on whether they are switched from OTC to BTC or prescription only to BTC. Space behind the prescription counter is expensive, and if transitioned from OTC to BTC, medications would have to be moved to that more expensive space. Moreover, some facilities would need to redesign private consulting space. On the other hand, medications switched from prescription to BTC should not require additional space because those medications are already located in the pharmacy department.

Ensuring safety
Safety ultimately depends on the structure of the BTC program. Concerns exist about the reliability of patient self-diagnosis as a criterion for prescription of BTC medications. A delay in appropriate physician care because of an incorrect self-diagnosis could result in reduced safety. Hence, patients will need routine monitoring for safety and effectiveness. However, if the BTC format requires ancillary health professional monitoring and physician referrals, these potential delays should be minimal and might even be shortened because of reduced cost, increased access to health professionals, and improved triaging to the appropriate level of professional care. One assumption central to this concern is that appropriate monitoring and referral is the norm currently. Appropriate monitoring and referral frequently have been shown to not occur regularly at venues focusing on dispensing services but appear to be more common at facilities with emerging MTM services, consult services in hospitals, Department of Veterans Affairs medical centers, and pharmacy residencies, among others. If BTC rules and regulations require guideline-compliant screening and monitoring, appropriate physician triage could be enhanced. However, scant scientific evidence exists on this point.

Another safety concern is “pharmacy shopping.” Similar to “doctor shopping,” patients go from pharmacy to pharmacy to obtain medications. Pharmacy shopping is a problem with prescription-only medications and would not be unique to BTC medications. Pharmacy shopping could be addressed by a comprehensive electronic, patient-specific medical record or patient medical information cards.

Storage
Whether more or less space will be required to store BTC medications depends on whether they are switched from OTC to BTC or prescription only to BTC. Space behind the prescription counter is expensive, and if transitioned from OTC to BTC, medications would have to be moved to that more expensive space. Moreover, some facilities would need to redesign private consulting space. On the other hand, medications switched from prescription to BTC should not require additional space because those medications are already located in the pharmacy department.

Record keeping/laboratory testing
Both GAO reports noted concerns about pharmacists not completing required paperwork. In two U.S. studies, only 67% of pharmacists maintained required patient profiles in one case and only 9 of 19 pharmacies maintained the required profiles in another case. Australian officials reported difficulty in getting pharmacists to comply with record-keeping and counseling requirements. Considerable improvements in documentation occurred when the number of medications tracked was reduced to the most essential, counseling standards and legislative controls were improved and tightened, and professional associations participated in monitoring quality (e.g., mystery shopper program).

The 2009 GAO report reported that a category of medications that may be appropriate for a BTC category are drugs that are subject to abuse and drugs that are to be sold only to patients of a minimum age. For example, the Combat Methamphetamine Epidemic Act of 2005 placed pseudoephedrine, ephedrine, and phenylpropanolamine drug products under the federal Controlled Substances Act as scheduled listed products. This regulation restricted access to these medications by requiring them to be placed BTC. The regulations also created purchase limits on these medications and required identification and record keeping for purchases. However, contrary to the intent of a BTC category as outlined in this report, the primary purpose of the methamphetamine legislation is to police the availability of these medications for use as a substrate for manufacture of methamphetamine. However, the effectiveness of this “policing” strategy remains unknown, as is compliance with the identification and signature requirements. Anecdotal reports indicate that retailers’ enforcement of the identification regulations is not policed as intended. Would community...
based practitioners view the regulations and requirements for BTC medications used for therapeutic purposes in the same manner as they view medications for which access is restricted to reduce abuse versus provision of optimal care? The purpose of a BTC classification and the accompanying motivation for health care providers’ regulatory compliance warrants careful study.

Finally, some nonphysician providers will not have access to important laboratory data.23 However, overcoming this concern is technically feasible now and will be even less concerning in the future in light of the recent implementation of the HIP-TECH Act of 2009. Laboratory data could be obtained directly from patients and physicians or via referral to Clinical Laboratory Improvement Amendment (CLIA) qualified labs, or CLIA waivers could be obtained to conduct tests on site.

**Privacy**

Patient privacy is an important concern surrounding a BTC category of medications, and modifications to existing pharmacy practice and pharmacies may be needed14,15,48 because some individuals may not be willing to discuss personal issues without enhanced privacy.9 However, patients often ask pharmacists for advice on OTC and other health issues with few documented complaints about inadequate privacy. New and remodeled pharmacies generally have incorporated solutions into current designs by, for example, separating drop-off from pick-up areas, constructing privacy screens, and offering private consultation rooms.

**Reimbursement**

Professionals providing services required by regulation to dispense BTC medications should be paid for their clinical services.11–16,50 After the basic regulations for appropriate BTC dispensing are established, models can be developed to examine reimbursement policies, practices, and levels.

Clinical services reimbursement should be separate from medication cost fees.16,50 Many factors affect service levels, including patient age, health status, complexity of the visit, and use of other medications. Payment for expanded clinical services is central to attracting adequate providers of services, including patient assessment, counseling, monitoring, and documentation, and will require considerable time on the part of providers.50 Mechanisms are already established to determine reimbursement, taking these factors into consideration. Standardized documentation for both clinical and reimbursement purposes was supported universally. Third-party billing could be facilitated by Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant National Drug Codes and the recently approved permanent Category I Current Procedural Terminology codes (99605, 99606, and 99607), which are used for face-to-face MTM services.15,16 Pharmacy services or federal billing guidelines that are already available could be used.51–55

Inadequate reimbursement is a barrier to consistently meeting performance standards. Financial incentives for product and services, though separate, are important for providing high-quality services. The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) first mandated specific pharmacy services with the dispensing of state Medicaid prescriptions. Experience since 1990 suggests that uncompensated services may be performed less consistently with minimal impact. One study found that one-half of the surveyed pharmacists counseled patients for between 1 and 2 minutes during the first year after the implementation of OBRA 90, with 23% reporting less time and the remainder more time.56 The top two barriers to implementation were excessive workload (lack of time) and lack of financial compensation. Reimbursement for services and medications should be based on different considerations. Reimbursement for clinical services should be based on the time, skill, and complexity necessary for the level of care provided. Reimbursement for medication costs should cover costs of acquiring goods and provide adequate return on inventory investment.

**Oversight**

Oversight both by FDA and state boards of pharmacy would be appropriate and within the scope of current FDA statutes.14,15 FDA should provide oversight for demonstration projects, determine which medications receive BTC status, and determine specific or special requirements for that medication or therapeutic category. State boards of pharmacy, which regulate the practice of pharmacy within each state, can better ensure adherence to rules and regulations regarding BTC use and safety. As an example, in Florida, oversight for pharmacist-prescribed medications from an approved list is provided by the board of pharmacy.42 An important aspect of any discussion about a BTC category of medication must include mechanisms to ensure compliance with BTC policies and procedures for both reimbursement and quality-assurance purposes.

**Professional relationships**

Maintaining the physician–patient and physician–nonphysician communication regarding medications to treat chronic conditions is especially important.11,22 The overriding concern is that difficult-to-recognize symptoms will be missed and proper diagnoses or optimal treatment will remain unrealized. Some health professionals are concerned that adequate histories, differential diagnosis, and assessments may not be done or communicated to physicians. Effective collaboration and communication channels to keep physicians informed with patients’ consent is required to meet these goals.14

Physician referrals could increase with more oversight by nonphysician health professionals, with a concomitant improvement in quality of care. If seen by another health professional, heretofore under- or unsupervised patients who need more complex care or are experiencing suboptimal care could be referred to a physician. For example, 96% of colleges of pharmacy reported teaching some level of physical assessment, including pulmonary examination, vital signs, and cardiovascular assessment.57 However, the authors also pointed out substantial variability in the “topics covered, depth of content, types of instruction, and evaluation methods.”57 Consistency of practitioners’ knowledge and abilities is important to ensure optimal services.
Physicians have legitimate concerns about a decline in the number of visits if medications were switched to BTC status, especially among those without insurance coverage. Third-party payers are concerned that their overall costs will increase if nonphysician visits increased without a concomitant decline in physician visits. Whether nonphysician-provided care would be substituted directly for physician-provided care is unknown and should be examined in demonstration projects.

**Hurdles and barriers to implementing BTC model**

Earlier sections of the current work presented issues regarding potential barriers and hurdles to the implementation of a BTC category of medications. The following information will address hurdles and barriers to BTC raised by pharmacy and other health professionals from professional- and patient-based viewpoints.

**Overcoming professional biases**

Professional role–related differences are not new. In a survey of website visitors conducted by Medpage Today, 73% of 783 respondents believed that pharmacists are qualified to provide the same type of counseling required for the safe use of many prescription medications. Physician respondents were about equally split. Some professionals were concerned about pharmacists becoming more involved in diagnosis. Physician groups have suggested that pharmacists’ role in BTC should not be diagnosing and managing complex patients with chronic disease. This should not be an issue, however, as drugs selected for BTC status would most likely be indicated for conditions that are appropriately self-diagnosed or that can be treated with the advice of a qualified health professional.

Consumer groups have noted barriers to pharmacists taking on these roles. For example, pharmacists may not have time to provide counseling or critical information necessary to provide optimal BTC services. On the other hand, pharmacists also are said to be “thoroughly trained in the uses and risks of the medications they dispense, and they often render detailed advice to patients on both prescription and OTC products.” Anecdotal reports provide evidence that when pharmacists and other health care providers work together, the patient benefits and these concerns are no longer a major issue.

Health professionals stand on both sides of the BTC issue. A BTC category of medications will not instantly solve these issues. However, it may serve to enhance communication of professionals working together for the patient. Professional concerns about colleagues’ abilities to perform activities necessary to ensure safe use of medications are legitimate. However, studies provide sufficient evidence that pharmacists are able to provide monitoring and counseling and communicate with physicians regarding medications that are most likely to be switched to BTC. Moreover, currently, nearly as much money is spent on the adverse effects of medications that are used incorrectly as that spent on medications in the first place. This fact indicates that the current system is suboptimal, even dangerous by some standards, and may benefit from alternative delivery systems. The current structure of medication delivery in the United States (prescription only and OTC) is likely an insurmountable barrier to achieving optimal care. The motivation to empower alternative health professionals to provide the degree of oversight necessary for safe medication use is complex and warrants major changes from the status quo.

**BTC practices outside of the United States**

BTC experience from other countries may have limited applicability to the health care system in the United States because other countries’ health care systems and medication practices vary widely. However, aspects of this discussion may provide insight into different countries’ experiences. Information presented below was obtained from both published literature and correspondence with pharmacy associations of other countries. In addition, the 2009 GAO report on the BTC category of medications has an exceptional review of switching from prescription status to another nonprescription status (BTC or OTC and vice versa) nationally and internationally. The 2009 GAO report details specific medications and types of switches among the countries.

**Canada**

Canada has four categories of medications compared with the two categories found in the United States. BTC status in Canada is referred to as Schedule II and requires intervention from a pharmacist. Schedule I medications require a prescription. Schedule III medications are OTC products that must be sold in a licensed pharmacy, and unscheduled medications can be sold anywhere (e.g., convenience and grocery stores). The process is managed by the National Drug Scheduling Advisory Committee (NDSAC) under the National Association of Pharmacy Regulatory Authorities. Information provided by the Canadian Pharmacists Association indicates that most provinces follow NDSAC decisions automatically, while others review and (usually) adopt them.

**National Association of Pharmacy Regulatory Authorities (NAPRA)**

NAPRA has developed national standards of practice for pharmacists. Standards correspond to the level of professional intervention and advice necessary for patients to use medications within each schedule safely and effectively. Compliance with the five specific Canadian standards and requirements for the pharmacy manager and staff could be incorporated into a U.S. BTC category.

The federal government (Health Canada) does not directly participate in the standard-setting process. The government's role is determining whether a medication falls into a specific prescription category and whether it is a narcotic or controlled medication. All prescription-only medications are placed in Schedule I. If a medication is not assigned, then the medication can be classified to prescription-only status. Schedule II, Schedule III, or remain unscheduled. However, NDSAC may decide that a medication still requires prescription status. A detailed overview of NAPRA, the NDSAC committee, drug lists, and other information is provided elsewhere.

**United Kingdom**

The United Kingdom divides medication into three categories:

1. Prescription-Only Medications that must be prescribed by
a physician, dentist, or other qualified health professional and should not be bought over the Internet; (2) Pharmacy medications that only can be obtained from a pharmacy and are sold under the supervision of a pharmacist (e.g., sales assistant shows the medication to the pharmacist when you buy it); and (3) General Sales List (GSL) medications that are suitable for sale and normal use without supervision or advice from a pharmacist or physician (e.g., in a supermarket).\(^2\)

According to the Royal Pharmaceutical Society of Great Britain both Pharmacy and GSL medications are commonly referred to as OTC. The Pharmacy category is the most similar to the BTC category being discussed in the United States. More detailed information about classification of medications can be found at the website of the Medicines and Healthcare Products Regulatory Agency, which licenses medications in the United Kingdom.\(^6\) The Royal Pharmaceutical Society of Great Britain also publishes the document to which all pharmacists are required to adhere (Medicines, Ethics and Practice: A Guide for Pharmacists and Pharmacy Technicians); the guide details pharmacists’ responsibilities regarding Pharmacy-status medications.\(^6\)

### Australia

BTC status in Australia\(^2\) falls into the Schedule 3 category of medications. The National Drugs and Poisons Schedule Committee,\(^8\) which is within the Therapeutic Goods Administration,\(^9\) produces the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).\(^10\) Individual state governments use SUSDP as a regulatory document. Including medical products in the Australian Register of Therapeutic Goods is required.\(^11\)

Australian community pharmacists are reimbursed to conduct medication reviews that take place in patients’ homes (face to face) or within intermediate- or long-term residential homes for a A$120 payment. Patients’ physicians also receive A$100 for participating in the government program. Pharmacists are trained and accredited to conduct reviews, and 80% of community pharmacies are registered.\(^12\)

Finally, the Pharmacy Guild of Australia wants the government to provide payment for both the medication and the medication review to the same pharmacy. The guild’s request aims to ensure that the pharmacist performing the review is directly linked to the pharmacy supplying the medication. This approach is intended to encourage pharmacist-conducted drug use evaluation and training on medication issues for staff providing direct patient care.\(^13\)

### Recommendations

As with most other controversial processes, “the devil is in the details” regarding establishing a BTC medication category. However, the paucity of rigorous evidence regarding the issues surrounding BTC is striking. Our recommendations are based on the submitting organizations’ comments to FDA, research that has been conducted, and experiences from other countries. In addition to implementation recommendations, we also summarize the evidence that needs to be gathered to optimize the BTC model.

### Demonstrating whether benefits outweigh risks

Greater access to medication and higher quality of care at a lower overall cost are central to the BTC model. In most cases, the easiest costs to measure are direct costs (e.g., medications). However, genuine efforts to measure indirect costs and benefits of the BTC model will be required. The majority of the accumulated savings likely will be derived from indirect costs and benefits, including fewer medication misadventures and improved outcomes of care through the improved monitoring and adherence.\(^4\) Multiple comprehensive studies are needed to ascertain the total direct and indirect benefits and costs associated with a BTC category of medications. Health reform legislation, no matter its final form, is likely to focus on “comparative effectiveness.” Effectiveness of the BTC category of medications versus usual care is well suited to this type of study.

One goal for a BTC category of medications is ensuring safety of patients’ medication use through a quality patient–provider interaction. In the case of BTC medications, enhanced patient–provider interaction is important because the candidate transition medications will be more complex with greater risks than OTC medications. Therefore, the following criteria are necessary:

- Patient identity must be verified.
- Evidence-based guidelines must inform situations in which a physician must be consulted.
- Practitioners dispensing BTC medications must be accountable for meeting rules and regulations.
- The primary purpose of BTC dispensing must not be seen as a policing activity with perfunctory signature requirements.
- BTC medications dispensed and services provided as part of the process (e.g., medication review, lab tests, counseling in specific areas such as potential interactions, proper medication use, proper monitoring and follow-up, and potential adverse effects) must use standardized documentation for both clinical and reimbursement purposes.

Another goal of BTC is to provide higher quality and safer care at a reduced cost to patients, payers, and society. Process and terminal outcomes have to be measured to show that these goals are being met. Evidence-based clinical goals need to be agreed upon (e.g., National Committee for Quality Assurance [NCQA], PQA [a pharmacy quality alliance]) and the BTC health care team must be held responsible for meeting those goals for BTC categories. For example, with statins, metrics need to be agreed upon and monitored for low-density lipoprotein, tri-glyceride, and high-density lipoprotein levels. Similar metrics might include blood pressure goals, glycosylated hemoglobin for diabetes, migraines averted, change in therapy, satisfaction with services, and other quality indicators used by programs such as NCQA\(^7\) and PQA.\(^2\) Indirect and direct cost savings associated with beneficial intermediate and terminal outcomes cannot be determined without measurable outcomes.

### Resources to ensure safety and access

Many of the unknowns about the safety and access issues associated with a BTC category of medications are centered on
adequacy of resources. First, the qualifications for health professionals participating as BTC providers need to be determined and clarified. A minimum level of appropriate clinical, anatomy/physiology, and pharmacotherapy training must be identified, and certificate programs or specialty recognition may be required.

Second, are current clinical care models adequate? Anecdotal reports and studies indicate legitimate concerns. Are contemporary strategies used for clinical care with prescription-only medications in the general population sufficient? If not, then adding a medication expert to the team and paying them adequately for both the service and product may improve care for a far larger segment of the population. Would a BTC category of medications warrant more monitoring and control than prescription-only medications? Would demonstration projects inform some of these questions? For example, do clinical and economic outcomes differ depending on the level and type of professional providing oversight? The effectiveness of information and technology systems necessary for ongoing monitoring and control need to be investigated. A careful examination of these questions is important during the next 5 years, especially considering the emphasis placed on health information technology by the Obama Administration. Answers to these questions will likely depend on the specifics of the final BTC model.

Developing appropriate compensation structure
Reimbursement for services likely is the most important factor in the success or failure of a BTC category of medications. Optimal payment mechanisms are essential to the issue of access to the medications, whether payment is tied to insurance coverage, and rebates or copayment discounts. Unfunded mandates with inadequate financial support likely will result in poor provider participation and less-than-optimal outcomes of care. OBRA 90, when it was first passed, was heralded as a means of providing patients with much needed medication information. However, the results of the program have been less than encouraging. State boards have found that pharmacies seldom provide OBRA 90-mandated counseling because prescription profit margins have continuously decreased.23 Hence, the perverse incentive of asking pharmacists to do more service-oriented activities while simultaneously requiring larger service and prescription volumes with a lower return on investment is unlikely to result in the desired outcomes.

Anecdotal evidence and history regarding payment for OTC medications suggest that lack of insurance coverage influences physician-prescribing and patient-purchasing behaviors. However, whether BTC medications would be affected in the same manner is unclear. Also unclear is whether outcomes would be improved if covered at the same rate as physicians or at a lower rate for other qualified professionals.

The literature clearly shows that patients make purchasing decisions based on prescription copayment amounts. Studies examining the impact of insurance coverage or noncoverage should be conducted to determine the impact on optimal use and access to these medications. Patient decisions are responsive to financial changes, and patients’ purchasing behaviors may be shifted to or from BTC with appropriate incentives.

Financial incentives must be incorporated into the rules and regulations to encourage development and sharing information among providers. Historically, most primary care/ambulatory health care providers and dispensers of medications have practiced in different geographical sites. For example, community-based pharmacists and physicians have not generally practiced in close enough proximity to facilitate information sharing. Substantial technological barriers still exist that inhibit effective sharing of patient care information. Many of those barriers are being overcome in managed care organizations and federal agencies such as the Department of Veterans Affairs, where electronic records are shared, including diagnosis, admission complaints, patient histories, laboratory results, allergies, and medication histories. A combination of strategies to reduce barriers and provide positive incentives is needed.

Payers could be encouraged to provide incentives for collaboration among providers rather than separate payment pools to encourage models analogous to some of the proposed “medical home” models. Traditionally, geographical and professional separation reinforced separation of services and lack of sharing of information. New care models (e.g., medical home, accountable care organizations, personalized medication, chronic care models) will reinforce/emphasize collaboration among providers. The Institute of Medicine report To Err is Human posits that providers working together with special expertise generally have better outcomes. For example, hospitals and practitioners that specialize in cardiovascular surgeries have fewer adverse outcomes and better outcomes. Others have suggested that providers with special expertise about medications may provide better care, and the literature seems to support this view.

The adequacy of training and competence to perform specific skills necessary to provide the services needed for a BTC category of medications was among the concerns expressed in the FDA comments and other forums (e.g., Medpage Today). Nonphysicians have the training and ability to provide the services needed to provide the services essential to BTC. However, some constituencies have questioned the rigor and outcomes of those studies. Demonstration projects evaluating different models suggested by the current work and other comments should be conducted. The evidence will inform rules and regulations regarding the limits to nonphysician provider care.

Documentation and sharing
First, standardized encounter and outcomes documentation for sharing clinical care information and payment purposes are needed. As information technology for the health care sector improves as a result of American Recovery and Reinvestment Act funding and required enhancements, it must be incorporated into BTC models. Information must be shared across platforms to facilitate collaboration among providers on patients’ health care team. Hence, interoperability of systems is an important future direction. Demonstration projects must include systems in which information sharing is on the cutting edge versus usual care. The sharing of essential information
and teamwork among health professionals will provide the opportunity to reduce interprofessional turf battles that may not be in patients’ best interests.

Criteria for transition

Interdisciplinary panels of experts must be routinely convened to develop criteria for medications nominated for transition from prescription to BTC. Similar to other FDA panels, these panels should focus on initial category assignment to OTC or BTC or returning a medication to prescription-only status. Just as medications that are approved by FDA for legend status, experience after approval is important to continued safety. Analogous to Phase IV studies with prescription-only medications, post-BTC marketing studies must be required. Although the eventual source of the funding remains unclear, the product’s manufacturer must participate actively in the demonstration of the medication’s continued safety in the new BTC market.

Using lessons learned from other countries

The 1995 GAO report concluded that the experience in other countries was insufficient to provide guidance for United States decision making. Although that remains true to some extent, we can use lessons learned since then for guidance. For example, Canadian standards could be used to develop minimum standards for initial and continued participation in U.S. BTC dispensing. After 2 years of professional experience, bachelor’s degree– or master’s degree–trained U.K. pharmacists may seek a Practice Certificate in Independent Prescribing. Certification requires a minimum of 26 days of postgraduate didactic training and 90 hours of structured postgraduate practice experience tailored to the pharmacist’s practice. Independent pharmacist practitioners in the United Kingdom may prescribe Pharmacy-category medications for clinical conditions within their area of competence. Independent prescribing U.K. pharmacists use common diagnostic aids (e.g., stethoscope, sphygmomanometer) and develop working diagnoses, formulate treatment plans, ensure patient safety, monitor responses to therapy, and prescribe medications and refer patients to physicians if appropriate.

In the United States, the 6-year doctor of pharmacy degree program includes training in similar clinical sciences. Clinical training in the United States includes patient assessment (e.g., patient history, auscultation, point-of-care testing devices, blood pressure assessment and monitoring), triage and referral, interpretation of common clinical laboratory and diagnostic tests for use in diagnosis, and staging and monitoring of diseases. Although the U.S. and U.K. health care systems are not the same, experience suggests that U.K. pharmacists are able to appropriately diagnose, monitor, and refer patients to physicians with modest additional training. Comparably trained U.S. pharmacists are probably equally capable of appropriately handling a limited formulary of BTC medications.

The Australian government and pharmacist/physician organizations may inform U.S. policy regarding payment mechanisms. For example, both the pharmacist and primary care provider get paid in Australia. Primary care providers need to review and possibly act on the information provided to them by pharmacists. It may be that in the United States, the “team” may include a payment to the medical home participants and participation in risk-sharing programs in which a larger or smaller portion is paid depending on the final outcomes (e.g., pay for performance).

Conclusion

Based on the accumulated evidence, comments to FDA’s request, and information from other countries, implementation of a BTC model is probably feasible in the United States. However, the optimal model remains uncertain and various aspects of a program need to be prioritized and rigorously tested.

References


