

February 2009

# NONPRESCRIPTION DRUGS

## Considerations Regarding a Behind-the-Counter Drug Class



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Highlights of [GAO-09-245](#), a report to congressional requesters

## Why GAO Did This Study

In the United States, most nonprescription drugs are available over-the-counter (OTC) in pharmacies and other stores. Experts have suggested that drug availability could be increased by establishing an additional class of nonprescription drugs that would be held behind the counter (BTC) but would require the intervention of a pharmacist before being dispensed; a similar class of drugs exists in many other countries. Although the Food and Drug Administration (FDA) has not developed a detailed proposal for a BTC drug class, it held a public meeting in 2007 to explore the public health implications of BTC drug availability.

GAO was asked to update its 1995 report, *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated* ([GAO/PEMD-95-12](#)). Specifically, GAO is reporting on (1) arguments supporting and opposing a U.S. BTC drug class, (2) changes in drug availability in five countries since 1995 and the impact of restricted nonprescription classes on availability, and (3) issues important to the establishment of a BTC drug class.

GAO reviewed documents and consulted with pharmaceutical experts. To examine drug availability across countries, GAO studied five countries it had reported on in 1995 (Australia, Italy, the Netherlands, the United Kingdom, and the United States) and determined how 86 drugs available in all five countries were classified in each country.

To view the full product, including the scope and methodology, [click on GAO-09-245](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crosse@gao.gov](mailto:crosse@gao.gov).

## NONPRESCRIPTION DRUGS

### Considerations Regarding a Behind-the-Counter Drug Class

#### What GAO Found

Arguments supporting and opposing a BTC drug class in the United States have been based on public health and health care cost considerations, and reflect general disagreement on the likely consequences of establishing such a class. Proponents of a BTC drug class suggest it would lead to improved public health through increased availability of nonprescription drugs and greater use of pharmacists' expertise. Opponents are concerned that a BTC drug class might become the default for drugs switching from prescription to nonprescription status, thus reducing consumers' access to drugs that would otherwise have become available OTC, and argue that pharmacists might not be able to provide high quality BTC services. Proponents of a BTC drug class point to potentially reduced costs through a decrease in the number of physician visits and a decline in drug prices that might result from switches of drugs from prescription to nonprescription status. However, opponents argue that out-of-pocket costs for many consumers could rise if third-party payers elect not to cover BTC drugs.

All five countries GAO studied have increased nonprescription drug availability since 1995 by altering nonprescription classes or reclassifying some drugs into less restrictive classes. Italy and the Netherlands, which previously allowed nonprescription drugs to be sold only at specialized drug outlets, made some or all of these drugs available for OTC sale. Australia, the United Kingdom, and the United States switched certain drugs from more restrictive to less restrictive drug classes, increasing these drugs' availability. However, the impact of restricted nonprescription drug classes on availability is unclear. When we examined the classification of 86 selected drugs in the five countries, we found that the United States required a prescription for more of those drugs than did Australia or the United Kingdom—the study countries using a BTC drug class. However, the United States classified more of the 86 drugs as OTC—the option that provides greatest access to these drugs for consumers—than all four of the other study countries.

Pharmacist-, infrastructure-, and cost-related issues would have to be addressed before a BTC drug class could be established in the United States. For example, ensuring that pharmacists provide BTC counseling and that pharmacies have the infrastructure to protect consumer privacy would be important. Issues related to the cost of BTC drugs would also require consideration. For example, the availability of third-party coverage for BTC drugs would affect consumers' out-of-pocket expenditures and pharmacists' compensation for providing BTC services would need to be examined.

In commenting on a draft of this report, the Department of Health and Human Services (HHS) agreed that cost-related issues would have to be addressed before implementing a BTC drug class and also provided technical comments. The Department of Veterans Affairs (VA) also reviewed the report and provided technical comments. We have incorporated HHS and VA technical comments as appropriate.

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## Abbreviations

AIDS	acquired immunodeficiency syndrome
BTC	behind-the-counter
CMS	Centers for Medicare & Medicaid Services
EU	European Union
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IHS	Indian Health Service
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MTM	medication therapy management
OBRA '90	Omnibus Budget Reconciliation Act of 1990
OTC	over-the-counter
VA	Department of Veterans Affairs

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United States Government Accountability Office  
Washington, DC 20548

February 20, 2009

The Honorable Henry A. Waxman  
Chairman  
The Honorable John D. Dingell  
Chairman Emeritus  
Committee on Energy and Commerce  
House of Representatives

The Honorable Bart Stupak  
Chairman  
Subcommittee on Oversight and Investigations  
Committee on Energy and Commerce  
House of Representatives

The United States has a two-tier system for the classification of drugs: prescription and nonprescription. Prescription drugs can be dispensed only with written or oral orders (i.e., a prescription) from a licensed prescriber—such as a doctor, nurse practitioner, or physician’s assistant—to a pharmacist or other licensed dispenser. Most nonprescription drugs are available for sale over the counter (OTC) by self-service in pharmacies and in nonpharmacy outlets such as grocery stores, mass merchandisers, and gas stations. The two-tier system in the United States is distinct from other countries that have more or different categories of nonprescription drugs. In other countries, levels of restriction on where and by whom a nonprescription drug can be sold vary. For example, certain nonprescription drugs may be sold only under the supervision of a pharmacist.

Pharmacists, academics, and other experts have suggested that an additional class of nonprescription drugs could increase drug availability, because more drugs could be made available without the need to obtain a prescription. In the United States, the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), has authority to approve drugs prior to their marketing, to ensure that they are safe and effective, and to determine their prescription or nonprescription status. Although FDA has not developed a specific proposal, in November 2007, it held a public meeting to explore the public health implications of behind-the-counter (BTC) availability of certain

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drugs.<sup>1</sup> BTC drugs would be held behind a pharmacy counter and available without a prescription, but dispensed only after intervention by a pharmacist. The primary purpose of a BTC class would be to increase access to drugs to promote public health by making drugs available without a prescription when intervention by a pharmacist or other means can help ensure the safe and effective use of such drugs. Similar proposals have been considered in the past and, in 1995, GAO issued a report titled *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated* (GAO/PEMD-95-12).<sup>2</sup> In that report, we stated that there was little evidence to support the establishment of a BTC or similar class of drugs in the United States. The evidence at the time tended to show that countries with a BTC or similar drug class were not obtaining major benefits from that class.

In light of the FDA hearing on BTC drugs and the fundamental change that a BTC drug class would represent in the U.S. drug classification system, you asked us to update our 1995 report. Specifically, we are reporting on (1) the arguments that have been made supporting and opposing the creation of a BTC drug class in the United States; (2) changes in drug availability in our five study countries<sup>3</sup> since 1995 and the impact of restricted nonprescription drug classes on drug availability; and (3) issues that would be important to the establishment of a BTC drug class.

To describe the arguments that have been made supporting and opposing a BTC drug class in the United States, we reviewed published literature, reports, and meeting minutes of FDA hearings on prescription-to-OTC switches,<sup>4</sup> and the transcript of and docket submissions for the November 2007 FDA meeting on BTC drugs.<sup>5</sup> We interviewed officials at FDA, pharmacy associations, drug manufacturers, consumer groups, and

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<sup>1</sup>A transcript of this meeting, *Behind the Counter Availability of Certain Drugs: Public Meeting*, is available at [http://www.fda.gov/oc/op/btc/transcripts11\\_14\\_07.html](http://www.fda.gov/oc/op/btc/transcripts11_14_07.html).

<sup>2</sup>GAO, *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated*, GAO/PEMD-95-12 (Washington, D.C.: Aug. 24, 1995).

<sup>3</sup>In addition to the United States, the study countries are Australia, Italy, the Netherlands, and the United Kingdom. We also describe drug classification in the European Union (EU).

<sup>4</sup>The reclassification of drugs from one class to another is referred to as switching.

<sup>5</sup>One issue that has been raised, but is beyond the scope of this report, is whether FDA has authority to create such a class without a legislative change.

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industry associations in the United States. We also interviewed academics and other officials knowledgeable about pharmaceutical practice.

To determine the impact of restricted nonprescription drug classes on drug availability, we interviewed experts to ask them to help us identify countries that had evaluated drug classification since our 1995 report. Based on this information, we selected 5 of the 11 countries covered in our previous report.<sup>6</sup> We also examined drug classification in the European Union (EU), because it affects drug availability in three of our study countries. We reviewed published literature, reports, and agency documents on drug classification and prescription-to-nonprescription switches in our study countries. We also interviewed agency officials, industry representatives, and others knowledgeable about pharmaceutical practices in the United States and the other study countries. We examined changes since 1995 in the drug classification systems in two study countries (Italy and the Netherlands) that changed the number or type of nonprescription drug classes in use. We also determined the number of drugs switched from one drug class to another (e.g., prescription to BTC) between 1995 and 2008 for the three study countries (Australia, the United Kingdom, and the United States) that maintained the same number and type of nonprescription drug classes during that time. Additionally, we determined the classification of selected drugs in our study countries. We chose a sample of drugs using World Self-Medication Industry data on the classification of more than 200 drugs in 36 countries and identified 86 of these drugs as available in all five study countries.<sup>7</sup> We examined the survey format used to collect information on drug classification and response rates from the most recent survey, and determined that the data were sufficiently reliable for our purposes. We then used drug classification documents published by the regulatory agencies in each of the study countries and information from agency officials to determine how each of the 86 drugs was classified in each country. The data in these

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<sup>6</sup>In addition to the United States, in our previous report we examined the drug classification systems in Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, the United Kingdom, and the EU ([GAO/PEMD-95-12](#), pp. 85-10). In this report, the study countries are Australia, Italy, the Netherlands, the United Kingdom, and the United States.

<sup>7</sup>The World Self-Medication Industry is a federation of more than 50 member associations representing manufacturers and distributors of nonprescription medicines. Methodology adapted from A. Gilbert, D. Rao, and N. Quintrell, "A Review of Pharmaceutical Scheduling Processes in Six Countries and the Effect on Consumer Access to Medicines," *International Journal of Pharmacy Practice*, vol. 14, no. 2 (2006).

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reference documents are standard data sources published by each country's regulatory authority and were sufficiently reliable for our purposes.

To identify issues that would be important to the establishment of a BTC drug class in the United States, we reviewed published literature and reports. We interviewed officials at FDA, the Centers for Medicare & Medicaid Services (CMS), the Department of Veterans Affairs (VA), the Indian Health Service (IHS), pharmacy associations, drug manufacturers, consumer groups, industry associations, and drug regulatory agencies in other countries. We also interviewed academics and other experts—including individuals who have testified before FDA on the possible creation of a BTC drug class in the United States—knowledgeable about pharmacists' prescribing authority. Appendix I provides a more detailed explanation of the scope and methodology for this report. We conducted our work from March 2008 through February 2009 in accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

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## Results in Brief

Arguments supporting and opposing a BTC drug class in the United States have been based on public health and health care cost considerations, and these arguments reflect general disagreement on the likely consequences of the establishment of such a class. Some who support a BTC drug class suggest that such a class would lead to improved public health through increased availability of nonprescription drugs. For example, a BTC class might allow more drugs to be switched out of the prescription class, providing increased access to these drugs for consumers. Additionally, proponents argue that pharmacists have extensive knowledge of drug use and drug interactions and could help consumers to assess their medical needs and determine whether a physician's visit would be appropriate. However, opponents are concerned about the potential for a BTC class to become a default class for all drugs switching from prescription to nonprescription status even when the additional restrictions of BTC classification are not necessary for safe use of all such drugs; BTC classification would reduce consumers' access to drugs if those drugs would otherwise have switched to OTC status. Opponents also note that pharmacists are not trained in clinical diagnosis, generally do not have access to relevant patient information (such as laboratory results), and



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lack the time to provide counseling to patients. Health care cost arguments in favor of a BTC drug class center on possible reduced costs through a decrease in the number of physician visits and a decline in drug prices that might result from nonprescription status. However, opponents argue that out-of-pocket costs for many consumers could rise if prescription drugs currently covered by insurance are switched to BTC status and third-party payers elect not to cover BTC drugs. Additional costs to consumers could result if pharmacists require a fee in order to provide counseling.

All five study countries have increased nonprescription drug availability since 1995; however, the impact of restricted nonprescription drug classes on drug availability is unclear. The five study countries—selected because they evaluated drug classification in their countries since 1995—have increased drug availability in two ways: by changing nonprescription drug classes or by switching some drugs into less restrictive classes. Italy—in 2006—and the Netherlands—in 2007—changed their nonprescription drug classes by making some or all of their nonprescription drugs available for OTC sale at nonpharmacy outlets, such as grocery stores. Previously, the Netherlands restricted drug sales to drugstores (operated by a licensed druggist and allowed to sell certain nonprescription drugs) or pharmacies (operated by a pharmacist and allowed to sell all prescription and nonprescription drugs); Italy also previously limited the sale of all drugs to pharmacies. Since 1995, Australia, the United Kingdom, and the United States have switched a number of drugs from more restrictive to less restrictive drug classes, again resulting in an overall increase in drug availability. When we examined the classification of 86 selected drugs in the five study countries, we found that the impact of restricted nonprescription drug classes on availability is unclear. The United States required a prescription for more of those drugs than did Australia or the United Kingdom—the study countries using a BTC drug class. However, the United States also classified more of the drugs from our sample as OTC—the option that provides greatest access to these drugs for consumers—than all four of the other study countries. Additionally, we did not find an association between the restrictions placed on the availability of particular drugs in our sample by the study countries and the presence of a BTC drug class. The United States gave more restrictive classification to some drugs and less restrictive classification to other drugs when compared to the other four study countries.

Pharmacist-, infrastructure-, and cost-related issues would have to be addressed before a BTC drug class could be established in the United States. The roles and responsibilities of pharmacists in a BTC drug class that would need to be considered include defining pharmacist

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responsibilities for dispensing BTC drugs, ensuring that pharmacists provide the necessary BTC counseling, and determining whether additional training would be needed for pharmacists and pharmacy staff. In addition, whether or not there is a sufficient pharmacist workforce to make such a class viable would need to be determined, and pharmacists' new role would need to be communicated to the public. Ensuring that pharmacies have the data infrastructure necessary to provide pharmacists with patient information and the physical infrastructure to protect consumer privacy would also be important. Additionally, several cost issues would be important to the implementation of a BTC drug class. For example, the availability of third-party coverage for BTC drugs would affect consumers' out-of-pocket expenditures. If BTC drugs were more expensive than prescription or OTC alternatives, it could discourage consumer use of BTC drugs. Also, pharmacists' compensation for providing BTC services would need to be considered. The level of pharmacist compensation might influence pharmacists' willingness to engage in activities required for dispensing BTC drugs, such as providing counseling, and therefore could affect their participation in a BTC drug class. Other cost issues might also affect the viability of a BTC drug class. Pharmacists' liability risk could increase as a result of their expanded role in a BTC drug class and thus deter pharmacists from participating in a BTC drug class.

In commenting on a draft of this report, HHS agreed that cost-related issues would have to be addressed before implementing a BTC drug class and also provided technical comments. VA also reviewed the report and provided technical comments. We have incorporated HHS and VA technical comments as appropriate.

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## Background

In the United States, although drugs are classified as prescription or nonprescription at the federal level by FDA, the practice of pharmacy is typically regulated by states. For example, states license pharmacists and enforce pharmacists' continuing education requirements.

The 1951 Durham-Humphrey Amendments to the Federal Food, Drug, and Cosmetic Act provided the statutory basis for the two-tier drug classification system that currently exists in the United States.<sup>8</sup> Since that time, there have been a number of proposals to introduce a third category

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<sup>8</sup>Pub. L. No. 82-215, 65 Stat. 648 (1951).

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of drugs in the United States. This category has been called by a number of names, including pharmacist-legend, pharmacist-only, third class of drugs, and BTC. Although there is some variation between proposals, the basic idea is the same: a class of drugs would be established that would be available without a prescription, but only in pharmacies. The BTC idea that FDA sought comment on would require that these drugs be sold only in pharmacies, and that a pharmacist's intervention with a consumer occur before the drug could be dispensed.<sup>9</sup>

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## Use of a BTC Drug Class

There are two general views on how a BTC class of drugs would be used in the United States. The first is that BTC would be a permanent class. It would be similar to the current prescription and OTC classes, in that drugs would be placed in the BTC class with no expectation that they would eventually switch to the prescription or OTC class. Drugs in the BTC class would be those determined by FDA to be nonprescription but would require the intervention of a pharmacist. Drugs in the BTC class could come from the current prescription and OTC classes or new drugs could be classified as BTC, although proposals for a BTC drug class generally seek to increase access to medications by switching drugs out of the prescription class.

The second view is that the BTC drug class could function as a transition class for some drugs and a permanent class for others. A drug being switched from prescription to nonprescription would spend time in the transition class, during which the suitability of the drug for OTC status could be assessed. In addition to studies specifically designed for such an assessment, consumer use of the drug as a prescription drug and as a BTC

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<sup>9</sup>Since FDA has not issued a detailed BTC proposal, it is unknown if mail-order or Internet pharmacies would be permitted to dispense BTC drugs. At the November 2007 public meeting, one FDA official stated that the specific role of the pharmacist would need to be determined. See FDA, *Behind the Counter Availability of Certain Drugs: Public Meeting*, p. 1. A pharmacist's intervention with a consumer might include reviewing drug interactions and reading and interpreting laboratory results.

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drug could be examined.<sup>10</sup> The argument is that this would provide a better picture of how the drug would be used by the public if it were available as an OTC product. Information that could be gathered while the drug was in the transition class includes types and levels of misuse among the general public, incidents of adverse drug reactions, and interactions with other medications. At some point after the product has been BTC, a decision might be made based on the available data to switch the drug to OTC, return the drug to prescription status, keep the drug in the BTC class for future study, or keep the drug in the BTC class with no expectation that it would eventually be switched to the prescription or OTC class.

FDA has not indicated which drugs might be classified as BTC in the United States. However, among the drugs suggested by some proponents are certain drugs that treat chronic conditions such as high cholesterol, asthma, high blood pressure, diabetes, urinary incontinence, and osteoporosis. Vaccines; the epinephrine auto-injector used in emergency situations following insect bites, stings, or exposure to other allergens; and oseltamivir—which is used to treat influenza and might be effective in the event of an influenza pandemic—have also been suggested as possible BTC products. More generally, drugs that are subject to abuse and drugs that are to be sold only to consumers of a minimum age have been mentioned as possible candidates for a BTC class.

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## Nonprescription Drug Classes in Other Countries

Figure 1 defines the terms we use to describe the drug classes in the United States and other countries and how the levels of restriction vary among classes based on the conditions under which drugs are sold. As discussed in our previous report, varying levels of restriction on nonprescription drugs already exist in other countries.<sup>11</sup> Among the

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<sup>10</sup>Currently, label comprehension, self-selection, and actual use studies are conducted to help support a request to switch a drug from prescription to OTC status. For some drugs, clinical safety and efficacy trials are also needed. Label comprehension studies are used to determine whether the label clearly communicates the uses, directions, and warnings to diverse populations and enables the consumer to make appropriate judgments about self-selection. Self-selection studies are used to evaluate whether consumers can appropriately select a product based on the product label and their unique medical histories. Actual use studies are clinical studies designed to simulate the OTC use of a drug. They are meant to assess drug selection, compliance with labeling, and safe use of the drug.

<sup>11</sup>In addition to the United States, in our previous report we examined the drug classification systems in Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, the United Kingdom, and the EU. [GAO/PEMD-95-12](#), 85-103.

criteria foreign countries have used for switching a drug from prescription to a less restrictive nonprescription drug class are: (1) the symptoms or circumstances for use of the drug are suitable for self-medication, including self-diagnosis, with the intervention of a pharmacist; and (2) the drug has a low potential for side effects or overdose, and intervention by a pharmacist could minimize these risks. In contrast, nonprescription drugs in the United States generally have these characteristics: (1) their benefits outweigh their risks; (2) consumers can use them for self-diagnosed conditions; (3) they can be adequately labeled for self-medication; and (4) a prescription by a licensed prescriber is not needed for the consumer to safely and effectively use the drug and the conditions or symptoms are generally self-limiting. Appendix II provides details on the drug classification systems in each study country and the European Union (EU).

**Figure 1: Definitions and Relative Levels of Restriction for Drug Classes Used in This Report**

Term used in the report	Definition	Levels of restriction
<b>Prescription drugs</b>		
Prescription	Available only from a pharmacist or other licensed dispenser upon submission of a prescription	Most restrictive
<b>Nonprescription drugs</b>		
BTC	Available only in pharmacies; contact with pharmacist required	
Pharmacy	Available only in pharmacies; contact with pharmacist not required	
Drugstore	Available only in pharmacies or drugstores; contact with pharmacist not required <sup>a</sup>	
OTC/pharmacist	Available for self-selection in pharmacies and other retail outlets, but a pharmacist must be present	
OTC	Available for self-selection in pharmacies and other retail outlets, including those without pharmacists or druggists	

Source: GAO analysis of agency documents from the study countries.

<sup>a</sup>In the Netherlands, a distinction is made between pharmacies (run by pharmacists and able to sell all prescription and nonprescription drugs) and drugstores (run by druggists with less training than pharmacists and able to sell only some nonprescription drugs).

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While Figure 1 indicates how the levels of restriction for prescription and nonprescription drug classes affect drug availability, there are other factors that can also affect availability including cost, patient participation in health decisions, and purchase site convenience. For example, the number of pharmacies in a country affects the availability of BTC drugs. The more pharmacies there are, the greater the availability of BTC drugs and the smaller the difference in availability between BTC and OTC drugs. Also, the distribution of pharmacies can affect availability. Areas without a local pharmacy but with outlets that sell OTC drugs, would be more affected by not having drugs available OTC than would areas with nearby pharmacies.

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## Arguments Made Supporting and Opposing a BTC Drug Class Reflect Disagreement on Its Impact on Health Care and Health Care Costs

Arguments that have been made supporting and opposing a BTC drug class are generally based on public health or cost considerations and reflect disagreement on the likely consequences of the establishment of such a class. Many of the arguments are concerned with how a BTC drug class might affect consumers' access to medications, pharmacist involvement in selecting drugs, the costs of drugs, and payment policies.

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## Some Proponents of a BTC Drug Class Argue It Will Improve Public Health

Some of those who support a BTC drug class, including representatives of pharmacist associations and some academics, suggest that such a class would lead to improved public health through increased availability of nonprescription drugs.<sup>12</sup> Proponents of a BTC drug class argue that such a class would increase access because drugs that might not otherwise be suitable for general OTC use could be available without a prescription. The switching of a drug from prescription to OTC represents a large change in the distribution of the drug, from requiring a prescription to requiring no medical intervention at all. Proponents argue that pharmacists could help bridge this gap if there were a BTC drug class. By providing a new avenue for switches from prescription to nonprescription,

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<sup>12</sup>Academics, pharmacy association officials, manufacturer representatives, and others presented many arguments supporting and opposing a BTC drug class at FDA's November 2007 public meeting. See FDA, *Behind the Counter Availability of Certain Drugs*.

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a BTC drug class would give consumers access to more drugs that could benefit their health. Pharmacists could counsel consumers on BTC medications and, consequently, some drugs that were unsuitable for OTC availability could be made available as BTC drugs. Proponents argue that this would be particularly important for underserved populations, such as the uninsured, underinsured, or those with limited access to a primary care provider and, thus, to prescription drugs. Moreover, an FDA official told us that many of the drugs that could be switched to OTC under the current two-tier drug classification system have already been reclassified and that a BTC drug class might allow additional drugs to be switched out of prescription status.. The convenience of acquiring BTC drugs at a pharmacy could improve consumer adherence to drug regimens by eliminating the need for a visit to a physician to obtain refill prescriptions. Additionally, FDA has noted that people are now taking a larger role in managing their health. Experts have stated that increased access to drugs through a BTC class could give them even more tools to do so, thus potentially improving their health.

Other arguments in favor of a BTC drug class focus on the expanded role of pharmacists under such a class, suggesting that greater use of pharmacist expertise would improve health outcomes. Proponents of a BTC drug class note that pharmacists are successfully engaging in activities beyond their traditional role of dispensing drugs, such as prescribing drugs under certain circumstances<sup>13</sup> or reviewing individuals' drug regimens if they participate as providers of medication therapy management (MTM) in programs where they are authorized to perform

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<sup>13</sup>VA and IHS allow some specially trained VA and IHS pharmacists to prescribe drugs. Additionally, according to the American College of Clinical Pharmacy, 44 states now allow some form of collaborative drug therapy management, in which pharmacists enter into collaborative practice agreements with physicians and other prescribers. Under these agreements, pharmacists can be authorized to select appropriate drug therapies and regimens for patients who have a confirmed diagnosis by a physician and adjust them on the basis of patients' responses.

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such reviews.<sup>14</sup> Proponents also point out that pharmacists are well trained in medication therapy, and a BTC drug class would make better use of pharmacists' knowledge of drug use, drug interactions, and other factors. Additionally, pharmacy schools are becoming more patient focused, integrating training on counseling, physical assessments of patients, and interpretation of lab results into their curricula. Because pharmacists might be more accessible than physicians, better health outcomes could result from the greater consumer interaction with pharmacists brought on by a BTC drug class. During such interactions, pharmacists might also refer individuals with potentially serious medical conditions to a physician; these individuals might not have otherwise entered the health care system. Moreover, proponents of a BTC class note that numerous studies have demonstrated that expanded pharmacist roles in individuals' care can result in health improvements. They note that the pharmacy practice literature generally supports the ability of community pharmacists<sup>15</sup> to reduce adverse reactions and improve clinical outcomes

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<sup>14</sup>Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), for example, drug plan sponsors participating in Medicare Part D—a voluntary insurance program for outpatient prescription drug benefits—must offer MTM programs to improve prescription drug use and outcomes among individuals with multiple chronic diseases and taking multiple drugs covered under Part D. (Individuals targeted for MTM programs must also be identified as likely to incur annual costs for covered Part D drugs that exceed a level specified by the Secretary of Health and Human Services.) See Pub. L. No. 108-173, § 101(a), 117 Stat. 2066, 2085-87 (2003). MTM services are designed to optimize therapeutic outcomes through improved drug use and to reduce the risk of adverse events. Examples of MTM services might include performing assessments of the individual's health status; initiating, modifying, or administering drug therapy; monitoring and evaluating the response to therapy; and providing verbal education and training designed to enhance individuals' appropriate use of their drugs.

<sup>15</sup>Community pharmacy settings include independent, chain, mass merchandiser, and supermarket pharmacies. This term excludes pharmacists who practice in hospitals and other institutional settings.



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for conditions such as asthma, diabetes, hypertension, and high cholesterol.<sup>16</sup>

Proponents also argue that a BTC drug class would improve public health by permitting additional data to be obtained that would better indicate when a drug would be appropriate for OTC availability. For example, BTC availability might allow consumer–pharmacist interactions to be studied to determine if consumers really need the pharmacist’s input. Additionally, information might be collected from pharmacists about whether consumers could understand product information and appropriately assess their suitability for a medication without pharmacist prompting. This could affect the labeling if the drug were switched to OTC availability. Depending on a drug’s safety and usage profile in a BTC class, a drug could either remain permanently in the BTC class or subsequently transition to OTC.

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### Some Opponents of a BTC Drug Class Raise Concerns about Potential Harm to Public Health

Opponents of a BTC drug class, including some academics and representatives of drug manufacturers, raise concerns that such a class could harm public health by decreasing the availability of nonprescription drugs. Overall, opponents believe that the current two-tier drug classification system works well and provides consumers with an appropriate level of drug availability.<sup>17</sup> Opponents of a BTC drug class argue that such a class could become the default option for drugs being switched from prescription status due to the cautious approach of regulators. Prescription drugs that could have switched to OTC might instead be placed into a BTC drug class, resulting in decreased consumer

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<sup>16</sup>For example, see B. A. Bunting and C. W. Cranor, “The Asheville Project: Long-Term Clinical, Humanistic, and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma,” *Journal of the American Pharmacists Association*, vol. 46, no. 2 (2006); T. Fera, et al., “The Diabetes Ten City Challenge: Interim Clinical and Humanistic Outcomes of a Multisite Community Pharmacy Diabetes Care Program,” *Journal of the American Pharmacists Association*, vol. 48, no. 2 (2008); D. G. Garrett and B. M. Bluml, “Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic, and Economic Outcomes,” *Journal of the American Pharmacists Association*, vol. 45, no. 2 (2005); B. J. Isetts, et al., “Clinical and Economic Outcomes of Medication Therapy Management Services: The Minnesota Experience,” *Journal of the American Pharmacists Association*, vol. 48, no. 2 (2008); and B. A. Bunting, et al., “The Asheville Project: Clinical and Economic Outcomes of a Community-based Long-term Medication Therapy Management Program for Hypertension and Dyslipidemia,” *Journal of the American Pharmacists Association*, vol. 48, no. 1 (2008).

<sup>17</sup>Opponents argue that if a drug is not suitable for OTC use, it should be available only by prescription. Consequently, they believe that a BTC class is inappropriate.

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access compared to OTC availability. Drugs might also remain in a BTC drug class even if suitable for OTC use. Concerns have also been raised that current OTC products could be moved into a BTC class, thereby reducing availability. Additionally, depending on how well information is communicated to consumers about a BTC drug class, both in public campaigns and within pharmacies, consumers could be unaware of available BTC drugs. Underserved and rural communities with few or no pharmacies might also experience barriers to accessing BTC drugs, which would only be available through pharmacies.

Opponents also raise concerns about the potential harm that might be done to consumers if pharmacists are not able to provide high-quality, reliable BTC services. Physician association representatives and others have stated that pharmacists lack adequate clinical training to properly diagnose and treat illnesses, skills which might be required when dispensing BTC drugs.<sup>18</sup> Opponents also raise the concern that pharmacists are very busy and might not have enough time to provide individualized counseling to consumers regarding BTC drugs. Additionally, pharmacists might not have access to relevant information (e.g., a complete medical record, laboratory results, and a complete list of medications taken by the individual) necessary to make an optimal and safe BTC drug recommendation. Opponents also argue that, currently, pharmacists counsel infrequently and sometimes incorrectly. Beyond concerns over inadequate service, opponents suggest that a lack of private confidential areas in pharmacies for consumer-pharmacist interactions could discourage individuals from seeking care for sensitive matters.

Some opponents of a BTC drug class assert that adverse health outcomes could result from improper use of BTC drugs. Individuals who use BTC drugs without consulting a physician might treat symptoms but not the

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<sup>18</sup>Although some pharmacists are engaging in expanded roles, such as providing MTM services or participating in collaborative practice agreements, some experts we interviewed do not consider these experiences adequate preparation for the role pharmacists would be expected to assume for a BTC drug class. Whereas physicians and prescription drug plans can initiate the provision of MTM services, BTC counseling would be initiated by a pharmacist. Additionally, MTM programs primarily focus on managing consumers' current drug therapy, not initiating new therapy, as pharmacists would for BTC drugs. Collaborative practice agreements involve physicians delegating some responsibilities to pharmacists, whereas a BTC drug class would give pharmacists independent decision-making authority. Physician-pharmacist interaction is also formalized through collaborative practice agreements, but physician involvement would likely not be a requirement of a BTC drug class.

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underlying cause of the illness, thus delaying appropriate therapy. Readily available BTC drugs could also encourage individuals with chronic conditions to seek pharmaceutical remedies instead of lifestyle changes that could alleviate the conditions. Additionally, an individual's personal physician might not be aware when a person begins a pharmacist-recommended BTC drug regimen and thus might not be able to monitor the individual appropriately. Experts told us this uncoordinated care could further fragment the provision of health care.

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### Some Proponents of a BTC Drug Class Argue that It Would Reduce Costs

Proponents of a BTC class have argued that establishment of such a class would likely reduce costs. In the past, the price of a drug has decreased when it was switched from prescription to OTC. Consequently, if a BTC drug class permits increased switching of drugs and pricing follows this pattern, it could reduce costs to consumers and to the overall health care system. Cost savings could also result from a decrease in the number of physicians' visits. The availability of BTC drugs that previously had prescription status could result in fewer physician office visits for patients seeking prescriptions and, accordingly, fewer co-payments and third-party reimbursements to physicians. This would reduce costs for both consumers and insurers, as well as overall health care system expenditures. The pharmacy practice literature also supports the ability of community pharmacists to provide cost-effective interventions and reduce the cost of drug therapy.<sup>19</sup>

Additionally, because third-party payers do not typically reimburse consumers for nonprescription drugs and thus might not provide coverage for BTC drugs, drug expenditures for third-party payers could decrease if prescription drugs were switched to a BTC class. Cost reductions for

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<sup>19</sup>For example, pharmacists participating in a diabetes care program in Asheville, North Carolina helped individuals set and monitor treatment goals, performed physical assessments, and provided physician referrals, as needed. Pharmacists also provided individuals with diabetes education training, home glucose monitor training, and information about adherence to their treatment regimens. Individuals in the study maintained clinically meaningful improvements in their levels of glycosylated hemoglobin—a diabetes-related indicator—over time, and third-party payers experienced an overall decline in mean total direct medical costs during each year of follow-up. Pharmacists were reimbursed for their services by employers' health plans. Based on the clinical improvements and financial savings associated with this diabetes management program, the participating employers made the program a permanent component of their health plan benefit. See C. W. Cranor, et al., "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program," *Journal of the American Pharmaceutical Association*, vol. 43, no. 2 (2003).

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insurers could also be realized in the area of compensation for professional services. Although pharmacist associations maintain that pharmacists would need to be compensated for health care services provided under a BTC paradigm, health services provided by pharmacists are less expensive than those provided by physicians—pharmacists are reimbursed at approximately 80 percent of physician rates for similar time-based services.<sup>20</sup>

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### Some Opponents of a BTC Drug Class Cite the Potential for Increased Costs

Many arguments against a BTC drug class are based on the potential increased costs to individuals, third-party payers, and the overall health care system that such a class might cause. For instance, because insurers do not typically reimburse consumers for OTC drugs and thus might not provide coverage for BTC drugs, out-of-pocket expenses for consumers could increase if prescription drugs were switched to a BTC drug class and if the cost of the BTC product were greater than the previous copay.<sup>21</sup> Opponents of a BTC drug class have argued also that costs could increase as the result of the pharmacy services required for establishing such a class. Compensation for pharmacists providing BTC services could result in greater costs for consumers and third-party payers than if the drugs had been made OTC in the current two-tier system. Furthermore, restricted competition could also increase costs. It has been noted that there would be fewer outlets for BTC drugs than for OTC products because BTC products could not be sold at retail outlets other than pharmacies. This reduced availability could adversely affect retail competition and, as a result, drive up prices.

Additionally, improper use of BTC drugs and the absence of physician consultations in the BTC process could result in expensive adverse health outcomes. For example, without a physician's diagnosis, a pharmacist might recommend a BTC drug to treat stomach pain. However, potentially serious gastrointestinal problems might underlie this symptom, and delays

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<sup>20</sup>Under MMA, plans offering Part D prescription drug coverage must include a MTM program for certain plan enrollees which may be provided by a pharmacist and may include elements to promote the appropriate use of medications by enrollees and adherence with prescription medication regimens. Pharmacists are eligible to be compensated for the services they provide under such plans. Pub. L. No. 108-173, 117 Stat. 2086-7 (2003). Although MMA does not specify a payment schedule, the rate often used by CMS to pay for pharmacists' services under the Medicare program is 80 percent of the physician rate.

<sup>21</sup>Additionally, lack of third-party payment for BTC drugs may result in a shift by consumers to alternative and more costly prescription drugs, which could, in turn, result in additional expenditures.

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in obtaining appropriate treatment could have serious and expensive consequences to the consumer and the health care system as a whole.

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## All Study Countries Have Increased Nonprescription Drug Availability, but the Impact of Restricted Nonprescription Drug Classes on Availability Is Unclear

All five study countries have increased nonprescription drug availability since 1995; however, the impact of restricted nonprescription drug classes on availability is unclear. The five study countries increased drug availability in two ways: by changing nonprescription drug classes or by switching some drugs into less restrictive classes. Italy and the Netherlands established new OTC classes by making some or all nonprescription drugs available for sale at nonpharmacy outlets, while Australia, the United Kingdom, and the United States switched a number of drugs from more restrictive to less restrictive drug classes. When we compared the classification of 86 selected drugs in the five study countries, we found that the impact of restricted nonprescription drug classes on availability is unclear. The United States required a prescription for more of the selected drugs than did the two study countries (Australia and the United Kingdom) with a BTC drug class but also had more of these drugs classified as OTC—the option that provides greatest availability—than the other four study countries.

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## All the Study Countries Have Increased Nonprescription Drug Availability Since 1995 by Changing Drug Classes or Switching Drugs

Consumers in all five study countries have experienced an increase in nonprescription drug availability compared to 1995 due to changes in drug classes or reclassification of drugs into less restrictive classes. Two countries changed their drug classes. The Netherlands added an OTC class in 2007; previously, all nonprescription drugs in the Netherlands were restricted to pharmacy or drugstore sales.<sup>22</sup> As a result, the Netherlands now has three nonprescription drug classes: pharmacy, drugstore, and OTC. Italy also relaxed nonprescription drug sale restrictions in 2006 by making all nonprescription drugs available in nonpharmacy outlets; previously, nonprescription drugs could be sold only in pharmacies. Italy requires that a pharmacist be on the premises in any outlet that sells nonprescription drugs. As a result, Italy's single nonprescription drug class has changed from a pharmacy class to an OTC/pharmacist class. The

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<sup>22</sup>In the Netherlands, a distinction is made between pharmacies (run by pharmacists and able to sell all prescription and nonprescription medicines) and drugstores (run by druggists with less training than pharmacists and able to sell only some nonprescription drugs). Although the Netherlands has both pharmacy and drugstore classes for nonprescription drugs, contact with the pharmacist or druggist is not required. Therefore, the Netherlands does not have a BTC drug class.

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presence of a pharmacist is not a requirement for the OTC class in any of the other countries we examined. Due to the changes made by Italy and the Netherlands, all five of the study countries now have some form of OTC availability of drugs. The other three study countries made no changes to their drug distribution categories since 1995. Australia has three nonprescription drug classes: BTC, pharmacy, and OTC.<sup>23</sup> The United Kingdom has two nonprescription classes: BTC and OTC.<sup>24</sup> The United States has one nonprescription class: OTC. (Table 1 summarizes the drug classes in use in the study countries in 2008. Appendix II provides more details on the drug classification systems in each of the study countries.)

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<sup>23</sup>Although Australia has not changed its drug classification system since 1995, research is currently being undertaken to determine whether there is benefit in retaining separate BTC and pharmacy drug classes. These studies were prompted by the Galbally Review, which made a number of recommendations related to achieving uniformity of regulations between Australian states, territories, and the national government through legislative reforms. The review noted that the goals of the BTC and pharmacy drug classes (e.g., ensuring that consumers have sufficient information for the safe and appropriate use of drugs) were valid but concluded that use of these restricted classes resulted in reduced competition and higher costs to consumers, industry, and the government. As a result, the review recommended that standards be developed to facilitate a risk-based approach to pharmacist intervention in the supply of drugs to individual consumers and that research be conducted to determine the benefits obtained from such pharmacist intervention. See Galbally, Rhonda, *National Competition Review of Drugs, Poisons and Controlled Substances Legislation, Final Report Part A*, a special report prepared at the request of the State, Territory, and Commonwealth governments of Australia, December 2000. A report on the results of this research will be presented in 2011; the BTC and pharmacy drug classes will be retained if the report provides evidence to support doing so.

<sup>24</sup>The BTC drug class in the United Kingdom (called pharmacy medicines) has some characteristics of both the BTC and pharmacy classes as defined in figure 1. The United Kingdom makes these drugs available only in pharmacies under the supervision of a pharmacist and requires that they be stored behind the counter. The pharmacist establishes procedures so that all staff involved in the supply of these drugs should know when to refer a customer to the pharmacist. Although direct pharmacist–consumer contact is necessary for only some of these drugs, the requirement that pharmacists supervise the sale of all drugs in this class and store them behind the counter makes this class most similar to a BTC class.

**Table 1: Drug Classes Used in the Study Countries, 2008**

Drug class	Australia	Italy	Netherlands	United Kingdom	United States
<b>Prescription drugs</b>	X	X	X	X	X
<b>Nonprescription drugs</b>					
Subclasses:					
<i>BTC</i>	X			X	
<i>Pharmacy</i>	X		X		
<i>Drugstore</i>			X		
<i>OTC/pharmacist</i>		X			
<i>OTC</i>	X		X	X	X

Source: GAO analysis of agency data from the study countries.

Australia, the United Kingdom, and the United States have increased drug availability since 1995 by switching certain drugs from more restrictive to less restrictive drug classes.<sup>25</sup> For example, the United States switched 31 drugs—including nonsedating antihistamines, orlistat (a weight-loss aid), and levonorgestrel (an emergency contraceptive switched for consumers aged 18 and above)—from prescription to nonprescription status during this period; there were no switches from nonprescription to prescription status. Australia approved more than six times as many drug switches as the United States—193—to less restrictive classes in the same period. Australia does not require drugs to switch in a stepwise manner; for example, 28 percent of switches approved from 1995 to 2008—54 out of 193 switches—bypassed an intermediate class in favor of a less restrictive class (e.g., bypassing BTC when switching from prescription to pharmacy status). During this same period, an additional 67 drug switches resulted in more restrictive classification (e.g., from pharmacy to prescription).

The United Kingdom also switched drugs from more restrictive to less restrictive classes, approving more than 50 switches from prescription to BTC or BTC to OTC between 1995 and 2008. Among the switches approved were two that were the first of their kind for any country: the 2004 switch of a cholesterol-lowering statin—simvastatin—from prescription to BTC status and the 2008 switch of an antibiotic—

<sup>25</sup>In some cases, a switch in one country may have involved a drug that was not approved for use in one of the other countries or was not subject to regulation as a drug in another country.

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azithromycin for treatment of chlamydia—to BTC status.<sup>26</sup> In 2002, the United Kingdom began exploring ways to increase the number of drugs available without a prescription. As part of this process, the United Kingdom has changed its approach to nonprescription switches from a focus on switching drugs for short-term conditions to include drugs for chronic conditions. The United Kingdom uses a stepwise process in which drugs leaving prescription status are given BTC status for several years before they are considered for OTC sale. Thus the BTC drug class in the United Kingdom can serve as a transition class.

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### The Impact of Restricted Nonprescription Drug Classes on Drug Availability Is Unclear

It is unclear whether the presence of restricted nonprescription drug classes increases drug availability. The United States required a prescription for more of the drugs we examined than did the two study countries—Australia and the United Kingdom—using a BTC drug class in addition to other nonprescription drug classes. When we compared the classification status of 86 selected drugs in the five study countries, the United States required a prescription for 42 drugs while Australia and the United Kingdom each required a prescription for 23 of the drugs (see table 2). The United States had slightly more of the selected drugs available without a prescription than the two study countries—Italy and the Netherlands—that did not use a BTC drug class. (See app. III for further details on classification of these 86 drugs in the study countries.)

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<sup>26</sup>Chlamydia is a sexually transmitted disease that can damage a woman's reproductive organs. BTC azithromycin will be available only after a consumer purchases a chlamydia test kit from a pharmacy, sends a urine sample to an approved laboratory, and receives a positive result. The consumer can then visit a pharmacy where the test results will be confirmed via computer and azithromycin will be dispensed to the consumer and his or her partners.



**Table 2: Number of 86 Selected Drugs Assigned to Each Drug Class in the Study Countries**

Drug class	Number of drugs assigned to each drug class				
	Australia	Italy	Netherlands	United Kingdom	United States
Prescription drugs	23	43	45	23	42
Nonprescription drugs	63	43	41	63	44
Subcategories:					
<i>BTC</i>	11	NA <sup>a</sup>	NA <sup>a</sup>	34	NA <sup>a</sup>
<i>Pharmacy</i>	29	NA <sup>a</sup>	2	NA <sup>a</sup>	1 <sup>b</sup>
<i>Drugstore</i>	NA <sup>a</sup>	NA <sup>a</sup>	26	NA <sup>a</sup>	NA <sup>a</sup>
<i>OTC/pharmacist</i>	NA <sup>a</sup>	43	NA <sup>a</sup>	NA <sup>a</sup>	NA <sup>a</sup>
<i>OTC</i>	23	NA <sup>a</sup>	13	29	43
<b>Total (prescription + nonprescription)</b>	<b>86</b>	<b>86</b>	<b>86</b>	<b>86</b>	<b>86</b>

Source: GAO analysis of agency data from the study countries.

<sup>a</sup>Class does not exist in this country.

<sup>b</sup>In the United States, levonorgestrel (an emergency contraceptive) may only be sold in pharmacies—as a nonprescription drug for those 18 and over, and by prescription for those under 18.

However, the United States had more of the 86 selected drugs classified as OTC—the option that provides greatest availability of these drugs for consumers—than all other study countries. With the exception of levonorgestrel (an emergency contraceptive), all nonprescription drugs (43 drugs, or 98 percent) were OTC in the United States without any restrictions. In contrast, 54 to 100 percent of nonprescription drugs in the other four study countries had conditions placed on their sale that restricted their availability. These restrictions included limiting sale to pharmacies and requiring pharmacist involvement in the sale (Australia and the United Kingdom), limiting sales to pharmacies and drugstores (the Netherlands), or requiring a pharmacist to be on the premises at any retail outlet selling nonprescription drugs (Italy).

Therefore, an assessment of the restrictiveness of the drug distribution system in the United States compared to the other countries studied depends on the definition of availability. If availability is defined by the number of drugs available for OTC sale, the United States appears to have the least restrictive system, because more of the 86 drugs are available for OTC sale than in any of the other countries. However, if availability is defined by the number of drugs for nonprescription sale regardless of any other restriction on their sale, the United States is more restrictive than

Australia and the United Kingdom but slightly less restrictive than Italy and the Netherlands.

The classification of drugs in other countries and the existence of other classes provide little insight into the likely effect of a BTC drug class on nonprescription drug availability in the United States. It is unclear whether establishing a BTC drug class in the United States would allow more drugs to be switched out of the prescription class. We did not find a consistent association between the classification of particular drugs in our sample by a given country and the drug classification system in that country. For example, the United States gave less restrictive classification to some drugs and more restrictive classification to other drugs when compared to the other four study countries. Twelve drugs (14 percent) in the sample had OTC status in the United States but a more restrictive status in all of the other study countries, including two drugs with OTC status in the United States but prescription status in all of the other study countries (see table 3).

**Table 3: Drugs with OTC Status in the United States but a More Restrictive Status in All Other Study Countries**

Drug	Australia	Italy	Netherlands	United Kingdom	United States
Bacitracin ( <i>topical</i> )	Rx	OTC/P	Rx	Rx	OTC
Dextromethorphan	P	OTC/P	P	BTC	OTC
Insulin	Rx	Rx	Rx	Rx	OTC
Ketoprofen	BTC	OTC/P	D	BTC	OTC
Ketotifen	BTC	Rx	Rx	Rx	OTC
Miconazole ( <i>vaginal</i> )	BTC	OTC/P	Rx	BTC	OTC
Naproxen	P	OTC/P	D	BTC	OTC
Nizatidine	P	Rx	Rx	BTC	OTC
Omeprazole	Rx	Rx	D	BTC	OTC
Orlistat	BTC	Rx <sup>a</sup>	P	Rx <sup>b</sup>	OTC
Polymyxin B ( <i>topical</i> )	Rx	OTC/P	Rx	Rx	OTC
Tetracycline	Rx	Rx	Rx	Rx	OTC <sup>c</sup>

Legend: Rx = prescription; BTC = behind-the-counter; P = pharmacy; D = drugstore; OTC/P = over-the-counter (pharmacist required); OTC = over-the-counter.

Source: GAO analysis of agency data from the study countries.

Note: This table indicates the least restrictive class to which each drug was assigned regardless of pack size, dosage, or combination ingredients. Other formulations of a drug may only be available under a more restrictive class. For example, in the United States some types of insulin are available as prescription drugs and other insulin products are available OTC.

<sup>a</sup>On January 21, 2009, the European Commission approved orlistat (60 mg) for nonprescription use in the EU. At the time of this report, nonprescription orlistat was not yet available to consumers.

<sup>b</sup>In the United States, the topical dosage form of tetracycline is OTC.

Conversely, we found that seven drugs (8 percent) in the sample had prescription status in the United States and nonprescription status in all other study countries (see table 4).

**Table 4: Drugs with Prescription Status in the United States but Nonprescription Status in All Other Study Countries**

Drug	Australia	Italy	Netherlands	United Kingdom	United States
Aciclovir ( <i>topical</i> )	OTC	OTC/P	OTC	OTC	Rx
Diclofenac	P	OTC/P	D	OTC	Rx
Econazole	OTC	OTC/P	D	BTC	Rx
Hyoscine ( <i>Scopolamine</i> )	P	OTC/P	D	BTC	Rx
Lactulose	OTC	OTC/P	D	BTC	Rx
Nicotine ( <i>oral inhaler</i> )	P	OTC/P	D	OTC	Rx
Penciclovir	P	OTC/P	OTC	BTC	Rx

Legend: Rx = prescription; BTC = behind-the-counter; P = pharmacy; D = drugstore; OTC/P = over-the-counter (pharmacist required); OTC = over-the-counter.

Source: GAO analysis of agency data from the study countries.

Note: This table indicates the least restrictive class to which each drug was assigned regardless of pack size, dosage, or combination ingredients. Other formulations of a drug may only be available under a more restrictive class.

Additionally, we found that seven drugs (8 percent) in the sample had prescription status in the United States, Italy, and the Netherlands but had nonprescription status in Australia and the United Kingdom, the two countries with a BTC drug class (see table 5). Study countries without a BTC drug class, therefore, had reduced availability of a small percentage of drugs when compared with the study countries using a BTC drug class.

**Table 5: Drugs with Prescription Status in Countries without a BTC Drug Class but Nonprescription Status in Countries with a BTC Drug Class**

Drug	Australia	Italy	Netherlands	United Kingdom	United States
Beclometasone ( <i>nasal</i> )	P	Rx	Rx	OTC	Rx
Budesonide ( <i>nasal</i> )	P	Rx	Rx	BTC	Rx
Cyproheptadine	BTC	Rx	Rx	BTC	Rx
Fluticasone	P	Rx	Rx	BTC	Rx
Nitroglycerin	P	Rx	Rx	BTC	Rx
Nystatin	P	Rx	Rx	BTC	Rx
Theophylline	BTC	Rx	Rx	BTC	Rx

Legend: Rx = prescription; BTC = behind-the-counter; P = pharmacy; D = drugstore; OTC/P = over-the-counter (pharmacist required); OTC = over-the-counter.

Source: GAO analysis of agency data from the study countries.

Note: This table indicates the least restrictive class to which each drug was assigned regardless of pack size, dosage, or combination ingredients. Other formulations of a drug may only be available under a more restrictive class.

## Pharmacist-, Infrastructure-, and Cost-Related Issues Would Be Important Considerations if a BTC Drug Class Were Established

Pharmacist-, infrastructure-, and cost-related issues would have to be addressed before a BTC drug class could be established in the United States. Several issues involved with implementing a BTC drug class pertain to the roles and responsibilities of pharmacists, such as defining their BTC dispensing responsibilities and training needs. Infrastructure issues, such as establishing systems for the transfer of patient information and private consultation areas, would also be important if a BTC drug class were established. In addition, cost-related issues, such as the availability of third-party coverage for BTC drugs and counseling, would also be important considerations.<sup>27</sup>

<sup>27</sup>In addition to these issues, it would also have to be determined whether a BTC drug class could be established administratively by FDA or whether legislation would be necessary; however, this issue is beyond the scope of this report.

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## Issues Related to Pharmacists' Roles and Responsibilities Would Be Important to Consider if a BTC Drug Class Were Established

If the United States were to establish a BTC drug class, it would be important to establish pharmacists' responsibilities for dispensing BTC drugs. According to FDA, pharmacists' responsibilities for dispensing BTC drugs could include but are not limited to reviewing or conducting an initial screening for clinical laboratory results, contraindications, or drug interactions; advising consumers on safe drug use; and monitoring for continued safe or effective use. Additionally, a pharmacist could be required to document interventions with consumers when dispensing BTC drugs. Experts told us that dispensing procedures could vary depending on the product and disease. Determining whether a standard set of BTC dispensing requirements would apply to all pharmacies and pharmacists across the country would also be important. Determining whether BTC drugs could be sold through mail-order and Internet pharmacies—where physical observation of the consumer would not be possible—would be important, as well as determining whether pharmacists in these settings would need to fulfill additional dispensing requirements, such as using screening questions designed for remote counseling to ensure appropriate drug use.

Ensuring that pharmacists meet their responsibilities for dispensing BTC drugs, including providing necessary counseling, would be an important issue to resolve. One potential purpose of classifying drugs as BTC is for pharmacists to ensure that consumers meet specified criteria for using these drugs and then to provide education on the proper use of these drugs. Failure to ensure that such counseling occurs would diminish the value of a BTC drug class. In Australia, one of our study countries with a BTC drug class, a 2000 government-sponsored review of the drug classification system found that pharmacist counseling did not occur to the intended extent and called for an enhancement of professional standards for pharmacists. Australian agency officials told us that since the time of this report, pharmacists' provision of counseling for BTC drugs has improved with the development of counseling standards and clarification of legislative controls which regulate these professional standards. Professional associations have also played a role in monitoring the quality of pharmacist counseling in Australia. A study examining the Quality Care Pharmacy Support Centre's "mystery shopper" visits—used to monitor and provide feedback on Australian pharmacies' performance

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since 2002—found that repeated mystery shopper visits led to notable improvement in pharmacists’ handling of nonprescription drugs.<sup>28</sup>

FDA officials told us that, if a BTC drug class were created in the United States, FDA would need to work with the states to determine the mechanisms through which oversight would be provided. An official from the National Association of Boards of Pharmacy told us that, if a BTC drug class were created, the state boards of pharmacy would need to establish national standards for a number of issues, including the types of data systems, consumer interactions, documentation, and expertise required for a BTC practice. This official noted that it could be challenging for the state boards of pharmacy to provide oversight for a BTC drug class because of resource constraints. Pharmacy practice experts and others have also raised concerns that BTC verbal counseling requirements would need to be more stringent than the counseling requirements associated with the Omnibus Budget Reconciliation Act of 1990 (OBRA ‘90).<sup>29</sup> Under OBRA ‘90, consumers are allowed to waive their right to speak with a pharmacist, and according to pharmacy practice experts and others, many consumers do so. These experts told us that verbal counseling for a BTC drug class should be mandatory.

Another consideration in the establishment of a BTC drug class would be determining if additional training would be needed for pharmacists and pharmacy staff and assessing whether all pharmacists and pharmacy staff would need to undergo this training. In pharmacist education today, more emphasis is being placed on patient care and assessment than was the case in earlier years. To fulfill degree requirements, pharmacy students must now earn a Doctor of Pharmacy degree, for which they are required to complete a minimum of 4 academic years, with at least 30 percent of the program spent in clinical training in settings such as community

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<sup>28</sup>Australia’s Quality Care Pharmacy Support Centre, a joint effort of the Pharmacy Guild of Australia and the University of Sydney, has monitored the application of practice standards in community pharmacies since 2002. Mystery shopping involves researchers acting as consumers or potential consumers in order to monitor the quality of service delivery.

<sup>29</sup>See Pub. L. No. 101-508, § 4401(a)(3), 104 Stat. 1388, 1388-143 to 1388-161 (1990). As a result of OBRA ‘90, states participating in the Medicaid program must require pharmacists to offer to counsel Medicaid beneficiaries on matters which the pharmacist, in his or her professional judgment, deems significant, including special directions for preparation and administration, common severe side effects that may occur, and techniques for self-monitoring drug therapy. In addition, 45 states extended these counseling requirements to cover all individuals receiving prescriptions. J. C. Vivian and J. L. Fink III, “OBRA ‘90 at Sweet Sixteen: A Retrospective Review,” *U.S. Pharmacist*, vol. 33, no. 3 (2008).

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pharmacy, hospital pharmacy, ambulatory care, and acute care general medicine to develop advanced professional practice skills.<sup>30</sup> However, one study found significant variation in courses used to teach patient assessment skills—which have been mentioned as potentially important for pharmacists providing BTC counseling.<sup>31</sup> Further, pharmacists who received their education prior to the current shift toward patient care and assessment might not have the same skills and abilities as recent graduates. Consequently, several experts told us that additional training would be necessary for at least some pharmacists in order for them to appropriately dispense BTC drugs. At VA and IHS, where some pharmacists have expanded dispensing responsibilities and have been authorized to prescribe drugs, credentialing programs are used to assess pharmacists' competencies before they are granted expanded privileges. Pharmacy associations have indicated that they could design and administer training for a BTC drug class. It would also be necessary to determine whether all pharmacists and pharmacy staff would be required to be trained in BTC-related skills. For example, one retail chain we spoke with suggested that each pharmacy should have the discretion to designate certain pharmacies or pharmacists who would be responsible for dispensing BTC drugs. However, if BTC drugs were only dispensed at certain pharmacies or by BTC-accredited pharmacists, confusion about how to access BTC drugs could result.

To implement a BTC drug class, it would be important to evaluate whether a sufficient pharmacist workforce would be available to make such a program viable. Pharmacy practice experts told us that there is currently a pharmacist shortage that will continue for some time.<sup>32</sup> The Health Resources and Services Administration found that pharmacists have

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<sup>30</sup>The Accreditation Council for Pharmacy Education adopted the Doctor of Pharmacy degree as the sole professional practice degree offered by schools of pharmacy in the United States in 1997. The deadline for implementing the new standards for entering professional classes was in academic year 2000-2001, and the last student graduated from an accredited baccalaureate in pharmacy program in the academic year 2004-2005.

<sup>31</sup>J. W. Spray and S. A. Parnapy, "Teaching Patient Assessment Skills to Doctor of Pharmacy Students: The TOPAS Study," *American Journal of Pharmaceutical Education*, vol. 71, no. 4 (2007).

<sup>32</sup>The duration of the pharmacist shortage is uncertain. The supply of pharmacists is affected by factors such as the number of new graduates entering the workforce, the creation of new schools of pharmacy, annual hours of employment, and losses through death and retirement. K. K. Knapp and J. M. Cultice, "New Pharmacist Supply Projections: Lower Separation Rates and Increased Graduates Boost Supply Estimates," *Journal of the American Pharmacists Association*, vol. 47, no. 4 (2007).

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experienced increasing demand for their time in part because of an increase in prescription volume and in part because of the increased amount of time needed to address insurance coverage problems for prescriptions. In addition, experts we interviewed raised the possibility that some pharmacists might not want to take on the additional duties associated with dispensing BTC drugs, which could further reduce the number of pharmacists available to participate. In other countries, pharmacists have been unwilling at times to dispense BTC products. For example, a survey of 1,156 community pharmacists regarding their views and early experiences with BTC simvastatin (a cholesterol-lowering drug) in Great Britain revealed that pharmacists had a number of concerns and infrequently sold simvastatin.<sup>33</sup> Despite feeling well prepared to counsel on BTC simvastatin, pharmacists were still reluctant to dispense the drug without cholesterol or blood pressure testing—which was not required by the drug’s protocol—and therefore infrequently sold it.

Another example of this can be seen in Florida, which in 1985 authorized pharmacists to independently prescribe certain drugs.<sup>34</sup> Experts have stated that despite having this authority, pharmacists in Florida have rarely done so. Florida pharmacists’ rare use of their prescribing authority is primarily attributable to drugs being available without a prescription that are just as effective as those they are allowed to prescribe. Pharmacists were also concerned that they would increase their liability risk if they prescribed and they considered the recordkeeping requirements associated with prescribing a drug to be excessively time consuming. Having an inadequate number of pharmacists willing to carry out BTC functions could reduce the value of such a class.

Communicating pharmacists’ new role to the public could influence demand for products and services and would be an important issue for the implementation and viability of a BTC drug class. Experts have stated that consumers would need to understand protocols for obtaining BTC drugs, such as the necessity of consulting with a pharmacist before obtaining a BTC drug. Consumers would also need to be aware that, after a consultation, the pharmacist could decide that a BTC drug is not appropriate for the consumer or that a physician visit is necessary. If a BTC drug class were established in the United States, consumers might

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<sup>33</sup>BTC simvastatin is indicated to reduce the risk of a first major coronary event in individuals who are likely to be at moderate risk of such events.

<sup>34</sup>See 1985 Fla. Laws ch. 85-35.



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need time to adjust to pharmacists' new role under such a class. For example, in the United Kingdom, which has had a BTC drug class since 1968, pharmacists have expressed concerns that consumers have a poor understanding of the pharmacist's role. Researchers have suggested that marketing pharmacists' professional services could help to create a demand for these services. Officials with the United Kingdom Department of Health consider increasing the public's awareness of pharmacist services to be a goal. According to these officials, while some consumers are comfortable obtaining health advice through a pharmacy, very few use a pharmacy's full range of services.<sup>35</sup>

In implementing a BTC drug class, it would be important to determine whether restrictions on the size of a BTC drug class are necessary. Experts raised concerns that if a BTC drug class were too large or if whole categories of drugs switched to BTC at once, it could overwhelm pharmacies because of the time burden involved in dispensing these drugs and the need to train pharmacists and pharmacy staff on new procedures associated with BTC drugs. As a consequence, this situation could create unintended gaps in care by disrupting pharmacies' regular prescription dispensing duties or interfering with their ability to provide BTC drugs. For instance, pharmacists in the United Kingdom found following different dispensing procedures for multiple drugs to be burdensome. Their ability to make appropriate recommendations was hampered by the time involved in following these procedures. However, some pharmacy officials we spoke with told us that restricting the size of a BTC drug class would not be necessary because pharmacists are accustomed to managing a large number of drugs for various individuals.

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### Infrastructure Issues Would Be Important Considerations in the Establishment of a BTC Drug Class

An assessment of infrastructure needs would be important to the establishment of a BTC drug class in the United States. Implementing a BTC drug class could entail infrastructure changes for pharmacies so that pharmacists could have better patient information on which to base dispensing decisions. For example, data infrastructure enhancements would be necessary for some pharmacies to meet the possible record-keeping requirements of a BTC drug class and to facilitate communication between pharmacists and physicians. Other countries consider

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<sup>35</sup>United Kingdom Department of Health, *Pharmacy in England: Building on Strengths—Delivering the Future* (Norwich, 2008). Also available online at <http://www.official-documents.gov.uk/document/cm73/7341/7341.asp> (accessed Oct. 8, 2008).

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information-sharing systems important for supporting physician–pharmacist communication. For example, in the Netherlands, physicians and pharmacists communicate regularly through electronic prescribing systems, and health officials are developing a system that physicians and pharmacists can use to share patient-specific drug data. Electronic patient health information, such as laboratory results and diagnoses, could also help U.S. pharmacists make better decisions when dispensing BTC drugs. Although commentators note that most state regulations require that a patient drug profile be maintained at the pharmacy and reviewed prior to dispensing a drug, pharmacies currently have limited access to electronic patient health information.<sup>36</sup> For example, a study of Nebraska pharmacists found that 6 percent of surveyed pharmacists had access to electronic patient health information from other providers. Additionally, a 2003 survey of community pharmacies from across the United States found that 54 percent of the respondent pharmacies were using a paper documentation system.<sup>37</sup> Researchers have found several challenges associated with a paper system, all of which could impact implementation of a BTC drug class; these challenges include documentation time, retrieval of patient data, tracking consumer outcomes, and storage. Improving pharmacists’ access to patient information has been shown to improve decision-making. One study found that pharmacists performing drug utilization reviews made better decisions when they had access to more complete patient information on which to base decisions.<sup>38</sup>

The need for private pharmacy consultation areas is another important infrastructure issue that would require consideration if a BTC drug class were implemented. Several groups have identified a need to establish

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<sup>36</sup>D.B. Christensen and K.B. Farris, “Pharmaceutical Care in Community Pharmacies: Practice and Research in the US,” *The Annals of Pharmacotherapy*, vol. 40, no. 7 (2006). Pharmacists may also have difficulty transferring patient information to physicians electronically. In a national survey, 4 percent of physicians reported having an extensive, fully functioning electronic health records system—13 percent of physicians reported having a basic system. See C. M. DesRoches, et al., “Electronic Health Records in Ambulatory Care—A National Survey of Physicians,” *New England Journal of Medicine*, vol. 359, no.1 (2008).

<sup>37</sup>This is the most recent survey that we identified of community pharmacies that examined pharmacies’ use of paper and electronic documentation systems. It is likely that the percentage of pharmacies using electronic documentation systems has increased since 2003.

<sup>38</sup>T. Warholak-Juarez, et al., “Effect of Patient Information on the Quality of Pharmacists’ Drug Use Review Decisions,” *Journal of the American Pharmacists Association*, vol. 40, no. 4, 2000.

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private counseling areas in pharmacies to ensure consumer privacy. Consumers might be reluctant to receive counseling from pharmacists if they have concerns about privacy. A study of Dutch pharmacies indicated that if individuals are aware that a pharmacy has a separate consultation room, they might be more likely to seek a private consultation with a pharmacist.<sup>39</sup> Similarly, researchers have found that enclosed counseling areas in Australian pharmacies increase the likelihood that screening activities and other enhanced pharmacy services occur.<sup>40</sup> One pharmacy practice expert told us that the majority of Australian pharmacies are including private consultation areas when updating their infrastructure.<sup>41</sup> If private consultation rooms were required as part of a BTC drug class, U.S. pharmacies could incur costs to remodel their facilities. Although the National Association of Boards of Pharmacy currently recommends that U.S. pharmacies have a private area for confidential conversations, states have varied in requiring these areas.<sup>42</sup>

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### Cost-Related Issues for Drugs, Pharmacists' Services, and Drug Switches Would Be Important Considerations in Establishing a BTC Drug Class

Several cost-related issues would be important for the establishment of a BTC drug class. One consideration would be the availability of third-party coverage of BTC drugs. Pharmacy association and consumer group officials we spoke with told us that the effect of a BTC drug class on consumers' out-of-pocket drug expenses would depend on the reimbursement decisions of third-party payers such as health insurers, who often pay all or most of the cost of prescription drugs but generally do not pay for OTC products. A 1999 review of insurance plan benefits reported that less than one-third of plans covered selected OTC products

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<sup>39</sup>M. P. Mobach, "The Counter and Consultation Room Work Explored in the Netherlands," *Pharmacy World & Science*, vol. 30 (2008).

<sup>40</sup>C. G. Berbatis, et al., "Enhanced Pharmacy Services, Barriers and Facilitators in Australia's Community Pharmacies: Australia's National Pharmacy Database Project," *International Journal of Pharmacy Practice*, vol. 15 (2007); and Andrew Joyce, et al., "Analysis of Primary Prevention Service for Cardiovascular Disease in Australia's Community Pharmacies," *Australian and New Zealand Journal of Public Health*, vol. 31, no. 6 (2007).

<sup>41</sup>Australia's Quality Care Pharmacy Program Standards require that community pharmacies maintain a Professional Services Area that, among other requirements, is easily identifiable by consumers as the area of the pharmacy from which therapeutic products are available and that will accommodate privacy and confidentiality requirements.

<sup>42</sup>Regulations implementing title II of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, require most health providers, including pharmacists, to have in place appropriate physical safeguards to protect the privacy of health information. See 45 C.F.R. §164.530(c)(2008).

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and that less than one-third of plans continued to cover products switched from prescription to OTC status.<sup>43</sup> A 2003 study found that although 39 of 43 state Medicaid programs reporting in 2003 covered some OTC drugs when ordered by a prescriber, only 12 provided coverage for OTC drugs that switched from prescription to OTC.<sup>44</sup> HHS officials told us that legislative changes might be necessary to allow for Medicare Part D coverage of BTC drugs. A similar consideration concerns drugs now covered under the Medicaid program. If third-party payers do not reimburse consumers for drugs that were switched from prescription to BTC, consumers' out-of-pocket expenditures could increase.

The cost of nonreimbursable BTC drugs could also affect the extent to which consumers use BTC drugs. Evidence from other countries suggests that drug costs can be prohibitive to consumers. In the view of pharmacists in Great Britain, the high cost of BTC drugs such as omeprazole, especially relative to prescription or OTC alternatives, might deter consumers from using the drug.<sup>45</sup> Another expensive BTC drug in the United Kingdom is simvastatin, which is intended for use by individuals who do not qualify for National Health Service coverage of statin treatment. However, according to pharmacists, the high cost of the drug could discourage some consumers from using it. Officials with the Medicines Evaluation Board of the Netherlands told us that consumers often oppose switches of drugs from prescription to pharmacy status because they lose insurance coverage when a drug becomes nonprescription. Therefore, in the Netherlands, prescription drugs that are not already covered by insurance are more likely to be considered viable switch candidates for pharmacy class status. A survey of individuals with indigestion or hypertension found that about half of all Italian respondents—regardless of their ability to pay for drugs—had obtained prescriptions for drugs that were available OTC in order to obtain

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<sup>43</sup>Novartis Pharmaceuticals Corporation, "Novartis Pharmacy Benefit Report, Facts & Figures, 2001 ed.," (East Hanover, N.J., 2001).

<sup>44</sup>J. S. Crowley, et al., "Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003," Kaiser Commission on Medicaid and the Uninsured (Washington, D.C., 2003).

<sup>45</sup>Great Britain includes England, Scotland, and Wales, while the United Kingdom includes Great Britain and Northern Ireland.

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insurance coverage because they considered the OTC products too expensive.<sup>46</sup>

The availability of third-party coverage for BTC counseling could influence pharmacists' involvement in a BTC drug class and the quality of pharmacists' services, and third-party coverage for BTC counseling could also increase drug prices. Officials from the American Pharmacists Association have raised concerns about whether it would be financially feasible for pharmacies to carry BTC drugs unless pharmacists were able to bill and be fully paid for the clinical services that might be required for a BTC drug class. In addition to influencing pharmacists' willingness to participate in a BTC drug class, whether or not pharmacists are compensated might also affect their performance. One study of the factors that increase the prevalence of patient care services in community pharmacies found that paying pharmacists increased their detection of drug-related problems.<sup>47</sup> Another study found that providing pharmacists with a financial incentive was associated with significantly higher documentation levels and higher advanced service levels.<sup>48</sup> A counseling fee could lead to higher drug prices if pharmacist compensation were included in the price of BTC drugs. However, consumers might be willing to pay more for BTC drugs if they consider pharmacist services valuable. A survey of 2,500 adults in the United States found that the majority of respondents were willing to pay an out-of-pocket fee for pharmaceutical care services, even if they were not currently receiving such services.<sup>49</sup> Third-party payers might also be willing to cover pharmacist services. In one diabetes management study, self-insured employers reimbursed pharmacists for consultation services, and based on the clinical

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<sup>46</sup>V. Atella, et al., "Affordability of Medicines and Patients' Cost-Reducing Behaviour: Empirical Evidence Based on SUR Estimates from Italy and the UK," *Applied Health Economics and Health Policy*, vol. 4, no. 1 (2005).

<sup>47</sup>D. B. Christensen and R. W. Hansen, "Characteristics of Pharmacies and Pharmacists Associated with the Provision of Cognitive Services in the Community Setting," *Journal of the American Pharmaceutical Association*, vol. 39, no. 5 (1999).

<sup>48</sup>D. B. Christensen, et al., "Frequency and Characteristics of Cognitive Services Provided in Response to a Financial Incentive," *Journal of the American Pharmaceutical Association*, vol. 40, no. 5 (2000).

<sup>49</sup>Pharmaceutical care services were described in the survey as pharmacists consistently providing detailed counseling, monitoring outcomes, determining the appropriateness of drugs based on individual medical history, and consulting with physicians on prescriptions. See R. A. Larson, "Patients' Willingness to Pay for Pharmaceutical Care," *Journal of the American Pharmaceutical Association*, vol. 40, no. 5 (2000).

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improvements and financial savings associated with the diabetes management program, decided to retain the program as a permanent component of their health plan benefit.<sup>50</sup>

Compensation for BTC services might be necessary to offset increased liability. Additional liability could be incurred by pharmacists and pharmacies as a result of their participation in BTC counseling. Pharmacy officials raised the possibility that pharmacists participating in the implementation of a BTC drug class could have a greater exposure to liability because they would dispense drugs without a physician's order. Concerns about liability might deter pharmacists from dispensing BTC drugs. For instance, such concerns were cited by pharmacists in Florida who were hesitant to use their prescribing authority.

Costs might also be affected by new incentives necessary to encourage drug manufacturers to invest funds in a two-stage switch process (from prescription to BTC and then from BTC to OTC). Clinical trials, including actual use studies, are often conducted to help determine whether a drug could be switched from prescription to OTC, and an FDA official indicated that these trials may also be needed to determine if a product could be switched from prescription to BTC and from BTC to OTC. Currently, drug manufacturers may receive 3 additional years of exclusive marketing rights for drugs switched from prescription to OTC status if the switch requires additional clinical trials.<sup>51</sup> Some FDA officials and manufacturers we spoke with believe it might be necessary to provide manufacturers with exclusive marketing rights for drugs switching from prescription to BTC status and also for BTC-to-OTC switches. It is unclear what period of exclusivity would make drug manufacturers' investment in clinical studies for prescription-to-BTC and BTC-to-OTC switches worthwhile. However, FDA noted that granting this additional period of market exclusivity could reduce competition.

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<sup>50</sup>C. W. Cranor, et al., "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program," *Journal of the American Pharmaceutical Association*, vol. 43, no. 2 (2003).

<sup>51</sup>21 U.S.C. § 355(c)(3)(E)(iv).

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## Agency Comments and Our Evaluation

HHS provided comments on a draft of this report. The comments are reproduced in appendix IV. In its comments HHS agreed that cost-related issues would have to be addressed before implementing a BTC drug class.

HHS recommended that GAO add a discussion regarding the statutory authority to provide reimbursement under Medicare Part D for drugs that would be included in a BTC drug class if it were to be created. Such discussion is beyond the scope of this report, but we noted in the report that the ramifications for Medicare, as well as Medicaid, would need to be considered before establishment of a BTC drug class.

HHS also suggested that a footnote in the report could mislead the reader to believe that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires pharmacists to review Medicare beneficiaries' prescription drug regimens as a component of MTM under Medicare Part D. While pharmacists are required to participate in the development of such programs, we added text to the main body of the report to clarify that MMA does not require that pharmacists furnish the services provided in MTM programs but also does not prohibit them from doing so.

HHS stated that while MMA required Part D sponsors to implement MTM programs, the Part D program does not establish any payment schedules for either physicians or pharmacists performing MTM. HHS was concerned that a footnote in the report might be read to mean that MMA specified such a payment schedule. We have revised the text to clarify that MMA does not specify a payment schedule but that CMS often uses a rate that is 80 percent of the physician rate to determine their payments under Medicare.

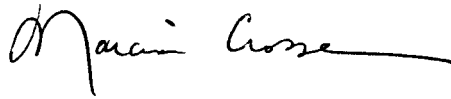
In addition, HHS and VA provided technical comments on the report draft, which we have incorporated as appropriate.

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As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, the Commissioner of the Food and Drug Administration, committees, and others. The report also will be available at no charge on the GAO's Web site at <http://www.gao.gov>.

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If you or your staff have questions about this report, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal line extending to the right.

Marcia Crosse  
Director, Health Care



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# Appendix I: Objectives, Scope, and Methodology

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## Objectives

In light of the November 2007 Food and Drug Administration (FDA) public meeting to explore the public health implications of behind-the-counter (BTC) availability of certain drugs in the United States and the fundamental change that BTC availability would represent in the U.S. drug classification system,<sup>1</sup> we are updating information we first presented in our 1995 report.<sup>2</sup> Specifically, we are reporting on (1) the arguments that have been made supporting and opposing the creation of a BTC drug class in the United States; (2) changes in drug availability in our five study countries<sup>3</sup> since 1995 and the impact of restricted nonprescription drug classes on drug availability; and (3) issues that would be important to the establishment of a BTC drug class.

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## Scope and Methodology

To describe the arguments that have been made supporting and opposing a BTC drug class in the United States, we reviewed published literature, reports, and meeting minutes of FDA hearings on prescription-to-over-the-counter (OTC) switches, and the transcript of and docket submissions for the November 2007 FDA meeting on BTC drug availability.<sup>4</sup> We interviewed officials at FDA, pharmacy associations, drug manufacturers, consumer groups, and industry associations in the United States. We also interviewed academics and other officials knowledgeable about pharmaceutical practice.

To determine the impact of restricted nonprescription drug classes on drug availability, we interviewed experts to ask them to help us identify countries that had evaluated drug classification in their countries since our 1995 report. Based on this information, we selected 5 of the 11

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<sup>1</sup>While our study defined BTC drugs as those that require the intervention of a pharmacist, FDA noted that there may be other models for providing access to these drugs. They stated that these may include other health care personnel (e.g., nurse practitioners or physician assistants) providing access to BTC drugs in various professional settings.

<sup>2</sup>GAO, *Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated*, GAO/PEMD-95-12 (Washington, D.C.: Aug. 24, 1995), [www.gao.gov/archive/1995/pe95012.pdf](http://www.gao.gov/archive/1995/pe95012.pdf).

<sup>3</sup>In addition to the United States, the study countries are Australia, Italy, the Netherlands, and the United Kingdom. We also describe drug classification in the European Union (EU).

<sup>4</sup>One issue that has been raised, but is beyond the scope of this report, is whether FDA has the regulatory authority to create such a class without a legislative change.

countries covered in our previous report.<sup>5</sup> We also examined drug classification in the European Union (EU) because these factors affect drug availability in three of our study countries. We reviewed published literature, reports, and agency documents on drug classification and prescription-to-nonprescription switches. We also interviewed agency officials, industry representatives, and others knowledgeable about pharmaceutical practices and the relevant laws and regulations in our study countries.<sup>6</sup> Although some countries—including the United States—place additional restrictions on certain prescription drugs, a complete analysis of prescription drug classification was beyond the scope of this report.<sup>7</sup> For our analysis, all prescription drugs were placed in the same class. We examined changes since 1995 in the drug classification systems in two study countries (Italy and the Netherlands) that changed the number or type of nonprescription drug classes in use. We also determined the number of drugs switched from one drug class to another (e.g., prescription to BTC) between 1995 and 2008 for the three study countries—Australia, the United Kingdom, and the United States—that maintained the same number and type of nonprescription drug classes during that time. We examined relevant documents and interviewed knowledgeable officials in those countries. We counted the first switch of a particular drug (e.g., ibuprofen) from one drug class to another that occurred after January 1, 1995, but did not count subsequent switches of additional products containing the same drug between the same two drug classes (except in the case of different nicotine dosage forms such as gum and patches) in order to achieve consistency with the World Self-Medication Industry (WSMI) data discussed below.<sup>8</sup> We also did not count switches that changed only the allowable dosage, pack size, or indications for a drug that had previously been switched. In some cases, a switch in one country may have involved a drug that was not approved for use in

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<sup>5</sup>In addition to the United States, in our previous report we examined the drug classification systems in Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, the United Kingdom, and the EU ([GAO/PEMD-95-12, 85-103](#)). In this report, the study countries are Australia, Italy, the Netherlands, the United Kingdom, and the United States.

<sup>6</sup>We did not perform the legal analysis of any laws and regulations of foreign jurisdictions, but relied on summaries provided by those jurisdictions.

<sup>7</sup>For example, some prescription drugs classified in the United States as controlled substances cannot be refilled and have stricter documentation requirements than ordinary prescription drugs.

<sup>8</sup>WSMI is a federation of more than 50 member associations representing manufacturers and distributors of nonprescription medicines.

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one of the other countries or was not subject to regulation as a drug in another country.

Additionally, we determined the classification of selected drugs in the United States and the other study countries. We selected a sample of drugs using the WSMI databases that describe the classification status—prescription or nonprescription—of more than 200 drugs in 36 countries.<sup>9</sup> We used the February 1, 2007, tables; these were the most recent tables available at the time we were conducting our study. We excluded from the list any drugs listed as “not registered” or with a blank entry for Australia, the Netherlands, the United Kingdom, or the United States; a sample of 110 drugs resulted. We examined the survey format used to collect information on drug classification and response rates from the most recent survey, and determined that the data were sufficiently reliable for our purposes. After drawing the initial sample from the WSMI tables, we added Italy to our scope. We then determined the classification status of the sample drugs in each of the study countries using agency information including information from knowledgeable agency officials and an examination of the Standard for the Uniform Scheduling of Drugs and Poisons No. 22 (Australia); the *Prontuario Farmaceutico Nazionale* and the *Elenco indicativo dei farmaci SOP e OTC in commercio con prezzo in vigore al 31/12/2006 ai sensi del comma 802 dell’art. 1 Legge 27 dicembre 2006, n. 296* (Italy); the Medicines Evaluation Board Database Human Medicines (Netherlands); List A: Consolidated list of substances which are present in prescription only medicines (POM), with exemptions for pharmacy sale or supply (P), List B: Consolidated list of substances which are present in authorised medicines for general sale, and List C: Consolidated list of substances which are present in authorised products which have been reclassified since 1 April 2002 (United Kingdom); the list of Approved Drug Products with Therapeutic Equivalence Evaluations, 28th Edition (i.e., the Orange Book) (United States); and other agency documents. The data in these reference documents are standard data sources published by each country’s regulatory authority and were sufficiently reliable for our purposes. We found that 24 of the 110 drugs in our initial sample were not approved in one or more of the five study countries and eliminated these drugs from our sample, resulting in a final sample of 86 drugs. We then compared the classification of these drugs across the five study countries

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<sup>9</sup>Methodology adapted from A. Gilbert, D. Rao, and N. Quintrell, “A Review of Pharmaceutical Scheduling Processes in Six Countries and the Effect on Consumer Access to Medicines,” *International Journal of Pharmacy Practice*, vol. 14, no. 2 (2006).

in order to determine the least restrictive class to which each drug was assigned regardless of pack size, dosage, or combination ingredients.

To identify issues that would be important to the establishment of a BTC drug class in the United States, we interviewed officials at FDA, the Centers for Medicare & Medicaid Services (CMS), the Department of Veterans Affairs (VA), the Indian Health Service (IHS), pharmacist associations, drug manufacturers, consumer groups, and industry associations. We interviewed academics and other experts knowledgeable about pharmacists' prescribing authority, including individuals who have testified to FDA on the possible creation of a BTC drug class in the United States. We also interviewed agency officials, industry representatives, pharmacist association representatives, and others knowledgeable about pharmacy practices in our other study countries. We reviewed reports and the transcript of and docket submissions for the November 2007 FDA meeting on BTC drugs. We also reviewed published, peer-reviewed pharmacy practice literature, focusing on articles published since our 1995 report and relating to the United States or our other study countries. For this literature review, we searched 67 databases, including International Pharmaceutical Abstracts, EMBASE, Pharmaceutical News Index, Gale Group Health & Wellness Database, Pharm-Line, Science Citation Index, and MEDLINE. Key search terms used were pharmacy practice, pharmacist counseling, pharmacist intervention, pharmacist prescribing authority, pharmaceutical care, collaborative practice, medication therapy management, drug classification, and drug reclassification. We also reviewed literature cited in these studies and studies recommended to us by those we interviewed.

We conducted our work from March 2008 through February 2009 in accordance with all sections of GAO's quality assurance framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

# Appendix II: Description of Drug Classification Systems in the Five Study Countries and the European Union

In this appendix, we describe the drug classification systems in our five study countries—Australia, Italy, the Netherlands, the United Kingdom, and the United States. We also describe drug classification in the EU because it affects drug availability in three of our study countries. Although the terms used for different drug classes are included for each country, a standardized set of terminology is also used to facilitate comparisons (see fig. 2).

**Figure 2: Definitions and Relative Levels of Restriction for Drug Classes Used in This Report**

Term used in the report	Definition	Levels of restriction
<b>Prescription drugs</b>		
Prescription	Available only from a pharmacist or other licensed dispenser upon submission of a prescription	Most restrictive
<b>Nonprescription drugs</b>		
BTC	Available only in pharmacies; contact with pharmacist required	
Pharmacy	Available only in pharmacies; contact with pharmacist not required	
Drugstore	Available only in pharmacies or drugstores; contact with pharmacist not required <sup>a</sup>	
OTC/pharmacist	Available for self-selection in pharmacies and other retail outlets, but a pharmacist must be present	
OTC	Available for self-selection in pharmacies and other retail outlets, including those without pharmacists or druggists	

Source: GAO analysis of agency documents from the study countries.

<sup>a</sup>In the Netherlands, a distinction is made between pharmacies (run by pharmacists and able to sell all prescription and nonprescription drugs) and drugstores (run by druggists with less training than pharmacists and able to sell only some nonprescription drugs).

## Australia

The Therapeutic Goods Administration within the Department of Health and Ageing is responsible for the evaluation and approval of new drugs in Australia. The National Drugs and Poisons Schedule Committee makes recommendations on the appropriate classification of drugs and is also

responsible for all decisions to switch a drug from one class to another.<sup>1</sup> Generally, the committee requires that a drug be marketed for 2 years before it will consider allowing it to move to a less restrictive classification; applications that do not meet this requirement may be considered when sufficient evidence is presented. While each state or territory has the authority to determine drug classification independently, all states and territories agreed in 2005 to adopt the national scheduling committee's decisions in full in order to reduce barriers to commerce in Australia.<sup>2</sup>

Australia has a complex, multilevel classification system for drugs that includes

- Schedule 2 (equivalent to pharmacy),
- Schedule 3 (equivalent to BTC),
- Schedule 4 (equivalent to prescription),
- Schedules 5 and 6 (certain essential oils for human therapeutic use, as well as household and agricultural chemicals); available without a prescription at nonpharmacy outlets, and
- Schedule 8 (controlled substances for which restrictions on availability are necessary to reduce abuse, misuse, or dependence; e.g., opioids and amphetamines).

Additionally, if a substance does not appear in a schedule, it is referred to as unscheduled; unscheduled drugs can be supplied to the public from any retail outlet (i.e., these are OTC drugs).<sup>3</sup> Schedule 1 (formerly containing a number of toxic volatile oils) is not currently in use; Schedule 7 contains dangerous agricultural and industrial poisons; and Schedule 9 contains

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<sup>1</sup>The National Drugs and Poisons Schedule Committee also determines the classification of agricultural, veterinary, and household chemicals.

<sup>2</sup>Rhonda Galbally, *National Competition Review of Drugs, Poisons and Controlled Substances Legislation, Final Report Part A*, a special report prepared at the request of the State, Territory, and Commonwealth governments of Australia, December 2000, 27.

<sup>3</sup>Except in Queensland and South Australia, where an unscheduled new drug or poison is deemed to be a prescription drug until the classification is determined by the National Drugs and Poisons Schedule Committee.

substances whose manufacture, possession, sale, or use is prohibited except under specific circumstances (e.g., heroin and cannabis).<sup>4</sup>

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## Italy

The Italian Pharmaceutical Agency (l'Agenzia Italiana del farmaco), an autonomous agency under the oversight of the Ministry of Health, authorizes the marketing of drugs in Italy. The agency is assisted by the Scientific and Technical Committee which evaluates and issues opinions on marketing applications. Italy currently has the following drug classes:

- prescription, and
- nonprescription.<sup>5</sup>

All nonprescription drugs in Italy are available for sale in nonpharmacy outlets such as supermarkets as long as a pharmacist is on the premises. The requirement that a pharmacist be present wherever nonprescription drugs are sold means that nonprescription drugs in Italy are in an OTC/pharmacist class. However, Italian officials are evaluating the possibility of making small packs of some drugs available in nonpharmacy outlets without the presence of a pharmacist.

The agency is also responsible for the decision to switch drugs from one classification to another. Switches from prescription to nonprescription status are generally initiated by the manufacturer; switches from nonprescription to prescription status are much less frequent. Drugs can also be switched from prescription to more restrictive classification on rare occasions for safety reasons.

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## Netherlands

The Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen) is responsible for drug approval and classification in the Netherlands. The Medicines Evaluation Board is also responsible for approving requests to switch a drug; requests for OTC classification must be initiated by the company holding the marketing authorization.

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<sup>4</sup>The specific circumstances are when use of the substance is required for medical and scientific research, or for analytical, teaching, or training purposes with the approval of the Australian government and/or state or territory health authorities.

<sup>5</sup>Italy subdivides its nonprescription drugs into two categories based on whether they can be advertised to the public; there is no other difference between the two categories.

The drug classification system in the Netherlands includes four categories:

- prescription,
- pharmacy only (equivalent to pharmacy),
- pharmacy and drugstore (equivalent to drugstore), and
- general sale (equivalent to OTC).

The last three categories are all nonprescription and differ primarily in the locations at which the drugs are available for sale. OTC classification in the Netherlands is based, in part, on a determination of public benefit and the risk–benefit profile of the drug. The drugstore class is the default class for all nonprescription drugs that do not meet the criteria for pharmacy or OTC sale. In the Netherlands, the distinction between drugstore and OTC classification is often based on the dosage or pack size; large pack sizes or higher dosages of a drug might be restricted to pharmacies and drugstores even when smaller pack sizes or lower dosages are available for OTC sale. The pharmacy class in the Netherlands is reserved for drugs requiring interaction with pharmacy staff although not necessarily a pharmacist; agency officials told us that they do not expect to place many drugs into this class. At the time of our analysis, six drugs were assigned to the pharmacy class: domperidone (to suppress nausea), orlistat (weight loss aid), aliskiren (treatment of hypertension), clotrimazole (antifungal agent), hexamidine, and dextromethorphan (cough suppressant).

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## United Kingdom

The Medicines and Healthcare products Regulatory Agency (MHRA) within the Department of Health is responsible for drug approval and classification in the United Kingdom. The United Kingdom continues to use the three-tier drug classification system that was in place in 1995. This system includes

- prescription only (equivalent to prescription),



- pharmacy (equivalent to BTC),<sup>6</sup> and
- general sale list (equivalent to OTC).

The presumption under law is that all drugs are restricted to the BTC drug class unless they meet the criteria for prescription or OTC status.<sup>7</sup>

MHRA encourages wider availability of drugs as soon as there is adequate evidence of safety in use. Manufacturers or other interested parties can initiate switches, which proceed in a stepwise manner (prescription to BTC, then BTC to OTC). Experience gained at one level is used to inform the decision to switch the drug to the next level. For example, MHRA guidelines indicate that substances suitable for OTC classification will have been in widespread use in BTC products for many years. Switching to more restrictive classes can also occur when warranted; this was done for large pack sizes of paracetamol in 1998 in an attempt to reduce adverse events associated with this drug.

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## United States

In the United States, FDA has authority to approve drugs before they are marketed, to ensure that they are safe and effective, and to determine whether they will be available only by prescription. The United States uses a two-class drug system—prescription and nonprescription—established by the 1951 Durham-Humphrey Amendments to the Federal Food, Drug, and Cosmetic Act.<sup>8</sup> Prescription drugs can be dispensed only with written or oral orders (i.e., a prescription) from a licensed prescriber—such as a doctor, nurse practitioner, or physician’s assistant—to a pharmacist or other licensed dispenser, while nonprescription drugs do not require a prescription. Although most nonprescription drugs in the United States are publicly available without any restrictions, a few are stored behind the

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<sup>6</sup>The BTC drug class in the United Kingdom (called pharmacy medicines) has some characteristics of both the BTC and pharmacy classes as defined in figure 2. The United Kingdom makes these drugs available only in pharmacies under the supervision of a pharmacist and requires that they be stored behind the counter. The pharmacist establishes procedures so that all staff involved in the supply of these drugs should know when to refer a customer to the pharmacist. Although direct pharmacist–consumer contact is necessary for only some of these drugs, the requirement that pharmacists supervise the sale of all drugs in this class and store them behind the counter makes this class most similar to a BTC class.

<sup>7</sup>The Medicines Act 1968 and EU Directive 2001/83/EC.

<sup>8</sup>Pub. L. No. 82-215, 65 Stat. 648 (1951).

counter due to refrigeration requirements (e.g., insulin), to monitor quantity of purchase (e.g., pseudoephedrine), or are restricted to pharmacy sale in order to monitor consumer age (e.g., levonorgestrel). Nonprescription drugs are often referred to in the United States as OTC drugs.

Between 1995 and 2007, FDA assigned 99.7 percent (1233 out of 1237) of newly approved drugs to the prescription class, with four new drugs—a topical herpes simplex treatment, a sunscreen product, a nicotine lozenge, and a product to block contact with poison ivy—classified as nonprescription. Drugs can be switched from prescription to OTC status in a number of ways, including through rulemaking or submission of a supplemental new drug application to FDA by the sponsor. In making switch decisions, FDA may seek advice from the Nonprescription Drugs Advisory Committee, often in conjunction with an appropriate specialty committee (e.g., the Pediatric Advisory Committee or the Gastrointestinal Drugs Advisory Committee). Although not bound by the advisory committee's advice, FDA follows the committee's recommendation most of the time.

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## European Union

The Pharmaceuticals Unit of the European Commission Directorate General for Enterprise and Industry is responsible for approving new drugs submitted for marketing throughout the EU, and the European Medicines Agency makes a recommendation on whether the new drug should receive prescription or nonprescription status. The EU leaves to each member state the decision on whether to use subcategories within the prescription and nonprescription classes. Pharmacy experts told us that European countries have a long tradition of restricting drug sales to pharmacies and that about 60 percent of EU countries do not have an OTC drug class.

There are four primary methods to receive marketing approval for a drug in the EU. These include national authorization procedures that allow a drug to be marketed in a specific country based on an individual application and for which the classification decision is made by the appropriate national authority, plus three methods that are handled at the EU level:

- The centralized approval procedure allows applicants to market an approved product throughout the EU with a single application.

- The mutual recognition procedure can be used to request that a drug approval from one EU country be recognized as valid in one or more other EU countries.
- The decentralized procedure allows a company to apply for simultaneous approval in multiple EU countries for a drug that is not yet approved in any EU country.

Centralized approval is required for certain categories of drugs, including all drugs developed through biotechnology; drugs for the treatment of certain diseases, including acquired immunodeficiency syndrome (AIDS), cancer, neurodegenerative diseases, diabetes, and autoimmune diseases; and orphan drugs.<sup>9</sup> Although most drugs currently on the market in the EU were originally approved through national authorization procedures prior to the development of a centralized approval process, about 95 percent of new drugs brought to market are now approved through the centralized procedures. The first-ever application for the centralized switch of a drug (orlistat) from prescription to nonprescription status, which will make orlistat available without a prescription in all EU countries, was recently approved.<sup>10</sup> Orlistat was granted centralized approval as a prescription drug in 1998.

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<sup>9</sup>In the EU, orphan drugs are defined as those intended for the diagnosis, prevention, or treatment of life-threatening or chronically debilitating conditions that affect no more than 5 in 10,000 people in the EU, or are drugs which, for economic reasons, would be unlikely to be developed without incentives.

<sup>10</sup>On January 21, 2009, the European Commission approved orlistat (60 mg) for nonprescription use in the EU. At the time of this report, nonprescription orlistat was not yet available to consumers.

# Appendix III: Classification of 86 Drugs in Australia, Italy, the Netherlands, the United Kingdom, and the United States

Ingredient	Australia	Italy	Netherlands	United Kingdom	United States
Acetylcysteine	OTC	OTC/P	OTC	Rx	Rx
Acetylsalicylic acid	OTC	OTC/P	D	OTC	OTC
Aciclovir ( <i>topical</i> )	OTC	OTC/P	OTC	OTC	Rx
Adenosine	Rx	Rx	Rx	BTC	Rx
Azelastine	P	Rx	OTC	BTC	Rx
Bacitracin ( <i>topical</i> )	Rx	OTC/P	Rx	Rx	OTC
Beclometasone ( <i>nasal</i> )	P	Rx	Rx	OTC	Rx
Benzoyl peroxide	OTC	OTC/P	D	OTC	OTC
Bisacodyl	OTC	OTC/P	D	OTC	OTC
Budesonide ( <i>nasal</i> )	P	Rx	Rx	BTC	Rx
Calcium carbonate	OTC	OTC/P	D	OTC	OTC
Cetirizine	P	OTC/P	OTC	OTC	OTC
Chloramphenicol	Rx	Rx	Rx	BTC	Rx
Cimetidine	BTC	OTC/P	Rx	BTC	OTC
Clindamycin	Rx	Rx	Rx	Rx	Rx
Clotrimazole ( <i>topical</i> )	OTC	OTC/P	D	OTC	OTC
Clotrimazole ( <i>vaginal</i> )	BTC	OTC/P	Rx	OTC	OTC
Colestyramine	Rx	Rx	Rx	Rx	Rx
Cromoglicic acid	P	Rx	OTC	BTC	OTC
Cyproheptadine	BTC	Rx	Rx	BTC	Rx
Dextromethorphan	P	OTC/P	P	BTC	OTC
Diclofenac	P	OTC/P	D	OTC	Rx
Dimeticone	OTC	OTC/P	Rx	OTC	OTC
Econazole	OTC	OTC/P	D	BTC	Rx
Epinephrine ( <i>not for asthma</i> ) ( <i>adrenaline</i> )	OTC	Rx	Rx	BTC	OTC
Erythromycin ( <i>topical</i> )	Rx	Rx	Rx	Rx	Rx
Famotidine	P	Rx	D	OTC	OTC
Fexofenadine	P	Rx	Rx	Rx	Rx
Flunisolide ( <i>nasal</i> )	Rx	Rx	Rx	BTC	Rx
Fluoride (sodium)	OTC	OTC/P	D	OTC	OTC
Flurbiprofen ( <i>lozenges</i> )	P	OTC/P	Rx	BTC	Rx
Fluticasone	P	Rx	Rx	BTC	Rx
Hydrocortisone ( <i>topical</i> )	P	OTC/P	Rx	OTC	OTC
Hydroxyzine	Rx	Rx	Rx	BTC	Rx
Hyoscine (scopolamine)	P	OTC/P	D	BTC	Rx

**Appendix III: Classification of 86 Drugs in  
Australia, Italy, the Netherlands, the United  
Kingdom, and the United States**

<b>Ingredient</b>	<b>Australia</b>	<b>Italy</b>	<b>Netherlands</b>	<b>United Kingdom</b>	<b>United States</b>
Ibuprofen ( <i>oral</i> )	OTC	OTC/P	D	OTC	OTC
Insulin	Rx	Rx	Rx	Rx	OTC
Itraconazole	Rx	Rx	Rx	Rx	Rx
Ketoconazole ( <i>topical</i> )	OTC	OTC/P	Rx	OTC	OTC
Ketoprofen	BTC	OTC/P	D	BTC	OTC
Ketotifen	BTC	Rx	Rx	Rx	OTC
Lactulose	OTC	OTC/P	D	BTC	Rx
Levonorgestrel	BTC	Rx	D	BTC	P <sup>a</sup>
Lidocaine ( <i>topical/oral topical</i> )	OTC	OTC/P	OTC	OTC	OTC
Loperamide	P	OTC/P	OTC	OTC	OTC
Loratadine	P	OTC/P	OTC	OTC	OTC
Mebendazole	P	Rx	D	BTC	Rx
Metoclopramide	BTC	Rx	Rx	Rx	Rx
Miconazole ( <i>topical</i> )	OTC	OTC/P	D	BTC	OTC
Miconazole ( <i>vaginal</i> )	BTC	OTC/P	Rx	BTC	OTC
Minoxidil ( <i>topical</i> )	P	OTC/P	D	OTC	OTC
Mometasone ( <i>nasal</i> )	P	Rx	Rx	Rx	Rx
Mupirocin ( <i>topical</i> )	Rx	Rx	Rx	Rx	Rx
Naproxen	P	OTC/P	D	BTC	OTC
Nicotine ( <i>gum</i> )	OTC	OTC/P	OTC	OTC	OTC
Nicotine ( <i>oral inhaler</i> )	P	OTC/P	D	OTC	Rx
Nicotine ( <i>patch</i> )	OTC	OTC/P	D	OTC	OTC
Nitroglycerin	P	Rx	Rx	BTC	Rx
Nizatidine	P	Rx	Rx	BTC	OTC
Nystatin	P	Rx	Rx	BTC	Rx
Omeprazole	Rx	Rx	D	BTC	OTC
Orlistat	BTC	Rx <sup>b</sup>	P	Rx <sup>b</sup>	OTC
Orphenadrine	Rx	Rx	Rx	Rx	Rx
Oxymetazoline	P	OTC/P	D	OTC	OTC
Pantoprazole	Rx	Rx	Rx	Rx	Rx
Paracetamol	OTC	OTC/P	OTC	OTC	OTC
Penciclovir	P	OTC/P	OTC	BTC	Rx
Phenylephrine	OTC	OTC/P	Rx	OTC	OTC
Polymyxin B ( <i>topical</i> )	Rx	OTC/P	Rx	Rx	OTC
Povidone iodine	OTC	OTC/P	OTC	OTC	OTC
Pravastatin	Rx	Rx	Rx	Rx	Rx
Prednisolone	Rx	Rx	Rx	Rx	Rx

**Appendix III: Classification of 86 Drugs in  
Australia, Italy, the Netherlands, the United  
Kingdom, and the United States**

<b>Ingredient</b>	<b>Australia</b>	<b>Italy</b>	<b>Netherlands</b>	<b>United Kingdom</b>	<b>United States</b>
Prilocaine	P	Rx	D	BTC	Rx
Promethazine	P	OTC/P	Rx	BTC	Rx
Ranitidine	P	Rx	D	OTC	OTC
Salbutamol	BTC	Rx	Rx	Rx	Rx
Selenium sulfide	OTC	OTC/P	D	BTC	OTC
Silver sulfadiazine 1%	Rx	OTC/P	Rx	Rx	Rx
Simvastatin	Rx	Rx	Rx	BTC	Rx
Sumatriptan	Rx	Rx	Rx	BTC	Rx
Terbinafine	OTC	Rx	OTC	BTC	OTC
Tetracycline	Rx	Rx	Rx	Rx	OTC <sup>c</sup>
Theophylline	BTC	Rx	Rx	BTC	Rx
Tretinoin	Rx	Rx	Rx	Rx	Rx
Xylometazoline ( <i>nasa</i> )	P	OTC/P	D	OTC	OTC
Zolmitriptan	Rx	Rx	Rx	Rx	Rx

Legend: Rx = prescription; BTC = behind-the-counter; P = pharmacy; D = drugstore; OTC/P = over-the-counter (pharmacist required); OTC = over-the-counter.

Source: GAO analysis of agency data.

Note: This table indicates the least restrictive class to which each drug was assigned regardless of pack size, dosage, or combination ingredients. Other formulations of a drug may only be available under a more restrictive class. For example, in the United States some types of insulin are available as prescription drugs and other insulin products are available OTC.

<sup>a</sup>In the United States, levonorgestrel (an emergency contraceptive) may only be sold in pharmacies—as a nonprescription drug for those 18 and over, and by prescription for those under 18.

<sup>b</sup>On January 21, 2009, the European Commission approved orlistat (60 mg) for nonprescription use in the EU. At the time of this report, nonprescription orlistat was not yet available to consumers.

<sup>c</sup>In the United States, the topical dosage form of tetracycline is OTC.

# Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

**FEB 2 2009**

Marcia G. Crosse  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street N.W.  
Washington, DC 20548

Dear Ms. Crosse:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "NONPRESCRIPTION DRUGS: Considerations Regarding a Behind-the-Counter Drug Class (GAO-09-245).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark  
Acting Assistant Secretary for Legislation

Attachment

**Appendix IV: Comments from the Department  
of Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW  
Washington, DC 20201

**JAN 29 2009**

**DATE:**

**TO:** Barbara Pisaro Clark  
Acting Assistant Secretary for Legislation  
Office of the Secretary

**FROM:** *Charlene M. Frizzeta*  
Charlene M. Frizzeta  
Acting Administrator

**SUBJECT:** Government Accountability Office (GAO) Draft Report: "NONPRESCRIPTION DRUGS: Considerations Regarding a Behind-the-Counter Drug Class" (GAO-09-245)

Thank you for the opportunity to review and comment on the GAO's draft report entitled, "NONPRESCRIPTION DRUGS: Considerations Regarding a Behind-the-Counter Drug Class." The Centers for Medicare & Medicaid Services (CMS) agrees with GAO's finding that cost-related issues would have to be addressed before implementation of a behind-the-counter (BTC) drug class. We also offer these specific comments:

1. The CMS recommends GAO include some discussion about statutory authority to provide reimbursement under Medicare Part D for a potential BTC class. The statutory definition of "covered part D drug" includes drugs that may be dispensed only upon a prescription. CMS currently interprets the phrase "dispensed only upon a prescription," to mean a drug that is recognized by the Food and Drug Administration (FDA) as a prescribed drug requiring "Rx only" on the label as set forth in section 503(b)(4) of the Federal Food Drug and Cosmetic Act. Depending upon FDA implementation of a BTC provision, a BTC drug class may not meet the existing statutory definition and subsequently would not be covered under Part D. Lack of Medicare payment for BTC drugs may result in a shift by Medicare beneficiaries to alternative and more costly prescription drugs, which could, in turn, result in additional Federal expenditures. As a result, we believe GAO should address the potential lack of Medicare Part D payment for a BTC class in its report to Congress.
2. Page 13, footnote 14: This footnote references the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in support of pharmacist review of individuals' drug regimens. We believe this may mislead the reader to thinking that the MMA requires pharmacists to review Medicare beneficiaries' prescription drug regimens as a component of medication therapy management (MTM) under Part D. The MMA only specified that licensed pharmacists and physicians be involved in the development



Page 2 –

of Part D sponsors' MTM programs, not that they provide any corresponding interventions. Given the larger body of evidence supporting pharmacists' efforts in this area, we believe this reference to the MMA should be deleted and replaced with current pharmacy practice literature.

3. Page 17, footnote 20: This footnote references the MMA in support of paying pharmacists 80 percent of the physician reimbursement rate. While the MMA required Part D sponsors to implement MTM programs, the Part D program does not establish any payment schedules for either physicians or pharmacists performing MTM. Thus, we recommend the first and second sentence of this footnote be deleted.

We appreciate the effort that went into this report. Again, we thank you for the opportunity to review and comment.

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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## Acknowledgments

In addition to the contact above, Thomas Conahan, Assistant Director; Robert Copeland; Cathy Hamann; Karen Howard; Kristen Jones; Marisa Lee; and Julian Klazkin made key contributions to this report.

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