

GAO

Report to the Ranking Minority Member,  
Committee on Commerce, House of  
Representatives

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August 1995

# NONPRESCRIPTION DRUGS

## Value of a Pharmacist- Controlled Class Has Yet to Be Demonstrated







United States  
General Accounting Office  
Washington, D.C. 20548

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**Program Evaluation and  
Methodology Division**

B-252141

August 24, 1995

The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Commerce  
House of Representatives

Dear Mr. Dingell:

In response to your request, we are pleased to submit this report assessing the evidence for creating an additional class of drugs in the United States that would not be for sale outside pharmacies but would be available without a physician's prescription. As you requested, to determine if there are significant benefits or costs from such a class, we review the drug distribution systems in ten countries and the European Union. The report also reviews the practice of pharmacy, focusing on pharmacists counseling of patients on the use of nonprescription drugs.

We are sending copies of this report to interested congressional committees and government agencies, and we will make copies available to others upon request. If you have any questions or would like additional information, please call me at (202) 512-3092. Major contributors to this report are listed in appendix VIII.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Kwai-Cheung Chan', written in a cursive style.

Kwai-Cheung Chan  
Director for Program Evaluation  
in Physical Systems Areas

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# Executive Summary

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## Purpose

The classification of drugs in the United States into one of two classes, prescription or nonprescription, is unique. Other countries have a class of drugs that is available without a prescription but can be obtained only in a pharmacy and sometimes can be dispensed only by a pharmacist. To determine whether the United States would benefit from adding such a drug class, the Ranking Minority Member of the House Committee on Commerce asked GAO to examine the drug distribution systems in 10 countries. Because their health care systems differ, their experiences may not be completely applicable in the United States; however, they can help inform the debate. Accordingly, this report answers the following questions: (1) What conclusions can be drawn from studies or reports on the development, operation, and consequences of different drug distribution systems? (2) What are the drug distribution systems for the 10 countries? (3) What drug distribution system will be implemented in the European Union? (4) How does access to nonprescription drugs vary between the study countries and the United States? (5) How do pharmacists ensure the proper use of nonprescription drugs? (6) What is the U.S. experience with dispensing drugs without a physician's prescription but only by pharmacists?

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## Background

The United States has very few restrictions on where nonprescription drugs can be sold. It has been argued that the United States would benefit from the creation of a pharmacy- or pharmacist-class of drugs.<sup>1</sup> Of two general views on such a class, the first sees it as a fixed class into which drugs could be placed permanently with no expectation that they would eventually be moved into a different class. The second (and the one generally advocated by proponents of an intermediate class at this time) sees it as a transition class from prescription to nonprescription: a drug would spend a period of time in the transition class, during which its suitability for sale outside pharmacies could be assessed.

Supporters of an additional class of nonprescription drugs argue that, because pharmacists would be more involved in patients' selection and use of nonprescription drugs, such a class would (1) increase the number of drugs available to consumers without a prescription, (2) reduce drug misuse, and (3) lower health care costs by reducing the number of visits to physicians for ailments that could be treated with the wider range of drugs

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<sup>1</sup>A pharmacy class of drugs is defined as a category of nonprescription drugs that may be sold only in pharmacies. There are no restrictions on who may sell the product. A pharmacist class of nonprescription drugs may also be sold only in pharmacies, but unlike the pharmacy class, the pharmacist must be involved in the sale. In this report, intermediate class refers to either a pharmacy or pharmacist class.

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that would be available without a prescription. To assess the merits of these arguments, GAO reviewed the pertinent literature and interviewed or requested information from national and state government health officials, representatives of professional and consumer associations, academics, and pharmacists in the United States, the European Union, Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom.

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## Results in Brief

Little evidence supports the establishment of a pharmacy or pharmacist class of drugs in the United States at this time, as either a fixed or a transition class. The evidence that is available tends to undermine the contention that major benefits are being obtained in the countries that have such a class. This conclusion is substantiated by six points.

(1) Reliable and valid studies that examine the effect of different drug distribution systems on overall health and health care system costs do not exist. (2) While a pharmacy or pharmacist class exists in all 10 countries, it is not used with any frequency in any of them to facilitate the movement of drugs to sale outside specialized drug outlets. (3) The European Union has decided not to impose any particular drug distribution system on its member countries because it has found no evidence of the superiority of one system over another. (4) There is no clear pattern of increased or decreased access to drugs as nonprescription products where a pharmacist or pharmacy class exists. (5) While a pharmacy or pharmacist class is assumed by some to improve safeguards against drug misuse and abuse, in the 10 countries these safeguards are easily circumvented, and studies show that pharmacist counseling is infrequent and incomplete. (6) Experience in Florida with a class of drugs similar to a pharmacist class has not been successful; pharmacists have not regularly prescribed these drugs, and recordkeeping requirements have not been followed.

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## GAO's Analysis

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### Extant Studies

No systematic evidence supports the superiority of one drug distribution system over another. Studies have not attempted to link different systems with differences between countries in health care costs, adverse drug reactions, and quality of care. No studies show that problems or benefits arise from either restricting the sale of nonprescription drugs to pharmacies or allowing them to be sold outside pharmacies.

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## Drug Distribution Systems

All 10 countries restrict the sale of some or all nonprescription products. France, Italy, and the Netherlands restrict the sale of all nonprescription drugs to specialized drug outlets, while the 7 other countries allow the sale of only some nonprescription drugs outside these outlets. No country limits nonprescription drugs to sale by pharmacists or in pharmacies in order to assess their suitability for sale outside pharmacies. Instead, drugs are placed in the pharmacy or pharmacist class with no assurances that they will eventually be assessed for more general sale.

The European Union has set criteria for distinguishing prescription from nonprescription products. However, since EU officials could find no evidence showing the superiority of a particular drug distribution system, each country will decide the nature and number of its own drug distribution classes.

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## Access to Nonprescription Drugs

There is no consistent pattern across the 10 countries and the United States on the accessibility of 14 selected drugs. The United States allows the sale of some of the drugs without a prescription that most of the other countries restrict to prescription sale. Conversely, the United States restricts some drugs to prescription sale that most of the other countries allow to be sold in a pharmacist or pharmacy class.

The United States has fewer community pharmacies per capita than 6 of the 10 countries, so that restricting the sale of some nonprescription drugs to community pharmacies in the United States would appear to be somewhat of a greater inconvenience. However, this could be partially or completely offset if other outlets such as managed-care and mail-order pharmacies also sold these products or if new pharmacies opened.

Access could be reduced in the United States if consumers had to request these drugs from a pharmacist or an employee, as is generally the case in the other countries. However, even if self-selection were not allowed, if the intermediate class were used to move drugs out of prescription status that would not otherwise have been reclassified, access to the drugs would increase since a prescription would no longer be needed.

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## The Role of Pharmacists

Only in Australia (and only for some drugs in some states) do requirements that pharmacists counsel customers on nonprescription drug use explicitly state what information should be discussed. In 3 countries, pharmacists are expected to provide sufficient information for the proper

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use of nonprescription drugs, but there are no detailed counseling requirements. Other countries typically require that a pharmacist be aware of sales, be on the premises when a sale is made, or promote proper drug use. However, counseling and other pharmacist interventions with customers often do not occur. Although counseling by pharmacists on the use of nonprescription drugs has improved, it is often infrequent and incomplete.

Only in some states in Australia and only for some drugs are pharmacists required to maintain records on nonprescription drug use. In none of the countries are pharmacists required to report adverse drug reactions. In Italy and the United Kingdom, such reports from pharmacists are not accepted, while in the others pharmacists rarely report these reactions.

Pharmacist associations in the United States and other countries advocate “pharmaceutical care,” a concept that seeks to expand pharmacy practice from only dispensing drugs to being more involved in monitoring drug therapy (for instance, checking for adverse drug reactions). Pharmaceutical care is being implemented in some community pharmacies, but even if its value there can be documented, there will still be reason for debate on the need for an intermediate class.

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## The U.S. Experience

The Florida Pharmacist Self-Care Consultant Law allows pharmacists to prescribe specific medications without the supervision of a physician. However, they rarely use this authority and, when they do, seldom follow the law’s recordkeeping requirements. As in the 10 countries, Florida pharmacists often gather incomplete information and spend little time in assessing and responding to their patients’ medical complaints.

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## Recommendations

GAO is making no recommendations in this report.

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## Agency Comments

Officials from the Food and Drug Administration reviewed a draft of this report and provided written comments (see appendix VI). Their comments were brief and stated that the report does not address all the changes that would be necessary for the United States to adopt an intermediate class of drugs. A comprehensive assessment of all such changes was beyond the scope of GAO’s work.

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**Abbreviations**

AMA	American Medical Association
APhA	American Pharmaceutical Association
DIN	Drug identification number
EU	European Union
FDA	Food and Drug Administration
GAO	General Accounting Office
GP	General public
IHS	Indian Health Service
NARD	National Association of Retail Druggists
NDMA	Nonprescription Drug Manufacturers Association
OTC	Over the counter
VA	Department of Veterans Affairs

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# Introduction

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In the United States, there are essentially two categories of drugs for distribution: prescription and nonprescription. Nonprescription drugs are often referred to as over-the-counter (OTC) medications (the terms are used interchangeably in this report). The term “prescription” has several meanings but generally refers to the order of a physician to a pharmacist for the delivery of certain medications to a patient. A prescription drug may be dispensed to a patient only on the basis of such an order. Nonprescription drugs are available for general sale without a prescription by self-service in pharmacies and in nonpharmacy outlets such as grocery stores, mass merchandisers, gas stations, and restaurants.<sup>1</sup> The principal factors used to determine the prescription or nonprescription status of drugs are the margin of safety, method of use and collateral measures necessary to use, benefit-to-risk ratio, and adequacy of labeling for self-medication. Nonprescription drug sales were over \$13 billion in 1992 and may reach \$18 billion by the end of 1995 or 1996 (Covington, 1993, p. xxv). The importance of these medicines is growing, partly as a result of the reclassification of some commonly used drugs from prescription to nonprescription status.<sup>2</sup>

The two-tier system in the United States is unusual. Other countries typically have either more or different categories. There can be limitations on where and by whom a nonprescription drug can be sold. In some countries, the sale of some or all nonprescription drugs is restricted to pharmacies. Additionally, in some countries, certain nonprescription products have to be dispensed personally by a pharmacist.

The 1951 Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act of 1938 provided the statutory basis for the two-tier drug classification system in the United States. Since that time, there have been a number of proposals to introduce a third category of drugs in the United

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<sup>1</sup>There are several exceptions to the two-class system. First, in some states selected schedule V controlled substances are available without a prescription but must be dispensed by a pharmacist. (Controlled substances are psychoactive drugs regulated under the Controlled Substances Act on the basis of their abuse potential, medical acceptance, and ability to produce dependence.) Second, insulin is a nonprescription product in some states but can be dispensed only by a pharmacist. Third, in Florida pharmacists can prescribe a limited number of prescription drugs without a prescription having been written by another health professional. Fourth, in some states pharmacists have “dependent” prescribing authority in which typically they can prescribe drugs under protocols established by supervisory physicians. These exceptions are discussed in chapter 5.

<sup>2</sup>This is commonly referred to as switching. Between 1976 and July 1995, FDA switched 55 drug products. The pace of drug switches has increased in the past 10 to 15 years and the current pace is expected to continue. When a drug becomes available without a prescription, it is sometimes sold for different ailments and at different strengths than it was as a prescription product. For example, ibuprofen was prescribed for chronic arthritis in 400 mg and larger doses. As an OTC product, it is marketed as a general pain reliever and is available only in doses of 200 mg or less. In these situations, the prescription product remains available as well.

States. These proposals have been called by a number of names, including pharmacist-legend, pharmacist-only, third class of drugs, and transition class. Although there is some variation between them, the basic idea is the same: a class of drugs would be established that would be available only in pharmacies but no prescription would be needed. One variation is that the pharmacist would have to be personally involved in the sale of a drug in this class; a sales clerk could not sell the drug without the permission of the pharmacist. (For additional information on the history of this issue in the United States, see appendix I.)

There are two general views on how an additional class of drugs would be used in the United States. The first, and the one advocated in the past by various pharmacist organizations such as the American Pharmaceutical Association (APhA) and the California Pharmacists Association, sees it as a permanent class. It would be similar to the current classes in that drugs would be placed in the class with no expectation that they would eventually be moved to the prescription or nonprescription class. Drugs in the new class would be thought not to be appropriate for use without some supervision by a health professional but a physician's oversight would not be necessary. Drugs in this middle class could come from either the prescription or nonprescription classes, although it is generally believed that they should come from the prescription class. Opponents of this proposal have included the Nonprescription Drug Manufacturers Association (NDMA) and the American Medical Association (AMA).

The second, advocated first in 1982 by the National Association of Retail Druggists (NARD) and currently supported by such groups as APhA and the National Consumers League, sees the intermediate class as a transition class. A drug that was being switched from prescription to nonprescription status would spend a period of time in the transition class, during which the suitability of the drug for general sale could be assessed.<sup>3</sup> The assessment could be based not only on experiences with the drug as a prescription product (as is currently done) but also on experiences with the drug in the transition class, where it would not be limited to prescription sale. The argument is that this would give a better picture of how the drug would be used if it were available for general sale (that is, without a prescription and outside of pharmacies). 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 the end of a

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<sup>3</sup>The length of time a drug would spend in the transition class has not been specified, although Penna (1985) gives 5 years as a possibility.

specified period, the Food and Drug Administration (FDA) would decide to switch the drug to the general sale class, return the drug to prescription status, or keep the drug in the transition class for further study.<sup>4</sup> This proposal has also been opposed by, among others, NDMA and AMA.

The effect of an intermediate class of drugs in the United States would depend on whether the drugs in it would come from the prescription or general sale class. Figure 1.1 illustrates the several ways an intermediate drug class might function in the United States.

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<sup>4</sup>This report uses the following definitions:

—Fixed, intermediate class = a class of nonprescription drugs into which pharmaceuticals would be permanently placed. The sale of these drugs would be restricted to sale either in pharmacies or by pharmacists.

—Transition class = a class of nonprescription drugs into which a drug could be temporarily placed while its suitability for less restrictive sale was being assessed. As proposed in the United States, drugs in the transition class would be available for sale without a prescription but only from a pharmacist. The class would be used for assessing the appropriateness of selling a drug in any retail outlet.

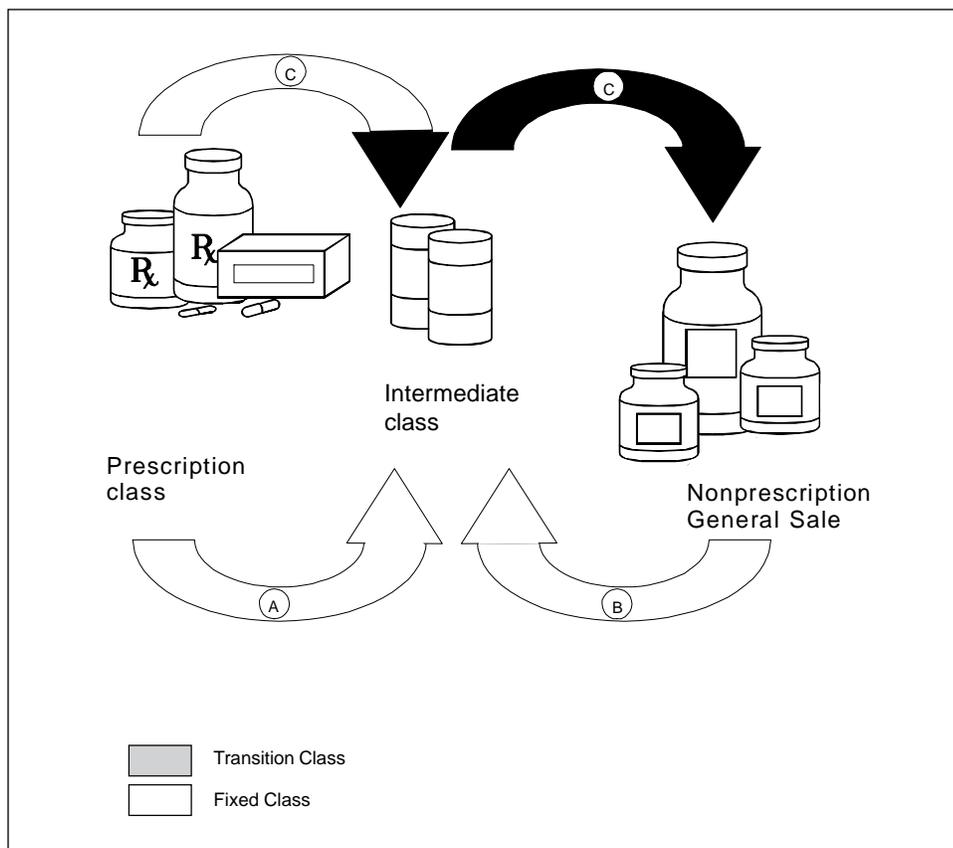
—Intermediate class = a general term encompassing both a fixed, intermediate class and a transition class.

—Pharmacist class = a class of nonprescription drugs that can be sold only in pharmacies and if the pharmacist is personally involved in the sale.

—Pharmacy class = a class of nonprescription drugs that can be sold only in pharmacies, but the pharmacist does not have to be personally involved in the sale. The distinction between a pharmacy class and a pharmacist class is relevant for both a fixed, intermediate class and a transition class.

—General sale class = a class of nonprescription drugs available for sale outside pharmacies and drugstores.

Figure 1.1: Possible Uses of an Intermediate Drug Class in the United States



Note:

A = If the intermediate class were viewed as a fixed class, it would primarily be used to switch prescription drugs into it rather than into the unrestricted sale category. The intermediate class would increase access by removing the need for a prescription in order to purchase the product but sales would be restricted to pharmacies or by a pharmacist.

B = If it were determined that a nonprescription drug available for general sale should be more restricted, it could be moved to the intermediate class rather than to the prescription class. The intermediate class would be used to decrease access to the drug by providing safeguards (for instance, sale only in pharmacies) that are not available if there are no restrictions on the sale of the drug.

C = If the intermediate class were viewed as a transition class, a prescription drug would be switched into it for a period of time and then reassessed to determine if sale should be allowed outside pharmacies. The intermediate class would be used to allow nonprescription access to drugs but would include the safeguard of pharmacist counseling and the assessment of safety for future switching to the general sale class.

## Arguments for and Against an Intermediate Class of Drugs

Arguments for and against an intermediate class of drugs fall into two general (but sometimes related) categories: health and economic. Table 1.1 lists some of the arguments that have been put forth in support of and opposition to an intermediate class of drugs. Most of the arguments are relevant for both a fixed and a transition class. The principal difference between a fixed and a transition class is not the benefits and costs that would ensue but their goals. The goal of a transition class in the United States would be to facilitate the movement of drugs into the general sale category. The goal of a fixed class would be to place drugs permanently in the class.

**Table 1.1: Arguments for and Against an Intermediate Class of Drugs**

For	Against
<p>With the establishment of a transition class, consumers would have access to more pharmaceuticals without a prescription. Medications formerly available only by prescription would become available earlier without a physician's prescription but with pharmacists' counseling (National Consumers League, 1991).<sup>a</sup> This argument, made specifically in support of a transition class, could also be made for a fixed class. Advocates of a transition class further state that drugs would be moved only from prescription status into the intermediate class; current OTCs would not be moved into it. (Fixed- class proposals did not address this issue)</p>	<p>The NDMA president (Cope, 1984) has argued that access to nonprescription products would decrease because the intermediate class would be limited to sale in pharmacies: there are approximately 54,000 U.S. community pharmacies but over 750,000 stores that sell nonprescription products.<sup>b</sup> NDMA has not uniquely addressed the transition class proposal. Instead, it has grouped it with the proposals calling for a fixed class and stated that both will restrict access to some nonprescription drugs. NDMA argues that current OTCs could be moved into the intermediate class under any of these proposals</p>
<p>APhA has stated that customers could use the expertise of pharmacists, well trained in pharmacology, as an added resource on nonprescription drug use, drug interactions, and other factors. This is relevant for both a fixed and a transition class</p>	<p>Industry officials have noted that pharmacists' counseling is infrequent and sometimes incorrect and this would not change with an additional drug class; in addition, a new class of drugs is not needed for pharmacists to give counseling. This is relevant for both a fixed and a transition class</p>
<p>APhA officials have stated that because of their training, pharmacists can play a useful role in helping customers assess their medical needs and determining whether a physician's visit is necessary. Through this advice, visits to physicians for minor ailments would decrease and physicians would have more time for patients with serious illnesses. In addition, patients would not have to go to the doctor for a medication previously available only by prescription, so the cost of the physician's visit would be saved. This is relevant for both a fixed and a transition class</p>	<p>NDMA has stated that only physicians possess the skills necessary for diagnosing and treating illnesses; pharmacists could not replace physicians.<sup>c</sup> A visit to the physician can be not merely to receive a drug but also to be diagnosed. Improper diagnosis can lead to symptoms being treated and the patient feeling better but, because of the lack of a physician's diagnosis, what was treated might not be the true underlying cause. Improper treatment could have serious and expensive consequences, thereby negating the savings from not visiting a physician. For example, an antiulcer medication might make the patient feel better but the underlying cause might be not an ulcer but stomach cancer. This is relevant for both a fixed and a transition class</p>
<p>National Consumers League officials have stated that an intermediate class facilitates the giving of advice to individuals who cannot read drug labels or have difficulties understanding them.<sup>a</sup> This is relevant for both a fixed and a transition class</p>	<p>Consumers practice self-medication responsibly. NDMA has stated that consumers read and understand drug labels, which contain all the information they need. This is relevant for both a fixed and a transition class</p>

(continued)

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**Chapter 1**  
**Introduction**

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<b>For</b>	<b>Against</b>
Proponents state that until consumers learn how to properly use recently switched drugs, pharmacists should be particularly accessible for them because of their high potential for toxicity and abuse. While this argument holds for both a fixed and a transition class, it is most relevant for the latter because of the implication that once there is more experience with these drugs as nonprescription products, pharmacists will not have to be involved in their sale	NDMA has stated that drugs unsafe for unsupervised use by consumers on the basis of their labeling directions should be prescription products; they should not be available for nonprescription sale even with pharmacist counseling. <sup>d</sup> Opponents have also argued that there have been no problems with already switched drugs; they have not been abused or caused widespread toxicity. This is relevant for both a fixed and a transition class
Penna writes that pharmacists could provide FDA postmarketing surveillance information on misuse, adverse reactions, and the extent of the use of a drug as a nonprescription product. <sup>e</sup> This would be useful information for both a fixed and a transition class; it is most relevant for the latter because of the use of the class to facilitate and better assess the appropriateness of switching drugs. This information could be used to determine whether to allow sales in any retail outlet, keep the drug in the intermediate class, or return it to prescription status	NDMA president Cope writes that the current two-tier system works well; an additional class is not necessary to ensure safety. <sup>b</sup> If they wish, consumers can go to pharmacies for advice but are not compelled to do so (NDMA, 1992). This is relevant for both a fixed and transition class
Proponents argue that when necessary, recalls of nonprescription products would be facilitated since there would be fewer outlets from which to recall intermediate-class drugs. APhA officials have stated that pharmacists have a commendable record in facilitating drug recalls. This is relevant for both a fixed and a transition class	Opponents argue that FDA and the pharmaceutical industry have an excellent record in recalling products from both pharmacy and nonpharmacy outlets. Thus, an intermediate class is not needed for this purpose. This is relevant for both a fixed and a transition class
Proponents have argued that abuse of nonprescription drugs would be reduced because a pharmacist would check if the drug and quantity being purchased were appropriate. Pharmacists could educate consumers on proper drug use. This is relevant for both a fixed and a transition class	Opponents argue that an intermediate class would not be effective in preventing abuse since it would not address the underlying problem and would represent only a small inconvenience in obtaining the product. In addition, they argue that the abuse of OTCs is often localized and generally sporadic and subsides after a short period. Consumer education at the local level is the best approach to solving these problems. This is relevant for both a fixed and transition class
More drugs would be available without a prescription because of the safeguard of restricting sale to pharmacies or by a pharmacist; proponents argue that health care costs would decrease because the nonprescription version of a drug is generally less expensive than the prescription version. This is relevant for both a fixed and transition class	Opponents argue that because of restricted competition and pharmacists' wanting to be compensated for counseling, the price of intermediate-class drugs would be higher than if they had been made nonprescription in the current two-tier system, without any corresponding benefit to consumers or the health care system <sup>c</sup>

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<sup>a</sup>National Consumers League, Taking Your Medicine: Providing Consumer Safeguards (Washington, D.C.: September 1991).

<sup>b</sup>J. D. Cope, "A Third Class of Drugs Would Release a New Flood of Problems," Pharmaceutical Executive, September 1984, pp. 42-43.

<sup>c</sup>Nonprescription Drug Manufacturers Association, National Consumers League Symposium on Transition [Third Class] of Drugs: An NDMA Response (Washington, D.C.: 1992).

<sup>d</sup>Nonprescription Drug Manufacturers Association, Self-Medications' Role in U.S. Health Care: A Briefing Book (Washington, D.C.: 1993).

<sup>e</sup>R. P. Penna, "A Transition Category: How APhA's Policy Would Work," American Pharmacy, NS25 (1985), 46-47.

Many of the arguments for an intermediate class of drugs suggest that the quality of health care would improve if pharmacists' involvement were greater. Proponents such as APhA argue that pharmacists are well trained in pharmacology and that their expertise is underused. They could play an important role in improving drug use. It is argued further that making use of this expertise is especially important for recently switched drugs whose potential for widespread abuse and toxicity is great. In the case of a transition class, Penna (1985) writes that pharmacists would be in a position to aid FDA in its switch decisions by maintaining records of the medications they dispense and by providing access to them to researchers assessing the safety and efficacy of these drugs. They might also be encouraged or required to report adverse drug reactions and be involved in postmarketing evaluation studies. Currently, FDA derives this information only from the use of drugs as prescription products.

Some arguments against an intermediate class of drugs come from industry officials who have argued that while pharmacists have useful information to pass on to consumers, an intermediate class is not necessary for tapping into it. If customers are interested in getting advice from pharmacists, they can go to a pharmacy and ask for it but are not forced to do so. They also note some difficulties with an increased role for pharmacists. Counseling for nonprescription products is infrequent and sometimes inappropriate, and they argue that this would not change with the establishment of an intermediate class of drugs. In addition, consumers use nonprescription drugs responsibly. They read and understand drug labels. There is nothing for the pharmacist to add. NDMA agrees that pharmacists are well-trained in pharmaceuticals but believes that they are not trained in other roles—in particular, diagnosing illnesses (NDMA, 1992). Only physicians have this training and should be performing this role. Improper diagnosis could lead to treating symptoms rather than the underlying cause of an illness. Finally, opponents argue that the current two-tier system works well (NDMA, 1992). It is simple and effective. Either a drug is safe enough to be taken without medical supervision or it is not. There is no need for an intermediate class of drugs.

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## Objectives, Scope, and Methodology

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### Objectives

To find out whether there would be significant advantages to creating an additional class of drugs, the Ranking Minority Member of the House Committee on Commerce asked us to examine the operation of drug distribution systems in 10 countries that have a pharmacist or pharmacy class of drugs and to compare these systems with that in the United States. To respond to this request, we posed specific evaluation questions:

1. What conclusions can be drawn from studies or reports on the development, operation, and consequences of different multiple-classification drug distribution systems?
2. What are the drug distribution systems for the 10 countries?
3. What drug distribution will be implemented in the European Union?
4. How does access to nonprescription drugs vary between the study countries and the United States?
5. How do pharmacists ensure the proper use of nonprescription drugs?
6. What is the U.S. experience with dispensing drugs without a physician's prescription but only by pharmacists?

Our purpose was to learn generally about factors that affect drug distribution in other countries and, in particular, about the perceived costs and benefits of a pharmacist or pharmacy class of drugs. This can raise important issues about the desirability or usefulness of such a class of drugs in the United States. By studying other countries, it is possible to bring empirical data to the debate.

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### Scope

We examined the drug distribution systems in Australia, Canada, Denmark, France, Germany, Italy, the Netherlands, Sweden, Switzerland, and the United Kingdom. (See appendix II.) As requested, we also studied the harmonized system for the members of the European Union (EU).<sup>5</sup> We

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<sup>5</sup>The 15 members of the European Union are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

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examined the classification of the following 14 drugs: aspirin, cimetidine, codeine, diclofenac, diflunisal, ibuprofen, indomethacin, naproxen, phenylpropanolamine, promethazine, ranitidine, sulindac, terfenadine, and theophylline. (See appendix III and IV.) We chose these drugs because they either are past switches or have been suggested as candidates for switching in the United States or another country.

We focused on an intermediate class of drugs as it has generally been discussed in the United States and practiced in other countries—that is, a class of nonprescription drugs available only in pharmacies or from a pharmacist. We did not assess the more general notion of pharmaceutical care, although we discuss it briefly in chapters 4 and 5.<sup>6</sup> An intermediate class of drugs might be considered one form of pharmaceutical care. While some arguments and evidence regarding pharmaceutical care are therefore relevant for an intermediate class of drugs, a complete evaluation of pharmaceutical care was beyond our scope.

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## Methodology

To determine what is known about the operation of drug distribution systems that include a pharmacist or pharmacy class of drugs, we examined extant information and gathered expert opinion on six general issues. (1) The findings of studies on the health and economic effects of a pharmacist or pharmacy class. (2) The experiences of other countries and the European Union with a pharmacist or pharmacy class, including its use to move a drug to a general sale class, its usefulness in preventing drug abuse, and its effect on drug expenditures. (3) The effect on consumers' access to nonprescription drugs of restricting their sale to pharmacies or personal sale by pharmacists. (4) The role of pharmacists in the study countries and the United States and the findings of studies on pharmacist counseling for nonprescription drugs. (5) The limited experience in the United States of pharmacists prescribing drugs without a physician's involvement and of restricting some nonprescription drugs to sale only by pharmacists.

We gathered information from a number of sources and used several data collection methods. We did not do independent analyses of data bases.

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## Literature Review

We conducted computerized literature searches on the following topics: (1) drug distribution systems in the study countries, (2) the behavior of

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<sup>6</sup>Pharmaceutical care involves pharmacists "designing, implementing, and monitoring a therapeutic plan, in cooperation with the patient and other health professionals, that will produce specific therapeutic outcomes" (Klein-Schwartz and Hoopes, 1993, p. 11).

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pharmacists, (3) the classification of the 14 drugs, (4) the advantages and disadvantages of an intermediate class of drugs, and (5) assessments of the health and economic effects of different drug distribution systems.

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## Interviews With U.S. Experts and Officials

We conducted interviews with officials of FDA involved in the regulation of prescription and nonprescription drugs, pharmacy associations, drug manufacturers, consumer groups, and drug manufacturer associations. We also interviewed academics who have written on this subject. In addition, we met with officials and academics in Florida to discuss their experiences with the Florida Pharmacist Self-Care Consultant Law (see appendix V).

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## Country Studies

We requested information from government and pharmacy association officials in the 10 study countries. Because Canada's individual provinces have a great deal of power over drug distribution, we also requested information from officials in Ontario.<sup>7</sup> We sought to gather descriptive information on the drug distribution system in each country, including criteria for drug classification, the classification of the 14 drugs, requirements for pharmacist counseling, and liability issues.

To obtain more in-depth information about the systems and experiences of particular countries, we traveled to Australia, Canada, Germany, the Netherlands, Switzerland, and the United Kingdom. We chose these countries because each allows the sale of some drugs outside pharmacies. The extensiveness of this general sale class varies greatly between countries; however, it was important to assess the experiences of countries where at least some drugs are available in the same manner as in the United States. We met with government officials, industry and pharmacy representatives, and other individuals knowledgeable about drug distribution in each country. The trips also allowed us to gather the views of a wider range of people than we contacted by mail, such as consumer groups, physicians' associations, drug manufacturers, and academics. We also visited officials in Brussels, Belgium, to understand the rationale behind the decisions of the European Union regarding drug distribution in the member countries.

We conducted our evaluation between February 1993 and December 1994 in accordance with generally accepted government auditing standards.

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<sup>7</sup>We chose Ontario because it is the most populous Canadian province and the distribution system there is typical of (although not exactly the same as) the systems in other provinces.

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## Study Strengths and Limitations

Although studies have examined individual drug distribution systems, we found that little effort has been made to systematically compare systems. Our study brings together information about the drug distribution systems in 11 countries (including the United States), Ontario, Canada, and the European Union. In addition to describing the systems, we examine the accessibility of nonprescription drugs in the study countries and the United States, describe the role of pharmacists in the countries, and assess evidence for implementing a class of nonprescription drugs available only from pharmacies (or personally from a pharmacist) in the United States. This information allows the assessment of the operation of a pharmacist or pharmacy class of drugs in the study countries as well as raises issues that would have to be addressed if such a class of drugs were considered in the United States.

One important difference between the United States and the other countries limits the lessons that can be learned. In all the countries other than the United States, there is some government provision of health care to the general public or universal health insurance through the private sector but regulated by the government. Thus, the context in which drugs are acquired, sold, and paid for can be quite different in these countries from that in the United States. If the barriers to obtaining a prescription drug in these countries are smaller than in the United States because individuals do not directly pay for physician visits and drugs prescribed in them, there may be less incentive there to purchase nonprescription products.

Another limitation is that the available data did not allow us to directly assess the effect of a pharmacy or pharmacist class on adverse drug effects, quality of care, and cost of drugs to the consumer and health care system. Instead, we had to rely on the assessments of government officials, association representatives, and other experts in each country. We also did not examine in great detail the individual drug classification decisions made in each country. That is, we did not examine the documentation that supports particular classification decisions to assess how decisionmaking varies between countries. Additionally, because of cost and resource limitations, we did not visit every country included in the study. (We did not travel to Denmark, France, Italy, and Sweden.)

Finally, because our focus is on the experiences of other countries and what can be learned from them, we did not assess the principal reason FDA has given for not establishing an intermediate class of drugs—namely, that a public health need for such a class in the United States has not been

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demonstrated. Consequently, we did not address issues such as the frequency of adverse effects for nonprescription drugs in general and, more specifically, for recently switched drugs in the United States.

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## Agency Comments

Officials from FDA reviewed a draft of this report and provided written comments (see appendix VI). They stated that the report does not consider certain additional requirements establishing an intermediate class of drugs would impose upon FDA, drug manufacturers, or pharmacists such as new FDA labeling requirements and additional training of pharmacists. The report discusses other potential additional requirements for pharmacists in chapters 2, 3, and 5. However, we did not attempt to address all additional requirements because a comprehensive assessment was beyond the scope and objectives of our report. An assessment of the additional requirements for FDA and drug manufacturers was also beyond our scope.

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## Report Organization

The following chapters address each of the five evaluation questions. Chapter 2 summarizes studies that have assessed the effects of different drug distribution systems and describes the drug distribution systems in the 10 countries as well as officials' views on the operation of their systems. It also describes the system in the European Union. Chapter 3 presents information on access to nonprescription drugs in the study countries, including the classification of the 14 drugs. Chapter 4 summarizes the role of pharmacists in each country and examines studies of pharmacists' behavior in the study countries and the United States. Chapter 5 examines the U.S. experience, focusing on Florida with its Pharmacist Self-Care Consultant Law. Chapter 6 summarizes our findings and presents conclusions.

# Drug Distribution Systems

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Drug distribution systems differ from country to country. In this chapter, we summarize information from studies on the consequences of the different systems. To show how the United States differs, we describe the drug distribution systems for the 10 countries and the European Union. Our purpose is to identify the countries that have a pharmacist or pharmacy class of drugs and examine possible benefits that the United States does not receive because they have such a class and the United States does not. Specifically, we answer the following questions:

1. What conclusions can be drawn from studies or reports on the development, operation, and consequences of different drug distribution systems?
2. What is the structure of the drug distribution system in each country?
3. What are the criteria for the initial classification, and subsequent classification changes, of a given drug product in each country?
4. To what extent is the pharmacist or pharmacy drug class used as a transition class for drugs being moved from prescription to general sale?
5. How effective is a pharmacist or pharmacy class in preventing the abuse of drugs?
6. What is the effect on expenditures on a drug when the drug is switched from prescription to nonprescription status?
7. What drug distribution system will be implemented in the European Union?<sup>1</sup>

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## Studies on the Consequences of Different Drug Distribution Systems

Little or no analysis has been done to show the advantages and disadvantages of different drug distribution systems. For example, as of March 1995, researchers had not attempted to determine how differences in drug distribution systems may affect health care costs. A number of studies have found significant differences in prescription drug prices across countries, both at the retail and manufacturers' level. However, as the costs of production and distribution make up only a small share of the total cost of any prescription drug, it is unlikely that differences in distribution systems are major sources of country-by-country differences

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<sup>1</sup>A major argument made in favor of a pharmacist or pharmacy class of drugs—the counseling role of pharmacists—is addressed in chapter 4.

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in drugs prices (GAO, 1994a, p. 29). The effect of different drug distribution systems on nonprescription drug prices has not been assessed.<sup>2</sup>

Similarly, no studies have attempted to link the type of drug distribution system in a country to the frequency of adverse drug reactions or have attempted to relate different drug distribution systems to the quality of health care.

The studies that have been done focus on the experiences of a single country when switching specific drugs and do not attempt to assess the merits of alternative drug distribution systems (Andersen and Schou, 1993; Bytzer, Hansen, and Schaffalitzky de Muckadell, 1991; Halpern, Fitzpatrick, and Volans, 1993; Hansen, Bytzer, and Schaffalitzky de Muckadell, 1991; Hopf, 1989; Perry, Streete, and Volans, 1987; Ryan and Yule, 1990; and Temin, 1992). While some researchers have found health and economic benefits to switching specific drugs in a particular country, no attempt has been made to determine what the effects would have been under a different drug classification system. For instance, would cough and cold remedies have been switched earlier in the United States if an intermediate-drug class had been available? If so, what would the benefits have been? If not, are there costs (for instance, adverse drug reactions) that would have been avoided if they had been switched into an intermediate class? There are also no studies that explicitly attempt to link the drug distribution system with the switching of specific drugs. In sum, it is necessary to examine other data to assess how a new class of drugs in the United States might operate.

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## The Number and Type of Drug Classes in the Study Countries

Table 2.1 summarizes the drug classes in the 10 countries, Ontario, and the United States. Note that in the Netherlands and Switzerland, a distinction is made between pharmacies and drugstores. Pharmacies are run by professionals with university degrees in pharmacy. All nonprescription drugs can be sold in pharmacies and prescriptions can be dispensed. Conversely, in drugstores, the principal “drug expert” is the druggist. Although some training is required to become a druggist, it is not university-based and is not as extensive as that for a pharmacist. In

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<sup>2</sup>The only comparative information we identified on nonprescription drugs costs, drawn from OTC News, indicated that of 6 countries examined, the United States had the lowest percentage markup (33 percent) from manufacturers’ price to retail price (“Editorial,” 1993, p. 391). The figures do not indicate why the differences existed and whether there was a difference in the average markup for drugs restricted to sale in pharmacies and those available for general sale (in countries that have both distribution classes). Moreover, these results do not necessarily mean that the United States has the lowest nonprescription drug prices, since manufacturers’ prices may vary between countries. The 6 countries were France, Germany, Italy, the Netherlands, the United Kingdom, and the United States.

**Chapter 2**  
**Drug Distribution Systems**

contrast to pharmacies, prescription drugs cannot be dispensed in drugstores, nor can all nonprescription drugs be sold there.

**Table 2.1: Drug Classes in Ten Countries, Ontario, and the United States**

Country	Prescription <sup>a</sup>	Pharmacist <sup>b</sup>	Pharmacy <sup>c</sup>	Drugstore <sup>d</sup>	General sale <sup>e</sup>
Australia	x	x	x		x
Canada <sup>f</sup>	x		x		x
Ontario	x	x	x		x
Denmark	x	x			x
France	x	x			
Germany	x	x <sup>g</sup>			x
Italy	x	x			
Netherlands	x	x <sup>g</sup>		x	
Sweden	x		x		x
Switzerland	x	x		x	x
United Kingdom	x	x <sup>g</sup>			x
United States	x				x

<sup>a</sup>Prescription = class of drugs available only with a prescription. Some countries have multiple classes of prescription drugs. For instance, in some countries, refillable prescriptions are not allowed for certain prescription drugs. For our purposes, it is sufficient to combine these categories into a single prescription class.

<sup>b</sup>Pharmacist = class of drugs available without a prescription but the pharmacist must be involved in a sale. Involvement may be defined as loosely as being on the premises when the sale is made.

<sup>c</sup>Pharmacy = class of drugs available without a prescription but only in pharmacies. The pharmacist does not have to be involved in a sale.

<sup>d</sup>Drugstore = class of drugs available without a prescription but only in pharmacies or drugstores. In some countries, pharmacies and drugstores are distinguishable drug outlets. A pharmacist does not have to be employed at a drugstore. Instead, it is sufficient for someone with less training to be the "drug expert." Fewer drugs are available in drugstores than in pharmacies.

<sup>e</sup>General sale = class of drugs available without a prescription and outside pharmacies and drugstores.

<sup>f</sup>The federal government classifies a drug as either prescription or nonprescription. Each province determines where the drug can be sold in that province. However, the federal government does recommend whether the drug should be available outside pharmacies. Because of this, we list three drug classes at the national level in Canada.

<sup>g</sup>The name of this class is "pharmacy restricted" in Germany, "pharmacy-only products" in the Netherlands, and "pharmacy medicines" in the United Kingdom. We list these classes here under pharmacist class because the requirements to sell drugs in these classes fit our definition of pharmacist class rather than pharmacy class.

In Australia, Canada, and Switzerland, some of or all the power for classifying drugs for distribution rests with the states, provinces, or cantons rather than the national government. For our purposes, it is sufficient to note that drug classification is rather uniform throughout Australia and Switzerland and, therefore, we categorize these systems as being national rather than local. In Canada, since the number of drug classes and classification decisions varies greatly between provinces, we present information on Ontario as well as the national government.<sup>3</sup>

As table 2.1 shows, the two-tier system in the United States is unique. All the other countries restrict the sale of at least some nonprescription drugs to pharmacies. France, Italy, and the Netherlands do not allow the sale of any drugs outside pharmacies or drugstores. Although some drugs are available for sale outside pharmacies in Denmark, Germany, Sweden, and Switzerland, this general sale class is quite small.<sup>4</sup> In Australia, Canada (including Ontario), and the United Kingdom, the general sale class is larger than in these 4 countries but smaller than in the United States.

The general rationale for restricting the sale of nonprescription drugs is the same in all the countries. Drugs are not typical consumer products. The dangerous aspects to them means they should be treated accordingly. A pharmacist can help provide guidance to patients on the proper use of the drugs and, thereby, reduce the possibility of adverse effects.<sup>5</sup>

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## Criteria for Classifying Drugs

All 10 countries and the United States generally use a drug's safety, efficacy, and quality for approving it. Each country then uses related criteria for determining the drug's distribution class. For instance, among the criteria the United Kingdom uses when switching a drug from prescription to pharmacist class is that the medicine has an acceptable margin of safety during unsupervised use, including safety in overdose or following accidental misdiagnosis. Officials in the United Kingdom also

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<sup>3</sup>There is currently an effort in Canada to harmonize the drug distribution regulations among the provinces. The proposal calls for four classes: prescription, pharmacist, pharmacy, and general sale.

<sup>4</sup>For instance, in Denmark this class is limited to such items as vitamins, certain medicines for animals, and anthelmintics (that is, medicines for killing or ejecting intestinal worms).

<sup>5</sup>The origins of restricting drugs to sale in pharmacies dates back hundreds of years. For instance, in Germany between the 14th and 18th centuries pharmacists were given exclusive rights to market drugs and other products such as sugar, spices, liquors, wine, tobacco, coffee, and chocolate in order to ensure a livelihood to pharmacists. Over time, the exclusive rights to sell products became increasingly limited to medicines. However, the rationale for these restrictions remained the same: to protect the pharmacies on behalf of the public welfare. In the 17th century, apothecaries were given exclusive right to sell medicines in Britain. (See Sonnedecker, 1976.) More information on current drug classification systems is in appendix III.

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told us that when making classification decisions, they take into account the role that pharmacists are expected to play. Among the criteria Denmark uses is that the drug should be available by prescription for 2 years without problems before it is switched. (A detailed comparison of the specific classification criteria was beyond our scope.)

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## An Intermediate Class as a Transition Class

Over the last 15 years, the number of drugs switched from prescription to nonprescription status has increased in the United States. In fact, this is a worldwide trend. Despite arguments for a transition class in the United States, an intermediate class is not frequently used as a transition class in the study countries. It is operative only in Australia (and there was some support for it by government officials in Ontario and by Canadian national pharmacy association officials). In the Australian state of Victoria, after a drug is switched from prescription class to pharmacist class, officials watch for reports of adverse drug effects (they do not actively track users of the drug). If reports do not materialize, they consider switching the drug from pharmacist to pharmacy class. It is important to emphasize that even when the class is considered a transition class, the goal is not to allow the drug to be sold outside pharmacies. One Australian official told us that she could remember only paracetamol (acetaminophen in the United States) being moved into the general sale category.<sup>6</sup>

In Canada, although some government and pharmacy officials told us they support the general idea of a transition class, the intermediate class is not generally used in this manner. Some manufacturers' officials were concerned that drugs could get "stuck" in a transition class. They said that ibuprofen was switched in the provinces in 1989 out of prescription class into pharmacist class, where it was supposed to remain for only a short time, but it still remains there today, 6 years later. More generally, a Canadian official questioned the idea of whether a transition class would allow drugs to be switched from prescription status faster if the data package for switching remained the same. Only by altering the package could the process be made faster: either fewer or shorter tests would be required or drugs would have to be switched before the tests were completed. The same official raised the issue of the usefulness of the data that might be gathered through a transition class. There would be no controls in the studies. The official thought that because of the lack of controls, the studies would provide little useful information. A U.S.

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<sup>6</sup>Since this conversation, aspirin in 500 mg packages of 16 pills or less (single ingredient only) has been switched to general sale in Australia. The movement of drugs to general sale is also very rare in the United Kingdom. However, U.K. officials did speculate that cost considerations might increase movement in the future.

manufacturer echoed this idea and stated that FDA responds to randomized, double-blind studies in which the experimental drugs are compared to placebos. (In a double-blind medical experiment, neither the patients nor the persons administering the treatment and recording the results know which subjects are receiving the drug and which are receiving the placebo.) This allows the effectiveness and adverse effects to be accurately assessed. A transition class would not provide this type of study. An official in the United Kingdom stated that, theoretically, new adverse reactions could be found when a drug is switched to a pharmacist or pharmacy class but that, as a practical matter, the adverse-effect profile for a drug is established by the time a drug is switched.

In the other countries we visited, the intermediate classes were not transition but permanent. There was no certainty that the drugs would be assessed for reclassification after a period of time. Thus, little helpful information is available from other countries as to whether or how a transition class might speed the switching of drugs.

If a transition class is to play a role in speeding approval of a change from prescription to nonprescription status, it must regularly employ a system to track adverse effects. Without this information, the class could not aid FDA in assessing a drug for general sale. Tracking studies would help link drug use (or at least purchases) to adverse effects. They could also give some indication of the pattern of use in the population. Two difficulties with such a recordkeeping requirement are the time burden it places on pharmacists and the likelihood of increased costs.

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## Preventing Abuse

Proponents for an intermediate class of nonprescription drugs argue that limiting the availability of certain drugs to pharmacies would impede abuse. For example, the pharmacist would be expected to intervene if a customer wanted to purchase inordinate amounts of a drug (either at one time or over a period of time) or if the customer appeared to have no medical need for it. The class could be used in two ways. First, for drugs being switched from prescription to nonprescription status, abuse could be studied and a decision made at a later time on appropriate classification. Second, nonprescription products that were being abused could be moved back to the intermediate class for some safeguards.<sup>7</sup>

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<sup>7</sup>For example, this issue has been raised in regard to phenylpropanolamine, an appetite suppressant and an ingredient in some weight-reduction products. Various officials raised the issue of young women taking large amounts of these products in attempts to lose weight. Associations between the drug and bulimia and anorexia have been suggested.

The advantage of moving a drug from general sale to an intermediate class is that it would still be available to customers for legitimate uses. Although access would be restricted to pharmacies, the added impediment of a prescription would not be required. Currently, if access is to be restricted, the drug must be moved to prescription class.<sup>8</sup>

The usefulness of an intermediate class to prevent drug abuse has not been demonstrated. We identified no studies that addressed the general issue of using an intermediate class to deter drug abuse. Few government and pharmacy officials whom we spoke with in the United States and abroad thought that an intermediate class would be completely successful in doing so. They agreed that it would be quite easy for an individual who wanted a large amount of a drug simply to visit several pharmacies and buy what appears to be a reasonable amount in each one, thereby avoiding potential surveillance. Having to deal with a pharmacist might be an impediment, as would the necessity of visiting several pharmacies; however, it would not be overly difficult to get around the system.

The difficulties in using a pharmacist class to prevent abuse can be illustrated by experience in New South Wales, where Australian truck drivers were taking ephedrine to try to stay awake. At the time, the drug was restricted to sale by pharmacists. New South Wales officials decided to move the drug back to prescription status, and eventually the other Australian states followed their lead. In this case, since restricting the sale of ephedrine to pharmacists did not prevent abuse, officials thought it necessary to put tighter controls on the product.

Similarly, a study in Germany indicated the difficulty of preventing the sale of nonprescription drugs even when they are restricted to pharmacies (Product Testing Foundation, 1991). Children between the ages of 10 and 14 were sent to pharmacies to see how easily they could purchase nonprescription medications containing alcohol. In all 54 pharmacies the children visited, they were allowed to purchase the drugs. In only one case was the purchaser questioned intensively. The consumer association that did the study criticized the pharmacists, and the pharmacy association called the results “lamentable.”

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<sup>8</sup>This recently occurred in Oregon when the state switched ephedrine (which is used, among other uses, as a nasal decongestant in the treatment of asthma) from nonprescription to prescription status. Oregon investigators had found that large amounts of ephedrine tablets were being sold weekly by a few retailers. The drug was being used in the illegal production of methamphetamine. To deal with the problem, Oregon officials restricted ephedrine to prescription sale. An intermediate class of drugs would have allowed the drug to remain a nonprescription product but sale would have been limited to pharmacies or pharmacists.

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## The Economics of an Intermediate Class of Drugs

Much of the discussion about the proposed roles for an intermediate drug class has centered on public health issues. For example, a primary concern has been the effect of an intermediate class on consumers' ability to use pharmaceuticals safely and effectively. In addition, an intermediate class of drugs would also have an economic effect. Establishing a pharmacy or pharmacist class could affect the price and availability of drugs to consumers and might also alter the revenues or profits of both manufacturers and retailers.

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## Drug Expenditures

Pharmacy experts in the United States told us that drugs cost less as nonprescription than prescription medicines, although initially the nonprescription cost may be higher than was the prescription price. Ibuprofen is an example. However, the experiences of other countries do not clarify what the economic effect of establishing an intermediate class of drugs would be in the United States. The few studies that have been done focus on the switching of particular drugs in particular countries. The studies do not generalize beyond the study country and do not attempt to determine the effect of the presence or absence of a pharmacist or pharmacy class.

Ryan and Yule (1990), examining the economic benefits of switching loperamide (an antidiarrheal) and topical hydrocortisone from "prescription only medicines" to "pharmacy medicines" in the United Kingdom, found that the costs of obtaining each drug decreased after the products were switched. However, in the United Kingdom (and all the study countries), prescription drug prices are controlled in some manner by the government.<sup>9</sup> Nonprescription drug prices generally are not, although some are controlled if the drugs are purchased with a prescription. Therefore, a comparison of drug prices before and after a switch is not a comparison of two free markets. Because there is no U.S. government price control, a comparison of drug prices in the study countries before and after switching would not yield useful insights for the United States. (Thus, the Ryan and Yule findings do not necessarily indicate what would occur in the United States if a drug were switched to an intermediate class.)

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<sup>9</sup>For example, in France the government regulates both new product prices and price increases. In Germany and Sweden, the government sets an upper limit on the amount the insurer can pay for groups of identical or equivalent drugs. In the United Kingdom, the government determines how much profit a company is allowed to make from selling medicines to the National Health Service. (See GAO, 1994b.)

When Temin (1992) studied the costs and benefits of switching cough-and-cold medicines in the United States, he found that visits to doctors for common colds fell by 110,000 per year (from 4.4 million) from 1976 to 1989, coinciding with the switching of the medicines.<sup>10</sup> After ruling out other possibilities, he concluded that the decrease in physicians' visits was attributable to the switching of these drugs.<sup>11</sup> He estimated this to be a saving of \$70 million per year.

Although there is thus some evidence of cost savings from switching drugs, the effect of an intermediate class of drugs has not been assessed. Ryan and Yule did not assess what the savings would have been if loperamide and topical hydrocortisone had been sold outside pharmacies. Temin did not study how the savings would have been different if cough-and-cold medications had been restricted to sale by pharmacists.<sup>12</sup> Therefore, while the studies do indicate potential savings from switching drugs, we cannot use them to assess empirically the relative savings from different drug distribution systems.

Our interviews with officials in the study countries indicated that the cost savings from fewer physicians' visits may not be as great as expected. They said that many patients do not pay the full price for a prescribed drug. For instance, an insured patient might have only a \$5.00 copayment for a prescription drug while having to pay the full price for a nonprescription product. Patients might thus have an incentive to go to doctors for a prescription. It could be for either a different but therapeutically equivalent product or the original drug if insurance covers it. The latter has occurred in Denmark with antiulcer medications that were switched in 1989. Bytzer, Hansen, and Schaffalitzky de Muckadell (1991) estimated that only 3 percent of the sales of cimetidine and ranitidine were made without some medical assessment or control. In Germany, approximately half of nonprescription drug sales are prescribed and reimbursed.

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<sup>10</sup>In 1983, Temin estimated the potential costs and benefits of switching topical hydrocortisone, thiazide diuretics, and oral penicillin. He based his estimates not on empirical data but on a theoretical exploration of switching. He concluded that there would be clear benefits to switching hydrocortisone and penicillin but that the net benefit from switching thiazide diuretics would be small.

<sup>11</sup>The factors he considered and rejected as possible explanations were different definitions of the common cold, decreased incidence of the common cold, decreased number of potential patients, a general decrease in visits to physicians, and a relative increase in the cost of visits to physicians.

<sup>12</sup>It should be clear that neither study was meant to assess the effect of an intermediate drug class; each followed the norm in the country where it was conducted. In the United Kingdom, drugs are normally switched from "prescription only medicines" to "pharmacy medicines." Few drugs have been switched to the "general sale list." In the United States, Temin studied the only possible switch to make a drug available for less-restrictive sale, from prescription to general sale.

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A somewhat similar situation exists in the Netherlands with respect to acetaminophen. This drug can be purchased without a prescription as a general pain reliever; however, it is also commonly used as a pain killer for cancer patients and, in fact, is the most prescribed drug in the country. When it is prescribed, it is reimbursable. An official told us that this results in consumers being able to get their headache remedy free of charge.

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## Economic Factors

The economic effects of an intermediate class of drugs depend on several different factors and the current literature does not provide a comprehensive analysis of them. A complete treatment of economic issues was outside our scope. In the remainder of this section, however, we briefly illustrate some of the unresolved economic issues in assessing proposals for an intermediate class of drugs.

The economic effect of an intermediate class of drugs would largely depend on how this class were structured and used—that is, whether it was a transition or a permanent class and, if the latter, whether the drugs in this class were coming largely from the prescription or the nonprescription category. For example, if drugs were moved to pharmacy or pharmacist class from prescription status, then the drug choices available to consumers without a prescription would increase. However, if drugs were largely moved to the intermediate class from the general sale category, then these drugs would be less widely available to consumers because fewer retail outlets could sell them (although they would still be available without a prescription).

A major unresolved question is how the availability of a pharmacist or pharmacy class would affect pharmaceutical prices. Depending on the structure of the new class, several factors might strengthen or soften its effect. The following four examples provide an illustrative, but not comprehensive, list of scenarios that could play out if the United States adopted an intermediate class of drugs.

- The availability of an intermediate class of drugs might prompt a change in manufacturers' pricing patterns. For example, if the introduction of an intermediate class permitted a drug to be switched from prescription status, the price might decline.
- If drugs were switched from general sale to the intermediate class, they would be available in fewer retail outlets. It is possible that the decrease in the number of retailers selling these drugs could adversely affect retail competition and, as a result, drive up prices. However, the availability of

mail-order pharmacies and other outlets (provided they sold the drugs in the intermediate class), and the likelihood of new pharmacies opening, could mitigate or eliminate this effect.

- If drugs were moved to the intermediate class from the general sale category, the greater role of pharmacists might lead to higher prices if a counseling fee were implemented.
- The effect of an intermediate class of drugs on consumers' out-of-pocket drug expenses would depend on the behavior of third-party payers such as health insurers, which often pay all or most of the cost of prescription drugs but generally do not pay for over-the-counter products. If insurers elected not to reimburse consumers for drugs that were moved from prescription status to an intermediate class, consumers' out-of-pocket expenditures would increase. However, if fewer drugs were reimbursed, health insurance costs might decrease and partially or fully offset consumers' greater out-of-pocket drug expenditures.

An intermediate class of drugs could also produce savings in other health care costs. The cost of obtaining a prescription drug includes not only the cost of the drug itself but also the cost of the visit to a physician. Patients would be saved the cost of the visit to the physician for a pharmacy- or pharmacist-class drug.<sup>13</sup> While this is potentially true for new prescriptions, cost savings for refilling prescriptions is less clear, since refills are often ordered on the telephone.

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## Drug Distribution in the European Union

The 15 member countries of the European Union are moving toward the creation of a single international market, without barriers to the free movement of goods, services, persons, or capital. One aspect of this is the harmonization of requirements governing the manufacturing and marketing of pharmaceuticals. Regulatory authority rests with Directorate General III "Industry." Section III-E-3 deals with pharmaceutical products. Decisions of the European Union must be approved by a vote of the member countries.

EU directives for pharmaceuticals establish the same requirements throughout the European Union, including requirements for advertising, labeling, and wholesale distribution. A 1992 directive "concerning the classification for the supply of medicinal products for human use"

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<sup>13</sup>However, we saw in the previous section that savings from reduced physicians' visits may not be as large as anticipated.

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establishes criteria for determining whether a drug will be a prescription or nonprescription product.<sup>14</sup> Article 3 states that

“Medicinal products shall be subject to medical prescription where they:

—are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or

—are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

—contain substances or preparations thereof the activity and/or side effects of which require further investigation, or

—are normally prescribed by a doctor to be established parenterally.”

The directive goes on to state that “Medicinal products not subject to prescription shall be those which do not meet the criteria established in Article 3.”

Despite this directive, the member countries will retain the authority for classifying drugs into prescription and nonprescription classes. This power will not be transferred to the European Union. Nonetheless, the expectation is that because of the EU classification criteria, drugs will be increasingly classified as prescription or nonprescription throughout the union. It is expected that classification into prescription and nonprescription classes will become harmonized throughout the European Union in the next 15 to 20 years.

However, the European Union has decided not to impose a particular drug distribution system on the member countries. It will be up to each country to determine the number and nature of nonprescription drug classes in it. If a country decides that it wants to restrict the sale of nonprescription drugs to pharmacies, this will be allowed. Similarly, if a country wants to allow the sale of some or all nonprescription drugs outside pharmacies, it may do so. Thus, despite the European Union’s developing criteria to distinguish prescription from nonprescription products, member countries can have more than two drug distribution classes.

An EU official with major responsibilities for and involvement in the directive told us that the reason the European Union decided not to

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<sup>14</sup>Directive 92/26/EEC. See Official Journal of the European Communities, April 30, 1992.

require a particular drug distribution system was that sufficient evidence did not exist to recommend one system over another. EU officials were not convinced that restricting drug sales to pharmacies was a commercial barrier to trade. Conversely, they were not convinced that allowing the sale of drugs outside pharmacies would increase health concerns. We were told that as long as a country's requirements are the same for both domestic and foreign entities, the European Union will accept its drug distribution system.

Drug distribution systems are seen, in part, as a function of tradition. Member countries were unwilling to give up their current systems. In general, the northern European countries are less restrictive on the sale of medications than are the southern countries. The northern countries did not want to restrict the sale of all nonprescription drugs to pharmacies, while the southern countries did not want to allow their sale outside pharmacies. In the absence of sound evidence to support one system as superior to the other, the European Union decided to allow the countries to determine their own individual systems.

While there will be no required changes in the number and type of drug classes in a country, officials in the Netherlands told us that they are planning to adapt to EU guidelines by moving from a three-tier to a two-tier system. Their plan is to combine the pharmacist and drugstore classes into one class and allow the drugs to be sold in both locations. It was noted that some nonprescription drugs currently restricted to sale by pharmacists will be moved back to prescription status. Officials of the Netherlands indicated that they perceived no major, consistent benefit from requiring that a large category of nonprescription drugs be available only from pharmacists.

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## Summary

Proponents of an intermediate class of drugs, as either a fixed or transition class, in the United States argue that it would create certain benefits. Evidence supporting this contention is small. No studies have assessed the relative merits of alternative drug distribution systems. All 10 of our study countries had a pharmacist or pharmacy class of drugs or both, but it was not used as a transition class to facilitate the movement of drugs to general sale. We also found no evidence that such a class of drugs is successful in preventing abuse. At most, it is an impediment. No studies have assessed whether an intermediate class deters drug abuse and anecdotal evidence suggests that drug abuse is not easily deterred with such a class. An additional class would not necessarily reduce drug

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expenditures. Physicians' visits might not be reduced as greatly as expected if the drug costs remained reimbursable with a prescription or if a reimbursable prescription product could be substituted. Finally, the European Union has not found evidence to support the superiority of one drug distribution system over another and, thus, is not requiring the establishment of a particular drug distribution system in its member countries.

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# Access to Nonprescription Drugs

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Proponents of an intermediate drug class argue that access to pharmaceuticals would increase in the United States if an additional nonprescription drug class, either fixed or transition, were established. Opponents argue that access would decrease. The actual change in access would depend on how the intermediate class were used.

In general, access would decrease if (1) drugs that are currently available without a prescription were to be moved into the intermediate class or (2) drugs that would have been switched to general sale were instead placed into the intermediate class.

However, access would increase if (1) drugs that would have been moved back to prescription status were placed in the intermediate category or (2) the effect of an intermediate class were to allow drugs to move into it that could not be moved into the general sale class. While the number of outlets (54,000 pharmacies) selling the product would not change, accessibility would increase because a prescription would not be necessary.

Beyond these general observations, it is unclear exactly how access would change. No studies have assessed this issue and, moreover, it would be very difficult to do so. A complete understanding of how access would be affected would require assessing a number of factors, including the number of drug outlets that would sell the drugs, how the class would be used, and the number and nature of drugs that would be placed in it. None of these can be precisely predicted.

In this chapter, we report our comparison of access to nonprescription drugs in the United States with that in the study countries. Making this comparison helped us understand what the effects of an intermediate class might be in the United States regardless of whether a fixed or transition class were established. We focused on the following three aspects of access: the number of community pharmacies and drugstores in each country, the availability of nonprescription drugs by self-selection, and, more generally, the classification of particular drugs as either prescription or nonprescription products. In particular, we answer the following questions:

1. How many pharmacies and drugstores are there in each of the study countries and the United States?

2. In the study countries, can consumers select nonprescription drugs themselves, or must they request such drugs from a pharmacist?

3. How does the classification of the 14 drugs we selected vary between the study countries and the United States?

The drugs include a number of pain relievers, antiulcer medications, and allergy medicines (see appendix IV). Their classification varies from country to country, and all have been either switched or mentioned as candidates for switching in the United States or another country. Private sector officials in the United States indicated that the 14 are a good list for getting a general indication of the access to nonprescription drugs in a country.<sup>1</sup> However, it is not possible to generalize from this list about drug classification in a country—that is, the classification of these drugs does not necessarily indicate the overall availability of nonprescription drugs in a country. Instead, the drugs should be viewed as examples of differences between countries.

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## The Access to Pharmacies and Drugstores

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### Number of Pharmacies and Drugstores

The number of community pharmacies can give some indication of how available intermediate-class drugs would be in the United States. However, there are a number of other drug outlets that could increase the availability of these products, including government, managed care, and mail-order pharmacies.<sup>2</sup> If these outlets were to sell intermediate class drugs, consumers would not have to go to a community pharmacy to purchase them. However, we cannot be certain that all or any of these potential outlets would choose to sell the drugs. Thus, any analysis of how accessible intermediate class drugs would be is limited by uncertainty over the number of outlets.

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<sup>1</sup>As our work progressed, we encountered some criticism of the list based on the belief that it should have included a more diverse array of drugs such as antibiotics and muscle relaxants.

<sup>2</sup>Government pharmacies include those operated by the Department of Defense, the Department of Veterans Affairs, and the Public Health Service (including the Indian Health Service). The importance of noncommunity pharmacies is illustrated by the fact that one fourth of all prescriptions are dispensed in these outlets.

Similarly, any comparison between countries of the number of drug outlets must note that in some countries physicians are permitted to dispense drugs where there is no convenient pharmacy. For example, in France and Italy physicians are allowed to dispense nonprescription drugs in rural areas where no pharmacy is available. The effect is to increase the number of drug outlets for nonprescription drugs and, hence, their accessibility. For countries that have more specialized drug outlets than the United States, physicians' dispensing would increase the difference between the countries while narrowing the difference for countries that have fewer pharmacies than the United States. If the United States were to allow physicians to dispense intermediate-class drugs where no pharmacy was available, this would also reduce inconvenience but negate one rationale (not having to visit a physician to receive the drug) for such a class of drugs.

To get some indication of how many U.S. outlets would be able to sell these drugs and how similar this is to other countries, we compared the number of community pharmacies per capita in the United States with a comparable measure in other countries. We found that the United States has considerably fewer community pharmacies or drugstores per capita than 6 of the countries.<sup>3</sup> (See table 3.1.) However, only Denmark, with one pharmacy for every 17,500 residents, and Sweden, with one for every 10,200 residents, have substantially fewer pharmacies per capita than the United States, which has one for every 4,800 residents. The United Kingdom, Canada, and Ontario have a similar number per capita to the United States. This gives some indication that restricting nonprescription drugs to sale in pharmacies might be more of an inconvenience in the United States than it is in 6 of the countries we studied.

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<sup>3</sup>While the Netherlands has fewer pharmacies per capita than the United States and Switzerland has approximately the same, there are also drugstores in these countries that can sell some but not all nonprescription drugs. Taking the pharmacies and drugstores together, there are proportionately more of these drug outlets in these countries than pharmacies in the United States.

**Table 3.1: Number of Community Pharmacies and Drugstores in Ten Countries, Ontario, and the United States in 1993-94**

Country	Pharmacies	Drugstores	Pharmacies and drugstores per capita
Australia	5,000	a	1:3,600
Canada	6,121	a	1:4,500
Ontario	2,400	a	1:4,200
Denmark	297	a	1:17,500
France	22,377	a	1:2,600
Germany	20,648	a	1:3,900
Italy	15,633	a	1:3,700
Netherlands	1,500	3,000	1:3,400
Sweden	857	a	1:10,200
Switzerland	1,500	900	1:2,900
United Kingdom	12,025	a	1:4,800
United States	53,841 <sup>b</sup>	a	1:4,800

<sup>a</sup>Not applicable.

<sup>b</sup>Includes drug chain, independent, food store, and mass merchant pharmacies. (See Drug Store News for Pharmacists, April 11, 1994.)

### Accessibility of Community Pharmacies in the United States

If drugs in the intermediate class were to come from the general sale rather than prescription class, change in access to these products would depend on not only the number of community pharmacies but also their distribution. In some parts of the country, the nearest pharmacy can be 100 or more miles away. Even within a city, the number of pharmacies varies between neighborhoods, and nonpharmacy drug outlets generally sell fewer products than do pharmacies. Therefore, people with a nearby pharmacy already have an advantage in the number of nonprescription products readily available to them. Moving drugs from the general sale class to an intermediate class could make this difference somewhat larger. The number of outlets selling the drugs would decrease, and individuals with easy access to pharmacies would find these drugs readily available to them while those without accessible pharmacies would not.

However, moving drugs from the prescription class to an intermediate class would not change the number of outlets (that is, pharmacies) selling them (assuming noncommunity pharmacies chose to sell the products), and, therefore, the difference in access for individuals with readily available pharmacies and those without would remain the same. It would

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still be necessary to go to a pharmacy to purchase the drug. The difference would be that a prescription would not be required.

Moreover, introducing an intermediate class of drugs in the United States would constitute a large change in nonprescription drug distribution since the more than 690,000 nonpharmacy drug outlets would not be allowed to sell these products. Consumers would have to learn that not all nonprescription drugs could be sold in all retail outlets. Individuals who wanted to purchase a drug in the intermediate class would need to know that it was necessary to purchase the drug at a pharmacy. This would affect all residents, regardless of location.

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## The Self-Selection of Drugs

In the United States, nonprescription products (except for controlled substances available without a prescription and insulin) are generally available by self-service—that is, consumers can select their nonprescription products from the shelves personally. Consumers have the power to choose their own nonprescription drug regimen by comparing different products on such items as dosing, side-effects, and price. Of course, if they are in a pharmacy, they can always ask the pharmacist for information or advice. In other countries, self-selection of pharmaceuticals is limited to certain drug classes or not allowed at all. Table 3.2 summarizes the direct availability of nonprescription drugs to consumers.

**Table 3.2: Self-Service for Nonprescription Drugs in Ten Countries, Ontario, and the United States<sup>a</sup>**

<b>Country</b>	<b>Pharmacist</b>	<b>Pharmacy</b>	<b>Drugstore</b>	<b>General sale</b>
Australia	No	Varies by state		Yes
Canada <sup>b</sup>	No <sup>c</sup>	Varies by product		Yes
Ontario	No	Yes		Yes
Denmark	No			
France	No			
Germany	No			Yes
Italy	No			
Netherlands	No		No	
Sweden		Varies by product		Yes
Switzerland	No		No	Yes
United Kingdom	No			Yes
United States	No <sup>d</sup>			Yes

<sup>a</sup>The table reports on actual availability of drugs by self-service rather than by what the law allows. In some countries, self-service is legally allowed but pharmacy association policy (which is followed) forbids self-selection. A blank cell indicates the country does not have the indicated drug class.

<sup>b</sup>Access to pharmaceuticals is a provincial responsibility in Canada. The federal government indicates whether it believes products should be restricted to sale only in pharmacies or be available for general sale. Some provinces do not allow self-selection for some nonprescription drugs sold only in pharmacies.

<sup>c</sup>This category exists only for controlled substances.

<sup>d</sup>This category exists only for controlled substances and insulin in some states.

The table shows that the ability to choose one’s own drugs is limited, except for drugs available outside pharmacies (in countries where this is allowed). Only in Australia, Canada (as determined by the individual provinces such as Ontario), and Sweden is self-service allowed for some or all pharmacist or pharmacy drugs.

If the United States were to follow the general pattern in other countries of not permitting self-service for pharmacist- or pharmacy-class products (as is done for controlled substances available without a prescription and insulin in some states), purchasing these products would be much different from purchasing other nonprescription drugs. Consumers would not only be unable to buy the products in outlets such as convenience stores and gas stations but would also find it more difficult to compare

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products if they could not select pharmacist- or pharmacy-class drugs directly from the shelf.<sup>4</sup>

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## The Effect of an Intermediate Class on Drug Classification

One of the principal benefits cited by proponents of an intermediate class is that the number of products available without a prescription would increase because FDA would have the option of putting drugs in a class that provides for consumer counseling (National Consumers League, 1991). To see if there is a pattern of greater nonprescription availability in countries that have a pharmacist or pharmacy class, we examined the classification of 14 drugs in the study countries and the United States. (See appendixes III and IV.) These drugs have either been switched or mentioned as candidates for switching in the United States or in another country, but they are only examples meant to illustrate differences between the countries. It is not possible to generalize from them to the entire drug classification system in a country. Our analysis shows only that the presence or absence of a pharmacist or pharmacy class has no consistent effect on drug classification. It is unclear what effect establishing an intermediate class in the United States would have on the classification of drugs as prescription or nonprescription products.

Specific examples illustrate how classification varies between countries. Ibuprofen is available for general sale in the United States but, although it is a nonprescription product in 10 other countries, its distribution is limited to specialized drug outlets in all of them. Naproxen is also available for general sale in the United States but as a nonprescription product in only 2 of the 10 countries. For these two drugs, the United States clearly has the most open system and the lack of an intermediate class has not prevented their being switched here. In fact, the United States was among the first to classify ibuprofen (1984) and naproxen (1994) as nonprescription products.

However, for other drugs the United States is more restrictive. For the 10 countries studied, only France, Italy, and Sweden, like the United States, do not allow nonprescription sale of the antihistamine terfenadine. Similarly, only Germany, Sweden, and the United States do not allow the

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<sup>4</sup>While some control over the sale of intermediate-class drugs would be necessary if the theoretical benefits of such a class were to be achieved, this would not necessitate prohibiting self-selection for these drugs. Instead, the requirement could be that the pharmacist would have to consult with consumers when the purchase was made. This would allow customers to select their own drugs and compare one with another.

nonprescription sale of promethazine, another antihistamine.<sup>5</sup> In the seven countries, these drugs are available in either a pharmacist or pharmacy class; the U.S. system is less open than theirs are. It is unclear whether the theoretical safeguards associated with a pharmacist or pharmacy class would be sufficient for regulators to switch these drugs from prescription to nonprescription.

It is thus unclear whether establishing an intermediate class of drugs in the United States would allow more drugs to be switched, since the United States already classifies some drugs as nonprescription that other countries that have a pharmacist or pharmacy class still restrict to prescription class. What is clear is that other factors in addition to or instead of the existence of a pharmacist or pharmacy class account for differences in drug classification between the study countries.

An assessment of the relative openness of the current drug distribution system in the United States compared to the other countries studied depends on one's definition of "access." If access is defined by the availability of drugs for general sale, the United States appears to have the most open system, since more of the 14 drugs are available for sale outside pharmacies than in any of the other countries. However, if access is defined by the availability of drugs for nonprescription sale regardless of where they can be sold, the United States falls somewhere in the middle. Some countries have more of the 14 drugs available without a prescription than the United States does, but others have fewer.

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## Summary

There is no simple answer to the general question of how access to nonprescription drugs would be affected by creating an intermediate class of drugs in the United States. It would depend partly on where drugs in the class came from. If they were switched from prescription class (as both fixed- and transition-class proposals emphasize), access could increase, since the drugs would be available without a prescription. But if they were switched from general sale (which advocates of a transition class argue would not occur), access could decrease, since their sale would be limited to pharmacies.

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<sup>5</sup>In the 1980's, FDA approved promethazine as a nonprescription product. However, in response to comments and a citizens' petition, FDA withdrew its approval. There were allegations that the drug was connected with Sudden Infant Death Syndrome (often referred to as SIDS). At the time, the manufacturer volunteered to withdraw the drug as a nonprescription product. FDA has not approved an application to switch terfenadine to nonprescription status because of concern about drug interactions as well as complications for patients with heart or liver disease.

Restricting the sale of some nonprescription drugs to pharmacies could be somewhat more inconvenient in the United States than in the 6 study countries that have substantially more community pharmacies and drugstores per capita than the United States. In addition, the accessibility of pharmacies varies greatly between areas in the United States. People without ready access to a community pharmacy would be at a disadvantage if they wanted to purchase drugs in the intermediate class. However, this could be partially offset if outlets such as mail-order pharmacies chose to sell these products. The larger change might be that people would have to adjust to not being able to buy some nonprescription medicines outside pharmacies.

All 10 study countries have some restrictions on self-selection of nonprescription drugs. Only the United States allows self-service for all nonprescription products (except for controlled substances available without a prescription and insulin). Other countries restrict consumer access to some or all nonprescription products. Thus, on this dimension, consumers in the United States have greater access to nonprescription drugs than do consumers in the other countries. The establishment of an intermediate class could change this. Because the benefits of such a class would be difficult to achieve without some control on the distribution of these drugs in pharmacies, self-selection might not be allowed for them.

No clear picture of the effect of a pharmacist or pharmacy class on drug classification decisions emerges from our analysis of 14 drugs. There is no consistent pattern of greater or lesser nonprescription drug availability as a result of the existence of a pharmacist or pharmacy class. The United States allows the sale of some drugs without a prescription that many other countries do not, while the opposite is also true. Whether the establishment of such a class in the United States would allow more drugs to be moved out of the prescription class is unknown.

# The Practice of Pharmacy

Many of the theoretical benefits associated with a pharmacist or pharmacy class of drugs (whether a fixed or transition class) involve improving drug use or, conversely, reducing misuse. The assumption is that pharmacists will pass on to consumers the information they need to take a drug properly. Critics of an intermediate class in the United States do not question the potential value of pharmacists' relaying information to consumers but do not believe that it is necessary to have an additional drug class to do this.

In this chapter, we describe the role pharmacists play in monitoring the use of pharmacist- and pharmacy-class drugs in the study countries. We focus on pharmacist practices that would have to be engaged in for a fixed or transition class to be effective. We also report on selected aspects of pharmacy practice in the United States, including counseling on nonprescription drugs. Specifically, we answer the following questions:

1. Are pharmacists in the 10 countries required by law to counsel consumers on the proper use of nonprescription drugs?
2. What are the legal sanctions for failing to provide counseling?
3. What studies show whether pharmacists in the study countries and the United States counsel purchasers of nonprescription drugs, and what is the quality of that counseling?
4. What are the requirements and practices of pharmacists in monitoring adverse drug reactions and maintaining patient profiles?
5. How might recent developments in the practice of pharmacy affect the counseling behavior of pharmacists in the United States?

## Counseling Requirements on Nonprescription Drugs

One reason proponents commonly give for limiting nonprescription drugs to sale in pharmacies (even if no counseling is required) is that it allows customers to ask for advice if they want it. Table 4.1 summarizes the counseling requirements for nonprescription drugs in the 10 study countries and Ontario. Only in Australia, Denmark, Germany, and Italy are pharmacists required to provide information to patients on the use of nonprescription drugs. In Australia, these requirements vary by state: some states require counseling on pharmacist class drugs but others do not. For instance, in Victoria, the pharmacist is required to speak with the patient every time a pharmacist-class drug is sold. In Denmark, Germany,

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and Italy, the pharmacist is required to provide information to patients on their medications; however, there are no specific counseling requirements. In Ontario and the United Kingdom, nothing is required beyond the pharmacists' supervision of sales. In France, the Netherlands, and Switzerland, pharmacists need merely be physically present on the premises of the pharmacy. In Sweden, while the pharmacist is expected to promote proper drug usage, there is no requirement that a pharmacist be present when a nonprescription drug is sold. There are no national counseling requirements in Canada.

**Table 4.1: Pharmacist Counseling Responsibilities for Nonprescription Drugs in Ten Countries and Ontario**

<b>Country</b>	<b>Pharmacist responsibility</b>
Australia	Counseling requirements are set by the states. There are no counseling requirements for pharmacy-class drugs. Some states have counseling requirements for pharmacist-class drugs. For instance, in Victoria pharmacists must “give appropriate and adequate advice in respect of dosage, frequency of administration, general toxicity, adverse effects, contra-indications or precautions to be observed in the usage of that potent substance”
Canada	There are no national counseling requirements
Ontario	Pharmacists must “make [the] decision to” sell a pharmacist-class drug. This is defined as the pharmacist “must be aware of the sale.” No counseling requirements state what specific information must be given to the consumer
Denmark	The pharmacist must provide information about pharmaceuticals. The pharmacist is required to be on duty when a pharmaceutical is sold. No counseling requirements state what specific information must be given to the consumer
France	The pharmacist must be on duty when a drug is sold. No counseling requirements state what specific information must be given to the consumer
Germany	The pharmacist must render the information necessary for proper administration of nonprescription drugs to the consumer. No counseling requirements state what specific information must be given to the consumer
Italy	The pharmacist is expected to provide the consumer with sufficient information for the proper use of the drug. The pharmacist must be on the premises when nonprescription drugs are sold and must identify the packaging as well as the expiration date of the product. No counseling requirements state what specific information must be given to the consumer
Netherlands	The pharmacist must be on the premises when nonprescription drugs are sold. No counseling requirements state what specific information must be given to the consumer
Sweden	The agreement between the government and Apoteksbolaget (the corporation of Swedish pharmacies) states that “the company shall promote the development of good information in the drug field.” However, there are no counseling requirements. There is no requirement that a pharmacist be present when a nonprescription drug is sold
Switzerland	Pharmacists must be on the premises when nonprescription drugs are sold. They must be available to give advice on pharmacist-class drugs. No counseling requirements state what specific information must be given to the consumer
United Kingdom	Pharmacy-only medicines must be sold under the supervision of a pharmacist. No counseling requirements state what specific information must be given to the consumer

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## The Enforcement of Counseling Requirements

In the 6 countries we visited—Australia, Canada, Germany, the Netherlands, Switzerland, and the United Kingdom—and Ontario, there is some enforcement of the requirements for pharmacists selling nonprescription drugs, but it is somewhat limited. Enforcement is sometimes by a professional association and is sometimes focused on physical aspects of the pharmacy rather than the counseling of patients. The number of inspectors is sometimes small and nonprescription drugs can be less emphasized than prescription products.

Counseling requirements are set by the states in Australia. Officials in the state of Victoria told us that enforcement is done primarily through three pharmacy inspectors of the Pharmacy Board of Victoria on the basis of professional standards. One reason for the board's enforcing the law rather than the state is that the board's standard of proof is less stringent, thereby making it easier to discipline recalcitrant pharmacists. The state standard of proof, "beyond a reasonable doubt," has been replaced by the less strict "balance of probabilities." The pharmacy board brings its case before pharmacy representatives who may impose penalties ranging from letters of admonition and fines to temporary suspension or permanent cancellation of a pharmacist's registration. There are three or four suspensions or cancellations per year. We were told that generally there is not a great deal of enforcement in Australia unless there are complaints or drug abuse concerns.

Enforcement of pharmacist requirements is done at the state and regional level in Germany and focuses on the physical aspect of the pharmacy rather than the behavior of pharmacists. Inspectors check such items as cleanliness of the pharmacy, proper storage of medicines, size of the laboratory, availability of instruments, and orderliness of records.

In the Netherlands, the State Public Health Inspectorate supervises all matters relating to the sale of drugs. Pharmacists must give access at any time to inspectors to examine the pharmacy and everything in it. If inspectors find that the pharmacy is not operating in accordance with the law, they inform the pharmacist and stipulate a time within which the problem must be corrected. We were unable to determine the amount of effort put forth in identifying violations of counseling requirements for nonprescription products.

In Switzerland, each canton has a pharmacist organization that conducts inspections. Inspectors examine the shop and laboratory to determine if

they are in accordance with regulations. They also check to see if the pharmacist is present when the pharmacy is open, as required by law.

In the United Kingdom, pharmacy medicines are to be sold only under the supervision of a pharmacist. This is normally defined as being present, aware of the transaction, and in a position to intervene. Enforcement of the law is not by the government but by the Royal Pharmaceutical Society of Great Britain. The society has 18 pharmacy inspectors and 2 inspectors for nonpharmacy drug outlets. This works out to about 650 to 700 pharmacies per inspector.

We were told that a large number of cases are brought to the attention of the Royal Pharmaceutical Society every year by competitors and consumers. After the society visits the pharmacy to meet with the pharmacist, it decides whether to handle the case informally or to take formal evidence. Often it sends only a warning letter. Approximately 15 cases a year are prosecuted. Additional cases (6 in 1993) are dealt with through the pharmacy code of ethics. However, we were told that the society is unlikely to base action on the sale of pharmacy-class drugs (for instance, selling a pharmacy medicine without appropriate counseling).

Overall, Royal Pharmaceutical Society officials thought that a great deal of effort was put into identifying violations of laws and regulations concerning purchases of nonprescription drugs. Government officials told us that enforcement of pharmacy practice requirements is successful mainly as a deterrent. Pharmacists are aware of the law and try to stay within it.

In Ontario, pharmacists (or an intern) must make the “decision to sell” a pharmacist-class drug. This is generally defined as the pharmacist’s being “aware of the sale.” There is no requirement that pharmacists actually speak with the patients. Enforcement is done by the Ontario College of Pharmacists, a professional and regulatory association. Officials told us that compliance with the law is minimal. There is no method for monitoring pharmacist interventions other than through consumer complaints to the college, which are then investigated.

We asked pharmacy officials in the countries we did not visit how much effort is put forth in enforcing nonprescription drug counseling requirements. Officials in France and Denmark told us that “moderate” effort is put into enforcing counseling requirements in those countries; Swedish officials said that there is “some” effort. In Italy, there are no

sanctions against pharmacists who do not counsel patients on the use of nonprescription drugs.

Officials noted that the enforcement of counseling requirements can be problematic. It is difficult to determine what is or is not appropriate counseling behavior. Appropriateness needs to be assessed case by case. What appears to be a lack of counseling might reflect a legitimate judgment by the pharmacist, such as that a particular customer regularly uses the drug and does not need counseling on it. This makes enforcement of counseling requirements quite difficult.

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## Studies of Pharmacist Counseling on Nonprescription Drugs

Various academics, consumer groups, and pharmacy associations have conducted studies of the behavior of pharmacists when they sell nonprescription drugs. Typically, participants in a study go to a pharmacy and attempt to purchase a particular nonprescription product or describe their symptoms (or those of the person for whom they are buying the product), seeking advice from the pharmacist on what drug to purchase. Each shopper has been trained by the investigators to act in accordance with a script developed for the study. The pharmacist's advice is recorded and compared to what the pharmacist should have done according to criteria determined by a group of experts. We refer to these investigations as trained shopper studies. Other common study designs are investigators' observation of pharmacists' behavior and pharmacists' completion of a questionnaire on their counseling activities.

Table 4.2 lists the pharmacist counseling studies, their methodologies, and what they assessed. Studies have not been conducted in all the countries. While the studies vary considerably in design and objective, a number of common themes are evident. Despite differences in the law and regulations across countries, counseling is generally incomplete and infrequent.

**Table 4.2: Description of Studies of Pharmacist Counseling on Nonprescription Products in Five Countries and the United States**

Country, author, and date <sup>a</sup>	Methodology	Sample selection	Aspect of counseling assessed <sup>b</sup>
<b>Australia</b>			
Feehan (1981)	2 trained shoppers	2 random samples of 43 pharmacies each in Victoria	Quality, quantity
Harris et al. (1985)	1 trained shopper	Random sample of 40 pharmacies in Perth	Quality
Ortiz, Walker, and Thomas (1989)	Observation	Random sample of 50 pharmacies in Sydney; 28 agreed to participate	Quantity
Ortiz et al. (1984a, b)	Mail survey of pharmacists	Commercial mailing list covering 98.1% of pharmacies in the Australian Capital Territory and New South Wales	Quantity
Stewart, Garde, and Benrimoj (1985)	Observation	Sample of 10 pharmacies in Brisbane chosen using specific criteria	Frequency, quantity
<b>Canada</b>			
Poston, Kennedy, and Waruszynski (1994)	Survey of pharmacists	Random sample of 681 pharmacies stratified by province	Quantity
Taylor and Suveges (1992a)	Observation and consumer questionnaire	Random sample of 11 pharmacies in Saskatoon	Frequency, quantity
Taylor and Suveges (1992b)	Observation	4 pharmacies in Saskatoon; selection method not given	Frequency, quantity
Willison and Muzzin (1992)	8 trained shoppers	Random sample of 37 pharmacies in Ontario; 30 agreed to participate	Quality
<b>Germany</b>			
Glaeske (1989)	30 trained shoppers	222 pharmacies in 27 cities; selection method not given	Quality
Product Testing Foundation (1984)	944 trained shoppers	Random sample of 1,530 pharmacies	Frequency, quality
Product Testing Foundation (1991)	"Several hundred" trained shoppers	Selection method for pharmacies not given	Frequency, quality
<b>Sweden</b>			
Marklund, Karlsson, and Bengtsson (1990)	Observation by pharmacy personnel	4 pharmacies in 4 towns; in 3 of the towns, there was only 1 pharmacy; in the other town, 1 of the 2 pharmacies was studied; selection method not given	Frequency
<b>United Kingdom</b>			
Consumers Association (1985)	6 trained shoppers	Over 200 pharmacies in 3 areas; selection method not given	Quality, quantity
Consumers Association (1991)	8 trained shoppers	240 pharmacies; selection method not given	Quality, quantity
Consumers Association (1994)	Trained shoppers; number not given	30 pharmacies in 4 cities; selection method not given	Frequency, quality

(continued)

**Chapter 4**  
**The Practice of Pharmacy**

Country, author, and date <sup>a</sup>	Methodology	Sample selection	Aspect of counseling assessed <sup>b</sup>
Goodburn et al. (1991)	Interviews with pharmacists, 1 trained shopper	Random sample of 20 pharmacies in Newcastle upon Tyne; random sample of 10 pharmacies for trained shopper part of project	Quality
Hardisty (1982)	Observation	Nonrandom sample of 225 pharmacies in England, Scotland, and Wales	Quality, quantity
"Most Pharmacists 'Give Good Advice'" (1984)	Observation, 4 trained shoppers	Observation of 6 pharmacies in Birmingham, selection method not given; for trained shoppers component, 123 visits to a random sample of 85 pharmacies, location not given	Frequency, quality, quantity
"Over-the-Counter Advice" (1988)	7 trained shoppers	Random sample of over 200 pharmacies in 3 cities	Frequency, quality, quantity
Phelan and Jepson (1980)	Mail survey of pharmacies	Random sample of 417 pharmacies in England	Frequency
Smith, Salkind, and Jolly (1990)	Observation	Random sample of 64 (5%) of pharmacies in London	Quality
Taylor et al. (1987)	Pharmacist recording of activities	313 pharmacies throughout Britain; selection method not given	Frequency
United States			
Barnett, Nykamp, and Hopkins (1992)	6 trained shoppers; 2 scenarios	84 randomly selected pharmacies in Atlanta; 72 visited for both scenarios	Quality
Carroll and Gagnon (1983)	Mail survey of households	Random sample of 300 households in Raleigh, N.C.	Quantity
Jang, Knapp, and Knapp (1975)	6 trained shoppers	Random sample of 48 pharmacies in 1 city	Quality
Knapp et al. (1969)	Trained shoppers asking questions on the telephone; number not given	Random sample of 36 pharmacies in 1 city	Quality
Linn and Davis (1973)	2 trained shoppers; pharmacist questionnaire	Random sample of 133 pharmacies in Los Angeles for trained shopper method (164 visits were made, with 31 pharmacies visited twice to interact with a different pharmacist); the same 164 pharmacists were later sent questionnaires	Quality
Market Facts (1994)	Telephone interviews with adults who had a prescription filled in the past 6 months	Sample of 1,302 adults chosen to represent all U.S. households	Quantity
Meade (1992)	Telephone interviews with pharmacists	200 randomly selected pharmacists	Quantity
Vanderveen, Adams, and Sanborn (1978)	Trained shoppers either visited or telephoned pharmacies; number not given	72 pharmacies in Michigan; selection method not given	Quality

(continued)

Country, author, and date <sup>a</sup>	Methodology	Sample selection	Aspect of counseling assessed <sup>b</sup>
Vanderveen and Jirak (1990)	Trained shoppers; number not given	46 pharmacies in Michigan; selection based on location	Quality
Wertheimer, Shefter, and Cooper (1973)	1 trained shopper for each of 3 scenarios	86, 50, and 31 pharmacies for each of the respective scenarios; selection method not given for two scenarios, random selection for the other	Quality

<sup>a</sup>Complete citations are in the bibliography.

<sup>b</sup>Quality = appropriateness of counseling, such as the recommendation of the correct drug, discussion of possible side effects, and completeness of advice. Quantity = time spent counseling, number of counseling events per day, or availability of pharmacist for counseling. Frequency = percentage of patients receiving counseling.

Estimates of the frequency of pharmacists' counseling on nonprescription products (that is, the percentage of patients receiving advice) ranged from 11.1 percent in Sweden (Marklund, Karlsson, and Bengtsson, 1990) and 12.3 percent in Canada (Taylor and Suveges, 1992a) to 93.75 percent in Germany (Product Testing Foundation, 1991).<sup>1</sup> Germany's was by far the highest estimate.<sup>2</sup> The second highest, based on self-reports of pharmacists, was 37.6 percent in the United Kingdom for single proprietor pharmacies (Phelan and Jepson, 1980). (The lowest estimate for the United Kingdom was 21 percent for chain pharmacies, also found by Phelan and Jepson.) However, even in Germany, the researchers generally thought that too little counseling was being done. In one third of the cases in Germany, only one piece of information was being passed to the consumer.

An Australian study found that the vast majority of pharmacists thought that they should counsel for both prescription and nonprescription medications (Ortiz et al., 1984b). However, pharmacists gave a number of reasons for not counseling. The three most important were

- lack of adequate medical histories,
- lack of feedback from the person counseled, and
- the belief that counseling may not be necessary.

<sup>1</sup>The Swedish estimate was based on reports by pharmacy personnel, the Canadian estimate on observation of pharmacists, and the German estimate on a trained shopper study.

<sup>2</sup>This estimate is somewhat misleading since an unspecified proportion of the shoppers actively requested advice from the pharmacist while the others requested a product but relied on the pharmacist to provide information without the shopper's requesting it. Thus 93.75 percent is an estimate of pharmacist counseling based on active and passive shoppers. It is unclear from the study what proportion of shoppers received information without requesting it.

Another reason counseling may not occur is that customers may not want it. In Canada, Taylor and Suveges (1992a) found that 195 of 207 customers who did not receive advice on a nonprescription product indicated that they did not want counseling. The main reasons they gave were that they had “used [the] medicine before with good results” and “had already received advice elsewhere on what to buy.”

Regarding the quantity of counseling (that is, the availability of pharmacists to counsel, the number of counseling events per day, and the time spent counseling), a Canadian study found that pharmacists responded to requests from patients for advice on nonprescription drugs an average of 2.8 times a day (Poston, Kennedy, and Waruszynski, 1994). The range between pharmacies was from 0.07 to 38.64 counseling events per day. A study in Australia found that 23 percent of pharmacist counseling activities involved OTC medications (Ortiz, Thomas, and Walker, 1989). (This was the second most frequent counseling activity behind giving advice on prescribed medications.) Patients initiated the counseling in 259 of 438 cases. In 394 of the cases, counseling took 2 minutes or less.

The quality of counseling was somewhat mixed. Recommended products and advice (when given) were generally found to be appropriate. Willison and Muzzin (1992) found that in Canada the quality of advice varied by ailment, with patients receiving better advice on less complex problems. For three of four scenarios in which the use of a prescription medication was not involved, the percentage of patients receiving totally safe and appropriate advice ranged from 62 to 77 percent. For the fourth scenario, only 17 percent received such advice. In Germany, the Product Testing Foundation (1991) found that pharmacists’ explanations tended to be accurate for preparations requiring special explanations (for instance, appetite suppressants and iron preparations) and that performance had improved since 1984. There are also examples of inappropriate advice being given. For instance, Goodburn et al. (1991) found that pharmacists in the United Kingdom gave inappropriate advice for the treatment of childhood diarrhea 70 percent of the time. In Germany, Glaeske (1989) found that 61 percent of all nonprescription products sold were ineffective or presented dangers to the uninformed user.

In all the countries where studies have been conducted, researchers found that information-gathering and advice were often incomplete (that is, the information given was appropriate but not everything that should have

been covered was discussed). In Australia, Feehan (1981) found a lack of information-gathering on patients' characteristics. For instance, 25 of 43 pharmacists were prepared to sell a weight-reduction product without checking on the patient's health or to see whether she was taking other medications. Glaeske (1989) reported that in Germany no pharmacist asked all the questions considered to be essential. For instance, not one trained shopper who was a woman was asked if she was pregnant or lactating. Consultation on side effects was unsatisfactory—for example, such simplistic statements as “every medication has side effects” and “there are no side effects” were sometimes made. In a 1991 study, the Consumers Association (1991) of the United Kingdom found that customers were not adequately questioned. Only 10 percent of pharmacists asked the trained shoppers what other medications they were taking.

Studies in Australia (Harris et al., 1985), Canada (Willison and Muzzin, 1992), and the United Kingdom (Smith, Salkind, and Jolly, 1990) found a wide range of skills and performance between pharmacists. Feehan (1981) in Australia and Willison and Muzzin (1992) in Canada thought that this could indicate a shortcoming in pharmacists' education for dealing with patients and that there is a need to strengthen their clinical interviewing skills. Interestingly, Smith, Salkind, and Jolly (1990) in the United Kingdom found that pharmacists' counseling was either very good or very poor. Few pharmacists were in the middle.

The studies generally found that pharmacy practice has improved as more and better counseling has been given. This is so when the same organization collected the same data at different times (Product Testing Foundation, 1984 and 1991) as well as when the results of different studies over time were compared (Willison and Muzzin, 1992).

The results of studies in the United States of pharmacist counseling on nonprescription drug use are quite similar to the findings in other countries. However, no studies in the United States have assessed the frequency of pharmacy counseling on these products.

Three studies assessed some aspect of the quantity of counseling. In a mail survey, Carroll and Gagnon (1983) found that 96 percent of households said the pharmacist was available to answer questions about nonprescription medications half the time or more. Meade (1992), reporting on a study conducted for APhA, noted that 69 percent of pharmacists said they counsel patients 10 or more times per day on

nonprescription products, well within the range reported in Canadian pharmacies. Another survey conducted for APhA (Market Facts, 1994) indicates that pharmacist counseling for nonprescription drugs is increasing. The 1993 National Prescription Buyers Survey found that the percentage of respondents who had ever asked a pharmacist for advice about a nonprescription drug had increased from 37 percent in 1979 to 64 percent in 1993. (There was evidence that interactions with pharmacists for prescription advice had increased as well.)

The other U.S. studies in table 4.2 examined the quality of counseling. In the 1960's and early 1970's, two studies examined pharmacists' counseling regarding nonprescription drugs in U.S. pharmacies (Knapp et al., 1969, and Wertheimer, Shefter, and Cooper, 1973). The conclusions of both studies were generally negative. Insufficient inquiries of patients were made, counseling was infrequent, and inappropriate drugs were sold.<sup>3</sup>

Jang, Knapp, and Knapp (1975), while finding some positive aspects of pharmacists' counseling, also had criticisms, including poor performance on drug monitoring and controlling OTC drug use.

The Wertheimer, Shefter, and Cooper (1973) study was replicated by Vanderveen and colleagues (Vanderveen, Adams, and Sanborn, 1978; Vanderveen and Jirak, 1990). In the 1978 study, the authors concluded that the pharmacy "profession has not made any great strides in the area of OTC product counseling." The only question asked by more than one fourth of the pharmacists was the age of the child for whom the medicine was being purchased. The 1990 study found some improvement, with a majority of pharmacists asking about both the age of the child and the duration of the illness. However, no other issue was raised by more than half the pharmacists. The general conclusion was that while pharmacists' counseling had improved, it could still be better.

Barnett, Nykamp, and Hopkins (1992) found that the majority of pharmacists questioned customers before making OTC recommendations and gave directions on their use. For one scenario, an average of 2.81 out of 5 pertinent questions were asked; for a second, an average of 1.58 questions out of 5 were asked. Combining results from the two scenarios, they found that 68.2 percent of product recommendations by pharmacists younger than 30 were appropriate while 42.4 percent by pharmacists 30

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<sup>3</sup>Linn and Davis (1973) also studied nonprescription drug counseling in the United States but had a different focus. They found some support for the hypothesis that "business oriented" pharmacists were more likely to recommend medications than were "professional oriented" pharmacists.

and older were appropriate. Overall, the authors concluded in 1992 that pharmacists had made strides in OTC counseling since the earlier studies.

In a study of pharmacist counseling for prescription drugs in Wisconsin, where there is a requirement that pharmacists provide appropriate consultation for a prescription, Pitting and Hammel (1983) sent trained shoppers to 84 pharmacies. (The number of trained shoppers and the selection method for the pharmacies was not given.) They found that 61.5 percent of pharmacists did not consult with the patient when a prefabricated drug was dispensed, although 87.5 percent did consult on compounded products. Thus, even when pharmacists were legally required to counsel patients, not all pharmacists did so.<sup>4</sup>

The results of the studies in the United States are rather similar to those in countries where the sale of at least some nonprescription drugs is restricted to pharmacies. In general, the theory of pharmacy practice diverges from the reality. The advice of pharmacists is often appropriate but not universally given. In addition, it is often incomplete, with little information being given to customers on such items as possible side effects. In other words, what information is given is accurate, but not enough was passed on to consumers. Researchers consistently found a lack of information-gathering on the part of pharmacists. For instance, information is often not gathered on symptoms and other medications. More positively, within a range of pharmacists' behavior, many pharmacists do a good job. In addition pharmacists' performance, while still often deficient, has improved over time.

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## Activities of Pharmacists

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### Reporting Adverse Drug Reactions

One argument for an intermediate class of drugs is that pharmacists would be in a position to monitor patients for adverse drug reactions to medications in this class. In the case of a transition class, this information could be passed on to FDA and aid in its decision whether to allow the sale of a drug outside pharmacies. However, in Italy and the United Kingdom,

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<sup>4</sup>The authors speculated that their overall estimates of counseling might be high because (1) the prescription mix was dominated by prefabricated dosage forms for which a low rate of appropriate consultation was observed, (2) the prescriptions in the study were all new prescriptions and the consultation rate is probably lower for renewals (counseling is required for both new prescriptions and renewals), and (3) most prescriptions contain more specific instructions to the patient than those in this study and specific instructions would seem less likely to stimulate the pharmacist to consult.

adverse drug reaction reports from pharmacists are not accepted. In the other countries, reports from pharmacists are accepted but not required. This is the same as in the United States. Government, pharmacy, and manufacturers' officials stated that pharmacists rarely submit adverse drug reaction reports. Thus, the experiences of the 10 other countries do not allow us to assess the benefits from or costs of requiring pharmacists to report adverse drug reactions.

However, there is some limited information from the United States that suggests that community pharmacists can, at least in some situations, successfully monitor patients for adverse drug reactions. Meade (1994a and b) gives examples of pharmacists who have successfully done this. She reported on a pharmacist in Minnesota who, through consultation with a patient, detected that a prescription drug was causing the patient dizziness, chest pain, and swelling and tingling in the hands. When the prescribing physician took the patient off the drug, the symptoms disappeared. Meade also reported on a pharmacist in Tennessee who discovered from a patient's reaction to a prescribed drug that the patient had diabetes.

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## Maintaining Patient Profiles

One potential role for pharmacists is to record prescription and nonprescription drug sales in patient profiles. This information could help link drug use with adverse drug reactions and other complications. Other uses for profiles would be prospective. For instance, a patient profile could alert a pharmacist to medical conditions that might be affected by a prescribed drug's side effects. The pharmacist could alert the physician to the problem and, if it were appropriate, the physician or pharmacist could select a different drug without these side effects. Similarly, a profile could alert the pharmacist to possible adverse interactions with other drugs that a patient was currently taking.

It is not possible to judge the usefulness of such a procedure for nonprescription products. Only in Australia are pharmacists ever required to include nonprescription drug use in patient profiles.<sup>5</sup> These requirements are determined by the individual Australian states and exist only in certain states and for particular pharmacist-class drugs. The drugs for which sales must be recorded vary from state to state. There are no requirements in any of the states for recording sales of pharmacy-class drugs or drugs available outside pharmacies. Officials in Victoria told us

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<sup>5</sup>As we show in chapter 5, a similar recordkeeping requirement exists for some prescription drugs that pharmacists themselves can prescribe in Florida. The experience has been that patients' profiles are not adequately maintained.

that there has been some difficulty in getting pharmacists to comply with recording requirements. They attributed this to the requirements' covering too many drugs and, consequently, they have reduced the list of nonprescription drugs for which the sale must be recorded to those for which they believe recording is most important.

The situation in Victoria is similar to one in the state of Washington in the United States for prescription drugs. Washington has mandatory regulations governing pharmacy practice that include a requirement that pharmacists maintain and use patient profiles. In a trained shopper study, Campbell et al. (1989) found that 67 percent maintained these profiles. While this was an increase from 54 percent in 1974 (when the law was enacted), it was considerably below the law's 100 percent. The authors speculated that it was doubtful that maintaining and using patient profiles was significantly greater in Washington than it was in states that did not have the same requirements.

In 1987, the National Association of Retail Druggists surveyed pharmacists through the NARD Newsletter (The NARD Survey, 1988). More than 1,300 pharmacists responded.<sup>6</sup> While 92 percent of the pharmacists reported that they maintain patient profiles, only 15 percent said that they record OTC drug sales in them.

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## Officials' Views

The views of many of the government officials in the countries we visited (Australia, Canada, Germany, the Netherlands, Switzerland, and the United Kingdom) were consistent with the results of the studies discussed above. There was agreement that pharmacists have done a rather poor job of passing their knowledge on to consumers. Many officials questioned the frequency of pharmacists' counseling and thought that not enough counseling was being done. Pharmacists were selling drugs and providing little or no advice on their use. Officials gave several possible explanations for this, including time constraints and a lack of counseling skills.

Nonetheless, the officials thought that pharmacists had the potential to improve drug use if they passed their knowledge on to patients. There was general agreement that pharmacists are knowledgeable and have a great deal to offer patients on the proper use of medications. This position was held even by those who opposed or questioned the usefulness of

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<sup>6</sup>The number of pharmacists who were sent the survey was not reported. It is possible that there is a selection bias problem in this study—that is, the pharmacists who responded to the survey might not be representative of all pharmacists. Those who responded could be among the more or less active pharmacists.

restricting the sale of some nonprescription drugs to pharmacies. Pharmacists could ask key questions about other drugs a patient is currently taking and about underlying medical conditions and could monitor compliance and report adverse drug reactions.

Professional pharmacist associations in these countries are taking criticisms seriously, and many have initiated various programs to address them. They have instituted continuing education courses to give pharmacists the skills necessary to better perform their counseling role. A number of officials noted that pharmacy education has changed a great deal in the past 10 or so years. There is currently more of an emphasis on clinical pharmacy with its focus on patient service. Pharmacists who received their training before this change are often described as not having the “people skills” to be good counselors.

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## Recent Developments in Pharmacy Practice

In this section, we briefly describe some recent developments in the practice of pharmacy that are relevant to our assessment of an intermediate class of drugs. Our purpose is not to evaluate these changes but to make the reader aware of them.

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## Pharmaceutical Care

The idea of pharmaceutical care constitutes a major change in the practice of pharmacy. It moves pharmacists away from their traditional role of dispensing drug products and involves them more in selecting and monitoring drug therapies. The idea has been advocated in the United States by academics in university-based pharmacy schools and pharmacy organizations and has spread to other countries (the initiatives mentioned above have often been undertaken under the name of pharmaceutical care). Hepler defined pharmaceutical care as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that increase a patient’s quality of life” (1991, pp. 141-42). It involves “designing, implementing, and monitoring a therapeutic plan, in cooperation with the patient and other health professionals, that will produce specific therapeutic outcomes” (Klein-Schwartz and Hoopes, 1993, p. 11).

The proponents of pharmaceutical care point to various studies (most of them in institutional settings where complete patient information exists) that show the benefits that pharmacists can have on health care. For instance, one hospital study showed shorter length of stay, smaller total cost per admission, and smaller pharmacy cost per admission for patients who received either of two programs involving pharmaceutical care

(Clapham et al., 1988).<sup>6</sup> In another study, elderly apartment residents were instructed in drug use and given access to drug counseling by pharmacists (Hammarlund, Ostrom, and Kethley, 1985). After 1 year, the residents who initially had the greatest number of medication problems (and were available for follow-up interviews) were found to have had an 11-percent decrease in the number of prescriptions taken and a 39-percent decrease in the number of medication problems.

There is some evidence of the value of pharmaceutical care in community pharmacies. McKenney et al. (1973) examined the effect of a clinical pharmacist's counseling hypertensive patients in three community pharmacies. Throughout the study, the pharmacist maintained close contact with the patients' physicians. The patients who received the counseling were more likely than those who did not receive it to show an increased knowledge of hypertension and its treatment, comply more often with their prescribed therapy, and maintain their blood pressure within the normal range. In a later study, pharmacists in six community pharmacies in Virginia were trained to provide similar services (McKenney et al., 1978). Results showed improved compliance and better blood pressure control in patients receiving counseling than in those not receiving it. Pharmacists also detected 38 instances of adverse drug reactions.

Rupp (1992) estimated the value of community pharmacists intervening to correct prescribing errors. Of 33,011 prescriptions that were examined, 623 (1.9 percent) were found to be problematic. The estimated value of these interventions was \$76,615.<sup>7</sup> Nichols et al. (1992) examined the effect of counseling on nonprescription drug purchasing decisions. They found that 25.4 percent of patients purchased a different product than they had intended after receiving counseling, 13.4 percent did not purchase a drug, and 1.3 percent were referred to their physician. However, the study did not measure the importance of these decisions (for instance, how much of an improvement was brought by changing medications).

More research is being conducted on the effect of pharmaceutical care in community pharmacies. Studies are focusing on the effect of drug use reviews by pharmacists, the use of protocols by pharmacists in managing and monitoring diseases, and a pharmaceutical care program for pediatric

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<sup>6</sup>The two programs were (1) pharmacist monitoring of drug therapy in the patient-care area and (2) centralized pharmacist monitoring of computerized patient profiles.

<sup>7</sup>These projected savings include only the estimated direct costs of medical care that was avoided because of the pharmacists' intervention. Such items as losses in patient productivity, pain and suffering cost, and the value of possible litigation were not estimated.

and adolescent patients with asthma. In addition, there appears to be at least some movement among community pharmacists to implement pharmaceutical care. Training courses are offered on how to implement pharmaceutical care (Martin, 1994) and articles have been written on pharmacies where it has been established (Meade, 1994a and b).

For our purposes, it is important to note that the methods and goals of pharmaceutical care are consistent with those of an intermediate drug class. The general idea of both is that pharmacists would be more involved in a patient's drug therapy by such actions as consulting with patients. The evaluation of pharmaceutical care in community pharmacies would give some indication of the potential value of a greater role for pharmacists and, consequently, would provide some information on the value of an intermediate class of drugs. However, even if a positive value were established, or at least indicated, a number of the difficulties we have identified in this report would still have to be addressed. For nonprescription drugs, pharmacists would need to counsel patients, monitor and report adverse drug reactions, refer patients to physicians when necessary, and perform many other activities. This has not been the norm.

Other issues would also need to be addressed. For instance, pharmaceutical care can take a great deal of time. Pharmacists would probably have to delegate more responsibility to technicians. The appropriate role for technicians would have to be determined. Pharmacists' compensation for pharmaceutical care activities may be especially important. Many pharmacies now charge a fee for pharmaceutical care services. (Some pharmacies have different fees depending on the level of services offered.) However, some insurance companies have been reluctant to pay for the services (Martin, 1994).

It should be clear that pharmaceutical care regarding nonprescription drugs can be given without an intermediate class of drugs. When and if pharmaceutical care is established in community pharmacies, the need for an intermediate class will still need to be established. It will still be unclear what benefits would accrue from establishing such a class of drugs. Arguments such as we hear now will still be heard (for instance, more drugs would be switched and health care costs would be reduced). The difference would be that, at least in some areas, pharmacists would be doing what is necessary for an intermediate-drug class to be successful. How much, if anything, would be gained by establishing an intermediate class of drugs, even under these circumstances, is unclear.

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## Omnibus Budget Reconciliation Act of 1990

Within the Omnibus Budget Reconciliation Act of 1990 are new requirements for the practice of pharmacy that went into effect on January 1, 1993, and that mandate prospective drug use reviews, counseling of patients, and maintenance of patient profiles for Medicaid recipients. Although these requirements cover only Medicaid beneficiaries, most (44) state boards of pharmacy have extended them to cover other patients receiving prescriptions. The goal, of course, is to improve health care through helping patients understand and follow medication directions better. Success is being evaluated by several studies funded by the Health Care Financing Administration.

The applicable regulations require prospective drug use reviews before each Medicaid prescription is filled. Prescriptions are to be screened for potential problems from therapeutic duplication, drug-disease interactions, drug-drug interactions, incorrect dosage or duration of treatment, drug-allergy interactions, and clinical abuse or misuse. The pharmacist is to intervene, if necessary, before the prescription is dispensed.

Additionally, in drug use reviews pharmacists must offer to counsel patients about their prescription medications. Exact counseling requirements are defined by each state. Information that might be passed on includes the name and description of the medication, the dosage, special directions and precautions, common severe side or adverse effects, interactions, therapeutic contraindications, and proper storage. Pharmacists must also make a "reasonable effort" to obtain, record, and maintain at least the following information:

- the patient's name, address, telephone number, date of birth or age, and gender;
- the patient's individual history, where significant, including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices;
- the pharmacist's comments relevant to the patient's drug therapy.

The reaction of practicing pharmacists to the new requirements has been mixed. Some see it as an opportunity while others are wary. While the law requires pharmacists to perform additional duties, it does not stipulate that they should be compensated for them, despite some pharmacies' having had to hire new employees and buy new computer software. Pharmacists are also concerned that lawsuits against them will increase.

A 1994 survey conducted for the National Association of Boards of Pharmacy found that only 38 percent of all customers stated that someone in the pharmacy offered to have a pharmacist discuss their prescription medications with them. The president of the association stated that the results “clearly indicate that too few patients and caregivers are being counseled on their prescription medications.” However, the same study found that pharmacist counseling is perceived positively by the public. Seventy-one percent of offers to counsel were accepted, and the same percentage of patients thought that counseling was very important. The counseling that was done also appears to have been of a high quality, with 99 percent of respondents believing that the pharmacist had clearly presented the information and with pharmacists telling patients how and how often to use their medications at least 93 percent of the time. A large majority of patients were also told the dosage amount, the name (along with a description) of the medication, how long it should be taken, special directions or precautions, and any side effects. However, less than half of the pharmacists told patients how to monitor the effects of their medications and what they should do in the event of a missed dose.

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## Liability

Pharmacists’ liability is becoming a concern throughout the United States.<sup>8</sup> Data from the Chicago Insurance Company show that claims against pharmacists rose 22 percent from 1987 to 1990. Recent court rulings have expanded a pharmacist’s liability under some circumstances. Pharmacists in some states may now be held liable if they fail to instruct a patient about the maximum safe dosage or fail to identify a potential adverse drug interaction for a prescribed drug. (Chapter 5 discusses pharmacists’ liability in prescribing drugs in Florida.)

A 1994 ruling by an Arizona appellate court also indicates that pharmacists’ liability might be increasing. According to one source, a majority of court decisions involving pharmacy liability between 1986 and 1994 had concluded that pharmacists generally did not have a responsibility to warn patients of potential adverse effects of their drug regimen. However, in *Lasley v. Shrake* (880 P.2d 1129 (1994)), the appellate court ruled that pharmacists have a general duty of “reasonable care” that could include a duty to warn. The case was sent back to the trial court to determine what constitutes reasonable care.

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<sup>8</sup>Liability was not a concern to officials in other countries where there is a general lack of litigiousness compared to the United States.

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In addition, some pharmacists have speculated that requirements of the Omnibus Budget Reconciliation Act of 1990 will also increase pharmacists' potential liability, as could pharmaceutical care.

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## Summary

The success of an intermediate class of drugs, whether a fixed or transition class, depends in part on the role of pharmacists in the drug distribution system. The theory of pharmacy practice diverges from the reality. In all 10 study countries, pharmacists are expected to play a role (although the role varies between countries) in ensuring the proper use of drugs in a pharmacist or pharmacy class. Despite these requirements, pharmacists' counseling of patients, although increasing, is not as frequent and complete as it should be. Our findings for the United States are similar.

Pharmacists in the study countries are not required (or not allowed) to report adverse drug reactions. In only one instance are they required to record the sale of nonprescription drugs in patient profiles. Thus, in these countries, nonprescription drug sales are limited to pharmacists or pharmacies in order to restrict distribution or promote counseling, not to increase surveillance of nonprescription drug use.

Our findings indicate the difficulty of successfully establishing an intermediate class of drugs. Active pharmacist involvement is necessary for an intermediate class to serve its purpose of improving drug use. However, pharmacists will not necessarily counsel patients simply because it is expected or required, and enforcing such requirements is quite difficult. Also, it is unclear whether requiring pharmacists to maintain patient profiles and monitor adverse drug effects would succeed. There is little international experience in these matters.

Recent developments in pharmacy practice in the United States indicate that the role of community pharmacists may be changing. The implementation of pharmaceutical care and the counseling requirements of the Omnibus Budget Reconciliation Act of 1990 are beginning to move pharmacists from their traditional role of dispensing medications to one of monitoring their patients' drug therapies. The activities involved are similar to those that would be required for the theoretical benefits of an intermediate class to be achieved. However, even if pharmacists begin to regularly perform these activities, there will still be reason to determine the need for establishing such a class of drugs.

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# The U.S. Experience

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While the United States has essentially only two classes of drugs (prescription and general sale, the latter commonly referred to as OTCs), there are situations in which a pharmacist may supply a prescription drug to a patient without a physician's prescription and instances in which nonprescription drugs are not available for general sale. These include dispensing a small number of controlled substances (for instance, particular amounts of codeine) regulated under the Controlled Substances Act (Public Law 91-513, title II) and insulin. Similarly, in Florida pharmacists have been given the independent authority to dispense a limited number of prescription drugs without a doctor's prescription. Federal law requires that prescriptions be dispensed by "practitioners" but allows individual states to determine who is a "practitioner." In Florida, this group includes pharmacists. Finally, in some states pharmacists have been given dependent prescribing authority—that is, they may prescribe under the supervision of a physician. In this chapter, we describe these situations. The lessons that can be learned from them are relevant for both a fixed and transition class since, as with an intermediate class, pharmacists are expected to do more than simply dispense medications.

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## Schedule V Controlled Substances and Insulin

Under the Controlled Substances Act of 1970, the manufacturing, distribution, and dispensing of controlled substances (that is, psychoactive drugs) is regulated. The act's purpose, among other things, is to prevent drug abuse and dependence and strengthen law enforcement authority in the field of drug abuse. These drugs are placed into one of five categories (referred to as schedules) based on three criteria: currently accepted medical use, abuse potential, and human safety. Schedule V drugs have the fewest restrictions and may be made available by FDA without a prescription. They are defined as drugs having a low abuse potential relative to drugs or other substances in schedule IV, having a currently accepted medical use in treatment in the United States, and leading to limited physical or psychological dependence when abused relative to drugs or other substances in schedule IV.

Schedule V drugs are classified as prescription or nonprescription products as determined under the Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act of 1938. Some schedule V drugs classified as nonprescription under this act are available without a prescription in some states but not all. However, even when a prescription is not required, schedule V drugs are still available only from a pharmacist. Schedule V products are few. They are the narcotic buprenorphine, the stimulant pyrovalerone, and products containing specific amounts of the

narcotics codeine, dihydrocodeine, ethylmorphine, diphenoxylate with atropine sulfate, opium, or difenoxin with atropine sulfate. Larger doses of these products (when available) are in a more restricted schedule.

Sellers of schedule V products must follow federal and state requirements. For instance, in Connecticut the seller must keep a record containing “the full name and address of the person purchasing the medicinal preparation, in the handwriting of the purchaser, the name and quantity of the preparation sold and the time and date of sale.” Federal regulations state more generally that the purchaser must be 18 years old or older and furnish suitable identification and that all transactions must be recorded by the dispensing pharmacist.

While one purpose of the Controlled Substances Act is to improve public health, the requirements for selling a product differ from what is typically discussed for an intermediate class of drugs. Under the act, the focus is on recordkeeping; in an intermediate class of drugs, activities such as counseling and monitoring patients would be stressed. Nonetheless, the two are somewhat similar in that the pharmacist is involved in the sale and that reducing drug abuse is a goal. Any information on how successful the establishment of schedule V has been in reducing drug abuse would be helpful in evaluating the potential value of an intermediate class of drugs.

However, we were unable to locate any studies evaluating the usefulness of schedule V in preventing abuse or monitoring the use of the products.<sup>1</sup> Therefore, while it would be useful to know how successful schedule V has been, we have no data with which to find out.

Insulin is also available without a prescription but restricted to dispensing by pharmacists in most states.<sup>2</sup> However, a physician must first determine the patient’s insulin needs and provide instructions for controlling diabetes. As with schedule V products, we located no studies that evaluated the effect of this restriction.

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<sup>1</sup>In an earlier study, we reported on state prescription drug monitoring programs. While 11 states had programs, schedule V drugs were not covered in any of them (GAO, 1992).

<sup>2</sup>In the other states, insulin either is restricted to prescription sale or may be sold without a prescription by any retailer.

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## The Florida Pharmacist Self-Care Consultant Law

The Florida Pharmacist Self-Care Consultant Law (sometimes referred to as the Florida Pharmacist Prescribing Law), which went into effect on October 1, 1985, is unique in the United States. It allows pharmacists to independently prescribe specific categories of medications that under federal law may be dispensed only upon the prescription of a licensed practitioner; in Florida, this includes pharmacists. Perhaps the most important point about the law is that pharmacists are able to independently prescribe medicines—that is, they are not operating under the supervision of a physician.<sup>3</sup>

Despite this independence, the law does limit what pharmacists can do. Pharmacists are not allowed to order injectable products, treat a pregnant patient or nursing mother, order more than a 34-day supply of the drug, prescribe refills unless specifically authorized to do so in the formulary, or order and dispense anyplace but in a pharmacy.<sup>4</sup> Pharmacists recommending a drug must advise patients to see a physician if their condition does not improve at the end of the drug regimen.

When the law went into effect, there were 35 drugs in the formulary. Since then, 7 drugs have been added, bringing the total to 42. Responsibility for the original list, as well as for adding and deleting drugs, rests with a seven-member committee.<sup>5</sup> The law states that any drug sold as an OTC product under federal law may not be included in the formulary. Among the categories of drugs in the formulary are oral analgesics, antinausea preparations, and antihistamines and decongestants.

Under the law, pharmacists are not required to perform the prescribing role. However, if they choose to do so, a number of requirements pertain, including the labeling of products, creating prescriptions, and maintaining patients' profiles. (More detail on the products in the formulary and the requirements for pharmacists is in appendix V.)

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## Evaluation

In 1990, a group of researchers from the College of Pharmacy at the University of Florida reported on the effect of Florida's Pharmacist

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<sup>3</sup>In some states, other health professionals (physicians' assistants, nurse practitioners, and pharmacists) may prescribe medications but only under protocols established by supervisory physicians. (These situations for pharmacists are described later in this chapter.)

<sup>4</sup>The formulary is the list of drugs pharmacists are allowed to prescribe and the conditions under which they may be prescribed.

<sup>5</sup>The committee consists of two members of the Board of Medicine, one member of the Board of Osteopathic Medicine, three members of the Board of Pharmacy, and one additional person with a background in health care or pharmacology.

Self-Care Consultant Law during its second and third years of operation (Eng et al., 1990). Four methods were used in the study: a survey of pharmacists, pharmacy audits, shopper visits, and a survey of consumers. The following four subsections summarize the results that are most relevant to our report.

### Survey of Pharmacists

In a mail survey of pharmacists, Eng and colleagues found that pharmacists infrequently prescribed drugs from the formulary. Thirty-three percent of community pharmacists had prescribed a drug at least once. Of this group, 60 percent had prescribed less than one drug per month. The principal reasons given for not prescribing were that drugs in the formulary offered no advantages over nonprescription drugs, prescribing increased the risk of liability, and time was too short. Conversely, the main reasons for prescribing were that it helped the patient maximize self-care, used the pharmacist's knowledge, and saved the patient money.

No differences were found between the prescribers and nonprescribers with respect to gender, professional degree, position (for instance, prescription department manager and pharmacy owner), and prescription volume. The study authors did find that pharmacists with fewer years of practice were more likely to prescribe than those with more years of practice, and independent community pharmacists were more likely to prescribe than chain pharmacists.

### Pharmacy Audits

The law requires that if a pharmacist prescribes a drug, the pharmacy must maintain a profile of the patient. Of 19 pharmacies that reported that their pharmacists prescribed drugs, only 9 maintained the required profiles. The audits showed that pharmacists' prescriptions made up a small proportion of the total number of prescriptions: less than 0.25 percent of all the medications that were prescribed in the 9 pharmacies. These prescriptions were primarily limited to topical pediculicides (lindane shampoo), oral analgesics, and otic (ear) analgesics. These categories constituted 82 percent of all pharmacists' prescriptions.

### Shoppers' Visits

Trained shoppers found that the quality of the pharmacists' performance in 21 community pharmacies was high in two areas: (1) following the law's labeling and quantity limitation requirements and (2) practicing the art of communication. In more than 70 percent of the cases, the shoppers found that the pharmacist was friendly, provided some privacy, and appeared to be interested.

However, the pharmacists spent very little time in assessing and responding to medical complaints presented by patients. Less than 17 percent of the 62 pharmacists asked about chronic medical conditions, medication allergies, and current prescription and nonprescription drugs that the patients were taking. Only 5 percent of the pharmacists asked about the onset, duration, and frequency of the medical problem while 13 percent asked if they had tried other medications. In less than 40 percent of the visits, pharmacists provided information on topics such as the number of doses to be taken per day, the duration of the treatment, and side effects. The authors noted that when counseling was provided, the information was generally accurate but incomplete.

The performance of the 21 pharmacists in three scenarios was mixed. In a scenario leading to the recommendation of an OTC product, all 21 pharmacists recommended the correct product. However, for a scenario that should have led to referral to a physician, only 1 pharmacist made the referral. In a scenario leading to the pharmacist's prescribing a product, the patient asked for a specific shampoo that was in the formulary; only 5 pharmacists prescribed it. The four reasons given for not prescribing were that liability insurance did not cover the pharmacist's prescribing, it is against company policy to prescribe, a prescription is needed, and the particular pharmacist does not prescribe.

## Consumer Survey

Consumers in the pharmacies were surveyed to determine their attitudes toward receiving advice from pharmacists.<sup>6</sup> Three principal reasons were given for seeking advice from pharmacists: confidence in their abilities, convenience, and the problem's not being serious enough to consult a physician. All 149 of the patients who answered the question on how pleased they were with the pharmacist's actions indicated that they were satisfied. Ninety percent of consumers said that they would follow the pharmacists' advice regarding seeing their physician or taking a recommended OTC product or pharmacist prescribed drug. A small majority (52.3 percent) also indicated a willingness to pay a fee for a pharmacist's services if a drug were prescribed by the pharmacist but not if the pharmacist only provided advice, recommended a nonprescription product, or referred the patient to a doctor. Of those willing to pay a separate fee, one third were willing to pay more than \$5.00.

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<sup>6</sup>The pharmacists selected the customers to be surveyed. Of 362 surveys distributed by the pharmacists, 163 were returned.

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## Officials' Assessment of the Effect of the Law

Officials we met with in Florida invariably thought that the effect of the law had been minimal because few pharmacists were using their prescribing authority. One official who had previously done pharmacy inspections in Florida estimated that 1 in 50 pharmacists actually prescribed drugs.

The officials' reasons for the lack of prescribing mirrored those given by the pharmacists themselves. The first involved the drugs in the formulary. There is a belief that the drug categories available to the pharmacists and the specific drugs in them are not very useful because some OTC products work just as well. Therefore, there is no incentive for a pharmacist to use one of the drugs in the formulary to treat patients.<sup>7</sup>

The second explanation involved the liability issue. Individual pharmacists were concerned that they would increase their liability risk if they prescribed. Insurance companies did not want to insure individuals who prescribed drugs. The policies of some pharmacists who prescribed were canceled while others had riders attached. At one point, there was an insurance surcharge if a pharmacist wanted to prescribe.

The third common reason given for pharmacists' not prescribing was the presence of time constraints. As shown in appendix V, a number of recordkeeping requirements are associated with prescribing a drug. They take time (one official estimated 10 minutes per prescription). One official tied the recordkeeping requirements to the liability issue, noting that the paperwork involved with prescribing brings pharmacists into the spotlight and makes them more fearful of liability.

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## Comparisons With Studies in Other Countries

In chapter 4, we discussed the practice of pharmacy in the study countries, including reports on pharmacists' counseling on nonprescription drugs. The experiences in Florida are generally similar to those in the other countries. For example, Florida is similar to Australia—the one country where pharmacists are ever required to maintain patient profiles on nonprescription drug use—in that pharmacists often did not maintain the required profiles. Recordkeeping requirements were seen in both places as being excessive. In Florida, this was attributed to the requirements taking

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<sup>7</sup>In addition, a number of the drugs were switched to nonprescription status at the national level soon after the development of the Florida formulary, thereby limiting pharmacists' prescription authority (since no drug sold OTC under federal law may be included in the formulary). Moreover, some of the products were available at lower doses without a prescription, which could lessen the incentive for pharmacists to prescribe. Thirteen of the drugs fell into one of these categories within 3 years of the law's going into effect.

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too much time, while in Australia the requirements were viewed as covering too many drugs.

Similarly, in counseling their patients, pharmacists in other countries and Florida did not gather sufficient information from them on such items as medical conditions and other medications being taken. In many cases, counseling was more incomplete than inappropriate.

Consumers' views toward pharmacist counseling were also quite similar. Customers in Florida were generally positive toward pharmacists' counseling, but they were less willing to pay for advice from pharmacists if only a nonprescription drug was involved. A study in Canada also found that most customers did not want advice on nonprescription drugs.

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## Pharmacists as Dependent Prescribers

While pharmacists in Florida have been given independent (although limited) prescribing authority, some pharmacists elsewhere in the United States have been given dependent prescribing authority. Typically, the pharmacists are constrained by protocols established by supervisory physicians. Dependent prescribing has not normally been discussed in terms of an intermediate class of drugs, but it does indicate roles that pharmacists have played in addition to the traditional one of dispensing medications. Because these activities are outside the scope of this report, we do not evaluate them here. Instead, we only describe alternative roles that pharmacists sometime have in the United States.

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## Pharmacists in the Indian Health Service and the Veterans Administration

The Indian Health Service (IHS), part of the U.S. Public Health Service in the Department of Health and Human Services, provides health services to American Indians and Alaskan Natives, including hospital and ambulatory medical care. IHS pharmacists are authorized to provide certain prescription drugs directly to patients without a physician's authorization. At the outset of the program, the pharmacists could modify doses, dosage forms, and quantities of medicines and make therapeutic substitution of medicines. Later, their responsibilities were expanded to include treating minor acute illness and monitoring patients receiving chronic drug therapy between physician visits. The activities of pharmacists are defined by approved protocols that indicate their functions, responsibilities, and prescribing privileges. The protocols are organized by disease and include such elements as the criteria for inclusion in pharmacy-based care, specific definitions of the role of the referring physician or nurse and the

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pharmacist, criteria for periodic visits by physicians to review a patient's status and the quality of care the pharmacist delivers, and drug therapy.

In March 1995, the Department of Veterans Affairs (VA) issued a directive establishing medication prescribing authority for, among others, clinical pharmacy specialists.<sup>8</sup> The directive defines inpatient and outpatient prescribing authority for clinical pharmacy specialists and other professionals, it lists the requirements for pharmacists to be given prescription authority, and it notes that each professional given the prescription authority will be limited by "a locally-determined scope of practice" that indicates his or her authority. Prescriptions written within the scope of practice do not require a physician's signature, but those outside the scope of practice do.

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## Dependent Prescribing Authority in the States

Nine states have established dependent prescribing privileges for pharmacists.<sup>9</sup> In California, Nevada, and North Dakota, pharmacists are allowed to prescribe only in institutional settings; there are no such restrictions in the six other states. Only in New Mexico is special training required for pharmacists to prescribe.

In these nine states, prescribing is done by a protocol that involves a voluntary agreement between the pharmacist and the physician. The pharmacist is responsible for initiating, monitoring, and modifying drug therapy while the physician supervises the process and overall patient care. For example, in Washington, all practicing pharmacists are eligible to initiate and modify drug therapy by protocol, but a written agreement must be developed between the pharmacist and an authorized prescriber. The agreement must be sent to the Washington State Board of Pharmacy for review. It must include, among other items, the type of prescribing authority to be exercised (including types of medical conditions and drugs or drug categories), documentation of prescriptive activities to be performed, and a mechanism for communicating with the authorizing practitioner.

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<sup>8</sup>See VHA Directive 10-95-019, "General Guidelines for Establishing Medication Prescribing Authority for Clinical Nurse Specialists, Nurse Practitioners, Clinical Pharmacy Specialists and Physician Assistants."

<sup>9</sup>The nine states are California, Mississippi, Missouri, Nevada, New Mexico, North Dakota, Oregon, South Dakota, and Washington. A number of evaluations of pharmacist prescribing have been done. For instance, in California they have been conducted in a hospital (Chenella et al., 1983), nursing facility (Thompson et al, 1984), and health maintenance organization (McGhan et al., 1983).

North Dakota recently gave pharmacists the right to prescribe but only in institutional settings (a hospital, skilled nursing facility, or swing bed facility) in which a patient's medical records are readily available to the physician. Following diagnosis and initial patient assessment by a licensed physician, pharmacists in these settings (under the supervision of the same licensed physician) can initiate or modify drug therapy.

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## Summary

We found no data to evaluate the experience of pharmacists in the United States dispensing schedule V controlled substances or insulin. However, the data on Florida show that the experience there of pharmacists prescribing drugs, whether a fixed or transition class, has been quite similar to that in 10 countries we studied. A number of lessons for the success of an intermediate class of drugs, whether a fixed or transition class, in the United States can be learned from Florida. First, the drugs in an intermediate class must be seen as worth the effort of dispensing. If not, the drugs will not be used and the benefits of the class will not be realized. Second, the liability and insurance issues have to be addressed. Third, recordkeeping requirements can be burdensome. Pharmacists are busy and, if the recordkeeping requirements are too extensive, they will either not maintain the records or not dispense the drugs. A method of collecting the data would have to be developed that does not impose too great a burden on pharmacists. This would be especially important for a transition class of drugs, for which recordkeeping would be a necessity if FDA were to gather data on the suitability of a drug for sale outside pharmacies.

Calls for an intermediate class of drugs do not focus on pharmacists' dependent prescribing authority, but it gives some indication of roles pharmacists may play other than the traditional one of dispensing medications. An evaluation of these roles would have to study the counseling of patients, monitoring adverse drug reactions, any reductions in cost, and the setting in which the prescribing takes place. Pharmacists in institutional settings (including IHS and VA) have access to patients' records that indicate their health status and drug regimen while pharmacists in community pharmacies (from where intermediate-class drugs would be dispersed) might not have this information. Prescribing under these two circumstances is quite different. The results of evaluating one may not be applicable to the other.

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# Summary and Conclusions

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The purpose of this report was to examine the structure and operation of drug distribution systems in other countries in order to better understand the potential advantages and disadvantages of establishing an intermediate class of drugs in the United States. The assumption is that while the experiences of other countries might not be models for the United States, they might provide a useful starting point for discussion. This chapter summarizes our findings and presents our conclusions.

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## Extant Studies

The two-tier U.S. drug distribution system with its prescription and general sale classes is unique among the 10 countries we studied. These countries restrict the sale of at least some nonprescription drugs to pharmacies or personal sale by a pharmacist. However, their drug distribution systems differ, and no efforts have been made to study systematically the consequences of the different systems. We found no systematic evidence to support the superiority of one drug distribution system over another.

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## Drug Distribution Systems

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### The Benefits of a Transition Class

It is unclear how some of the benefits of a transition class would be realized in the United States. The experiences of other countries cannot be used to assess its usefulness because their intermediate classes are not used in this manner. Instead, they are generally viewed as fixed classes into which drugs are placed permanently. The intermediate classes are used solely to restrict access to drugs, not to facilitate their movement to general sale.

It is unclear whether a transition class could be effective in monitoring adverse drug reactions while a drug is being considered for general sale. Several officials, questioning the usefulness of the data that would be collected, argued that toxicity profiles are well established through clinical research and experience with drugs as prescription products. Additionally, the data that would be collected when a drug was in the transition class would not be from well-controlled studies. The conclusions that could be drawn from the data would not be as well supported as conclusions from other types of studies.

If an intermediate class were used to increase knowledge to better assess drugs for switching, pharmacists would have to keep records on patients' drug purchases. This would allow the purchase of a drug to be linked with adverse outcomes. Pharmacists would have to record symptoms, other medical conditions, the practitioners who recommended the product, and the amount purchased. They would also have to follow up, recording experiences with a product such as efficacy, side effects, and interactions with food, drugs, and medical conditions. These recordkeeping requirements would take time and add costs; much less demanding recordkeeping requirements deter pharmacists in Florida from prescribing such drugs. Similarly, in the Australian state of Victoria, we found that pharmacists often did not maintain records of patients' use of pharmacist-class drugs, despite being required to do so.

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### The Use of an Intermediate Class to Prevent Abuse

Officials in the United States and abroad thought that an intermediate class, whether fixed or transition, would do little to prevent drug abuse. While having to buy drugs in pharmacies rather than in other outlets would be a deterrent (for instance, a consumer would have to talk to the pharmacist or would be able to buy only a small amount of the drug), this safeguard would be relatively easy to circumvent. Consumers could visit the same pharmacy on numerous occasions or go to several pharmacies to purchase the drug. Experiences in Australia and Germany in which pharmacist-controlled nonprescription drugs were either used or purchased improperly are consistent with these conclusions.

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### Drug Expenditures

All 10 countries control the prices of prescription drugs but not necessarily nonprescription products. Consequently, we could not draw useful lessons for the United States (where neither prescription nor nonprescription prices are controlled) on how prices change when a drug is switched.

We did find some evidence from the United States and the United Kingdom that the price of a drug decreases when it is switched from prescription to nonprescription status. However, the effect on price of the presence or absence of an intermediate drug class has not been assessed.

We also found that moving a drug to nonprescription status did not necessarily reduce health care costs. An incentive is created to obtain a drug with a prescription when such drugs remain reimbursable if they are prescribed but not if bought without a prescription. This can occur if

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patients have less out-of-pocket costs (for instance, because of a small copayment) for a prescription drug than for a nonprescription product, even if the nonprescription product is less expensive.

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## The European Union

The European Union has decided not to require that the member countries establish a particular drug distribution system. The European Union was not convinced of the superiority of any particular system. Each member country will be allowed to establish whatever drug distribution it wants, provided the requirements for domestic producers and importers are the same. The European Union has established criteria for distinguishing prescription from nonprescription drugs in the hope that drugs in these categories will become consistent from country to country.

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## Access to Pharmaceuticals

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### Number of Pharmacies and Drugstores

There are approximately 54,000 community pharmacies in the United States. This is substantially less per capita than 6 of the countries studied (if drugstores are included), while 2 other countries and the Canadian province of Ontario have approximately the same number as the United States. Only Denmark and Sweden have many fewer community pharmacies per capita than the United States. This suggests that limiting the sale of some nonprescription drugs to pharmacies in the United States would create somewhat greater access problems than in 6 of the countries. However, this is complicated by the number of other outlets such as mail-order and managed care pharmacies that might choose to sell these drugs. If such outlets chose to sell these products, the reduced access to these drugs from limiting them to sale in pharmacies could be offset.

While the number of pharmacies gives some indication of access, the distance to a pharmacy is also very important. The distance that people live from pharmacies varies greatly in the United States. The nearest pharmacy can be 100 or more miles away. Restricting the sale of some nonprescription drugs to pharmacies would give individuals who have ready access to a pharmacy a greater number of nonprescription drugs from which to choose. However, if the drugs were to come from the prescription class, relative access between customers with and without ready access to a pharmacy would remain the same. The drugs would still

be available for sale only in pharmacies; the difference would be that a prescription would not be required.

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## Self-Selection of Drugs

Of the countries studied, only the United States allows self-selection of all nonprescription drugs. Denmark, France, and Italy do not allow self-service for any drugs, while the remaining countries allow it for some but not all nonprescription products. If the United States were to establish an intermediate class of drugs (whether fixed or transition), it might not allow the self-selection of these products, since the theoretical benefits associated with the class would be difficult to achieve without some control on their distribution in pharmacies. This could change the way nonprescription drug purchases are made, since comparisons between products would be more difficult for consumers to make, not being able to select intermediate-class products from the shelf personally.

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## Classification of Drugs

Our examination of the classification of 14 selected drugs in the study countries indicated no clear pattern of increased nonprescription drug availability because of the existence of a pharmacist or pharmacy class. It appears that other factors in addition to or instead of the existence of a pharmacist or pharmacy class account for differences in drug classification between the countries. Despite the absence of an intermediate class, the United States allows the sale of some of the 14 drugs without a prescription that many other countries restrict to prescription sale. Conversely, the United States restricts to prescription sale some drugs that other countries allow to be sold without a prescription but only in a pharmacist or pharmacy class.

It also appears that access in one country relative to another depends in part on how access is defined. More of the 14 drugs were available for sale outside pharmacies in the United States than in any of the other countries. However, the United States restricts the sale of more of these drugs to prescription status than do 5 of the countries. These drugs, while available for sale without a prescription, are restricted to a pharmacist class. Thus, if the criterion used for defining access is the number of drugs available for general sale, the United States has the most accessible system. However, if the criterion is the number of drugs available without a prescription, the United States is somewhere in the middle in terms of accessibility.

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## Pharmacy Practice

Officials in the countries we visited and the literature on pharmacist counseling generally agree that the theory of pharmacy practice diverges from the reality. The theory of pharmacy practice involves (and the success of a fixed-intermediate or transition class requires), for example, the complete and appropriate counseling of patients on such issues as dosing instructions and potential adverse drug reactions, as well as maintaining patient profiles. However, pharmacists have often not performed these roles (especially for nonprescription drugs), either in the United States or abroad, even when doing so is expected and, in some cases, required. Pharmacist counseling, as practiced, is less frequent and less thorough than desired, although it has improved over time. In efforts in the United States and elsewhere to increase the role of pharmacists, professional associations and academics are advocating the idea of “pharmaceutical care,” with its emphasis on monitoring a patient’s drug therapy rather than on dispensing the drugs. There is evidence that in institutional settings such as hospitals, there are benefits from pharmaceutical care. However, pharmaceutical care is only now being implemented in community pharmacies and its value has yet to be established.

Improved drug use is often cited as a justification for an intermediate drug class, and evidence for it gives support for expanding the role of pharmacists in general. Such an expansion does not necessitate creating an additional drug class. Indeed, the current system would benefit from an improvement in pharmacist counseling.

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## The Florida Experience

The Florida Pharmacist Self-Care Consultant Law has had very little effect on the practice of pharmacy. Pharmacists rarely prescribe drugs in the formulary. This is attributed to (1) drugs being available without a prescription that are just as effective as the ones in the formulary, (2) the perception of increased liability, and (3) burdensome recordkeeping requirements.

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## Conclusions

Other countries’ and Florida’s experiences do not support a fundamental change in the drug distribution system of the United States such as creating an intermediate class of drugs, whether fixed or transition, at this time. Its benefits are unclear. No evidence at this time shows the overall superiority of a drug distribution system that restricts the sale of at least some nonprescription drugs to pharmacies. However, it should also be clear that there is no evidence that systems that do this are necessarily

inferior to drug distribution systems that allow some or all nonprescription drugs to be sold outside pharmacies.

The evidence that does exist tends to undermine the contention that major benefits are being obtained in countries with a pharmacist or pharmacy class. Such a class is not being used to facilitate the movement of drugs to sale outside pharmacies. Also, pharmacist counseling as it is currently practiced does not support the goals of either a fixed or a transition class. Pharmacists are not regularly counseling patients, maintaining patient profiles, or monitoring for adverse drug effects. Thus, there is no evidence to show that the role that U.S. pharmacists would have to play to support the appropriate use of an intermediate class of drugs (either fixed or transition) would be fulfilled reliably and effectively. The evidence indicates that at this time major improvements in nonprescription drug use are unlikely to result from restricting the sale of some OTCs to pharmacies or by pharmacists, nor are the safeguards for pharmacy- or pharmacist-class drugs that would have otherwise remained in the prescription class likely to be sufficient.

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# History of the Intermediate-Drug Class Issue in the United States

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The 1951 Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act of 1938 provided the statutory basis for two classes of drugs in the United States: (1) those restricted to sale by prescription and (2) those that can be sold without prescription. The latter are available without any medical intervention and can be sold in both pharmacy and nonpharmacy outlets. A little over a decade after the passage of this amendment, various organizations began to call for an additional class or classes of drugs. In 1964, the APhA House of Delegates sought the establishment of the following four drug classes:

1. prescription-only, renewable only with the prescriber's authorization;
2. prescription-only, renewable at the pharmacist's discretion;
3. nonprescription, dispensed by a pharmacist only at a patient's request; and
4. nonprescription, available directly to the public without professional direction or control.

Each year from 1967 to 1970, the APhA House of Delegates reaffirmed its support for four classes of drugs, but FDA took no action.

In 1974, FDA wrote that there have been "comments by pharmacy organizations that a so-called 'third class of drugs,' under the control of pharmacists be created," but

"no controlled studies or other adequate research data have been supplied to support the position that any class of OTC drugs must be dispensed only by pharmacists in order to assure their safe use . . . There is at this time no public health concern that would justify the creation of a third class of drugs to be dispensed only by a pharmacist or in a pharmacy. The 'third class of drug' issue is at this time solely an economic issue. The Commissioner therefore categorically rejects the establishment of a third class of drugs at this time" (39 Fed. Reg. 19881 (June 4, 1974)).

This response drew on a 1974 letter from the Department of Justice to the Department of Health, Education, and Welfare that dealt with proposals for a new class of drugs. The letter stated that "these proposals would severely restrain competition in the distribution and sale of OTC drug products and inconvenience the consuming public."

In 1982, NARD passed a resolution calling for a “pharmacist legend” class of drugs—drugs moving from prescription to nonprescription status that could be dispensed only under a pharmacist’s supervision. Drugs would remain in this class only until consumer understanding was demonstrated and a drug’s safety as a nonprescription medicine had been evaluated.

This resolution formed the basis for a 1984 petition from NARD to FDA asking it to restrict the right to sell ibuprofen (which FDA was considering moving from prescription to nonprescription status) to pharmacists. In the petition, NARD also sought that all drugs being switched initially be considered for the “pharmacist legend” category. Later in 1984, the APhA House of Delegates passed a resolution favoring the idea of a category of drugs that supported the movement of drugs from prescription to nonprescription status.

In response to the NARD petition, FDA stated that “the agency has continued to conclude that limiting certain drugs to sale-by-pharmacist only is unnecessary because a public health need for such a limitation has not been demonstrated” (FDC Reports, 46:50 (December 10, 1984), 12). FDA went on to question whether it has the authority to establish an additional class of drugs, the implication being that legislation would be needed.

Also in 1984, AMA adopted a resolution against a third class of drugs: “Resolved, that the Association oppose the establishment of a third class of drugs” (American Medical Association, 1984, p. 432). It stated that AMA supported the present classification into prescription and OTC drugs. Seeing no reason to change the classification system, FDA took no action and the two-tier system remained in place.

Florida established a class of drugs quite similar to a fixed, intermediate class of drugs in 1986. Pharmacists were given the power to prescribe approximately 30 prescription drugs. In other words, the state (which has the power to grant prescribing authority) gave pharmacists the right to dispense particular prescription drugs. (The Florida experience is discussed in detail in chapter 5.)

In 1987, APhA reaffirmed its 1984 position and also supported the use of the term “transition class of drugs” for this drug category.

In 1992, in response to a petition from the Pharmacists Planning Service (a pharmacy advocacy group based in California) that an intermediate class of drugs be created, FDA reiterated its position on the lack of empirical

support for one and its lack of authority to establish such a class. In a 1994 letter to the Consumers for World Trade, FDA made the same points.

In addition to these national efforts, there have been attempts at the state level to establish an intermediate class of drugs. For instance, in 1959 a bill was proposed in Minnesota that a pharmacy board be allowed to restrict certain nonprescription products to pharmacy sale. In 1985, a bill was introduced in the Illinois state legislature that called for pharmacist-only sale of switched drugs. More recently, a 1993 Oregon bill proposed establishing a transition class of drugs. Except for the Florida law discussed above, none of these, or other similar bills, have passed.<sup>1</sup> In 1992, the California legislature passed a resolution calling for the Congress and FDA to investigate a transitional class of drugs. The resolution was forwarded to the president, the Congress, and FDA.

Throughout this period, the Nonprescription Drug Manufacturers Association (formerly called the Proprietary Association), an industry trade association, has been a principal opponent of an additional class of drugs. Among other activities, it has opposed bills considered in state legislatures that would have restricted to pharmacists the sale of switched drugs. Other current opponents of a transition class of drugs include AMA, the Food Marketing Institute, the National Coalition of Hispanic Health and Human Services Organizations, the National Council on Aging, and the National Grange.

Current supporters of a transition class include APHA, the American College of Apothecaries, the Consumers Federation of America, the National Association of Retail Druggists, the National Consumers League, the National Council of Senior Citizens, and the Public Citizen Health Research Group.

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<sup>1</sup>As discussed in chapter 5, drugs have been made available for sale under certain circumstances without a prescription but only from pharmacists and in nine states pharmacists have been given dependent prescribing authority. However, these situations are not what has typically been discussed when an intermediate class of drugs has been considered.

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# Description of Drug Classification Systems in Ten Countries, Ontario, and the United States

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## Australia

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### Regulatory Authority

The Therapeutic Goods Administration of the Ministry of Health is responsible for the quality, safety, and efficacy of drugs in Australia. After the administration completes its assessment, the scheduling (distribution class) of drugs is determined. The National Health and Medical Research Council, acting upon the advice of its Drugs and Poisons Scheduling Committee, recommends to the states and territories what drugs should be in what class. The drug classes are enforced by state or territory legislation. The states and territories do not have to accept the recommendation of the national committee. In practice, there is only slight variation in the scheduling of drugs from one state or territory to another.

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### Drug Classes

Drugs are classified into one of the following poisons schedules.

“Schedule 1: Poisons of plant origin of such danger to health as to warrant their being available only from medical practitioners, pharmacists or veterinary surgeons.

“Schedule 2: Poisons for therapeutic use that should be available to the public only from pharmacies; or where there is no pharmacy service available, from persons licensed to sell Schedule 2 poisons.

“Schedule 3: Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental, or veterinary practitioners.

“Schedule 4: Poisons that should, in the public interest, be restricted to medical, dental or veterinary prescription or supply, together with substances or preparations intended for therapeutic use, the safety or efficacy of which requires further evaluation.

“Schedule 5: Poisons of a hazardous nature that must be readily available to the public but require caution in handling, storage, and use.

“Schedule 6: Poisons that must be available to the public but are of a more hazardous or poisonous nature than those in Schedule 5.

“Schedule 7: Poisons which require special precautions in manufacture, handling, storage or use, or special individual regulations regarding labelling or availability.

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“Schedule 8: Poisons to which the restrictions recommended for drugs of dependence by the 1980 Australian Royal Commission of Inquiry into Drugs should apply.

“Schedule 9: Poisons which are drugs of abuse, the manufacture, possession, sale or use of which should be prohibited by law except for amounts which may be necessary for medical or scientific research conducted with the approval of Commonwealth and/or State or Territory Health Authorities.”

Pharmacists deal primarily with drugs in schedules 2, 3, 4, and 8. Drugs in schedule 2 are available in pharmacies or from a licensed dealer where there is no pharmacy within a certain distance. Schedule 2 drugs are considered to be dangerous to human life if misused or carelessly handled. Schedule 3 drugs are available from a pharmacist but a prescription is not required. The general criterion for schedule 3 is that professional supervision over the supply of a drug is needed but the prescription of a physician is not necessarily required. These drugs are not accessible to the public. Schedule 4 drugs are available only on the prescription of a medical practitioner, dentist, or veterinarian. Addictive substances, such as morphine and other narcotics, are listed in schedule 8. Storage and recording provisions for schedule 8 poisons are very strict.

Additionally, an “unscheduled” group of drugs is available for sale in retail outlets other than pharmacies.

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**When the System Began**

The current classification system was developed in response to a 1954 request of the Public Health Committee. Originally, there were eight schedules. In 1985, a ninth schedule was formed at the national level. Schedule 8 was divided into two parts and named schedule 8 and schedule 9. All the states and territories still have eight schedules except Queensland, which has nine.

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**Switch Decisions**

Drugs are switched between distribution classes based on the recommendations of the National Health and Medical Research Council. Manufacturers can petition that drugs be switched. Drugs can also be switched by the states and territories based on their processes. The following are the principal types of data required for a switch:

“—Full details of investigations made with respect to the safety of the substance, including tests carried out by universities and/or research institutions, and clinical trials,

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- Known side effects,
- Occurrence of sensitivity tolerance or idiosyncrasy in response to the substance,
- Metabolism, rate, extent and mode of elimination of the substance,
- Any tendency towards accumulation in the body,
- Any special incompatibility,
- Any recognised standard such as pharmacopoeial monograph,
- Complete bibliography relating to pharmacological and therapeutic actions,
- Summary of animal studies,
- Adverse drug reactions from Australia and overseas,
- Occurrence of unusual or alarming reactions,
- Occurrence of abuse or habituation,
- Any epidemiological data that may be available,
- Details of scheduling status of the product in other countries,
- A copy of any data submitted to any overseas regulatory bodies in support of a scheduling change,
- If that application was unsuccessful, the rationale for refusal by the regulatory authority,
- Indications for which claims are to be made if proposal is for a Schedule 3 product,
- Strength, dose and frequency proposed,
- Full details of proposed labelling and packaging,
- Warning statements and limitations proposed for the label,
- Whether an insert is proposed and, if so, the text,
- What aspects the applicant expects the pharmacist to advise on during Schedule 3 supply,
- Any other data the Company feels is relevant to the submission,
- Risk/benefit analysis data.”

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The guidelines do not lay out the criteria by which this information is assessed.

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## Canada

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### Regulatory Authority

Regulatory authority for pharmaceuticals is divided between the federal and provincial governments. Generally, federal law determines what may be sold as a drug and what may be said about it. Provincial law regulates how and where drug products may be sold.

At the federal level, the regulation of drugs rests with the Drugs Directorate of the Health Protection Branch, Health Canada. Within the directorate, there are the bureaus of Human Prescription Drugs and of Nonprescription Drugs. The principal federal drug law is the Food and Drugs Act.

Authorities in each province also have control over some aspects of drug regulation. The authority in Ontario is described later in this appendix.

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### Drug Classes

At the federal level, there are two classes of drugs: prescription and nonprescription. Nonprescription drugs are further divided into proprietary medicines (GP, or general public) and products assigned a drug identification number (DIN). GP products are “drugs intended for the symptomatic treatment of minor self-limiting illnesses that do not require the advice or intervention of a health professional.” GP numbers are assigned to products available for sale outside pharmacies. DINs are normally assigned to prescription and nonprescription drugs restricted to pharmacies. This allows the federal government to indicate its preference for place of sale.

However, provincial authorities make the final determination on place of sale. They may allow the sale outside pharmacies of any drug classified as a nonprescription product by the federal government, whether it has a GP number or a DIN. Provinces may make federal regulations more but not less strict. For instance, a province could require that a drug classified nonprescription be sold only with a prescription in that province. Five provinces (British Columbia, New Brunswick, Nova Scotia, Ontario, and Saskatchewan) require that some nonprescription drugs be kept in a “no

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public access” area. Others may be stored on shelves accessible to the public.

A provincial effort is under way to harmonize the number and types of drug classes throughout the country. The proposal calls for four drug classes: prescription, pharmacist, pharmacy, and general sale.

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## When the System Began

Regulations of the Food and Drugs Act were amended in 1975 to include drugs intended for sale without a prescription and outside pharmacies. (These drugs had been covered by the Proprietary or Patent Medicines Act.) In 1976, British Columbia became the first province to establish a class of nonprescription drugs to which the public did not have direct access.

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## Switch Decisions

Switch decisions are made by the Bureau of Nonprescription Drugs. The Health Protection Branch has published the following guidelines on the information needed for a switch decision:

“1. Efficacy data will be required if the indication of use or dosage differ from those approved for prescription use . . . .

“2. A summary of all animal and human clinical safety data, including data that may have been part of an original New Drug Submission, as well as data which have accumulated since the product’s introduction.

“3. A summary of all known and foreign adverse reaction reports since the introduction of the medicinal ingredient on the market, and a summary of adverse effects, their frequency and the dose at which they occurred. Any adverse effects that could require patient monitoring by a physician should be clearly described. Any potential for misuse or abuse and actual occurrences thereof should also be discussed.

“4. All proposed nonprescription labelling and promotional material demonstrating that the safe and effective use of the product can be assured by nonprescription labelling, rather than depending upon the professional judgement of a physician. The appropriate cautions and contraindications must be expressed in lay terms.

“5. . . . Chemistry and manufacturing data will be required where they differ from the prescription product.

“6. Date of introduction of the prescription drug onto the Canadian market and a summary of the sales data . . . . A summary of international market status, i.e. countries where

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requests for authorization to sell (either prescription or nonprescription) have been made and the status (approved, pending, rejected) of those authorizations. If an authorization has been refused, the reason for refusal, for both the prescription and nonprescription products. If an authorization has been approved for nonprescription sale, the date of introduction onto the market and confirmation that the product is currently marketed.”

Switch decisions may be changed by the individual province to further restrict access to the drug by specifying place of sale.

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## Ontario

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### Regulatory Authority

The Ontario Ministry of Health is responsible for the classification of drugs for distribution. It is advised by the Ontario College of Pharmacists, which makes scheduling recommendations. The ministry rarely disagrees with the recommendation of the college. Statutory authority is contained in the Health Disciplines Act.

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### Drug Classes

Drug distribution classes are divided into prescription and two nonprescription classes—namely, products available only from pharmacists and products that can be sold in both pharmacies and other retail outlets.<sup>1</sup> The former category of nonprescription drugs is referred to as schedule C. A further refinement on schedule C drugs is that they must be kept in areas to which the public does not have access. This “no public access” rule is not by statute but is College of Pharmacists policy.

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### When the System Began

We were unable to determine when the drug classification system was established.

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### Switch Decisions

Switch decisions are made by the Ontario Ministry of Health with the advice of the Ontario College of Pharmacists.

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<sup>1</sup>The prescription and nonprescription classes are divided into a number of subclasses, each with particular requirements. For our purposes, the three-tier division of one prescription and two nonprescription classes is sufficient.

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## Denmark

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### Regulatory Authority

The National Board of Health (Sundhedsstyrelsen) under the Minister of the Interior gives final approval to recommendations on classification by the Licensing Committee.

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### Drug Classes

Denmark has seven pharmaceutical distribution classes.

1. Group A Narcotics: prescription only, no refills.
2. Group A: prescription only, no refills.
3. Group B: prescription only, refills allowed.
4. Group BEGR: prescription only, dispensing only to hospitals.
5. Group NB-S: prescription only, dispensing only to hospitals or after prescription by specialists defined by the National Board of Health.
6. Group H: nonprescription, sale in pharmacies only.
7. Nonprescription: a few medicinal products that can be sold outside pharmacies (for example, certain pharmaceutical specialties for animals, vitamins, and anthelmintics—that is, medicines for killing or ejecting intestinal worms).

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### When the System Began

The drug classification system was revised in the Medicines Act of 1975. At that time, a small class of drugs available for sale outside pharmacies was established. Further revisions to this system were made in 1993 as part of the implementation of European Union directive 92/26/EEC. (See chapter 2 for a discussion of this directive.)

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### Switch Decisions

There is no formal procedure for switches. Switch decisions are made by the National Board of Health. Six principles are used to guide switch decisions:

1. OTC products should be safe in ordinary use,

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2. risks of overdose reactions should be minimal,
  3. the drug should not possess an abuse potential,
  4. the drug should be indicated for minor diseases and symptoms easily diagnosed by lay persons,
  5. the drug should not need professional supervision, and
  6. the regulatory authorities should have great experience with the drugs in question.
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## France

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### Regulatory Authority

The regulatory authority for drugs rests with the National Drug Administration (Agence du médicament) in the Ministry of Health.

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### Drug Classes

France has four drug classes:

1. Prescription, list A: nonrefillable prescriptions.
2. Prescription, list B: controlled narcotics and certain psychotropics.
3. Prescription, list C: refillable prescriptions.
4. Nonprescription.

All drugs may be sold only in pharmacies. In rural areas where there is no pharmacy, physicians may be authorized to dispense drugs.

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### When the System Began

We were unable to determine when the current drug classification system was established. However, the distribution of drugs has been limited to pharmacies since the Royal Declaration in 1777 (and even earlier).

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**Switch Decisions**

Safety, efficacy, and quality are the factors considered when a drug approval decision is made. We were unable to gather specific information on the criteria used for reclassifying drugs.

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**Germany**

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**Regulatory Authority**

The registration of pharmaceuticals and market approval are regulated by the Drug Institute Federal Health Office (Institut für Arzneimittel des Bundesgesundheitsamts). Its authority rests in the drug law, Arzneimittelgesetz.

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**Drug Classes**

Pharmaceuticals are categorized into one of three classes for distribution.

1. Prescription. These products are available only with a prescription and only in pharmacies.
2. Pharmacy restricted. These are nonprescription products sold only in pharmacies.
3. Free-to-sell. These drugs are nonprescription but their sale is not restricted to pharmacies. However, the retailer has received some special education.

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**When the System Began**

The drug classification system was adopted in 1961.

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**Switch Decisions**

Switch decisions are made by the Federal Health Office. Dr. Walter Alhterr, a member of the German Parliament and Deputy Chairman of the Committee for Health, cited the following factors as being particularly important when assessing a switch candidate:

- Is the drug sufficiently effective?
- Can the application and the indications of the drug be assessed by the self-medicating consumer?
- Is the margin of safety large enough?
- What about the safety profile at high dose?
- Is there a specific toxic risk?
- What about the adverse reaction profile?

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- What about interactions?
  - Has the drug been used for a sufficiently long time under prescription rules?
  - What is the marketing experience?
  - Do we already have OTC experience?

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## Italy

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### Regulatory Authority

Regulatory authority for classifying drugs into distribution classes rests with the United Commission for Drugs (Commissione Unica per il Farmaca).

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### Drug Classes

Italy has the following three drug classes:

1. Prescription only.
2. Free sale (nonprescription, sale in pharmacies only).
3. Hospital use only (for use in hospitals and other health centers).

Further distinctions are made between drugs that are reimbursable by the government and those that are not.

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### When the System Began

The current classification was adopted in 1992. At that time, a subcategory of the free sale class was established for switch products. Unlike other nonprescription medications, these drugs cannot be advertised to the general public.

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### Switch Decisions

Authority to switch drugs resides in the Ministry of Health.

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## Netherlands

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### Regulatory Authority

The responsibility for drug approval resides in the Ministry of Welfare, Health, and Cultural Affairs (Ministerie van Welzijn, Volksgezondheid en Cultuur). Within the ministry is the Committee for the Evaluation of

Medicines, which judges the efficacy and safety of drugs. The committee consists of 18 experts on pharmacy, clinical pharmacology, toxicology, and related disciplines. The committee is assisted in its work by the National Institute for Drug Analysis and Control, which performs drug analyses and evaluates chemical and pharmaceutical data, and the National Institute for Public Health and the Environment, which assesses pharmacological and toxicological data. The drug approval process includes the classifying of drugs into classes for sale.

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## Drug Classes

In the Netherlands, drugs are classified into one of three schedules for sale.

1. Prescription-only medicines. Drugs in this class can be sold only in pharmacies and only with a prescription from a physician. In rural areas, physicians may dispense drugs.
2. Pharmacy-only products. This class of nonprescription products is available without a prescription but only in pharmacies. (Despite drugs in this class being legally available for sale without a prescription, most pharmacists will not sell them without a prescription.)
3. Over-the-counter. These drugs are available without a prescription in both pharmacies and druggist shops. In the pharmacy, the leading professional is the pharmacist, who is licensed to dispense all drugs registered by the Medicines Evaluation Board. The leading professional in a druggist shop is the druggist, who is licensed to dispense only drugs that are neither prescription-only medicines nor pharmacy only.

The Dutch government plans to move to a two-class system consisting of their current prescription and over-the-counter classes.

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## When the System Began

The legal structure for the supply of medicines and, therefore, the drug classification system are based on the Direct Supply Act of 1958, which became effective in 1963.

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## Switch Decisions

Decisions to change the classification of a drug are made by the Ministry of Welfare, Health, and Cultural Affairs, acting on the advice of the Committee for the Evaluation of Medicines.

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The criteria for classifying a drug as a pharmacy-class product are

- the diagnosis of the disease can be made by the patient with the help of the pharmacist,
- taking the drug according to the dosage instructions in the leaflet does not result in severe side effects,
- there are no dangerous interactions with other drugs, and
- a dosage two to three times the recommended dose has no severe toxic effects.

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## Sweden

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### Regulatory Authority

The regulatory authority responsible for the classification of drugs is the Medical Products Agency (Lakemedelsverket) of the Ministry of Health and Social Affairs.

The exclusive right to market pharmaceuticals at the retail level in Sweden belongs to the National Corporation of Swedish Pharmacies (Apoteksbolaget). Only the corporation may sell pharmaceuticals directly to patients and customers in the outpatient-care sector and to hospitals in the inpatient-care sector. The corporation is owned two thirds by the state and one third by Apoteksbolaget's Pension Foundation. Because of its exclusive right to the retail sale of pharmaceuticals, all pharmacists who dispense medication at the retail level are employees of the state. The current agreement with the government expires December 31, 1995. There has been some discussion of allowing the sale of some nonprescription drugs outside pharmacies.

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### Drug Classes

There are four drug classes in Sweden: prescription, nonprescription (which can be sold only in pharmacies), free medicines, and herbal medicines. Some antiseptic solutions and liniments are classified as free medicines and can be sold outside pharmacies. Herbal medicines can also be sold in general stores.

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### When the System Began

The prescription and nonprescription categories were established in 1934. We were unable to determine when the free medicines and herbal medicines classes were established.

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## Switch Decisions

Authority to switch drugs rests with the Medical Products Agency. Among the criteria for assessing the reclassification of a drug to nonprescription status are pack size, toxicity, adverse reactions, interactions, drug dependence, years of prescription use, suitability for self-medication, and worldwide experience.

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## Switzerland

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### Regulatory Authority

Marketing approval for drugs is the responsibility of the cantons, not the central government. However, five cantons concluded in 1900 that it was not feasible for each of them to regulate pharmaceuticals individually. They formed the Intercantonal Office for the Control of Medicaments (Interkantonale Kontrollstelle für Heilmittel) “to investigate and assess the secret medicines and medical specialties sent to it by the participating Cantons as to harmfulness, appropriate composition, misleading character of advertisements, labels and inserts, and the relationship of price to value.” By 1934, all 25 cantons were parties to the agreement. This agreement has been revised on several occasions. The 1971 agreement gave four principal purposes for the office:

1. the quality control of marketed drugs,
2. the quality control of manufacturing,
3. the licensing of new drugs, and
4. continuous review. Licenses are issued for only 5 years, so the office is continually reviewing products that are already on the market.

Proposals have been made to give the federal government more power, but none has been accepted.

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### Drug Classes

Pharmaceuticals are categorized into one of five distribution classes in Switzerland.

1. Class A: nonrefillable prescription. These drugs are available only with a prescription, in pharmacies, and the prescription cannot be refilled. This class includes restricted pharmaceuticals such as narcotics.

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2. Class B: prescription only. Like class A products, drugs in class B are available only with a prescription and in pharmacies. However, unlike class A, the prescription can be refilled.

3. Class C: nonprescription, pharmacies only. Drugs in this class are available without a prescription but only from a pharmacy.

4. Class D: nonprescription, pharmacies and drugstores. Class D drugs are available without a prescription but only in pharmacies and drugstores.<sup>2</sup> Drugstores specialize in the sale of certain nonprescription products such as herbal medicines, cosmetics, health foods, household items, and chemicals.

5. Class E: nonprescription, all stores. These products are sold without a prescription and are available outside pharmacies and drugstores. Items in this category are limited to such health products as herbal cough candy, bandaids, dietetics, and baby products.

The decisions of the Intercantonal Office for the Control of Medicaments are binding for prescription drugs, but the cantons have some freedom on the classification of nonprescription products. In practice, there is little variation between cantons.

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**When the System Began**

Classes A, B, and C were established in 1927. Class D dates from 1948. We were unable to determine when class E was established.

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**Switch Decisions**

Switch decisions are made by the Intercantonal Office for the Control of Medicaments. A medication switched from prescription to nonprescription status is placed in class C (pharmacy only). In recent years, a number of drugs have been switched from class C to class D (nonprescription, pharmacies and drugstores).

The factors examined when a drug is considered for switching include

- need for diagnosis by a physician,
- adequate labeling for nonprescription use,
- consistency in the expected benefits of the drug,
- efficacy,

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<sup>2</sup>Pharmacies are managed by university-trained and licensed pharmacists, while drugstores are managed by druggists who undergo a 4-year nonacademic apprenticeship and a specialty examination.

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- consistency in expected side effects,
- side effects of long-term use,
- side effects of short-term use,
- toxicity (acute and chronic),
- potential for interaction with other drugs,
- potential for interaction with foods,
- masking symptoms of another disease,
- habit-forming or abuse potential,
- history of use,
- method of use,
- indications amenable to self-treatment,
- risk-benefit relationship.

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## United Kingdom

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### Regulatory Authority

Marketing authorizations for all drug products are granted by the Licensing Authority, which consists of the health and agriculture ministers. The regulatory authority for human drugs is contained in the Department of Health. (The Department of Agriculture is responsible for animal drugs.) Within the Department of Health, the Medicines Control Agency is responsible for the approval (licensing) of human drugs. It is advised by the Medicines Commission. The commission gives general advice on the administration of the Medicines Act of 1968 and on any matter relating to medicinal products. It must have at least eight members, who together cover the following areas of expertise: (1) the practice of medicine, (2) the practice of veterinary medicine, (3) the practice of pharmacy, (4) chemistry other than pharmaceutical chemistry, and (5) the pharmaceutical industry. The commission may recommend the establishment of expert committees. Among the committees established are the Committee on the Safety of Medicines and the Committee on the Review of Medicines. The Committee on the Safety of Medicines is responsible for advising on the efficacy, safety, and quality of new medicines for human use. The Committee on the Review of Medicines advises on the efficacy, safety, and quality of products already on the market that have not previously been reviewed by the regulatory authorities.

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**Drug Classes**

For the purpose of retail sale or supply, drugs for human use are divided into three classes.

1. Prescription-only medicines. Drugs in this category may be sold or supplied only from a registered pharmacy and in accordance with a prescription issued by an authorized practitioner.
2. Pharmacy medicines. These products may be sold or supplied only from a registered pharmacy or under the supervision of a pharmacist. A prescription is not required. If the pharmacist is not present or on the premises, the staff may not sell the drug.
3. General sale list. General sale medicines can be sold without the supervision of a pharmacist. Sales must be made from places that can be closed to the public. This prohibits sales from market stalls, street markets, or vehicles. Some of these medicines may be sold by means of automatic machines.

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**When the System Began**

The classification system was established under the Medicines Act of 1968.

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**Switch Decisions**

The responsibility for switching drugs between classes rests with the Licensing Authority, which amends the product license if a switch is approved. The Department of Health receives requests to change the classification of drugs. The Medicines Control Agency, advised by the Committee on the Safety of Medicines and the Medicines Commission, recommends approval or disapproval of a switch. The criteria for switching a drug from prescription-only medicine to pharmacy class are

“Indications suitable for self-medication including self-diagnosis (may be recurrent attack of condition requiring physician aided diagnosis on first attack);

“Medicine has acceptable margin of safety during unsupervised use including safety in overdose or following accidental misdiagnosis;

“Medicine is not a new drug substance for which further postmarketing evidence of safety is required;

“Medicine does not present a hazard to the community (indirect danger) from unsupervised use as might occur with development of resistant flora to antibiotics;

“Medicine has no major abuse or dependence potential; and

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“Medicine is not for parenteral use.”

Reclassification of a drug from pharmacy only to general sale may be requested formally through either a variation in the product license or an abridged application for a product license, requesting general sale status for the product. The Licensing Authority makes the decision on whether to allow general sale list status. The request may also occur informally through a submission to the Department of Health that asks that the switch be considered. The evidence may then be referred to the Committee on the Safety of Medicines. Very few switches of drugs have been made from pharmacy class to general sale.

Generally, the product license-holder applies for a change in the product license. The authorities or a third party may also initiate a switch. However, if the manufacturer does not want a product switched to a less restricted distribution class, it will not normally be reclassified.

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## United States

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### Regulatory Authority

FDA has regulatory authority for classifying drugs for distribution. Each individual state has the power to determine who has prescribing authority in it.

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### Drug Classes

There are two drug classes in the United States: prescription and nonprescription. Nonprescription drugs may be sold in any retail outlet. Prescription drugs may be dispensed pursuant to a “practitioner’s” order, usually a doctor’s prescription. There are several exceptions to this. First, in Florida, some prescription drugs may be dispensed by pharmacists, who are considered “practitioners” under Florida law. (See appendix V.) Second, insulin is available in some states without a prescription but only from pharmacists. Third, in some states some controlled substances may be dispensed by a pharmacist without a prescription if there is low abuse potential. Fourth, there are some situations in which pharmacists have dependent prescribing authority. Typically, in this situation, pharmacists may prescribe drugs but only under protocols established by supervisory physicians. (See chapter 5 for more discussion on these four cases.)

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**When the System Began**

The two-tier classification was enacted into law by the 1951 Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act of 1938.

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**Switch Decisions**

Switch decisions are made by FDA with the advice of advisory committees. The Durham-Humphrey Amendment specified three classes of drugs that were required to be limited to prescription use:

- certain habit-forming drugs listed by name in the Federal Food, Drug, and Cosmetic Act;
- drugs not safe for use except under the supervision of a licensed practitioner because of toxicity or other potentiality for harmful effect, the method of use, or the collateral measures necessary for use; and
- drugs limited to prescription under an approved new drug application.

For purposes of switching, the second criterion is the most important. A former director of the Center for Drug Evaluation and Research discussed 13 issues that should be considered when making switch decisions. These build on the second criterion.

1. Does the switch candidate's frequency of dosing affect its safe use?
2. Is the minimally effective dose for the proposed OTC indication known?
3. Has the candidate been used for sufficiently long time on the prescription market to allow a full characterization of its safety profile?
4. Does the candidate have a large margin of safety?
5. Has the candidate's safety profile been defined at high dose?
6. Does the candidate have a special toxicity in its class?
7. Have possible drug interactions for the candidate been characterized?
8. Is there a full understanding of the pharmacodynamics of the switch candidate?
9. Has a vigorous risk analysis been performed?

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**Appendix II**  
**Description of Drug Classification Systems**  
**in Ten Countries, Ontario, and the United**  
**States**

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10. Has the efficacy literature been reviewed in a way that would support the expected usage and labeling of the candidate?

11. What do “use data” (from National Prescription Audit, National Drug/Disease, and other sources) show?

12. What foreign countries market the candidate otc? What is its experience in those countries?

13. What is the worldwide marketing experience of the candidate?

# Classification of 14 Drugs in Ten Countries, Ontario, and the United States

Table III.1 displays the current classification of each of the 14 drugs in 8 of the study countries (we were unable to obtain complete classification information for France and Italy). In some of the countries, particular drugs appear in more than one distribution class because classification can depend on dosage, intended use, pack size, and other factors. For instance, naproxen is both a pharmacy-class and prescription-class drug in Australia. It is a pharmacy-class drug when it is “the only therapeutically active substance in packs of 12 or less dosage units, for treatment of spasmodic dysmenorrhoea.” In all others cases, naproxen is a prescription drug. Therefore, in table III.1, Australia is indicated as classifying naproxen as both a prescription- and pharmacy-class product.

**Table III.1: Classification of 14 Drugs in Ten Countries, Ontario, and the United States<sup>a</sup>**

Country	Not available	Prescription	Pharmacist	Pharmacy	Drugstore	General sale
Australia		Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Promethazine, Ranitidine, Sulindac, Terfenadine, Theophylline	Codeine, Ibuprofen, Indomethacin, PPA <sup>b</sup> (as a decongestant), Promethazine, Terfenadine, Theophylline	Aspirin, Codeine, Naproxen, Promethazine		Aspirin
Canada	PPA <sup>b</sup> (in weight- reduction products)	Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, Ranitidine, Sulindac, Theophylline	Codeine <sup>c</sup>	Ibuprofen, Promethazine, Terfenadine		Aspirin, PPA <sup>b</sup> (as a decongestant)

(continued)

**Appendix III  
Classification of 14 Drugs in Ten Countries,  
Ontario, and the United States**

<b>Country</b>	<b>Not available</b>	<b>Prescription</b>	<b>Pharmacist</b>	<b>Pharmacy</b>	<b>Drugstore</b>	<b>General sale</b>
Ontario	PPA <sup>b</sup> (in weight-reduction products)	Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, PPA <sup>b</sup> (as a decongestant), Ranitidine, Sulindac, Theophylline	Aspirin, Codeine, Ibuprofen, Promethazine, Terfenadine			Aspirin, PPA <sup>b</sup> (as a decongestant)
Denmark	PPA <sup>b</sup> (both as a decongestant and in weight-reduction products)	Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, Promethazine, Sulindac, Theophylline	Aspirin, Cimetidine, Codeine, Ibuprofen, Promethazine, Ranitidine, Terfenadine			
Germany		Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, Promethazine, Ranitidine, Sulindac, Theophylline	Aspirin, Ibuprofen, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Terfenadine			
Netherlands		Cimetidine, Codeine, Diclofenac, Diflunisal, Indomethacin, Promethazine, Ranitidine	Aspirin, Cimetidine, Ibuprofen, Naproxen, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Promethazine, Ranitidine, Sulindac, Terfenadine, Theophylline <sup>d</sup>		Aspirin, Ibuprofen	

(continued)

**Appendix III  
Classification of 14 Drugs in Ten Countries,  
Ontario, and the United States**

<b>Country</b>	<b>Not available</b>	<b>Prescription</b>	<b>Pharmacist</b>	<b>Pharmacy</b>	<b>Drugstore</b>	<b>General sale</b>
Sweden	PPA <sup>b</sup> (in weight-reduction products)	Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, PPA <sup>b</sup> (as a decongestant), Promethazine, Ranitidine, Sulindac, Terfenadine, Theophylline		Aspirin, Ibuprofen		
Switzerland		Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, PPA <sup>b</sup> (as a decongestant), Promethazine, Ranitidine, Sulindac, Terfenadine, Theophylline	Codeine, Diclofenac, Ibuprofen, Indomethacin, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Promethazine, Terfenadine		Aspirin	
United Kingdom		Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Ranitidine, Sulindac, Terfenadine	Aspirin, Cimetidine, Codeine, Diclofenac, Ibuprofen, PPA <sup>b</sup> (both as a decongestant and in weight-reduction products), Promethazine, Ranitidine, Terfenadine, Theophylline			Aspirin

(continued)

**Appendix III  
Classification of 14 Drugs in Ten Countries,  
Ontario, and the United States**

Country	Not available	Prescription	Pharmacist	Pharmacy	Drugstore	General sale
United States		Cimetidine, Codeine, Diclofenac, Diflunisal, Ibuprofen, Indomethacin, Naproxen, Promethazine, Ranitidine, Sulindac, Terfenadine, Theophylline	Codeine <sup>e</sup>			Aspirin, Cimetidine, Ibuprofen, Naproxen, PPA <sup>b</sup> (both as a decongestant and in weight- reduction products), Theophylline

<sup>a</sup>In France, cimetidine, diclofenac, diflunisal, indomethacin, naproxen, ranitidine, and terfenadine are limited to prescription sale. Aspirin, ibuprofen, PPA as a decongestant, promethazine, and theophylline are pharmacist class; we were unable to determine if these drugs are ever restricted to prescription sale as they sometimes are in other countries. PPA as a weight-control product is not available. We were unable to obtain information on codeine and sulindac. In Italy, naproxen, ranitidine, and terfenadine are limited to prescription sale. Aspirin, cimetidine, diclofenac, diflunisal, ibuprofen, indomethacin, PPA as a decongestant, and promethazine are in the pharmacist class in at least some cases. We were unable to determine if these drugs are ever restricted to prescription sale. Theophylline is not available. We were unable to obtain information on codeine, PPA in weight-control products, and sulindac.

<sup>b</sup>Phenylpropanolamine.

<sup>c</sup>Codeine is regulated under the Narcotics Control Act in Canada. Some codeine products are available from pharmacists without a prescription.

<sup>d</sup>Although all these drugs are legally available without a prescription in the Netherlands, most pharmacists will not dispense them without a prescription.

<sup>e</sup>Some codeine products are available from pharmacists without a prescription in some states.

All the U.S. nonprescription medications are restricted either to prescription sale or to nonprescription sale in pharmacies or drugstores in most of the study countries. The United States allows the sale of 7 (counting both indications of phenylpropanolamine as 1 drug) of the 14 drugs without a prescription. This includes ibuprofen and naproxen, for which only doses of 200 mg have been switched, and cimetidine, which has been switched only in doses of 100 mg. Larger doses of these products remain available only by prescription. It also includes codeine, which is available in low doses in some states without a prescription, and theophylline, which is available without a prescription only in combination products. Thus, 6 of the drugs are available outside pharmacies. It is clear from the table that none of the other countries allow the sale of as many of

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**Appendix III**  
**Classification of 14 Drugs in Ten Countries,**  
**Ontario, and the United States**

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these drugs outside pharmacies as does the United States.<sup>1</sup> However, 5 of the countries (Australia, Italy, the Netherlands, Switzerland, and the United Kingdom) allow more of the drugs to be sold without a prescription than the United States. (Denmark allows the same number to be sold while Canada, France, Germany and Sweden allow fewer.)

Of the 7 drugs available without a prescription in the United States, only aspirin and phenylpropanolamine (as a decongestant) are available for sale outside pharmacies in any of the study countries. All but aspirin and the 200 mg dose of ibuprofen are restricted to prescription sale in at least 1 country. Thus, for these 7 drugs, the United States has the most open system.<sup>2</sup>

All 7 drugs available only by prescription in the United States are available in at least 1 of the study countries without a prescription. In addition, ibuprofen is available in larger doses in the United Kingdom as a nonprescription product than it is in the United States, while cimetidine may be sold without a prescription in larger doses in Denmark and the Netherlands.<sup>3</sup>

Two of these drugs (promethazine and terfenadine) are allowed for nonprescription sale in 3 or more of the countries. Each of these has been considered for nonprescription status in the United States.<sup>4</sup>

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<sup>1</sup>This observation holds even if France and Italy are included, since these countries limit the sale of all drugs to pharmacies. Codeine, when it is available as a nonprescription drug in the United States, is available only from pharmacists. Thus, 5 of the drugs are sold outside of pharmacies in the United States.

<sup>2</sup>When codeine is available without a prescription in the United States, it must be dispensed by a pharmacist. Thus, for codeine, the United States is more restrictive than Australia, where pharmacist involvement is not required, and equally restrictive as Canada, Ontario, Denmark, Switzerland, and the United Kingdom.

<sup>3</sup>We were unable to determine what doses of cimetidine are available without a prescription in Italy.

<sup>4</sup>In addition, cimetidine was just recently switched after a long process. In 1993, FDA's Nonprescription Drugs and Gastrointestinal Drugs Advisory committees considered evidence for switching cimetidine. The dose under consideration (200 mg or less), which is smaller than the prescription dose, was for the treatment of heartburn. (Larger doses of cimetidine are used in the treatment of ulcers. These were not considered for switching.) The committees decided that the effectiveness of cimetidine at the lower dosage had not been demonstrated. The same committees reassessed cimetidine in 1994. They concluded that, based on additional analyses and a new dosing regimen, the lower dose of cimetidine was effective. However, they still recommended against switching the drug because of concerns about drug-drug interactions. They said that the drug could be approved for nonprescription sale if the results of new drug interaction tests are sufficient for approval and committee recommendations for labeling are implemented. At the joint meeting of the Nonprescription Drugs and Gastrointestinal Drugs Advisory committees in March 1995, it was recommended that cimetidine be approved for nonprescription use. The drug, in doses of 100 mg, was switched in June 1995. (Dosing is 200 mg up to twice daily.)

In the 1980's, FDA approved promethazine as a nonprescription product. However, in response to comments and a citizens' petition, FDA withdrew its approval. There were allegations that the drug was connected with Sudden Infant Death Syndrome (often referred to as SIDS). At the time, the manufacturer volunteered to withdraw the drug as a nonprescription product.

FDA has not approved an application to switch terfenadine to nonprescription status because of concern about drug interactions as well as complications for patients with heart or liver disease. Terfenadine had been sold without pharmacists' intervention in Canada. However, because of concerns about drug interactions, the Canadian federal government suggested to the provinces that they restrict it to sale only by pharmacists.

There are competing explanations for why these drugs are allowed for sale without a prescription in some countries but not here. Certainly, at least these two drugs have been considered for nonprescription status in the United States but have been denied for what appear to be appropriate reasons. Whether they would be nonprescription products now if an intermediate drug class were available is not possible to know.

Moreover, 9 of the study countries (all but Sweden) have used their pharmacist or pharmacy class to allow nonprescription sale of some drugs restricted to prescription sale in the United States. None of these drugs can be sold outside pharmacies in any of the countries. It is unclear whether these drugs would be more or less restricted if these countries had a two-tier system like the one in the United States. However, it is clear that officials in these countries see a role for their pharmacist or pharmacy class as they have restricted the sale of these drugs to pharmacies or by pharmacists. However, some FDA officials told us that they were unclear about the purpose of an intermediate drug class and how it would be used in the United States.

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# Descriptions of Drugs Examined in This Study

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This appendix briefly describes the 14 drugs whose classification in the study countries we examined. We include common brand names, the purpose of the drug, adverse effects, and interactions with other pharmaceuticals. The information presented comes primarily from two publications by the American Medical Association and from The Essential Guide to Prescription Drugs by James W. Long, M.D., and The Complete Drug Reference by the U.S. Pharmacopeia (American Medical Association, 1993; Clayman, 1988; Long, 1992; U.S. Pharmacopeia, 1992).

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## Aspirin

Aspirin is known chemically as acetylsalicylic acid, or ASA. It has been commonly used since 1899. It is a nonnarcotic analgesic that relieves pain, reduces fever, and alleviates the symptoms of arthritis. In small doses, it helps prevent blood clots. Common adverse effects are indigestion, nausea, and vomiting. Aspirin has a tendency to irritate the stomach and even cause bleeding. Taken in large doses, it can aggravate ulcers, kidney disease, and liver disease. It has been linked to Reye's syndrome, a rare brain and liver disorder occurring usually in children.

Aspirin can increase the effect of anticoagulants, leading to an increased risk of abnormal bleeding. Nonsteroidal antiinflammatory drugs can increase the likelihood of stomach irritation when taken with aspirin. Corticosteroids taken with aspirin can also increase the likelihood of stomach irritation. Aspirin may reduce the effect of drugs for gout and increase the effect of oral antidiabetic drugs.

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## Cimetidine

Cimetidine was introduced in 1976. It is marketed under the brand name Tagamet. Cimetidine is used in the treatment of peptic ulcer disease. It works by inhibiting the secretion of stomach acid and, thus, creating a more favorable environment for the healing of peptic ulcers of the duodenum, esophagus, and stomach. The overall incidence of adverse reactions to cimetidine is low. As cimetidine promotes healing of the stomach lining, there is a risk that it may mask stomach cancer. It is therefore usually prescribed only when the possibility of stomach cancer has been ruled out. Lower doses are used to treat heartburn, acid indigestion, and sour stomach.

Antacids may reduce absorption of cimetidine. Cimetidine can cause an increase in the blood level of some benzodiazepine drugs (a family of psychoactive compounds with a common molecular configuration),

leading to an increased risk of adverse effects. It can increase the effect of anticoagulant drugs and the blood levels of anticonvulsant drugs.

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## Codeine

Codeine is an analgesic narcotic that was introduced in 1886. It is used primarily to relieve mild to moderate pain and control cough. It is often used in combination with milder analgesics, such as aspirin and acetaminophen, to enhance their effectiveness. It is frequently added to cough mixtures containing antihistamines, decongestants, and expectorants to make these preparations more effective in reducing the frequency and severity of cough. It is an ingredient in many prescription cold medicines and coughs. All drugs that have a sedative effect on the central nervous system are likely to increase sedation with codeine. Codeine may interact with monoamine oxidase inhibitors to cause a dangerous rise in blood pressure.<sup>1</sup>

Serious adverse effects are rare. The most common is constipation. In fact, codeine has been used to control diarrhea. Codeine can be habit-forming if taken for extended periods, especially if higher-than-average doses are taken. It is normally used only for short-term relief of symptoms.

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## Diclofenac

Diclofenac is a nonsteroidal antiinflammatory drug that was introduced in 1976. It is marketed under the brand name Voltaren. Its principal uses are to relieve the symptoms associated with major types of arthritis, menstrual cramps, and bursitis, tendinitis, and related conditions. The most common side effects are gastrointestinal disturbances, particularly abdominal pain, indigestion, nausea, and either diarrhea or constipation. Fluid retention is the only expected side effect.

In combination with a number of drugs, diclofenac can increase the risk of bleeding. It may also increase the toxicity of a number of other drugs.

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## Diffunisal

Diffunisal, introduced in 1982, is a nonsteroidal antiinflammatory drug with a prolonged duration of action. It is marketed under the brand name Dolobid. It reduces mild to moderate pain and inflammation. It is used to relieve discomfort in osteoarthritis and rheumatoid arthritis, although it does not cure the underlying disease. It is also effective for pain relief after

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<sup>1</sup>Monoamines play an important part in the metabolism of the brain. An excessive accumulation of monoamine can induce a dangerous reaction characterized by high blood pressure, palpitations, sweating, and a feeling of suffocation. Monoamine oxidase is a naturally occurring enzyme involved in the breakdown of monoamines.

minor operations and dental work and may also be given to treat sprains, strains, and some types of back pain. Serious adverse effects are rare, even with prolonged use. Common adverse effects are nausea and diarrhea, heartburn and indigestion, abdominal pain, and rash.

Diflunisal can interact with a wide range of drugs to increase the risk of bleeding or peptic ulcers. The beneficial effects of antihypertensive drugs and diuretics may be decreased by diflunisal.

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## **Ibuprofen**

Ibuprofen is a nonsteroidal antiinflammatory drug that was introduced in 1967. Among the common brand names are Advil, Medipren, Motrin, Nuprin, PediaProfen, and Rufen. It is an effective treatment for the symptoms of rheumatoid arthritis, osteoarthritis, and gout. It also relieves mild to moderate discomfort of headache, menstrual pain, soft tissue injury, and pain following an operation. Ibuprofen has fewer side effects than many of the other nonsteroidal antiinflammatory drugs. The most common adverse effects are diarrhea or constipation and nausea or vomiting.

Ibuprofen can interact with a wide range of drugs to increase the risk of bleeding and peptic ulcers. Ibuprofen can reduce the beneficial effects of antihypertensives and diuretics. It can also increase the blood-sugar-lowering effect of oral antidiabetic drugs.

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## **Indomethacin**

Indomethacin was introduced in 1963. Common brand names are Indameth, Indocin, and Indocin SR. It is a nonsteroidal antiinflammatory drug that reduces pain, stiffness, and inflammation. It is used in the treatment of many arthritic conditions, acute attacks of gout, bursitis, and tendinitis. It has several potentially serious adverse effects, including gastrointestinal disorders, severe headache, and dizziness, and it may mask the symptoms of infections. It is generally not given to people with poor kidney function.

Indomethacin can interact with a wide range of drugs to increase the risk of bleeding and peptic ulcers. Indomethacin can reduce the beneficial effects of antihypertensive drugs and diuretics. It may increase the blood-sugar-lowering effects of oral antidiabetic drugs.

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## Naproxen

Naproxen is a nonsteroidal antiinflammatory drug that was introduced in 1970. Common brand names include Aleve, Anaprox, and Naprosyn. It reduces pain, stiffness, and inflammation. It is used primarily to relieve mild to moderately severe pain associated with musculoskeletal injuries, acute and chronic gout, adult and juvenile rheumatoid arthritis, osteoarthritis, menstrual cramps, and dental, obstetrical, and orthopedic surgery. Gastrointestinal side effects are fairly common, and there is an increased risk of bleeding.

Naproxen can interact with a wide range of drugs to increase the risk of bleeding and peptic ulcers. The beneficial effects of antihypertensive drugs and diuretics may be reduced by naproxen.

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## Phenylpropanolamine

Phenylpropanolamine, commonly known as PPA, has two principal uses. It works as a decongestant by reducing the inflammation and swelling of blood vessels in the nose, thus relieving stuffiness and nasal congestion in colds, hay fever, and sinusitis. Phenylpropanolamine is also used in weight-reduction products. It acts as an appetite suppressant. Among the common brand names are Acutrim, Dexatrim, Prolamine, Propagest, and Rhindecon. Overall, adverse effects are rare. However, concern has been raised about the drug as a cause of dangerously high blood pressure, kidney disease, heart muscle damage, heart rhythm abnormalities, and seizures.

Other sympathomimetic drugs (those producing an effect comparable to that produced by stimulation of the sympathetic nervous system) can increase the risk of adverse effects if taken concurrently with phenylpropanolamine. Phenylpropanolamine can reduce the blood-pressure-lowering effect of antihypertensive drugs. Monoamine oxidase inhibitors dangerously increase the risk of high blood pressure when taken with phenylpropanolamine.

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## Promethazine

Promethazine is an antihistamine that was introduced in 1945. Common brand names include Anergan, Phenazine, Phenergan, Prorex, and Prothazine. Its principal use is as a single drug product to provide symptomatic relief in allergic disorders, to control nausea and vomiting, and to produce mild sedation. Common side effects are drowsiness and lethargy, dry mouth, and blurred vision.

Promethazine is used in combination with analgesics, such as aspirin and codeine, to enhance their pain-relieving actions by producing mild sedation. It is also used in cough mixtures for its drying effect. All drugs that have a sedative effect are likely to increase the sedative properties of promethazine. Antacids can reduce the absorption of promethazine from the stomach, thus reducing its effect.

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## **Ranitidine**

Ranitidine is an antiulcer medication that was introduced in 1981. It is marketed under the brand name Zantac. Ranitidine is used primarily in the treatment of peptic ulcer disease. It works by inhibiting the secretion of stomach acid and thus creating a more favorable environment for the healing of peptic ulcers. Ranitidine also reduces discomfort and inflammation from reflux esophagitis. Headache is the most common adverse effect. As ranitidine promotes healing of the stomach lining, there is a risk that it may mask stomach cancer. It is therefore usually prescribed only when the possibility of stomach cancer has been ruled out.

There are no known interactions with other drugs. This means that ranitidine can be taken with other medications without reducing its effectiveness or that of the other drug.

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## **Sulindac**

Sulindac is a nonsteroidal antiinflammatory drug that was introduced in 1976. It is marketed under the brand name Clinoril. Sulindac is used primarily to relieve mild to moderately severe pain and inflammation associated with rheumatoid arthritis and osteoarthritis, acute and chronic gout, and bursitis, tendinitis, and related disorders. It has not been completely established how the drug works. Indigestion, nausea and vomiting, diarrhea, and constipation are fairly common adverse effects. There is also a risk of stomach bleeding or peptic ulcer.

Sulindac can interact with a wide range of drugs to increase the risk of bleeding and peptic ulcers. The beneficial effects of antihypertensive and diuretic drugs may be reduced by sulindac. Concurrent use of sulindac with oral antidiabetic drugs can increase the blood-sugar-lowering effect of these drugs.

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## **Terfenadine**

Terfenadine is an antihistamine that was introduced in 1977. It is marketed under the brand name Seldane. Its main use is in the treatment of allergic

rhinitis, particularly hay fever. Allergic skin conditions may also be helped by terfenadine. It works by reducing the intensity of the allergic response by blocking the action of histamine after it has been released from sensitized tissue cells in the eye, nose, and skin.<sup>2</sup> Terfenadine differs from older antihistamines in that it has little or no sedative effect on the central nervous system. Nausea and loss of appetite occur occasionally with terfenadine. There are concerns about persons with heart or liver disease using the drug. Other side effects are very rare.

Terfenadine can increase the sedative effects on the central nervous system of anti-anxiety drugs, sleeping drugs, antidepressants, and antipsychotic drugs. The anticholinergic effects (lowered blood pressure and increased motion of the alimentary canal and other hollow organs) of terfenadine are likely to be increased by all drugs that also have these effects. There is a risk of a dangerous rise in blood pressure if terfenadine is taken within 14 days of monoamine oxidase inhibitors.

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## Theophylline

Theophylline is a bronchodilator that was introduced in 1929. Some commonly used brand names are Slo-Bid, Slo-Phyllin, Theo-24, and Theo-Dur. It has two main actions. First, theophylline relaxes and dilates the airways in the lungs. Second, it stimulates breathing and the heart rate. Theophylline is used primarily in the treatment of asthma. It is also helpful in heart failure. It is sometimes given to premature infants who are prone to attacks of apnea (stopped breathing). Treatment with theophylline must be monitored because the effective dose is very close to the toxic dose. Common adverse effects are agitation, dizziness, and nausea and vomiting. Some drugs increase the level of theophylline in the blood while others decrease it.

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<sup>2</sup>Histamine is a stimulant of gastric juice, a constrictor of smooth muscle including that of the bronchi, and a dilator of arterioles and capillaries.

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# The Florida Pharmacist Self-Care Consultant Law

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The Florida Pharmacist Self-Care Consultant Law went into effect on October 1, 1985. It gives pharmacists the authority to prescribe specific medications without the approval of a physician. It is stated in Florida law (Fla. Stat. Ann. S. 465.186) that the formulary (that is, the list of drugs a pharmacist can prescribe) may include products falling within the following categories:

- any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for OTC sale by FDA,
- any medicinal drug recommended by the FDA Advisory Panel for transfer to OTC status pending approval by FDA,
- any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination,
- any medicinal drug containing fluoride in any strength, and
- any medicinal drug containing lindane in any strength.

Any drug that is sold as an OTC product may not be included in the formulary.

Florida Board of Pharmacy rules 21S-27.220 and 21S-27.230 state that

“A Pharmacist may order and dispense from the following formulary, subject to the stated conditions:

(1) Oral analgesics for mild to moderate pain: magnesium salicylate/phenyltoloxamine citrate, acetylsalicylic acid (Zero order release, long acting tablets), choline salicylate and magnesium salicylate, IBUPROFEN (no more than 400 mg per dosage unit for minor pain and menstrual cramps limited to a six (6) day supply for one treatment). When appropriate, such prescription shall be labeled to be taken with food or milk.

(2) Urinary analgesics; phenazopyridine, not exceeding a two (2) day supply. Such prescriptions shall be labeled as to the tendency to discolor urine and when appropriate shall be labeled to be taken after meals.

(3) Otic analgesics; antipyrine 5.4%, benzocaine 1.4%, glycerin, which shall be labeled for use in the ear only.

(4) Hemorrhoid medications; 0.5% hydrocortisone acetate and 0.5% dibucaine ointments and creams, limited to a seven (7) day supply.

(5) Leg cramps; quinine sulfate tablets, except to patients with cardiac arrhythmias, and

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not to patients currently using anticoagulant or digitalis containing drugs. When appropriate, such prescriptions shall be labeled to be taken with or after meals.

(6) Anti-nausea preparations; Meclizine up to 25 mg except for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants. Scopolamine not exceeding 1.5 mg per dermal patch. Patient to be warned 'if eye pain develops, seek appropriate medical attention.'

(7) Antihistamines and decongestants. The following, including their salts, either as a single ingredient product or in combination, including nasal decongestants, may be ordered for patients above six (6) years of age:

- (a) Diphenhydramine
- (b) Carbinoxamine
- (c) Clemastine—1.34 mg
- (d) Pyrilamine
- (e) Chlorpheniramine
- (f) Dexchlorpheniramine
- (g) Brompheniramine
- (h) Tripolidine
- (i) Terfenadine

“The patient should be warned that antihistamines should not be used by patients with bronchial asthma or other lower respiratory symptoms, glaucoma, cardiovascular disorders, hypertension, prostate conditions and urinary retention. Antihistamines shall be labeled to advise the patient of drowsiness and caution against the concomitant use with alcohol or other depressants.

- (j) Pseudoephedrine
- (k) Phenylpropanolamine
- (l) Ephedrine
- (m) Phenylephrine
- (n) Phenyltoloxamine
- (o) Azatadine
- (p) Diphenylpyraline

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“Oral decongestants shall not be ordered for use by patients with coronary artery disease, angina, hyperthyroidism, diabetes, glaucoma, prostate conditions, hypertension, or patients currently using monoamine oxidase inhibitors.

(8) Anthelmintic: Pyrantel pamoate. The drug product may only be ordered for use by patients over 2 years of age.

(9) Topical antifungal/antibacterials; Iodochlorhydroxyquin with 0.5% Hydrocortisone (not exceeding 20 grams), Haloprogin 1%, Clotrimazole topical cream and lotion. Nystatin topical cream, ointment, lotion or powder, miconazole nitrate topical cream. The patient shall be warned that all of the above products should not be used near deep or puncture wounds, and Iodochlorhydroxyquin preparations shall be labeled as to the staining potential.

(10) Topical anti-inflammatory; preparations containing hydrocortisone not exceeding 0.5%. The patient shall be warned that hydrocortisone should not be used on bacterial or fungal infections or by patients with impaired circulation. Such prescriptions shall be labeled to avoid contact with eyes and broken skin.

(11) Otic antifungal/antibacterial; acetic acid 2% in aluminum acetate solution which shall be labeled for use in ears only.

(12) Keratolytics; salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under two (2) years of age, and those with diabetes or impaired circulation. Prescriptions shall be labeled to avoid contact with normal skin, eyes and mucous membranes.

(13) Vitamins with fluoride. (This does not include vitamins with folic acid in excess of 0.9 mg.)

(14) Medicinal drug shampoos containing Lindane may be ordered pursuant to the following conditions:

(a) The pharmacist shall limit the order to the treatment of head lice only and provide the patient with the appropriate instructions and precautions for use.

(b) The amount allowed per person shall be four ounces.

(15) Antidiarrheal: Loperamide 2 mg per dosage unit. No more than a two day supply may be dispensed.

(16) Smoking cessation products: Nicotine polacrilex not exceeding 2 mg per dose. Before prescribing, the pharmacist:

(a) Must receive written authorization from the patient’s physician allowing participation in a smoking cessation program.

(b) Must ensure patient involvement in a behavior modification program.

(17) Ophthalmics: Naphazoline 1% ophthalmic solution . . . .

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**Appendix V**  
**The Florida Pharmacist Self-Care**  
**Consultant Law**

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“Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:

- (1) The fluoride content of drinking water does not exceed 0.5 ppm.
- (2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment.
- (3) If the fluoride content is less than 0.5 ppm then the following dosage schedule for oral usage shall be followed:
  - (a) 1. For ages 0-2 years
    - a. less than 0.2 ppm in water—supplement with 0.25 mg F/day
    - b. 0.2-0.5 ppm in water—no supplementation
    - c. 0.5 ppm in water—no supplementation
  2. For ages 2-3 years
    - a. less than 0.2 ppm in water—supplement with 0.5 mg F/day
    - b. 0.2-0.5 ppm in water—supplement with 0.25 mg F/day
    - c. 0.5 ppm in water—no supplementation
  3. For ages 3-13 years
    - a. less than 0.2 ppm in water—supplement with 1.00 mg F/day
    - b. 0.2-0.5 ppm in water—supplement with 0.5 mg F/day
    - c. 0.5 ppm in water—no supplementation
- (b) No more than 264 mg of sodium fluoride may be dispensed at any one time to a patient
- (c) . . . a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.”

Pharmacists are not required to perform the prescribing role. However, if they choose to, there are a number of requirements. The first, concerning product labeling, is given in section 465.186 of the pharmacy statutes.

“Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:

- (a) The name of the pharmacist ordering the medication.
- (b) The name and address of the pharmacy from which the medication was dispensed.
- (c) The date of dispensing.
- (d) The order number or other identification adequate to readily identify the order.
- (e) The name of the patient for whom the medicinal drug was ordered.
- (f) The directions for use of the medicinal drug ordered.
- (g) A clear, concise statement that the order may not be refilled.”

The second set of requirements is laid out in section 21S-27.210 of the pharmacy regulations.

“Pharmacists may order the medicinal drug products . . . subject to the following terms and limitations:

- (1) Injectable products shall not be ordered by the pharmacist.
- (2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.
- (3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.
- (4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer’s recommended dosage.

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**Appendix V**  
**The Florida Pharmacist Self-Care**  
**Consultant Law**

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(5) The pharmacist may only perform the acts of ordering and dispensing in a pharmacy which has been issued a permit by the Board of Pharmacy.

(6) The pharmacist shall create a prescription when ordering and dispensing medicinal drug products which shall be maintained in the prescription files of the pharmacy. The pharmacist shall place the trade or generic name and the quantity dispensed on the prescription label, in addition to all other label requirements.

(7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of seven (7) years.

(8) In the patient profiles, the pharmacist shall record as a minimum the following information if a medicinal drug product is ordered and dispensed.

(a) Patient's chief complaint or condition in the patient's own words.

(b) A statement regarding the patient's medical history.

(c) A statement regarding the patient's current complaint which may include onset, duration, and frequency of the problem.

(d) The medicinal drug product ordered and dispensed.

(e) The pharmacist ordering and dispensing the medicinal drug product shall initial the profile.

(f) The prescription number shall be recorded in the patient's profile.

(9) A medicinal drug product may be ordered and dispensed only by the pharmacist so ordering.

(10) Only legend medicinal drug may be prescribed by a pharmacist. Over-the-counter drugs are exempt from the requirement of this rule and shall be recommended as over-the-counter products.

(11) Pharmacy interns and supportive personnel may not be involved in the ordering of the medicinal drugs permitted in this Rule."

# Comments From the Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

SEP 10 1998

Mr. Kwai-Cheung Chan  
Director,  
Program Evaluation in  
Physical System Areas, PEMD  
U. S. General Accounting Office  
441 G Street, N.W.  
Washington, D. C. 20548

Dear Mr. Chan:

FDA has reviewed the GAO draft report entitled "Nonprescription Drugs: Usefulness of a Restricted Sale Class Has Not Been Demonstrated."

It should be noted that the report does not consider the additional requirements establishing a third class of drugs would impose upon the FDA, the drug manufacturers or the prescribing pharmacists. For example, new labeling regulations would be required to cover the proper use of such drugs as prescribed and dispensed by pharmacists and additional training would be required for pharmacists.

FDA has no additional comments on the report.

Sincerely,

*Diane Thompson*  
Diane Thompson  
Associate Commissioner for  
Legislative Affairs

# Reviewers of This Report

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The following experts and organizations reviewed the report; however, they do not necessarily endorse the positions we have taken in it.

David Brushwood, J.D.  
Professor, Pharmacy Health Care Administration  
College of Pharmacy  
University of Florida

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American Medical Association

American Pharmaceutical Association

National Association of Retail Druggists

National Consumers League

Nonprescription Drug Manufacturers Association

# Major Contributors to This Report

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In addition to the persons named above, Gerald L. Dillingham, who served as the initial project director, made an important contribution to this report.

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# Glossary

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Druggist	In the Netherlands and Switzerland, druggists, as distinguished from pharmacists, are health professionals. Some training is required to become a druggist but it is not as extensive as that for a pharmacist. The training is not university-based.
Drugstore	Drugstores, as distinguished from pharmacies, in the Netherlands and Switzerland are run by druggists. Prescriptions cannot be dispensed in drugstores and not all nonprescription drugs can be sold.
Durham-Humphrey Amendment of 1951	An amendment to the Federal Food, Drug, and Cosmetic Act of 1938 that established the statutory basis for the present two-tier (prescription and nonprescription) drug distribution system in the United States.
Fixed, Intermediate Class	A class of nonprescription drugs into which pharmaceuticals would be permanently placed. These drugs would be restricted to sale either in pharmacies or by pharmacists.
Formulary	A collection of recipes, formulas, and prescriptions. In Florida, the formulary lists the drugs a pharmacist may prescribe and the conditions under which they may be prescribed.
General Sale Class	A class of nonprescription drugs available for sale outside pharmacies (and also drugstores in Switzerland). The nonprescription class in the United States is a general sale class.
Indication	The ailment a drug is meant to treat.
Intermediate Class	A general term encompassing both a fixed, intermediate class and a transition class.
Nonprescription Drug	A drug available without a prescription. Also referred to as over-the-counter drug or OTC.

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Over-the-Counter Drug	A drug available without a prescription. Also referred to as a nonprescription drug or OTC.
Pharmacist Class	A class of nonprescription drugs that can be sold only in pharmacies and if the pharmacist is personally involved in the sale. The distinction between a pharmacist class and a pharmacy class is relevant for both a fixed, intermediate class and a transition class.
Pharmacy	A drug outlet where prescriptions can be dispensed and all nonprescription drugs can be sold.
Pharmacy Class	A class of nonprescription drugs that can be sold only in pharmacies, but the pharmacist does not have to be personally involved in the sale. The distinction between a pharmacy class and a pharmacist class is relevant for both a fixed, intermediate class and a transition class.
Prescription	Generally, an order from a physician to a pharmacist to dispense a particular drug.
Switching	The reclassification of drugs from one class to another. Generally, switching reduces restrictions on the sale of a drug.
Third Class of Drugs	In the United States, a proposed class of nonprescription drugs that would be available for sale only in pharmacies. One variation would be to allow the drugs to be sold only by pharmacists.
Transition Class	A class of nonprescription drugs into which a drug could be temporarily placed while its suitability for less restrictive sale was being assessed. In the United States, drugs in the transition class would be available for sale without a prescription but only from a pharmacist. The class would be used for assessing the appropriateness of selling the drug in any retail outlet.

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**Glossary**

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# Related GAO Products

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Nonprescription Drugs: Over the Counter and Underemphasized  
(GAO/PEMD-92-9, Jan. 1992)

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