the manufacturer before the product can be marketed and sold in the United States, dietary supplement manufacturers are responsible for determining only the safety of their products. There is no efficacy requirement. Moreover, the dietary supplement regulations do not require the manufacturer to submit its safety data to FDA for review and approval prior to marketing their products, as is required for drug manufacturers. If FDA has concerns about the safety of a dietary supplement and wants the product removed from the market, DSHEA places the burden on FDA to prove that the supplement is unsafe.[20]

Next, unlike drug manufacturers, dietary supplement manufacturers generally do not need to register with FDA. As a result, FDA does not maintain a list of manufacturers, distributors, or the dietary supplement products sold in the market, as it does with prescription and nonprescription drugs.

Finally, there are currently no FDA regulations that establish a minimum standard for manufacturing dietary supplements. The industry has been largely self-regulated, with each supplement manufacturer free to establish its own manufacturing practice guidelines.

This is not to say, however, that FDA has no role in the regulation of dietary supplements. Under DSHEA, FDA has the authority to stop the sale of dietary supplements proven to be unsafe after they reach the market. FDA monitors safety through postmarketing surveillance, including voluntary dietary supplement adverse event reporting, and product information, such as labeling, claims, package inserts, and accompanying literature.

FDA also has the authority to prescribe, through regulation, good manufacturing practices, including regulations addressing potency and stability of products and the cleanliness of manufacturing facilities. In 2003, FDA exercised its authority under DSHEA, and took the first formal step towards establishing current good manufacturing practices aimed at reducing the risks associated with adulterated and misbranded dietary supplement products.[21] FDA published a proposed rule that would require the use of industry-wide standards in the manufacturing, packing, and holding of dietary supplements, and that would ensure the identity, purity, quality, strength, and composition of dietary supplements are accurately reflected on the product label.[22] The proposed manufacturing practices would apply to all firms that manufacture, package, or hold dietary ingredients or dietary supplements, including those involved with testing, quality control, packaging, labeling and distribution activities. FDA received diverse comments on this proposed rule, particularly from the dietary supplement industry, and will consider these comments as it develops final standards.

Labeling of Dietary Supplements

Under DSHEA, supplement manufacturers are permitted to make certain claims on their labels, as long as the claims are accurate and truthful. Regarding the types of claims that can be made, DSHEA prohibits "disease claims" that explicitly or implicitly indicate that the product can be used to prevent, treat, cure, mitigate, or diagnose a disease. Disease claims are reserved for drug products, and if a dietary supplement label makes a disease claim, FDA can step in and regulate the dietary supplement as a drug. "Structure/function" claims, on the other hand, are permitted under DSHEA. A structure/function claim describes the role that the supplement plays in affecting the normal structure or function of the human body.[23] Thus, for example, it may be permissible for a manufacturer to claim that its product helps to improve mood, but not that its product can be used to treat depression.

In addition, when a manufacturer makes a structure function claim, it must also include the following disclaimer: "This statement has not been evaluated by FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." Manufacturers making structure/function claims must also notify FDA of its use of the specific claim no later than 30 days after marketing the product, and must have support that any labeling claims it makes are truthful and not misleading. However, there is no requirement that FDA approve labeling before a supplement is marketed.

For herbal products, the label must also state the part of the plant used in the product (e.g., root, stem, or leaf). Figure 4–5 illustrates the standard label format. A standardized format provides the patient with certain minimum information about the product prior to consumption.

Advertising and Promotion of Dietary Supplements

FTC regulates advertising of dietary supplements and other products marketed to consumers in any media. Its reach includes traditional magazine advertising, television and radio, "infomercials," catalogs and similar direct marketing materials, and advertising and promotion over the Internet. The role of FTC, which enforces federal laws prohibiting "unfair or deceptive acts or practices," is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.[24]

FTC works with FDA under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, FDA, through its Center for Food Safety and Applied Nutrition, has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of

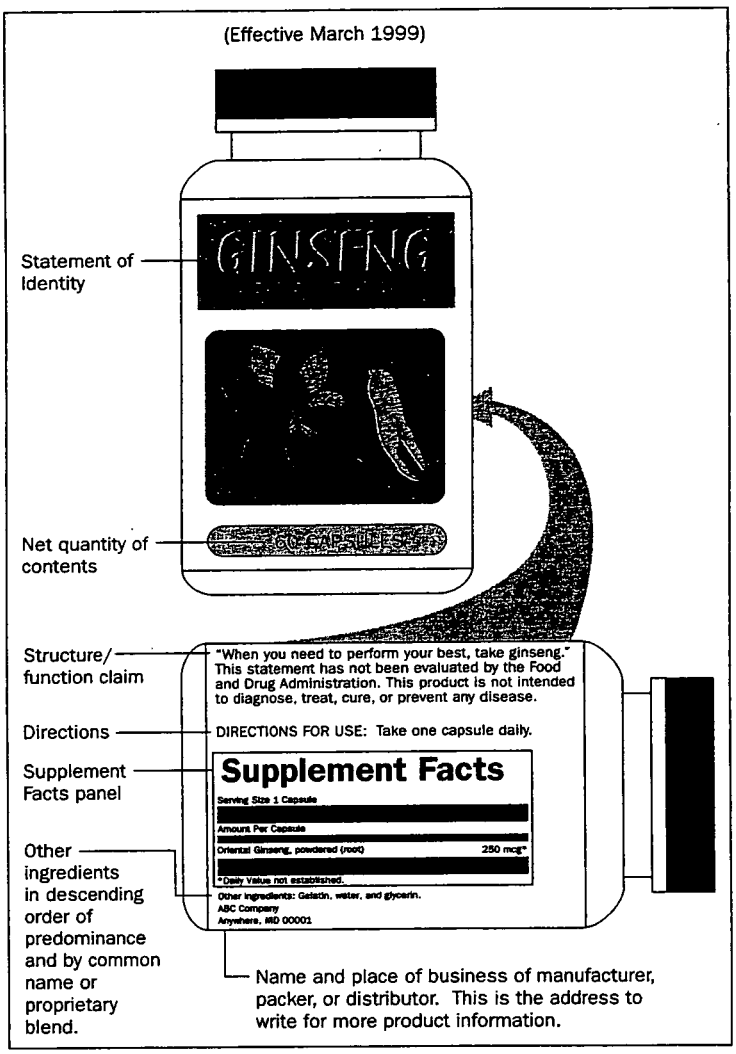

FIGURE 4-5 Statutory labeling format for all dietary supplements. (Reprinted from US Food and Drug Administration. *Anatomy of the New Requirements for Dietary Supplement Labels*. Available at: http://www.cfsan.fda.gov/~acrobat/fdsupp1a.pdf. Accessed September 24, 2003.)

sale, whereas FTC has primary responsibility for claims in advertising.

Homeopathy

Homeopathic medicines include substances that have evoked positive images (e.g., chamomile, marigold, daisy, and onion) as well as those that are considered the cruelest of creations (e.g., poison ivy, mercury, arsenic, pit viper venom, and hemlock). Homeopathy is based on a medical theory that potency increases with dilution and has been practiced for more than 200 years. Principally, homeopathic medicines are made from a variety of sources (e.g., plants, minerals, and animals). Their use is based on a person's genetic history, personal health history, body type, and present status inclusive of all physical, emotional, and mental symptoms.

Some homeopathic remedies are so dilute that the molecules of the healing substance are difficult and sometimes impossible to identify, even by utilizing some of the most sophisticated technologies of the 21st century. Homeopaths, however, believe that the substance leaves its imprint or a "spirit-like" essence that stimulates the body to heal itself. (See Chapter 55 for a discussion of homeopathic concepts and techniques.)

FDA Regulation of Homeopathic Products

It is widely believed that Senator Royal Copeland of New York, a homeopathic primary care provider and the chief sponsor of the FD&C Act, was responsible for

writing into the Act the recognition of any product listed in the *Homeopathic Pharmacopoeia of the United States* (*HPUS*).[25] Homeopathic drugs are recognized as drugs under the Federal Food, Drug, and Cosmetic Act, which defines the term *drug* as "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, (i) or any supplement to any of them...."[26] Further, the Act provides that whenever a drug is recognized in both the *United States Pharmacopoeia* and the *HPUS*, it shall be subject to the requirements of the *United States Pharmacopoeia* unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the *HPUS*, and not to those of the *United States Pharmacopoeia*.

FDA regulates homeopathic remedies under provisions of the FD&C Act but in significantly different ways from other drugs. Manufacturers of homeopathic drugs are not required to submit an NDA to FDA before marketing their products. Furthermore, these products are exempt from good manufacturing practice requirements related to expiration dating and from finished product testing for identity and strength. This disparity exists because homeopathic products contain little or no active ingredient, and so there is a diminished concern for safety or toxicity. Another disparity is in the concentration of alcohol in the preparation. Conventional drugs for adults can contain no more than 10% alcohol and the amount is even less in medications intended for pediatric use.[27] Homeopathic products, however, are exempt from these limits, and can contain much higher amounts of alcohol.

Homeopathic products are not, however, exempt from all FDA regulations. If a homeopathic drug claims to treat a serious disease (e.g., cancer), it can be sold only by prescription. Only products sold for the so-called self-limiting conditions—colds, headaches, and other minor health problems that eventually resolve on their own—can be sold as nonprescription items.

Labeling of Homeopathic Products

Homeopathic drug products are subject to the same labeling provisions of the FD&C Act as are other drug products. However, if these products are labeled in accordance with the existing Compliance Policy Guide for homeopathic products, they will not be subject to regulatory action.[28]

FDA is focusing on educating the homeopathic industry about FDA regulations. FDA is aware of a few reports of illness associated with the use of homeopathic products. Investigation of such reports revealed that the homeopathic product was not the cause of the adverse reaction. In one instance, arsenic, which is a recognized homeopathic ingredient, was implicated, but, as would be expected, the FDA analysis revealed the concentration of arsenic was so minute that no cause–effect relationship could be established. Even with the lack of clinical research, homeopathy's popularity in the United States is growing.

Drug-Cosmetic Products

Some OTC drug products are also considered cosmetic products.[29] The claim(s) that are made for the product determine whether it is a drug, a cosmetic, or a drug–cosmetic. There are different labeling and marketing requirements depending on how a product is classified. Often this distinction is not apparent to the consumer, but a consumer may wonder why a product that they considered to be a cosmetic contains Drug Facts labeling. If a product has a "drug" intended use and a "cosmetic" intended use, it is considered a drug–cosmetic. For example, a shampoo is a cosmetic because its intended use is to clean the hair, which is a cosmetic claim. An antidandruff shampoo is a drug because its intended use is to treat dandruff, which is considered a drug claim. Therefore, an antidandruff shampoo that claims to clean the hair and treat dandruff would be a drug–cosmetic and have OTC Drug Facts labeling. Other drug–cosmetic products include toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and some makeup that are marketed with sun-protection claims.

Identifying and Removing Potentially Dangerous Products from the Market

Adverse Event Reporting

The pharmacist stands out as the one health care provider that has the most frequent and ready access to consumers of prescription and nonprescription drugs. Through counseling of patients in the pharmacy or assisting a customer in selecting the appropriate OTC treatment for some health-related condition, pharmacists often obtain information that suggests that a drug or other FDA-related product, including dietary supplements, may be causing unintended adverse health consequences. Pharmacists play a critical role in helping FDA and industry manage the risks associated with regulated products. To fulfill this important responsibility, it is important for the pharmacist to understand FDA's adverse event reporting system.

The FDA MedWatch program is a voluntary adverse event reporting system that allows health care providers and consumers to report serious adverse drug reactions directly to the agency. FDA analyzes trends and correlations between drug use and adverse reports from information submitted to MedWatch.

There is no cost to either the health care professional or the consumer for filing a report. Though the program is voluntary, it is ineffective unless properly utilized. Health care providers should take their role in patient safety seriously and, as part of that responsibility, should see that serious adverse drug reactions suspected to be associated with drugs are reported to FDA. Official reporting forms are available from FDA by calling 1-800-FDA-1088. Reports can also be submitted online by accessing the MedWatch Web site at http://www.fda.gov/medwatch/index.html. FDA safety alerts and product recall information are also accessible at this site.

It is important to understand that submitting a report to FDA does not constitute a legal claim, nor does it in any way constitute an acknowledgment that there has even been an adverse drug reaction associated with use of the product. The identities of the practitioners and the patients are confidential. Health care providers are encouraged to report all suspected adverse reactions, and to ensure effective review of the reports, FDA asks that practitioners describe the reaction, the exposure to the regulated product, the time between exposure and reaction, and the underlying disease.

Product Recalls

When a product regulated by FDA is identified as a potential risk to the public, it may be necessary to have that product removed from the market. Products may pose a risk for a variety of reasons, including adulteration or misbranding or because an unacceptable risk of adverse effects that had not been previously discovered is later discovered through postmarket surveillance.

FDA has two methods available to force the removal of a product from the market. First, if the drug is misbranded or adulterated, the FD&C Act allows FDA to seize the product and order that it be held pending a review by the court concerning the safety of the product.[30] Next, FDA can also seek a court injunction, preventing further distribution or sale of the product. Both of these remedies are potentially expensive and time consuming and, more importantly, do not address the issue of retrieving drugs that have already been purchased by a consumer.

A third avenue FDA may pursue is to request the manufacturer to recall their product from the market. FDA has no statutory authority to order a recall, but when potentially serious health risks are associated with the use of a drug product, typically manufacturers are more than willing to institute a recall. If a recall is instituted, FDA does have the authority to prescribe the procedures to which the recall must conform. This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible. FDA guidelines governing product recalls make clear that FDA expects manufacturers to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so.[31]

The guidelines categorize all recalls into one of three classes according to the level of hazard associated with the product at issue:

- *Class I* recalls are for dangerous or defective products that predictably could cause serious health problems or death.
- *Class II* recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature.
- *Class III* recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations.

The manufacturer is responsible for notifying sellers of the recall. The sellers, including pharmacists, are responsible for contacting customers, if necessary. A pharmacist is also responsible for knowing what drugs or other regulated products have been recalled. Failing to remove a recalled product from the shelf, and providing the product to a consumer, may violate the FD&C Act and also exposes the pharmacist to civil liability in the event that someone is injured by use of the product.

FDA issues general information about new recalls it is monitoring through FDA Enforcement Reports, a weekly publication available on FDA's Internet page at http://www.fda.gov.

Conclusion

Self-care plays an increasingly important role in health care, and nonprescription pharmacotherapy represents a significant element in that self-care process. Consumers, manufacturers, governmental agencies, and professional groups, particularly pharmacists, should become even more intent on recognizing that each group fulfills essential functions in ensuring the safe, appropriate, effective, and economical use of nonprescription drugs.

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資料 4

Commit, Nicorette & NicoDerm CQ

ADVANTAGES:

Commit LOZENGE
- The newest FDA-approved stop smoking aid to help smokers quit
- Easy way to get effective delivery of medicine
- New and novel way to select dosing strength—"Time to First Cigarette"

Nicorette GUM
- You control how much nicotine you use
- Convenient to carry and use
- You can use an extra piece when you experience strong or frequent cravings
- Oral gratification and available in three flavors: Mint, Orange, and Original

NicoDerm CQ PATCH
- Once-a-day convenience
- Step down dosing to gradually reduce your nicotine dose
- Delivers constant support to help calm cravings for 16 or 24 hours (use for 24 hours to handle morning cravings)
- Offers discreet therapy options, including Clear® and opaque

COMMITTED QUITTERS
Stop Smoking Plan

What is Committed Quitters?
Committed Quitters is a stop smoking plan personalized just for you. You receive customized materials designed to help you cope with the smoking habits you want to break.

How does it work?
After buying a Commit 4mg or 2mg, Nicorette Gum Starter Kit or NicoDerm CQ patch Step 1 or Step 2 pack, call the 1-800 number in the box to speak to a live counselor. We quickly send your FREE stop smoking plan designed specifically for you.

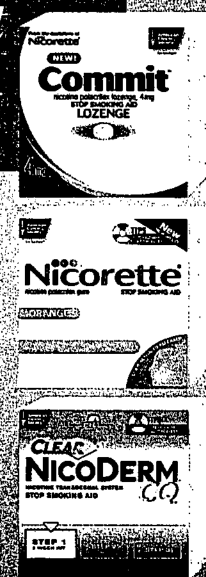
Why does it work?
Having a plan will help you quit.
Your program materials are tailored to your specific situation. After telling us your smoking habits, your answers are used to create your personalized materials.

Personalization is the key.
Your plan will be specifically customized to you. It will cover:
- things that could keep you from quitting
- situations that could tempt you to smoke
- people around you who can help you quit
- your unique reasons for quitting smoking

You will receive a totally unique plan designed for you to help you quit smoking for good.

The Commit, Nicorette and NicoDerm CQ Committed Quitters plans offer the following materials:
- Personalized Stop Smoking Plan & Calendar
- Customized Newsletter with success stories
- Tips & Strategies Brochure
- Customized guide for successfully completing your plan
- Weight Loss tips (if you request them)

Your Health Care Professional Is Committed To Help You Quit Smoking



Which stop smoking aid is right for you?

DO YOU:

- ☐ Prefer a new stop smoking aid?
- ☐ Prefer an easy to use oral form?
- ☐ Want easy to use dosing directions?

If you checked 2 or 3 boxes above, Commit Lozenge may be your best choice

- ☐ Want to control how much nicotine you use?
- ☐ Like the flexibility of an extra piece to address your toughest cravings?
- ☐ Prefer an oral form?

If you checked 2 or 3 boxes above, Nicorette Gum may be your best choice

- ☐ Smoke at regular intervals (such as once every 1/2 hour)?
- ☐ Want once-a-day convenience?
- ☐ Prefer a non-oral form?

If you checked 2 or 3 boxes above, NicoDerm CQ Patch may be your best choice

Commit

How to use Commit properly

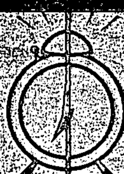
- Stop using Commit at the end of 12 weeks.
- If you still feel the need to use Commit, talk to your doctor.

How to use Commit properly

- Avoid food and beverages 15 minutes before and during use of Commit.

STRENGTH BASED UPON TIME TO FIRST CIGARETTE OF THE DAY

Use 2mg	Use 4mg
If you smoke your first cigarette *more than* 30 minutes after waking up.	If you smoke your first cigarette *within* 30 minutes of waking up.

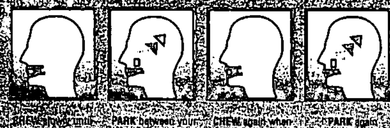


Nicorette

Nicotine Polacrilex Gum

What is Nicorette Gum?

How to use Nicorette Gum



- Then repeat for no longer than 30 minutes, parking gum in different parts of your mouth. Most of the time Nicorette is in your mouth, it should be parked.
- Don't consume acidic foods or beverages 15 minutes before and during use of Nicorette, as this may interfere with nicotine absorption.

What is the correct Nicorette dosage for you?

- 2mg if you smoke less than 25 cigarettes/day
- 4mg if you smoke 25 or more cigarettes/day

Weeks [illegible] to 6 ⟶	1 piece every 1 to 2 hours
Week 7 to 9 ⟶	1 piece every 2 to 4 hours
Week 10 to 12 ⟶	1 piece every 4 to 8 hours
	Do not exceed 24 pieces a day

NicoDerm CQ

Stop Smoking Patch

What is the NicoDerm CQ Patch?

How to use NicoDerm CQ Patches

- Stop smoking completely when you begin using NicoDerm CQ.
- Read and follow all package instructions.
- Use this schedule to develop your quitting plan and choose which patch to wear.

Step 1	Step 2	Step 3
6 Weeks	2 Weeks	2 Weeks
21mg/day	14mg/day	7mg/day

If you smoke 10 or less cigarettes per day, use Step 2 for six weeks and then step down to Step 3 for two weeks.

Wear each patch 16 or 24 hours a day.

The NicoDerm CQ program uses a simple, step down program that reduces your nicotine dose gradually, rather than stopping suddenly.

Completing the full program will increase your chances of quitting successfully.

Can the NicoDerm CQ Patch get wet?

Yes, as long as it is applied properly.

Is NicoDerm CQ safe?

Can NicoDerm CQ be worn for 24 hours?

COMMIT, NICORETTE & NICODERM CQ $5.00 CASH REFUND BY MAIL

Buy: Any one Commit, Nicorette or NicoDerm CQ product.

Send:
- Package UPC symbol from Commit, Nicorette or NicoDerm CQ product purchased.
- Cash register receipt dated April 1, 2003 through June 15, 2004 with purchase price circled.
- This completed certificate.

Receive: $5.00 cash refund by mail.

Send To: Commit/Nicorette/NicoDerm CQ $5.00 Refund Offer, P.O. Box 1022, Grand Rapids, MN 55745-1022

Please send my cash refund to:

Name ____________

Address ____________

(Requests from P.O. Boxes will not be honored or acknowledged or returned.)

City ____________

State ______ Zip ______

Offer limited to one refund request per household or address and valid only for the person who purchased this product. Actual certificate and receipt must accompany request. Requests from groups, clubs or organizations will not be honored. Offer may not be reproduced without written permission. Void where taxed, restricted or prohibited by law. Please allow 6 weeks for delivery. Offer good only in the U.S. Submission must be received by 8/30/04.

GlaxoSmithKline
Consumer Healthcare

資料 5

1

CHAPTER

Self-Care and Nonprescription Pharmacotherapy

Somnath Pal

In the 21st century, nonprescription products will continue to be essential, cost-effective components of the U.S. health care system. A recent (effective October 1, 2003) Internal Revenue Service ruling will allow employers to reimburse properly substantiated nonprescription medication expenses, but not dietary supplements, from flexible health care spending accounts.[1] This ruling provides economic incentive to use nonprescription drugs and will expand opportunities for pharmacists to help consumers with their self-care decisions.

Nonprescription drugs provide self-care options to treat more than aches and pains (see Chapter 5); some can prevent diseases such as tooth decay (see Chapter 32), cure infections such as athlete's foot (see Chapter 43), and, with medical supervision, help to manage recurrent conditions such as vulvovaginal candidiasis (see Chapter 8) and the minor pain of arthritis (see Chapter 7). Nonprescription drugs are also used to treat reproductive (see Section III), respiratory (see Section IV), gastrointestinal (see Section V), otic (see Section VII), and dermatologic (see Section VIII) disorders. Nonprescription drugs promote healthy lifestyles and general wellness, in addition to preventing skin cancer (see Chapter 39) and helping smokers kick the habit (see Chapter 50). Nonprescription drugs, herbals, and/or dietary/nutritional supplements (see Section VI) are generally used safely and effectively by millions of Americans every day and are found in nearly every medicine cabinet. Complementary and alternative medicine (e.g., homeopathic medicines; see Chapter 55) is an important though sometimes controversial area of self-care with retail sales of $11.3 billion in 2000.[2]

Figure 1–1 demonstrates the 2001–02 sales of the 10 top therapeutic categories of nonprescription drugs. With new opportunities in self-medication come new responsibilities and an increased need for knowledge. As people live longer, work longer, and take a more active role in their health care, they need to become better informed about self-care options. And there is no health care professional better suited to help them be informed than the pharmacist.

Shift Towards Self-Medication

Many consumers are taking active roles in addressing their own health care needs. Hundreds of health-related self-help books, newspaper features, television and radio programs, instructional audio and videotapes, and Internet Web sites and portals are evidence of the proliferation of self-medication. Although a consumer may find this information overwhelming and confusing, the practicing pharmacist has the expertise to screen this information and apply it to individual health care needs.

Consumers need to know which self-care practices to adopt, and how and why to do so, and health care professionals should incorporate this concept into their daily practices. Much to the convenience of consumers, such health care–related information is readily accessible on the Internet. These resources can be accessed globally, and updated information can be obtained in the privacy and comfort of a consumer's home. But the major drawback is the information may lack quality control, which in many instances compromises the welfare of consumers.[3] Because no one individual/group owns the entire Internet, there is no single group or organization accountable for the quality and accuracy of the information available on Web sites.[4] Many sites contain inadequate information, and so it is not safe to simply surf and self-medicate.[5]

In response to concerns for public safety in the practice of pharmacy on the Internet, the National Association of Boards of Pharmacy (NABP) provides valuable information about the credentials of online pharmacies through the Verified Internet Pharmacy Practice Sites (VIPPS) program.[6] It is a voluntary program, and an online pharmacy must agree to strict conditions in order to be certified. The program also includes a provision for inspection by an NABP team. The influence of the Internet on self-care and acquisition of health care information creates a new challenge for health care professionals. Pharmacists have a great potential to reach approximately 100 million Americans who are on the Internet.[7]

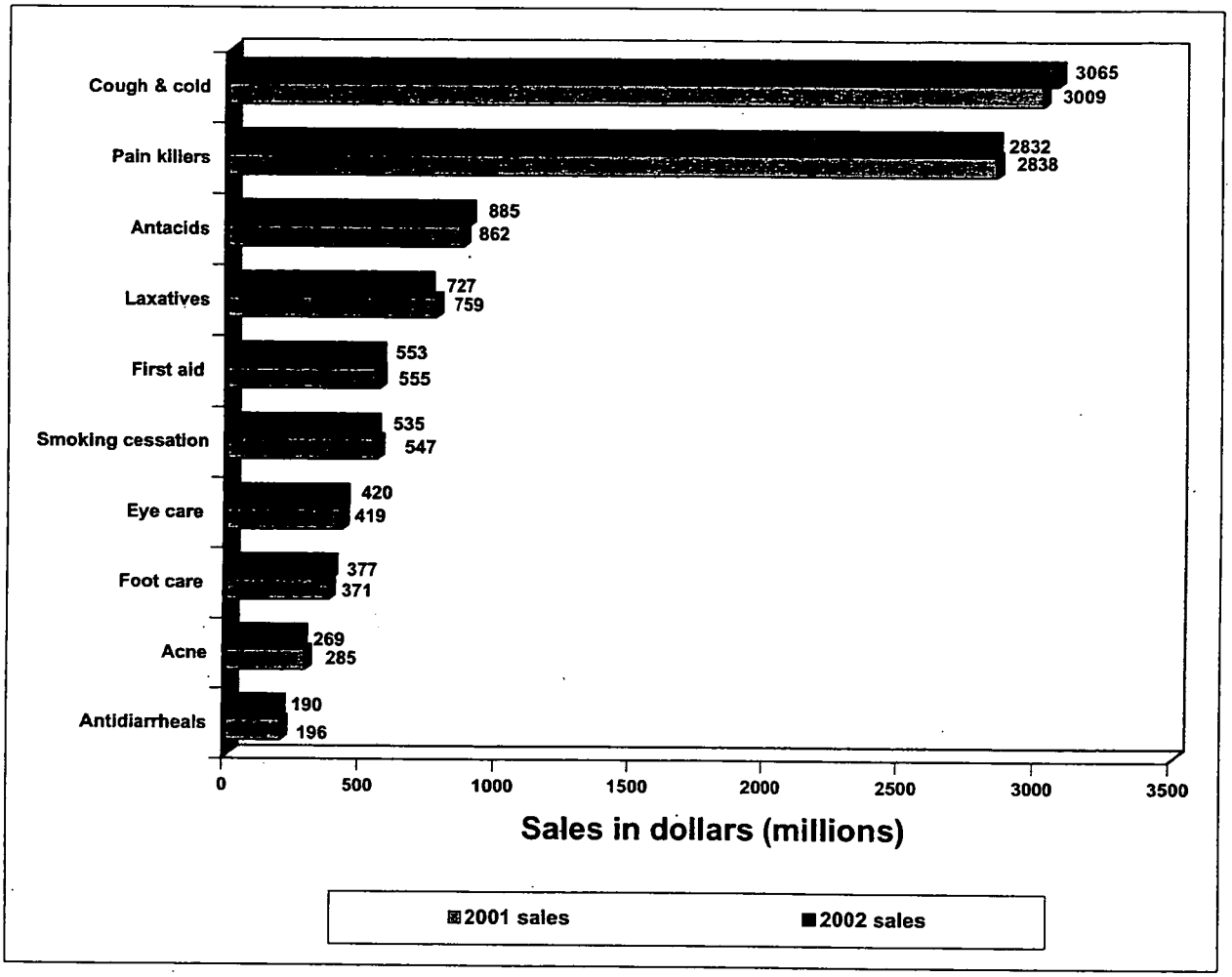


FIGURE 1–1 Top 10 categories of nonprescription drugs sold in 2001 and 2002. Source: Consumer Healthcare Products Association. OTC sales by category; OTC sales statistics 2001–02. Available at http://www.chpa-info.org/statistics/OTC_Sales_by_Category.asp. Accessed July 3, 2003.

The following highlights demonstrate consumer behaviors related to nonprescription drug use:

- Making their own health-related decisions is favorably viewed by 96% of the people surveyed by the Consumer Healthcare Products Association.[8]
- Nonprescription drugs are considered safe by 87% only if they follow the direction on the labels.[8]
- When selecting the appropriate nonprescription drug product, 89% read the label.[8]
- When taking a nonprescription drug for the first time, 95% read the "directions" on the label.[8]
- Before taking a nonprescription drug for the first time, 91% read the side effects and interactions on the label.[8]
- When the problem is major (as perceived by the patient), 84% consult their primary care providers before using the nonprescription drugs.[9]
- When the problem is minor (as perceived by the patient), 7% ask their pharmacist.[9]
- At the first sign of a health problem, 38% take nonprescription drugs.[8]

Trends in Self-Medication Among Americans of Advanced Age

America is aging and, significantly, persons of advanced age consume a disproportionately large share of nonprescription drugs. The growth of the population in the 65 and older age group provides opportunities for health care providers, including pharmacists. The "baby boom" generation will begin reaching age 65 in 2011, and by 2030, this group will number 70 million.[10] Self-medication has also become one of the most common forms of medical care among persons of advanced age. Persons over the age of 65 buy 30% of all prescription drugs and 40% of all nonprescription drugs.[11] Increased

use of nonprescription drugs by older Americans can be attributed to the following:

1. Conditions for which nonprescription drugs are used, such as arthritis pain, insomnia, and constipation, become more prevalent with advancing age.
2. Nonprescription drugs provide low-cost alternatives to more expensive primary care provider visits and prescription drugs.
3. Accessibility to the pharmacist in the community setting makes it an acceptable alternative to scheduling a visit to the primary care provider's office.

The fastest-growing subset of the older population is the 85 and older age group. In 2000, 2% of the population was older than 85, and in the coming years people 85 and older will make up nearly 25% of the older population.[10,12] Because these individuals tend to be in poorer health and require more services than individuals between 65 and 85, they will have a bigger impact on shaping the future of our health care system. Currently, people of advanced age account for at least 25% of nonprescription drug use, even though they make up only 13% (34.2 million) of the population.[13,14]

Some of the findings of the consumer survey about self-medication among older Americans are:[8]

- Within a given 3-month period, 37% of those older than 65 years of age have been ill.
- Self-diagnosing and self-treating were preferred by 48% of those 65 and older.
- Before going to a primary care provider, 66% of those older than 65 had a good idea about the diagnosis.
- Self-treatment of serious conditions was preferred by 42% of those older than 65 if nonprescription drugs were made available for such treatments.

Trends in Self-Medication Among Women and Men

As is true worldwide, there are more women than men of advanced age in the United States. The percentage of the population that is female increases with age, and more women than men suffer from minor illnesses that are self-treatable with nonprescription drugs (Figure 1–2). This would predict that older women will probably be utilizing nonprescription drug products more than older men will. However, before taking any prescription drugs, both men and women should inform their primary care provider about any nonprescription drugs they use, including laxatives, aspirin, diet aids, calcium supplements, treatments for vaginal infections, and sleep aids. Following are some highlights of a survey that revealed some interesting information about self-treatment among older men and women:[15]

- In the past 3-month period, 44% of men and 52% of women were sick.
- In the past 1-year period, 47% of men and 31% of women did not seek the help of a primary care provider for their health problems.
- In the past 6-month period, 82% of women and 71% of men used a nonprescription drug to treat one ailment.
- In the past 6-month period, 46% of men and 60% of women used a dietary supplement.
- Pharmacists were regarded as a resource for minor health problems by 44% of women and 46% of men.

Accessibility to Nonprescription Drugs

The Food and Drug Administration (FDA) has the final authority to categorize a drug as a prescription item or a nonprescription item based on the provisions of the 1951 Durham-Humphrey amendment to the Food, Drug, and Cosmetics Act of 1938. Prescription drugs are safe and effective when used according to the instructions of the prescriber. On the other hand, nonprescription drugs are medicines that in the judgment of FDA are safe and effective even if used without a prescriber's directive. FDA has the final say in reclassifying a drug from prescription to nonprescription status. Three specific questions need to be answered in the affirmative in order for a prescription drug to be switched to the nonprescription category:

1. Can the patient adequately self-diagnose the clinical abnormality?
2. Can the clinically abnormal condition be successfully self-treated?
3. Is the self-treatment product safe and effective for consumer use, under conditions of actual use?

As with prescription drugs, the Center for Drug Evaluation and Research (CDER), a division of FDA, oversees the formulation, production, and distribution of nonprescription drugs to ensure that they are properly labeled and that the benefits associated with their use outweigh the risks. The easy access to nonprescription drugs plays a vital role in America's health care system. Millions of American consumers use these drugs each year.

More than 700 nonprescription products on the market today use ingredients or dosages that were available only by prescription 25 years ago.[16] The pharmacist is ideally situated to advise the consumer on appropriate choices of nonprescription drugs, especially the newer available drugs that have been "switched" from prescription status. Figure 1–3 demonstrates the trend in nonprescription drug sales over the last 2 decades. The retail sales of nonprescription drugs increased about 3-fold during this period, yielding an average rate of increase of 5.4% per year.

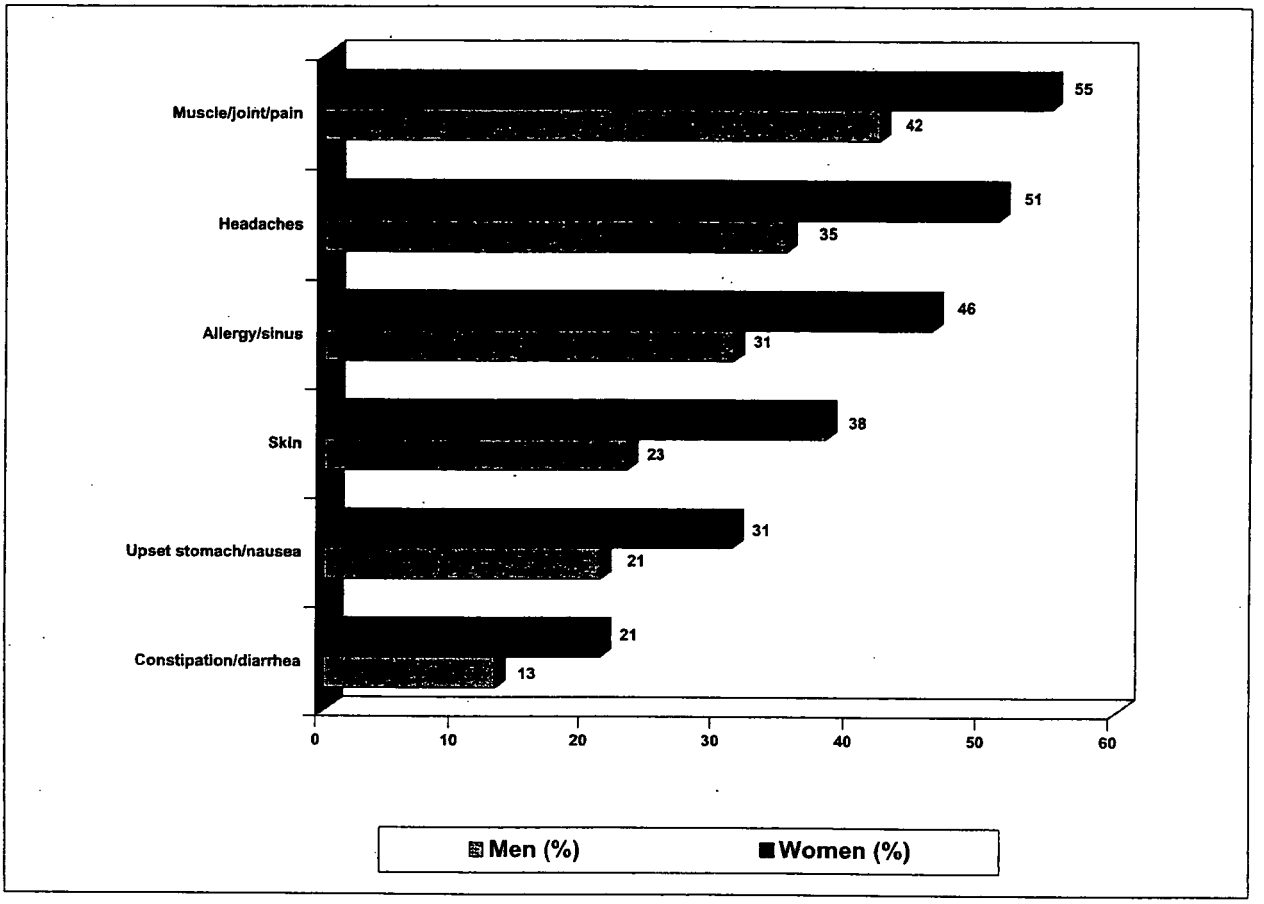


FIGURE 1–2 Selected ailments self-treated by men and women. Source: Consumer Healthcare Products Association. Roper Starch Worldwide study. Available at http://www.chpa-info.org/publications/aging_and_health.asp. Accessed July 3, 2003.

Nonprescription Drug Therapy

Nonprescription drug therapy is gaining popularity within the system of health care delivery and financing. A host of professional, economic, and public interest issues and opportunities are converging to enhance the position of this form of drug therapy in the management of self-limited illnesses. Americans can now economically benefit from the wide range of therapeutic products that are available without a prescription. Table 1–1 lists some medical disorders that can be self-treated with nonprescription drugs. However, these products must be taken properly to ensure they are safe and effective. For example, evaluation of the safety of nonprescription antihistamines on the market has recently been completed. The advisory panel of FDA concluded that the side effects (such as drowsiness) of nonprescription antihistamines should be listed on the label as a specific warning for consumers. This requirement was imposed even though 850 million packages of antihistamines have been sold over the last 10 years and no significant correlation has been found between the use of antihistamines and serious accidents.[17] But safety is a priority for FDA.

Many nonprescription drugs have powerful active ingredients that interact with the human body in different ways in a few individuals, and diet and lifestyle can have a significant impact on a drug's ability to work in the body. Certain foods, beverages (such as grapefruit juice), alcohol, caffeine, and even cigarettes can interact with drugs. These interactions may make the drugs less effective or may cause dangerous side effects or other therapeutic problems. Table 1–2 lists a few of the commonly used nonprescription drugs and their interactions with food, alcohol, herbal products, other nonprescription drugs, and certain disease conditions.[18–40]

Inactive ingredients in nonprescription drugs, such as binders, disintegrants, fillers, and preservatives, do not affect most consumers, but can cause allergic reactions in a few. For the safety of the very few who may encounter an allergic reaction, FDA requires that the inactive ingredients be listed on the label so that consumers can be

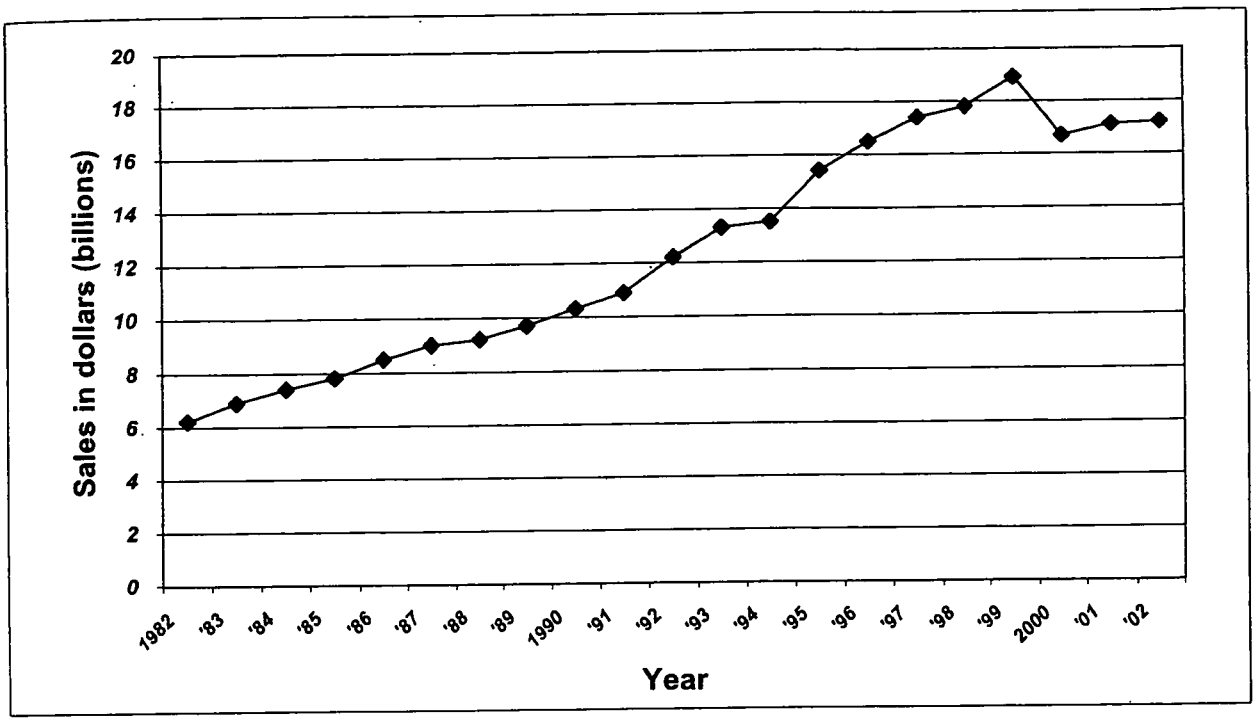


FIGURE 1–3 Nonprescription drug retail sales (1982–2002). *Source:* Consumer Healthcare Products Association. OTC retail sales (1964–2002). Available at http://www.chpa-info.org/statistics/OTC_Retail_Sales.asp. Accessed July 3, 2003.

informed as to what they are taking. Table 1–3 lists some of the inactive ingredients with known adverse effects found in drug formulations.[41–48]

Importance of Nonprescription Drug Labeling

Nonprescription drugs are appropriate for the prevention, treatment, symptomatic relief, or cure of diseases, injuries, and other conditions that consumers can self-diagnose and treat with or without the assistance of pharmacists or other health care professionals. Nonprescription drugs are effective for their intended uses, and the recommended doses provide a wider margin of safety as a safeguard against the consequences of inappropriate use by consumers. For example, ranitidine 300 mg is a prescription item, while its nonprescription version is 75 mg. To assist consumers in distinguishing between similar and therapeutically different self-care drug products, FDA has developed a required standard label format for each of the product categories, namely herbals, dietary supplements, and nonprescription drugs.[49]

The standard product label is titled Drug Facts and has specific sections for active ingredients, uses, warnings, when to use the product, directions, and inactive ingredients (see Chapter 4). In addition, the wording in the Drug Interactions area was changed to "Ask your physician or pharmacist."

The best way to become informed—for young and old alike—is to read and understand the information on nonprescription drug labels. In the ambulatory care sector, noncompliance to the therapeutic regimen, inappropriate choice of drug, and poor health outcomes related to the use of nonprescription drugs can be particularly pronounced when patients lack information, have limited reading skills, and have language barriers. The National Adult Literacy Survey found that nearly 44 million Americans cannot read and write, which in turn affects their day-to-day activities.[50] The same study found that 90 million adults have difficulty understanding information related to health care. Health illiteracy's impact is particularly profound on Medicaid recipients, 90% of whom have reading skills at the fifth-grade level.[51] Such a low level of literacy adversely affects the health care outcome of the use of nonprescription drugs. The Medicaid recipients also encounter difficulty in understanding the information provided to them by health care professionals.[52] While the Omnibus Budget Reconciliation Act of 1990 mandates pharmacists to "offer to counsel" on prescription drugs they dispense, nonprescription drugs do not benefit from this legislation. Understanding what is on the label is critically important for self-care that includes self-diagnosis and self-treatment, and pharmacists are well positioned to answer consumers' questions after consumers have read the label.

TABLE 1–1 Selected Medical Disorders Amenable to Nonprescription Drug Therapy[a]

Abrasions	Congestion (chest, nasal)	Halitosis	Pharyngitis
Aches and pains (general, mild to moderate)	Constipation	Hangover morning relief	Pinworm infestation
Acne	Contact lens care	Head lice	Premenstrual syndrome
Albumin testing	Contraception	Headache	Pregnancy (diagnostic)
Allergic reactions	Corns	Heartburn	Prickly heat
Allergic rhinitis	Cough	Hemorrhoids	Psoriasis
Anemia	Cuts (superficial)	Herpes	Ringworm
Arthralgia	Dandruff	Impetigo	Seborrhea
Asthma	Deficiency disorders	Indigestion	Sinusitis
Athlete's foot	Dental care	Ingrown toenails	Smoking cessation
Bacterial infection	Dermatitis (contact)	Insect bites and stings	Sprains
Blisters	Diabetes mellitus (insulin, monitoring equipment, supplies)	Insomnia	Strains
Blood pressure monitoring	Diaper rash	Jet lag	Stye (hordeolum)
Boils	Diarrhea	Jock itch	Sunburn
Bowel preparation (diagnostic)	Dry skin	Migraine	Teething
Burns (minor, thermal)	Dysmenorrhea	Motion sickness	Thrush
Calluses	Dyspepsia	Myalgia	Toothache
Candidal vaginitis	Dyslipidemia	Nausea	Vomiting
Canker sores	Feminine hygiene	Nutrition (infant)	Warts (common and plantar)
Carbuncles	Fever	Obesity	Xerostomia
Chapped skin	Flatulence	Occult blood in feces (detection)	Wound care
Cold sores	Gastritis	Ostomy care	
Colds (viral upper respiratory infection)	Gingivitis	Ovulation prediction	
	Hair loss	Periodontal disease	

[a] The pertinent nonprescription drug(s) for a particular disorder may serve as primary or major adjunctive therapy.

To increase patient safety, FDA is requiring all drugs (including nonprescription drugs) to be labeled with bar codes, which would ensure (for hospital inpatients) that nurses and health care professionals dispense the right drugs in the right amount and at the right time. A growing number of hospitals have implemented a bar code/wireless scanner system for both prescription and nonprescription drugs.[53] Twenty percent of the doses of all prescription and nonprescription drugs are dispensed in error, and 7% lead to potentially serious problems.[53] A review of death certificates revealed 7300 people died in 1993 because of medication error, a number that could be rising. In these cases, accidental poisoning by drugs, medicaments, and biologicals was the result of acknowledged errors by patients or medical personnel.[54] Another study reports that the total cost of preventable drug errors is between $17 billion and $29 billion per year.[55] To reduce medication errors, several devices have been marketed to assist ambulatory patients in complying with their therapeutic regimens. These devices include: beeping pillboxes, pill dispensers, alphanumeric electronic pagers, automated medication dispensers, handheld medication reminder devices, talking wristwatches, and a device that is attached to the bottom of a pill container for the patient to listen to the message left by the caregiver.[56]

Handling and Storage of Nonprescription Drugs

In order for the patient to optimally benefit from nonprescription drug therapy, the drug has to have the potency stated on the label when it is used (assuming that this occurs before the drug's expiration date). To retain its potency, a drug has to be stored properly. Every house is equipped with a cabinet in the bathroom, often above the sink. Both prescription and nonprescription drugs generally get stored here. Humidity and heat from the shower and the sink get trapped in the

TABLE 1–2 Potential Interactions With Selected Nonprescription Drugs

Drug–Drug Interactions

OTC Drug	OTC Drug	Potential Adverse Effect
Aluminum-containing antacids	Ascorbic acid	↓ Aluminum absorption[18]
Antidiabetic agents (metformin)	Psyllium	↓ Metformin absorption[19]
Aspirin	Products containing aluminum, calcium, or magnesium	↓ Aspirin blood concentration by increasing aspirin elimination[20]
Cimetidine	Antacids	↓ Cimetidine absorption[21]
Iron	Products containing aluminum, calcium, or magnesium	↓ Iron absorption[22]
Mineral oil	Docusate	↑ Mineral oil absorption[23]

Drug–Food/Beverage Interactions

OTC Drug Category	Food/Beverage	Potential Adverse Effect
Acetaminophen	Garlic	Delays acetaminophen absorption[24]
Aspirin	Garlic	↑ Risk of bleeding[25]
Calcium	Oxalic acid foods (spinach, rhubarb); phytic acid foods (bran/whole cereal)	Alters calcium absorption[26]
Zinc	Caffeine; dairy products (milk)	↓ Zinc absorption[27]

Drug–Disease Interactions

OTC Drug	Condition	Mechanism
Aspirin	Hyperuricemia	↓ Renal excretion of uric acid[28]
Naproxen; ketoprofen	Peptic ulcer disease	Changes gastric mucosal barrier[29]
Doxylamine succinate; phenylephrine HCl	Glaucoma	Obstructs aqueous outflow[30]
Pheniramine maleate; naphazoline HCl; nicotine	Hypertension	↑ Vascular resistance[31]

Drug–Alcohol Interactions

OTC Drug/Herbal	Potential Adverse Effect	Mechanism
Aspirin	↑ GI blood loss	Bleeding time prolongation[32]
Diphenhydramine	↑ Sedation	Central nervous system depression[33]
Insulin	↑ Hypoglycemia	↓ Hepatic gluconeogenesis[34]
Ketoconazole (topical)	Vomiting, tachycardia	Disulfiramlike reaction[35]
Yohimbine	↑ Blood pressure	↑ Norepinephrine level[36]

Drug–Herbal Interactions

OTC Drug	Herbal	Potential Adverse Effect
Aspirin	Ginkgo	↑ Probability of bleeding[37]
Brompheniramine	Belladonna	↑ Cholinergic effect[38]
Calcium	Guar gum	↓ Calcium absorption[39]
Loperamide	St. John's wort	Causes delirium[40]

TABLE 1–3 Adverse Effects of Some Inactive Ingredients Used in Drug Preparations

Inactive Ingredient	Use	Found in	Adverse Events
Aspartame	Sweetener	Liquid sucrose-free preparations	Headaches, hallucinations, panic attacks[41]
Benzalkonium chloride	Preservative	Antiasthmatic drugs, nasal decongestants	Airway constriction[42]
Benzyl alcohol	Preservative	Liquid preparations	Neonatal deaths, severe respiratory and metabolic complications[43]
Lactose	Filler	Capsules and tablets	Diarrhea, dehydration, cramping[44]
Propylene glycol	Solubilizes drugs	Liquid preparations	Respiratory problems, irregular heartbeat, low blood pressure; seizure, skin rashes[45]
Saccharin	Sweetener	Liquid preparations	Cross-sensitivity with sulfonamides, dermatologic reaction, pruritis[46]
Sulfites	Antioxidant	Antiasthmatic drugs; anti-inflammatories	Wheezing, breathing difficulties[47]
Yellow tartrazine	Coloring agent	Solid/liquid preparations	Allergic reaction similar to that of aspirin[48]

TABLE 1–4 Recommended Storage Places of Selected Nonprescription Health Care Products

Closet/Kitchen Cabinet Shelf	Bathroom Medicine Cabinet
Analgesics (relieve pain)	Adhesive bandages
Antacids (relieve upset stomach)	Adhesive tape
Antibiotic ointments (reduce risk of infection)	Alcohol wipes
Antihistamines (relieve allergy symptoms)	Calibrated measuring spoon
Antipyretics (adult and child)	Dental floss
Antiseptics (help stop infection)	Disinfectant
Decongestants (relieve stuffy nose and cold)	Gauze pads
Hydrocortisone (relieve itching and inflammation)	Thermometer

Source: Adapted from Lewis C. Your medicine cabinet needs an annual checkup, too. *FDA Consumer.* 2000;34(2):25–8.

cabinet very easily, accelerating the degradation of the drugs even though they may be in a prescription vial or a nonprescription bottle. Consumers need to be aware that all drugs should be stored in a cool, dark, dry place to ensure that they retain their potency and effectiveness. All drugs should preferably be stored on a closet or cabinet shelf that is high enough to be out of children's reach. Table 1–4 lists some nonprescription drugs and health care products generally kept on hand to treat minor ailments or injuries with the recommendations as to where they should be stored. It is a good practice to encourage the consumers to purge the medicine cabinet at least once every 6 months. Drugs should be checked for expiration dates and a pharmacist/health care provider should be consulted before discarding them.

Role of Pharmacists in Nonprescription Drug Therapy

With numerous clinical and economic factors fostering the growth of nonprescription drug therapy, the pharmacy profession needs to continue to expand its professional and business role. Following are some of the justifications for the expansion of the pharmacist's role in this realm:

- The public is becoming increasingly health conscious, and wants a better understanding of disease and disease management.
- The reclassification of prescription drugs to nonprescription status has accelerated markedly and is expected to continue at a significant pace. Figure 1–4

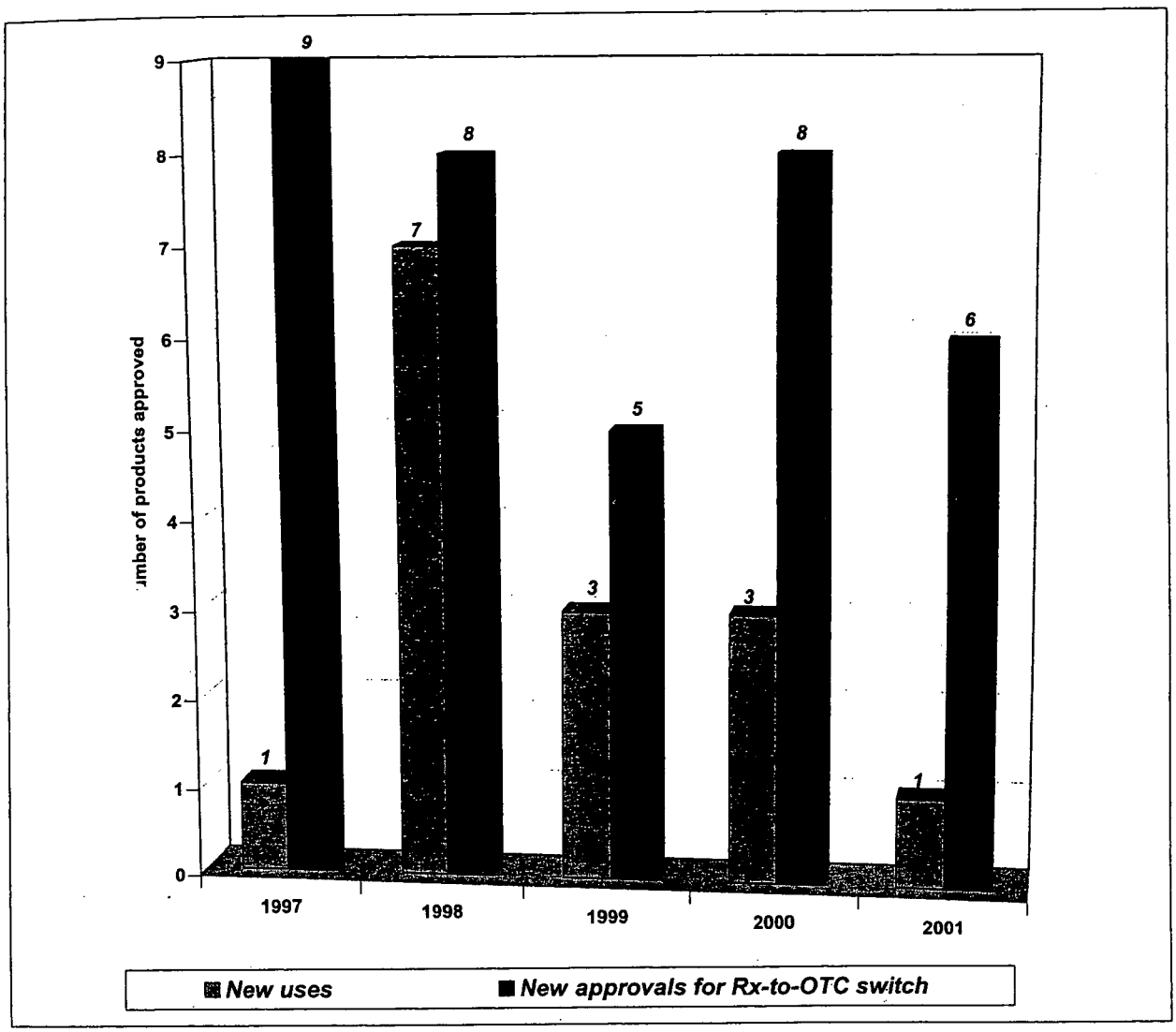


FIGURE 1–4 Nonprescription drugs: new approvals and new uses. Source: Over the counter drug review: new OTC medicines and new uses. *CDER Report to the Nation: 2001.* Available at http://www.fda.gov/cder/reports/rtn/2001/rtn2001-2.htm. Accessed July 9, 2003.

shows the number of new nonprescription drugs and new uses approved over the last 5 years. For example, as a result of the recent switch from prescription to nonprescription status of the allergy medicine Claritin (loratadine), FDA expressed its interest in switching other allergy drugs, such as Allegra and Zyrtec. In a recent development, Blue Cross of California filed a "citizen petition" with FDA requesting all second-generation antihistamines and antihistamine/decongestant combinations to be switched to nonprescription status. Since the FDA initiative is further strengthened by this "citizen petition," FDA commissioner Mark McClellan said that the issue of forced switches is being considered. However, the industry claims that FDA does not have the legal right to act without agreement by the company that owns and markets the drugs. This further demonstrates that FDA has continued its interest in making more nonprescription drugs available to the public.

- FDA has approved the switch of a number of drugs under the New Drug Application process. These include antidiarrheals (loperamide), topical antifungals (clotrimazole, terbinafine HCl), antihistamines (clemastine fumarate), vaginal antifungals (clotrimazole, miconazole nitrate), analgesics (ketoprofen, naproxen sodium), acid reducers (cimetidine, famotidine), hair growth treatments (minoxidil), and smoking cessation aids (nicotine polacrilex). Antihistamines top the list of 10 single-ingredient products switched from prescription to nonprescription status

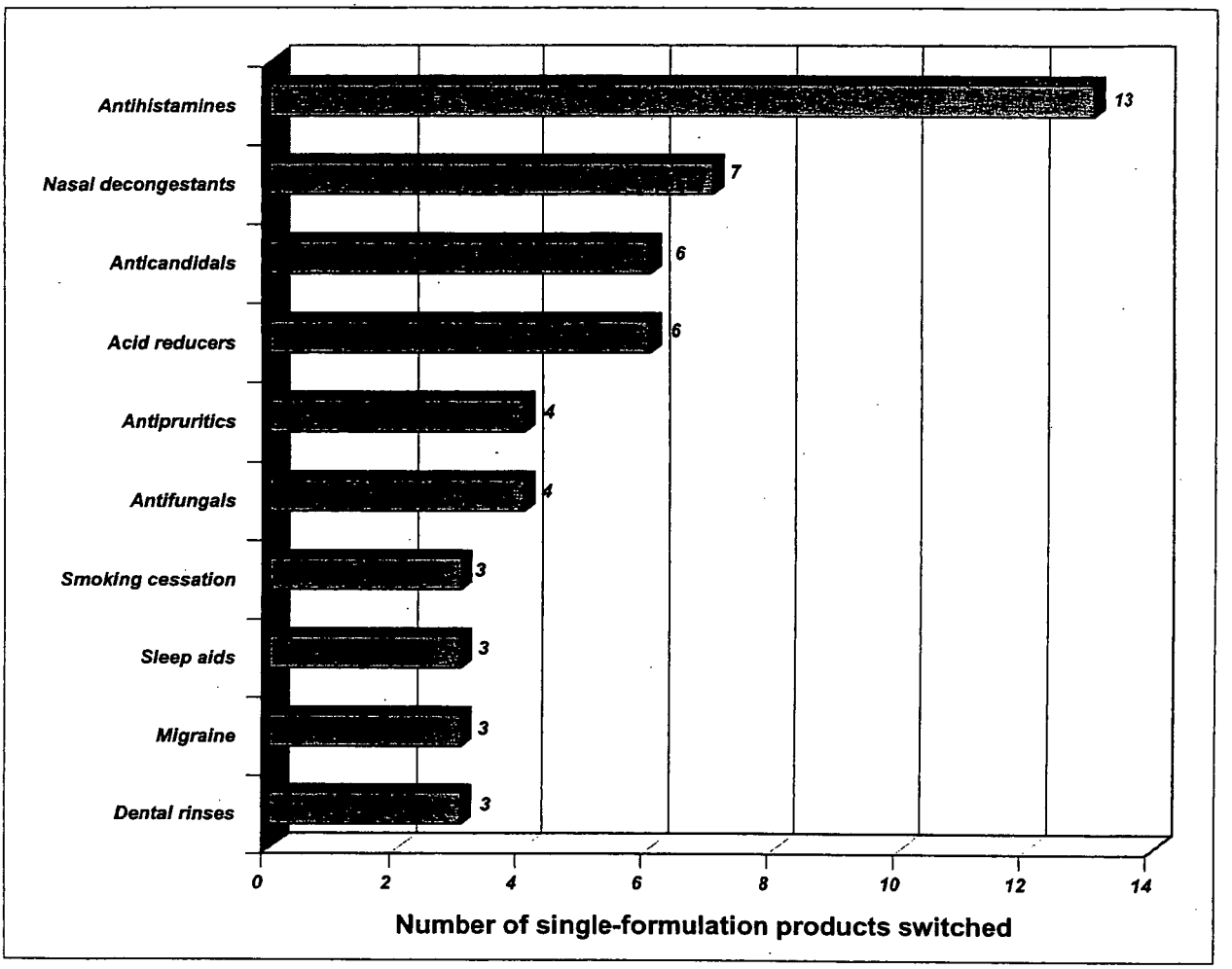


FIGURE 1–5 Top 10 therapeutic categories switched from prescription to nonprescription since 1975. Source: Ingredients and dosages transferred from Rx-to-OTC status (or new approvals) by the Food and Drug Administration since 1975. Available at http://www.chpa-info.org/pdfs/28-issues-switch-switchlist.v1.pdf. Accessed July 3, 2003.

since 1975, as shown in Figure 1–5. During the same period, 15 multi-ingredient products have been switched from the prescription to the nonprescription category. The growing number of switches is an indication that nonprescription drug therapy is here to stay and may have a significant impact on health care in the future. The practice of pharmacy must recognize the growing importance of nonprescription drugs to the society.

- Increased access to nonprescription medicine is especially important for our aging population. Figure 1–6 shows the prevalence of the most common health problems in persons 65 years of age and older. Some of these chronic conditions are treated by nonprescription drugs alone, or by nonprescription drugs serving as an adjunct to prescription drug therapy. As the number of people over 65 doubles by 2030, so will the consumption of nonprescription drugs.[10]
- Just as the accessibility to nonprescription drugs increases, so does the potential for interactions. Pharmacists should therefore be consulted by consumers in selecting herbals or nonprescription drugs. Table 1–2 lists selected interactions among nonprescription drugs, and among nonprescription drugs and alcohol, nonprescription drugs and herbals, and nonprescription drugs and disease conditions.
- The pharmacist is formally trained in drug pharmacotherapy, and thus can play a very important role in helping the consumer select the proper nonprescription drug.
- Consumers save $20 billion in health care costs each year due to nonprescription drug treatment of 12 common health conditions. Savings come from prescription costs, primary care provider visits, loss of wages, and loss of productivity, among others.[57] The rising cost of prescription drugs is making it difficult

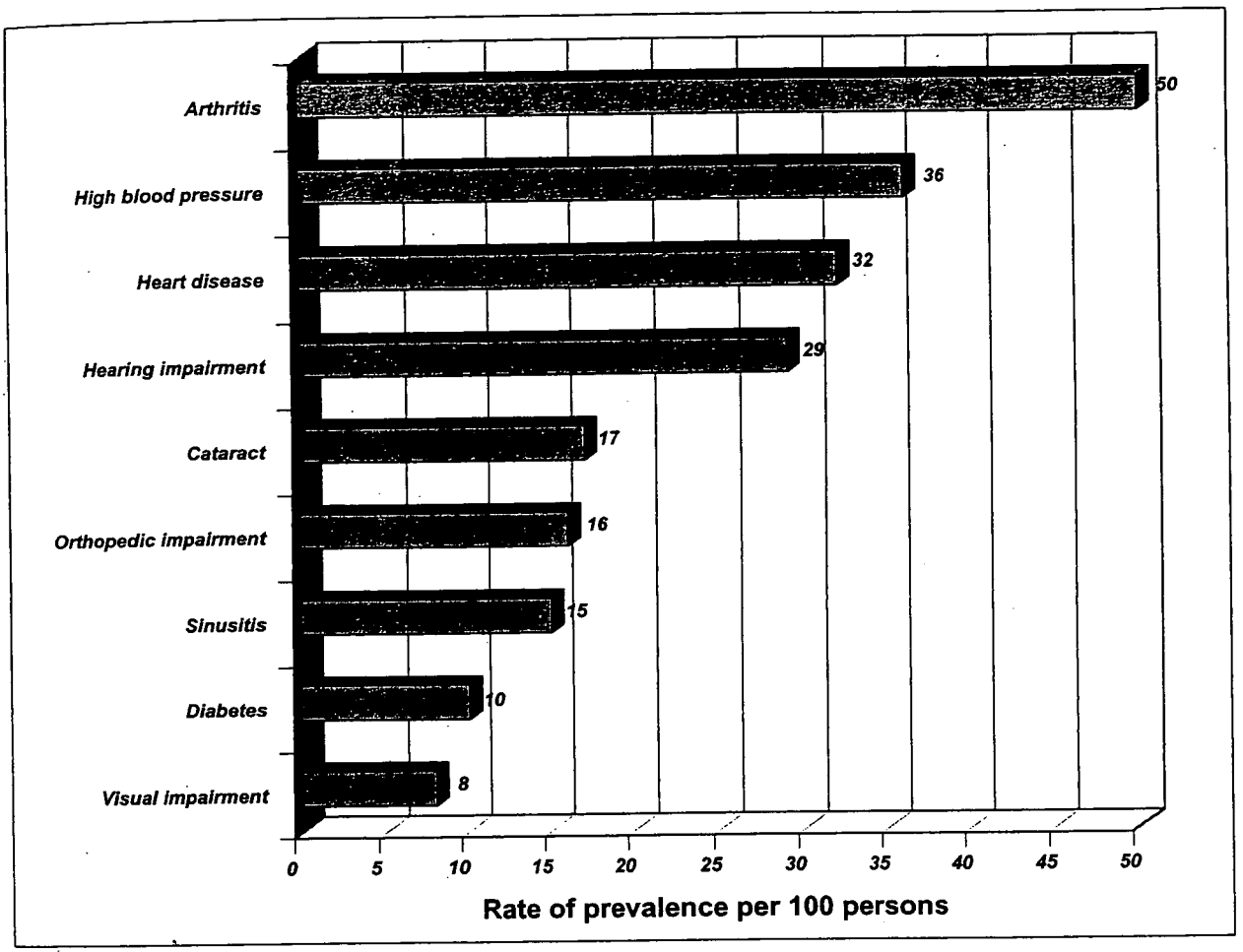


FIGURE 1–6 Common health problems for persons age 65 years and older. Source: Aging and health: the role of self-medication. Available at http://www.chpa-info.org/publications/aging_and_health.asp. Accessed July 3, 2003.

to provide an affordable broad-based prescription benefit. So nonprescription drug therapy is the next best alternative.

- There are more than 100,000 nonprescription drugs currently on the market, containing 1000 active ingredients.[57] So it pays for pharmacists and other health care providers to remain current with the expanding nonprescription market.

Role of Pharmacists in Pharmaceutical Care

Self-care with nonprescription drugs is often the most sought-after first level of care. The self-medication revolution focuses on the development of knowledge and skill in promoting wellness, as well as in treating medical conditions with nonprescription drugs. Informed, appropriate, and responsible use of nonprescription drugs is a large part of self-medication. Data suggest that most patients respect these drugs, recognize their limitations, and read labeling information carefully.[8] Yet, many consumers do not understand the circumstances under which the use of nonprescription drugs should be discontinued. For example, for self-treatment of itching of the skin, if the condition worsens or if the symptoms persist for more than 7 days or clear up and occur again within a few days, then they should stop using the hydrocortisone (1%) cream and seek medical attention. Casual and inappropriate use of nonprescription drugs can lead to serious adverse consequences of both a direct (e.g., liver toxicity with prolonged intake of acetaminophen, and other drug–drug interactions as listed in Table 1–2) and indirect (e.g., delays in seeking appropriate medical attention) nature. FDA, pharmaceutical manufacturers, and pharmacists should discourage casual and inappropriate use of nonprescription drugs through the following measures:

1. Adequate package labeling.
2. More emphasis on "indications for use," rather than emphasizing promotion of nonprescription drugs in direct-to-consumer advertising.

3. Patient education and counseling by pharmacists about the consequences of casual and inappropriate use of nonprescription drugs.

Pharmacists are uniquely qualified to serve the public interest in nonprescription pharmacotherapy because they receive university-level education and training, with in-depth instruction in pathophysiology, pharmacology, medicinal chemistry, pharmaceutics, and pharmacokinetics. Furthermore, the pharmacist is easily accessible to the public and is strategically stationed in the community to serve as a provider of the drug and the information on how to maximize the value of drug therapy, while minimizing any potential adverse consequences.

In the initial encounter with a patient seeking assistance with nonprescription drug use, the pharmacist should:

- Assess, by interview and observation, the patient's physical complaint/symptoms and medical condition (see Chapter 2).
- Differentiate self-treatable conditions from those requiring a primary care provider's intervention.
- Advise and counsel the patient on the proper course of action (i.e., no drug treatment, self-treatment with nonprescription drugs, or referral to a primary care provider or other health care professional).
- Advise the patient about the outcome of the course of action that the patient has selected.

If self-treatment with nonprescription drugs is in the best interest of the patient, then the pharmacist can be consulted for the following services:

- Assist in product selection.
- Assess patient risk factors (e.g., contraindications, warnings, precautions, comorbidity, age, organ function).
- Counsel the patient about proper drug use (e.g., dosage, administration technique, monitoring parameters, and duration of self-therapy).
- Maintain a patient drug profile that includes nonprescription drugs and prescription drugs the patient may be taking.
- Assess the potential of nonprescription drugs to mask symptoms of a more serious condition.
- Prevent delays in seeking appropriate medical attention.

The public's ability to discern critical information about the condition being treated and about the clinical risk and benefit of the product is highly variable. The array of product choices, line extensions, and overstated or vague and misleading marketing messages create confusion at the very least. Package labeling is generally limited in the breadth and depth of the message it communicates; it can never address the informational needs of patients in all clinical circumstances. Moreover, comorbidity and polypharmacy create an infinite number of special considerations in ensuring safe, appropriate, and effective use of nonprescription drugs. Thus, the pharmacist–patient interaction is vital to optimal nonprescription drug therapy. Although the pharmacist's active involvement in self-care of the patient usually bears no direct cost to the patient nor is a reimbursement scheme in place, this is still an important area of consumer-oriented pharmaceutical care. It can be viewed much like other disease management services. Thus, there is an extremely high need to develop reimbursement strategies for the pharmacists to reward them for their expertise and knowledge. In the meantime, pharmacists do enormous good and service through their efforts in self-care practice with the underlying goal to ensure that the patient gets correct, practical information and understands what the information means in the context of the ailment being treated. Validation of the patient's understanding is critically important. The pharmacist should always encourage the patients to ask questions and learn more.

Complementary and Alternative Therapies

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defines *dietary supplement* as a product taken by mouth that contains a dietary ingredient intended to supplement the diet. The term *dietary ingredient* includes vitamins, minerals, herbs, amino acids, and/or enzymes. While much remains unknown about many dietary supplements (e.g., their health benefits and potential risks), consumers can count on one thing: the availability of a wide range of such products. Consumers who decide to take advantage of the expanding market should do so with care, making sure they have the necessary information and consulting with their primary care provider and/or their pharmacist as needed. The majority of the dietary supplement manufacturers are responsible and careful, but, as with all products on the market, consumers need to be discriminating. Dietary supplements are recognized to be a subset of foods under the federal law and are therefore regulated by FDA and the Federal Trade Commission. DSHEA, which regulates dietary supplements, requires that manufacturers have substantiation for all claims they make on product labeling. FDA, the dietary supplement industry, and health care professionals have important roles to play in providing safe products, but consumers must also take responsibility for learning all they can about dietary supplements. Table 1–2 includes examples of herbal–food, herbal–alcohol, and drug–herbal interactions.

FDA is authorized to remove any dietary supplement product from the market if it has reason to believe

that the product poses unreasonable risk of injury or illness to consumers. In addition to its enforcement role, FDA is also focusing on preventing problems by educating the homeopathic industry about FDA rules and regulations. If an individual thinks he or she has suffered a serious harmful effect or illness from a product that FDA regulates, including dietary supplements and homeopathic medicines, the individual should contact a health care provider immediately. The health care provider and the individual should then report the problem to FDA and/or the manufacturer of the product. Prompt reporting will reduce the chance of other individuals being adversely affected. FDA has provided a number of means to facilitate reporting of adverse events. Reporting can be done by calling 1-800-FDA-1088, or by using the internet portal http://www.fda.gov/medwatch and completing the MedWatch Online Voluntary Reporting Form (3500).

FDA has dedicated a considerable amount of its resources to protecting consumers from unsubstantiated therapeutic claims by dietary supplement distributors.[58] In 2002, FDA took action against ephedrine, coral calcium, severe acute respiratory syndrome products, and SeaSilver.[58] Other products with misleading and unsubstantiated claims included weight loss products and supplements for smokers and drinkers.

Conclusion

Self-care will play an increasingly important role in health care, and nonprescription pharmacotherapy represents a significant element in the self-care process. Consumers, manufacturers, governmental agencies, and professional groups, particularly pharmacists, should become even more intent on recognizing that each group fulfills essential functions in ensuring the safe, appropriate, effective, and economical use of nonprescription drugs.

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