Now Available Without A Prescription

For those who yearn to break their cigarette addiction but don't fancy a trip to the doctor's office, the ability to get the nicotine patch without a physician's prescription may be just what the doctor ordered.

Less than 10 years ago, the nicotine patch was available by prescription only. However, since 1996, nicotine drug products for use as "stop smoking aids" have been available without a prescription. In February 1996, the Food and Drug Administration (FDA) approved the "switch" of Nicorette gum to over-the-counter (OTC) status. In the summer of 1996, the FDA also approved the prescription-to-OTC switch of two transdermal nicotine patch products (Nicotrol in July 1996 and NicoDerm CQ in August 1996). Switches of other nicotine patch products followed (Prostep in December 1998 and Habitrol in November 1999). In October 2002, the FDA approved Commit, the first lozenge dosage form containing nicotine.

The patch, gum and lozenge join more than 700 other OTC drugs that would have required a prescription only 20 years ago, according to the Consumer Healthcare Products Association (CHPA), which represents the leading manufacturers and distributors of OTC medicines and nutritional supplements. The 700-plus products are now available without a prescription because the FDA, in cooperation with panels of outside experts, determined they could be used safely and effectively without a doctor's supervision.

The FDA has given OTC approval to drugs with such household names as Children's Advil and Children's Motrin (ibuprofen), Orudis KT and Actron (ketoprofen), and Aleve (naproxen sodium) for pain relief and fever reduction; Femstat 3 (butoconazole nitrate) for vaginal yeast infection; Pepcid AC (famotidine), Tagamet HB (cimetidine), Zantac 75 (ranitidine hydrochloride), Axid AR (nizatidine), and Prilosec OTC (omeprazole magnesium) for heartburn; Rogaine (minoxidil) for hair growth; and Claritin (loratadine), the first non-sedating antihistamine.

The FDA believes that there is an important trend toward consumer participation in their own health care. It's part of the agency's mission to keep up with consumers' wish to be more involved.

Switches have a huge impact on the health care economy. The greater availability of medicines over the counter saves approximately $20 billion each year, according to a 1997 study by the CHPA. The $20 billion takes into account prescription costs, doctor visits, lost time from work, insurance costs and travel.

The Switch Process

The original Federal Food, Drug, and Cosmetic Act of 1938 made no clear-cut distinction between prescription and OTC drugs. The 1951 Durham-Humphrey amendments to the act set up specific standards for classification.

The amendment requires that drugs that cannot be used safely without professional supervision be dispensed only by prescription. Such drugs may be deemed unsafe for nonprescription use because they are habit-forming or toxic, have too great a potential for harmful effects, or are for medical conditions that can't be readily self-diagnosed.

All other drugs can be sold OTC. A drug must be made available without a prescription if, by following the labeling, consumers can use it safely and effectively without professional guidance.

The process of reclassifying drugs from prescription to OTC status is referred to as an "Rx to OTC switch." Drugs are commonly switched one of two ways: under the "OTC drug review," or by a manufacturer's submission of additional information to the original new drug application.

The OTC drug review, which began in 1972, is an ongoing assessment of the safety and effectiveness of all nonprescription drugs. In the first phase of the OTC drug review, panels of non-government experts review active ingredients in marketed

OTC drug products to determine whether they can be classified as safe and effective. The panels also review prescription ingredients to determine whether some are appropriate for OTC marketing. About 40 former prescription-only drug ingredients have been switched by this process.

The second common path to OTC approval is under the new drug application process. Under this process, manufacturers submit data to the FDA showing the drug is appropriate for self-administration. Data are submitted in a new drug application or a supplement to an already approved drug application. Often the submission includes studies showing that the product's labeling can be read, understood, and followed by the consumer without the guidance of a health care provider. The FDA reviews the new data, along with any information known about the drug from its prescription use. Under the new drug application process, some drugs are approved initially as OTC drugs, but most are first approved for prescription use and later switched to OTC.

In almost every case for the first drug switched in a drug category, the agency has sought the recommendation of a joint advisory committee made up of members of the agency's Nonprescription Drugs Advisory Committee and another advisory committee with expertise in the type of drug being considered.

For example, because Rogaine is for conditions of the hair and scalp, representatives of the Dermatologic and Ophthalmic Drugs Advisory Committee participated.

While not bound by the advisory committee's counsel, the FDA almost always follows its recommendation.

Benefit-Risk Comparison

When considering an Rx-to-OTC switch, the key question for the FDA is whether patients alone can achieve the desired medical result without endangering their safety.

No drug is absolutely safe. There are risks associated with every medication, so the FDA does a benefit-to-risk comparison to determine whether it is appropriate for consumers to self-medicate with a drug for a certain use.

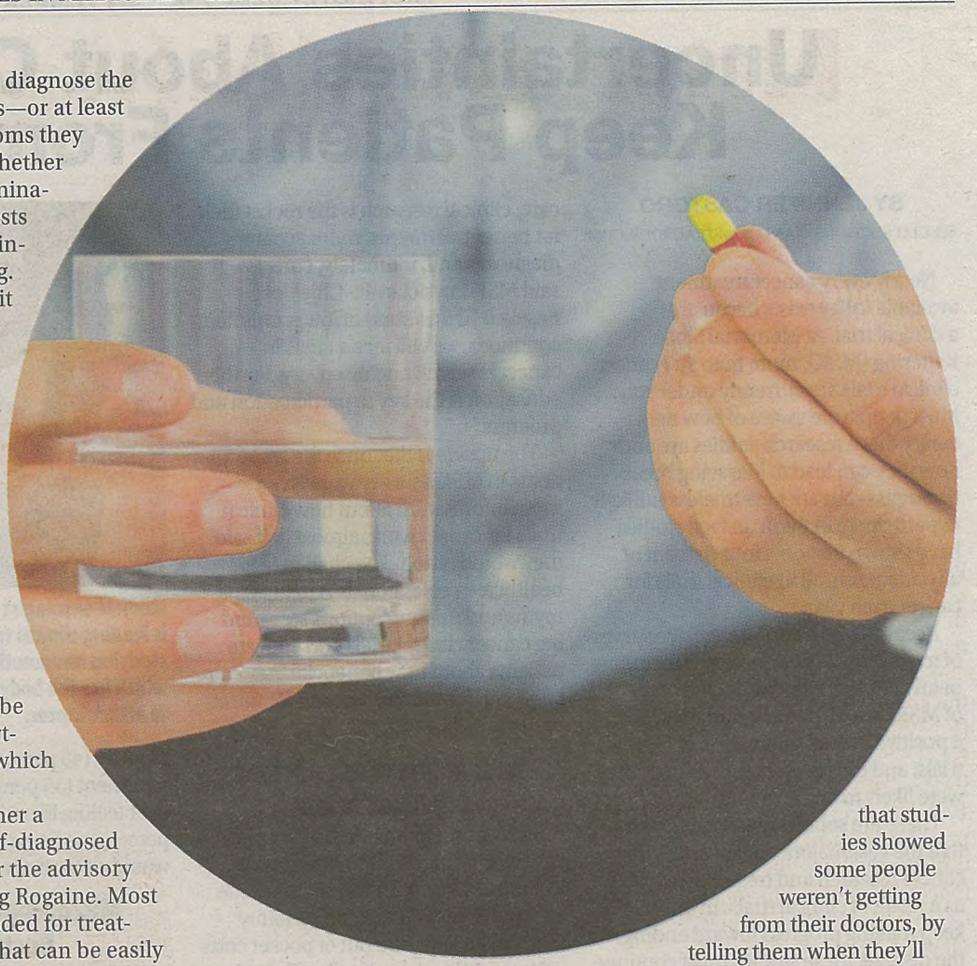
On the safety side, the agency looks at the drug's toxicity—its potential for poisonous effects—when the drug is used according to its labeled directions, and also from foreseeable misuse of the drug.

The FDA weighs a drug's safety against its benefit to patients. The agency considers whether consumers will be able to understand and follow label directions, whether patients can diagnose the condition themselves—or at least recognize the symptoms they want to treat—and whether routine medical examinations or laboratory tests are required for continued safe use of a drug.

No easy risk-benefit formula exists. The FDA does a case-by-case review of each drug because each drug raises unique issues.

Concerns about side effects can sometimes be managed by approving OTC drugs at lower doses than their prescription counterparts. The drugs must still be effective for the short-term symptoms for which they're intended.

The issue of whether a condition can be self-diagnosed was a central one for the advisory committee reviewing Rogaine. Most OTC drugs are intended for treatment of symptoms that can be easily recognized, like headache or upset stomach. Others, though, are intended to treat diseases like asthma or vaginal fungal infections, which cannot be consumer-diagnosed.



Consumer-Friendly Labeling

Labeling is an influential element in the OTC risk-benefit comparison. The decision about a drug's safety for OTC use can't be made in a vacuum, by looking only at the drug ingredients. Every drug, used improperly, can cause adverse reactions. Even appropriate use can lead to side effects (antihistamine use may cause drowsiness, for example). And some drugs can be dangerously unsafe or ineffective if taken while using certain other drugs.

Labeling can alert consumers to such potential problems. Labeling of all drugs must be clear and truthful. For OTC drugs, the intended uses, directions and warnings have to be written so consumers, including individuals with low reading comprehension, can understand them.

In March 1999, the FDA finalized regulations to increase the readability of OTC labels by making the language more consumer-friendly and standardizing the format, including where important information is placed.

The FDA believes that, in some cases, consumers can get more information in the OTC labeling than they would get from their doctors. For the nicotine patch, the package contains not only a drug that relieves withdrawal symptoms, but also behavioral modification information. The package provides an element of support that studies showed some people weren't getting from their doctors, by telling them when they'll most likely feel the urge to smoke, what they can do in place of smoking, and where they can go for support.

A Popular Alternative

Under the law, OTC drugs may be advertised directly to consumers without the many restrictions placed on prescription products. OTC status provides a greater opportunity for direct communication with the consumer, not only by advertising in magazines and on television, but also with packaging, brochures and retail displays.

Today's emphasis on self-care fuels the popularity of nonprescription drugs. But OTC products are intended to supplement the medical options of the consumer, not substitute for a prescriber's medical knowledge. If a health problem persists or worsens while using an OTC drug, consult a health care provider.

People must be in a partnership with their health care providers for optimal health. Many situations aren't appropriate for self-treatment, and others may require professional guidance for self-treatment.

If you do choose OTC treatment, heed this warning: Drugs aren't candy; they aren't risk-free. You have to follow the label and take appropriate responsibility for your own self-care.

—Courtesy of the Federal Drug Administration (FDA)