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NONPRESCRIPTION DRUGS

Considerations Regarding a Behind-the-Counter Drug Class

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Highlights

Highlights of GAO-09-245, a report to congressional requesters

Why GAO Did This Study

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

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

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

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

What GAO Found

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

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

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

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