

MONITORING AND REPORTING DRUG SHORTAGES

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Introduction

No federal agency – including the Food and Drug Administration (FDA) – is required to report to physicians all shortages and discontinuations of prescription drugs in the United States. Because the FDA Center for Drug Evaluation and Research (CDER) posts very little information on the availability of prescription drugs on its website, physicians and other medical professionals find it difficult to determine whether a medical therapy is unavailable at any given time. Endocrinologists and other medical professionals have expressed serious concern over this lack of information, and physician groups have attempted to provide suggestions to the FDA on how to share relevant information with medical specialties. The FDA currently has limited authority to manage the effects of shortages and discontinuations, in part because only a small portion are required by law to be reported.

Background

Federal law provides limited guidance on how the FDA should handle drug shortages and discontinuations. The Agency is required to provide information on the intentional discontinuation of a life-supporting or life-sustaining drug for which there is a single manufacturer and no alternative therapies.¹ However, it is required only to report this information to physician and patient groups “to the maximum extent practicable.” As a result, the FDA has devised a system for determining whether these life-supporting or life-sustaining drugs fall into the category of “medically necessary drugs.” Medical necessity is judged by evaluating the seriousness of the medical condition(s) that the drug is used to treat, assessing the availability of other brand name or generic alternatives, and by gauging the opinion of health professionals on the usefulness

of the drug.² If the drug is determined to be one of medical necessity and its availability is expected to be affected for more than a short time, the FDA takes measures to manage the situation and posts the information on its website.³

Despite the efforts of the FDA, news of medically necessary drug shortages and discontinuations are not adequately disseminated to physicians and other healthcare providers. There is even less information available on drugs that are not deemed medically necessary. In response to increased concern over this lack of information, organizations such as the American Society of Health-System Pharmacists have attempted to track drug shortages and discontinuations across the country. While efforts such as these are small steps forward, they are inadequate to ensure that prescribers have up-to-date information.

Considerations

Unanticipated and poorly reported drug shortages and discontinuations increase the burden on healthcare providers and put patients at risk. Endocrinologists are at a particular disadvantage when these shortages and discontinuations occur as they treat a wide range of conditions, such as diabetes and thyroid disorders, whose medications are life sustaining. Accommodating increased numbers of appointments, changing prescriptions, and taking additional calls from pharmacists and patients both increase staff time and decrease productivity. Most importantly, patients may begin to suffer from suboptimal care when prescribed or preferred therapies are not available and alternative

² Nordenberg, Tamar. *Inside FDA: When a Drug is in Short Supply*. U.S. Food and Drug Administration. Accessed online at http://www.fda.gov/fdac/features/1997/797_drug.html.

³ American Journal of Health-System Pharmacy. 2002; 59:1423-5

¹ Federal Food, Drug, and Cosmetic Act. 21 U.S.C. Section 356(c).

medical interventions are required. Shortages and discontinuations of necessary drugs often cause hospitals, healthcare providers, and pharmacists to limit the dispersion of the drugs to the sickest and most desperate patients. This can cause those who may not initially be as ill to deteriorate more quickly because they are unable to obtain needed prescriptions or optimal medications for their conditions. If properly informed of impending and current changes in the supply of a prescription drug, providers could anticipate their patients' needs and devise an appropriate and effective alternative treatment strategy.

Because some reductions in a drug's supply may be regional or otherwise limited, medical professionals must be able to differentiate between isolated shortages with minimal impact and shortages or discontinuations that are permanent or widespread. They must have information to help them determine how long a drug's availability is expected to be affected and whether there are alternative therapies available. Active alerts to healthcare providers from the FDA would ensure that physicians and other medical professionals have reliable information in a reasonable timeframe, increasing provider and staff efficiency and improving patient health and safety.

According to the FDA, during the last ten years, the number of drug shortages has steadily increased. Multiple factors have contributed to this increase, such as manufacturing complications that cause plant shutdowns; anti-trust laws that prevent manufacturers of different versions of the same drug from sharing shortage and discontinuation information amongst themselves; distribution complications that occur through wholesalers; and FDA oversight complications including the lack of timely investigation of manufacturing facilities to prevent the use of antiquated equipment.

The FDA does not have the resources to investigate and oversee many of the aforementioned issues that contribute to drug shortages and discontinuations. Manufacturers have demonstrated that, absent regulatory or legislative requirements, they will not consistently and voluntarily share information with the Agency. As such, the most effective way to

ensure that providers and patients obtain this information is to require manufacturers to report shortages and discontinuations to the FDA and to require the Agency to collect and disseminate the information. Such requirements should not be limited to medically necessary drugs, but should include all brand and generic drugs requiring a prescription.

Positions

The Endocrine Society is concerned that access to important medications may be limited without prior notice to the FDA, providers, and patients. Therefore, the Society supports:

- Mandatory reporting to the FDA by drug manufacturers when a brand name or generic drug shortage or discontinuation occurs, regardless of the availability of alternative medications.
- Strict enforcement and expansion of U.S. Code requiring the FDA to distribute information to appropriate physician, healthcare provider, and patient organizations when a brand or generic drug shortage or discontinuation occurs, regardless of the availability of alternative medications.