

FDLI'S FOOD
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POLICY FORUM

CAN THE UNITED STATES ENSURE
AN ADEQUATE SUPPLY OF CRITICAL
MEDICATIONS?

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Can the United States Ensure an Adequate Supply of Critical Medications?

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I. INTRODUCTION

Shortages of prescription drugs in the United States have gained increasing attention in recent years due to the scope and severity of the drugs in short supply. According to the University of Utah Drug Information Service, which has been working with American Society of Health-System Pharmacists (ASHP) to track drug shortages since 2001, the number of shortages has nearly tripled since 2006.¹ The majority of these shortages have occurred in drugs that are generic injectables, which are generally administered in a hospital or clinic setting. Drug shortages have occurred in all drug classes, but have been especially problematic for anti-cancer drugs, anesthetics and nutritional therapies—all of which play crucial roles in the care of patients. As a result of drug shortages, clinicians must scramble to find the drug, or use an alternative therapy, if one is available. Even when a therapeutic alternative exists, it is likely a drug that may not be the therapy of choice because it is less effective, associated with significant side effects, or more likely to interact with other medications the patient is taking. Further, drug shortages have caused widespread fear among clinicians who are deeply concerned that care could be delayed, rationed or provided in a suboptimal manner in order to preserve scarce supplies. In 2010 alone, there were 211 unique drug shortages.² That trend is expected to continue in 2011 as the number of drug shortages had already reached 180 through July and is expected to exceed the 2010 number.³

This dramatic rise in the extent, duration and severity of shortages is occurring in an environment that is characterized by a near absence of communication between drug manufacturers and the Food and Drug Administration (FDA). This lack of transparency is a significant barrier to efforts to address drug shortages, and it represents a real and growing danger to patient safety. FDA has worked diligently to address this issue, but this work is hampered by the agency's inability to require reporting of information that could be instrumental in minimizing the impact of a shortage or averting it all together.

To address this public health crisis, ASHP partnered with several healthcare, provider and safety-related groups to hold a drug shortages summit in November 2010 that was aimed at defining the causes of drug shortages and identifying potential avenues to address the problem through legislation, regulation and within the marketplace itself.⁴ The co-conveners of the drug shortages summit included ASHP, the Institute for Safe Medication Practices (ISMP), the American Society of Anesthesiologists (ASA) and the American Society of Clinical Oncology (ASCO). The summit brought together diverse members of the supply chain, including drug manufacturers, product distributors, group purchasing organizations, organizations representing other healthcare professionals and hospitals, and FDA. The recommendations provided here are based, in part, on some recommendations from the summit as well as the opinions of the authors.

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POLICY RECOMMENDATIONS

Congress should:

- Expand FDA authority to require manufacturers to notify it of supply interruptions and product discontinuations.
- Allow FDA to require manufacturers to develop continuity of supply plans.
- Require development of an expedited approval pathway for pre-1938 drugs.

FDA should:

- Encourage confidential notification to FDA when there is a single-source Active Pharmaceutical Ingredient.
- Explore incentives that encourage manufacturers to enter the market, stay in the market, or implement processes that minimize the potential for shortages for vulnerable drugs.
- Collaborate with the DEA to alter Active Pharmaceutical Ingredient quotas for controlled substance products in short supply.

II. BACKGROUND

ASHP collaborates with the University of Utah Drug Information Service to track drugs in short supply as reported at the end-user level (e.g., clinicians and patients). These reports are compiled and listed at the ASHP drug shortages web resource center (www.ashp.org/drugshortages), which is accessible to the public. The listing of drug shortages is updated frequently as new drugs become in short supply or changes occur in product availability for existing shortages (e.g., estimated date of product availability changes or the shortage is resolved). While FDA has a similar website, the agency focuses on providing information on drugs deemed “medically necessary” by the agency,⁵ whereas the ASHP website tracks shortages of all prescription drugs. The ASHP website also provides information on alternative therapies. The number of drug shortages reported on both the ASHP and FDA websites has increased significantly over the last several years, prompting a heightened awareness and concern about the availability of adequate drug supplies.

Causes of drug shortages are many and complex.⁶ Manufacturing issues that lead to drug shortages include product quality issues that result in production halts or recalls, product discontinuations, and unavailability of active pharmaceutical ingredients (APIs) or other raw materials. Secondary shortages—or shortages that occur based on shifts in market demand caused by an initial shortage of another drug—are also common. Other contributing causes to drug shortages include quality issues that arise from the ever-increasing reliance on foreign ingredient and manufacturing sources and a lack of FDA resources to expedite approval of supplemental new drug applications and conduct foreign inspections. While not a cause of drug shortages, just-in-time inventory practices by product distributors and practice sites have removed the buffer previously provided by larger inventories and resulted in an immediate impact of drug shortages on patient care.

While information on the root cause of each drug shortage is not always publicly available, the cause of most shortages can be traced back to aspects of the manufacturing process.⁷ These manufacturing issues are compounded by substantial industry consolidation over the last few years that has resulted in fewer manufacturers producing critical drugs.⁸ When one manufacturer experiences a production interruption, the other companies must ramp up production of their product to meet market needs. This increased production is sometimes, but not always, possible. In the case of sole-source drugs, this situation almost instantly results in a shortage situation.

III. ISSUES IN DISPUTE

A. Notification System

Under current law, manufacturers are not required to report to FDA when they experience an interruption in the production of their products, unless that drug is deemed medically necessary by the agency.⁹ The same holds true for manufacturer plans to discontinue a product. Even in cases where the drug is deemed medically necessary and reporting is required, FDA has no enforcement mechanism to penalize a drug maker for failing to report these problems. This information could be extremely useful to FDA in the case of drugs with multiple suppliers where the agency could urge alternate suppliers to step up production of a product to offset the decrease in supply due to the interruption or discontinuation of the initial product. In some instances, FDA is not told there is a problem, or the nature of the problem. This information could be useful in determining the duration and severity of the interruption and may allow the agency to implement countermeasures to help ensure supply. By FDA's own account, in 2010 the agency was able to avoid 38 drug shortages when this type of notification was made available.¹⁰

The importance of notification is highlighted by quality concerns associated with the increased globalization of pharmaceutical manufacturing.¹¹ A number of drug shortages can be traced back to quality concerns with foreign-produced APIs. An extreme example was the heparin contamination that occurred in 2007, which resulted in a recall, and subsequent product shortage that was immediate and continued for an extended duration of time. While FDA has increased foreign inspections, it still lacks the resources necessary to fully address this issue. Therefore, drug shortages precipitated by recalls caused by substandard APIs will continue and likely increase.

B. Confidential Notification for Single-Source API

In addition, information that can make drugs vulnerable to shortages, such as a single API source, is also frequently unknown beyond the manufacturer. This information is, and should be considered proprietary, but this lack of transparency hinders the development of contingency plans for vulnerable drugs.

C. Continuity of Supply Plans

Related to the reporting or an early warning system, FDA could work with manufacturers to develop continuity of supply plans. The current lack of transparency acts as a significant barrier to this type of collaboration. With increased information exchange, contingency plans could be developed that include countermeasures such as manufacturing redundancies or backup supplies; more effective communication among FDA, manufacturers and others in the supply chain; and finally, development of plans that utilize production capabilities of other manufacturers either here in the United States or abroad to ensure availability of a drug in short supply.

D. Expedited Approval

Another factor that appears to inhibit manufacturing is the time it takes to obtain FDA approval to market a product, or to make changes in production processes for previously approved drugs (e.g., alternate sources for API).¹² In addition, new manufacturers of existing products have reported delays in getting product applications approved, further slowing the ability of new manufacturers to enter the marketplace. These delays and other barriers frequently dissuade manufacturers

from entering or maintaining a presence in the market. This is especially true for drugs commonly referred to as pre-1938 drugs that are technically unapproved for use by FDA, but have been on the market for years. While some pre-1938 drugs have little therapeutic value, others play a critical role in patient care. Examples of these therapies that have been in short supply include concentrated oral morphine solution and emergency syringes (e.g., epinephrine, dextrose) used in life-threatening situations. While FDA hasn't taken action against these and other medically necessary but unapproved products, manufacturers may self-select to leave the market rather than face the cumbersome new drug application process that would be required for FDA approval. Development of an expedited approval pathway for unapproved drugs may help alleviate these issues and get products to market faster. Another consideration could be for FDA to discount the new drug application fee for these products or pursue other regulatory changes that facilitate resolution of drug shortages under the retrospective review of existing rules mandate.

E. Incentives

Further, shortages are occurring overwhelmingly among generic injectable drugs,¹³ where production processes tend to be more complex than their pill counterparts. Low margins for these off-patent products coupled with complex manufacturing processes may lead some manufacturers to abandon production of these drugs altogether in favor of products with higher profit margins, thus reducing the number of potential suppliers of products critical to patient care. A way to offset this problem may be to explore incentives to encourage manufacturers to either stay in the market or enter the market with a new product line. There are several ways this could potentially be accomplished: 1) explore tax incentives for manufacturers to produce a drug in short supply or one deemed "vulnerable" to a shortage; 2) grant temporary exclusivity for a new product line of a drug in shortage or deemed "vulnerable" to one; 3) if a generic user fee program is created within the next reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA could explore reduced user fees for drugs in short supply or deemed "vulnerable." However, it should be noted that the current user fee program only covers branded products and this would require a change in the FDA user fee program.

F. Collaborate with DEA to Alter Quotas

Finally, the Drug Enforcement Administration (DEA) uses several types of quotas for controlled substances to prevent diversion. The quotas essentially limit the amount of controlled substance a manufacturer produces during a set period of time. There is concern over the unintended consequence of these requirements should a manufacturer suffer a production interruption; other manufacturers may be limited in their ability to ramp up production due to the quota set by DEA. At a minimum, FDA should collaborate with DEA to establish criteria and procedures for emergency authorization to increase quotas for controlled substances in short supply. Further, it is worth noting that the Justice Department has identified these quota regulations for re-evaluation in its plan for retrospective analysis of existing rules, as required by Executive Order 13563.

IV. RESEARCH AND RESPONSE

Historically, drug shortages have been considered an inventory management issue that inconveniences clinicians. However, there is mounting evidence that drug shortages impact the quality, safety and costs of patient care.

A. The severity, unpredictability, and lack of information associated with drug shortages negatively influences the availability, effectiveness and safety of patient care.

Delayed treatments are attributed to drug shortages, and the inability to provide care when needed is becoming increasingly common as noted in the lay and trade press.¹⁴ During the height of the propofol shortage, surgeries and diagnostic procedures were cancelled or rescheduled because of the lack of this anesthetic. Shortages of oncology therapies have resulted in delayed treatments and use of alternative therapies that frequently lack evidence demonstrating improved morbidity and mortality compared to the preferred therapy that is experiencing a shortage. Cytarabine, etoposide, paclitaxel and doxorubicin are among these critical therapies that have been in shortage in the last year. The full impact of these shortages on long-term patient morbidity and mortality will not be realized until long after these shortages resolve.

Drug shortages can also cause medication errors. Use of unfamiliar product formulations and alternative drugs increases the complexity of medication use and upsets the careful system of checks and balances that health systems use to ensure safety for patients. In a survey of 1,800 healthcare providers conducted by ISMP in fall 2010, 1 in 3 respondents reported at least one near miss occurred at their facility because of drug shortages, with a total of more than 1,000 near incidents reported overall.¹⁵ Further, 1 in 4 respondents reported that an actual medication error had occurred and 1 in 5 respondents reported adverse patient outcomes resulting from drug shortages.

B. Drug shortages represent significant increases in direct and indirect costs to individual health systems and overall costs to the nation.

Other studies have demonstrated the impact of drug shortages on the healthcare system. A recent study published in the *American Journal of Health-System Pharmacy* reported that the overall personnel costs associated with managing drug shortages costs health systems an estimated \$216 million annually.¹⁶ This increased burden on staff affects pharmacists, physicians, nurses and pharmacy technicians, but is concentrated within the pharmacy department and includes activities such as securing alternative products, updating information technology systems, and educating nursing and other staff about product substitutions. The time pharmacists spend managing drug shortages has nearly tripled since 2004, from two to three hours a week to an average of nine hours per week. This dramatic increase is alarming because the expertise of pharmacists, which has been shown to improve the safety and effectiveness of drug therapy, is being diverted from patient care to distributive functions.

Drug shortages are also associated with significant direct costs to the health system attributed to the increased costs of obtaining drugs. A recent survey by Premier, Inc. of 311 hospital pharmacy experts representing 228 hospitals; infusion, oncology and surgery centers; and outpatient and retail pharmacies estimated that drug shortages cost U.S. hospitals at least \$200 million annually through the purchase of more expensive generic or therapeutic substitutes.¹⁷

Increased acquisition costs can be attributed to a number of factors, including costs of alternative therapies and increased shipping costs for products purchased directly from the manufacturer or alternative suppliers.¹⁸ There are also anecdotal reports of products in shortage being offered for sale at higher than normal prices from companies outside the facility's established product suppliers. Prices have ranged from double to hundreds of times that of normal contract price for the same product. It is important to note that the emergence of high- cost products available through these non-traditional

sources is a symptom and not a cause of drug shortages. If the causes of drug shortages were addressed, the influence of these non-traditional suppliers would be lessened.

V. IMPACT OF POLICY RECOMMENDATIONS

Congress should:

A. Expand FDA authority to require manufacturers to notify it of supply interruptions and product discontinuations.

Congress should authorize FDA to require notification and penalize manufacturers for failing to report discontinuations or interruptions in their production of drugs. FDA states that some companies already report this information and when FDA is aware of these interruptions, the agency can take action to avoid a shortage. As noted earlier, according to FDA, in 2010, 38 drug shortages were avoided when manufacturers reported production interruptions to the agency. While not a solution in and of itself, required reporting would enable FDA to proactively work with the initial manufacturer and others in the supply chain to avoid drug shortages as described previously. Further, FDA's ability to share information with members of the supply chain could help improve communication among manufacturers, distributors and clinicians, who can use information about the scope, duration and intensity of the shortages to better manage remaining inventories.

Legislation (S. 296/H.R. 2245) in Congress would mandate that companies notify FDA of the interruption in production of any product six months in advance, or as soon as possible in the event of an unplanned stoppage. Manufacturers that fail to report this information would be subject to civil monetary penalties. This early warning system would allow the agency to communicate more effectively with manufacturers and others in the supply chain to plan for pending supply interruption. The early warning system should be the cornerstone of congressional action to address drug shortages.

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B. Allow FDA to require manufacturers to develop continuity of supply plans.

In 2010, FDA worked with APP Pharmaceuticals to help alleviate a shortage of propofol, a widely used anesthetic preferred by anesthesiologists because of its excellent safety profile compared to other available drugs. By enabling the company to work with its German counterpart to import the drug, FDA was able to substantially improve product availability after the shortage occurred. Using this example, if an acceptable foreign alternative could be identified before a shortage occurs through establishment of continuity of supply plans for vulnerable drugs, then importation could be expedited and the negative impact of a specific shortage on patient care could be minimized or averted. Importation represents an extreme example of contingency planning. In its simplest form, manufacturing strategies that include collaborating with other manufacturers, establishing back-up suppliers of raw materials and APIs, and creating alternative production capabilities that can be used as countermeasures would be a significant step forward to combating drug shortages. Contingency planning by companies producing drugs critical to patient care must be a standard of practice. S. 296/H.R. 2245 support the development of contingency plans for drugs that are vulnerable to shortages.

C. Require development of an expedited approval pathway for pre-1938 drugs.

FDA must find a way to abbreviate and prioritize approval processes for existing therapies that are unapproved, but widely used and essential for patient care. For these drugs, the agency should work with manufacturers to fast track their

approval for the U.S. market, especially in cases where the potential exists for those drugs to fall in short supply. Barriers to manufacturing and marketing these drugs must be minimized in order to foster production and availability of these drugs.

FDA should:

A. Encourage confidential notification to FDA when there is a single-source API.

As noted previously, FDA can avert drug shortages, or minimize their impact, when information is available that enables the agency to identify situations when shortages are more likely to occur. This is especially true with single-source API products. This characteristic makes a drug more vulnerable to shortages and should prompt FDA requirements for contingency plans to ensure product availability. However, manufacturers are frequently reluctant to make this information available for confidentiality reasons. FDA should establish mechanisms that support confidential notification of sole-source API drugs, thereby alleviating manufacturer concerns and preventing the unintended consequence of hoarding that might occur if this information was not privileged. Admittedly, knowledge of single-source APIs may not avert a shortage if there are no other viable API sources. However, knowledge of single-source APIs can prompt the development of contingency plans, including development of recommended use guidelines, early and improved notification, or inclusion of the product in a national stockpile of critical therapies.

B. Explore incentives that encourage manufacturers to enter the market, stay in the market, or implement processes that minimize the potential for shortages for vulnerable drugs.

FDA and Congress could also explore incentives to manufacturers to either stay in the market or begin producing new products. For example, incentives that have the potential to avert drug shortages, including those that encourage manufacturing redundancies (e.g., multiple sites, 24/7 production lines) should be considered. Other options could include tax incentives for manufacturers that achieve gold-standard good manufacturing practices (GMPs) or incentives for new manufacturers to enter the marketplace through limited exclusivity periods for manufacturers wishing to produce a new product line that is currently in short supply due to a product discontinuation. These and other incentives could produce an environment that encourages, rather than dissuades, market competition.

C. Collaborate with the DEA to alter quotas for controlled substance products in short supply.

FDA should collaborate with DEA to explore the impact DEA's quota limits have on manufacturing capacity. If DEA quota requirements are in fact burdensome for manufacturers seeking to increase production, both agencies should work to establish criteria and procedures for emergency authorization to increase quotas for controlled substances in short supply.

VI. CONCLUSION

There is no magic bullet that can prevent the occurrence of all drug shortages. The complexity of manufacturing processes, the requirement for safe and high-quality products, and globalization of the pharmaceutical supply chain all contribute to fluctuating product supplies that may never be entirely eliminated. However, there are critical steps that Congress, FDA and other stakeholders can implement to ensure that patient care remains available and safe. While the adjustments and

compromises required from all stakeholders are difficult, the need for change is critical. First and foremost is the need for increased communication and transparency.

ASHP, along with several other stakeholder groups (ASCO, ISMP, ASA and the American Hospital Association) have been working collaboratively with Congress and supply chain stakeholders to develop solutions to the drug shortage problem. As indicated before, there is legislation in both houses of Congress as well as broad bipartisan support in the Senate for action. Passage of legislation that provides additional authority to FDA is a step in the right direction. In the long term, FDA will require additional resources to best address this and other issue that impact the quality and safety of drugs.

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