Associate Editor's Commentary: The Danger of Shorting Drug Shortages

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All of a sudden the mainstream media (highlighted by a much-ballyhooed *New York Times* Week in Review piece by Zeke Emanuel) has discovered the problem of drug shortages (1). Except it's not a new problem.

According to a recent analysis (2), the frequency and impact of drug shortages have risen to critical levels, more than tripling since 2005, and affecting all segments of the health care community. In 2010, over 240 drugs were either in short supply or completely unavailable and more than 400 generic equivalents were backordered for more than 5 days. In most instances, these did not progress to critical shortages, but they nonetheless point to instabilities in the supply chain that cause national concern. Many of the drugs identified in 2010 remain unavailable or in short supply in 2011.

In 2010, 77% of drugs in short supply were sterile injectable products, critical in the acute care setting. Recent media coverage highlights the plight of patients and physicians faced with shortages for cancer drugs, anesthetic agents, and critical care medications that have contributed to delays in treatment and surgery, or changes in care plans. Drug back orders cause patients to receive substitute therapies that add expense to patient care.

A major reason for shortages is quality and manufacturing issues. However there are other reasons, such as production delays at the manufacturer and delays companies have experienced receiving raw materials and components from suppliers. Discontinuations are another factor contributing to shortages. (The FDA cannot require a firm to keep making a drug it wants to discontinue.)

Focus must fall not on blame, but on fixing the problem. Let's start with the FDA. In 2010, 178 drug shortages were reported to the FDA. Is that a reliable number? It's hard to say, because current regulations do not require companies to notify FDA of shortages. The only requirement is that companies inform FDA 6 months in advance for discontinuations of sole-source medically necessary drugs. (In 2010, for example, 38 shortages were prevented by companies notifying FDA voluntarily of potential issues that could lead to shortages, and FDA was able to work with the company to avoid a shortage.)

The FDA's Drug Shortage Program (DSP) resides in the Center for Drug Evaluation and Research (CDER). The DSP was established to address potential or actual shortages of drugs that have a significant impact on public health. Through communication, facilitation, and negotiation, DSP works with pharmaceutical manufacturers, review divisions, compliance, and other components of FDA to manage product shortages. For example, when the drug shortage is for a generic product (as it often is), the FDA works with other firms making the drug to help them ramp up production if they are willing to do so. Often they need new production lines or new raw material sources approved to help increase supplies. FDA can and does expedite review of these to help resolve shortages of medically necessary drugs. However, it cannot require the other firms to increase (or commence) production. The agency tries to do the

best it can with limited authority, spare resources, and shared staff. In addition to direct communication with industry, the DSP also gets reports from health care professionals, patients and other individuals, or professional organizations using the email address drugshortages@fda.hhs.gov.

However, there is not a lot of email traffic. Similarly, there is no social media effort to promote either its purpose or existence. While the DSP is a good start, it is not getting the job done. The problem is getting worse. The FDA needs both more authority and greater resources. In short, more needs to happen. The Institute for Safe Medication Practices reports that, according to a survey of 1,800 health care practitioners, more than half of respondents frequently or always encounter difficulties associated with drug shortages. The top three problems fall squarely within the zone of appropriate FDA attention and action:

- Little or no information available about the duration of a drug shortage (85%)
- Lack of advance warning from manufacturers or FDA to alert practitioners to an impending drug shortage and suggested alternatives (84%)
- Little or no information about the cause of the drug shortage (83%)

Survey respondents felt "unsupported by the FDA and are perplexed regarding why the US is experiencing drug shortages of epic proportion that are often associated with third-world countries" (3).

Should the issues of both authority and funding for the FDA's efforts to mitigate drug shortages be hung on the PDUFA Christmas tree or addressed in separate legislation? Whether it's one or the other, it's an issue that must be addressed with alacrity before it becomes a political question of "Who lost drug shortages?"

And before it becomes a question of American lives.

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