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What's Really To Blame For Drug Shortages?

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Drug shortages have become national news yet again. A recent article (<http://www.wsj.com/articles/u-s-drug-shortages-frustrate-doctors-patients-1433125793>) in the Wall Street Journal detailed the current supply scarcity of BCG, a drug used to treat bladder cancer, and the troubling impact this shortage is having on patients. News like this is difficult to swallow. It seems like in the modern era, extended shortages of medications patients desperately need simply should not occur. Yet, they do occur — and with shocking frequency. The FDA defines a drug shortage as a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply. According to FDA data (<http://www.fda.gov/Drugs/DrugSafety/ucm050796.htm>), the drug shortage crisis in the U.S. peaked in 2011 with 251 shortages reported. Since then, 117 new drug shortages were reported in 2012 and 44 in 2013. Most of these shortages were of sterile injectable medications. While the figures are trending in the right direction, the number of shortages remains high and disconcerting. The big question is why drug supply issues occur in the first place and what can be done to eliminate them.

Are Quality/Manufacturing Issues The Cause?

Addressing the drug shortage crisis was a huge area of focus at this year's ISPE/PQRI Quality Manufacturing Conference in Washington DC. The leading minds at this conference — which included ISPE and PQRI board members, FDA officials, and pharmaceutical company executives — all believe quality and manufacturing issues are at the root of drug shortages.

In her presentation at the conference, Captain Valerie Jensen, Associate Director of the FDA Drug Shortages Program, outlined how existing pharmaceutical manufacturing challenges directly contribute to drug shortages. For example, Jensen explained that currently only seven pharmaceutical manufacturers make up the vast majority of the sterile injectable market. Furthermore, she said these drugs require complex manufacturing processes and the facilities in which they are produced often lack the redundancy necessary to overcome production interruptions caused by contamination issues, supply chain problems, or equipment malfunctions.

Quality/manufacturing issues were definitely at play in the shortage of BCG. Supplies began to dwindle in 2012 when mold infestation halted production of the drug for more than two years at a Toronto facility owned by Sanofi, the primary manufacturer of BCG. The shortage was exacerbated when Merck, the only manufacturer of the drug, suffered production delays as well.

The ISPE has taken special steps in an effort to prevent drug shortages resulting from manufacturing and quality issues. In 2014, the Society released its *Drug Shortages Prevention Plan* (<http://www.ispe.org/drug-shortages-initiative>) which outlines a framework of six dimensions that are essential for pharmaceutical manufacturers to master in order to avoid issues that contribute to restricted drug supplies. These six dimensions — Corporate Quality Culture, Robust Quality System, Metrics, Business Continuity Planning, Communication with Authorities, and Building Capability — were established based upon the results of an industry survey and are designed to provide pharmaceutical manufacturers with a tool to support process improvement initiatives.

During her presentation, Jensen also offered “4 Steps to Preparedness” that could help drugmakers prevent many of the quality/manufacturing issues that lead to drug shortages. These steps mirror some of the six dimensions outlined in the ISPE *Drug Shortages Prevention Plan* and include:

1. Corporate commitment to shortage prevention culture — acceptance of accountability
2. Gap assessment
3. Remediation
4. Embed drug shortage prevention as part of the corporate culture

Or, Are Drug Shortages A Result Of Bad Economics?

While organizations like the ISPE and the FDA believe quality/manufacturing issues are the leading cause of drug shortages, others feel the broken economic models at play in the pharmaceutical and healthcare industries are the primary culprit. For example, Phil Zweig, Executive Director of the patient advocacy group Physicians Against Drug Shortages (PADS), believes healthcare GPOs (group purchasing organizations) are to blame for the drug shortage crisis.

A GPO is an entity that helps healthcare providers (e.g. hospitals, ambulatory care facilities, nursing homes, etc.) realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors¹. For nearly a century, the GPO model worked as intended until, Zweig argues, Congress passed the Medicare and Medicaid Patient and Program Protection Act of 1987. This piece of legislation included a provision that provided GPOs with safe harbor from kickback activities. Basically, it exempted these organizations from criminal prosecution for accepting kickbacks from suppliers.

According to Zweig, this Act incentivized GPOs to increase revenue by offering exclusivity to suppliers rather than actually saving money for hospitals. These practices, in essence, helped create monopolies — reducing the number of makers of a specific drug to one or two (or sometimes none at all). He claims this trend has (albeit unintentionally) helped create the drug shortage issues we encounter today.

Prior to this Act being implemented in 1991, Zweig asserts that if one pharmaceutical company encountered manufacturing problems with a specific drug, others could quickly make up the shortfall. Now, since only one or two manufacturers make a specific drug, other pharma companies are unable to pick up the slack. You can read more about Zweig’s and PADS’ take on GPOs and drug shortages here (<http://www.physiciansagainstdrugshortages.com/how-gpo-cartels-caused-the-crisis.html>).

Not everyone agrees with Zweig’s assessment of GPOs. For example, according to the website and blog www.drugshortage.org (<http://www.drugshortage.org/>), Zweig’s claims about GPOs causing drug shortages are unsubstantiated. The site states that the FDA, HHS, and Government Accountability Office have extensively examined the causes behind prescription drugs and do not include GPOs among them. Moreover, the site claims that GPO cost savings, administrative structure, and business practices have been reviewed by the FTC, U.S. Supreme Court, and others which have found their business practices to be ethical and transparent. In the interest of full disclosure, I had difficulty finding any drug shortage figures that could either support or refute Zweig’s claims that the drug shortage trend began after the Medicare and Medicaid Patient and Program Protection Act of 1987.

Regardless of where you stand on the GPO issue, it’s not the only example of questionable economic policies influencing drug supplies. For example, we all know that the pharmaceutical industry isn’t governed by true free market dynamics. Instead, Medicare and other payers dictate the reimbursement healthcare providers receive for generic medications while pharmaceutical manufacturers are free to charge whatever they want for drugs under patent. In this type of economic environment, the laws of supply and demand don’t necessarily dictate which medications are produced. For example, a pharmaceutical manufacturer may choose to cease production of a low-margin generic drug needed by a sizable patient population in favor of producing increased quantities of its more profitable patented products. This wasn’t the case in the aforementioned BCG shortage (it’s a high-margin patented drug), but the practice is somewhat common.

Even the FDA acknowledges the influence this economic model has on drug supplies. On its website (<http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm#q2>), the FDA stresses that it can’t require a firm to keep making a drug it wants to discontinue and that sometimes older drugs are terminated in favor of newer, more profitable, medications. The FDA views these discontinuations as another contributing factor to drug shortages.

So, what truly is to blame for the recent wave of drug shortages — quality/manufacturing issues or bad economics? Well, clearly, the answer is “both.” One can’t deny that quality/manufacturing issues such as contamination and facility flooding are most directly responsible for production interruptions and the resulting drug shortages. However, even if the efforts of the ISPE and the FDA eliminate quality/manufacturing issues altogether, there’s a good chance drug shortages would still exist. **Get more pharma manufacturing insight with our FREE newsletter** [sign up here \(Use Email Only, to add Hello Bar Modal\)](#) wouldn’t be as inevitable an occurrence due to consolidation and discontinuation. It seems like many industry thought leaders have put strong action plans in place to remedy the quality/manufacturing issues contributing to drug shortages, but little has been done to address the economic side of the equation. If we truly want to eliminate drug shortages, we can’t continue to ignore this elephant in the room.

¹ Definition taken from *A Primer On Group Purchasing Organizations* by the HSCA (Healthcare Supply Chain Association)

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