Getting a Handle on Drug Shortages

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HealthTrust Addresses the Challenge of Sourcing Mission-Critical Drugs

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The U.S. Food and Drug Administration's green-lighting of revamped manufacturing processes in 2012 somewhat eased the chronic shortages that were wreaking havoc in the generic injectable pharmaceutical industry.

However, **Craig Coulter**, director, Pharmacy Strategic Sourcing for HealthTrust, and **Stephanie Thompson**, PharmD, BCPS, former director of Clinical Pharmacy Services for HealthTrust (now director of clinical economics, HCA Clinical Excellence), caution that renewed stability won't prevent occasional spot shortages caused by temporary manufacturing or delivery interruptions or gray market opportunists. They also note the price of stability is higher costs for even generic versions of these drugs.

Still, the anticipated turnaround can't come soon enough for HealthTrust members or vendors, as the situation has only worsened with time.

"Our members really want answers to this issue. Their pharmacy budgets have been devastated, and patients are seeing higher charges for those drugs." Thompson says. "There's very little that members can do at their level, and that's the biggest source of frustration they have."

According to member responses in HealthTrust's Annual Drug Shortages Impact Survey, more than 98 percent of respondents experienced a shortage of one or more drugs in 2011 and 2012. According to HealthTrust, a record-breaking 211 medications were scarce at some point in 2010, and 267 shortages were logged in 2011. Even more sobering,

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72 percent of respondents reported experiencing daily shortages in 2012 compared to 47 percent in 2011. And more than 26 percent reported a significant adverse patient outcome over the last 12 months as a direct result of drug shortages.

Nationwide, virtually all hospitals confront shortages of mission-critical drugs, and at least 15 deaths have been linked to the crisis. It has added hundreds of millions of dollars to pharmacy and operating budgets and to the costs of patient care. And it has created untold confusion and concern among patients and their families.

How Did We Get Here?

While the overall problem of drug shortages in the U.S. market is multifaceted and complex, the reasons for the current situation of prolonged, chronic drug shortages can be reduced to two primary factors: years of inadequate FDA oversight and lax manufacturing quality control, Coulter says.

After revelations about intentionally adulterated heparin surfaced in 2008, the FDA reacted by ordering immediate implementation of stricter current good manufacturing practices (cGMP). While vigorous enforcement of cGMP has, in the long run, been good for the country, the FDA did so without adequately considering how such a move would impact the U.S. generic injectables market, Coulter says.

“The generic injectables industry was caught unprepared, because the FDA had been lax with cGMP for so long,” Coulter adds. “And industry was

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slow to react at first until the FDA made some examples, and then they responded either by introducing numerous new quality assurance steps or by shutting down troubled production lines."

These actions severely interrupted supplies and inventories dried up quickly. In some cases, there were only one or two manufacturers worldwide of a specific medication or Active Pharmaceutical Ingredient (API), so backup producers were scarce or non-existent.

"To fully comply with cGMP requirements, many manufacturers have had to make significant investments in new production equipment and personnel," Coulter says. "In certain significant cases, whole production lines have been taken down and rebuilt. Product manufacturing schedules had to be reevaluated and reprioritized."

To make matters worse, the majority of these drugs are decades old and have such low profit margins that some manufacturers could not justify the expense to upgrade their processes and exited the business.

Hoarding of scarce pharmaceuticals and gray market opportunism helped prolong some shortages or spark rumors of shortages that were in reality temporary hiccups in production or supply, Thompson says.

However, some shortages have little or nothing to do with regulation or market manipulation, notes **Bob Fink**, PharmD, senior director, chief pharmacy executive, at Franklin, Tenn.-based Community Health Systems. For example, the shortage of

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furosemide, which is used in the treatment of heart patients, arose when a fire knocked out the production facilities of the sole global manufacturer of its API.

Politics interrupted the supply of pentobarbital sodium, which is used as a sedative and also in lethal injections. Most of the U.S. supply of this drug is made in Italy, which bans capital punishment. Threats of violence against the plant and its workers by anti-death penalty groups forced the manufacturer to suspend production.

Falling reimbursement rates for medications also contribute to shortages, Fink says. “In effect, the government is putting price controls on the free market, which has led some manufacturers to decide to exit the market,” he says.

In recent months, with new production lines and new quality control processes in place, the industry has made great strides in meeting FDA requirements. Delays continue, however, because the FDA is understaffed and swamped by the number of needed inspections and abbreviated new drug approvals, Coulter says.

“The FDA is doing a much better job now of communicating about potential shutdowns and the expected impact on the market,” he adds.

The onus does not rest entirely on the FDA and the generic injectable manufacturing industry, Coulter says. Even some GPO contracting practices continue to contribute to the overall drug shortage problem. While no GPO should ever apologize for removing costs out of the healthcare system by negotiating

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lower prices, an argument can be made that increased dual- and multi-source awards versus sole-source awards over the last few years have become problematic.

“Some GPOs think that they are benefiting their members by hedging and spreading the risk of a shortage among multiple manufacturers, but the truth is this poorly considered practice is only exacerbating the problem,” Coulter explains.

Manufacturers depend heavily on predictable demand in order to adequately manage their production schedules and resources. Non-sole-source awards and poor GPO contract compliance work against predictability and, in many cases, they lead to unanticipated demand fluctuations, resulting in inadequate production needed to meet new demand.

“This is another reason why HealthTrust’s business practice of awarding sole-source pharmacy contract positions drives better pricing for drugs compared to other GPOs,” Coulter says. “HealthTrust has a very compliant membership. That, coupled with sole-source awards, leads to predictability, which is extremely valuable to manufacturers. As a general rule, manufacturers will also seek to satisfy their sole-source award obligations first if for no other reason than to avoid failure to supply penalties.”

HealthTrust Responds

Recognizing that misinformation and a lack of communication about shortages and alternative medications had exacerbated the original problem,

in February 2011 HealthTrust launched its Emergency Room drug shortage information program to provide members with clear, reliable and up-to-date intelligence on current and potential drug shortages.

Through constant contact with vendors, HealthTrust is able to provide reasonable predictions on when the standard drugs will be back on hospital pharmacy shelves, Thompson says. The reports advise members on clinical alternatives to scarce medications, including possible side effects and ways to deal with those. “We help them determine how much of ‘drug Y’ they’ll need to buy so they don’t overstock the alternative to ‘drug X,’ ” she says.

The communication is provided in PDF format through HealthTrust’s Member Portal. “Our members wanted a format that was user-friendly, portable and easily transferable,” she says.

HealthTrust’s relationship with its vendors makes this valuable resource possible, “Most of our vendors who have significant shortages communicate with us every two weeks on the status of the shortage and reasonable expectations for its resolution,” Thompson says.

“We rely on our close partnership with vendors to provide accurate information to us so members can develop more realistic strategies for providing patient care,” she adds.

The CHS organization includes 134 affiliated hospitals, as well as ambulatory surgery centers, some retail drug stores and thousands of physicians serving on the medical staffs of the hospitals. Like

HealthTrust, CHS leadership also relies on information to deal with the chronic shortages, Fink says.

“Prior to the creation of HealthTrust’s website, we created a website that reported information from manufacturers about the causes of shortages and updates on what drugs were in short supply,” Fink says. “The website provides our hospitals more background into the reasons for the shortages. We provide links to other websites such as the FDA, the American Society of Health-System Pharmacists and HealthTrust, as well as updates from our distributors and manufacturers.”

They have also worked with physicians to help them understand the nature of the problems and to find alternatives to scarce medications. Most of these drugs have reliable alternatives, but younger physicians may be unfamiliar with them, Fink says. Physicians with many years of practice experience may have used alternative therapies and can be especially helpful in briefing other colleagues on their use.

Where permitted by state law and with the blessing of state regulators, CHS has facilitated loaning drugs between facilities. “We’ve also told hospitals that they need to place orders every day to have a standing order with a vendor when a supply becomes available,” he says.

Jittery Future

While the prospect of fewer shortages is good news, the renewed availability of the medications comes with a bigger price tag for several reasons:

• The manufacturing and regulatory changes and widespread rebuilding of infrastructure have forced market prices upward—double- and, in some cases, triple-digit increases for single-source generics.

• Single-source suppliers will have unprecedented leverage in contract negotiations, which may serve to suppress competition from smaller manufacturers, Coulter says. “Competition for products that are currently single source in the generic market must be encouraged in some fashion to offset this and also to protect against possible future shortages of those materials,” he adds.

• The pharmaceutical manufacturing industry will continue to experience consolidations and departures that will mean fewer sources for APIs and finished products. This concentration gives large suppliers increased leverage in negotiating prices.

Fink worries about the reliance on large, foreign manufacturers of APIs. About 80 percent of API production is done offshore; in some cases, these are only single suppliers, which creates significant vulnerabilities.

“U.S. plants are trying to mitigate this situation by signing contracts with secondary suppliers, if they exist. I hope that this works, but I couldn’t guarantee it,” Fink says.

These factors will continue to strain the operating budgets of hospital pharmacies and impact patients' bills. To counter this, HealthTrust works to contract for longer agreements to stabilize pricing, Coulter says. The GPO also has been favoring contracting with suppliers that have redundancy built into their supply chain by backing up their contracted API providers with secondary providers in case the main API vendor encounters a production or delivery problem, Coulter adds.

At CHS, Fink says the organization anticipates higher prices and looks for opportunities in other areas to offset the increases. "We used to rely on drugs going generic to see prices fall, but now we don't anticipate the same kind of dramatic price drop as in the past," Fink says.

The renewed flow of APIs and finished products doesn't mean shortages will vanish entirely, Thompson and Coulter warn. And gray marketers will continue to try to create illusory shortages by commandeering large quantities of sought-after medications, they say.

Also, wholesalers no longer have the inventories to provide a cushion against minor manufacturing blips. This has created, and will likely continue to create, transitory spot shortages that can lead to panic buying and hoarding of the affected pharmaceuticals.

Timely, reliable information can help calm shortage fears in such cases, they say. "We will need to be very responsible and cautious about labeling a blip a shortage," Thompson says. "Clear, reliable and

consistent communication will be key to preventing or at least diminishing panic buying or hoarding during a temporary interruption."

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