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Falling Short

A recent, severe increase in the number of drug shortages has become a significant part of our national health care crisis. Which drugs are short, and why? The answers are unexpectedly complex. Gundy Sweet, Pharm.D., director of drug information and medication use policy for the U-M Health System, unravels some of the tangled factors behind the drug shortage crisis and shares the impact shortages are having on U.S. health systems and the national health care budget. →

Q: What is the scope of the drug shortage problem in the U.S.?

A: Drug shortages have been around for more than a decade. There were roughly 70 newly identified shortages annually through 2006. Then the numbers started to skyrocket, with 267 shortages in 2011 — up from 211 in 2010 and 166 in 2009. The American Society of Hospital Pharmacists (ASHP) lists 283 active drug shortages as of this interview. Ten percent of those were newly identified in 2012, with the other roughly 250 being carry-overs — shortages are not resolving as quickly as they did in the past. Also concerning are shortages of related drugs, making identification of alternative therapies challenging.

Q: What kinds of drugs are involved?

A: Virtually every therapeutic drug class has been touched. Most are generic; the vast majority are parenteral (drugs administered by injection). FDA data on shortages classified as "medically necessary" show that 80 percent of shortages are for parenteral products.

Q: What's causing this crisis?

A: Many factors come into play. When brands go generic, more companies come to market. Competition drives the price down and eventually there is no good return on investment. Manufacturers pull out of the market and those that remain are unable to supply the market demand. The FDA reports that the top three generic injectable manufacturers hold 71 percent of the market volume. Most sterile injectables have one manufacturer that produces at least 90 percent of the product's market share. It doesn't take much to tip the apple cart.

Law requires that the FDA approve the active pharmaceutical ingredient (API) source and the production line for any drug product. If the API source dries up, the FDA must approve a secondary source prior to use. Any needed equipment recalibration can cause further delays. It's a domino effect. I suspect there's also production equipment that's dated or in need of repair. Lines shut down either voluntarily or at the request of the FDA when they're not able to produce a quality product that meets good manufacturing practice requirements. When that involves one of just three major U.S. suppliers, it's a bad situation.

A global market complicates the situation further. Many active ingredients come from foreign sources whose plants also need to be inspected and approved. In addition, nearly everyone in the product supply chain has moved to just-in-time inventory. It's not uncommon for us to have a one-week inventory on-hand for a given drug, and the same is often true for our suppliers. There are good reasons for this, but it leaves no cushion in the market — the entire supply chain becomes reactionary.

It's important to remember that the FDA must work within what's defined in the law. It literally will take an act of Congress to allow the FDA to do some things that could help, although no one quick fix will solve this very complicated problem.

Q: What about legislation to address the crisis?

A: There are two bills in Congress: the Preserving Access to Life-Saving Medications Act and the Drug Shortage Prevention Act. While slightly different in scope and content, both bills would require companies to notify the FDA sooner if they intend to pull out of the market for any reason, or if they anticipate production problems. A lot of that is happening on its own now. The FDA was able to avert nearly 200 drug shortages in 2011, in large part because of collaboration with manufacturers. An additional 200 drug shortages last year would have been catastrophic.

Other components of the bills include expediting the approval process for new critical drug applications, addressing the issue of controlled substance quotas, and establishing

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inter-agency coordination and communication with the FDA to mitigate and prevent drug shortages. The bills are good steps in the right direction, and both were collaborative efforts by many stakeholders who recognize that we still need to dig deeper for true solutions.

Q: You and your colleagues studied the impact of drug shortages on U.S. health systems and the national cost of health care. What did you learn?

A: Drugs that are short right now — such as ketorolac, loop diuretics, and sodium bicarbonate — are affecting health care facilities across the country. Large teaching institutions like the U-M that treat diverse patient populations are affected by additional products, such as the oncolytic agents. While a small rural hospital may not be affected by some drug shortages, they face additional challenges such as reduced buying power and physical isolation from neighboring institutions from whom they can borrow. In our survey and another by the American Hospital Association, more than 99 percent of hospitals reported being affected by drug shortages. We looked only at hospitals — there are also home care companies, nursing homes, long-term care facilities and outpatient pharmacies that are affected.

Our study quantified the personnel resources required to manage drug shortages — physicians, nurses, pharmacy staff — at just under $250 million a year. A study conducted by large pharmacy suppliers estimated another $250 million is spent on more costly alternative drugs. Both are probably huge underestimates and, again, represent just hospitals.

Q: Are shortages compromising patient care?

A: If you're not using the standard of care — because you can't — how can care not be compromised? Are people dying? I don't think you can say across the board that because a patient didn't have a particular drug the patient died, but in some scenarios that can be true, particularly in oncology if the curative therapy is no longer available. Alternatives don't always work as well. Medication errors happen because people either have to compound something, or use an unfamiliar product or different concentration. Some of these medications are used in high-stress, critical, life-and-death situations: the patient isn't breathing — how much time do you have to figure out something unfamiliar?

Q: Fundamentally, what must we do?

A: You can't solve a problem of this complexity without a collaborative effort, and that means putting aside differences and agreeing that everything's on the table. While that's beginning to happen, there's still a lot of work to be done. The more people who look at this as a problem we all need to fix, rather than pointing fingers, the more creative ideas we'll explore and the more likely we will collectively be able to make an impact. In the meantime, it's a daily struggle to stay on top of the product supply chain to ensure medications needed to provide optimal patient care are available. [M]

Interview by Rick Krupinski