

Drug Shortage Guidelines: Sign of an Ongoing Problem?

— Shortages continue as some push for changes in anti-kickback law

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Last week's publication of ethical guidelines for distributing pediatric oncology drugs during a shortage appeared to be a sign that the shortage issue isn't going away any time soon.

"Over the past decade, drug shortages, defined as a supply of a marketed drug inadequate to meet current or projected demand, have become increasingly common," wrote [Yoram Unguru, MD](#), a pediatric hematologist/oncologist at the Herman and Walter Samuelson Children's Hospital at Sinai in Baltimore, and colleagues online in the *Journal of the National Cancer Institute*.

"Although there have been fewer new drug shortages in the United States since 2012, the number of active drug shortages has steadily increased, reaching an all-time high of 320 as of September 30, 2014, with 265 drugs currently in shortage," they noted.

The authors' ethical guidelines include considerations of "'curability,' prognosis, and the incremental importance of a particular drug to a given patient's outcome." And in the end, they concluded, "Solving the drug shortage problem will ultimately require a major policy shift, one that is grounded in coordination and cooperation."

The shortage problem continues to be the result of a number of factors, [Joseph Famulare](#), chairman of the International Society for Pharmaceutical Engineering, said Monday on the public radio program [The Diane Rehm Show](#). "The majority of shortages are attributed to manufacturing and quality problems," he explained.

"Pharmaceuticals, especially sterile ones, are made to very exacting standards with very high technologies. With some of these older drugs, the manufacturing capacity has diminished over time, and actions [have been] taken involving removal of products due to manufacturing defects."

The FDA has attempted to address the shortage problem: In 2012, it [instituted a rule](#) requiring manufacturers to notify the agency of any impending drug shortages. The FDA, in turn, would work with the drugmaker to lessen the shortage. However, these efforts haven't eliminated the problem, although the number of new shortages has dropped from 117 in 2012 to 44 in both 2013 and 2014, [according to the FDA](#).

The problem won't go away until a market-based solution is implemented, according to [Joel Zivot, MD](#), former president of [Physicians Against Drug Shortages](#) (PADS), a grassroots group of doctors concerned about the issue. "A drug company decides to make a drug because it anticipates a reasonable return on investment," said Zivot, an associate professor of anesthesiology and surgery at Emory University in Atlanta, who was speaking for himself.

"If there's no market for a drug, the vendor won't make the drug, unless the government decides it's going to supplement the difference or loss to make it economically worthwhile," he said in a phone interview. "In our desire to get a better and better price, we forced vendors out of the market."

Zivot and other members of PADS blame the problem in large part on group purchasing organizations. "They gather up many hospitals and go to a vendor and say, "We're going to give you this contract; you're going to make a small amount of money per unit, but it's going to be worth your while because we're a huge group of buyers," he said.

"If you fail to get that contract ... you may leave the market, and say you are not going to make the drug any more," Zivot continued. The purchasing group may then be left with only one or two vendors for that drug, and if one of them stops production due to a manufacturing problem, "because of the way modern manufacturing is in the style of 'just in time,' no one has anything on the shelf and no other vendor can nimbly enter the market."

PADS supports getting rid of a safe-harbor exemption in the federal anti-kickback law that allows group purchasers to extract a fee from drug companies who sign contracts with them. "Purchasing groups can demand an extra price to make the deal -- you're saying to the vendor, 'You have to pay me a fee to make this deal; it's a kickback.'"

"A repeal of the anti-kickback statute safe harbor exemption would go a long way toward solving this problem," he said. However, the group has not had much success selling the idea on Capitol Hill. "We asked then-Rep. Ed Markey (D-Mass.) -- now [Sen. Markey](#) -- for a [Government Accountability Office] investigation -- so far, nothing. That was in 2012."

Some have suggested that maybe the FDA could stockpile drugs that tend to go into shortage, and then distribute them when a shortage occurs. PADS Executive Director [Phillip Zweig](#) in an email called that proposal a "dumb idea" that would "only exacerbate the shortages."