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## What Is The Solution To Drug Shortages?

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When I interviewed David Meeker, M.D., CEO of Genzyme for the October 2012 cover feature article, the focus was on how the company was helping Sanofi to break free from the blockbuster model. However, during our conversation, Dr. Meeker shared that one of the most difficult lessons learned in his career was failing a patient community by not being able to provide an adequate drug supply. This lesson involved Genzyme receiving FDA warning letters necessitating a shutdown of its Alston, MA, site in 2009. The result was a severe drug shortage for two life-sustaining rare-disease medications. When the article went live on the *Life Science Leader digital edition*, I tweeted about it. This resulted in one of my Twitter followers replying to the tweet — focusing *not* on the article but instead on Genzyme's failure.

Having worked in the industry for nearly 20 years, I am of the opinion, and perhaps naively so, that companies strive to invent life-sustaining drugs in order to help patients while, of course, making a profit. I

do not believe Genzyme's failure to have been deliberate. That being said, the shortage not only damaged a company's reputation but also resulted in litigation and, most importantly, preventable patient pain and suffering. When I worked at Organon Pharmaceuticals, in 2004 we experienced a drug shortage for the neuromuscular-blocking agent Zemuron (rocuronium) — resulting from a manufacturing problem. The frustration on the part of the hospital sales team responsible for Zemuron was equal to that of clinicians clamoring for a resolution to the shortage. Nearly 10 years later, drug shortages seem to be getting worse. A recent *New York Times* editorial notes that as of July 31, 2013, 302 drugs were in short supply — up from 211 a year earlier. According to the article's authors, the drug shortage is not the result of numerous manufacturing issues but of something far more sinister.

In 1987, Congress enacted the Medicare anti-kickback "safe harbor," which exempted buying groups from criminal prosecution for accepting vendor kickbacks. A study in the fall 2011 issue of the *Journal of Contemporary Health Law and Policy* found that group-purchasing organization kickbacks inflated supply costs by at least \$30 billion annually. Because these giant purchasing organizations control the procurement of up to \$300 billion in drugs, devices, and supplies annually for some 5,000 healthcare facilities, it can be difficult to distinguish how these activities differ from those of a cartel. The Government Accountability Office (GAO) is investigating the role of group purchasing organizations in the drug shortages with a report expected in 2014.

In the meantime, if you want to learn more about some of the causes of drug shortages and possible solutions, check out Cliff Mintz's article on page 44. Some might argue the solution to rising drug shortages is not as simplistic as reigning in healthcare GPOs (group purchasing organizations). The fact that most of the problem involves cheap sterile injectables sold through hospital-purchasing organization contracts, we need to realize — if it walks like a cartel, quacks like a cartel, looks like a cartel — it's a cartel. And the best way to deal with a cartel is not by enabling its activity through government legislation.

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