Commentary

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“Doctor, We Have No Saline Today”: The Curious Case of the Generic Injectable Drug Shortage

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Emergency physicians across the nation have increasingly struggled with the inability of their institutions to obtain many of the common drugs used in our daily practice. The past decade has seen a huge increase in the number of drugs in short supply.[1] Most of these are time-honored, well-established, and critical drugs for our practice. These are not rare or "orphan" drugs. These are not new or complex agents that require cutting-edge technology to produce. Recently, these have included shortages of such staples as injectable nitroglycerin, succinylcholine, propofol, 50% dextrose, and even normal saline.[1] These are drugs that we have manufactured for decades. These are drugs we use every hour of every day in our collective practice. They have a huge and predictable market. So why then is that market failing us?

It is, perhaps, telling that the problem is largely limited to sterile, generic, injectable medications. What are the unique characteristics of this market that have led us to this place? This is a "disease" that is having a huge detrimental effect on our practice and is undoubtedly harming our patients. To understand that disease, we must understand the environment in which it developed. One thing seems certain: to date we have largely only addressed the symptoms of this disease and not the root cause. The FDA and Congress have held hearings, mitigation strategies have been suggested, Congress has acted, and hands have been wrung. Yet the disease marches on and on.

This issue of *Academic Emergency Medicine* includes a special contribution that has expertly chronicled and framed the problem.[2] The authors correctly state that the problem has been frequently described as "multifactorial." But is it really? Something seems to have abruptly changed to lead us to this point. Yes, sterile production lines are complex and expensive and break down frequently. Yes, there have been quality control problems and an increase in regulatory oversight. Yes, there have been problems with the supply of raw materials.[3] But each of these problems is identical to problems facing the nongeneric, branded, sterile medication market, yet we see few such shortages within that market segment. Why is that?

Certainly, we must learn to predict and report impending shortages promptly and develop mitigation strategies when they occur. But that is treating the symptoms of the "disease" and not the true cause. We simply must ask, "What is the etiology of this illness, and how can we cure it"?

To answer, we must first identify how the generic injectable market is unique. Mazer-Amirshahi and colleagues[4] have correctly pointed out that there has been a dramatic contraction in the number of manufacturers of generic injectable drugs.[4] But, by definition, there is typically only one manufacturer for each proprietary injectable drug. Yet we don't see shortages in that market segment. Another unique aspect of the injectable drug segment is that compared to generic oral medicines, there is a relatively constrained number of purchasers. Most of these drugs are only given in a hospital or EMS setting. There are 5,000 or so hospitals and 10,000 or so advanced life support EMS agencies that make up the total potential

market.[5] But in reality, there are actually only a handful of purchasers. Perhaps it is no coincidence that, in the same time frame that saw the development of this drug shortage problem, hospitals were moving increasingly to a group purchasing model. Currently a very few of the largest group purchasing organizations (GPOs) are responsible for over 90% of hospital drug purchases.[6] A similar situation exists within the EMS market.

GPOs have been embraced by hospitals to control skyrocketing costs. The federal government has encouraged this by granting those GPOs special "safe harbor" protections from federal antikickback laws.[7] GPOs are judged by hospitals almost solely on their ability to keep the prices for drugs low. That is how they lure hospitals into contracts. They are very good at it. As Mazer-Amirshahi and colleagues have pointed out, this has resulted in small profit margins for generic injectable drugs. The Medicare Modernization Act of 2003 has further constrained the ability of the price of those medications to "float" to appropriate levels for profitability, by limiting how much those prices can fluctuate within a given time frame.[8] The result is that the price cannot adjust rapidly to changes in production or demand.

The unintended consequence of hospital group purchasing has been the creation of a monopsony—or more accurately, an oligopsony. A monopsony (or oligopsony) is the opposite of a monopoly (oligopoly). It is a buyer's monopoly. Instead of one, or a few, *producers* controlling the price, a monopsony (or oligopsony), occurs when one, or a few, *purchasers* have so much power that they can control the price. An example would be the current situation where large warehouse retail stores have become so powerful as purchasers that they can dictate prices to suppliers.[9] A monopsony can cause just as much distortion to free-market forces as a monopoly, but is less well understood by the public. Perhaps this is the true cause of our ongoing drug nightmare. Perhaps this is what has changed to lead us to this point. The timeline certainly fits this assertion.

One of the more interesting aspects of this problem is that both the manufacturers and the purchasers (GPOs) are relatively silent on this issue. The purchasers (GPOs), of course, would be reluctant to acknowledge their own role in this problem. They simply turn to the hospitals they purchase for, and say, "Sorry, that drug is not available." Perhaps if the GPOs were judged not just by price, but by their ability to obtain the drugs, the price could "float" to where it needs to be to assure a sustainable profit margin. More interesting to some of us is that the producers have also been relatively silent. Why are they not screaming for higher prices and therefore higher profit margins? Perhaps it is because the pharmaceutical producers have to sell their higher profit, branded, injectable drugs to the same handful of GPOs.

Perhaps it is because the GPOs have "safe harbor" protections from federal antikickback laws that serve to potentially pervert the free-market economy. Under that exemption the GPOs make a significant portion of their money by collecting "administrative" fees directly from the producers.[7] In another setting, those could be interpreted as kickbacks. Through those fees, the pharmaceutical industry might very well be able to manipulate GPO purchasing patterns and steer them toward higher-priced, nongeneric drugs.

One thing is certain. We will not solve this problem until we have a national, nonpartisan, in-depth discussion of the root cause(s) of this problem. The FDA can't fix this. The drug companies and the GPOs have not been willing to fix this. Perhaps it is time for the medical community to show some leadership and host a consensus conference that seeks to illuminate the true origins of this problem. Only then will we be able to craft a cure for this pernicious disease and end our collective, recurring nightmare.

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