EDITORIAL

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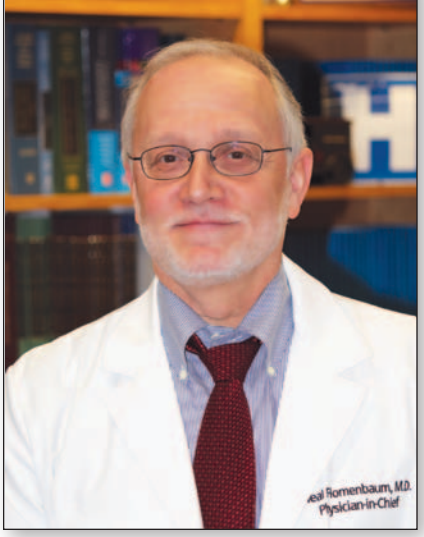

A National Disgrace

More than 20 years ago, the Soviet Union came to an end and it is now "gathering dust on the ash heap of history," as President Reagan once predicted. But Cold War images of empty shelves in Russian supermarkets still remain vivid reminders of a failed system of government. So who would have predicted that in the 21st century, the mighty United States of America, winner of the Cold War, would have hospital pharmacy shelves bereft of essential medications, including many of the sterile, injectable, crash-cart meds that we rely on during resuscitations? According to a November 2011 GAO report (GAO-12-116), there were 1,190 drug shortages between January 1, 2001, and June 20, 2011—with the number increasing annually since 2006. Drug shortages have not escaped physician or public attention, and there has been a lot of finger pointing among government agencies, manufacturers, and distributors, making most of us feel like the parent who tries to break up a loud argument between siblings: "I don't care *who* started it, just stop it NOW!"

To help end the shortages, the more common patterns and causes have to be recognized and addressed. One of the most critical types of shortages involves sterile, injectable, generic meds (such as epinephrine), which have accounted for more than half the shortages since 2009. During resuscitations, we physicians and paramedics rely on the immediate availability of premixed, ready-to-use unit doses packaged in sealed, prefilled syringes. All such preparations must be sterile, most are generic, and both of these characteristics contribute to shortages. Sterility necessitates short expiration dates and tightly controlled inventories, while contamination during the manufacturing process results in nationwide recalls and production halts. Because these generic medications have no patent protection and do not command the higher prices of newer, brand-name drugs, there is little incentive for manufacturers to make costly changes in production methods that are aimed at reducing future shortages. Also, as described in an August 2010 *NEJM* article on a shortage of propofol (2010;363[9]:806-807), most such drugs are manufactured by two or three companies—some by only one. Should one of the manufacturers suspend or discontinue production, a widespread shortage is immediately felt. The FDA has the authority to regulate pharmaceutical production to ensure safety but cannot mandate continued production—a system known even to Soviet-era school children as "free enterprise."

So what can be done? Here are a few possible short-term solutions that might help avoid shortages until something better comes along: First, identify a short list of "never event" drug shortages, similar to the list of complications in admitted patients that CMS will no longer reimburse hospitals for. For established medications and formulations that are too essential to allow to fail, the federal government should consider relaxing or delaying requirements for new, costly changes in their manufacture, or it should pay for the changes it mandates. The government should also consider offering incentives for pharmaceutical companies to continue producing critically needed low-profit generics that require costly manufacturing changes, perhaps by extending patent protection for one of the company's other, more profitable products. As a last resort, the government should consider manufacturing the medication itself, in its own facility.

In a 2002 *Annals of Emergency Medicine* article on "the challenge of drug shortages for emergency medicine" (2002;40[8]:598-602), the authors noted the dramatically increased number of recent shortages and their effect on patient care. Almost 10 years have elapsed since that article appeared, enough time for two Soviet-style "5-year plans" to fix the problem—so far with the same results. **EM**