

by John Goodman, 6/08/2011

Cass Sunstein, President Obama's regulatory czar, announced last week that the administration intends to [repeal cost-increasing, unnecessary regulations](#) <sup>[1]</sup> from 30 different agencies. If the administration is serious in this effort, a good place to start is with a web of regulations that are preventing life saving drugs from reaching the patients who need them.

Doctors at the Johns Hopkins cancer center are [rationing cytarabine](#) <sup>[2]</sup>, a drug used to treat leukemia and lymphoma. They are literally deciding who will live and who will die. The drug is also in short supply at the Stanford, Wisconsin and Nebraska university medical centers. Large medical centers, in Oklahoma and Maryland have completely run out.

All of this might be dismissed as an unfortunate turn of events were it not for the fact that a lot of other drugs are also in short supply. About [90 percent of all the anesthesiologists in the country report](#) <sup>[3]</sup> they are experiencing a shortage of at least one anesthetic, for example. Drug shortages are also endangering cancer patients, heart attack victims, accident survivors and a host of other ill people. The vast majority involve [injectable medications](#) <sup>[4]</sup> used mostly by medical centers, in emergency rooms, ICUs and cancer wards.

Currently, there are about [246 drugs that are in short supply](#) <sup>[5]</sup> and as the chart shows, the number has been growing for some time. There were 74 newly reported drug shortages in 2005; the number dipped slightly to 70 in 2006, then rose to 129 in 2007, 149 in 2008, 166 in 2009, and 211 in 2010.

As early as 2005, hospitals and clinics complained to [Health and Human Services Secretary Michael Leavitt](#) <sup>[6]</sup> that drug manufacturers and distributors were often out of certain drugs. The problem has been getting progressively worse ever since. A new [report](#) <sup>[7]</sup> from the Premier healthcare alliance that found that drug shortages have risen to "critical levels," endangering the public's health. [Hospitals are scrambling to make up the shortfall](#) <sup>[8]</sup>, in some cases rationing medications, postponing surgeries and using alternative drugs.

So what's going on?

Industry insiders point to numerous causes of the problem, including the fact that the generic drug market may be inherently more volatile than the market for brand-name drugs. Others point to [supply chain problems](#) <sup>[9]</sup>. Then there is government regulatory policy.

**Output Controls.** The Federal Food and Drug Administration (FDA) has been stepping up its quality enforcement efforts — levying fines and forcing manufacturers to retool their facilities both here and abroad. Not only has this more rigorous regulatory oversight slowed down production, the FDA's "zero tolerance" regime is forcing manufacturers to abide by rules that are rigid, inflexible and unforgiving. For example, a drug manufacturer must get approval for how much of a drug it plans to produce, as well as the timeframe. If a shortage develops (because, say, the FDA shuts down a competitor's plant), a drug manufacturer cannot increase its output of that drug without another round of approvals. Nor can it alter its timetable production (producing a shortage drug earlier than planned) without FDA approval.

Even the [Drug Enforcement Agency](#) <sup>[10]</sup> (DEA) has a role — because minute quantities of controlled substances are often used to make other drugs. This is the apparent reason for a nationwide [shortage of ADHD drugs](#) <sup>[11]</sup>, for example, including the [generic version of Ritalin](#) <sup>[12]</sup>. And like the FDA, DEA regulations are rigid and inflexible. For example, if a shortage develops and the manufacturers have reached their preauthorized production cap, a manufacturer cannot respond by increasing output without going back to the DEA for approval.

The Centers for Medicare and Medicaid Services (CMS) also has a role — levying large fines for "overcharging," forcing some companies to leave the generic market altogether.

**Price Controls.** Also contributing to the problems of many facilities is a little known program that forces drug manufacturers to give discounts to certain end users. The federal 340B drug rebate program was created in 1992 to provide discounted drugs to hospitals and clinics that treat a high number of indigent patients, clinics treating patients on Medicaid,

hospitals and clinics in the Public Health Service and certain Federally Qualified Health Centers ([more listed here](#) <sup>[13]</sup>). Currently, the law requires drug companies to provide rebates of **23.1 percent for brand drugs; and 13 percent for generic drugs** <sup>[14]</sup> off of their average manufacturer's price on qualifying outpatient drug use. States have the right to negotiate further discounts and actual rebates negotiated are typically much steeper than the federal requirement.

This state of affairs did not start with the Affordable Care Act (ObamaCare). By expanding the number of hospitals and clinics that are allowed to participate in the program, however, the Affordable Care Act will make things worse. In 2002, about **8,000 hospitals and clinics** <sup>[15]</sup> were in the program. By 2010 more than **14,457** <sup>[16]</sup> were participating. The total number of eligible hospitals and clinics is now estimated at **nearly 20,000** <sup>[17]</sup>.

Economics teaches that when prices are kept artificially low, shortages develop. People cannot get all of the care they try to obtain at the existing rate. Also, regardless of the apparently multiple causes of the shortages, certain patterns tend to emerge. People respond to persistent shortages by doing things that invariably make the problem worse.

**Stockpiling.** Buying organizations will typically respond by trying to stockpile quantities of drugs where supply is uncertain. That is, they will try to hoard more of the drugs than they ordinarily would keep in inventory in order to try to make sure they are available when needed. As the Healthcare Alliance Report explains, "drug shortages have been exacerbated by stockpiling on the part of providers," who are trying to "protect themselves from the instability of the drug supply chain by placing orders that exceed normal requirements."

**Black Markets.** Another thing that happens is the development of black (or gray) markets, where price gougers buy up quantities of a drug in short supply and sell it for a much higher price — even higher than would have been charged if the government had simply left the market alone. For example, in their 2005

letter to Secretary Leavitt, hospitals complained that shortages were exacerbated by drug distributors who filled their more lucrative commercial orders instead. ([The federal government, incidentally, claims this is illegal](#) <sup>[18]</sup>.)

Members of the Premier healthcare alliance report paying "gray market" prices as much as 335 percent above the approved rate. A recent [Kaiser Daily Health Policy Report](#) <sup>[19]</sup> highlighted how "the chain of custody in the gray market may pass from one distributor to another, creating a string of transactions that lead to higher prices and drug integrity concerns."

#### **Cascading Effects on Other Markets.**

Another consequence of shortages is that the effects in one market begin to cascade to other markets. In general, when hospitals cannot get a drug, they will turn to the next best alternative drug that creates the least adverse effects for patients. But as a [Premier healthcare alliance analysis explains](#) <sup>[20]</sup>, when a shortage of one drug causes increased demand for a therapeutically similar product, the substitute product may also then be in short supply because it "is not normally produced in quantities sufficient to meet unanticipated market needs." This scenario occurred last year with the morphine and subsequent hydromorphone shortages.

**Solutions.** Again, the Obama administration did not create this problem. But up till now, its preference for regulation rather than market forces to solve safety problems is making the entire health care system less safe than it otherwise would have been.

Years ago, Milton Friedman argued that government should be in the business of certification, not regulation. Let government investigate, evaluate and publish for all to read. Then let hospitals (duly forewarned) make their own decisions about whether to buy and use drugs supplied by various manufacturers and distributors.



Author Bio & Linked Footnotes on next page.

**John C. Goodman** founded the National Center for Policy Analysis (NCPA) in 1983 and has served as President and CEO since the center's inception. The Wall Street Journal called Dr. Goodman "the father of Health Savings Accounts," and National Journal declared him "winner of the devolution derby" because his ideas on ways to transfer power from government to the people have had a significant impact on Capitol Hill.

He is the author of nine books, including Handbook on State Health Care Reform, Lives at Risk: Single-Payer National Health Insurance Around the World; Leaving Women Behind: Modern Families, Outdated Laws; Economics of Public Policy, a widely used college textbook, and Patient Power: Solving America's Health Care Crisis, the condensed version of which sold 300,000 copies and is credited with playing a pivotal role in the defeat of the Clinton administration's plan to overhaul the U.S. health care system. Dr. Goodman received a Ph.D. in economics from Columbia University. He has taught and done research at several colleges and universities including Columbia University, Stanford University, Dartmouth University, Southern Methodist University and the University of Dallas.

From Health Affairs Blog: <http://healthaffairs.org/blog>

[1] repeal cost-increasing, unnecessary regulations:

<http://online.wsj.com/article/SB10001424052702304066504576345230492613772.html>

[2] rationing cytarabine: <http://online.wsj.com/article/SB10001424052748704547804576261282159840442.html>

[3] 90 percent of all the anesthesiologists in the country report: <http://www.asahq.org/For-the-Public-and-Media/Press-Room/ASA-News/Survey-Reveals-90-Percent-of-Anesthesiologists-Experiencing-Drug-Shortages-of-Anesthetics.aspx>

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[5] 246 drugs that are in short supply: <http://healthcare.utah.edu/pharmacy/druginfo/>

[6] Health and Human Services Secretary Michael Leavitt:

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[10] Drug Enforcement Agency:

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[12] generic version of Ritalin:

<http://online.wsj.com/article/SB10001424052748703730804576313441404251246.html>

[13] more listed here: <http://www.hrsa.gov/opa/introduction.htm>

[14] 23.1 percent for brand drugs; and 13 percent for generic drugs:

<http://www.cov.com/files/Publication/4919ebd6-465f-4e9e-a49b-dceab424b387/Presentation/PublicationAttachment/65c0be10-20f3-402c-861f-e10bb94fc4e6/Health%20Care%20Reform%20-%20340B%20Drug%20Pricing%20Program.pdf>

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<http://www.cjaonline.net/events/SustSeries/Calls/Call20080918/OverviewSection340B2.pdf>

[16] 14,457: <http://www.ncsl.org/default.aspx?tabid=14469>

[17] nearly 20,000: <http://www.ptcommunity.com/ptjournal/fulltext/35/11/PTJ3511632.pdf>

[18] The federal government, incidentally, claims this is illegal:

<http://www.drugdiscountmonitor.com/members/Issue10.pdf>

[19] Kaiser Daily Health Policy Report: <http://www.kaiserhealthnews.org/Daily-Report.aspx>

[20] Premier healthcare alliance analysis explains: <http://www.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf>

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