Defining Ideas
A HOOVER INSTITUTION JOURNAL
ideas defining a free society

The Hoover Tower observation deck is currently closed for maintenance. Please click here for more information.

The Libertarian
by Richard A. Epstein
August 30, 2011
defining ideas

The Perils of Price Controls

by Richard A. Epstein (Peter and Kirsten Bedford Senior Fellow and member of the Property Rights, Freedom, and Prosperity Task Force)

Why is there a shortage of cancer drugs in the United States?

The Libertarian Archives

Most Read (last 24 hours)

1. The Perils of Price Controls
2. How Is Warren Buffett Like the Pope?
3. Five Myths About Social Security and Medicare

4. Obama Versus Obama
5. Can Google Make Non-Violence Cool?

Hoover Institution home
Hoover Task Forces & Working Groups
Hoover Daily Report
Advancing a Free Society
The Perils of Price Controls
by Richard Epstein
Libya unrest stirs up questions over fate of Lockerbie bomber
by Tod Lindberg
NY Regents: Stop the madness!
by Michael Petrilli
Que Sarah, Sarah…
by Bill Whalen
Care for a Coke with that tree?
by Laura Huggins
August 30, 2011
defining ideas

The Perils of Price Controls

by Richard A. Epstein (Peter and Kirsten Bedford Senior Fellow and member of the Property Rights, Freedom, and Prosperity Task Force)
Why is there a shortage of cancer drugs in the United States?

Last week in the New York Times, veteran health correspondent Gardiner Harris wrote of the recent sharp and puzzling shortages of critical drugs used for treating a wide range of life-threatening cancers and bacterial infections. The total number of shortages has increased from 58 vital drugs in 2004 to 211 in 2010. These shortages have prompted some wholesalers to hoard certain scarce drugs, which has only aggravated the problem.

Harris reports that public officials and policy makers are now anxiously preparing a set of proposals to deal with these shortages. One such proposal calls, not surprisingly, on the federal government to take on a greater role in stockpiling dry ingredients of key drugs, which in times of need could be released to hospitals where pharmacists could then convert them into injectable compounds. A second legislative proposal, introduced by Senator Amy Klobuchar, a Minnesota Democrat, would give the Food and Drug Administration the power to demand that drug companies give the FDA early warnings when they anticipate a cutback in the quantities of goods they ship to the market. Still a third proposal calls for removing restrictions on importing generic drugs from overseas in order to ease the current shortages.

Illustration by Barbara Kelley

One of the real difficulties in understanding these shortages is that they appear to stem from multiple causes. Some shortages come from the failure of various suppliers to meet FDA inspection standards for safety. Other shortages appear to stem from the scarcity of drugs in their cheaper generic forms. Harris says that the FDA attributes this shortage to "capacity problems at drug plants or lack of interest because of low profits." Low profits follow inexorably from price caps. These caps in turn interact with safety issues, creating possible synergistic effects, Let's tackle each cause of the drug shortages separately, starting with the pricing issues.

Those pricing quandaries were the topic of a short but instructive New York Times article written by Ezekiel Emanuel earlier this month, who formerly held a high healthcare position in the Obama administration. Early on in his article, Emanuel asserts that markets are not up to the task of insuring a regular supply of key prescription drugs:

If the laws of supply and demand were working properly, a drug shortage would cause a price rise that would induce other manufacturers to fill the gap. But such laws do not really apply to cancer drugs.

The first sentence clearly captures an essential truth about markets. The second contains a revealing error. One great strength of *unregulated* markets lies in the ability to adjust for shortages in supply, should any current supplier cut back on its output. Existing suppliers can expand output, new companies can enter the marketplace, or both. That delicate interaction presupposes of course that close substitutes are available from other suppliers when drugs are in short supply. Patented cancer treatments have, almost by definition, no perfect substitutes. Should the drug stock of the exclusive supplier dwindle, then physicians and patients would have

to hunt down second-best substitutes, often in the middle of a course of treatment, and often with disastrous results.

The risk of denying sick people access to critical medicines is too great to bear.

As a nation, we are willing to suffer the potential inconvenience of patenting a drug because only patents can ensure high profits to the company that manufactures the drug. Without the lure of high profits, drug companies would never make the billion dollar investments needed in order to bring new drugs to market. Ironically, however, once these drugs reach the market, there are rarely shortages. The marginal cost of drug production is far below the market price, so that the drug manufacturers will take strenuous steps, including complex licensing agreements—often to multiple licensees—to keep ample supplies of safe drugs available for sale for as long as their patents last.

In practice, most of the drug shortages arise with generic treatments that enter the market in droves once the drug's patent has expired. Since the law does not require companies that produce the generic drugs to do all the original research of the branded company, the price of these generics is typically a tiny fraction of that of the patented drug. Once generics hit the markets, the high levels of competition do allow for perfect substitution, which suggests that the market should continue to operate without shortages. Unfortunately, the law of supply and demand "really apply to cancer drugs," for it confidently predicts shortages whenever price controls are applied. That is what is happening here.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 introduced a set of complex price controls as part and parcel of the new prescription drug benefit contained in Medicare Part D. These are not garden-variety price controls, like those on gasoline or rents, which interfere with solely private transactions. They are controls that the government introduced as an effort to prevent overpayments under the Medicare program. The problem here is universal. It has long been well understood that market systems do not easily adjust to third-party payers. No healthcare plan, public or private, can allow physicians and patients to purchase as much as they want of any good on their insurer's dime. The 2003 Medicare restrictions impose a rigid cost-plus system, under which price is determined by first finding the actual average selling price, to which the government tacks on an additional 6 percent fee for handling. To keep Medicare costs down, the law stipulates that the base price of the drug may not increase by more than 6 percent every six months.

Price controls cause drug manufacturers to leave the market, resulting in shortages.

As Emanuel rightly notes after his initial false step, all price restrictions deprive markets of the flexibility needed to respond to cost surges attributable to some outside shock. Generic drugs are especially vulnerable to these shifts because they normally sell at very low prices. In the short run, many vendors will refuse to sell at a loss. In the long run, price controls will induce many manufacturers just to leave the market. This one-two punch can lead to the shortages now in place.

The proposed administrative remedies, however, will not do much to solve the situation. Letting importers into American markets makes sense, but that long overdue move will have little effect if these sellers are subject to the same price restrictions that apply to domestic suppliers. Asking drug companies to give notice of their intention to leave the market is no panacea either.

More regulation is not the answer either. Here is a quick test: draft in 10,000 words or less those regulations needed to deal with an interruption of supply that must consider, according to the Klobuchar bill, "(A) adjustments related to the supply of raw materials, including active pharmaceutical ingredients; (B) adjustments to production capabilities; and (C) business decisions that may affect the manufacture of the drug, such as mergers, discontinuations, and a change in production output; and D) other adjustments as determined appropriate by the Secretary."

It cannot be done. These types of regulations will lead some manufacturers to exit the market en masse rather than let the costs of regulatory compliance eat into their already slender profits. No amount of notification can increase supply. Likewise, nonprofit organizations will be hard-pressed to make a dent in this market if they sell at a loss.

The only way to induce the supply is to allow prices to rise to market levels. Ideally, it would be appropriate to return to the pre-2003 status quo, but there is a catch: that will be difficult to do as long as Medicare Part D is in place. At the very least, the permissible prices should not be frozen for a six month period, but should be pegged if at all possible to the prices that these drugs sell for outside the Medicare system—at least if that market is large enough to absorb the hit, which may not be the case. Nor should the mark-up be kept to the low six-percent figure, given the low cost of generics. It is not easy for the government to set reimbursement rates. The blunt truth is that once there are government subsidies there must be government regulations. Everyone would like to keep prices for these generics low, but it would be better for there to be ample supplies at prices that may run higher than they do today, so long as there are supplies to match the demand. The risk of denying sick people access to critical medicines is too great to bear.

No drug company is going to sell its products at a loss.

The larger moral of this episode is that the government does not function well when it adds to its portfolio the dubious role of master insurer. Today we would be in a better place if the government had not gotten into the Medicare business in 1965—a position I took then as a law student and which still holds true today. But once the government is in that market to stay, the adequate provision of healthcare becomes a decidedly second-best affair, with high hidden costs and few decent remedies to counteract the evident dislocations of price controls. First-best, or ideal, solutions are just not in the cards.

The inspection risks raise a different question, but one which is every bit as intractable. As an initial premise, it is clear that every actor in the pharmaceutical industry is in favor of some government regulation intended to assure the purity and safety of prescription drugs, which can easily prove deadly or contaminated. In part, private companies could remedy this problem. They could take strenuous steps to guarantee the purity of their own drugs in order to preserve their good brand names. Of course, a smaller company that cannot meet the high compliance costs

might choose short-term profits over long-term reputation. But the prospect of tort liability and criminal sanctions for deliberate wrongs makes that a highly improbable outcome. The bigger risk by far is that all sorts of imposters will seek to infiltrate supply chains with bogus goods that the pharmaceutical company will find difficult to keep out without the help of government custom agents, domestic search warrants, and criminal sanctions against malefactors.

The key question here is not whether we have inspection for health, but exactly how it ought to be done. In dealing with this issue, as with other government functions, it is never easy to craft a program that chooses the right means to the correct ends. As a matter of general trade theory, it is well established that nations will often impose onerous, but dubious, health regulations on foreign goods in order to protect domestic firms from economic competition. It is equally the case that overzealous bureaucrats could easily impose restrictions whose costs clearly exceeds their benefits. This will surely happen whenever someone announces a zero tolerance program for certain types of risk.

Yet what is going on here? The exact role that these inspections play in the shortages is not clear from the public accounts, so it is hard to make any judgments about the overall efficiency of the system. It's worth noting, however, that that the FDA's general rules on licensing new drugs onto the market systematically overstates the risk of letting bad drugs into the market relative to that of keeping good drugs out of it. It would be disastrous if that mindset also controlled the inspection issue.

All that can be said for now is that the entire matter has to be addressed from the right standpoint, which always treats both sorts of error as having equal importance. The person who dies from the want of needed drugs is every bit as dead as the one who is treated with bad medicines. Let us hope that the pharmaceutical companies, the FDA, and Congress find ways to minimize the current dangers. Shortages are very public events, so that the failure to respond to them adequately will not escape the attention of those who depend on a steady supply of these goods. In this case, the proper initial response is to start with price increases, and save more exotic solutions for another day.

Richard A. Epstein, the Peter and Kirsten Bedford Senior Fellow at the Hoover Institution, is the Laurence A. Tisch Professor of Law, New York University Law School, and a senior lecturer at the University of Chicago. His areas of expertise include constitutional law, intellectual property, and property rights. His most recent books are *The Case against the Employee Free Choice Act* (Hoover Press, 2009) and *Supreme Neglect: How to Revive the Constitutional Protection for Private Property* (Oxford Press, 2008).

Letters to the editor may be sent to definingideas@stanford.edu. Editors reserve the right to reject or publish (and edit) letters.

http://www.hoover.org/publications/defining-ideas/article/91011