

# **Not Enough Cancer Drugs, Too Many Price Controls**

*Wall Street Journal*

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**November 11, 2012**

Cancer patients face daunting challenges, including side effects of treatment, impact on family life and work disruptions. They now face another problem: shortages of vital drugs.

Imagine an oncologist talking to his patient: Everything is going well with your treatment, he says, but one of the drugs you've been receiving is unavailable. There's a substitute—sort of. Your Medicare copayment for the drug we've been using is \$9. Now it will cost you \$520 each time the substitute is given.

Unfortunately, while this is an actual case, at least there was a substitute drug. In many other cases, there are only inferior treatments or no substitute drugs.

How could products in high demand face such shortages? The answer is the 2003 Medicare Modernization Act, which has upset the market for injectable generic drugs. Thanks to this law, manufacturers are unable to adjust their prices due to artificially low government price caps. In too many cases they must either produce drugs at a loss or pull them from the market.

Yes, the Medicare Modernization Act has lowered the cost of pharmaceuticals for seniors. But it has in an increasing number of cases made them less available. These drugs in short supply are needed to treat all cancer patients including children.

Before this legislation, providers of these pharmaceuticals received reimbursement proportional to the drugs' average wholesale price. Among other changes, the new law also addressed concerns that the average wholesale price was often inflated above real costs and did not reflect actual market prices. Medicare began to reimburse providers at 106% of the average sales price of the drug over the previous two quarters of sales in lieu of the average wholesale price, so that average sales price corresponded to the sales price of a drug. This was intended to end abuse of the system.

In response to the change in Medicare's reimbursement system, many private insurance companies have switched to an average-sales-price-based reimbursement system.

Manufacturers who previously had an overwhelming financial incentive to produce generic drugs now face minuscule profits or losses, in addition to government requirements to provide discounts and rebates on drugs for high-need populations. With much to lose and little to gain, many manufacturers continue to leave the market for these reasons.

Since the reimbursement change became effective in 2005, there has been a tremendous increase in drug shortages. There were more than 250 generic drug shortages in 2011 compared with only 58 in 2004, as reported by the University of Utah Drug Information Services.

Almost all drug shortages have come about after their price has plummeted, and the problem is compounded by the fact that many generics have few suppliers. For example in 2010, 90% of all generic injectable oncology drugs were produced by three or fewer manufacturers.

Due to the highly complex and expensive infrastructure required to manufacture and store sterile injectables, there is no incentive for new manufacturers to enter the market in response to a sudden shortage. Thus a single manufacturing glitch can result in an almost immediate shortage with no backup.

Further, because low-cost drugs are associated with impending shortage potential, middlemen often step in when a drug reaches absolute lows to hoard the drug and sell it back at an exorbitant price. This reduces supply and drives up prices for America's most vulnerable citizens.

Some symptoms of the drug-shortage problem have been addressed by the Obama administration and Congress. For example, measures have been taken to strengthen the warning system when a manufacturer foresees a future shortage or an interruption in supply.

While helpful in the short term, such measures do nothing to address the true economic roots of the problem. FDA chief Margaret Hamburg recently stated, "There are economic factors as well as quality factors" that underlie the drug-shortage problem. The economic imbalance is the elephant in the room. Though challenging, the reimbursement system must be rectified in order to stabilize the market and avoid future shortages.

The Affordable Care Act could make this already bad situation worse. Under this legislation, if Medicare expenditures exceed a predetermined amount, the Independent Payment Advisory Board is mandated to cut expenses. One of the few areas the board can cut is drug costs. This will move the market for pharmaceuticals further away from market forces—and until market forces are acknowledged, drug shortages will persist.

Well-intentioned but ill-advised policy changes in the Medicare Modernization Act must be addressed immediately to ensure that lifesaving treatments remain available. This means Congress has to remove artificial price caps. As more sterile injectables are scheduled to go off patent in the near future, now is the time to craft healthy economic policies that ensure the unhindered production of these vital drugs.

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