Paul Howard » Manhattan Moment

Market better than FDA to address drug shortages

Last week, the Food and Drug Administration announced that it had taken critical steps to mitigate shortages of two vital cancer drugs, Doxil and preservative-free Methotrexate.

Doxil, a branded drug used to treat ovarian and other cancers, has been in short supply for months, after manufacturing problems shut down the drug's sole U.S. plant. The FDA will temporarily allow importation of Doxil from an Indian manufacturer, a move that is expected to effectively end that shortage.

For preservative-free Methotrexate, a critical generic cancer drug for pediatric acute lymphoblastic leukemia (ALL) and bone cancer, the FDA has asked other pharmaceutical companies to step in to fill demand after a major supplier, Ben Venue, shut down a plant making the drug for "maintenance and requalification of equipment."

The FDA reports that it has prevented nearly 200 shortages in 2011 thanks to advance notice from manufacturers, but 280 drugs (mostly generics) remain in short supply. The FDA's efforts are welcome, but policymakers will have to consider additional, longer-term solutions that improve incentives for manufacturers of critical generic drugs to stay in the market and upgrade their manufacturing facilities.

The U.S. market strongly encourages substitution of branded drugs by generics immediately after a drug loses patent protection. For very profitable drugs (like statins) generic companies will rush in to fill the vacuum, slashing prices and saving consumers and insurers billions in annual drug costs. For high-demand, high-profit generics (and branded drugs), shortages will be few and far between.

But for other medicines, like sterile injectable drugs, which have high manufacturing costs and narrow profit margins, fierce price competition may eventually drive all but one or two manufacturers from the market.

And when there are only one or two suppliers, it creates the opportunity for life-threatening drug shortages when unexpected manufacturing problems arise at a single plant or elsewhere in the supply chain.

In recent years, a combination of market forces and government price controls have reduced incentives for companies to either enter the market for critical generic drugs or make manufacturing investments to keep their plants up to date — and running safely.

Medicare restrictions on average sale prices (which can only be updated every six months) for generic medicines, just-in-time inventory supply practices at hospitals, reverse-auction contracts from large group purchasing organizations for supplying generic drugs, tougher FDA manufacturing and inspection standards for domestic companies (which can raise costs), and increased global competition from low-cost suppliers in India and China have all created a "perfect storm" for creating shortages of some vital generic medicines.

In other words, unless we improve incentives for makers of critical generic medicines to stay in the market and invest in manufacturing upgrades, drug shortages may become an endemic feature of the marketplace.

Removing Medicare price controls for generic drugs and creating tax or other incentives for companies making critical generic drugs to invest in state-of-the-art manufacturing facilities would do much to prevent future shortages.

The recent Generic Drug User Fee Program agreed to by the FDA and industry will also help address drug shortages, by giving the FDA new funding to accelerate the review of new generic drug applications (bringing new manufacturing capacity online), and expanding FDA inspections of foreign manufacturers that supply the U.S. market (leveling the playing field for U.S.-based manufacturers that adhere to higher, but more expensive, safety and quality standards).

The FDA is doing everything it can to prevent and reduce shortages of critical medicines. But, in the long run, creating an attractive market for quality manufacturers is the best way to ensure a stable supply of life-saving generic medicines.

Paul Howard is a senior fellow at the Manhattan Institute's Center for Medical Progress.

Paul Sherman

Uncle Sam spends in one day what all 2012 campaigns will cost

As the presidential primaries move forward, it seems like people can't stop talking about the amount of money being spent this campaign season. News reports cover the fundraising horse race in minute detail, while pundits complain about the staggering sums being raised and spent.

All told, it's estimated that $5 billion will be spent this year on political campaigns at the federal, state and local level, up to $1 billion of which may be raised by President Obama's re-election campaign alone.

But if that sounds like a lot of money, consider this: Last year, the federal government spent that much money every day between breakfast and dinner. And next year looks to be no different.

On Feb. 13, Obama unveiled his proposed 2013 budget, which calls for an eye-popping $3.8 trillion in spending.

Throw in state and local spending, and government at all levels will spend well over $6 trillion next year. That works out to more than $190,000 per second.

With that much at stake, it's no wonder that people are willing to spend so much money to influence who will hold elective office.

Indeed, the really surprising thing isn't how much money there is in politics, but rather how little of it there is.

This massive disparity between what we spend on campaigns and what we spend on government suggests that much of the conventional wisdom about money in politics is wrong.

For one thing, it undermines the common belief that political spending buys legislation. If that were true, we would expect to see much higher levels of political spending as special interests jockey for favorable legislation.

But not only do we not see this, the disparity we see today goes back decades. Economist Gordon Tullock first noted it in 1972, back when there were virtually no campaign finance laws to hold down political spending.

Despite the presence of few legal restrictions, campaign spending in 1972 amounted to about $200 million, less than one-thousandth of the federal government's expenditures that year. And the disparity remains despite huge increases in the size and scope of government over the intervening 40 years.

This disparity also makes the notion that we spend "too much" on political campaigns sound downright silly. Of course, how much is too much is a matter of personal opinion, but $5 billion seems a modest amount to spend on deciding who will be in charge of $6 trillion of taxpayer money.

To put that number in context, consider that the Coca-Cola Co. spends about $3 billion annually advertising sugar water, while Americans spent an estimated $11 billion earlier this month on merchandise and food for the Super Bowl.

Five billion dollars is also a small amount of money when you consider what it is that money gets spent on: namely, political speech aimed at a massive audience. There are more than 200 million voting-eligible citizens in the United States.

Yet all candidates, political parties and third-party groups combined will spend only $25 per eligible voter to communicate their views about who should hold elective office.

In the end, the big numbers we see in campaign financing may make for salacious headlines, but they tell us little about the state of our government or the health of our electoral process.

Moreover, campaign fundraising numbers distract us from the really big numbers — government budgets — that might actually tell us something about what our politicians are up to.

It's time to move past horse-race coverage of political fundraising. Obama's latest budget proposal has given us 3.8 trillion reasons to stop focusing on campaign finance and to start focusing on what the candidates running for office will ultimately be doing with our money and our lives.

Paul Sherman is an attorney at the Institute for Justice, which litigates campaign finance cases nationwide.

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