To ensure access to generic drugs, take a lesson from vaccines

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Outrage over huge price increases for some essential medications is completely understandable—especially in the case of generics. When once-cheap tablets and injections suddenly shoot up 100, 200, 1,000 percent or more, patients start cutting them in half or skipping them altogether, with often disastrous results.

Recently the price of the antibiotic tetracycline increased 17,000 percent over the course of a year. Digoxin, an important heart medication, went from about 10 cents to over a dollar for a 125 mg pill. While a dollar doesn't sound like much, costs mount quickly when you are taking two or more pills a day and your life depends on it.

Congress got the message. Last Fall it hiked the mandatory rebate that manufacturers owe Medicaid for generic drug purchases, hoping to control price spikes.

But that likely is a misfire. Using Digoxin as an example, the real problem isn't the dollar. It's the dime.

Some background:

Generic drugs overall are a huge boon to consumers compared to branded drugs. Brands have patent and regulatory protection in their early market years, enabling manufacturers to take full advantage of demand for their remedies, reward stockholders and pay for the high costs of research and development. Much of the movement we see in drug pricing year-to-year reflects cycles of innovation, wherein the mix of drugs changes. Newer brands have been more expensive. According to an AARP analysis, the average annual retail price of therapy for a branded drug rose from $2,068 in 2010 to $2,960 in 2013.

Generic versions of branded drugs enter the market when patents expire, spurring competition and driving prices lower. The same AARP analysis found the average annual retail price of therapy for a generic drug dropped from $551 in 2010 to $283 in 2013. Generics now make up 88 percent of all prescriptions, but account for only 28 percent of all drug spending.

The problem for consumers of generic drugs occurs when competition begins to flag. Competitors can drop out of a market for a variety of reasons, including being acquired by a rival. Most critically, small markets typically can't support multiple competitors. In the case of Digoxin, the number of makers dropped from eight to three between 2002 and 2013. With fewer manufacturers, the greater the opening for price sticker shock and for spot shortages, which can precipitate health crises.

Congress is now considering legislation that seeks to improve competition among generics. The Fair Access to Safe and Timely (FAST) Generics Act would speed the FDA approval process for generic applications, among other provisions.

Which brings us back to the dime. If competition drove the price of a drug down to a level that could not support multiple competitors, why would a manufacturer bother to enter the market even under expedited review? Inevitably, renewed competition would simply take the price back down.

The best way to ensure active participation by manufacturers--and thereby avoid price spikes and critical shortages--is to help them avoid the trap of price collapses.

The federal government already does this for vaccines. Although vaccines are made by private companies, the federal government buys billions of dollars worth annually, and the Department of Health and Human Services has several roles in regulating its production and availability. It is time to do the same for generic drugs.

Three agencies acting in concert can make it happen: the FDA, which ensures that generic drugs are safe and effective; the FTC, which monitors competition to protect consumers; and the Centers for Disease Control and Prevention, which has experience buying vaccines to forestall shortages.

Congress should mandate that the FTC report on an annual basis on the availability of generic drugs by indicating the number of manufacturers and the source and quantity of pills supplied to hospitals and pharmacies. These data would enable the FDA to assemble a 'watch list' of 'essential' generic drugs with competition and/or supply problems. In the short term, the FDA would be authorized to allow importation from foreign sources; this will solve the immediate crisis.

Longer term, the government would be authorized to intervene and begin buying the watch list generics on behalf of federal users, including the Veterans Administration, Medicaid, and Medicare. The purchases would set a price floor that would assure participation by manufacturers. The continued competition and the resulting stockpiles would act to keep prices from rising.

The result would be stability for makers and users, and prices that ultimately could save the federal government billions of dollars in pharmaceutical spending, depending on how many drugs make the watch list.

We live in a society where cheap drugs are the cornerstone of effective disease therapy. We just need to make sure they are not so cheap that no one can buy them.

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