The Daily Dish

The Drug Pricing Reform Effort

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Eakinomics: The Drug Pricing Reform Effort

Yesterday marked 100 days since President Trump announced his drug pricing blueprint, the basic goal of which is to "lower prices" somehow. How successful has it been?

In thinking about this question, it is useful to remind oneself that drug production and distribution is largely market-based, and the lesson of the market framework is that prices fall only if there is an increase in supply, a decrease in demand, or a reduction in taxes and other overhead-like costs. Broadly speaking, there is little interest in decreasing the demand for drugs *per se*, so most of the focus is on increasing supply.

Regarding supply, the Department of Health and Human Services (HHS) will quickly point out that in the past 100 days the Food and Drug Administration (FDA): approved a record number of generic drugs in July; approved the first generic drug under a pathway designed to fight price gouging; launched a working group on how safe, short-term importation of certain medically necessary drugs could address price spikes; and announced an FDA Biosimilar Action Plan to spur competition among expensive biologic drugs. To be honest, the last two of those are merely announcements — no action yet — and the impact of the second is limited, but the focus is on increasing supply.

But there have been lots (and lots) of other initiatives as well. Why? Digging a bit deeper reveals that not all drugs are the same. There are brand-name drugs protected by patents, and generic drugs that compete with those whose patent has expired. Among the patented drugs, certainly there are some that are therapeutically unique. In short, there are lots of situations where little can be done to increase supply, but there may be room for negotiating a better price on the few that are on the market and available for use.

For example, the Center for Medicare and Medicaid Services (CMS) took action to provide Medicare Advantage (MA) plans greater flexibility in their benefit design and coverage of certain medicines. MA plans will now be able to impose step therapy requirements as a way to manage utilization of physician-administered drugs (that is, not outpatient drugs taken at home) covered under the Medicare Part B benefit. It is hoped that this expanded authority will enable insurers to promote the use of higher-value medicines and better negotiate discounts for drugs. (In a managed care setting, "step therapy" is an approach to prescription drugs where a patient begins treatment for a medical condition with the most cost-effective drug therapy and progresses to other more costly or risky therapies only if necessary.)

Specifically, CMS rescinded a memo from September 2012 that stated MA plans were not allowed to impose additional requirements (such as step therapy) that would hinder access to Part B drugs or services. Additionally, MA prescription drug plans will have new authority to cross-manage Part B and Part D drugs by allowing drugs covered under one benefit to be the first step of a treatment plan before allowing use of a drug covered by the other benefit. Any step therapy requirement must be coupled with drug-management and care-coordination services, and at least half of the savings generated from reduced drug costs must be shared with the beneficiary. These requirements are intended to encourage patient participation, which is essential to realizing

better health management and medication adherence.

The other way to reduce prices of drugs is to reduce the explicit and implicit taxes on them. Congress made things a bit worse in this regard recently by increasing the fraction of Medicare Part D costs that must be paid by pharmaceutical firms — a tax in disguise. (See the discussion in Tara O'Neill Hayes' reform piece.) Among the most important of the implicit taxes is the 340B Drug Pricing Program (340B). Under the 340B program, manufacturers must provide discounts to eligible health care providers for covered outpatient drugs. There was no guarantee that those providers were passing along any of the discounts to the low-income patients they were intended to benefit, and the lost revenue from the discount has to be made up elsewhere (the implicit tax), so CMS introduced reforms in 2017. In the past 100 days, CMS extended this policy to 340B drugs provided at off-campus hospitals sites, while also reforming the calculation of the average sales price (ASP) for biosimilars.

The final lever that the government could pull is essentially shifting part of the price onto someone else. That might not make drugs cheaper for the health care system as a whole, but it could relieve some of the burden on, for example, consumers. CMS has instituted a wide range of proposals to reduce the out-of-pocket portion paid by consumers.

Nobody should have expected a 100-day miracle in drug pricing — the economics are simply too daunting. But by continuing to pursue policies of increased supply, stronger negotiations, and fewer explicit and implicit taxes, the administration can make additional progress.