Options to Promote Competitive Generics Markets in the United States

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In August, the price of the 62-year-old drug pyrimethamine (Daraprim), used to treat many potentially fatal parasitic infections, was increased practically overnight from $14 to $750 per tablet. This colossal increase attracted renewed attention to generic pharmaceutical price spikes, prompting public outrage and a new round of proposals to address this issue. Over the past few years, increasing drug shortages and price spikes have affected generic drugs, which now account for 86% of prescriptions and 29% of pharmaceutical spending.1 A stable supply of affordable generic pharmaceuticals is crucial to improve health care access and appropriate utilization for many Americans.

A 2014 report from the US Government Accountability Office found that the number of active drug shortages increased steadily from 154 in 2007 to 456 in 2012, and the majority of the affected drugs were generic.2 According to a recent Senate subcommittee investigation, many generic drugs prices have increased substantially as producers have left the market; for example, the price of albuterol sulfate tablets, used for asthma and other lung diseases, increased 4014% between October 2013 and April 2014 from $11 to $434.3 These generic drug shortages and price spikes are adverse outcomes of a malfunctioning marketplace.

Two features of the US generic drug market make it more prone to price swings and shortages than other commodity markets. First, entry into the generic drug market is restricted, including financial barriers (the cost of product formulation, quality assurance, and bioequivalence testing) and a time barrier due to the need for abbreviated clinical testing and the uncertainty of the Abbreviated New Drug Application (ANDA) review cycle. Second, again in contrast to more efficient commodity markets, there are barriers to the substitution of other products for a given generic drug molecule.

The economics of the generic drug market are driven by the opportunity for 180 days of market exclusivity for the first generic product on the market. These products are available at prices only slightly reduced from those of the originator products. Generic manufacturers may enter the market after 180 days in the hope of a substantial financial return in the short period of time before the price of the product declines. Firms take a calculated risk in financing bioequivalence studies and in entering the marketplace without knowing how many competitors will enter the market or how quickly the price of the product will decline. As other firms enter the market and the price of a product approaches its marginal cost, the incentive to remain a supplier diminishes.4 At that time, firms make decisions about exiting the market without knowledge of the actions of other firms. Eventually, exit of enough firms supplying a particular product can lead to substantial price increases as the remaining firms operate with little competition, or drug shortages if remaining firms lack the capacity to supply the entire market. These are the drug shortages and price increases observed by Congress.

Recently, Hillary Clinton unveiled a policy proposal that would require some of the largest pharmaceutical companies to reinvest revenue into research and development. Similarly, Senator Bernie Sanders has proposed several policies to address the pharmaceutical market, including a windfall profits tax and price negotiations directed between the US Department of Health and Human Services and manufacturers. Although well intentioned, these policies do not address the underlying market imperfections and they risk exacerbating price spikes and shortages by further decreasing incentives for pharmaceutical companies to enter or stay in the generics market.

Three Market-Based Proposals to Optimize Generic Drug Cost and Availability

Stabilizing the generic drug market will in turn help eliminate price swings and shortages. Three potential business strategies—restricted market entry, long-term contracting, and creation of a futures market—could stabilize the generics drug market, but each has strengths and limitations. Paradoxically, for free-market advocates, these proposals all entail efforts that appear to be somewhat anticompetitive. The intent is to create a generics market that is economically viable for several firms to supply each product in the market. This result will likely lead to the most stable market over time.

Option 1: Restrict Market Entry

Restricting the manufacturing of certain drugs to a limited number of manufacturers could bring greater transparency to the generics market, paradoxically attracting more manufacturers to remain as suppliers. Currently, there is no limit to the number of firms that could enter a given generics market. Rather than allow unlimited entry into a market, the US Food and Drug Administration (FDA) could offer a limited set of licenses to suppliers for a given generic drug. The number of licenses could be based on the size of the market, the complexity of the product, or other factors that make a given molecule more subject to possible shortages or price fluctuations. As with spectrum auctions, in which the Federal Communications Commission allocates certain bandwidths to telecommunications companies, the FDA could use generics license auctions to allocate a predetermined number of licenses.

Policies promoting restricted entry in the generics industry are not without risks. Offering too few or too many licenses may return pricing standards to monopo-
Generic drug price volatility results from the structure of the generic drug market in the United States. Our 3 different approaches to stabilizing the market differ from many proposed policy solutions for generic products. These potential approaches are designed to address the underlying economic model of the generics market in the hope of providing longer-term, structural solutions to price and supply swings that have occurred.