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How Did Free Market Competition For Generic Drugs Create a Public Health and National Security Crisis?

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Summary

The US introduction of generic drugs successfully reduced drug prescription prices, as intended. However, the result of using free-market forces to lower prescription drug prices included severe drug shortages and a national dependency on overseas manufacturing. An overview of the underlying reasons and consequences to US drug security will be presented.

Background

In 1984 the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. The law encouraged the manufacture of generic drugs by the pharmaceutical industry and established the modern government generic drug regulatory system in the United States (1).

Generic drugs are copies of a branded product whose patent has expired. The Hatch-Waxman act described the requirements for approval of a generic drug. On a high level, the approval of a generic drug only needs to demonstrate that the generic product's blood levels are equivalent to the branded drug product. Such a low bar encouraged many manufacturers to immediately apply for approval as soon as the branded drug's patent expired. The impact on the price of branded drugs was dramatic. Upon introducing the generic into the market, the product's cost dropped to 15% of the branded product (2).

The cost to develop, gain approval and commercialize a generic drug was extremely low. Many generic companies were able to file 10 -15 generic drug applications in a year. In 2018, 9 of 10 prescriptions filled in the United States were for generic drugs (3)

Competition

Lacking any form of exclusivity, generic companies began competing on price to gain market share. This was the US government's dream scenario; the free market would dictate the drug's price. As we have learned, more manufacturers resulted in an oversupply. When left unrestricted, the supply curve moved to the right, and prices dropped until a new equilibrium price was reached for the available supply (4).

As competition became fierce and gross margins dropped, three events occurred (5).

1. Competitors dropped out of unprofitable markets, leaving fewer companies producing the product
2. With fewer competitors, prices increased for some products
3. The generic companies found that overseas manufacturers could produce the drug ingredients much more cheaply than US companies. To improve margins, China and India became a significant source of generic drugs.

Today, virtually all generic drug manufacturing has moved out of the US, primarily to China (6).

The Consequences of Manufacturing Generic Drugs Overseas

Drug Shortages

Today, drug shortages have become a public health crisis (7). How prevalent are generic drug shortages in the US? In the third quarter of 2020, 265 drugs were in short supply in the US; 47% of these were injectable products. These included life-saving antibiotics, routine IV solutions, pain medications, and blood pressure medications (8).

Reasons for drug shortages include (9):

- The facility fails to comply with established quality standards
- A fire, earthquake, etc. at an approved FDA facility
- Only FDA approved facilities can manufacturer drug products
    - The time required to approve a new facility is too long for a rapid resolution of supply disruption

National Security Threat

In the past several years, the US has awakened to the fact that if the vast majority of pharmaceutical ingredients and generic drugs come from China, this represents a significant national security threat (10). Imagine what would happen to the drug supply if China suddenly stopped selling these essential products to the US.

Many US companies and lawmakers are proposing to bring back drug manufacturing to the US because of this perceived threat (11, 12). However, many obstacles and hurdles would be needed to overcome to make this a reality.

- Time to approve a site to make one drug is lengthy, but the US needs to stockpile 25 -50 of the top generic drugs. Some of the medicines in most need are injectables, which require special facilities
- US manufacturing cost will be significantly higher with low-profit margins
- A government-subsidized manufacturing plan would be necessary to make the strategy profitable
- The strategy must include drug sales to offset Government cost and prevent drugs from going out of date – now, distribution and sales must be added to the equation.

A possible scenario would be for the government to set a realistic, profitable price that would incentive US manufacturers to produce the drug or finished product. Adjusting the price depending on the critical need is a lever the government would have to entice producers. The government expenditures would cover the difference between the manufacturer's price and the current price charged to hospitals and pharmacies today.

Conclusion

The US introduction of generic drugs successfully reduced drug prescription prices as intended. However, the result of using free-market forces to lower prescription drug prices included severe drug shortages and a national dependency on overseas manufacturing.

In my opinion, a private sector/government collaboration is the fastest way to minimize the self-induced public health and national security crisis.

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