United States Senate Committee on Health, Education, Labor, and Pensions,

Subcomittee on Children and Families on

EpiPen Price Increases: how Regulatory Barriers Inhibit Pharmaceutical Competition

Testimony of

Brian K. Strow, Ph.D.

BB&T Professor the Study of Capitalism,

Professor of Economics Western Kentucky University

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My name is Brian Strow, Ph.D., WKU BB&T Professor for the Study of Capitalism and Professor of Economics at Western Kentucky University. I am grateful for the opportunity to come before the U.S. Senate Committee on Health, Education, Labor, and Pensions' Subcommittee on Children and Families to testify regarding the benefits to consumers of increased competion by producers, provide evidence of the value to consumers of increased producer competition in the pharmecuetical industry, explain how barriers to producer competition arise in marketss generally and the pharmaceutical industry specifically, and offer policy suggestions aimed at reducing said barriers for the benfits of consumers.

The Benefit to Consumers of Competition

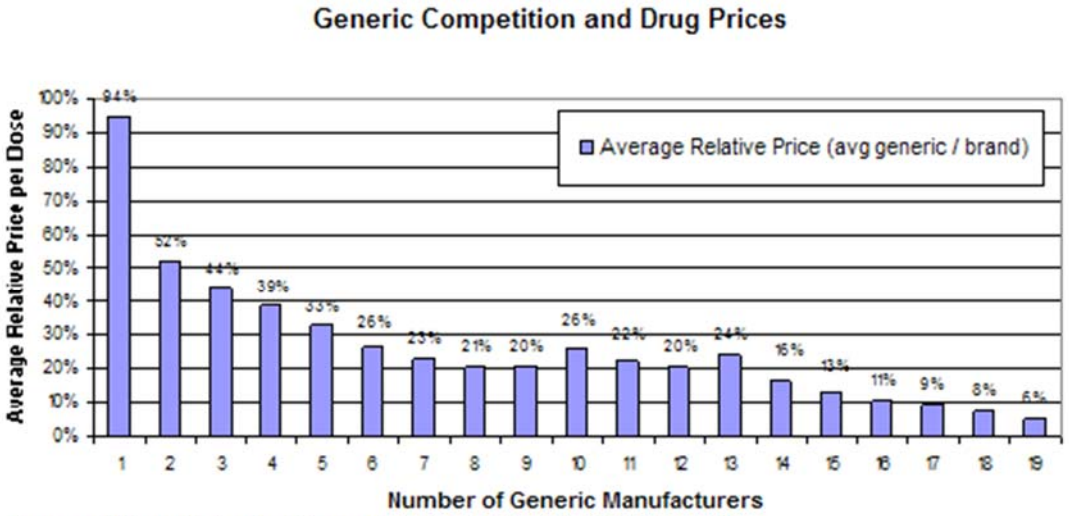
For consumers, choices are "good". More choices are "better". Economists measure "good" and "better" in terms of consumer surplus. Consumer surplus is the difference between the amount of money that consumers are willing and able to pay for a good or servie and the price they actually have to pay for the good or service. If one is willing and ablle to pay up to $10 per for one dose of a perscription drug and the price is set at $10, there is no consumer surplus. If the price of the perscriptin drug falls to $4, then the consumer gains $6 of consumer surplus when they purchase the drug.

Competition among producers in markets for goods or services works to lower prices and improve quality in said markets thereby increasing consumer surplus. In order to maximize profits, monopolists will tend to artificially restrict the quantity of a good or service available on

the market and increase the price of the good or service. As each new subsequent producer enters the market, consumers gain greater decision making power over what good or service to purchase. Any given producer loses power over the consumer and must compete for said consumer's business by offering a better good or service or lowering the price they charge. Standard microeconomic theory suggests that as the number of competing producers increases, prices fall.

The Benefit to Consumres of Pharmaceutical Competition

In 2005, the US Food and Drug Admistration reported a direct relationship between the number of drug producers in a market and the average price of the drug for sale that occurred between 1999 and 2004. Their chart is included below. While increased producer competition was found to generally lower average drug prices, the best news for consumers was that the largest percentage benefit from increased competition occurred when merely the second generic drug entered the market. Reductions in drug prices directly related to increased producer competition are the rule, rather than the exception, in the pharmecuetical industry.



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

Why Barriers to Competition Arise

In general, barriers to producer competition arise from a limited set of circumstances. These circumstances include control over scarce inputs (De Beers' control over costume grade diamonds), technological superiority (IBM at the beginning of super computers), large up-front costs (the jumbo jet industry), the presence of economies of scale (large scale electricity production may be cheaper than small scale production), and government regulations (patents, licensing rules, or government prohibition as in the case of the postal monopoly).

In the absence of these barriers, if a company were to dramatically increase the price of their good or service in absence of an increase in their production costs, one of two things will occur. Their competitors will not respond to the price increase and gain market share or they will respond by increasing their own prices (explicit price collusion is illegal). The larger the number of competitors, the greater the likelihood that one producer will attempt to gain market share and not raise prices. As they lose market share, the other producers are forced to reduce their prices or get squeezed out of the market.

If there are a small number of competitors and they all increase their prices, the increased price acts as a signal to potential producers indicating that resources need to be reallocated into the increased production of the very good or service whose price has been increased. As long as the price of the good or service remains above the price that would be derived from perfect competition, the signal for new entrants remains. New entrants will enter into the market until the price returns to the price suggested by a perfectly competitive market. (F.A. Hayek, *The Use of Knowledge in Society* 1945 and Milton Friedman, *Capitalism and Freedom,* Chapter 8).

As in the recent case of EpiPen price increases, one must address the question of what specific barriers to competition exist in the short run and the long run. If no barriers to entry existed for producers, they would have instantaneously responded to higher EpiPen prices with similar products aimed at the same consumers.

EpiPen producers don't have access to scarce resources or superior technology. Other drug makers also have the ability to engage in large scale drug production, so the argument that new production lines take time to implement only carries short term explanatory power. That is, a drug maker could only increase prices for a specific drug for a short period of time. Dramatically increasing their prices risks long term damage to the drug maker's public image which risks their relationship with consumers in other product markets.

The chief barrier to competition in the pharmaceutical industry is government regulation – In many forms. Patents, issued by the United States Patent and Trademark Office offer producers limited term monopoly rights to the production of a good. The US government purposefully restricts short term producer competition in order to incentivize long run innovation. If we were to the point where we had invented all there was public benefit to invent, disbanding the patent system would increase competition and consumer surplus. We do not yet live in such a world, and reducing the economic returns to patents risks diminished research and development in the pharmaceutical industry.

The FDA has to approve or license the production and sale of pharmaceutical drugs in the United States. The longer time (and financial burden) it takes to gain FDA approval for drug production to commence, the less competition pharmaceutical producers face in the short run which gives them increased pricing power thereby reducing consumer surplus.

Lastly, government monopolistic regulations themselves can contribute to the lack of competition. In the case of EpiPen, many state and local governments mandated that schools stock epinephrine. Some of these governments entered into agreements with Mylan (the producer of EpiPen) that they not buy from EpiPen's competitors.

Policies Designed to Lower Barriers to Competition in the Pharmaceutical Industry

As there are three specific factors that reduce long run competition in the pharmaceutical industry, reforms proposed to successfully increase competition in the pharmaceutical industry must specifically address one of these three factors: patent law, the FDA regulatory process, and direct government involvement in drug markets.

Patent reforms could include increasing the innovation bar necessary to qualify for patent protection. Is changing a pill from a daily pill to a twice a week pill really worthy of a patent extension if it decreases consumer surplus? At a minimum, the patent office should be required to do a cost benefit analysis before granting patent extensions.

Increase the speed at which generic drugs are approved by the FDA. While the approval process for generics is shorter than for new drugs, the FDA could be incentivized to use their scarce resources in ways that maximize consumer surplus. The FDA could be required to do a cost benefit analysis regarding their usage of scarce inputs. This would work to expedite the very drugs whose benefit to consumer surplus are the greatest.

Don't allow agents of the public sector to pick which specific producer gains monopoly access to a public market. Analysis by Best Practices LLC. Indicates that the most effective ways for drug makers to increase profits are through patent extension and large volume purchaser contracts. By eliminating public officials' ability to engage in exclusive drug deals, one can ensure increased competition in the pharmaceutical industry.

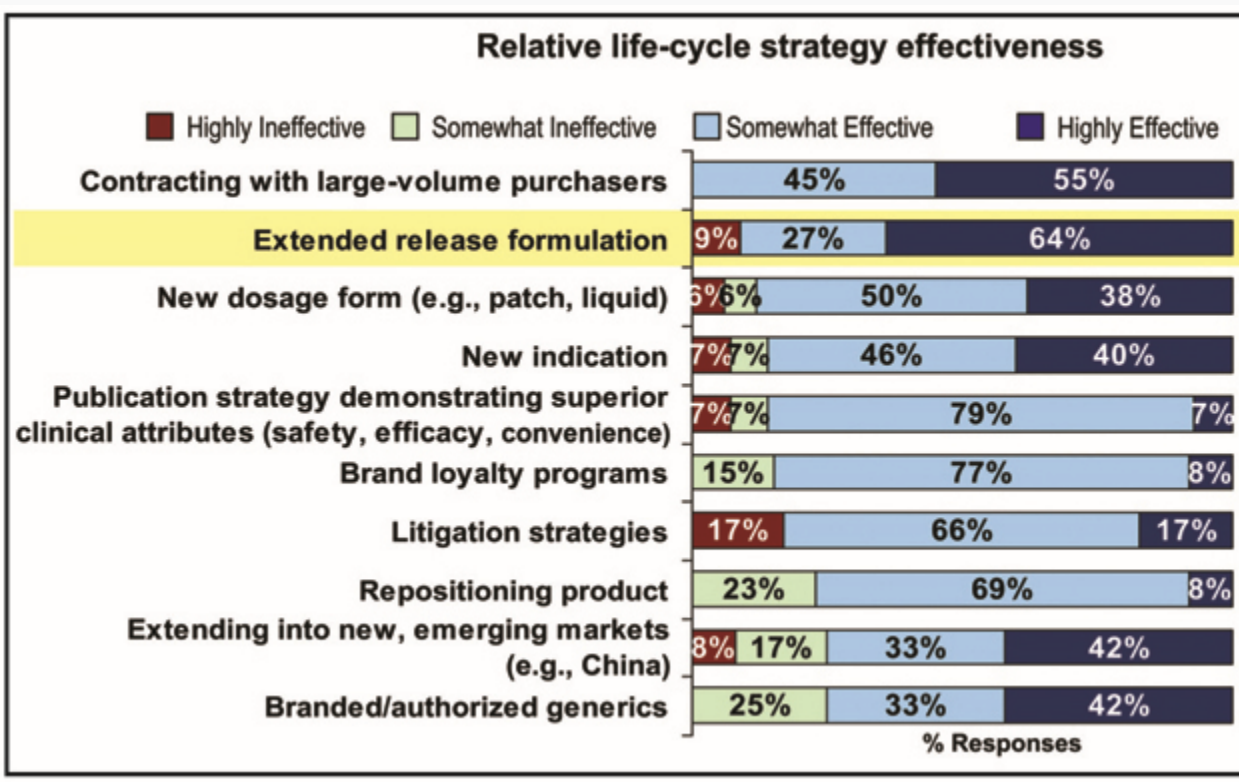


Fig. 1. Extended-release formulation is rated as one of the most effective methods of extending the life cycle of a drug. Credit: Best Practices LLC

To summarize: competition is good more competition is better, the chief barrier to increased competition in the pharmaceutical industry is government, policies designed to lower drug costs and increase consumer surplus need to begin with regulatory reform.