Simulating the Impact of Price Regulation on Pharmaceutical Innovation

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Abstract

Background: Because pharmaceutical price controls fall outside the domain of historical experience in the US, standard retrospective statistical analyses of firm- and/or industry-level data are not appropriate for studying the long-run impact of price controls on pharmaceutical innovation. Simulation modeling, however, can be used to address this issue.

Objective: To examine, through simulation experiments, the long-run impact of several hypothetical US price-control policies on pharmaceutical innovation; a computer simulation model of pharmaceutical competition and innovation was developed.

Study design: Using the most current economic data available, a hypothetical pharmaceutical industry was created. This industry was formulated to reflect many of the relevant aspects of innovation and competition found in today’s global pharmaceutical industry. This industry was then simulated over a 50-year time horizon, under several different price-control scenarios, in order to better understand the quantitative implications price regulation may have on pharmaceutical innovation.

Main outcome measures and results: The primary outcome of interest in this study was pharmaceutical innovative output. Because pharmaceutical firms finance their research and development (R&D) with internally generated funds (after-tax sales revenues), price controls in the model have the effect of reducing R&D investment, and therefore innovation. This was measured by two variables: annual innovative productivity (the annual number of drugs produced by the industry) and cumulative innovative productivity (the total number of drugs produced by the industry over the 50-year time horizon studied). Under a system of public-utility type, cost-based price controls, annual innovative productivity in the model fell by between 67 and 73% relative to baseline (the model without price controls); cumulative innovative output fell by between 30 and 37%.

Simulation experiments were also run assuming less extreme forms of pharmaceutical price regulation. These experiments produced smaller reductions in innovative output: annual and cumulative innovative productivity fell by between 21 and 49% and 6 and 24%, respectively.

Conclusion: The regulation of pharmaceutical prices in the US could have a precipitous effect on pharmaceutical innovation in the long run. Careful consideration must be given to any new policy that advocates imposing controls on pharmaceutical prices. Long run costs – in terms of forgone pharmaceutical innovation – must be weighed against any short-term benefits price regulation may impart.
such, firms depend critically on the revenues generated by new drug sales to fund ongoing and future R&D; price controls, opponents argue, would therefore have a precipitous effect on innovation by substantially curtailing R&D investment. It is on this latter point that this paper is focused.

Because pharmaceutical price controls fall outside the domain of historical experience in the US, standard retrospective statistical analyses of firm- and or industry-level data are not appropriate for studying the long-term impact of price controls on pharmaceutical innovation. Simulation modeling, however, can be used to address this issue.

In this article, a computer simulation model of pharmaceutical competition and innovation is presented. More specifically, the 50-year evolution of a hypothetical pharmaceutical industry under multiple price-control scenarios is simulated. The objective of these simulation experiments was to better understand the quantitative implications of price regulation on pharmaceutical innovation. While the industry simulated in this study is a hypothetical one, it does, nevertheless, reflect many of the relevant aspects of pharmaceutical innovation and competition found in today’s global pharmaceutical industry.

**Pharmaceutical Innovation: A Brief Overview**

Pharmaceutical innovation is a dynamic scientific and economic process with a number of highly unique characteristics. Unlike other forms of industrial innovation, for example advances in technological and manufacturing processes, the output of pharmaceutical innovation is almost exclusively new drugs. Driving innovation in this industry is R&D, which is characterized by long development times, high costs, and low probabilities of technical success. The returns to innovation in this industry are also very distinctive: only a small fraction of FDA-approved drugs will be successful from an economic perspective, the rest will generate returns that fail to cover the average cost of R&D.\(^{[1,2]}\) For the small percentage of drugs that are economically successful, however, the returns can be substantial and generate considerable profits for the firm.

This highly stochastic nature of the pharmaceutical industry – both from a drug development and product success perspective – makes simulation modeling a particularly appropriate methodology for studying the implications of price regulation on innovative output. Importantly, recent research in the areas of drug development costs and the distribution of drug returns has accelerated, and as a result very good data are now available for use in developing a computer simulation model – one with reliable parametric inputs. A brief summary of the key findings from this research is provided in the sections entitled: The Scientific Process: Development Times and the Probability of Technical Success, Research and Development (R&D) Costs of Introducing a New Drug, and Returns to Pharmaceutical R&D and the Cash Flow Cycle.

**The Scientific Process: Development Times and the Probability of Technical Success**

The pharmaceutical R&D process is one of discovering, developing, and bringing to market new ethical drug products. For an investigational compound to ultimately make it to market, it must successfully pass through discovery research, preclinical testing in animals, clinical testing in humans, and receive FDA approval. Despite dramatic advances in biomedical research, this is still largely a trial-and-error process.

For the successful drug candidate – the one that eventually makes it to market – this process takes between 12 and 15 years.\(^{[3,4]}\) On average, a compound will spend 6 years in discovery and preclinical research, 6 years in clinical research, and approximately 1 year under FDA review. This R&D process, along with a recent estimate of compound attrition rates, is illustrated in figure 1.

**Research and Development (R&D) Costs of Introducing a New Drug**

Several factors play a role in determining the cost of discovering and developing a new drug. These factors, and the methods used to estimate them, are briefly discussed in this section.

Theoretically, the cost of bringing a new drug to market must incorporate expenditures on failed – as well as successful – R&D projects. Without a priori information as to which projects will fail and which projects will succeed (and become FDA-approved drugs), it is impossible for firms to avoid the cost of research failures. Furthermore, because the overwhelming majority of R&D projects ultimately fail, these costs are quite considerable. Hence, the cost of developing a drug is more than the sum of expenditures on the successful drug’s R&D program: the true cost must include expenditures on failed and abandoned R&D programs too. Given the inter-temporal nature of pharmaceutical R&D investment, the timing of the investment expenditures is also an important determinant of the cost of developing a drug. This is