An Ounce of Prevention or a Pound of Cure? Short- and Long-Run Effects of Pharmaceutical Patents on U.S. Health Care Expenditures

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ABSTRACT: This study examines the relationship between pharmaceutical R&D and health care expenditures, distinguishing between the short- and long-run impacts. To measure these relationships quantitatively, we focus on patents as a key factor driving the costs of pharmaceuticals, and develop a structured vector autoregressive (SVAR) model to measure the social rate of return to pharmaceutical research as protected by patents. We conclude with unambiguous results that pharmaceutical patents are not correlated with higher short-run prices in any measure of medical costs. They are associated with higher long-run prices in pharmaceuticals themselves, but with lower long-run prices in the aggregate medical sector which includes pharmaceuticals as a component part. Further, the TRIPS Agreement and Hatch-Waxman Act to enable generic competition have both been demonstrably effective at lowering prices across the spectrum of medical sector prices. We conclude that pharmaceutical patents may be economically medicinal themselves, acting as the ‘ounce of prevention’ that saves a ‘pound of cure’, the cure which would come in the form of even higher costs elsewhere in the medical sector.

KEYWORD: patent, pharmaceutical, health, TRIPS, Hatch-Waxman

I. INTRODUCTION

Since 1992 the pharmaceutical industry has witnessed radical changes in its economic climate, as a direct result of major increases in U.S. health care expenditures. In 2007, the United States spent more per capita on health care than any other nation in the world [1]. Total national health expenditures rose 6.9% that year alone, twice the rate of inflation, to average $7,600 per person [2]. Rising expenditures have clearly put a huge drain on the public budget while creating opportunity for the pharmaceutical industry: pharmaceutical sales in the U.S. are projected to reach half a trillion dollars by 2012 [3]. In fact, prescription drugs are projected to be the fastest-growing health sector through 2013 [4].

Behind much of these expenditures is research. In 2007 the industry spent $58.8 billion on research and development (R&D), adding to the array of more than 2,700 medicines in development for nearly 4,600 different indications [5]. For example, new oncology drugs are finally fulfilling the promise of improved outcomes for millions of patients. The market for cancer-related pharmaceutical products has doubled in the last five years, and there are now more cancer treatments in late-stage development than in any other therapeutic area [6].

Potentially, pharmaceutical research could have a positive or a negative effect on health care spending [7]. Like any investment expenditure, research costs are undoubtedly passed along to consumers, but better treatment protocols could lower health care costs in the long-run. So it seems wise to ask the question of how long the payback period is on pharmaceutical research/investment. What is the social rate of return? Does the U.S. health care system distort incentives to research away from lowering health costs and toward other objectives instead?

The relationship between pharmaceutical R&D and health care expenditures has obviously been investigated before. This study aims to draw attention to an important yet hidden aspect of that interaction. As we will point out, the effects of pharmaceutical innovation on health care spending vary dramatically from the short- to long-run. To measure these relationships quantitatively, we will focus on the impact of patents as a key factor driving the costs of pharmaceuticals, as they confer exclusive rights to production and therefore enable short-term monopoly pricing. In order to compare these short-run and long-run impacts, we develop a structured vector autoregressive (SVAR) model to measure the social rate of return to pharmaceutical research as protected by patents.
We conclude with unambiguous results that pharmaceutical patents are not correlated with higher short-run prices in any measure of medical costs. They are associated with higher long-run prices in pharmaceuticals themselves, but with lower long-run prices in the aggregate medical sector which includes pharmaceuticals as a component part. Presumably, higher pharmaceutical costs are lowering hospitalization costs more than proportionately. Further, the TRIPS Agreement and Hatch-Waxman Act to enable generic competition have both been demonstrably effective at lowering prices across the spectrum of medical sector prices. We conclude that pharmaceutical patents may be economically medicinal themselves, acting as the ‘ounce of prevention’ that saves a ‘pound of cure’, the cure which would come in the form of even higher costs elsewhere in the medical sector.

The following section will review the literature on this topic, while Section III will describe our dataset. Section IV’s presentation of the model foreshadows the results in Section V. The final section concludes with implications for policy-makers and future academic study.

II. LITERATURE

Health care spending is commonly believed to be influenced by three factors primarily: rising prices, improving technology, and an aging population [8]. According to CBO analysis however, over the last fifty years the aging of the population had a relatively small impact on overall health spending growth. A general consensus among top analysts [9, 10, 11, 12] suggests that a significant share of annual real health care cost growth can be attributed to medical technology, predicated on an analysis of the “residual”: the unexplained variance in cost growth. In essence, since an aging population, health insurance, physician-induced demand, defensive medicine, administrative costs, and the costs of caring for the terminally ill in the last year of life do not account for large increases in spending growth, the cause must be the residual or the “march of science and the increased capabilities of medicine” [13].

The march of science is fueled by incentives to innovate, often created through the protection of intellectual property (IP), where IP is defined as an intangible asset such as skill, knowledge or information. In the pharmaceutical industry, patent incentivize firms by granting exclusive rights for twenty years to the holder of a novel, non-obvious, useful invention. Exclusivity applies to production, use or sale (including imports), effectively compensating the innovator for the risky investment in R&D with limited-term monopoly profits via prices higher than perfect competition would engender. The rationale is that it allows firms to collect profits sufficient to, a) cover high fixed costs of development and FDA regulation, b) induce more R&D within the firm, c) account for profits lost from new innovation being legally integrated into the public domain, and d) compensate for the risks of research.

Monopolistic pricing necessarily leads to higher health expenditures, because the demand for pharmaceutical products is clearly inelastic [14]. Since price increases will categorically lead to higher spending in the health care industry, these two terms will be used interchangeably within this study.

Expenditures on pharmaceuticals will therefore clearly depend on the duration of market exclusivity afforded by IP law. For patents filed prior to June 8, 1995, the US term for a patent was either 20 years from the earliest claimed filing date or 17 years from the issue date, whichever is longer [15]. Patents filed on a date later than June 8th comply with the worldwide patent length standard of twenty years from the filing date (a standard within the World Trade Organization, known as Trade Related Aspects of Intellectual Property Rights, or TRIPS).

Extensions to patent duration are made in three special cases [16]. In the cases of drugs to treat rare diseases and conditions affecting fewer than 200,000 patients, the Orphan Drug Act of 1983 grants up to seven extra years, and in the cases of pediatric drugs, the Food and Drug Administration Modernization Act of 1997, grants up to six extra months.

The most notable extensions are made under the Hatch-Waxman Act [17]. Officially entitled the Drug Price Competition and Patent Term Restoration Act of 1984, the Hatch-Waxman Act increases the life span of a patent by up to five extra years to restore patent life lost during the pre-market regulatory process. A second major provision of the law facilitates the entry of generic competitors after patent expiration [18]. Under the new Act, a generic drug company need only submit an Abbreviated New Drug Application (ANDA), requiring a demonstration of bioequivalence to the pioneer product. Grabowski and Vernon examine the net effect of R&D incentives that simultaneously promote generic competition and extend patent life, finding that the net effect is indeed positive for three cases.
Despite the assertion that technological change has accounted for the bulk of health care cost increases, there is no doubt that such innovation has made invaluable improvements to quality of life [19]. Vast literature on this side of the spectrum examines the benefits of patent-induced innovation in the long run. For example, Manton and Gu find a seven year increase in life expectancy between 1950 and 1990 [20].

Kim et al. [21] conclude that one reason for U.S. health spending is quite simply the public’s commitment to innovation and willingness to pay. Murphy and Topel [22] develop methods for valuing health improvements based on individuals’ willingness to pay. Their results indicate that past health improvements have been enormously valuable, with gains in life expectancy over the twentieth century worth more than $1.2 million per person, and rising longevity contributing about $3.2 trillion per year to the national wealth between 1970 and 2000. Compared to the $60 billion spent per year in applied health research, they suggest that progress is too slow and spending too low.

Lichtenberg [23] concludes similarly. His most conservative estimates indicate that the use of post-1990 drugs in 2002 reduced the number of pre-retirement life years lost by roughly one and a half million. Based on prescription drug expenditures and the reduced costs of hospitals and nursing homes, he concludes that the net cost per life-year saved before age 75 was a reasonable $15,974.

We propose to add to this literature’s discussion in the following way, adopting an argument from Charles and Williams [24]. Suppose that tomorrow we reduced the production of new innovation, leaving the current stock of ideas unchanged. We define the social rate of return to pharmaceutical innovation as the gain in expenditures associated with this change. We believe that an SVAR model will serve this new question well, and we will outline our own application of this technique after presenting a summary of our data.

III. DATA

Our goal in this paper is to model the time path of prices, accounting for natural short- and long-term relationships while identifying factors that may have caused one-time changes in price level or inflation rates. We use monthly data for 381 observation periods from 1978 through 2007, all adjusted to a base period of 1982-84.

We choose to measure prices in three separate manners. First, Medical Care Prices (mCPI) are measured by the consumer price index of medical care goods and services, designed by the Bureau of Labor Statistics to reflect inflation at the retail level based on a constant-quality market basket of medical goods and services [25]. The index includes four main divisions: medical care commodities, including prescription drugs; medical care services, including physician and dental; hospital and related services; and health insurance. Second, we consider hospital and related services (hCPI) separately, to determine whether there is a trade-off between pharmaceutical and hospital prices, since Lichtenberg [26] and others show that trade-off clearly in expenditures. Third, we consider prescription drugs explicitly (pCPI), to test whether IP affects pharmaceuticals more clearly than other medical costs/prices. The pCPI and hCPI will also be used as explanatory variables as well, since they are component parts of the mCPI.

Innovation is measured by the number of issued patents. There is a long tradition of using patents as imperfect indicators of innovation [27, 28, 29] because they represent an externally validated measure of technological novelty, and they confer property rights on the assignee so have economic significance [30]. While in some sectors, patents may be less used compared to trade secrets, patents are widely and consistently used in chemicals relative to most other economic sectors [31, 32]. We specifically consider the number of patents issued monthly between 1978 and 2007 to U.S. patent classes 514 and 424, both titled ‘Drugs, Bio-Affecting and Body Treating Compositions’. All data are drawn from the U.S. Patent and Trademark Office.

In the short-run, we expect increases in innovation to increase prices on prescription drugs, and by extension, prices on all medical goods. In the long-run we can expect the opposite: reduced prices for prescription drugs and medical goods because of the expiration of patents and increased competition with generic drugs [33], along with the possibility of advances in medicine that replace less cost-effective drug treatments.

We expect a negative correlation between hCPI and patents in both the short- and long-runs because prescription drugs may be substitute goods for hospital services.

The Food and Drug Administration (FDA) records generic drug approvals by date [34], and we use counts of those by month as a control variable. For all price variables in the short- and long-runs, we expect that more generic drugs will be associated with lower prices.
We also include two policy variables in our analysis, to reflect the signing of the TRIPS and Hatch-Waxman legislation respectively. Both are constructed as dummy variables taking the value of unity for the period under which the policy is in force. For all price indices, we expect TRIPS to have an inflationary effect in the short-run (due to an effective three-year extension of monopoly rights) and a deflationary effect in the long-run (due to an increase in the incentives to innovate for even more spectacular increases to life expectancy or cost-effectiveness of treatment plans). We expect similar impacts from Hatch-Waxman, as it was designed to increase R&D (higher costs to pass through in the short-run) but increase generic competition and improve cost-efficiency (lower costs in the long-run).

A summary table of the variables is presented in Table I, along with the expected signs of estimated coefficients. Notice that the range and variation for the three price indices is fairly similar, with a little wider dispersion in the health cost index. The number of patents varies quite widely, from zero to 63 patents in a given period. Generics similarly range widely, from zero to 1532 patents in a given period. Recall that the TRIPS and Hatch-Waxman variables are dummys, so their presentation is slightly different in the table below.

IV. A STRUCTURED VECTOR AUTOREGRESSIVE MODEL

The VAR was initially formulated by Sims [35] who suggested the need for an econometric model to capture the evolution and interdependencies between multiple time series. It was developed as a theory-free method to estimate economic relationships, as an alternative to the identification restrictions in structural models. However, successive generations of economists have imposed small structural constraints on VAR systems, for example to indicate known uni-directional causality. We use that established technique here.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>St. Dev.</th>
<th>Max</th>
<th>Min</th>
<th>Expected Impact on costs in</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mcpi</td>
<td>200.85</td>
<td>90.89</td>
<td>357.66</td>
<td>58.90</td>
<td></td>
</tr>
<tr>
<td>hCPI</td>
<td>244.37</td>
<td>138.13</td>
<td>515.68</td>
<td>51.80</td>
<td></td>
</tr>
<tr>
<td>pCPI</td>
<td>216.21</td>
<td>99.93</td>
<td>374.39</td>
<td>58.90</td>
<td></td>
</tr>
<tr>
<td>Patents (pats)</td>
<td>467.36</td>
<td>247.58</td>
<td>1532</td>
<td>99</td>
<td>+*</td>
</tr>
<tr>
<td>Generics (gens)</td>
<td>15.04</td>
<td>12.04</td>
<td>63</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>TRIPS</td>
<td>0.45</td>
<td>211</td>
<td>1</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>Hatch-Waxman (HW)</td>
<td>0.81</td>
<td>73</td>
<td>1</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>

* expected sign is negative for hCPI but positive for mCPI and pCPI.

As dependent variables we are using medical care prices instead of costs, making the assumption that households spend out-of-pocket on goods and services. We are considering out-of-pocket expenditures to be the measure of interest, although policymakers may easily make the valid point that in fact total expenditures are more important from a policy perspective.

Another critical assumption in many studies is the question of functional form, and propose an ECM (VAR) process [36, 37] to inform the analysis from the linearized first-order effects regardless of the underlying true functional form. Each section includes a long-run equilibrium equation (1.1, 2.1, and 3.1) and a short-run dynamic (lagged) equation (1.2, 2.2, and 3.2):

\[
(1.1) \, p_{CPI} = \beta_{h,1} + \beta_{h,2} pats + \beta_{h,3} TRIPS_{t} + \beta_{h,4} HW_{t} + \beta_{h,5} gens + \beta_{h,6} time + u_{h,1}
\]

\[
(1.2) \, \Delta p_{CPI} = \delta_{h,1} + \sum_{s=0}^{\infty} \delta_{p,s} \Delta pats_{t-s} + \sum_{s=0}^{\infty} \delta_{p,s} \Delta TRIPS_{t-s} + \sum_{s=0}^{\infty} \delta_{h,s} \Delta HW_{t-s} + \sum_{s=0}^{\infty} \delta_{h,s} \Delta gens_{t-s} + \delta_{h,6} time + \varepsilon_{h,1}
\]

\[
(2.1) \, h_{CPI} = \beta_{h,1} + \beta_{h,2} pats + \beta_{h,3} TRIPS_{t} + \beta_{h,4} HW_{t} + \beta_{h,5} gens + \beta_{h,6} time + \beta_{h,7} pCPI_{t} + u_{h,1}
\]
(2.2) \[ \Delta \text{hCPI}_t = \delta_{h,1} + \sum_{s=0}^{\infty} \delta_{h,2,s} \Delta \text{pats}_{t+s} + \sum_{s=0}^{\infty} \delta_{h,3,s} \Delta \text{TRIPS}_{t+s} + \sum_{s=0}^{\infty} \delta_{h,4,s} \Delta \text{HW}_{t+s} \\
+ \sum_{s=0}^{\infty} \delta_{h,5,s} \Delta \text{gens}_{t+s} + \delta_{h,6} \text{time}_t + \sum_{s=0}^{\infty} \delta_{h,7,s} \Delta \text{pCPI}_{t+s} + \delta_{h,8} \Delta \text{HW}_{t+s} + \epsilon_{h,t} \]

(3.1) \[ m\text{CPI} = \beta_{m,1} + \beta_{m,2} \text{pats}_t + \beta_{m,3} \text{TRIPS}_t + \beta_{m,4} \text{HW}_t + \beta_{m,5} \text{gens}_t + \beta_{m,6} \text{time}_t + \beta_{m,7} \text{pCPI}_t + \beta_{m,h \text{CPI}} + u_{m,t} \]

(3.2) \[ \Delta \text{mCPI}_t = \delta_{m,1} + \sum_{s=0}^{\infty} \delta_{m,2,s} \Delta \text{pats}_{t+s} + \sum_{s=0}^{\infty} \delta_{m,3,s} \Delta \text{TRIPS}_{t+s} + \sum_{s=0}^{\infty} \delta_{m,4,s} \Delta \text{HW}_{t+s} \\
+ \sum_{s=0}^{\infty} \delta_{m,5,s} \Delta \text{gens}_{t+s} + \delta_{m,6} \text{time}_t + \sum_{s=0}^{\infty} \delta_{m,7,s} \Delta \text{pCPI}_{t+s} + \delta_{m,8} \Delta \text{HW}_{t+s} + \epsilon_{m,t} \]

Notice that we model long-run costs to depend only upon ‘smaller’ concepts of cost (i.e. medical care prices depend on hospital and pharmaceutical prices, hospital prices depend on pharmaceutical prices but not overall medical care prices, and pharmaceutical prices do not depend on either larger concept of price). In the short-run, we permit some impact of lagged own-price values (e.g. past pharma prices may have an impact on today’s pharma prices), but otherwise retain the same small-to-big accumulation structure of costs.

We include all exogenous variables in each equation, permitting patents, the TRIPS Agreement, the Hatch-Waxman Act, the number of generic drugs and a time trend to potentially impact each level of costs.

V. ESTIMATION RESULTS

The appropriate lag length in each regression was determined via the Akaike Information Criterion (AIC). Both pCPI and hCPI models settled on a 13 month lag, with a slightly longer 16-month lag for the mCPI model. There are a number of surprises in the results below, alongside some comforting regularities.

Of greatest interest for this paper is the role that patents play in health costs at each level of aggregation. In the short run, there is no evidence that patents play any statistically significant role in price changes at any level of aggregation. In the long run, patents are (unsurprisingly) associated with higher prices for pharmaceuticals. The results conclude that an additional thousand pharmaceutical patents would raise long-run pharma prices by 2.79 points, or roughly 0.5 percent at the sample average. Considering that a typical month sees 467 pharma patents granted, patents overall correspond to a 0.60 percent average effect on pharmaceutical prices.

There is an insignificant direct impact of patents on hospital costs, but the indirect effect (via pharma prices in the VAR) is negative, restraining hospitalization costs as new pharmaceutical products reduce the severity and duration of hospital stays. Combined, an average monthly number of pharma patents would result in a net 0.41 percent increase in hospital costs.

The long-run effect of patents on overall medical costs is negative in a direct sense, but that is offset by the positive indirect impacts via pharma costs. Our empirical results suggest that the long run net effect of pharma patents would be a slightly deflationary -0.49 percent in an average month.

This combination of results is interesting for several reasons. First, there appears to be no evidence for the claim that patents raise pharmaceutical prices in the short term, but there is strong support for the claim that they raise prices in the long run instead. This pairing of results is consistent with competition between oligopolists, where short-run competition leads to prices that do not cover the long-run costs of new product development or advertising. However, those costs of market development and advertising must be incorporated in the long-run, and in fact raise the cost curves for all firms in the industry.
ably because new products reduce the cost of medical care in the aggregate. 

Second, pharmaceutical patents appear to be desirable for consumers in the long run via overall health care costs, presumably because new products reduce the cost of medical care in the aggregate. After all, presumably that is one of the primary reasons to engage in pharmaceutical research (alongside increased quality of outcomes).

The TRIPS Agreement, Hatch-Waxman Act and the increase of generic varieties have all lived up to their original intent, namely to reduce health costs at every lever in the long run. Presumably all three have done so by increasing competition among providers of patentable pharmaceutical products. Notice, however, that none of the three has any impact on any price levels in the short run, aside from the significant negative effect of more generic competition on pharmaceutical prices in particular. Even this effect is empirically very small, with an additional generic competitor lowering prices in pharmaceuticals overall by a mere 0.015 price index points (and potentially a little more via the indirect effect of pharma prices via the VAR).

To be concrete, our results suggest that the TRIPS Agreement is associated with a three point lower cost index in pharmaceuticals. Hatch-Waxman has been much more effective, associated with a 4.4 point decline in the pharma CPI and an additional 0.1 point decline for every generic that the Act enabled. The effects of Hatch-Waxman are more than twice as potent in the hospitalization cost measure of prices, with a more than 10-point decline in costs. Overall medical sector costs naturally show a result between these two, with TRIPS accounting for a 1.2 point decline in costs and Hatch-Waxman accounting for a 5.1-point decline in costs (plus the marginal effect of each additional generic).

Our results further suggest that at least some health-related costs are mean-reverting or self-containing in nature. For example, increases in pharmaceutical prices are associated with a subsequent decrease in hospitalization costs in the long-run, and are associated with subsequent declines in all variations of health costs.
in the short-run. While long-run overall medical costs rise with rises in the constituent parts, in the short run overall medical costs reverse the direction of previous changes in pharmaceuticals, hospital and even overall medical costs.

So why then are health costs rising? Our evidence suggests that there is a powerful time trend underlying the rise, one that naturally has little impact on short-run prices but has enormous and statistically significant impact on long-run costs. Pharmaceuticals are seeing the largest period-to-period gain in prices based on trend (0.65 CPI-points per month), followed by hospitalization costs (0.56 point per month). By the time the trend hits overall health costs, the impact has been cut in half by the combined impacts of patents and legislation like Hatch-Waxman, but that half is still large enough to raise overall medical costs by 0.32 point per month due to direct trend alone. That inertial effect amounts to 4.71 points per year of increase in overall medical costs once the VAR effects of pharma prices and hospitalization prices are included. Any policy to curb costs is fighting against that starting point.

VI. CONCLUSION

The United States health care system is defined by high and rising expenditures, uncontrolled costs, and system inefficiencies. Pharmaceutical patents have been blamed in part as the culprit for this outcome, and this study has attempted to shed more light on the ways in which prices (or costs) in the medical sector evolve over time.

We find very little evidence to suggest that patenting rates are in any way correlated with prices. Instead, we find that most inflation is inertial. Pharmaceutical patents are not at all correlated with short-run prices, and while they are associated with higher long-run pharma costs they simultaneously are associated with lower long-run medical costs overall. Policies aimed at encouraging competition, such as the TRIPS Agreement and Hatch-Waxman Act with ensuing generic competitors, have effectively counteracted any increases due to pharmaceutical patenting.

There is the strong possibility that our measure of patents is simply inadequate. Perhaps the ‘value’ of a patent, rather than their frequency, is essential for a robust analysis of this sort. An extension to this work will pursue that avenue of research, targeting the ongoing debate in the innovation literature about how to measure ‘value’ or impact without unintentionally biasing the result. Unfortunately, the available measures of patent value are problematic at best, relying on surveys of experts, patent renewal records, patent auction prices or academic citation records. Each carries a list of inconvenient concerns.

As academics concerned about health care issues, and as policymakers designing a revision to US health care policy in part to control costs, we offer these results. Innovation has long been the engine of US economic growth, a fact as true in health care as in any other sector. While innovation comes at an obvious cost, we have shown here that patents given as incentives to innovators in pharmaceuticals are not the driving force of recent medical inflation. Pharmaceutical research is the proverbial ‘ounce of prevention’ which prevent the need for a ‘pound of cure’ in the form of even higher hospitalization and overall medical sector costs.

We therefore encourage our community to think carefully about retaining the financial incentives to innovate where they stimulate long-run benefits to our society in terms of care or lower costs. Instead, let us target the inertial roots of medical inflation, whose roots apparently do not reside with patented innovations.

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