5

HITTING THE ROOF: CLINTON'S MEDICARE PRESCRIPTION DRUG PROPOSAL AND ITS EFFECT ON R&D INCENTIVES FOR PHARMACEUTICALS[1]

John McCoy

President Clinton's proposed prescription drug benefit for Medicare is examined with a view toward its effects on research and development incentives in the pharmaceutical industry. A simulation model based on Grabowski and Vernon's analysis of the 1984 Patent Term Restoration Act is developed. The model provides parameter-based estimates for patent extensions that might compensate pharmaceutical firms for various levels of price cuts. It also shows that any political tradeoff that tries to maintain R&D incentives by exchanging price cuts for patent extensions will run up against a fundamental limit. Policy considerations for alternate deals are discussed.

The stakes were high when Congress recently considered proposals to provide retirees with prescription drug coverage through the Medicare program. Democrats hoped to use the popular issue to take back the majority in the 2000 election. Republicans, wary of expanding a federal entitlement program, looked for ways to neutralize the assault.

In the Democrats' corner were senior citizens, whose prescription drug bills make up a rapidly growing share of their out-of-pocket health care

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costs. Prescription drug coverage was not included in the defined benefit when Medicare was created in 1965, as drugs were a relatively minor part of health care practice at the time. Since then, the number of prescription drugs has grown tremendously, as has their importance in modern medicine. Moreover, poorer seniors with the least access to supplemental health coverage often pay the highest retail prices. The lack of drug coverage is a growing hole in Medicare's safety net. Democrats sensed a winning issue and made it a central campaign theme.

In the Republicans' corner was the multibillion-dollar pharmaceutical industry. Although drug companies could expect to increase sales under the new program (which would bring new money into the market), industry leaders worried that the federal government would use some form of monopsony buying power to enforce price cuts. Worse, if a schedule of discounted Medicare prices were made public, the drug companies' other customers might demand similar breaks. Republicans sensed a severe danger in being caught on the wrong side of this issue. To prevent being clobbered at the polls, their strategists advised them to tell seniors that they, too, had a plan to provide prescription drug coverage. With a wink to the pharmaceutical industry, Republicans proposed to provide seniors with subsidies that would allow them to buy private-sector coverage through insurance companies. Never mind that the insurance industry said such a plan wouldn't work.

The battle lines were drawn: seniors vs. the drug industry. An organized, (potentially) angry voting bloc versus a deep-pocketed industry with its army of lobbyists and piles of campaign cash. It was a true clash of titans. In the end, the Republicans succeeded – no prescription drug plan was enacted – but at a cost: the Democrats fell just a few seats short of retaking Congress. This outcome, along with the continuing issue of retiree health care costs, practically guarantees that this debate will resurface soon. I propose to examine the policy debate and its underlying economic structure to explore some options for a future deal. The math suggests that unless Congress commits to paying generous prices, the drug industry's opposition to a government-administered prescription drug benefit is not likely to fade.

The Public Debate

Over the past two years, the public has heard quite a lot about this issue. The pharmaceutical industry took a lesson from the insurance lobby, whose "Harry and Louise" ads helped sink the Clinton health care plan in 1994. For the Medicare battle, American television viewers were intro-

Source: Citizens for Better Medicare

duced to the drug industry's front woman, Flo, a skeptical bottle blonde often spotted with her friends at the bowling alley. Flo is actually a professional actress playing a role, and she claims to represent a group called "Citizens for Better Medicare," which was funded almost exclusively by the pharmaceutical industry (Sarafini and Zeller 1999). Initially in fall 1999, Flo delivered her classic tagline: "I don't want big government in my medicine cabinet." After the Clinton administration applied pressure on the drug industry in early 2000 (Pear 2000), Flo softened her line a bit and said vaguely that Washington should adopt "the right Medicare reforms."

In policy circles, the pharmaceutical industry has a much different message (PhRMA website 2000). Its lobbying wing, the oddly ungrammatical Pharmaceutical Research and Manufacturers of America (PhRMA), points to all the wonderful drugs they have created and notes that price controls would damage their incentive to engage in research and development. This very expensive and financially risky process involves 12 to 15 years of work to bring a marketable drug forward, costing $500 million per drug on average (including the cost of failed research). Even then, most drugs are only modestly successful, and blockbuster drugs are relatively rare. High markups, protected by generous patent terms, are needed to keep entrepreneurs plugging at the problem and provide the next generation of cures.

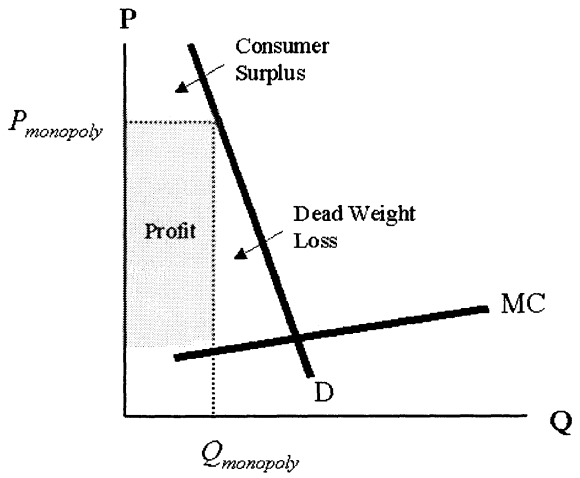
Tacking against the industry, skeptics like Public Citizen – a watchdog organization founded by Ralph Nader – call the industry's profits obscene (Public Citizen website 2000). How risky could the enterprise be, they ask, when pharmaceuticals show up as the most profitable industry in the *Fortune* magazine listing year after year?[2] No one but the firms really know how much they're spending on R&D, and they have an incentive to inflate the figure in public. Some of that $500 million is probably marketing expenses. Nearly all of it generates tax deductions under current law. Moreover, no one keeps reliable track of the billions in public research money that assist both basic research and the development of specific drugs, and no one ensures that the public gets its fair share of the profits from that investment. Most "new" drugs are not pioneering chemical forms that create new therapeutic classes, but rather are "me, too" drugs that chemically resemble existing medicines. Moreover, people across the

border in Canada and Mexico can buy the same drugs for up to 80 percent less – a fact not lost on many border-state politicians.

An Economic Understanding

So how should policy makers sort through all these competing claims? The economics field provides a useful framework for a large swath of the debate. As discussed by Schumpeter and Arrow among others (Viscusi 1998), the issue of innovation and monopoly pricing can be seen a tradeoff between ***static efficiency*** and ***dynamic efficiency***. Innovation is dynamic in that it creates new markets and new social welfare over time. To give entrepreneurs incentives to innovate, patents of appropriate lengths must be granted to generate temporary monopolies. These allow the innovator firm to capture some of the profits (new social welfare) that its effort generates. Otherwise, imitators could swoop in and compete away the entrepreneur's gain, and firms would have little incentive to innovate in the first place.

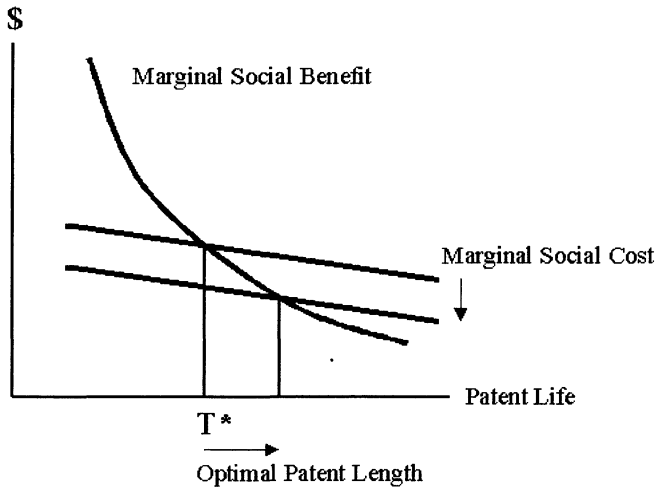
Figure 1
A monopoly drug market featuring low marginal costs and inelastic demand



On the other side, once innovation has occurred, static efficiency wants to push prices down to the marginal cost of production. The monopoly prices we see during the patent term result in dead weight losses that are inefficient for social welfare.

One key variable in this tradeoff is the patent length. Longer patents give us more innovation, but they also prolong monopoly power. This gives rise to the following equilibrium condition (Viscusi 1998):

Figure 2
The tradeoff between static and dynamic efficiency (Viscusi 1998)



Here, the marginal social cost of the deadweight losses (sloping down because of discounting for time) meets the marginal social benefit from the innovations at patent length T*. If we decrease the social costs with price discounts, then we could theoretically remain optimal by increasing the patent length. This idea provides a sense of where optimal patent policy should be set.[3] For the Medicare debate, it would be helpful to know which side of T* we are currently on. If innovation is above the optimal level and our static costs loom large, then price discounts could help restore the balance. If we are near or below optimum, then price discounts could push us further behind, and society would generate too little innovation.

There is just one problem with this approach: No one knows where the curves are (Comanor 1986; Comanor 2000). Econometricians have been unable to reliably model innovation, and the uncertainties of measurement abound (Cohen and Levin 1989). Do you count patents, which can be divided several different ways, or the economic value of those patents? How does one determine the economic value of patents with any reliability? Are there increasing or decreasing returns to scale in R&D produc-

tion? Are process innovations generated differently from product innovations (learning by doing vs. lab work)? What process innovations remain unpatented in order to keep them completely secret, and how much are they worth? How do you deal with spillover effects and synergies? Does market concentration produce more innovation, or is the causality reversed? How much does government spending on basic research contribute to any given private-sector innovation? The list goes on.

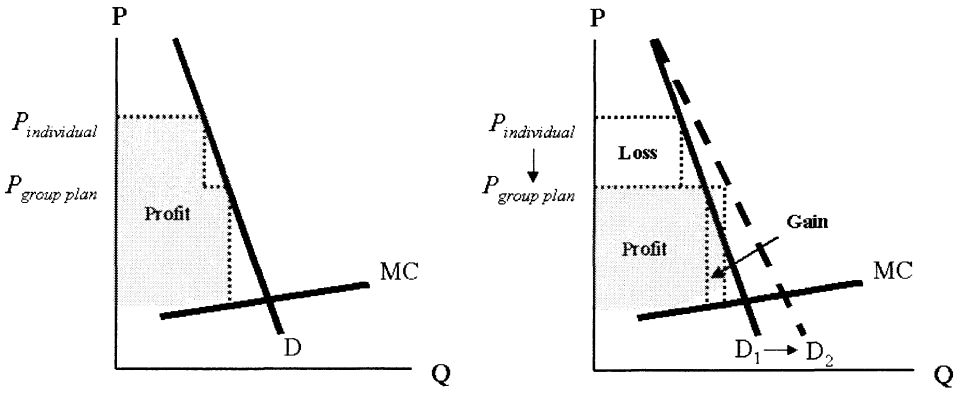
Without a solid estimate of the innovation supply curve, we cannot say how much monopoly profit it takes to produce a given level of social benefit. We do not know which side of T^* we are on, nor can we say much about the size of the effect that changes in profit conditions will have on the amount of innovation produced. Economics can frame the debate, which is important,[4] but it cannot yet provide us with the right answer.

So what can we say about the Medicare question? In the following pages, I will examine the President's proposal more closely and then develop a model that sheds some limited light on the economic viability of any political compromises.

The Proposal

The Clinton administration wanted to add a prescription drug benefit to the Medicare program. As originally conceived, a new entitlement, to be called Medicare Part D, was to be phased in by 2009, costing about $131 billion over ten years, according to Congressional Budget Office (CBO) estimates (CBO 2000). Seniors would pay a new Part D premium, with discounts for people near the poverty line. In exchange, Medicare would pay 50 percent of enrollees' prescription drug costs up to a cap, set to rise to $2,500 at the end of phase-in and then to be indexed for inflation. All told, the plan was expected to save seniors 25 percent off their pharmacy bills, though one can imagine that there would be political pressure to sweeten the deal over time. A key feature of the plan—the one that worried the pharmaceutical industry—was the use of Pharmacy Benefit Management companies (PBMs). These private-sector firms would be contracted to negotiate price discounts through volume purchases and utilization control for seniors who are not currently covered by group plans. The Clinton team made headlines with its finding that individual seniors at the retail pharmacy pay 15 percent more on average than those who get their medicines through managed prescription plans. PBMs were portrayed as a tool to help the victims of price discrimination.[5] In its analysis of the proposal, the CBO essentially guessed that the new Medicare managers could reduce costs by about 12.5 percent, noting that the operations of PBMs had not been worked out in detail.

Figure 3
Possible effect of Medicare Part D proposal on drug firm profitability



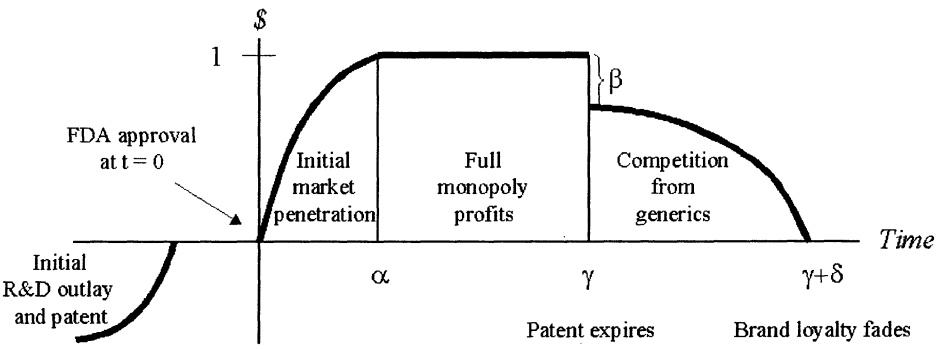
I am working under the assumption that drug makers will lose profits under the deal. Figure 3 shows one scenario where that might occur. Currently, pharmaceutical firms employ a strategy depicted by the left graph: they profitably price discriminate between customers who buy as individuals at the retail pharmacy and those who have access to group plans, whose collective bargaining power gives them access to discounts. A rigorous use of PBMs may shift the industry to the scenario on the right. Here, all Medicare beneficiaries would have access to group discounts and price discrimination would be less viable. The infusion of federal tax money into the market should boost demand, shifting the demand line to the right. Increased attention to price concerns (and generic substitution possibilities) should also pivot the demand curve, making it more elastic. Some of what the manufacturers lose from their inability to price discriminate is made up through increased volume. It is probable that the result will be a small net loss to manufacturers, though they might raise group plan prices to perfectly offset the change.[6]

A Tradeoff Model

While we cannot directly model the effect that Medicare discounts might have on innovation, we can engage in a thought experiment that will give us a sense of how profit levels during the effective patent term relate to the length of that term. Specifically, I am interested in the question: How much of a patent extension would drug firms demand should

Medicare's new PBMs succeed in reducing the firms' profitability? A deal along these lines would parallel the political deal struck in 1984 with the Patent Term Restoration Act. There, drug makers got to extend the effective life of their patents by crediting some of the time it takes the Food and Drug Administration (FDA) to review their drugs (Grabowski and Vernon 1987). In exchange, the law reduced the regulatory burden on generic competitors, allowing them to come in and compete much more quickly and for less cost once the innovator's patents expire.[7] For the sake of argument, this discussion presumes that the goal of policy is to maintain existing innovation incentives. The analysis that follows is a variation on a tradeoff first drawn by Henry Grabowski and John Vernon (1987). The mathematical form of the simulation model is my own, as are any errors in its construction.[8] Whereas Grabowski and Vernon were looking at the tradeoff between the 1984 patent length extension and increased competition from generics, I will attempt to divine a relationship between price discounts and patent lengths that hold overall profits constant.

Figure 4
Life cycle of new drug profits



To specify the model, we start with FDA approval at time zero. Let $\gamma > 0$ be the effective patent length. Let $0 < \alpha \leq \gamma$ be the time it takes for the firm to achieve full market penetration. $0 \leq \beta \leq 1$ is the percentage of the profit that generic competitors immediately compete away, and $\delta \geq 0$ is the time that the branded drug retains market power after the entry of generics.[9]

$$p(t) = \begin{cases} \sin\left(\frac{\pi}{2\alpha}\right)t & 0 \le t \le \alpha \\ 1 & \alpha < t \le \gamma \\ (1-\beta)\cos\frac{\pi}{2\delta}(t-\gamma) & \gamma < t \le \gamma + \delta \end{cases} \quad (1)$$

Integrating the function to get our total profit, we find:

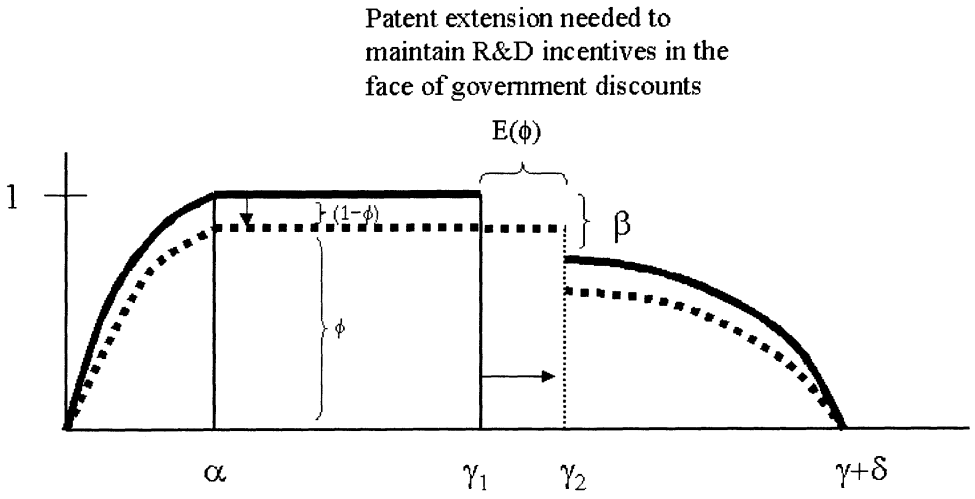
$$\int_0^{\gamma+\delta} p(t)\,dt = \int_0^{\alpha} \sin\left(\frac{\pi}{2\alpha}\right)t\,dt + \int_{\alpha}^{\gamma} 1\,dt + \int_{\gamma}^{\gamma+\delta} (1-\beta)\cos\frac{\pi}{2\delta}(t-\gamma)dt$$

$$= \frac{2\alpha}{\pi} + \gamma - \alpha + (1-\beta)\frac{2\delta}{\pi} = P(\alpha,\beta,\delta,\gamma) \quad (2)$$

Now we have a total profit function in terms of our parameters alone. To make sure our relationships make sense, let's check the partial derivatives of our parameters. $\frac{\partial P}{\partial \gamma} = 1 > 0$ means that a longer effective patent length increases profits. $\frac{\partial P}{\partial \delta} = \frac{2(1-\beta)}{\pi} > 0$ says that the longer the pioneer firm can maintain banded sales against the generics, the higher the profits. $\frac{\partial P}{\partial \alpha} = \frac{2}{\pi} - 1 < 0$says that the longer it takes the firm to get up to full speed on sales, the lower its profits will be. $\frac{\partial P}{\partial \beta} = \frac{-2\delta}{\pi} < 0$ means that bigger generic penetration into the post-patent market lowers profits for the pioneer firm.

Grabowski and Vernon (1987) varied these parameters according to the political deal struck in 1984. There, pioneer firms got some credit for the time it takes the FDA to approve their new drugs, boosting effective patent lives. In exchange, the law simplified the process for generics to gain approval for their own entry into the market, allowing them to come in much more quickly and for much less cost. That deal essentially exchanged more γ for more β and/or less δ). The trade was seen as generally enhancing social welfare, since it eliminated unnecessary barriers to generics. For producers, Grabowski and Vernon found that it probably reduced R&D incentives (profits) on balance.[10]

Figure 5
Discounts vs. patent extensions



For the current Medicare debate, we want to play with the relationship between profits and patent lengths. To get at the discount/patent length tradeoff, let $0 < \phi < 1$ represent a discount applied to the whole profit cycle. We want to know what $\gamma_2 > \gamma_1$ makes

$$\phi \cdot [P(\alpha,\beta,\delta,\gamma_2)] = P(\alpha,\beta,\delta,\gamma_1)$$

$$\phi \cdot \left[\frac{2\alpha}{\pi} + \gamma_2 - \alpha + (1-\beta)\frac{2\delta}{\pi}\right] = P(\alpha,\beta,\delta,\gamma_1)$$

$$\phi\gamma_2 + \phi \cdot \left[\frac{2\alpha}{\pi} - \alpha + (1-\beta)\frac{2\delta}{\pi}\right] = P(\alpha,\beta,\delta,\gamma_1)$$

$$\phi\gamma_2 + \phi \cdot [P(\alpha,\beta,\delta,\gamma_1) - \gamma_1] = P(\alpha,\beta,\delta,\gamma_1)$$

$$E(\phi) = \gamma_2 - \gamma_1 = \frac{(1-\phi)}{\phi} P(\alpha,\beta,\delta,\gamma_1) \qquad (3)$$

The function $E(\phi)$ tells us how much of an extension in years we will need to provide in exchange for knocking $(1-\phi)$ off the firm's profits. Using some reasonable parameters found in the literature, we plug in an effective patent length of 8 years, full market penetration after 2 years,

generic competitors that take 40 percent of profits immediately, and a post-patent life of the brand of 5 years. We find that a 10 percent profit loss (ϕ=.9) is equivalent to about a one- year patent extension.

This simple form of the model does not discount over time. Time, however, is a real issue to the pharmaceutical firm, since the profit earned on a patent extension in year eight is worth much less today than its nominal value. A fuller form of our model – one that incorporates discounting – might look like this.

$$p(t) = \begin{cases} e^{-rt}\sin\left(\dfrac{\pi}{2\alpha}\right)t & 0 \le t \le \alpha \\ e^{-rt} & \alpha < t \le \gamma \\ e^{-rt}(1-\beta)\cos\dfrac{\pi}{2\delta}(t-\gamma) & \gamma < t \le \gamma + \delta \end{cases} \quad (4)$$

Repeating the same integration steps yields the following much less friendly parameter function.

$$P(\alpha,\beta,\delta,\gamma,r) = \frac{2\alpha}{\pi^2+4r^2\alpha^2}\left(\pi - 2\alpha r e^{-r\alpha}\right) + \frac{1}{r}\left(e^{-r\alpha} - e^{-r\gamma}\right) + \frac{(1-\beta)2\delta}{\pi^2+4\delta r^2}\left(\pi e^{-r(\gamma+\delta)} + 2\delta r e^{-r\gamma}\right) \quad (5)$$

This function reduces to equation (2) when the discount rate is zero.[11]

Repeating the same next steps yields the following relation.

$$\frac{1}{r}\left(e^{-r\gamma_1} - e^{-r\gamma_2}\right) = \left(\frac{\pi^2+4\delta r^2}{\pi^2+4\delta r-(1-\beta)2\delta r\left(\pi e^{-r\delta}+2\delta r\right)}\right)\frac{(1-\phi)}{\phi}P(\alpha,\beta,\delta,\gamma_1,r) \quad (6)$$

Again, when we take the limit as r approaches zero of both sides, this equation reduces to equation (3) in the simple model. Solving for γ_2 and subtracting γ_1, we get a new extension function:

$$E(\phi) = \frac{-1}{r}\ln\left(e^{-r\gamma_1} - \frac{r\pi^2+4\delta r^3}{\pi^2+4\delta r-(1-\beta)2\delta r\left(\pi e^{-r\delta}+2\delta r\right)}\left(\frac{(1-\phi)}{\phi}\right)P(\alpha,\beta,\delta,\gamma_1,r)\right) - \gamma_1 \quad (7)$$

After coding this truly monstrous equation into Maple for computation, we can see the effect that discounting has on our earlier estimate.

Table 1

Patent Extensions Needed to Compensate Firms for Lost Profits

$\alpha = 2,\ \beta = .4,\ \delta = 5$ *and* $\gamma_1 = 8$

		5% discount rate r = .05	10% discount rate r = .1	15 % discount rate r = .15
$\phi = .95$	(5% loss)	.6 years	.7	.9
$\phi = .90$	(10 % loss)	1.2	1.5	1.9
$\phi = .85$	(15 % loss)	1.9	2.5	3.4
$\phi = .80$	(20 % loss)	2.8	3.7	5.6
$\phi = .75$	(25 % loss)	3.8	5.3	9.5

A five-year brand survival is more appropriate for a drug that doctors and patients make decisions on. Grabowski and Vernon (1992) found that drugs administered by hospitals, such as infusions, are much more quickly replaced with generics because hospital administrators select suppliers on price more attentively. Using a two-year brand survival time, $\delta = 2$, we get the following results.

Table 2

Patent Extensions to Compensate Firms for Lost Profits (Aggressive Generic Competition Scenario)

$\alpha = 2,\ \beta = .4,\ \delta = 2$ *and* $\gamma_1 = 8$

		5% discount rate r = .05	10% discount rate r = .1	15 % discount rate r = .15
$\phi = .95$	(5% loss)	.5 years	.6	.8
$\phi = .90$	(10 % loss)	1.1	1.4	1.8
$\phi = .85$	(15 % loss)	1.8	2.3	3.1
$\phi = .80$	(20 % loss)	2.5	3.4	5.0
$\phi = .75$	(25 % loss)	3.5	4.8	8.0

It is interesting and somewhat counterintuitive that the patent extensions are all smaller here than in the first scenario. This happens because the drugs with less brand identification had an initial expected profitability that was smaller, and the extensions vary in direct proportion to the expected profit.[12]

A third variation takes us to the limits (literally) of this proposed model. Grabowski and Vernon (1987) report that imitator or "me, too" drug can usually skip about three years of initial research that the pioneer drug requires, since the efficacy of the general chemical approach has already been demonstrated. This shortcut boosts the imitator's effective patent life to 11 years.

Table 3

Patent Extensions Needed to Compensate Firms for Lost Profits ("Me, Too" Drug Scenario)

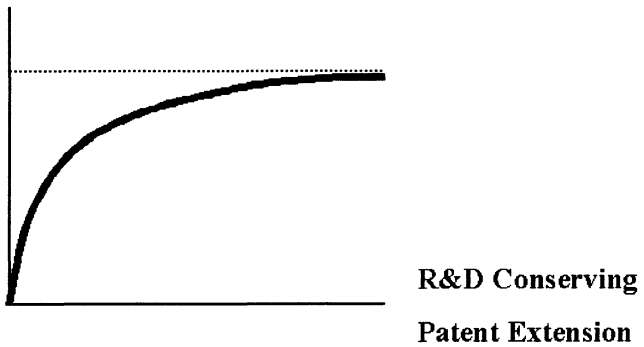
$\alpha = 2,\ \beta = .4,\ \delta = 5$ *and* $\gamma_1 = 11$

		5% discount rate r = .05	10% discount rate r = .1	15 % discount rate r = .15
$\phi = .95$	(5% loss)	.8 years	1.1	1.6
$\phi = .90$	(10 % loss)	1.8	2.5	3.9
$\phi = .85$	(15 % loss)	2.9	4.2	8.1
$\phi = .80$	(20 % loss)	4.2	6.7	**43.2**
$\phi = .75$	(25 % loss)	5.8	10.6	***undefined***

The chart shows us that imitators would demand longer extensions than pioneers because the gain for them is even more heavily time discounted.[13] Of course, the product lines of most pharmaceutical firms feature a combination of these types of drugs. The last column shows where the model hits an asymptotic wall. Specifically for high γ and high r, our extension function (7) tries to take the natural log of a negative number, resulting in an answer that is undefined in the set of real numbers. Close to that limit, the extension blows up to infinity. When future profits are sufficiently discounted and patent terms are sufficiently long, there is in effect no patent extension that will compensate firms for lower prices during the patent term. In graphical terms, this means that there cannot be enough area (profit) under a highly time-discounted curve to make up for the area lost in the early years of the profit cycle. This limit to our discount/extension tradeoff is highly illuminating for policy. In general, for any given set of parameters, a political deal will exhibit the following property:

Figure 6

The roof



The marginal returns to patent extensions are thus sharply diminishing, putting a limit on the viability of this particular political compromise.

Conclusion

Our little romp in the world of calculus does not solve the political debate, nor does it necessarily provide guidance about the optimal level of innovation. It does, however, illustrate some surprising relationships and circumscribe the range of political compromises that might be struck. If the goal is to maintain R&D incentives, then lawmakers need to be aware of the fundamental limit encountered in our third variation, lest they try and resolve the argument with a patent extension as they did in the 1984 case. In 1984, time discounting worked for the deal, since innovator firms gained early-year profits and lost later-year profits. In the current case, discounting works decidedly against it, and pharmaceutical firms will have good reason to argue that the proposal hurts them. For mild Medicare price discounts, there are many patent/price tradeoffs that make sense. For deeper cuts, the math says that the players will need to find a different deal. What's striking about this model is that the asymptote is reached using parameters that are close to their real-world values and the best estimates found in the economic literature. This explains, perhaps, the intensity of the drug firms' lobbying. The industry could be hitting the roof with furious lobbying in order to avoid hitting the roof depicted in Figure 6.

Indeed, the model almost certainly understates the constraint that a political deal would face. Specifically, it fails to discount later profits for the very real probability that the drug will be rendered obsolete or that a competitor will split the market with a copycat patents. Frank Lichtenberg and Tomas Philipson (2000) estimate that such "me, too" competition during the patent term (which they call "creative destruction of innovative return") costs the innovator firm as much, and perhaps twice as much, as competition from generics (uncreative destruction). A pioneer drug firm making its R&D investment decisions knows that there is significant chance that an imitator will come along and engineer a similar chemical form of its drug, possibly even an improved form. The pioneer firm's decision model will thus contain an additional risk-discounting factor that results in a lower expected profitability in later years. This addition would only increase the pressure on the patent term/profit tradeoff seen in the simpler model. It would lower the roof in Figure 6.

But again, from a social welfare perspective, it's difficult to say how much it matters to listen to the pharmaceutical industry's concerns.

Lacking an elasticity estimate on the innovation supply curve, we do not know whether decreased R&D incentives will mater a little or a lot in affecting the amount of innovation produced. Many exogenous factors could also be affecting the market. For example, the optimal patent policy T* could well shift to the left with the aging of the baby boom generation. If the increased demand for drugs causes the social costs of monopoly profits to grow faster than the social benefits to innovation, then a status quo-preserving policy option in that framework would call for reducing innovation levels now. As a member of Generation X myself, I am very aware of the increasing future liabilities facing the taxpayers. Cost containment, given reasonable consequences for innovation, could be an optimal strategy. If on the other hand, one believes that biotechnology advances are set to radically boost the social benefits to innovation at a given level of profit, we could take the opposite view and conclude that innovation incentives should be not only protected, but increased. In the international arena, recent trade agreements stand to boost the power of the pharmaceutical firms to protect their patents abroad. This should work to decrease the share of R&D incentives financed by U.S. consumers. Americans might see this as a way to avoid some of the monopoly markups they face in the domestic market, though from an international perspective it may appear wrong to ask the poorer nations of the world to shoulder more of the burden.

Economics can frame the debate, but the realm of politics with all its theatrics will ultimately make the decision on how to cover the elderly's prescription drug bills. The odds look good that unless Congress gets generous with the budget surplus, the next Medicare prescription drug debate will be another brawl.

NOTES

[1]I wish to thank Professors Robert Willig and F.M. Scherer for their helpful comments on earlier drafts of this paper.

[2]Economists argue that the drug industry's fabulous profitability – sometimes five times the median return on assets – is overstated, since R&D outlays are accounted as expenses rather than as capital investments. Comanor (1986) found that correcting for the disparity (which involves some assumptions about the correct depreciation rate), yields smaller but still higher-than-average returns to capital.

[3]Pankaj Tandon (1982) has proposed an interesting optimal tradeoff which would give innovators infinite patent lengths but require a system of compulsory licensing, under which the innovator charges a "reasonable" fee for

competitors to use the patent. While this option generates an optimal tradeoff using certain simplified models, Tandon notes that several practical issues would need to be solved before such a system is implemented.

[4]Members of Congress sometimes talk as if they do not understand this tradeoff at all. In Congressional hearings on the Orphan Drug act, some House members sounded shocked (shocked!) that giving manufacturers an exclusive marketing period resulted in high prices for patients.

[5]In contrast to the tone of the recent public debate, F.M. Scherer (1997) has argued that much of the markup is due to the market power of retail pharmacists, rather than the manufacturers.

[6]Public Citizen is citing a Merrill Lynch study to say that the net profit loss could be as little as 3.3 percent on even a large 40 percent cut in prices, since drug makers could make up much of the difference on increased volume. The pharmaceutical industry vigorously disputes this figure.

[7]This deal was not universally acceptable to the pharmaceutical industry. The drug industry's top lobbyist at the time was forced to resign after some drug companies bolted and lobbied against the deal (Hamilton 1984).

[8]For example, few economists would use sine and cosine functions as I do. Such a model would probably contain a logistic curve and an exponential decay term, instead. But as we shall see, the insight the model provides is not affected by these choices.

[9]Grabowski and Vernon (1992) curiously find that the price of brand name drugs rises with the onset of generic competition, though this may have changed in recent years with the rise of HMOs. The theory is that drug firms achieve strong brand name recognition during the patent term. Price-sensitive consumers switch when generics become available, leaving a much less elastic demand for the pioneer firm: a fat cat strategy. Grabowski and Vernon's study of 18 drug categories found that two years after entry, generics typically have captured only half the market, and competition between generic brands lowers their price over time. The gap between the generic and the brand, however, widened during the two years, with brands costing on average 2.7 times the generic price after two years.

[10] The fact that pharmaceutical R&D spending nonetheless soared since 1984 dramatically shows that patent terms are not the only factor in the investment decision. It is also possible that technical improvements in the field of biotechnology increased the expected return of R&D investments.

[11]Actually, we have to take the limit as r approaches zero because the middle term contains r in the denominator.

[12]In the simple model, it is easy to see that

$$\frac{\partial E}{\partial \, parameter} = \frac{(1-\phi)}{\phi} \frac{\partial P}{\partial \, parameter}$$ for parameters α , β, δ and γ.

[13]There is a danger of comparing apples and oranges here. The "me, too" scenario introduces competition into the patent cycle, with competitors eating into one another's market share and profits. The model deals in units that are essentially a percentage of the maximized monopoly profit. For an innovator, that profit shrinks when a competitor enters. The model's insight, however, derives from the shape of profit stream, not the actual dollar amounts that the "me, too" firm is looking at. "Me, too" competition and its implications for the model are discussed further in the conclusion.

BIBILIOGRAPHY

Citizens for Better Medicare <http://www.bettermedicare.org>.

Cohen, Wesley and Richard Levin. 1989 Empirical Studies of Innovation and Market Structure. In Handbook of Industrial Organization. Schmalensee, R.C. and R. Willig, eds. Elsevier Science Publishers. Chapter 18.

Comanor, William. 1986. The Political Economy of the Pharmaceutical Industry. Journal of Economic Literature, 3 (Sept): 1178-1217.

Comanor, William. 2000. Personal communication via e-mail.

Congressional Budget Office. 2000. An Analysis of the President's Budgetary Proposals for Fiscal Year 2001. April.<http://www.cbo.gov>.

Grabowski, Henry and John Vernon. 1987. Pioneers, Imitators and Generics – A Simulation Model of Schumpeterian Competition. The Quarterly Journal of Economics. (August): 492-525.

Grabowski, Henry and John Vernon. 1992. Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Drug Act. Journal of Law and Economics. (October): 331-350.

Hamilton, Martha. 1984. Drug Makers' Chief Resigns. The Washington Post. 22 August.

Lichtenberg, Frank and Thomas Philipson. 2000. Creative vs. Uncreative Destruction of Innovative Returns: An Empirical Examination of the U.S. Pharmaceuticals Market. NBER Working Paper. 28 July.

Pear, Robert. 2000. Drug Makers Drop Their Opposition to Medicare Plan. The New York Times. 13 January, A1.

Pharmaceutical Research and Manufacturers of America. <http://www.phrma.org>.

Public Citizen <http://www.citizen.org>.

Serafini, Marilyn and Shawn Zeller. 1999. Say It Ain't So, Flo. National Journal. 9 October.

Scherer, F.M. 1997. How US Antitrust Can Go Astray: The Brand Name Prescription Drug Litigation. International Journal of the Economics of Business. 3: 246.

Tandon, Pankaj. 1982. Optimal Patents with Compulsory Licensing. Journal of Political Economy. 3 (June): 470-486.

Viscusi, W. Kip et al, 1998. Economics of Regulation and Antitrust. Second Edition. Boston: MIT Press. 831-870.