

**“Pay-for-Delay” Settlements in the Pharmaceutical Industry:
How Congress Can Stop Anticompetitive Conduct, Protect Consumers’ Wallets, and Help
Pay for Health Care Reform
(The \$35 Billion Solution)**

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Many thanks to the Center for American Progress for hosting this exceedingly timely event. Your outstanding work has helped focus attention and inform public policy on a number of critical issues facing our nation, including health care reform. Ensuring access to affordable medicines is an essential part of this debate—so I appreciate the opportunity to be here today.

Getting health care costs under control is a daunting challenge. But one simple step could save consumers and the federal government billions of dollars annually: stopping pharmaceutical companies from colluding with their competitors to keep low-cost generic drugs off the market. At the FTC, we call these deals “pay-for-delay” settlements. (You may also hear them referred to as “exclusion payments” or “reverse payments.”)

No matter what you call them, eliminating these deals is one of the Federal Trade Commission’s highest priorities. And as Congress moves forward on health care reform, momentum to prohibit these agreements appears to be growing: just recently a House bill was passed out of subcommittee; its bipartisan Senate version is poised to be marked up as early as Thursday.

This morning I want to discuss how the Hatch-Waxman Act has been distorted to spawn these anticompetitive arrangements. Then I’ll talk about the FTC’s new empirical study (the first of its type) which shows that American consumers would save \$35 billion dollars over the

next decade if these deals were banned. Because the federal government pays for about a third of the nation's prescription drug bill, this means about \$12 billion in savings to federal programs. (Even in 2009, that is real money.)

But let me begin with a story recently in the news. Some of you may have read about U.S. District Judge Ricardo Urbina handing down an unusual sentence – ordering former Bristol-Myers Squibb senior vice-president Andrew Bodner to write a book about how he came to be convicted of lying to the FTC. Bristol-Myers was the subject of an FTC order stemming from charges that, among other things, it had paid a competitor to drop a patent challenge. So when it decided to settle a patent case with a company planning to sell a generic version of Plavix—no, that's not a Roman general, it's a blockbuster blood thinner used to prevent heart attacks and strokes, with annual U.S. sales of more than \$6 billion—Bristol Myers had a problem. Based on the earlier decree, it had to submit its proposed settlement to the FTC for approval. In an attempt to evade FTC review, Bristol-Myers lied about a secret deal, in which it agreed to provide substantial payments to a generic competitor to stay out of the market.

Both Dr. Bodner and his former employer subsequently pleaded guilty to criminal charges of making false statements. The company paid the maximum fine. Dr. Bodner was also fined and was ordered to write a book about the case, presumably to discourage other drug company executives from lying to the federal government.

The sad truth is, however, that if Bristol-Myers weren't under a previous order it probably could have gotten away with it. The cost of doing business this way would have been passed along to American consumers.

How did we get to this point?

A Brief History

Let me start with a brief history.

More than two decades ago, Congress passed a landmark law, the Hatch-Waxman Act, to make it easier for generic drugs to enter the market, while giving brand-name manufacturers the patent protection they needed to encourage the lifesaving research that is the hallmark of America's pharmaceutical industry. One of the critical steps was to set up a process that encourages generic drug firms to challenge weak branded drug patents—those that are likely invalid or not infringed.

For a time the legislation worked. Generic manufacturers brought patent challenges and, when the parties did not reach a settlement based on the strength of their claims, generic firms won often—getting victories for over two-thirds of the challenged branded drugs, according to a 2002 FTC study. The result was significantly lower prices for patients. The law truly spurred competition.

Now, as most of you already know, when multiple generics are on the market, the price for the generic version can drop more than 90 percent below the price of the branded product, which means enormous savings for Americans. For example, you can go to the pharmacy and get a month's supply of the generic version of the anti-ulcer drug Zantac for \$3, instead of paying \$111 for the brand-name product. You can spend \$12 a month to lower your cholesterol with generic Zocor, instead of \$164 for the brand-name version.

Those of us with the good fortune to have health insurance don't see these cost differences directly because we only pay the difference between the brand and the generic copay -- the rest of the additional cost is hidden in our health insurance premium. But if you are one of

the 46 million uninsured in this country with high cholesterol and need Zocor, it's an entirely different story—this can mean saving more than \$1800 a year. And it's not just a matter of economics: high prescription drug prices often cause patients to cut their pills in half or skip needed medications altogether.

So we had a good policy, and a law that implemented that policy effectively. But, unfortunately, drug companies have derailed that law by entering pay-for-delay deals.

The vastly cheaper prices and lower profit margins of generics create powerful incentives for both the brand and generic manufacturers to agree to avoid competition. So if it is legal for a brand to pay the generic to “sit it out,” why wouldn't it? And if a generic drug company is allowed to make more money by not competing than by going to market, isn't that a good business deal for the company and its shareholders?

Of course it is. Clearly, these are win-win deals for both companies. But they leave American consumers footing the bill.

That is why the Commission has made stopping these deals a top priority. Initially, under the leadership of both Democrat Bob Pitofsky and Republican Tim Muris, when the Commission found drug companies engaging in pay-for-delay settlements, we stopped them cold.

But unfortunately, since 2005, several circuit courts have mistakenly blessed these anticompetitive settlements. Essentially, these decisions conclude that because the brand's patent might block the generic's product, a brand can pay to eliminate the possibility of competition until its patent expires. This approach is at odds with both market realities and established antitrust principles.

An industry investment analyst got it right when he said that these court decisions “opened a Pandora’s box of settlements.” Instead of competing to be first to come to market, generic companies compete to be first to get paid off.

Some in the industry are quite candid – at least privately – about the overriding financial incentives that drive these deals. Some are even candid in public. Take the CEO of Cephalon, a company that is the subject of a current FTC action. When announcing settlements with four generic drug makers that kept the generic versions of Provigil off the market until 2012 (in return for compensation of roughly \$200 million collectively to the generics), he stated: “We were able to get six more years of patent protection. *That’s \$4 billion in sales that no one expected.*”¹

The FTC is continuing to bring cases to protect consumers from these anticompetitive settlements, and we hope the trend in courts will change. But waiting for a potential judicial solution is a time consuming and expensive prescription, so the agency strongly supports legislation to eliminate pay-for-delay deals.

Now, the lobbying strength of the pharmaceutical industry is legendary; according to the Center for Responsive Politics, the industry has 1325 registered lobbyists, and that is only in D.C. The industry is busy defending these arrangements but, to be blunt, their claims don’t hold up.

To begin with, they claim Hatch-Waxman patent cases cannot be settled without paying a generic to delay entry. But that is contradicted by actual market experience: from 2000 through 2004, when the prospect of antitrust enforcement was deterring such settlements, companies

¹ John George, *Hurdles Ahead for Cephalon*, PHILADELPHIA BUSINESS JOURNAL, March 17, 2006 (quoting Cephalon CEO Frank Baldino) (emphasis added).

continued to settle. They simply picked a date based on the strength of their case without any exclusion payments.

Brand companies also claim that barring pay-for-delay settlements would mean less innovation. If anything, however, brand companies are most likely to pay-off a generic competitor when they have not innovated. As defenders of these settlements have conceded, the incentive to pay a generic to abandon its patent challenge is greatest for the weakest patents. As all of us know, competition rather than collusion fosters creativity. The Supreme Court has repeatedly observed that protecting weak patents slows rather than promotes innovation.²

For their part, some generic firms—and not all by the way—are saying that banning pay-for-delay settlements will mean fewer patent challenges. I have seen no evidence to support that argument. In any event, if generics are filing patent challenges only to get a payoff, then those patent challenges are no longer serving consumers.

New FTC Analysis of Empirical Data

Now, everyone knows what lobbyists say in the Halls of Congress sometimes has only a distant relationship with the reality of a situation. So let me share with you what these settlements are actually costing consumers and how much consumers and the federal government could save if Congress stopped them.

² See, e.g., *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 419 (2007) (“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress.”).

Savings to Consumers and the Federal Government

For years, a lot of us at the Commission have been frustrated by the lack of empirical studies on the effect of pay-for-delay settlements. We could point to the Generic Pharmaceutical Association's own estimate that early generic competition following successful challenges to just four products— Prozac, Zantac, Taxol, and Platinol—saved consumers more than \$9 billion dollars. But the cost and growing prevalence of these deals call for more than anecdotes and back-of-the-envelope calculations.

More recently, Columbia University Professor Scott Hemphill analyzed 21 drug settlements involving reverse payments and estimated that, if entry was delayed just one year, the cost to consumers would be in the billions.³ His analysis was necessarily limited, however, because he did not have access to the entire universe of brand-generic settlements, the terms of which are often confidential. On the other hand, thanks to a law Congress enacted in 2003 that requires drug companies to file their Hatch-Waxman patent settlements with the FTC, we do.

Because the FTC is uniquely positioned to analyze these deals, it was the first thing I asked our new Bureau of Economics team to do. Not surprisingly, the dedicated economists at the FTC accepted the challenge.

Let me try to translate their methodology into layman's terms. Initially, they determined that currently 90 billion dollars of brand drug sales may face pre-patent expiration generic competition, depending on the outcome of current patent litigation. Based on the history of settlements from as early as 2004, *i.e.*, before the courts began to hand down decisions

³ Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, Hearing on H.R. 1706, "Protecting Consumer Access to Generic Drugs Act of 2009" (March 31, 2009) at 7, available at http://energycommerce.house.gov/Press_111/20090331/testimony_hemphill.pdf.

sanctioning these payments, the staff calculated that roughly 3.4 percent of cases settle each year with payments. On average, those settlements delay generic entry by 17 months more than settlements without payments. Based on a review of the economic literature and information obtained in FTC investigations, consumers save an estimated 85 percent compared to when only a brand is available. So the cost to consumers is 17 months savings.

These assumptions are quite conservative. For example, the estimate projects that the rate of settlements with payments as well as the average length of delay will remain the same. If the lenient court decisions stand, however, more and more companies will likely make these deals and agree to longer postponements. Moreover, we excluded injectable drugs—about a quarter of the market—because we did not have reliable sales data and because the post generic entry savings may be different for injectables than for tablets or capsules.

Even with conservative assumptions and limitations, eliminating these pay-for-delay settlements would still save consumers \$35 billion over ten years—or about \$3.5 billion per year. Conversely, that is the cost of failing to eliminate pay-for-delay patent settlements.

We know that the federal government alone pays about one third of the nation's \$235 billion annual prescription drug bill. Based on that, savings to federal programs would be about \$12 billion over 10 years. That is another conservative estimate because the government's share of drug expenditures is projected to rise to 40 percent within a decade.

These numbers were based on pretty conservative assumptions. Perfectly reasonable alternative assumptions would lead you to \$75 billion in savings for American consumers, which would work out to \$25 billion for federal programs over the next decade.

Naturally, these are estimates and the analytical work is ongoing.

Encouraging Signs

So where are we now?

I see encouraging signs in the Administration, in the courts, and in Congress. As the evidence mounts, there appears to be growing recognition that pay-for-delay deals should be stopped.

The New Administration: The arrival of a new Administration determined to make health care more available and affordable to all Americans has created momentum for a national solution to stop reverse payments.

Don't take my word for it; ask President Obama. As a Senator he co-sponsored the Kohl-Grassley bill to ban these anticompetitive settlements, and his February 2009 budget statement says barring "collusion between brand-name and generic drug manufacturers intended to keep generic drugs off the market" is one of the ways to achieve savings to help pay for health care reform.⁴ The new Assistant Attorney General for Antitrust, Christine Varney, has testified that she supports efforts to stop these anticompetitive deals.⁵

The Courts: In the courts, as many of you know, there has been a dramatic split. The Sixth Circuit says these deals are *per se* illegal, while other appellate courts have come close to rules of *per se* legality. Even with the decision by the Supreme Court yesterday not to take *cert.* in *Cipro*, the good news is that things may be changing. The Court of Appeals for the Second

⁴ OMB, EXEC. OFFICE OF THE PRESIDENT, BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2010 (2009) (proposed), at 28, *available at* http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

⁵ In response to a question in her recent confirmation hearing before the Senate Judiciary Committee, Ms. Varney testified that she supports efforts to stop "reverse payments" and would work to "align" the positions of the Department of Justice and the FTC. *Executive Nominations: Hearing Before the S. Judiciary Comm.*, 111th Cong. 38-39 (2009) (exchange between Sen. Herb Kohl, Member, S. Judiciary Comm., and Christine Varney, Nominee, Assistant Att'y Gen., Antitrust Division, Department of Justice).

Circuit originally issued a 2-1 decision in the *Tamoxifen* case with a very permissive standard—one that essentially says you can pay your competitor to stay out of the market until your patent expires. Now, however, it has done something extremely rare. It has questioned one of its own precedents, recently asking the new Solicitor General to propose a new standard. I am cautiously optimistic that the court's invitation may foreshadow a shift in the law.

The Congress: Perhaps most importantly, support is building in Congress for a solution. Earlier this month, in a critical vote, a House Energy and Commerce subcommittee by a vote of 16 to 10 approved legislation that would establish a clear, bright-line standard to prohibit pay-for-delay patent settlements.⁶ Just as important, the Subcommittee rejected a variety of industry-supported amendments that would have weakened the bill to such an extent that the only “protection” for consumers left would have been in the bill's title: the Protecting Consumer Access to Generic Drugs Act of 2009.

The Senate Judiciary Committee is poised to report out similar legislation as early as Thursday.

Looking Forward

As all of you recognize, fixing our broken health care system is an enormously complicated task. Should we have a government plan? How should we finance the program? Who should be insured? Each decision has complex ramifications.

From my perspective, though, the decision about whether to restrict pay-for-delay settlements should be simple. On the one hand, you have savings to American consumers of \$35 billion or more over ten years— about \$12 billion of which would be savings to the federal

⁶ Representatives Rush, Waxman, Dingell, Schakowsky, and others introduced the bill, titled “Protecting

government—and the prospect of helping to pay for health care reform as well as the ability to set a clear national standard to stop anticompetitive conduct. On the other hand, you have a permissive legal regime that allows competitors to make collusive deals on the backs of consumers.

Enacting legislation is always an uphill battle, but under these circumstances, I like our odds.

Thank you.

Appendix: calculation of consumer savings

This appendix describes a calculation of the potential savings from a prohibition on exclusion payments. The calculation below is a method of estimating the likely harm to consumers from the loss of competition when patent settlements delay generic entry. This calculation requires four factors: (1) the consumer savings that result from generic competition in any given month, (2) the likelihood that a generic manufacturer and brand-name manufacturer will reach a settlement that delays entry in return for compensation, (3) the length of entry delay resulting from such settlement, and (4) the combined sales volume of drugs for which settlements are likely. The analysis estimates that under relatively conservative assumptions, the annual savings to purchasers of drugs that would result from a ban on “reverse-payment” settlements would be approximately \$3.5 billion.

Consumer savings from generic competition

When generic entry occurs, purchasers immediately begin to benefit from the savings associated with lower generic drug prices. Following an initial entry period, the generic market matures and consumers receive the full savings from generic competition. Thus, any delay in entry results in a longer period of purchases at the full brand price and correspondingly fewer purchases at the mature competitive prices.⁷ This means that the costs to consumers (or what they would have saved but for the entry delay) are equal to the monthly savings from the mature generic market multiplied by the number of months of delay.

Publicly available information about recent generic launches suggests that a generic market typically matures about one year after the first entrant comes on the market. The generic penetration rate at that point is recently about 90% on average, i.e. pharmacists fill 90 of every 100 prescriptions for the molecule with an AB rated generic. The data show that generics are heavily discounted: on average the mature generic price is 85% lower than the pre-entry branded drug price was.⁸

Using the above figures and assumptions, the average consumer savings from a mature generic market relative to pre-generic levels are approximately 77% (85% savings multiplied by 90% of market demand). If purchasers discount future savings at the same rate as they expect drug prices to increase, then all future savings can be expressed in terms of today’s dollars without complicated net present value calculations. Thus, the costs of delay are the average

⁷ If one assumes some future end-point in the drug’s life on the market, delayed entry means that by that end-point consumers will have had less time buying in the mature competitive market.

⁸ The calculation assumes that the total demand for the drug/molecule (market size in unit sales) remains the same after generic entry occurs. It also assumes that the brand’s price stays the same after generic entry occurs. Data show that branded prices often rise following generic entry, but there are also instances when brand price declines. Assuming the price stays the same simplifies the analysis.

discount (77%) times the length of the delay times the pre-generic entry revenues of the branded drugs that will reach a settlement with delay.

Likelihood of Settlements with Payment to Delay, and the Length of Delay

It is more difficult accurately to estimate how much delay is likely to result from settlements that have not yet been reached, especially because future legislative or judicial decisions could alter the types of settlements that are likely. Therefore, the calculation assumes that recent settlements provide the best information about what may happen in the future. Data on settlements reported to the FTC from 2004 to 2008 show that of all patent settlements resulting from a Paragraph IV challenge, approximately 24% included both restrictions on timing of generic entry and a payment to the generic firm.

The effect of the length of the delay that is attributed to the payments in these settlements can be estimated by taking the universe of Paragraph IV settlements that have restrictions on entry, then comparing the average number of months between the execution of the agreement and generic entry in agreements with and without payments to the generic entrant. Agreements with payments on average allow entry 17 months (1.42 years) later than agreements without payments.

This does not mean that we are assuming that all settlements with payments would “become” settlements without payments if the former were banned. Some would; others might involve litigation of the patent. But since settlements without payments will tend to reflect patent strength, they can provide a benchmark for the consumer impact of either alternative.

Sales Volume of Drugs for which Settlements are Likely

Determining the set of drugs for which pay-for-delay settlements are likely is also a challenge. Once again, one can rely on recent history as a guide to the settlements likely to be seen in the future. The analysis starts with the FDA’s list of all drugs which have received a paragraph IV filing.⁹ It then uses information from the FDA’s Orange Book, IMS NPA retail sales data, and the settlement filings to determine whether there had been a generic version of a challenged drug launched before 2004. If a generic had entered, it was removed from the list of drugs that could have settled between 2004 and 2008. The analysis next uses the IMS data to determine the total dollar sales associated with those drugs remaining in the sample for each year. It adjusts these annual totals by removing drugs that reached a settlement or experienced generic entry due to a non-settlement event such as a court victory or patent expiration.

By the end of 2008, the above method estimates that there were \$90 billion of branded drug sales still facing a paragraph IV challenge. Since the IMS data used does not cover all purchasing channels and excludes injectable drugs, \$90 billion is a conservative estimate of the total branded dollars affected by possible settlements.¹⁰

⁹ This is based on a version downloaded from the FDA’s website on May 19, 2009.

¹⁰ While these effects understate the sales volume at issue, a possible effect in the other direction could arise if a

The next step is to look at the number of settlements per year as a percentage of all paragraph IV challenged drugs that could possibly settle. Over the 2004 to 2008 time period, the percentage of drugs that settled per year (not including injectables) increased from 7% to 18%, with most of the increase following the Eleventh Circuit's *Schering* decision. Since this post *Schering* era is probably a better reflection of likely future settlement patterns, it seems appropriate and conservative to use the 15% per year average from this period in the estimate calculations.

Multiplying \$90 billion by 15% yields \$13.5 billion in drug purchases that are predicted to be affected by settlements each year. Multiplying this \$13.5 billion total by 24% (an assumption based on the percentage of past settlements with payment and delayed entry), leads to a prediction of \$3.2 billion in drug sales that will be affected by a ban on reverse payments in a given year.

Final Estimate Calculation

The final steps in calculating the savings to be gained by avoiding pay-for-delay settlements are to factor in the discount consumers would receive from matured generic entry and the length of delay. From the 77% savings and 1.42 year delay figures above, the calculation is therefore:

$$(\$3.2 \text{ billion}) \times (0.77) \times (1.42) = \$3.5 \text{ billion.}$$

In sum, the calculation yields a conservative estimate of potential savings from a ban on pay for delay settlements of \$3.5 billion per year.

Results with Varied Assumptions

The estimate above is sensitive to changes in the model's assumptions. Reasonable estimates about the length of delay and the sales of drugs likely to be affected by the legislation

future legislative or judicial action made reverse payments illegal. To the extent that such an action would reduce generic firms' incentives to file Paragraph IV challenges, it could reduce the sales volume of drugs facing such challenges. Any such deterrent effect would likely be very low, however. As noted above, only 24% of all cases settled with both payment and delay, and presumably there would be no effect outside those 24% of cases. Even within the 24%, it would be extreme to assume that the underlying Paragraph IV filing would not have occurred without the prospect of a settlement payment: those filings might well still have occurred and either not settled or settled without payment. In particular, a generic would still have a strong incentive to challenge a weak patent in a large market, so any deterred filings will tend to be in respect of stronger patents (where generic entry is unlikely or will be long delayed even at best) and/or in smaller markets, where all these effects are less important in dollar terms.

can vary. The table below presents high and low estimates of savings derived from the data ranges.

77% savings x \$1.5 billion (7% per year settling) x 0.5 years (low of interquartile distribution of delay) = \$0.6 billion of annual purchaser savings	77% savings x \$3.9 billion (18% per year settling) x 2.5 years (high of interquartile distribution of delay) = \$7.5 billion of annual purchaser savings
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