APay-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 Apay-for-delay@ settlements. (You may also hear them referred to as Aexclusion payments" or Areverse 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 B 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.

An industry investment analyst got it right when he said that these court decisions Aopened 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 B at least privately B 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: AWe 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 laymans 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.

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 Acollusion 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 Areverse payments@ and would work to Aalign@ the positions of the [illegible]

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 Aprotection" 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 feder] f "s p v

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.

Consumer Access to Generic Drugs Act of 2009" (H.R. 1706).

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 m

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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 is 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 billion) x (0.77) x (1.42) = $3.5 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

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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**