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**TESTIMONY OF**

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**Before the**

**UNITED STATES SENATE  
JUDICIARY COMMITTEE**

**SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER  
RIGHTS**

**On**

**Pay-for-Delay Deals: Limiting Competition and Costing Consumers**

**July 23, 2013**

## **I. Introduction**

Chairman Klobuchar, Ranking Member Lee, and members of the Subcommittee, I am Mike Russo, Federal Program Director for the U.S. Public Interest Research Group (U.S. PIRG). Thank you for the opportunity to testify on the issue of pay for delay settlements, and how they hurt consumers by inflating drug prices – too often, putting needed medication out of reach for patients.

U.S. PIRG is the federation of state Public Interest Research Groups. As a non-profit, non-partisan public interest organization, we work to advance solutions that protect consumers; encourage a fair, sustainable economy; and foster responsive, democratic government. One of our key concerns as a consumer group is the fact that health care costs more than it should. Health care costs burden state and federal budgets, and high insurance premiums and out-of-pocket costs squeeze family budgets across our country. Given that, this issue of pay for delay settlements is one we've paid close attention to. It is an egregious example of how consumers and taxpayers are bearing higher costs than they should. Putting an end to it would cut wasteful spending and improve the lives of millions of patients.

In addition to our research on the issue, we are conducting a public education campaign on the problem of pay for delay. Since the details of these settlements rarely become public, consumers have been largely kept in the dark about the problem and how it affects them. We are working to change that by reaching out to consumers in communities across America. Due to that effort, our staff are hearing first-hand about how the high cost of prescription drugs affects people and how pay for delay makes it harder for patients to access the medication they need.

## **II. How Pay for Delay Hurts Consumers**

I wanted to start my testimony by sharing the story of someone who found out about this practice the hard way – Karen Winkler, a wife and mother of three who lives in Michigan. She has Multiple Sclerosis, and suffers from chronic fatigue caused by that disease. Her doctor prescribed Provigil, and without that medication, she found she could barely function. The drug made a big difference – but it cost her \$500 a month out of pocket, even with insurance. For years, the high price forced her to skip pills or split doses just to get by – she eventually had to stop taking the medicine for a time.

Fortunately, a generic version of Provigil went on the market last year. Karen now is able to get the medication she needs with a \$16 co-pay for a three-month supply. She’s back to living her life. Karen’s story eventually had a happy ending. But the truth is, that happy ending was put off due to a pay-for delay-deal struck by Cephalon, the maker of Provigil. In late 2005, Cephalon paid over \$200 million in a series of settlements that kept the generic off the market for six years<sup>1</sup> – six years during which Karen was stuck paying \$500 a month instead of \$16 every three. Even Cephalon’s CEO admitted the harm – he explained that by settling with the generics, “we were able to get six more years of patent protection. That’s \$4 billion in sales no one expected.”<sup>2</sup>

Karen’s story isn’t an isolated one. We are concerned that these pay-for-delay deals are becoming a routinely-used tool to keep generic versions of drugs off of the market.

## **III. Why Congress Must Act to End Pay for Delay**

It was good news when the Supreme Court ruled last month that these deals may violate antitrust law, and opened drug makers to lawsuits over these payoffs. It holds out the hope that

antitrust litigation may lead to some consumers being compensated for the harm they've suffered because of inflated drug prices. But we can't wait for years – perhaps decades – of litigation to solve this problem. Consumers need relief now.

That's why we believe Congressional action is urgently needed, and why we think it is so important that Senator Klobuchar and Senator Grassley have introduced S. 214, the Preserve Access to Affordable Generics Act. We are pleased to be supporting this bill, as well as the other bi-partisan bill in the Senate, which Senator Franken and Senator Vitter have brought forward, S. 504, the FAIR Generics Act.<sup>3</sup>

#### **IV. Recent Research**

In the wake of the recent Supreme Court ruling, our staff worked together with researchers at Community Catalyst to pull together examples of how pay for delay affects consumers. Earlier this month, we released a report listing 20 drugs known to be impacted by pay-for-delay deals.<sup>4</sup> We found that reverse payment settlements have affected drugs used by patients with a wide range of serious or chronic conditions, ranging from cancer and heart disease to depression and bacterial infection. A few examples: Tamoxifen – a widely used treatment for hormone-receptive breast cancer; Cipro – a key antibiotic and anti-anthrax treatment; and Provigil – needed by MS patients and others with fatigue and sleep disorders, and which costs as much as \$1,200 a month for the brand-name version.

We found the payoffs delayed these 20 drugs for five years on average, and as long as nine years. And the consequences for patients were significant – on average, the brand name drug was 10 times more costly than the eventual generic. In one instance, the brand name was 33

times more expensive. We conservatively estimated the total sales made by brand-name drug companies while the generic alternatives were delayed at \$98 billion.

Without reverse payments, we would expect the generic versions of these drugs to have become available much sooner. Without the option to pay off the generic drug maker, there are several alternatives all of which would lead to earlier generic entry.

First, if the brand name firm could withdraw its patent infringement lawsuit against the generic company, allowing the generic to enter the market immediately. It is worth noting that these settlements often are used to protect the weakest patent claims. Second, the firms could agree to a settlement without payment. In that situation the generic firm would bargain hard for the earliest possible entry date, since it could no longer accept payment in compensation for a later date. And third, the brand-name company could try to take the case to trial.

For the 20 drugs on our list, this last option appears to be the least attractive option, given the fact that the brand-name drug company apparently preferred paying off a would-be competitor over the option of having to prove that the generic actually would infringe on the patent. As the Supreme Court noted in their recent ruling, the very existence of a large payoff suggests the brand-name company doubts that it would succeed in its lawsuit against the generic, and the purpose of such a payoff is to maintain high brand-name drug prices rather than face what might have been a competitive market. There is therefore good reason to believe that if the makers of these 20 drugs went to trial, they would fare even worse than brand-name drug companies do on average in such lawsuits – failing against a generic challenger between 48 and 73% of the time, according to a range of studies.<sup>5</sup>

The Generic Pharmaceutical Association recently released a study that attempts to rebut these arguments and claims that pay for delay settlements actually save consumers money.<sup>6</sup> But

to reach this counterintuitive conclusion, they included all settlements between brand name and generic companies – not just those involving a reverse payment. In addition, they counted “savings” even when a settlement caused a generic to come to market after the expiration of the active ingredient patent, and assumed that there’s no cost to consumers from settlements even if the patent at issue would not have been upheld. In this case, the counterintuitive conclusion is just wrong.

When a brand-name company pays off a would-be competitor, one can be sure it’s not to bring generic competition to market earlier than it otherwise would. These payoffs delay generics, and without competition, brand-name drug companies can keep prices high. Pay for delay is a win-win for brand-name and generic drug makers. But it is lose-lose for the rest of us, who face delayed access to lower-cost generics, and inflated brand-name prices.

## **V. Conclusion**

Thank you for holding this hearing, and for giving us the opportunity to share our views on the issue. Increased attention to the way these deals are harming consumers comes at a critical time, and we urge all the members of this committee to support legislation to address this problem. The Supreme Court’s decision was a step in the right direction, but it’s up to Congress to finish the job and pass legislation that would finally put a stop to this anticompetitive practice that harms consumers.

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<sup>1</sup> Multiple pay-for-delay settlements starting in December 2005 allowed for generic entry in April 2012, causing a delay in generic access from Jan. 2006 to at least March 2012. Scott Hemphill, *An Aggregate Approach to Antitrust Using New Data and Rulemaking to Preserve Drug Competition*, Columbia Law Review, Jan. 2009, at 11, Table 2: Settlements with Monetary Payment; and Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets Industry Comment, Jan. 15, 2010, at Appendix C.

<sup>2</sup> John George, *Hurdles Ahead for Cephalon*, Philadelphia Business Journal (Mar. 20, 2006), <http://www.bizjournals.com/philadelphia/stories/2006/03/20/story1.html>.

<sup>3</sup> On May 8, 2012, the U.S. Public Interest Research Group joined Community Catalyst, the Consumer Federation of America, Consumers Union, Families USA, Health Care for America Now, and the National Legislative

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Association on Prescription Drug Prices on a letter to Senator Tom Harkin and Senator Mike Enzi supporting legislation to put an end to pay for delay.

<sup>4</sup> *Top Twenty Pay-for-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers*, U.S. PIRG and Community Catalyst, 2013. See <http://uspirg.org/reports/usp/top-twenty-pay-delay-drugs>

<sup>5</sup> The 48 percent figure is from the RBC study that included cases from 2000-2009, the period of time when the number of pay-for-delay deals grew. See Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets Industry Comment, Jan. 15, 2010. An earlier FTC study of cases from 1992-2002, before deals became prevalent, found that generic companies won 73 percent of the time. See *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002.

<sup>6</sup> IMS Institute for Healthcare Informatics, for the Generic Pharmaceutical Association, *Impact of Patent Settlements on Drug Costs: Estimation of Savings*, June 2013. See [http://www.gphaonline.org/media/cms/Impact\\_of\\_Patent\\_Settlements\\_on\\_Drug\\_Costs\\_Estimation\\_of\\_Savings\\_070813\\_FINAL\\_81.pdf](http://www.gphaonline.org/media/cms/Impact_of_Patent_Settlements_on_Drug_Costs_Estimation_of_Savings_070813_FINAL_81.pdf).