# TESTIMONY BEFORE THE SENATE COMMITTEE ON THE JUDICIARY, SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY AND CONSUMER RIGHTS

## "Pay-for-Delay Deals: Limiting Competition and Costing Consumers"

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Chairman Klobuchar, Ranking Member Lee, distinguished members of the Committee, on behalf of AARP's more than 37 million members, we thank you for holding this hearing on "pay-for-delay" agreements – reverse settlements that delay the availability of generic prescription drugs – and their impact on consumers' prescription drug costs. My name is Rob Romasco. I'm a member of AARP's all-volunteer board of directors, and I proudly serve as AARP President.

AARP is pleased that this Committee is examining how pay-for-delay agreements drive up consumers' prescription drug costs by delaying access to less expensive generic drugs. Older Americans use prescription drugs more than any other segment of the U.S. population. Two thirds of persons age 65 and older report using three or more prescription drugs within the past month, and forty percent used five or more.[1] Unfortunately, as evidenced by the AARP Public Policy Institute's Rx Price Watch reports[2], retail prices for brand name drugs are continuing to rise at rates that are several times higher than inflation, causing a strain on the budgets of individuals, federal and state governments, and other health care payers. In contrast, generic prescription drugs are considerably less expensive than brand name prescription drugs and, more importantly, their retail prices are actually *decreasing*.

Generic drugs have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs, and the use of generic drugs has been steadily increasing. In 1984, generic drugs accounted for 18.6 percent of all retail prescription drugs dispensed in the United States.[3] Now, generic prescription drugs account for 84 percent of all prescriptions dispensed in the United States[4] and 75 percent of prescriptions in the Medicare prescription drug benefit program.[5] However, while generic prescription drugs have been essential to the recent slowdown in health care spending, AARP believes that additional savings can be found by eliminating pay-for-delay agreements.

**Pay-for-Delay Agreements and the Hatch-Waxman Act**

Pay-for-delay agreements are a consequence of the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act. Hatch-Waxman gives generic drug manufacturers an incentive to challenge brand-name drug patents because the first generic drug manufacturer to receive Food and Drug Administration (FDA) approval to launch a generic copy of a brand name drug can receive a 180-day marketing exclusivity period for its product. The FDA cannot approve any other generic applications for the same drug until the first-to-file generic manufacturer has sold its product for 180 days or has forfeited its exclusivity period.

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[1] Centers for Disease Control and Prevention, Health, United States, 2012, Table 91 (May 2012), http://www.cdc.gov/nchs/data/hus/hus12.pdf

[2] Reports available at http://www.aarp.org/rxpricewatch

[3] Generic Drugs Research Report, AARP Public Policy Institute, publication IB61, May 2003.

[4] IMS Institute for Healthcare Informatics, *Declining Medicine Use and Costs: For Better or Worse? A Review of the Use of Medicines in the United States in 2012*, May 2013.

[5] Cynthia Tudor, "State of Part D: 2006-2012," 2012 Medicare Prescription Drug Benefit Symposium, March 20, 2012.

However, brand-name drug manufacturers often challenge generic drug manufacturers who try to launch their product prior to patent expiration, which results in litigation to determine whether the generic manufacturer is infringing on the brand-name manufacturer's patents. Rather than face the costs and uncertainty associated with patent litigation, some brand-name and generic drug manufacturers choose to settle before a final court decision. A growing number of these settlements also pay the generic drug manufacturer for agreeing to delay the launch of its competing product, which is what attracted the attention of the Federal Trade Commission (FTC). Such agreements can be particularly problematic when they involve the first-to-file generic manufacturer, because no other generic manufacturers can enter the market until the first-to-file manufacturer has marketed its product for 180 days.

These pay-for-delay agreements provide financial benefits to both parties at the expense of consumers: the brand-name manufacturer can continue to charge monopoly prices, and the generic company is compensated for its inaction. The FTC estimates that pay-for-delay agreements cost American consumers $3.5 billion per year – and if nothing changes, will cost consumers $35 billion over the next ten years.[6]

**Pay-for-Delay Agreements are Counter to Congressional Intent**

The Hatch-Waxman Act provides a means for the approval of generic drugs, but also allows for brand manufacturers to challenge the generic pharmaceutical company's entry prior to coming to market through patent infringement suits. Since the passage of Hatch-Waxman, there have been several well documented instances in which the brand manufacturers abused the legal system to block generic competition. In 2003, Congress took steps to address this in the Medicare Modernization Act, requiring that the FTC be notified of any settlements of patent cases involving prescription drugs.[7] Further, Senator Hatch, one of the original co-authors of the Hatch-Waxman Act has stated that "I find these types of reverse payment collusive agreements appalling. I must concede, as a drafter of the law, that we came up short in our draftsmanship. We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs …"[8]

**Cost to Consumers and Health Care Programs**

The FTC has found that pay-for-delay agreements prohibit generic entry for an average of nearly 17 months longer than patent settlement agreements without such payments. In the meantime, consumers must continue paying brand name drug prices, which are typically 80 to 85 percent higher than generic drug prices.[9] Any delay in generic entry results in a longer period of purchases at the full brand price and correspondingly fewer

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[6] Pay-for-Delay: How Drug Company Pay-offs Cost Consumers Billions, An FTC Staff Study, January 2010, http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf

[7] Pharmaceutical Agreement Filing Requirements available at http://www.ftc.gov/os/2004/01/04106pharmrules.pdf.

[8] Senator Hatch Congressional Record at S7567 (June 20, 2002).

[9] http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm

purchases at less expensive generic prices.[10] This negatively impacts both consumers and other payers, including taxpayer-funded health programs such as Medicare and Medicaid.

Pay-for-delay agreements can also impact patient health: researchers have found that cost is one of the primary reasons why older adults do not fill prescriptions, skip doses, or take smaller doses.[11] High cost sharing, typically associated with brand-name prescription drugs, has also been found to delay the initiation of drug therapy for patients newly diagnosed with chronic disease.[12] These behaviors can lead to negative health outcomes and also increase health care costs: patients who do not adhere to their prescription drug regimens use more urgent care and inpatient hospital services.[13] The annual excess health care costs due to medication non-adherence in the United States have been estimated to be as much as $290 billion.[14]

**Growth in the Number of Pay-for-Delay Agreements**

Unfortunately, the number of pay-for-delay agreements has been increasing. According to the FTC, the number of potentially anticompetitive patent settlements between brand name and generic drug companies increased from 28 in FY 2011 to 40 in FY 2012.[15] At the same time, there are numerous opportunities for pay-for-delay agreements as the pharmaceutical industry faces an unprecedented number of patent expirations. In 2011 and 2012, six of the ten top-selling prescription drug products on the United States market faced their first generic competition, and many more drug products are expected to go off patent over the next several years.[16]

**The Case of Lipitor**

A recent Rx Price Watch report released by the AARP Public Policy Institute examined events that took place as the popular anti-cholesterol drug Lipitor first faced generic competition, including a reported pay-for-delay agreement. Generic drug manufacturer Ranbaxy Laboratories was the first manufacturer to file for FDA approval of its generic version of Lipitor, submitting its application in 2003.[17] In 2008, Pfizer and Ranbaxy

[10] Federal Trade Commission, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, January 2010.
[11] K. Zivin et al., "Factors Influencing Cost-Related Nonadherence to Medication in Older Adults: A Conceptually Based Approach," Value in Health, Vol 13(4): 338-345.
[12] M. D. Solomon et al., "Cost Sharing and the Initiation of Drug Therapy for the Chronically Ill," Archives of Internal Medicine, Vol 169(8):740-748.
[13] M.C. Roebuck et al., "Medication Adherence Leads To Lower Health Care Use And Costs Despite Increased Drug Spending," Health Affairs, Vol 30(1):91-99.
[14] New England Healthcare Institute, Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, August 2009.
[15] FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market, http://www.ftc.gov/opa/2013/01/mmarpt.shtm
[16] IMS Health, "IMS Forecasts Global Pharmaceutical Market Growth of 5-8% Annually through 2014; Maintains Expectations of 4-6% Growth in 2010," April 20, 2010, http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c033208c22a/?vgnextoid=4b8c410b6c718210VgnVCM100000ed152ca2RCRD
[17] K. Eban, "The War Over Lipitor—Full Version," CNNMoney, May 6, 2011.

reportedly entered into an agreement that Pfizer would stop trying to block Ranbaxy's efforts to launch its product if Ranbaxy delayed introduction until November 2011.[18] Several major U.S. retailers have since filed lawsuits that accuse Pfizer and Ranbaxy of violating antitrust laws.[19,20]

Equally notable is the Rx Price Watch report's finding that the retail price of Lipitor increased by 17.5 percent in 2011. Lipitor's manufacturer was also raising its price while the alleged pay-for-delay agreement was in place. This resulted in the average annual retail price of Lipitor increasing by roughly $300 between the end of 2010 and the end of 2011.

**Recent Studies on Pay-for-Delay**

AARP is aware that recent studies have presented conflicting views of the impact of pay-for-delay agreements. While AARP is appreciative of the fact that some patent settlements may result in generic prescription drugs being launched prior to their brand name counterparts' patent expiration, the fact remains that objective government entities—including the Congressional Budget Office (CBO) and FTC—have concluded that pay-for-delay agreements result in costs to the government and consumers.

Some in the drug industry contend that pay-for-delay agreements are necessary to save the cost of patent litigation and that to prohibit such payments would chill patent settlements. However, while we recognize that patent litigation can be lengthy and expensive, it is AARP's contention that settlement agreements can be reached without negatively impacting consumers; and any potential litigation costs are dwarfed by the potential savings associated with timely access to generic drugs.

**The Supreme Court Decision in *FTC v. Actavis***

The Justice Department has challenged pay-for-delay agreements as anti-competitive and the Supreme Court issued its ruling last month in *FTC v. Actavis*. AARP filed a friend-of-the court brief in support of the FTC's argument that pay-for-delay agreements are anticompetitive.[21] In a 5-3 opinion, the Court held that pay-for-delay deals should be subject to the "rule of reason" to determine if they violate antitrust law.[22] Under this doctrine, the Court said the circumstances of an agreement must be considered. The ruling overturns a lower court decision based on the "scope of patent" doctrine that pay-for-delay agreements are with few exceptions per se lawful.

[18] Pfizer received a six-month patent extension in the European Union (EU) after developing a pediatric version for children with high cholesterol, allowing Lipitor to maintain exclusivity in most EU countries until May 2012. It has been estimated that this extension will bring in an additional $770 million to the company (A. Rappaport, "Pfizer Profits Surge on International Demand," Financial Times, November 1, 2011).
[19] D. Ingram, "Retailers press for damages in 'pay-for-delay' drug cases," Thomson Reuters News & Insight, March 6, 2013.
[20] Walgreen Co. v. Pfizer Inc., No. 3:12-cv-04115-PGS-DEA, at 67 (D.N.J. filed July 5, 2012).
[21] http://www.ama-assn.org/resources/doc/legal-issues/2013-01-29-amicus-brief-ftc-vs-watson-pharmaceuticals.pdf
[22] *FTC v. Watson Pharm.*, 677 F.3d 1298, 1309, 1312 (2012)

Although, the Supreme Court did not agree with the FTC's argument that these arrangements are presumptively illegal, the decision represents a major step forward in eliminating pay-for-delay agreements. It is now expected that more antitrust claims against pay-for-delay agreements will go to court and receive the closer scrutiny they deserve.[23] However, experts generally believe that pay-for-delay agreements, while now more legally risky, will still continue absent additional intervention from Congress.[24]

**Need for Congress to Act**

In light of the Supreme Court's decision and its expected impact, AARP believes a legislative solution is needed to finally eliminate pay-for-delay agreements and obtain cost savings for both consumers and taxpayers.

AARP urges Congress to take action on S. 214, the Preserve Access to Affordable Generics Act, sponsored by Senators Klobuchar and Grassley. This bipartisan bill would make it presumptively illegal for brand-name drug manufacturers to use pay-for-delay agreements to keep less expensive generic equivalents off the market. It would also establish relevant factors that would allow manufacturers to overcome this presumption by demonstrating that the procompetitive benefits of the settlement outweigh its anticompetitive effects. The CBO expects that enacting this legislation would accelerate the availability of lower-priced generic drugs and generate over $4.7 billion in savings between fiscal years 2012 and 2021.[25]

AARP is also a strong supporter of S. 504, the Fair and Immediate Release of Generics Act (FAIR GENERxICS Act), sponsored by Senators Franken and Vitter. This bipartisan bill would address a provision in the Hatch-Waxman Act that allows first-to-file generic manufacturers to "park" their 180-day period of marketing exclusivity as part of a patent settlement agreement, delaying market entry and effectively blocking other generic manufacturers from entering the market. The legislation would instead grant shared exclusivity rights to any subsequent generic manufacturer that wins its patent case or is not sued for patent infringement by the brand pharmaceutical company. It would also create more certainty around litigation for brand name and generic companies by prohibiting brand name manufacturers from suing generic challengers for patent infringement outside the 45-day window provided under Hatch-Waxman. According to estimates from the CBO, this legislation would generate $3.8 billion in savings between fiscal years 2013 and 2022.

AARP is committed to working to further lower the cost of prescription drugs through the enactment of responsible changes that improve access and reduce costs both for consumers and in the Medicare and Medicaid programs. We look forward to working with members of Congress from both sides of the aisle to address pay-for-delay agreements as we seek to ensure that all older Americans have access to affordable prescription drugs.

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[23] DataMonitor Healthcare, "Reverse payments: What next for generic market entry?," www.datamonitorhealthcare.com

[24] R. Bligh, "FTC v. Actavis: After the Verdict," DataMonitor Healthcare White Paper, June 2013.

[25] Klobuchar: New Report Underscores Need for Legislation to Crack Down on Anti-Competitive Pay-for-Delay Deals, July 11, 2013, http://www.klobuchar.senate.gov/newsreleases_detail.cfm?id=345314&