No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

AMICUS CURIAE BRIEF OF AMERICA'S HEALTH INSURANCE PLANS IN SUPPORT OF PETITIONER

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Amicus Curiae America's Health Insurance Plans ("AHIP" or "*Amicus*") respectfully submits this brief in support of Petitioner, The Federal Trade Commission ("FTC").

AMICUS' INTEREST IN THIS CASE[1]

AHIP is the national association representing the health insurance industry. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care through a competitive marketplace that fosters choice, quality and innovation.

In 2011, health insurers paid more than $214 billion for prescription drugs dispensed to beneficiaries of prescription drug benefit plans. www.cms.hhs.gov/nationalhealthexpenddata/. *Amicus'* members have a strong interest in a competitive market for prescription drugs, in which the availability of generic versions of brand-name drugs is unrestrained by agreements that artificially prolong brand drug market power past the

1. Under Rule 37.6, counsel certifies that no party, or counsel for a party, authored or paid for this brief in whole or in part, or made a monetary contribution intended to fund its preparation or submission. No person other than *Amicus*, its members and their counsel made a monetary contribution to the brief. The FTC has provided blanket consent to the filing of *amicus* briefs in a letter filed with the Court on December 20, 2012. Counsel of Record for all Respondents have provided their written consent to this filing and such consents are being submitted herewith.

time intended by Congress. The most insidious and economically damaging of these artifices is when brand drug manufacturers pay generic manufacturers to delay competing, generally under the guise of settlement of patent lawsuits. A 2010 FTC study estimated that such settlements increase the cost of U.S. prescription drug expense by $3.5 billion annually, with the lion's share of that borne by health benefit plans and their customers. Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions: A Federal Trade Commission Staff Study, at 2 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf. For the 2012 fiscal year (from October 2011 to September 2012), FTC's Bureau of Competition identified 40 such settlements where brand drug manufacturers paid would-be competitors to delay selling generic versions of 31 different brand-name drugs whose fiscal 2012 U.S. sales exceeded $8.0 billion. Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012: A Report By the Bureau of Competition (Jan. 17, 2013), available at http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

SUMMARY OF ARGUMENT

The FTC has prosecuted several actions under Section 5 of the Federal Trade Commission Act focusing on the potential harm to consumers and to competition generally posed by these agreements. *Amicus* wishes to communicate to the Court that such "pay-for-delay" reverse payment settlements harm health insurers and other third party payers such as self-funded employer sponsored ERISA plans, and those who receive their coverage from such insurers and plans.

ARGUMENT

I. Third Party Payers Bear The Vast Majority of the Adverse Economic Impact of "Pay-For-Delay" Agreements.

A. The Economics of U.S. Retail Prescription Drug Transactions.

A prescription drug is typically sold in capsule, tablet, gel, or injection form through a distribution chain of manufacturer to wholesalers to retail pharmacy, which delivers the product to the consumer. Prescription drugs usually pass in unaltered form through the chain from manufacturer to user. This is the case with Androgel, a testosterone gel.

A minority of consumers have no third party payer prescription drug insurance benefits and pay cash out of pocket at the pharmacy counter. However, a majority of Americans have private or government sponsored prescription drug reimbursement coverage or insurance, making the "consumer" for economic purposes a dual end-payer consisting of the individual benefit plan member and his or her third party payer (for simplicity this brief refers to these benefit plans with the more common parlance as "insurance" although some plans may have other than insured funding sources, such as self-funded ERISA plans). According to U.S. Census Bureau statistics for 2011, 63.9 percent of U.S. citizens had third party payer health benefits. INCOME, POVERTY AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2011, at 21 (Sep. 2012), available at http://www.census.gov/prod/2012pubs/p60-243.pdf.

Virtually all United States pharmacies have contracts with third party payers. Pursuant to these contracts, pharmacies typically charge the dual end-payer (the third party payer or insurer and the benefit plan member or insured), a retail price based on a percentage of pricing benchmark, plus a dispensing fee of a few dollars per prescription. The pharmacies generally collect a co-payment (or deductible) from the insured patient and charge the balance to the third party payer. These charges are generally determined electronically and instantaneously at the retail pharmacy counter (or by mail order pharmacies) through computer interfaces whereby a patient's benefit terms are verified, the third party payer is billed, and the co-payment is collected from the patient.

After a generic bioequivalent of a branded drug is approved by the FDA and made available by its manufacturer, third party payers' contracts with pharmacies and members typically reduce the amount third party payers will pay pharmacies for either version (brand or generic) of the drug using a pricing benchmark based upon the lower price of the generic drug. Following the Hatch-Waxman Act's 180-day period of marketing exclusivity granted to the first-filed generic company, later-filed generic companies typically offer the drug for even lower prices, and third party payer pharmacy contracts customarily contain pricing mechanisms that then further reduce how much they will pay for any version of the drug. *See* Prepared Statement of the Federal Trade Commission Before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry, at 2, 6, 10 (July 20, 2006), available at http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf; Pay-For-Delay:

How Drug Company Pay-Offs Cost Consumers Billions, FTC Staff Study, at 8 (Jan. 2010), available at http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf.

After generic versions of a prescription drug are available, a typical insured patient has a choice. He can either accept the lower-priced generic (for which he generally pays a lower co-payment, sharing with his insurer the benefit of the drug's lower price) or choose to pay more out of his pocket to buy the brand version of the drug. Consumers usually accept the lower priced generic, resulting in cost-savings for both the patient and his third party payer. "Publicly available information about generic drug launches suggests that a generic market typically matures about one year after the first entrant comes on the market," with "pharmacists fill[ing] 90 of every 100 prescriptions for the molecule with an AB-rated . . . generic." Pay-For-Delay, *supra*, at 8.

B. The Rising Costs of Prescription Drugs.

The Centers for Medicare and Medicaid ("CMS") estimate that for calendar year 2009, total prescription drug expenditures were approximately $254.5 billion, with private health insurance paying 46.44% (approximately $118.2 billion), patient out-of-pocket cash payments comprising 19.48% (approximately $49.6 billion), CMS payments comprising 29.8% (approximately $75.9 billion) and miscellaneous other private, state and federal programs accounting for the remainder. National Health Expenditures By Type of Service and Source of Funds: Calendar Years 1960 To 2011: CMS Study, available at http://www.cms.hhs.gov/nationalhealthexpenddata/. Total prescription drug expenditures rose to approximately

$263 billion in 2011, with private health insurance paying 46.42% ($122.1 billion), patient out-of-pocket cash payments representing 17.14% ($45 billion), and CMS payments representing approximately 32% ($84.23 billion). Prescription drug costs represented approximately 10% of total national healthcare expenditures for the calendar years 2009-2011. *Id.*

C. Cost Savings From Generic Use.

In January of 2012, The United States Government Accountability Office collected studies of cost savings estimates as a result of generic drug use. DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE: GAO STUDY (Jan. 31, 2012), available at http://www.gao.gov/assets/590/588064.pdf. While these studies varied in scope and end points, each concluded that wider use of generic pharmaceuticals resulted in health care savings. The GAO reported these studies' findings as including: (1) generic substitution "has saved the U.S. health care system more than $1 trillion" during the 12-year period of 1999 to 2010; and (2) "dispensing generic drugs rather than their brand-name counterparts reduced total Part D prescription drug costs in 2007 by about $33 billion," with $9 billion of these savings accruing to enrollees. *Id.* Hence, the health care system achieves tremendous cost savings with generic drugs.

CONCLUSION

Amicus encourages the Court to recognize the significant economic impact reverse-payment settlements like the one under review have on its members, those who receive coverage through its members, and the United States healthcare system.

Respectfully submitted,

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