05-2851-cv(L)

05-2852-cv (CON), 05-2863-cv (CON) *

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IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Arkansas Carpenters Health and Welfare Fund, Maria Locurto, Paper, Allied –Indus, United Food and Commercial Workers Union-Employer, Louisiana Wholesale Drug Co., Inc, CVS Pharmacy, Inc., Rite Aid Corporation, Arthur's Drug Store, Inc.

Plaintiffs-Appellants,

Sol Lubin, Ann Stuart, Linda K. McIntyre,

Plaintiffs,

v.

Bayer AG, Bayer Corp., formerly doing business as Miles Inc., Hoechst Marion Roussel, Inc., The Rugby Group, Inc., Watson Pharmaceuticals, Inc., Barr Laboratories, Inc.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of New York.

BRIEF OF AMICI CURIAE OF PRESCRIPTION ACCESS LITIGATION AND AFSCME DISTRICT COUNCIL 37 IN SUPPORT OF APPELLANTS' PETITION FOR EN BANC REVIEW

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* 05-2863-cv has been transferred to the Federal Circuit Court of Appeals, See order filed 11/7/2007

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Local Rule 29.1,[1] counsel for Amici Curiae certify that:

1. Prescription Access Litigation, LLC is a non-profit 501-c-3 organization, and a project of its parent organization Community Catalyst, Inc, another non-profit 501-c-3 organization. Neither Prescription Access Litigation LLC, nor Community Catalyst, Inc. have any other parent corporations, nor do they issue any publicly traded stock.

2. AFSCME DC 37 is a 501-c-3 non-profit organization with no parent corporation, and which does not issue publicly traded stock.

May 20, 2010 s/Audrey A, Browne, Esq.

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[1] No party's counsel authored any part of this amicus brief, nor did any party or party's counsel contribute any funds in connection with the preparation or filing of this amicus brief.

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STATEMENT OF INTEREST OF *AMICI CURIAE*

Prescription Access Litigation, LLC ("PAL") is a non-profit organization that promotes expanded access to needed medicines while also challenging deceptive, fraudulent, or illegal promotional drug industry practices that inflate drug costs, through litigation or other legal action. PAL has built a nationwide coalition of over 130 organizations in 36 states and the District of Columbia, with a combined membership of over 13 million people, comprised of consumers, seniors, health care advocacy organizations, labor unions, health plans, and union benefit funds. PAL has facilitated its coalition members' active participation in over 30 class action lawsuits.

PAL has opposed "reverse payment settlements" due to their harmful effects of on consumer access to affordable generic prescription drugs. PAL fostered the involvement of five consumer advocacy organizations and four individual consumers as plaintiffs in class action litigation challenging the reverse payment settlement concerning the drug Tamoxifen. PAL later helped three consumer organizations join litigation concerning K-Dur.

AFSCME District Council 37 Health and Security Plan ("AFSCME DC 37") is a public sector union-sponsored employee welfare benefit plan, which provides a prescription drug benefit for covered titles, retirees and their spouses and dependants. Contributions towards such benefits are bargained for with various municipal employers, including The City of New York, various authorities and

corporations and quasi-public institutions. AFSCME DC 37 provides supplement health benefits, including a prescription drug benefit for over 270,000 participants and beneficiaries in all but one state in the U.S.

Currently, PAL is working with AFSCME DC 37, who serves as a lead plaintiff in class action litigation challenging the four reverse payment settlements currently preventing access to generic forms of Provigil. See *In re Modafinil Antitrust Litigation*, No. 06-cv-01797-RBS, E.D. PA.

Amici Curiae PAL and AFSCME DC37 file this amicus in support of our concerns on behalf of consumers, patients, and non-profit insurers.

ARGUMENT

Generic drugs are the most effective means to ensure access to affordable drugs. Soon after the passage of Hatch-Waxman Act[2] access to affordable drugs and concomitant savings grew significantly. Generic drug use has also risen steadily, and now accounts for 69 percent of all drugs dispensed in the U.S. Generic Pharmaceutical Association, *Facts At A Glance*, available at http://www.gphaonline.org/about-gpha/about-generics/facts, citing IMS Health. The Hatch-Waxman Act has also saved consumers and their health plans billions of dollars

[2] The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355).

in drug costs. For example, the FTC noted that the early entry of generic forms of just four brand-name drugs (Zantac, Prozac, Taxol, and Platinol) resulted in more than $9 billion in overall savings. Thomas Rosch, FTC Commissioner, testimony, Mar. 31, 2009, before the House Subcommittee on Commerce, Trade and Consumer Protection, at 14, available at http://energycommerce. house.gov/ Press_111/ 20090331/ testimony_rosch.pdf (citing Generic Pharmaceuticals Marketplace Access and Consumer Issues: Hearing Before the Senate Commerce Comm., 107th Cong. Apr. 23, 2002, statement of Kathleen D. Jaeger, President and CEO, Generic Pharmaceutical Ass'n, at 12).

However since 2005, brand-name and generic drug makers have pursued a strategy which the Obama Administration has publicly characterized as "drug companies . . . blocking generic drugs from consumers [using] anticompetitive agreements and collusion [with] generic drug manufacturers [] to keep generic drugs off the market." Office of Management and Budget, Executive Office of the President, Budget of the US Government, Fiscal Year 2010 (2009) (proposed) at 28, available at http://www.socialworkers.org/advocacy/ healthcarereform/ documents/ a_new_era_of_responsibility2.pdf.

I. THE SIGNIFICANT FINANCIAL AND THERAPEUTIC IMPACTS OF INCREASINGLY COMMON REVERSE-PAYMENT SETTLEMENTS ARE AN ISSUE OF VITAL PUBLIC CONCERN

A. Reverse payment settlements are preventing tens of billions of dollars in potential savings on prescription drugs.

An FTC Staff Report concluded that most of the 63 agreements reached since 2004 that involved a reverse payment in exchange for delayed entry of a generic "are still in effect" and that "[t]hey currently protect at least $20 billion in sales of brand name pharmaceuticals from generic competition." Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study, at* 2 (January 3, 2010) (based on settlements from FY2004 to FY2009), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. This supports earlier estimates that reverse payment settlements could be costing $12 billion or more *each year* in lost savings on generic drugs. Scott Hemphill, testimony, Mar. 31, 2009, before the House Subcommittee on Commerce, Trade, and Consumer Protection, at 9, available at http://energycommerce. house.gov/ Press_111/ 20090331/testimony_hemphill.pdf. Thus reverse payment settlements threaten to prevent generic competition in the nationwide drug market, and undermine the central purpose of Hatch-Waxman Act – promoting access to generic drugs.

B. Rising brand-name drug costs have increased the significance and impact of reverse payment settlements.

The public interest in the impact of these settlements has grown, in part, because brand-name drug costs have risen at an alarming rate, while generic drug costs have declined. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate*, May 2010, at 2-3, available at http://assets.aarp.org/rgcenter/ppi/health-care/i43-watchdog.pdf (noting that the

average price of the most widely used brand-name drugs that have not gone 'off-patent' have risen an alarming 9.2 percent over the year ending March 31, 2010, while generic drug prices have dropped by 9.7 percent over the same time period.)

C. Reverse payment settlements have serious adverse effects upon consumer access to needed drugs, their quality of life, and the quality of their health care

Reverse payment settlements that prevent generic entry have negative and potentially serious effects upon the quality of patient care, and the quality of life for millions of Americans. An individual consumer will suffer a decreased quality of care if a brand name drug is (a) the most appropriate treatment, but (b) sold under a monopoly price which would cause a health plan to exclude it from coverage. For example Cephalon, which manufactures the drug Provigil, has entered into reverse payment settlements with four generic competitors. Provigil has a monthly price of $319.[3] But unlike other best-selling brand-name drugs, like the statin Lipitor, or the antacid Nexium, Provigil is unique in its therapeutic class, having neither a generic equivalent or any other brand-name competitor for its indicated uses to treat certain sleep disorders including narcolepsy and shift work sleep disorder.

PAL has received frequent complaints from Provigil consumers that, presumably due to its high price, some health plans have refused to cover the costs of Provigil. Consider the following recent complaints PAL has received in 2010 alone:

[3] Provigil is currently priced at $319.98 for thirty (30) 100 mg tablets, see www.drugstore.com, last checked May 19, 2010.

A teacher from Kansas reported that "my insurance denied [my coverage for Provigil] even though I had been taking Provigil since approximately 1999."

A consumer from Rhode Island reports that:

> The medical plan I have purchased through UnitedHealth since 2003 has covered the cost of [Provigil which my wife] as been taking []to fight MS fatigue [until] this year [when the plan] denied her the use of the drug . . . overrul[ing] the neurologist that has been overseeing her medication protocol for over 10 years.

A consumer from Minneapolis reports being forced to "swithc [sic] to another stimulant type drug as my new insurance will not cover provigil."

A pastor from Ohio with narcolepsy reports that after

> paying almost $17,000 in annual premiums for my family [health insurance plan, l] ast year, I was paying around $650/month [for Provigil. I]t now costs me $852/month. That is out of pocket money I have to come up with until later in the year when I reach my deductable and I can enjoy a few months of only paying $60/month. I cannot describe to you how much stress and difficulty this has caused for me and my family the last several years. As you can imagine, with my income, I often cannot afford to refill my prescription. I often take 1/2 or 3/4 of my dosage on days I know I won't be driving much so I can delay getting a refill. But I do a lot of driving for my work, so I am forced to spend lots of money I don't have just so I can be safe driving. Most of the time my only option is to use a credit card, but I cannot continue accumulating debt to pay for my medication.

The prohibitive cost of brand-name drugs also impacts millions of seniors, because high drug costs force Medicare Part-D beneficiaries to enter the 'donut hole' gap in coverage, where seniors must pay the full cost of their drugs. An estimated 4

million seniors are expected to exhaust their Medicare Part-D coverage and enter the 'donut hole' gap this year. U.S. Dept of Health and Human Services, *Letter to Hill Leadership from Secretary Sebelius Outlining HHS's Progress to Date on Implementation Efforts*, May 13, 2010, available at http://www.healthreform.gov/newsroom/implementation_efforts.html.

Those who choose to follow their medication regimens sometimes must sacrifice food or other necessities, reducing their economic security and quality of life. Other seniors modify their doses by splitting pills, taking their drugs only every other day, or ceasing drug treatment altogether due to cost. These and other strategies to cope with high costs expose seniors to all the medical risks attendant to interruption of their prescription drug therapy.

The following examples illustrate some consumer tactics:

A consumer from Oregon reported to our organization that they stop filling their Provigil prescriptions until they went completely through the donut hole:

> I went to pick up my Priovigil [sic] Rx and it was about $750...Needless to say, I need to wait until I reach 'Catastrophic Level' of Medicare D, before I can refill it!

Unlike higher cost estimates by FTC and others, these kinds of human costs, reflected in the possible decline in their health or the quality of life are so numerous and varied, they are impossible to quantify. These few examples illustrate the broad range of serious and harmful consequences these legal standards have upon the lives, health, and economic security of millions of Americans. Seniors, and millions of other

under- and uninsured consumers suffer from the higher costs, reduced quality care, or reduced quality of life when access to generic drugs is restricted by reverse payment settlements.

CONCLUSION

In light of the harmful economic and therapeutic impacts upon consumers and health plans, we pray the Court will grant petitioners request for a rehearing en banc.

Respectfully submitted:

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Certificate of Compliance with Fed. R. App. P. 32 (a)

1. This brief complies with the type-volume limitation under Fed. Rule App. P. 29(d) and 35(b)(2) because it is fewer than 7 ½ pages, excluded those sections exempted under Fed. Rule App. P. 32(a)(7)(B).

2. This brief complies with type face requirements under Fed. Rule App. P. 32(a)(5) and the type style requirements under Fed. Rule App. P. 32(a)(6) as it has been prepared in 14-point Times New Roman font, using MS Word 2003.

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Certificate of Service

I hereby certify that on May 20, 2010, I caused two copies of the forgoing brief to be served by first-class mail, and one copy of the PDF version of same to be served via email, on the following:

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