IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 2:12-cv-00995

IN RE LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION

Appeal from the United States District Court
for the District of New Jersey
(The Honorable William H. Walls)

BRIEF AMICI CURIAE OF AARP, THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES, AND THE UNITED STATES PUBLIC INTEREST RESEARCH GROUP IN SUPPORT OF PLAINTIFF-APPELLANT

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CORPORATE DISCLOSURE STATEMENT OF AARP

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) (1993) of the Internal Revenue Code and is exempt from income tax. AARP is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code 1951.

Other legal entities related to AARP include AARP Foundation, AARP Services, Inc., Legal Counsel for the Elderly, Experience Corps, d/b/a, AARP Experience Corps, AARP Insurance Plan, also known as the AARP Health Trust, and AARP Financial.

AARP has no parent corporation, nor has it issued shares or securities.

CORPORATE DISCLOSURE STATEMENT OF THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES

Founded in 2000, the National Legislative Association on Prescription Drug Prices ("NLARx") is a Section 501(c)(4) nonpartisan, nonprofit organization founded and directed by state legislators. NLARx has no parent corporation, nor has it issued shares or securities.

CORPORATE DISCLOSURE STATEMENT THE UNITED STATES PUBLIC INTEREST RESEARCH GROUP

Founded in 1983, United States Public Interest Research Group (U.S. PIRG) is a nonpartisan, nonprofit organization organized under Section 501(c)(4) of the Internal Revenue Code. U.S. PIRG has no parent corporation, nor has it issued shares or securities.

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JURISDICTIONAL BASIS TO FILE

Amici file this brief pursuant to F. R. A. P. 29 and 3rd Cir. L.A.R. 29. All parties have consented to the filing of this Brief Amici Curiae of AARP, the National Legislative Association on Prescription Drug Prices, and the United States Public Interest Research Group in Support of Plaintiff-Appellant.

INTEREST OF AMICI CURIAE[1]

Amici have a strong interest in this case because of their work to ensure access to affordable medications. In the course of amici's work representing the interests of prescription drug consumers, amici observed a significant rise in prescription costs, making them unaffordable to many of the people we work to protect. Amici's participation in this case will raise issues which might otherwise escape the Court's attention and will assist this Court in understanding the impact of anticompetitive agreements on consumers of prescription drugs.

AARP is a nonprofit, nonpartisan organization with a membership that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and

[1] Under Rule 29(c)(5) of the Federal Rules of Appellate Procedure, amici certify that (1) no party to this action, nor their counsel, authored this brief in whole or in part; (2) no party or party's counsel contributed money to fund preparing or submitting this brief; and (3) no person other than *amici curiae* contributed money that was intended to fund preparing or submitting this brief.

protection from financial abuse. Since its founding in 1958, AARP has advocated for affordable, accessible health care. AARP seeks to ensure that older adults have access to affordable prescription medications. AARP advocates for affordable prescription medication and produces reports and educational materials to inform people and policy makers about the significant negative impact that unaffordable medications have on older people and the overall economy.

The National Legislative Association for Prescription Drug Prices ("NLARx") is a national nonprofit, nonpartisan organization of state legislators who support policies to reduce prescription drug prices and expand access to affordable medicines and has promoted policies since 2000 to expand access to generic drugs and increase competition in the marketplace.

The United States Public Interest Research Group ("U.S. PIRG") is the federation of State Public Interest Research Groups ("PIRGs"), organizations that stand up to powerful special interests on behalf of the American public, working to win concrete results for Americans' health and well-being. With a network of researchers, advocates, organizers and students in states across the country, U.S. PIRG advocates the public interest on issues such as product safety, public health, political corruption, tax and budget reform, and consumer protection.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Over the past decade, health care consumers paid ever-increasing prices for prescription medications. The total annual spending on prescription medications in the United States was $234.1 billion in 2008, more than double the spending in 1999. Qiuping Gu, et al., *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008*, 1 (Sept. 2010), *available at* http://www.cdc.gov/nchs/data/databriefs/db42.pdf. Consumer spending for pharmaceuticals in the United States continues to climb, reaching $329.2 billion in 2013. Press Release, IMS Institute for Healthcare Informatics, *IMS Health Study: Spending Growth Returns For U.S. Medicines in 2012* (April 15, 2014), *available at* http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=d58b8b5776165410VgnVCM10000076192ca2RCRD.

Older adults often require more prescription medications due to higher rates of chronic and serious medical conditions amongst older adults, and this usage is increasing. From 2007 to 2010, 66.6 percent of the Americans age 65 and over took three or more prescription medications. By comparison, from 1999 to 2002, 51.8 percent of Americans age 65 and over utilized three or more prescriptions. Centers for Disease Control and Prevention, *Health, United States, 2012*, Table 91

(May 2013), *available at* http://www.cdc.gov/nchs/data/hus/hus12.pdf. Consequentially, older adults often pay higher costs for prescription medications.

With total prescription medication spending still at near-record highs, the use of generic substitutes is a critical factor in controlling cost. *See* Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. Times, A1 (Mar. 18, 2013). Generic alternatives typically cost 80-85% less than brand-name medications. *See* Food and Drug Administration, *Facts About Generic Drugs*, 2, *available at* http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM305908.pdf (hereinafter "FTC, *Facts About Generic Drugs*"). In fact, from 2003 through 2012, use of generic versions of name-brand drugs saved Americans $1.2 trillion: $217 billion in savings were achieved in 2012 alone. *Generic Drug Savings in the U.S.*, 1, Generic Pharmaceutical Association (5th ed. 2013), *available at* http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf.

Congress has long recognized the clear consumer benefit that accompanies generic drug competition and entry. Passed in 1984, the Hatch-Waxman Act serves to encourage quick and effective entry of generic pharmaceuticals into the marketplace. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355

(1994)). The purpose of the Act was to serve the dual purposes of ensuring that brand-name drug manufacturers would have meaningful patent protection and ensuring that, once those patent protections expired, consumers would benefit from the rapid availability of lower priced generic versions of innovator drugs. *See Examining the Senate and House Versions of the Greater Access to Affordable Pharmaceuticals Act: Hearings Before the Senate Committee on the Judiciary*, 108th Cong. (Aug. 1, 2003) (Stmt. of Daniel E. Troy, Chief Counsel, U.S. Food and Drug Administration), *available at* http://www.fda.gov/newsevents/testimony/ucm115033.htm.

The Hatch-Waxman Act grants a 180-day period of exclusivity in the market to the first manufacturer to challenge a brand-name firm's patent and file an application to produce a generic version of a prescription medication. 21 U.S.C. § 355(j)(5)(B)(iv). The manufacturer of the name-brand version of the drug may compete with the generic manufacturer, however, by offering its own "authorized generic" ("AG") within the 180-day period of exclusivity. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). After 180 days, any willing company can produce a generic drug to compete with the brand-name drug. The 180-day exclusivity period provided by the Hatch-Waxman Act was never intended to promote or prolong monopoly profits.

Over the past several years, brand-name drug manufacturers and their generic competitors sought to limit open entry of generics into the marketplace and maintain monopoly profits under patents of questionable validity. Rather than litigating the validity of the brand-name manufacturer's patent, pharmaceutical competitors seeking to market a generic medication frequently enter into anticompetitive, anti-consumer patent litigation settlements, more commonly known as "pay-for-delay" settlements. *See generally*, Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (hereinafter "FTC, *Pay-For-Delay Report*"). Pay-for-delay *settlements* terminate genuine patent challenges that would otherwise open competition to generic drugs, giving the manufacturers of a name-brand medication a monopoly over the market.

Generic manufacturers are sometimes, but not always, offered cash payments in these pay-for-delay settlements. More recently, brand-name drug manufacturers have utilized a new type of "payment" to deflect potential generic challengers. As compensation for the generic drug manufacturer dismissing its litigation challenging the validity of the brand-name manufacturer's patent, the brand-name manufacturer promises to not introduce its own authorized generic that

would compete with the generic manufacturer during the generic's 180-day period of exclusivity. This is sometimes referred to as a "no-AG settlement."

While money does not change hands, there is financial consideration: such settlements have the purpose and effect of dividing up the market into monopolies and significantly increasing costs for consumers. The brand name drug gets an exclusive sales period during most of the life of what is often an invalid patent followed by the generic drug receiving an exclusive 180-day marketing period without competition from an authorized generic. The Federal Trade Commission ("FTC") has found that no-AG settlements along with other pay-for-delay settlements will cost consumers $35 billion over the next decade. FTC, *Pay-For-Delay Report*, *supra*, at 2. Pay-for-delay agreements that utilize no-AG settlements harm consumers by creating fewer options and higher prices.

In 2013, the Supreme Court restricted the ability of pharmaceutical competitors to use pay-for-delay schemes, including those that use no-AG settlements. The Supreme Court determined that pay-for-delay settlements are generally disfavored and should be *individually scrutinized* under a "rule of reason" analysis that would consider multiple factors concerning the pay-for-delay agreement, including "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *FTC v. Actavis, Inc.*,

133 S. Ct. 2223, 2237 (2013). The Court's decision in *Actavis* did not state that the "payment" at issue must be a payment of money to be scrutinized under antitrust laws. *Id*.

The district court's decision in this case incorrectly applied *Actavis's* holding. On remand in light of the Supreme Court's decision, the district court in this case incorrectly applied *Actavis's* holding. The lower court held that in order to warrant antitrust scrutiny under *Actavis*, the patent settlement must involve the "unjustified reverse payment of *money*." *In re Lamictal Direct Purchaser Antirust Litig.*, 2014 U.S. Dist. LEXIS 9257, No. 12-CV-995, *30 (D.N.J. Jan. 24, 2014) (affirming dismissal) (emphasis added). As will be argued in Section II, below, nothing in the Supreme Court's *Actavis* decision supports an interpretation that unjustified reverse payment cases are limited to those involving a cash payment as opposed to other forms of financial inducement. Such an interpretation will open consumers to harm from widespread proliferation of anticompetitive settlements with exchanges of non-monetary benefits, including no-AG settlements, which will increase the cost of prescription medications.

Amici curiae submit this brief to illustrate several points. First, the district court's decision contradicts the consumer protections provided by the Hatch-Waxman Act. Second, consumers benefit significantly from robust competition between manufacturers of name-brand and generic pharmaceuticals. Finally,

upholding the district court's decision will harm competition and consumers by promoting anticompetitive no-AG settlements within the pharmaceutical industry.

ARGUMENT

I. The District Court's Opinion Contravenes the Purpose of the Hatch-Waxman Act

Congress passed the Hatch-Waxman Act in recognition of the clear consumer benefit that accompanies competition from generic drugs. The purpose of the Act was to establish a regulatory framework wherein a generic pharmaceutical manufacturer could bring its drug to market more quickly. H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted* in 1984 U.S.C.C.A.N. 2647 (purpose of Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). *See also* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 42 (2009) (explaining how Act's drafters "lamented the 'practical extension' of the patentee's 'monopoly position' beyond expiration" and how generic competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed").

The Hatch-Waxman Act successfully incentivized prompt entry of generics into the marketplace. Prior to the passage of the Hatch-Waxman Act, 12 percent of all medications prescribed were generic versions of brand-name medications. *See* Food and Drug Administration, *Greater Access to Generic Drugs* (2006), *available*

at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm. Today, thanks in large part to the Hatch-Waxman Act, nearly eight in ten prescriptions filled in the United States are for generic drugs. *See* FTC, *Facts About Generic Drugs*, *supra*, at 1.

Generic manufacturers view authorized generics from name brand manufacturers as a threat to their profits, particularly during the 180 days of exclusivity. Authorized generic entry during the period of exclusivity lowers estimated revenue of the first filer generic by 40 to 52 percent. Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, 33 (2011), *available at* http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (hereinafter "FTC, *Authorized Generics Report*"). With such a dramatic impact on potential profits, generic and name-brand manufacturers have clear financial incentives to utilize no-AG settlements to remove potential competitors. Just like a payment in cash, the agreement to withhold an authorized generic and thereby suppress generic competition runs contrary to the purpose of the Hatch-Waxman Act and other antitrust laws to protect consumers from unjustified monopolies by name brand drug manufacturers.

In violation of the goals and incentives of the Hatch-Waxman Act, GlaxoSmithKline ("GSK") and Teva determined in this case that a pay-for-delay arrangement with a no-AG settlement was more profitable to both parties. According to the allegations in the complaint, absent the settlement, GSK's patent would have been invalidated, vastly widening the scope of potential competitors. Rather than promoting competition between competitors, the no-AG agreement between GSK and Teva substitutes one unlawful monopoly for another. GSK would remain the sole provider of Lamictal tablets—a product yielding profits of over $2 billion per year—for the life of its patent *after* a court invalidated the underlying patent. In exchange, Teva would become the sole provider of a generic version of Lamictal tablets for a period of 6 months without competition from an authorized generic. Consolidated Amended Class Action Complaint, *In re Lamictal Direct Purchaser Antitrust Litigation*, No. 12-CV-995, 31-34 (D.N.J. June 25, 2012).

Although it did not involve a cash payment of money, this agreement clearly harmed competition and was highly profitable for both parties. As noted in their 2008 annual Securities and Exchange Commission filing, Teva stated that having the market exclusivity for generic Lamictal for 180 days would "substantially increase" Teva's profits. Teva Pharm Indus. Ltd., *Securities and Exchange Commission Annual Report (Form 20-F)*, 5 (Feb. 27, 2009). *See also*

GlaxoSmithKline, *Securities and Exchange Commission Annual Report (Form 20-F)*, 39 (February 29, 2008) ("[A] decline in [U.S.] sales of *Avandia* products…[was] partly offset by growth in sales of…Lamictal").

Such an arrangement is the antithesis of Congress's intent under the Hatch-Waxman Act: "Congress sought to get generic drugs into the hand of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir 1991). By allocating the market for Lamictal and Teva's generic counterpart to it, GSK and Teva effectively agreed to immunize GSK's patent from legal scrutiny, and to eliminate competition for the remaining life of the patent. This agreement ensured high profits for both parties at the expense of the American consumer.

II. Consumers are Harmed by Lack of Competition Between Prescription Drug Manufacturers

Competition between manufacturers of name-brand prescription medications and manufacturers of their generic versions leads to consumer savings, worth an estimated $217 billion in 2012 alone. *Generic Drug Savings in the U.S.*, *supra*, at 1. According to the U.S. Food and Drug Administration, the highest price drop in generic prescriptions occurs when the *second* generic medication is introduced. While the first generic entry typically charges a price marginally less than the brand-name drug, the second generic entrant can lower the price to nearly *half* the brand-name price. Food and Drug Administration, *Generic Competition and Drug*

Prices, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProducts andTobacco/CDER/ucm129385.htm (last visited Apr. 27, 2014).

Where pharmaceutical companies restrain the competition provided by the entry of generics into the marketplace, consumers ultimately bear the costs. In their landmark 2011 study of authorized generics, the FTC discovered that generic markets without an authorized generic have retail prices that are 4 to 8 percent lower than their name-brand counterparts. In markets with competition from an authorized generic, wholesale generic prices are 7 to 14 percent lower than name-brand drugs. FTC, *Authorized Generics Report*, *supra*, at ii. Competition between generic manufacturers and name-brand manufacturers helps bring prices down, which benefits consumers.

In some cases, markets without authorized generics see prices *increase* during the first few months of solo generic entry. Aidian Hollis and Bryan A. Liang, *An Assessment of the Effect of Authorized Generics on Consumer Prices*, 10 J. of Bio L. and Bus. 10, 14 (2007), *available at* http://anesthesia.ucsd.edu/ research/faculty-research/Documents/HollisLiangJBBAuthorizedGenerics.pdf.[2] In

[2] In the first month of generic entry into markets without authorized generics, consumers experienced increased prices for generics over name brand versions, including Torsemide 5 mg (41 percent), Mefloquine HCI 250 mg (2 percent), and Pergolide .05 mg (7 percent). Aidian Hollis and Bryan A. Liang, *An Assessment of the Effect of Authorized Generics on Consumer Prices*, 10 J. of Bio L. and Bus. 10,

these instances, due to a lack of competition from an authorized generic, consumers actually paid more for the generic than for the original brand-name medication. Industry experts agree that both competition between generics and entry of authorized generics are beneficial to consumers. In a recent survey of 120 drug and regulatory professionals, 69 percent agreed that authorized generics increase price competition, and 85 percent stated that authorized generics benefit consumers by offering a "lower-price alternative." M. Mangesh et al., *Authorized Generics: Effects on Pharmaceutical Market*, 2 Int'l. J. of Novel Trends In Pharm. Sci. 1, 2-4 (Feb. 2012), *available at* http://www.ijntps.org/File_Folder/0006.pdf.

Consumers, not the manufacturers who are parties to the settlement agreement, ultimately pay for anticompetitive activities restricting much-needed competition in generic markets. Higher prices and less competition dominate the pharmaceutical landscape leading to fewer options, and, most importantly, poor patient adherence to the regimens prescribed by their doctors. The anticompetitive agreements—including no-AG settlements—drive up prices, often forcing patients to forgo using the medication or refilling prescriptions for expensive medications. In 2012, a Consumer Reports survey found that 18 percent of consumers with prescription drug coverage declined to fill their medication due to cost, and 45

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14 (2007), *available at* http://anesthesia.ucsd.edu/research/faculty-research/Documents/HollisLiangJBBAuthorizedGenerics.pdf.

percent of consumers without prescription drug coverage skipped refills due to high prices. *Sluggish Economy Forces Americans to Cut Corners to Pay for Medications: Those without Prescription Drug Coverage Nearing Crisis Point*, Consumer Reports (Sept. 2012), *available at* http://www.consumerreports.org/cro/2012/09/sluggish-economy-forces-americans-to-cut-corners-to-pay-for-medications/index.htm. *See also* Becky A. Briesacher, Jerry H. Gurwitz, and Stephen B. Soumerai, *Patients At-Risk for Cost-Relating Medication Nonadherence: A Review of the Literature*, 22 J. Gen. Intern. Med. 864 (June 2007) (estimating that 32 percent of older Americans take less medication than prescribed to avoid costs).

Poor adherence to prescription medication orders leads to worse outcomes for patients and higher rates of preventable hospitalizations. Approximately 125,000 patients die each year as a result. *Medication Adherence—Improving Health Outcomes*, 6, Amer. Coll. Prev. Med. (2011), *available at* http://c.ymcdn.com/sites/www.acpm.org/resource/resmgr/timetools-files/adherenceclinicalreference.pdf. In fact, it is estimated that 30 to 50 percent of all treatment failures are likely attributable to nonadherence. Thomas H. Wroth and Donald E. Pathman, *Primary Medication Adherence in a Rural Population: The Role of the Patient-Physician Relationship and Satisfaction of Care*, 19 J. Am. Board Fam. Med. 478 (2006).

Along with deaths and failed treatments, patients who must forgo prescriptions are forced to spend more money in the form of re-hospitalizations and physician visits. In total, prescription nonadherence is estimated to have a direct cost to the U.S. health care system of between $100 billion to $289 billion annually. Centers for Disease Control and Prevention, *Medication Adherence*, 12 (Mar. 27, 2013), *available at* http://www.cdc.gov/primarycare/materials//medication/docs/medication-adherence-01ccd.pdf. Factors such as medication noncompliance are part of an estimated $290 billion per year wasted on "avoidable medical spending." *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease*, 1, New England Healthcare Inst. (Aug. 2009), *available at* http://www.nehi.net/writable/publication_files/file/pa_issue_brief_final.pdf.

For these reasons, consumers have a vested interest in preventing anticompetitive and anti-consumer agreements between pharmaceutical companies which prevent generic entry. In this case, without a no-AG settlement, consumers would have had a plethora of Lamictal generic options in or around 2005. *See In re Lamictal Direct Purchaser Antirust Litig.*, 2014 U.S. Dist. LEXIS 9257, No. 12-CV-995, *3 (D.N.J. Jan. 24, 2014) (recounting procedural history including court ruling that the original Lamictal patent was invalid). Instead, consumers were harmed when GSK and Teva entered into an agreement which ended litigation and

prevented generic entry. Consumers were further harmed because, as part of that agreement, GSK agreed to not introduce an authorized generic, thus allowing Teva to have a monopoly over the generic Lamictal for a six month period. If the district court's opinion is upheld, drug manufacturers will continue to strike anticompetitive deals that prematurely end litigation and that, while not involving an actual transfer of money, still provide vast financial incentives to limit market entry. In turn, consumers will be stuck with paying higher prices on vital, life-saving medications, or they will actually forgo treatment due to heightened costs.

III. Upholding the District Court's Decision Will Further Incentivize Usage of Anticompetitive No-AG Settlements.

From a consumer's perspective, it makes no difference whether a party to the agreement received money or some other form of compensation: the effects of these agreements on prices are the same either way. Just as the settlement struck in *Actavis* did, the economic reality of allowing anticompetitive no-AG settlements is that generic competition will be limited, forcing consumers to pay higher prices. *See* FTC, *Authorized Generics Report*, *supra*, at 140. No-AG agreements incorporated in a litigation settlement have a clear economic impact, governing the sales of drugs with a total market exceeding $23 billion. *Id.* Furthermore, patent settlements between brand-name brands and first filer generics utilizing no-AG settlements delayed the entry date of the generic drug by an average of 37.9 months. FTC, *Authorized Generics Report, supra,* at vi; *see also* FTC, *Pay-For-*

Delay Report, *supra*, at 2 (typical pay-for-delay cases only prohibit generic entry by an average of 17 months).

The FTC, which tracks pharmaceutical settlements, found an ever-increasing usage of anticompetitive no-AG settlements. From 2004 to 2010, the FTC noted that 39 patent settlements contained an explicit agreement by the brand-name not to compete via authorized generic with the generic company. FTC, *Authorized Generics Report*, *supra*, at 140. In recent years, even more settlement agreements contain a "no-AG" provision. In 2012 alone, of the 40 final, potential anticompetitive pay-for-delay settlements, 19 utilized no-AG agreements "as a form of compensation." Federal Trade Commission, *Agreements Filed with Federal Trade Commission under the Medicare Prescription Drug Improvement and Modernization Act of 2003: Overview of Agreements Filed in FY 2012*, 2 (2013), *available at* http://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf.

With an increasing usage of no-AG settlements between brand-name manufacturers and potential generic competitors, the district court's ruling could open the flood-gates of anticompetitive conduct and consumer harm. In particular, the district court held that the *Actavis* decision applies only to "patent settlements that contained an unjustified reverse payment of money." *In re Lamictal Direct*

Purchaser Antirust Litig., 2014 U.S. Dist. LEXIS 9257, No. 12-CV-995, *30 (D.N.J. Jan. 24, 2014). While parties, such as GSK and Teva, do not utilize actual cash payments, the conduct at issue is financially lucrative for both parties and has the same impact as cash payments. As noted by the FTC, "the frequency of [no-AG settlements] and [their] profitability may make it an attractive way to structure a pay-for-delay settlement, a practice that causes substantial consumer harm." FTC, *Authorized Generics Report*, *supra*, at vii.

If this Court upholds the district court's ruling, pharmaceutical manufacturers will be more likely to turn to no-AG settlements as a means for protecting their monopoly profits. Under no-AG settlements, generic competition is often stifled for years, forcing consumers to pay higher prices. For these reasons, the district court's decision has disastrous implications for consumers in search of affordable pharmaceuticals.

CONCLUSION

The district court's application of the standard enunciated in *Actavis* is incorrect and harmful to consumers of prescription medications. If upheld, consumers will wait longer and pay more for generic medications. For these reasons, amici respectfully support the Appellants' appeal and urge a reversal of the district court's decision to dismiss.

Dated: April 28, 2014

Respectfully Submitted,

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CERTIFICATE OF IDENTICAL COMPLIANCE AND VIRUS CHECK

I, Julie Nepveu, hereby certify that the foregoing brief amici curiae, electronically filed in PDF with this Court is identical to the brief amici curiae served with this Court in paper format, has been virus checked with the program Symantec Anti-Virus Endpoint Protection, ed. 2011.

Dated: April 28, 2014

/s/ *Julie Nepveu*
Julie Nepveu

CERTIFICATE OF BAR MEMBERSHIP

I, Julie Nepveu, hereby certify that I am admitted to practice before the United States Court of Appeals for the Third Circuit and that I am currently a member in good standing.

Dated: April 28, 2014

/s/ *Julie Nepveu*
Julie Nepveu

CERTIFICATE OF COMPLIANCE

Certificate of Compliance with Type-Volume Limitation, Typeface Requirements, and Type Style Requirements.

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 5249 words.

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements to Fed. R. App. P. 32(a)(6) because this brief has been prepared in Times New Roman using Microsoft Word 2010 in font size 14.

Dated: April 28, 2014

/s/ *Julie Nepveu*
Julie Nepveu

CERTIFICATE OF SERVICE

I hereby certify that this 28th day of April, 2014, I served through the ECF system the Brief Amici Curiae of Brief Amici Curiae of AARP, the National Legislative Association on Prescription Drug Prices, and the United States Public Interest Research Group in Support of Plaintiff-Appellant. Seven hard copies of this brief will be delivered to the Court's office within five days of electronically filing.

Dated: April 28, 2014

/s/ *Julie Nepveu*

Julie Nepveu