14-4624

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,

Plaintiff-Appellee,

v.

ACTAVIS PLC, FOREST LABORATORIES, LLC,

Defendants-Appellants.

On Appeal From The United States District Court
for the Southern District of New York, Case No. 14-CV-7473 (RWS)

AMENDED BRIEF FOR *AMICI CURIAE* AMERICA'S HEALTH INSURANCE PLANS AND ALLIANCE OF COMMUNITY HEALTH PLANS IN SUPPORT OF PLAINTIFFS-APPELLEES

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CORPORATE DISCLOSURE STATEMENTS

In conformance with Fed. R. App. P. 26.1 and Second Circuit Local Rule 26.1, *amicus curiae* America's Health Insurance Plans states that it is a non-profit corporation, has no parent corporation, does not issue shares of stock and, therefore, no publicly held corporation owns 10% or more of its stock.

In conformance with Fed. R. App. P. 26.1 and Second Circuit Local Rule 26.1, *amicus curiae* Alliance of Community Health Plans states that it is a non-profit corporation, has no parent corporation, does not issue shares of stock and, therefore, no publicly held corporation owns 10% or more of its stock.

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INTEREST OF *AMICI CURIAE*[1]

America's Health Insurance Plans ("AHIP") is a national trade association representing the health insurance industry. AHIP's members provide health insurance benefits, including health, pharmaceutical, long-term care, disability, dental and supplemental coverage to more than 200 million Americans. AHIP advocates for public policies that expand access to affordable healthcare coverage for all Americans through a competitive marketplace that fosters choice, quality and innovation.

The Alliance of Community Health Plans ("ACHP") is a national leadership organization bringing together innovative health plans and provider groups driven by a mission to deliver affordable, high-quality health coverage and care. Members are not-for-profit, community-based and regional health plans and provider organizations. ACHP's member health plans provide coverage and care for more than 18 million Americans in 27 states. These 23 organizations focus on improving the health of the communities they serve and are role models for other health plans in innovating to achieve the industry's "Triple Aim" – better health, better care, at a

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[1] Pursuant to Fed. R. App. P. 29(c), *amici curiae* state that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution intended to fund its preparation or submission. All parties have consented to the filing of this brief.

lower cost. Member plans provide prescription drug coverage in commercial, Medicare, Medicaid, state and local government, and other lines of business.

AHIP's and ACHP's members, who include primary payers for prescription drugs in the United States, have a strong interest in a competitive market for those drugs. As *amici* and their members are uniquely aware, increases in prescription drug costs are a leading driver of rising healthcare costs. Moreover, those increases have been accelerating at an alarming rate. In 2014, year-over-year national health spending grew by 5 percent compared to 2013, while prescription drug spending grew by 13 percent, to $319 billion—by far, the fastest growth rate of all major categories of health spending.[2] Prescription drug prices increased by 6.4 percent, the highest growth rate since 1992 and, by far, the most rapid growth rate of all major categories of price growth in the health sector.[3] Faster price growth in 2014 resulted from price increases for brand-name drugs, the unit cost of which grew by 15.4 percent compared to 0.2 percent for generic unit cost.[4]

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[2] *See* Altarum Institute, *Initial estimates suggest health spending grew by 5.0% in 2014* (Feb. 12, 2015), *at*: http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_February_2015.pdf.

[3] *See* Altarum Institute, *Health care price growth ticks up despite 16-year hospital growth low* (Feb. 12, 2015), *at*: http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Spending-Brief_February_2015.pdf.

[4] *See* S&P Dow Jones Indices, *Healthcare Expenditures for Commercial Plans up 3.2% in the Year to February 2014: S&P Healthcare Claims Indices* (June 30, 2014), *available at*: http://bit.ly/1m2hpDP.

A key component of any strategy to slow this growth in prescription drug spending is ensuring the availability of generic versions of brand-name drugs. AHIP, ACHP, and their members therefore have a strong interest in preventing brand name drug manufacturers from engaging in conduct that artificially prolongs their drug market power past the time intended by Congress. Specifically, AHIP, ACHP, and their members have an interest in opposing the practice of "product hopping," in which brand manufacturers make minor non-therapeutic changes to their product in order to foreclose competition from generic substitutes (also referred to herein as "product extension" strategies). As explained below, this conduct deprives health plans and the consumers who are their members of the benefit of competitive market choices and imposes a significant cost on plans and consumers without any corresponding therapeutic benefit.

SUMMARY OF ARGUMENT

Soaring prescription drug costs have resulted in significant increased costs for health plans and their customers, resulting in higher premiums and out-of-pocket costs for consumers. Health plans play a unique and important role in managing these rising costs by providing consumers information and helping consumers utilize the most clinically appropriate, safe and cost-effective medications available. Critical to these efforts has been the increasing importance of generic drugs as a competitive alternative in the marketplace. The widespread availability of generics has allowed consumers, along with their plans, to evaluate the relative merits of various product offerings and make choices among efficacious treatments informed by the relative costs of such treatments. Competition from generic drugs, which has been facilitated by both federal and state law, has resulted in significant cost savings for consumers without sacrificing quality of treatment.

Defendants candidly admit that the purpose of their decision to drastically curtail availability of Namenda IR was to avoid the effect of state drug substitution laws, which were enacted in large part to combat skyrocketing prescription drug costs. Indeed, there is no purpose to this kind of product withdrawal other than to eliminate or significantly diminish competition from generics. Such tactics— which here involved the effective removal of Namenda IR from the market prior to

release of its generic equivalent in order to coerce patients into switching to a reformulated drug, thereby circumventing the regulatory framework established by federal and state policymakers to facilitate price competition from generics—eliminate consumer choice, unreasonably restrain competition, and raise the cost of pharmaceuticals to health plans and consumers.

If, as we understand the district court's finding, the court had not stepped in to prevent Defendants from carrying out this strategy, it would have been too late to reverse the damage to consumers and their health plans. Physicians and caregivers are understandably reluctant to disrupt patients' medical routines without a medical reason to do so. This is particularly true with regard to vulnerable patient populations sensitive to changes in regime, like those battling Alzheimer's. Thus, had Defendants been permitted to convert more than 97% of their Namenda IR customers to Namenda XR, *amici* and their members would not be in a position to effectively reverse that change even after the lower-cost generic equivalent of Namenda IR becomes available later this year. Plans would be stuck paying substantially higher cost for this drug, and their members will face higher co-pays and premiums, without receiving any therapeutic benefit in return. The preliminary injunction should be upheld.

ARGUMENT

I. Health Plans Play A Key Role In Restraining The Accelerating Growth Rate In Prescription Drug Spending By Encouraging Members To Use Generic Drugs.

Because they provide consumers therapeutically equivalent alternatives to brand drugs at significantly reduced prices, generic drugs play an important role in combating escalating prescription drug prices. It is for this reason that Congress and many state legislatures (including New York's) have enacted numerous statutes designed to make generic drugs more quickly and widely available in the marketplace.

Congress, for its part, enacted the Hatch-Waxman Act. That statute was intended to mitigate the "serious anti-competitive effects" of then-existing FDA rules on generic drug approval and—of particular relevance here—to prevent the "practical extension of the monopoly position of the patent holder beyond the expiration of the patent." H.R. Rep. No. 98-857(II), Pt. 2, p. 4 (1984).

Many states have gone a step further by allowing—in New York's case, requiring—pharmacists to substitute an AB-rated drug when presented with a prescription for its brand equivalent. These state laws are intended to foster price competition between branded and generic drugs "by allowing the only principals who have financial incentives to make price comparisons—the pharmacist and the patient—to select drug products on the basis of price." *Drug Product Selection*,

Staff Report to the FTC, Bureau of Consumer Protection (Jan. 1979). As the district court noted, price competition at the pharmacy is the principal means by which generics are able to compete in the United States. (SA26).

These legislative efforts to promote price competition in pharmaceutical markets have resulted in significant tangible benefits for consumers. Over the 10-year period from 2003 through 2012, generic drug use generated more than $1.2 trillion in savings to the U.S. health care system. (SA27). These cost savings are critically important to assuring a sustainable health care system and achieving affordability for consumers in an environment where prescription drugs represent a significant and ever-increasing share of total health care costs. In 2014, year-over-year national prescription drug spending grew by 13 percent, to $319 billion, with the unit cost of brand-name drugs growing by 15.4 percent.[5]

Commercial health insurance plans play a critical role in combating this unsustainable cost growth by utilizing several tools and techniques that encourage the use of generic equivalents of prescription drugs. One way that plans encourage the use of generics is through their contracts with pharmacies for the provision of prescription drugs. Under these contracts, pharmacies typically charge the insurer

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[5] *See* Altarum Institute, *Initial estimates suggest health spending grew by 5.0% in 2014* (Feb. 12, 2015), *at*: http://altarum.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_February_2015.pdf; S&P Dow Jones Indices, *Healthcare Expenditures for Commercial Plans up 3.2% in the Year to February 2014: S&P Healthcare Claims Indices* (June 30, 2014), *available at*: http://bit.ly/1m2hpDP.

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 insurer.

After a generic bioequivalent of a branded drug is approved by the FDA and made available by its manufacturer, the health plans' contracts with pharmacies typically reduce the amount paid to pharmacies for either version (brand or generic) of the drug using a pricing benchmark based upon the lower price of the generic drug. Thus, after generic versions of a prescription drug are available, a typical insured patient has a choice: he or she can either accept the lower-priced generic (for which the patient generally pays a lower co-payment) or choose to pay a higher co-payment for the brand version of the same drug. Consumers usually accept the lower priced generic, resulting in cost savings for both the patient and the health plan, which in turn reduces the growth in health insurance premiums making coverage more affordable. Moreover, lower priced generic drugs increase patient adherence to prescribed medicines, which improves their health and wellbeing. As the district court noted, when generic drugs enter the market, a branded drug often loses more than 80-90% of its market share within six months. (SA28).

Health plans also help facilitate the use of generic drugs through prescription drug formularies that ensure patients have access to medications that are safe, effective and affordable. A "formulary" is a preferred drug list developed by a

health plan and continually updated to include both brand name and generic drugs. These formularies can broaden consumer access to medications and often place on the lowest cost-sharing tier, generic alternatives to brand name drugs. These formularies work in conjunction with state substitution laws, with pharmacies dispensing such low-cost generics at the point of sale. The consumer receives the resulting savings directly (through lower cost-sharing via the formulary) and indirectly (through lower premiums).

Finally, health plans have various other tools and techniques to encourage utilization of generic drugs, including the use of step therapy and prior authorization requirements. These practices generally require an insured person to first use a preferred—usually less costly—therapeutically-appropriate alternative to the branded drug before the health plan will cover the cost of that branded drug. The alternatives all must be therapeutically-appropriate and can include another brand-name drug that has provided greater discounts, a generic drug version of the original brand-name drug, or a generic alternative of the brand-name drug. When there is no therapeutically appropriate brand-name alternative to the name-brand drugs, generic alternatives to that drug provide the only avenue for consumers to receive therapeutically appropriate alternative medications. Even when such an alternative exists, generic alternatives provide consumers with much lower prices (and therefore greater access) to therapeutically appropriate medication.

Taken together, these contract provisions, formularies, and other tools and techniques have proved effective at encouraging the use of generic equivalents and thereby reducing costs to consumers. As explained below, however, these important cost-containment tools will be rendered largely ineffective if Defendants are permitted to force virtually all of their customers to switch to a new version of the same drug before the generic equivalent for the old version is released, thus allowing the new version to be shielded from generic competition for nearly fifteen more years. The potential harm to health plans and consumers would be compounded if other brand manufacturers were to use Defendants' conduct as precedent to engage in similar behavior.

II. Anticompetitive Product Extension Strategies Lead To Decreased Competition From Generic Drugs And Higher Costs For Health Plans And Consumers.

Health plans and consumers face increased costs when brand manufacturers manipulate the regulatory process in order to stifle competition from generic drugs. Such is the case with the product extension strategies challenged here, where the brand manufacturer makes minor non-therapeutic changes to the brand product (e.g., dosage), followed by the removal of the original product from the marketplace prior to generic entry. This results in patients and physicians being forced to abandon the original product and begin using the reformulated product,

not because they prefer or receive additional benefit from using the new product, but rather as a consequence of the brand manufacturer's coercive conduct.

While manufacturers' formulation changes that broaden the selection of prescription drugs on the market are not, in themselves, problematic, the use of restrictions on product access as a mechanism to coercively switch patients to the reformulated product in order to circumvent state generic substitution laws *are* of great harm to consumers. "[W]hen the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate" and the "basis for judicial deference [to the monopolist's conduct] is removed." *Abbot Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 421 (D. Del. 2006).

Consumers benefit when the choice of which drug to use (branded or generic) is the product of an understanding of the efficacy, quality, and relative cost of the various alternatives available, not the dictates of a monopolist brand manufacturer. Where the introduction of a new product is coupled with conduct that has the effect of preventing consumer choice, restraining competition and reducing the market's ambit, the antitrust laws are an appropriate vehicle for assessing that behavior to determine whether the anticompetitive effects of that conduct outweigh its procompetitive justification. *Id.* at 421-22.

The district court's opinion makes clear that consumer choice would be severely restricted as a result of Defendants' conduct. Prior to generic entry,

distribution of Namenda IR would be curtailed to a single, mail-order pharmacy and subject to a medical necessity requirement that, by Defendants' own admission, was adopted to limit usage to less than 3% of patients taking the drug. (SA67-68). The vast majority of patients would be forcibly switched to Namenda XR, thereby depriving those consumers and their health plans of the cost savings that otherwise would result from the application of state drug substitution laws and competition on the merits between Namenda IR and its generic substitutes. Absent the switch, however, a large number of the patients would have gone on to use generics. (SA85).

The tools available to health plans to manage pharmaceutical costs and drive utilization to generic drugs are not positioned to respond to this type of anticompetitive conduct, particularly given the patient population impacted here. These mechanisms require the existence of a clinically equivalent drug to which patients can be directed in lieu of the branded drug, yet no such equivalent will exist at the time defendants withdraw Namenda IR from the market. The 97% of patients who cannot obtain Namenda IR because of Defendants' practices will be forced to switch to Namenda XR. Once switched to Namenda XR, it is unlikely that health plans could persuade physicians, the patients or their caregivers to switch again to a generic substitute for Namenda IR when released later this year. As Defendants recognize, once patients are converted to Namenda XR, "it's very

difficult for the generics then to reverse-commute back." (SA51). As the district court found, health plans are reluctant to encourage patients to switch from a drug that they are already taking, a rule that is of particular importance when dealing with vulnerable patients such as those with Alzheimer's who are extremely sensitive to changes in routine. (SA87, SA89). In short, health plans will have limited ability to protect themselves and consumers from the competition-excluding impact of Defendants' conduct.

Applying antitrust principles to condemn the type of conduct alleged here is warranted given the regulatory context in which that conduct arises. As the Supreme Court has explained, "antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue," looking not only to the industry's market structure, but also to its coexisting regulatory regime. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). Here, both the Hatch-Waxman Act and the state generic substitution laws evince clear legislative intent to contain prescription drug costs through generic substitution. These laws implicitly recognize that "the forces of competition do not work well in [the prescription drug] market where the consumer who pays does not choose, and the physician who chooses does not pay." *Drug Product Selection* at 2-3.

Indeed, the failure to apply antitrust principles to Defendants' behavior could pose an existential threat to the entire purpose of the Hatch-Waxman Act and state generic substitution laws. As the facts of this case show, it is often relatively simple for a brand name drug manufacturer to redesign a groundbreaking drug in a way that allows a new version to be patentable even though it does not fundamentally change the drug's therapeutic effect. Those minor changes present an opportunity for the brand-name manufacturer to extend its monopoly potentially decades into the future. If this Court were to hold that the right to engage in coercive product switching is part and parcel of the right to exclude competition during the initial term of a patent, it will make such conduct even more common than it already is, with devastating effect on plans' ability to rein in accelerating prescription drug spending and provide consumer choice.

III. Prohibiting Brand Manufacturers From Engaging In The Product Extension Strategies Alleged Here Will Not Dampen Their Incentives To Innovate.

Even if prohibited from engaging in coercive product switching strategies, brand manufacturers still have a significant incentive to develop new and innovative drugs that benefit consumers. The other aim of the Hatch-Waxman Act (in addition to fostering the growth of generic drug competition) was to create new incentives for brand name drug manufacturers to innovate by extending patent protection for new drugs. H.R. Rep. No. 98-857(I), p. 14-15 (1984). These

incentives remain and serve as an impetus for continued innovation, as does competition from generics, which stand to gain significant sales from the brand manufacturer once patent exclusivity expires. *See Abbott Labs*, 432 F. Supp. 2d at 420 (new and improved products are one of the benefits brought about by healthy competition).

Through Hatch-Waxman and, more recently, the Biologics Price Competition and Innovation Act, Congress has encouraged the development of pharmaceuticals that provide true quality and efficiency enhancements for consumers via set patent protection and exclusivity periods. These reward innovation that has occurred and, by their finite nature, encourage the innovation that follows. Brand manufacturers that bring truly innovative new drugs to the marketplace can often successfully market their products to patients, health care providers, health plans and pharmacies to attract business away from existing alternatives. Such activities represent the usual competitive response of brand manufacturers to generic entry, one that enhances consumer choice and allows for competition on the merits between branded and generic products alike. Anticompetitive coercive product switching, such as the conduct here, undermines Congressional intent, chills the most beneficial innovations, and further burdens consumers with unsustainable, and unnecessary, costs.

CONCLUSION

Rapidly escalating prescription drug costs are placing an increasingly significant financial burden on health plans and consumers. Critical to managing these cost increases is ensuring the availability of generic versions of brand-name drugs. Product extension strategies such as those employed by Defendants that operate by eliminating consumer choice to foreclose competition from generic alternatives, impose a substantial cost on health plans and consumers while providing no therapeutic benefit, violate the antitrust laws and should be condemned. Prohibiting such conduct will not only ensure continued robust competition from generic drugs, but it also will maintain the incentives for brand manufacturers to develop new drugs with enhanced quality and efficacy that provide true therapeutic benefits for consumers.

The injunction below should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), undersigned counsel certifies that this brief:

(i) complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because it contains 3,431 words, including footnotes; and

(ii) complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2015, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Second Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

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