

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

**BRIEF AMICI CURIAE OF AARP, THE NATIONAL SENIOR CITIZENS
LAW CENTER, THE CENTER FOR MEDICARE ADVOCACY, AND
THE NATIONAL HEALTH LAW PROGRAM IN SUPPORT OF
PLAINTIFF-APPELLEE**

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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.

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NATIONAL HEALTH LAW PROGRAM**

The National Health Law Program ("NHLP") is a non-profit organization that offers no stock. It has no parent corporation, and no publicly held company owns 10% or more of its stock.

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JURISDICTIONAL BASIS TO FILE

Amici file this brief pursuant to F.R.A.P. 29 and 2nd Cir. L.A.R. 29. All parties have consented to the filing of this Brief Amici Curiae of AARP, the National Senior Citizens Law Center, the Center for Medicare Advocacy, and the National Health Law Program in Support of Plaintiff-Appellee.

INTEREST OF AMICI CURIAE¹

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 health care, employment and income security, retirement planning, affordable utilities and protection from financial abuse. Since its founding in 1958, AARP has advocated for access to affordable health care, including affordable prescription medications, and for controlling costs without compromising quality. Access to affordable drugs is particularly important to older adults because they have the highest rates of prescription drug use due to their higher rates of chronic and serious health conditions.

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.

The National Senior Citizens Law Center (NSCLC) is a non-profit organization that advocates nationwide to promote the independence and well-being of low-income older persons and people with disabilities. For more than forty years, NSCLC has served these populations through litigation, administrative advocacy, legislative advocacy, and assistance to attorneys in legal aid programs. Access to low-cost generic drugs is critically important for seniors living in poverty. NSCLC has been a leader in ensuring that low-income older adults are able to navigate the Medicare Part D program and successfully access essential, sometimes lifesaving, prescription benefits.

Founded in 1986, the Center for Medicare Advocacy, Inc. is a non-profit public interest law organization that represents older and disabled people throughout the United States. The Center works to advance fair access to Medicare, Medicaid, and quality health care through individual representation, education, policy analysis, administrative advocacy, and litigation. A crucial component of this effort is to ensure that the elderly and disabled are able to obtain needed medications at reasonable prices.

For over forty-five years, the National Health Law Program (NHeLP) has engaged in legal and policy analysis on behalf of low income people, people with disabilities, and older adults. NHeLP has provided legal representation, conducted research and policy analysis on issues affecting

the health status and health access of these groups, including access to affordable prescription drugs. NHeLP works to help consumers and their advocates overcome barriers to health care, including a lack of affordable services.

SUMMARY OF THE ARGUMENT

When approved by the FDA in 2004, Namenda (also known as “Namenda IR”) was the first medication on the market for the treatment of symptoms of advanced stages of Alzheimer’s disease. Today, it remains the only viable treatment for many who experience symptoms of moderate-to-severe Alzheimer’s disease. *New York v. Actavis, PLC*, No. 14 Civ. 7473, at *39-42 (S.D.N.Y. 2014). Thousands of people take Namenda daily, often in conjunction with other medications and as part of an overall treatment plan developed for the individuals and their families, caregivers, and/or physicians.

In 2013, with the end of the patent term for Namenda IR nearing, the manufacturer of Namenda IR (“Appellants”) sought to avoid or alleviate competition from generics. Appellants first tried to convince individuals and physicians to switch to Namenda XR through direct marketing efforts. However, when that strategy failed to yield expected sales, Appellants announced that they would discontinue producing Namenda IR and artificially restricted access to it. In order for individuals to continue taking a needed therapy, they would now have to

either switch to Namenda XR or would have to demonstrate the necessity of Namenda IR. *Id.* at *67. By taking these drastic measures, Appellants crossed a line between persuading and coercing individuals into taking Namenda XR. *See* John LaMattina, *Actavis' Stance on Namenda Is Harming Pharma's Image*, *Forbes*, Dec. 17, 2014, <http://goo.gl/pJa8e7>.

By limiting access, imposing onerous and unnecessary administrative burdens, and discontinuing the production of Namenda IR, Appellants engaged in anticompetitive behavior. Individuals benefit from competition between name-brand prescription drugs and generic versions of those drugs, and Appellants' conduct to prevent that competition imposes economic and noneconomic harms on individuals. Most critically, Appellants' actions in this case subvert the individual's right to make health care decisions and interfere with the individual's relationship with their physician. Because the district court's injunction safeguards against these harms, it must be maintained.

ARGUMENT

I. INDIVIDUALS BENEFIT WHEN GENERIC COMPETITION ENTERS THE MARKET

Prescription drug spending in the United States dramatically increased over the past twenty-five years, from \$40.3 billion in 1990 to over \$329.2 billion in 2013. *See* Kaiser Family Found., *Prescription Drug Trends* (2010), <http://goo.gl/6CjLg1>; IMS Inst. for Healthcare Informatics, *IMS Health Study*:

Spending Growth Returns for U.S. Medicines, Apr. 15, 2014, <http://goo.gl/GamJK0>. Affordable prescription medication is critical to older adults, who have the highest rate of prescription drug use due to the higher incidence of chronic and serious diseases. Ctrs. for Disease Control & Prevention, *Health, United States, 2013: With Special Feature on Prescription Drugs* 289 tbl. 92 (2014), <http://www.cdc.gov/nchs/data/hus/hus13.pdf>. In 2013, retail prices for the 227 brand-name prescription drugs most widely used by older people increased by 12.9 percent. Stephen W. Schondelmeyer & Leigh Purvis, AARP Pub. Policy Inst., *Rx Price Watch Report 1* (2014), <http://goo.gl/HGUVwp>. That increase was notably higher than any annual increase in the prior 7 years. *Id.*

Prior to the launch of Namenda XR, prices for Namenda IR likewise increased annually, even as prices for other goods remained stable. *See* Leigh Purvis & Stephen W. Schondelmeyer, AARP Pub. Policy Inst., *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate* 8 tbl. A1 (2010) (showing a 7.6% price increase in 2010); AARP Pub. Policy Inst., *Rx Watchdog Report: Prices for Brand Name Drugs Increasing at Record Rates* 3 tbl. 1 (2010) (showing an 8.5% price increase in 2009). Without competing generic versions of Namenda, consumers can expect to continue paying higher prices for name-brand Namenda.

Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales. *See, e.g.,* Fred Mogul, *Big-Name Drugs Are Falling off the 'Patent Cliff'*, Nat'l Pub. Radio, Oct. 24, 2011, <http://goo.gl/Cb2MTq>. Individuals realize significant benefits when generic competition is introduced into the market. In 2012 alone, competition between brand-name and generic drug companies resulted in a savings of \$217 billion to individuals. *See* Generic Pharmaceutical Assoc., *Generic Drug Savings in the U.S.* 1 (5th ed. 2013), <http://goo.gl/fe8aMd>. Recognizing the clear benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act. *See* H.R. Rep. No. 98-857, pt. 1 at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (the purpose of the Hatch-Waxman Act “is to make available more low cost generic drugs by establishing a generic drug approval procedure”). As recognized by individuals and Congress alike, access to generic drugs is a critical strategy to contain the cost of prescription drugs.

II. ANTICOMPETITIVE CONDUCT HARMS INDIVIDUALS BY INCREASING THEIR MEDICATION COSTS

Individuals suffer financially when pharmaceutical companies impair generic entry into the marketplace. One tactic companies use to obstruct generic entry is called “evergreening” (also known as “product hopping” or “product

switching”). Evergreening is a practice wherein brand-name drug manufacturers launch small reformulations of existing products that in many cases “had not been shown to be superior to the [original] product.” Nicholas S. Downing et. al., *Avoidance of Generic Competition by Abbott Laboratories’ Fenofibrate Franchise*, 172 *Archives Internal Med.* 724, 724 (2012). The reformulated products often yield little or no benefit to individuals. They involve minor changes to a drug, such as the form of the drug (i.e. from tablets to capsules or a liquid solution) or to its dosage. See Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 *Fla. L. Rev.* 1009, 1016-17 (2010).

These reformulations are often released sequentially, shortly before the patents on the original product expire. See, e.g., Jennifer Garcia, *Pharmaceutical Company Strategy Blocks Generic Drug Makers*, *Medscape Med. News*, Apr. 9, 2012. Many reformulated drugs are released into the market without an adverse impact on individuals’ choices because they compete with the original version of the drug. Nathalie Vernaz et al., *Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis*, 10 *PLOS Med.* 1, 2 (2013) (“The follow-on drug is usually marketed by the pharmaceutical company that owns the brand drug, and both drugs are marketed at the same time in most cases, effectively making them competitors.”).

However, evergreening harms individuals when a manufacturer restricts the availability of the original drug or removes the original drug from the market entirely several months prior to generic entry into the market. This strategy forces people who take the original drug either to use the new reformulated version or to go without the medication. Even if generic versions of the original drug do enter the marketplace, individuals are again faced with the dilemma of either switching back to the original drug or continuing their current medication regimen; very few who make the forced switch to the reformulated drug ever switch back to generic versions of the original drug that enter the market afterward. See Jonathan Lapook, *Forced Switch? Drug Cos. Develop Maneuvers to Hinder Generic Competition*, CBS News, Aug. 28, 2014, <http://goo.gl/HrS5CI>.

The record before the district court presents a textbook example of anticompetitive evergreening: Namenda IR and its “extended release” version, Namenda XR, are the only approved medications to alleviate the symptoms of moderate to severe Alzheimer’s disease with this kind of therapy. *New York v. Actavis, PLC*, No. 14 Civ. 7473, at *39 (S.D.N.Y. 2014). Namenda XR has no proven medical benefits over Namenda IR. *Id.* at *53 (“The benefits of a switch from Namenda IR to Namenda XR are often marginal. ... No studies have been done to show that Namenda XR is more effective than Namenda IR.”). Namenda XR labelling admits that “[t]here is no study addressing the comparative efficacy

of these 2 regimens.” *Highlights of Prescribing Information: Namenda XR*, at 2 (2010), <http://goo.gl/9Mr8w3>. In fact, according to the labelling for Namenda XR and Namenda IR, the therapeutic impact of Namenda XR on an individual’s impairment is somewhat less than Namenda IR. *Compare id.* at 14 (finding mean of 2.6 units improvement for patients taking Namenda XR), with *Highlights of Prescribing Information: Namenda*, at 16 (2013), <http://goo.gl/iYNsMP> (finding mean of 3.3 units improvement for patients taking Namenda IR).

Appellants announced the launch of Namenda XR in June 2013 as a once-daily substitute for Namenda IR. *Forest Announces U.S. Availability of New Once-Daily NAMENDA XR*, Business Wire, June 13, 2013, <http://goo.gl/9x01ai>. Six months before the entry of generics to market, when marketing efforts to individuals and physicians failed to yield expected “conversions” to Namenda XR, Appellants announced plans to discontinue Namenda IR and abruptly restricted access to Namenda. *New York v. Actavis, PLC*, No. 14 Civ. 7473, at *55-56, 62 (S.D.N.Y. 2014). In doing so, Appellants sought to coerce many people taking Namenda to switch to Namenda XR, because no alternative drug existed to treat their symptoms. *Id.* at *72 and 109.

“Evergreening” is an attractive strategy for brand-name pharmaceutical manufacturers when it “can significantly impair consumers’ access to the far less expensive generic product.” Steve D. Shadowen et al., *Anticompetitive Product*

Changes in the Pharmaceutical Industry, 41 Rutgers L. Rev. 1, 2 (2009). By engaging in this behavior, manufacturers of brand-name drugs are able to extend the life of the drug's underlying patents, and therefore the manufacturer's monopoly on the drug's production, by an average of 6 to 7 years. Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012). In this case, while Appellants' monopoly on Namenda IR is scheduled to end this year, its monopoly on Namenda XR does not end until 2029. *New York v. Actavis, PLC*, No. 14 Civ. 7473, at *36 (S.D.N.Y. 2014).

Anticompetitive evergreening harms people when it prevents them from obtaining lower cost generics. Individuals pay additional costs if their health plans do not cover the new, reformulated drug, or place it in a different tier with a higher co-payment. If the only medical justification for Namenda XR over Namenda IR is the reduced number of dosages, private insurance and Medicare Part D plans might not cover Namenda XR at all. *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., *Your Guide to Medicare Prescription Drug Coverage* 27 (2014), <http://goo.gl/n6s2x8> (noting that Medicare Part D plans need only cover "medically necessary" medications). Other insurance plans place Namenda XR at a higher "tier" than Namenda IR, forcing individuals to pay higher copays. *See, e.g.,* Anthem BlueCross BlueShield, *Prescription Program: Anthem Blue Cross*

and Blue Shield Drug List 4-5 (2013) <http://goo.gl/LAjCGa> (placing Namenda IR in Tier 2 and Namenda XR in Tier 3); Cigna HealthCare, *Drug List Search Results*, <http://goo.gl/w23QWv> (last visited Feb. 11, 2015) (same); Express Scripts Medicare (PDP), *Express Scripts Medicare (PDP) 2014 Formulary (List of Covered Drugs)* 13 (2013), <http://goo.gl/DcKBbD> (same).

Increased costs have a direct impact on the patient's health. Higher drug prices and less competition leave lower-income people with few options. In an effort to save money, some people forego medication; others poorly adhere to the drug regimens prescribed by their doctors. In 2012, a Consumer Reports survey found that 18 percent of people with prescription drug coverage declined to fill their medication due to cost, and 45 percent of individuals 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, <http://goo.gl/BPYOPC>; *see also* Becky A. Briesacher, Jerry H. Gurwitz & Stephen B. Soumerai, *Patients At-Risk for Cost-Related Medication Nonadherence: A Review of the Literature*, 22 J. Gen. Internal Med. 864, 864 (2007) (estimating that 32 percent of older Americans take less medication than prescribed to avoid costs).

Individuals who poorly adhere to a prescription medication regimen experience worse outcomes and higher rates of preventable hospitalizations.

Approximately 125,000 people die each year as a result of poor adherence to prescription regimens. Am. Coll. Preventive Med., *Medication Adherence – Improving Health Outcomes* 6 (2011), <http://goo.gl/HDZBTE>. In fact, it is estimated that 30 to 50 percent of all treatment failures are likely attributable to nonadherence. Thomas H. Wroth & Donald E. Pathman, *Primary Medication Adherence in a Rural Population: The Role of the Patient-Physician Relationship and Satisfaction with Care*, 19 J. Am. Board Fam. Med. 478, 478 (2006).

Along with deaths and failed treatments, people who poorly adhere to their medical regimen spend more money in the form of re-hospitalizations and physician visits. In total, prescription nonadherence costs the U.S. health care system up to \$289 billion annually. Ctrs. for Disease Control & Prevention, *Medication Adherence: CDC's Noon Conference, March 27, 2013*, at 12 (2013), <http://goo.gl/BgRgFC>; see also New England Healthcare Inst., *Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease* 1 (2009), <http://goo.gl/UEI7fC>.

For these reasons, individuals have a vested interest in preventing pharmaceutical companies from acting in anticompetitive ways to obstruct generic entry. Unless the district court's injunction is upheld, other drug manufacturers will look to Appellants' strategy as a means of compelling individuals to switch to newer, but pharmacologically equivalent, versions of drugs when the original

drugs are about to lose market exclusivity. Pharmaceutical companies will evergreen products and maintain market exclusivity in perpetuity. In turn, people will be stuck with paying higher prices on vital, life-saving medications, or they will actually forgo treatment due to heightened costs.

III. EVERGREENING ALSO HARMS INDIVIDUALS BY DISRUPTING THEIR MEDICATION REGIMEN WITHOUT WARNING OR CHOICE, LEADING TO POOR ADHERENCE

People who will have to switch from Namenda IR to Namenda XR experienced both a change in Namenda dosage and a change in how Namenda is administered. For those people taking Namenda IR alongside other medications multiple times a day, Namenda XR now stands out as a medication taken once daily. *See New York v. Actavis, PLC*, No. 14 Civ. 7473, at *53-54 (S.D.N.Y. 2014). The means of administering their medication also changed. Namenda IR tablets can be crushed and mixed into food, but Namenda XR capsules cannot be crushed and must instead be opened and sprinkled onto food. *Compare Highlights of Prescribing Information: Namenda XR*, at 19 (2010), <http://goo.gl/9Mr8w3> (“NAMENDA XR capsules must be swallowed whole and never crushed, divided or chewed.”), with *Highlights of Prescribing Information: Namenda*, at 16 (2013), <http://goo.gl/iYNsMP> (providing no such limitation).

Both the change in dosage and the change in administration pose potential risks to the individual. Amici supporting appellants state that reducing the daily

number of a medication's doses increases compliance with that medication regimen. See Br. Amici Curiae of Amer. Assn. of Long Term Care Nursing, et. al. at 9 (“The change from twice-daily to once-daily is also likely to increase compliance.”). However, changes to a person's medication directions, as well as administering medication on different schedules (i.e. administering some medications once daily while others are administered twice or three times daily), also leads to increased noncompliance with medication regimens. Bradley Williams, *Pharmaceutical Care in the Elderly*, 1 Health Notes 9, 10 (2003), <http://goo.gl/HSAo8I>.

Changes in medications and medication dosage also raise the risk of error in administering medication. Among the more common causes of medication errors are “[a]mbiguous strength designation on labels or in packaging” and “[d]rug product nomenclature [problems, i.e.] look-alike or sound-alike names, use of lettered or numbered prefixes and suffixes in drug names.” Am. Soc’y of Hosp. Pharmacists, *ASHP Guidelines on Preventing Medication Errors in Hospitals* 131 tbl. 2 (1993), <http://goo.gl/wsnZs4>. Given the sudden transition from Namenda IR to Namenda XR, which has a different dosage but similar name and packaging, caregivers may inadvertently administer an extra dose of Namenda XR on the mistaken assumption that it is the same as Namenda IR.

Frequent medication changes can also disrupt an individual's daily routine, which is essential to the person's overall quality of life. For individuals with memory loss, like most individuals taking Namenda, change is especially challenging "as they have problems with planning." Banner Alzheimer's Inst., *Living Day to Day with Alzheimer's Disease*, <http://goo.gl/Xek3Y7> (last visited Feb. 12, 2015). While maintaining a daily routine is also important to individuals without dementia, "sticking to a routine is not only sacred, but a necessity" in caring for individuals with Alzheimer's disease and other forms of dementia. Alzheimer's Found. of Am., *Education and Care: Caregiving Tips— Daily Routines*, <http://goo.gl/5EtraB> (last visited Feb. 12, 2015).

The record in this case demonstrates that, by limiting the availability of Namenda IR and leaving Namenda XR as the only option for many individuals, appellants severely disrupted individuals' medication regimens. Subsequent to appellants' forced switch, approximately 50% of individuals taking Namenda IR switched to Namenda XR. *New York v. Actavis, PLC*, No. 14 Civ. 7473, at *85-86 (S.D.N.Y. 2014). As many as 20% of individuals taking Namenda IR stopped taking Namenda altogether, "lost forever" to the market. Ed Silverman, *What Actavis Did Not Want You to See in That Antitrust Lawsuit*, Wall St. J., Sept. 25, 2014, <http://goo.gl/7uYDLD>.

IV. APPELLANTS' EVERGREENING SCHEME INTERFERES WITH BOTH AN INDIVIDUAL'S RIGHT TO DIRECT THEIR OWN HEALTH CARE AND THE RELATIONSHIP WITH THEIR PHYSICIAN

Individuals currently receiving a certain medication can and should have the option of switching to other versions of that drug when they are available, if appropriate for the individual. Appellants frequently claim that Namenda XR is a “better” product than Namenda IR. *See, e.g.*, Mem. in Supp. of Defs.’ Mot. to Dismiss 21 (“The Bureau fails to allege any ‘coercion’ that would justify punishing Forest Labs for seeking to transition to a better product.”); *accord id.* at 7 (“Forest announced plans to discontinue the sale of twice-a-day Namenda IR tablets and focus its sales on the new and improved version.”). However, what is “better” for a particular person is not a determination for pharmaceutical companies to make; instead, such decisions must be made by individuals in consultation with their physicians, families, and, if applicable, their caregivers. By planning to discontinue Namenda IR shortly after the launch of Namenda XR, appellants imply that, because Namenda XR is ostensibly a superior product, the individual’s choice is irrelevant and unnecessary.

People have the right to make choices about their own medical treatment, a concept firmly rooted in Western concepts of medical ethics. Gail Van Norman, *Informed Consent: Respecting Patient Autonomy*, 61 Cal. Soc’y Anesthesiologists Bull. 36, 36 (2012). Respect for this principle is evident in the evolving doctor-

patient relationship—increasingly, providers encourage their patients to take a more active role in their health care decision-making. *See, e.g.*, Nancy Calabretta, *Consumer-Driven, Patient-Centered Health Care in the Age of Electronic Information*, J. Med. Libr. Ass'n 32, 33 (2002); *see also* Laura Landro, *The Health-Care Industry Is Pushing Patients to Help Themselves*, Wall St. J., June 8, 2014, <http://goo.gl/bSCU18> (noting that “[h]ospitals, doctors and public-health officials are pushing patients to keep track of their medical data, seek preventive care and stay on top of chronic conditions”).

The right to autonomy in health care decision-making is also recognized in a wide variety of state and federal laws and policies empowering people to control the direction of their own health care; these policies include statutes allowing for surrogate decision-makers, advance medical directives to refuse treatment, and informed consent to treatment. *See*, Michael Ash & Stephen Arons, *Economic Parameters of End-of-Life Care: Some Policy Implications in an Era of Health Care Reform*, 31 W. New Eng. L. Rev. 305, 314 (2009) (“Although the reach and limitations of advance directives vary from state to state, they all express the principle of patient autonomy ... to refuse unwanted medical treatment or have it withdrawn”).

New York supports the principles of patient autonomy through policies affecting both people residing in long-term care facilities and people residing at

home. For example, residents of New York’s long-term care facilities enjoy statutory rights to “independent personal decisions and knowledge of available choices” and “to be fully informed of...proposed treatment unless medically contraindicated, and to refuse medication and treatment after being fully informed of and understanding the consequences of such action.” N.Y. Pub. Health Law § 2803-c(3)(a), (e) (Consol. 2014). Residents of long-term care facilities also have a robust means of enforcing their rights through a private action brought in New York state court. N.Y. Pub. Health Law § 2801-d (Consol. 2014). Residents of long-term care facilities, as well as people receiving care at home, have equal rights to appoint a surrogate decision-maker to make health care decisions, including consenting to the use of prescription drugs. N.Y. Pub. Health Law § 2981 (Consol. 2014) (describing the standards for a person to appoint a health care agent), and § 2994-ee (Consol. 2014) (compelling health care providers to honor an order not to resuscitate a patient).

According to the record established in this case, many physicians were indeed concerned about the encroachment upon individual choice imposed by appellants. *See New York v. Actavis, PLC*, No. 14 Civ. 7473, at *92 (S.D.N.Y. 2014) (“Other physicians specifically complained of the reduction in choice, stating that they ‘would be frustrated that a good therapy is no longer available.’”). When asked about appellants’ plan to withdraw Namenda IR from the market,

physicians reacted with “statements like ‘terrible’, ‘how awful’, ‘horrible’, [and] ‘[i]t puts an undue burden on us....’” *Id.*

By requiring appellants to make Namenda IR and Namenda XR available to people on equal terms, the district court’s injunction allows people to make a choice between continuing their existing medication regimen and switching to Namenda XR, rather than a pharmaceutical company making that choice for them. In doing so, the injunction prevents appellants from intruding into the individual’s right to make informed choices about their health care, as well as into the individual’s relationship with their physician.

CONCLUSION

For the foregoing reasons, this Court should affirm the District Court’s injunction requiring Appellants to offer Namenda IR “on the same terms and conditions” as Namenda XR.

Dated: February 20, 2015

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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Dated: February 20, 2015

/s/ Dara S. Smith

Dara S. Smith

CERTIFICATE OF SERVICE

I, Dara Smith, hereby certify under penalty of perjury that on February 20, 2015, I served a copy of Amici Curiae Brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: February 20, 2015

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