

14-4624-CV

In the United States Court of Appeals for the Second Circuit

State of New York

Plaintiffs-Appellee,

v.

Actavis, PLC, and
Forest Laboratories, LLC.,

Defendants-Appellants.

On Appeal from United States District Court
for the Southern District of New York
(The Honorable Robert W. Sweet)

BRIEF FOR *AMICI CURIAE* THE AMERICAN GERIATRICS
SOCIETY AND THE MEDICAL SOCIETY OF THE STATE
OF NEW YORK IN SUPPORT OF PLAINTIFF-APPELLEE

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CORPORATE DISCLOSURE STATEMENT

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* The American Geriatrics Society states that it is nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* the Medical Society of the State of New York states that it is nonprofit, non-stock corporation. It has no parent corporation and there is no corporation that has an ownership interest of any kind in it.

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JURISDICTIONAL BASIS TO FILE

Amici curiae file this brief pursuant to Fed. R. App. P. 29 and 2d. Cir. L.R.

29. All parties have consented to the filing of this Brief for *Amici Curiae* The American Geriatrics Society and the Medical Society of the State of New York in Support of Plaintiff-Appellee.

INTEREST OF *AMICI CURIAE*¹

Amicus curiae The American Geriatrics Society (“AGS”) is a not-for-profit organization of over 6,000 health professionals devoted to improving the health, independence and quality of life of all older people. AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy.

Amicus curiae the Medical Society of the State of New York (“MSSNY”) was founded in 1807 and has approximately 21,000 physician, medical resident, and medical student members located throughout the State of New York. It is the principal medical professional organization in the State, representing physicians in all specialties. Among MSSNY’s primary purposes include: “To enhance the

¹ Pursuant to FRAP 29(c)(5) and 2d Cir. L.R. 29.1, *amici curiae* state that no party’s counsel has authored this brief either in whole or in part; that no party or its counsel contributed money that was intended to fund preparing or submitting the brief; and that no person other than these *amici curiae* and their counsel have contributed money intended to fund preparing or submitting the brief.

delivery of medical care of high quality to all people in the most economical manner, and to promote and maintain high standards in medical education and in the practice of medicine in an effort to ensure that quality medical care is available to the public.”

INTRODUCTION AND SUMMARY OF ARGUMENT

Alzheimer’s disease is the most common form of dementia accounting for roughly 60 to 80 percent of all cases. *What Is Alzheimer’s?*, Alzheimer’s Association, http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp (last visited Feb. 18, 2015). Alzheimer’s is a progressive disease that creates abnormal deposits known as plaques and tangles in a patient’s brain which slowly decreases the effectiveness of the brain’s neuron cells eventually killing the cells. *See About Alzheimer’s Disease: Alzheimer’s Basics*, National Institute on Aging, <http://www.nia.nih.gov/alzheimers/topics/alzheimers-basics> (last visited Feb. 18, 2015). The loss of communication between and death of these cells causes Alzheimer’s patients to have memory loss, depletion of communication skills, and the inability to reason or process information. *Alzheimer’s Disease*, American Academy of Neurology, http://patients.aan.com/disorders/?event=view&disorder_id=844 (last visited February 18, 2015). In 2011, 84,974 Americans died from Alzheimer’s disease making it the sixth leading cause of death in the United States. CTRS. FOR DISEASE CONTROL, DEATHS: FINAL DATA FOR 2011 TABLES 9, 10 at 31 (2011),

available at http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_03.pdf.² There are currently over five million known cases of Alzheimer's disease in America.

Alzheimer's Association, *2014 Alzheimer's Disease Facts and Figures*, 10 J. ALZHEIMER'S ASSOC. 1, 21 (2014).

While there is no cure for Alzheimer's, there are pharmaceutical treatments designed to improve the symptoms of Alzheimer's patients, including treating memory loss and confusion. *Id.* at 34. Since 2004, physicians and other providers³ have prescribed brand name Namenda IR for patients suffering from moderate to severe Alzheimer's. The active ingredient of Namenda IR is memantine hydrochloride. In 2013, Namenda manufacturer Forest Laboratories ("Forest") introduced a new version of Namenda, XR. The only clinical difference between IR and XR is that IR is taken twice-daily while XR is a single dose, time release capsule. *Dosing for Patients Currently Taking Namenda*, Namenda XR, <http://www.namendaxrhcp.com/patients-currently-taking-namenda.aspx> (last visited Feb. 18, 2015).

² According to new research, the death rate for Alzheimer's is much higher due to "under-reporting" on death certificates. A recent study finds that in 2010, 503,400 deaths were attributed to Alzheimer's disease making it more deadly than heart disease or cancer. See Bryan D. James et al., *Contribution of Alzheimer's Disease to Mortality in the United States*, 82 NEUROLOGY 1045-50 (2014).

³ Eligible prescribers for pharmaceuticals include physicians, advanced practice nurses, physician assistants, and nurse practitioners. *Amici curiae* will hereinafter refer to this group as "providers."

In 2014, a mere year away from Namenda IR's patent expiration and the entry of generic memantine into the market, Forest announced the discontinuation of Namenda IR in order to move patients to Namenda XR. Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue Namenda Tablets, Focus on Once-Daily Namenda XR (Feb. 14, 2014).⁴ As a result of Forest's conduct, the State of New York filed an antitrust lawsuit alleging that Forest was utilizing anticompetitive practices to force a product switch. The State of New York sought and won a preliminary injunction to prevent Forest from removing Namenda IR from the market. *See generally* Opinion, *New York v. Actavis*, No. 14-7473, (S.D.N.Y. Dec. 11, 2014), Docket No. 80 (hereinafter "Op."). As *amici* representing the interests of providers treating those suffering from Alzheimer's disease, we agree with the lower court's decision and find that this forced switch from Namenda IR to XR is improper, intrusive, offers limited benefits, and potentially harms patients.

Amici curiae submit this brief to the Second Circuit to illustrate two points. First, a forced switch from Namenda IR to XR unnecessarily and unreasonably restricts the provider-patient relationship. Second, there are limited medical

⁴ Available at <http://investor.frx.com/press-release/business-development-news/forest-laboratories-discontinue-namenda-tablets-focus-once-d>.

benefits in switching from Namenda IR to XR, and such a forced switch could be problematic for some Alzheimer's patients.

I. Forest's Conduct Unreasonably Interferes With the Relationship Between Providers and Their Patients.

The provider-patient relationship “has been and remains a keystone of care: the medium in which data are gathered, diagnoses and plans are made, compliance is accomplished, and healing, patient activation, and support are provided.” Susan D. Goold & Mack Lipkin, *The Doctor-Patient Relationship: Challenges, Opportunities, and Strategies*, 14 J. GEN. INTERNAL MED. S26, S26 (1999) (footnote omitted). The provider-patient relationship is particularly important for Alzheimer's patients because the patient requires constant monitoring and medical attention. To care for Alzheimer's patients, a team of individuals is required. This includes the providers who monitor the patient's health and make important decisions regarding treatment, and the caregivers who assist the patient in the routine activities of daily living, including the taking of prescription medications.⁵

Providers make health-related decisions with a patient to improve the patient's health. In the case of incurable and debilitating Alzheimer's disease, it is particularly important for providers to create a medical plan that ensures a stable

⁵ Included in the caregiver category are “unpaid caregivers.” These individuals are typically family members or other friends of the patient. These individuals provide 17.7 billion of hours of care, a total value of \$220.2 billion. Alzheimer's Association, *2014 Alzheimer's Disease Facts and Figures*, *supra* at 30.

routine for patients, the patient's family, and the patient's caregivers. If pharmacology is sought to relieve symptoms, providers must appropriately and adequately convey to patients and their families the efficacy of medications in treating the symptoms of Alzheimer's disease. See David A. Casey et al., *Drugs for Alzheimer's Disease: Are They Effective?*, 35 PHARMACY & THERAPEUTICS 208-11 (2010). In particular, when suggesting memantine as a treatment option, providers note to patients and their families the modest clinical benefits, potential adverse effects, and cost. Bradford T. Winslow et al., *Treatment of Alzheimer Disease*, 83 AM. FAM. PHYSICIAN 1403, 1410 (2011). Once a provider's treatment plan is established for an Alzheimer's patient, stability and routine are key. See Op. at 54 ("For Alzheimer's patients, stability is key: this is a very vulnerable group of patients."). Moreover, providers do not switch drugs if the patient is responding well to treatment. See Op. at 89 ("Physicians are reluctant to disrupt patients' medical routines without a medical reason to do so") (citation omitted). If a provider were to switch an Alzheimer's patient to a new drug or new method of treatment: (1) the decision would be between the provider and patient or family, and (2) the switch would have to provide some meaningful and therapeutic benefit.

By severely restricting patient access to Namenda IR, Forest is interfering with the provider-patient relationship. Without access to Namenda IR, providers choosing to utilize a memantine treatment will be forced to switch their patients

over to Namenda XR and destabilize their routines. Such disruption in patient treatment is unnecessary and interferes with the provider's and patient's choice.

Appellants and their *amici* claim that Namenda IR will still be readily available through a simple "medical necessity" form. Appellant Brief, *State of New York v. Actavis et al*, at 30 (No. 14-7473) (2d Cir. Jan 12, 2015) (patients will "never have to switch; their physicians can sign a one-page form confirming IR's medical necessity"); Brief of Physician *Amici Curiae* In Support of Defendants-Appellants, *State of New York v. Actavis et al*, at 30 (No. 14-7473) (2d Cir. Jan 15, 2015) (stating that "writing a prescription is already, in effect, a statement of medical necessity"). However, Forest's own survey data predicted that "only 2.4 percent of patients would be able to obtain the drug" due to the impediments imposed by the medical necessity standard. Op. at 69. Therefore, the Appellants' rhetoric of availability does not match up with facts.

Moreover, both providers and caregivers directly told Forest of the problematic nature of such a forced switch. When surveyed about changing patients from Namenda IR to XR, providers treating Alzheimer's patients stated that the idea was "terrible" and "horrible," and some questioned its legality. Op. at 92. Furthermore, providers specifically noted that Forest's conduct directly interfered with the provider-patient relationship. *See Id.* (physicians noting that in

terms of choosing between Namenda IR and XR they “would like the choice to be decided between myself and my patients”).

Along with interfering with a provider’s medical decisions, Forest’s forced switch also directly interferes with the patient-caregiver relationship. Given the nature of the disease, caregivers develop specific routines for Alzheimer’s patients that are easily followed. *Id.* at 86. These routines are particularly important for the caregiver as the Alzheimer patient is less likely to become disturbed or confused under a strict routine. *See Alzheimer’s care: Simple tips for daily tasks*, Mayo Clinic, <http://www.mayoclinic.org/healthy-living/caregivers/in-depth/alzheimers-caregiver/art-20047577> (last visited Feb. 18, 2015). Appellants’ own survey data found that 21 percent of caregivers found that it would not be “acceptable” to remove Namenda IR from the market and forcibly switch patients to XR. *Op.* at 93. Moreover, Appellants’ own internal documents found that “caregivers may be confused or dissatisfied with either withdrawal or limited distribution...” *Id.* at 94. Even with this data and information, Forest is still seeking to effectively discontinue Namenda IR and restrict choice and access.

In issuing a preliminary injunction, the lower court has ensured that drug treatment decisions will continue to be made by the provider, patient, and family.

II. As Namenda XR Offers Limited and Uncertain Benefits, Patients, Providers, and Caregivers Should Decide Whether a Switch to Namenda XR Is Appropriate.

A forced switch for patients from Namenda IR to XR offers limited benefits to Alzheimer's patients. It is undisputed that Namenda IR and XR have the same compound and offer the same therapeutic benefits. Op. at 38. The only difference and stated benefit between these drugs is that Namenda XR can now be taken once daily instead of twice a day. Press Release, Forest Labs., Inc., Forest Laboratories to Discontinue Namenda Tablets, Focus on Once-Daily Namenda XR, *supra*. Furthermore, there have been no clinical studies suggesting that Namenda XR is more effective than Namenda IR. Op. at 53.

As noted by Appellants, Namenda XR will only benefit patients and their caregivers if they have difficulty following a twice a day drug regimen using Namenda IR. Appellant Brief, *State of New York v. Actavis et al*, *supra* at 51-52 (stating that "XR offers significant benefits over twice-daily IR" including reducing risk of missing pills and making it easier for patients to stay with family members). Namenda XR and IR are classified by the Food and Drug Administration as pharmaceutical alternatives, and they have the same therapeutic effect in Alzheimer's patients. Orange Book Preface, FDA.⁶ ("Different dosage

⁶ Available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>

forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are extended-release products when compared with immediate-release or standard-release formulations of the same active ingredient.”); *see also* Op. at 38. This suggests that a change from Namenda IR to XR will not improve the condition of Alzheimer’s patients. In fact, the only benefits listed by Appellants and their *amici* pertain to the *potential* convenience to patients and caregivers from having one less pill a day.

While Namenda XR’s potential benefits may be meaningful to some users, the majority of patients will likely see no benefit, or only marginal benefits, in a change to Namenda XR. This is especially true considering an Alzheimer’s sufferer may be taking several different medications. Alzheimer’s can cause a number of behavioral and psychological symptoms that may require pharmaceutical treatments including agitation, aggression, and psychosis. *See* Nathan Herrmann & Serge Gauthier, *Diagnosis and treatment of dementia: 6. Management of severe Alzheimer disease*, 179 CAN. MED. ASSOC. J. 1279, 1282 (2008). Moreover, Alzheimer’s patients are typically elderly and may have other medical conditions that require pharmaceutical treatment. *Alzheimer’s Disease Fact Sheet*, National Institute on Aging, <http://www.nia.nih.gov/alzheimers/publication/alzheimers-disease-fact-sheet> (last visited Feb. 18, 2015) (only 5% of Alzheimer’s patients are ages 30-60).

Patients in long-term care facilities, which is where most Alzheimer's patients are cared for, receive an average of nine pills per day. Op. at 53-54. These facilities typically dispense pills three times daily. *Id.* at 54. Benefits from a reduced pill burden or for patients experiencing sundowning (the description of Alzheimer's patients who become increasingly agitated throughout the day) are virtually nonexistent in patients who will have to take pills multiple times a day regardless of Namenda's reformulation.

While benefits from a switch to XR are not universal, the harms from a forced switch are. After generic entry, Namenda XR will come at a higher monetary price for all Alzheimer's patients. The lower court found that consumers would pay approximately \$300 million more in the absence of a preliminary injunction. Op. at 131. These costs would be passed on to fixed income, elderly Alzheimer's patients. *See Tom K. Xu, Financial Disparities In Prescription Drug Use Between Elderly And Nonelderly Americans, 22 HEALTH AFFS. 210, 220 (2003)* ("Elderly consumers overall are financially disadvantaged in out-of-pocket spending for prescription drugs."). In contrast, on average, a generic substitute costs 80 to 85 percent less than a brand name version. *See Facts About Generic Drugs, FDA.gov, <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingmedicinesafely/understandinggenericdrugs/ucm167991.htm>* (last visited Feb. 18, 2015). For patients using memantine, generic access could lead to savings

of \$3,060 per year. *See* Peter Loftus, *New York Sues to Block Early Withdrawal of Alzheimer's Drug*, WALL ST. J., Sept. 16, 2014, <http://www.wsj.com/articles/new-york-sues-to-block-early-withdrawal-of-alzheimers-drug-1410873810>.⁷ Without the preliminary injunction, patients and their families would not be able to freely choose whether Namenda's XR benefits outweigh its potential costs, based on their particular circumstances. Neil Averitt and Robert Lande, *Using the Consumer Choice Approach to Antitrust Law*, 74 ANTITRUST L.J. 175, 183 (2007) ("Antitrust should protect any type of choice that is of practical importance to consumers.").

Moreover, an unnecessary, involuntary change in drug regimen for Alzheimer's patients could cause direct harm to the patient. Given the vulnerability of Alzheimer's patients to disruption, stability is key. Any change in routine, including an unnecessary change in medication, could raise "the risk of an adverse event." *Op.* at 55 (citation omitted). Patients and caregivers will have to be educated on the change to the pill schedule. Mistakes or miscommunication in the transition process may create drug adherence issues and a risk of overdosing. These risks are compounded by the fact that for Alzheimer's patients "[a]ny small change in medication raises the risk of an adverse event" and "[e]ven a small

⁷ According to the Wall Street Journal, a yearly treatment of Namenda costs \$3,600. Assuming an 85 percent discount for a generic product, patients could spend *only* \$540 a year on a generic substitute memantine drug.

change in a patient's condition can require him or her to be moved to a care facility." *Id.* at 54-55.

In the case of Forest's forced switch, there is also a possibility of Alzheimer's patients going through two separate switches. The first switch occurs when patients are forced to take Namenda XR because of IR's discontinuation, and the second switch occurs for the few patients that seek an IR generic substitute when it is made available. *See Id.* at 91. With a fluctuating drug regimen, there is a rising risk of confusion for the generally older Alzheimer's patient, the family, and the caregivers. *See generally* Richard W. Pretorius et al., *Reducing the Risk of Adverse Drug Events in Older Adults*, 87 AM. FAM. PHYSICIAN 331-36 (2013) (noting that "medication error" and "drug overdose" are particularly problematic in older patient populations and that "prescribing new medications sparingly" is an appropriate strategy to reduce adverse events.).

Given the uncertain benefits to all Alzheimer's patients and the certainty of disruption and risk, whether or not to change from Namenda IR to Namenda XR should be a decision for healthcare providers to make in consultation with Alzheimer's patients, their families, and their caregivers. Appellants' anticompetitive use of a forced product switch robs those decision-makers of an important and procompetitive choice in the market.

CONCLUSION

For the reasons set forth above, the District Court's preliminary injunction should be upheld.

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**CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF
APPELLATE PROCEDURE 32(a)**

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 2,924 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).
2. This brief 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 in 14 point Times New Roman.

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CERTIFICATE OF SERVICE

I hereby certify that pursuant to Local Rule 25.1(h), on this 19th day of February, 2015, I filed the foregoing Brief as Amicus Curiae in support of Appellants with the Clerk of the United States Court of Appeals for the Second Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

I also certify that six hard copies of the foregoing Brief were sent today via third-party commercial carrier to:

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