14-4624-cv

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,

—against—

ACTAVIS PLC and FOREST LABORATORIES, LLC,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR *AMICI CURIAE* AMERICAN ASSOCIATION FOR LONG TERM CARE NURSING, CAREGIVER ACTION NETWORK AND THE TRECS INSTITUTE IN SUPPORT OF DEFENDANTS-APPELLANTS

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CORPORATE DISCLOSURE STATEMENTS

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* the American Association for Long Term Care Nursing ("AALTCN") states that it is a 501(c)(3) nonprofit organization incorporated under the laws of Maryland since 2007. AALTCN is a non-stock corporation and has no parent corporation.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* the Caregiver Action Network ("CAN") states that it is a 501(c)(3) nonprofit organization incorporated under the laws of Maryland since 1993. CAN is a non-stock corporation and has no parent corporation.

In accordance with Fed. R. App. P. 26.1 and 29(c)(1), *amicus curiae* The TRECS Institute ("TRECS") states that it is a nonprofit organization incorporated under the laws of Pennsylvania since 2004. TRECS is a non-stock corporation and has no parent corporation.

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INTEREST OF *AMICI CURIAE*[1]

The American Association for Long Term Care Nursing ("AALTCN"), the nation's largest network of long-term care professional caregivers, unites all levels of nursing staff employed in nursing home and assisted living settings to advance excellence in the specialty of long-term care nursing through education and advocacy. AALTCN advocates for an improved status and voice for long-term care nursing staff and encourages respect for long-term care nursing staff by informing colleagues and consumers about the complexities, competencies and commitment of the special caregivers who commit to this specialty.

The mission of the Caregiver Action Network ("CAN") is to promote resourcefulness and respect for the more than 65 million family caregivers in America. CAN seeks to empower family caregivers to act on behalf of their loved ones and to remove barriers to health and well-being. CAN envisions an America in which family caregivers can lead full and productive lives, free from depression, pain, isolation and financial distress. To fulfill its mission, CAN engages in public policy discussions and advocates on behalf of family caregivers to policymakers.

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[1] Under Fed. R. App. P. 29(c)(5), *amici curiae* certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund the preparation or submission of the brief; and no person other than the *amici* or their members contributed money intended to fund the preparation or submission of the brief.

The mission of The TRECS Institute ("TRECS") is to identify, research, test and promote opportunities that improve the quality of care provided to senior citizens and others in need of long-term care support, in the most cost effective manner possible, regardless of care setting. TRECS seeks to identify new programs, services and technologies that better meet the medical and non-medical needs of the elderly being cared for within the long-term care industry.

As such, AALTCN, CAN and TRECS (collectively, the "Caregiver *Amici*") have a strong interest in the administration of pharmaceuticals and ensuring that the needs of patients are met while minimizing the burden upon nurses and family caregivers who bear the responsibility for administering and monitoring the effects of medications. The potential consequences of the decision are of overriding importance to patients, their families, and nursing staff, particularly those in long-term care facilities.

Amici believe that their respective interests will be harmed if the District Court's injunction and decision remains intact and therefore submits this *amici curiae* brief in support of Defendants-Appellants in this matter. All parties have consented to the Caregiver *Amici* filing this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Forest Laboratories, LLC ("Forest") manufactures and sells Namenda, a drug for moderate to severe dementia in patients with Alzheimer's disease. By

facilitating patients' communication with their families and allowing them to perform daily tasks for a longer period of time, Namenda may delay the need for expensive professional long-term care and allow patients in long-term care greater autonomy. Forest's first version of Namenda, Namenda IR®, is an immediate release drug that is administered twice daily; Forest recently introduced an extended release version, Namenda XR®, that is administered only once a day. In 2014, Forest announced its intention to stop manufacturing Namenda IR. The New York Attorney General challenged this decision, alleging that Forest's unilateral attempt to switch patients to the extended release version is anti-competitive and that the antitrust laws require Forest to continue to sell the immediate release drug until Forest's patents expire and generic copies of Namenda IR may be marketed. The District Court issued a preliminary injunction mandating that Forest continue to sell Namenda IR on the same terms and conditions applicable since July 21, 2013. S.A. at 137.[2] The injunction ensures that generic drug companies can take advantage of state substitution laws and sell generic versions of Namenda IR to patients with existing prescriptions for Namenda IR when they enter the market.

The Caregiver *Amici* share a broad mission to advocate for caregivers and families of patients and submit this brief for two basic reasons. First, Caregiver

[2] References to the Special Appendix filed by Defendants-Appellants are in the form "S.A." References to evidentiary transcripts of proceedings before the District Court are in the form "Hr'g Tr."

Amici are concerned that the District Court has failed to recognize the value to patients, their families and caregivers of reducing the number of doses, particularly among patients suffering from memory loss and related symptoms as a result of Alzheimer's disease. The drug at issue in this case allows individuals with Alzheimer's disease to complete daily tasks for a longer period of time, which eases the burden for family caregivers who would otherwise provide that care. The District Court gave insufficient weight to this benefit to families. The Court found there may be a risk in switching from Namenda IR to Namenda XR as it is a change in one's medication. However, the only change is the reduction from two pills to one per day; the therapeutic benefits of the drugs are the same. Caregiver *Amici* have not witnessed patients experiencing harm as a result of switching to Namenda XR.

Second, Caregiver *Amici* are very concerned that this decision could adversely impact the willingness of pharmaceutical companies to spend resources to develop extended release dosages that require fewer administrations. Caregiver *Amici* believe that the rule established by the District Court, which appears to require all pharmaceutical companies to continue to manufacture a drug until patent expiry to minimize switching to a new drug, would cause pioneer drug companies not to innovate with regard to existing drugs, particularly as to their dosage or delivery.

For the foregoing reasons, this Court should overturn the District Court's injunction.

ARGUMENT

I. THE COURT SHOULD REJECT A RULE THAT DISCOURAGES INNOVATION AMONG PIONEER DRUG COMPANIES

A. Courts Should Encourage the Adoption of New Pharmaceutical Innovations and Delivery Methods

Antitrust laws should not impede innovation. Both the Supreme Court and Second Circuit have rejected claims by a party based on antitrust concerns where the remedy sought would "discourage rather than encourage competitive research," *United States v. Nat'l Lead Co*., 332 U.S. 319, 359 (1947), or "have an inevitable chilling effect on innovation," *Berkey Photo, Inc. v. Eastman Kodak Co*., 603 F.2d 263, 282, 285 (2d Cir. 1979) (explaining that "*National Lead* would caution against a decree that might stifle future innovations"). Antitrust laws should "safeguard the incentive to innovate." *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

Allowing companies to benefit from their innovation is key to antitrust policy and why courts have held that new product innovation should not be condemned under antitrust laws except under the most limited circumstances, even where that introduction of the innovative product and its related activities make it more difficult for competitors. *See New York v. Microsoft*, 224 F. Supp.2d 76, 158

(D.D.C. 2002) (refusing to order injunctive relief after trial where "[t]he evidence . . . establishes . . . that Microsoft's innovation would be stifled"); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1372 (7th Cir. 1998) ("It is without precedent to find antitrust liability premised on a theory that development of new products is illegally anticompetitive when the new product requires competing suppliers to adjust their product accordingly. . . [A]ntitrust jurisprudence has well understood that the enforcement of the antitrust laws is self-defeating if it chills or stifles innovation."). Herbert Hovenkamp et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 12.1 (2d ed. 2010) ("[T]he error costs of punishing technological change are rather high, and . . . [c]ourts should not condemn a product change, therefore, unless they are relatively confident that the conduct in question is anticompetitive."); Phillip Areeda et al., Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 776 (2014) (noting that such claims "must always be treated circumspectly by the courts, because the issues will always be highly technical and because undue interference will chill innovation"); Gregory J. Werden, *Identifying Exclusionary Conduct Under Section 2: The "No Economic Sense" Test*, 73 Antitrust L.J. 413, 414-15 (2006) (stating that Section 2 jurisprudence should provide a "prudential safe harbor[]" for "introducing a new product . . . because significant consumer benefits from such conduct are so overwhelmingly likely. Any social gains from

remedies in exceptional cases would be swamped by the chilling effect resulting from forcing businesses to defend such conduct and from false positive findings that such conduct was exclusionary.").

In this case, the Court has limited a company's efforts to promote its new innovation. The District Court has enunciated a rule that a company may not put all of its effort behind a new generation of a product because competitors may be able to make cheaper copies of the prior generation. Under these circumstances, innovators will be less likely to develop new generation products because they would not reap the rewards of their innovation. *Verizon*, 540 U.S. at 414.

The Caregiver *Amici* are concerned that the District Court's rule will discourage innovation. We understand that the existing injunction has already deterred innovation from reaching patients in need. Forest has developed a new version of Namenda, called Namzaric™, which will further reduce the number of pills to be administered by incorporating Namenda XR and will contain a medication for high blood pressure commonly taken by elderly patients. The introduction of this drug is being delayed due to the fact that Forest is forced to continue to produce Namenda IR. Page Proof Br. of Defendants-Appellants, at 32-33. This delay is precisely the effect that the Caregiver *Amici* believe must be avoided.

B. A Single Dosage Provides Significant Benefits to Patients, Nurses, Long-Term Care Facilities and Family Caregivers

The District Court erred in holding that the next generation Namenda was not a valuable innovation. As advocates for those who care for patients with Alzheimer's disease and other debilitating illnesses, Caregiver *Amici* believe that there is great value in reducing the number of pills that a patient must take. A 50% reduction in the number of administrations of Namenda, by switching from the immediate to extended release formulation, creates meaningful benefits for patients, the nurses and long-term care facilities in which such patients reside and the 15 million Americans who are family members, friends and neighbors who care for a loved one with Alzheimer's disease. To require caregiver time and long-term care resident disruption for an additional dosage on a daily basis when a single dosage can suffice is unnecessarily wasteful and not in the best interest of patients.

1. Patients Benefit from Switching to Once-Daily Dosages

Patients will benefit from switching to a once-daily dosage that will minimize the intrusion of another pill administration each day and increase patient compliance with their medication regimens.

A reduction of one pill per day is meaningful. According to the uncontroverted testimony of LuMarie Polivka-West, an expert qualified in the treatment of Alzheimer's disease, each time a pill is administered to a patient with

Alzheimer's disease, "it is an intrusion into their daily life. They don't recall—they have a memory recall of maybe less than five minutes, so they don't recall a patterned routine. So it is an intrusion. And the administration of each pill takes time." Polivka-West 11/13/14 Hr'g Tr. 624:9 - 625:5.

In addition, many individuals with dementias have difficulty swallowing medications due to behavioral issues, weakness of pharyngeal muscles or both that make the minor act of swallowing a pill difficult and disruptive.

The change from twice-daily to once-daily is also likely to increase compliance. Rigid adherence to a medication regime is challenging, particularly for individuals with multiple chronic diseases, multiple prescriptions and memory loss. The District Court correctly found that "[f]ewer pills generally lead to greater compliance with treatment." S.A. at 35. *See also Billhofer v. Flamel Tech., S.A.*, No. 07-9920, 2012 WL 3079186, *33 (S.D.N.Y. Jul. 30, 2012) (Sweet, J.) (holding that it is "essentially tautological" that "more convenient dosing regimens" have "obvious benefits," in a discussion of a pharmaceutical company advertising that "once-daily medications lead to greater compliance.").

When multiplied across a year, the few minutes per day that are saved and the 365 fewer pills that a patient must ingest improve patients' lives. Because Namenda assists patients in maintaining their daily activities for a longer period,

the benefits of increased compliance of Namenda are crucial for patients' well-being, longevity, comfort and independence.

2. Single Dosages as Compared to Twice-Daily Dosages Create Efficiencies that Benefit Nurses and Long-Term Care Facilities

Long-term care professionals and facilities also benefit from fewer pill administrations per patient, saving scarce nurse time. A large proportion of long-term care residents suffer from dementias and therefore are part of the population to whom this drug may be administered, and for whom drug administration is often more time-consuming. Multiplying the amount of time that can be saved by eliminating a single dose of Namenda, allows nurses to dedicate that time to other important nursing functions.

The demands on long-term care nursing staff have been increasing due to the increased complexity of the care needs of residents being admitted to their facilities, as well as the growing population of individuals who require long-term care services. Many patients in such facilities have some degree of cognitive impairment, multiple diagnoses, high levels of dependency and multiple medications. Most patients in nursing facilities have multiple chronic conditions.[3] Almost two-thirds (63.7%) of long-term residents in nursing facilities have some

[3] American Health Care Association, *2012 Quality Report* ("AHCA 2012 Report"), 11, available at http://www.ahcancal.org/quality_improvement/Documents/AHCA%20Quality%20Report%20FINAL.pdf .

form of dementia (including Alzheimer's disease).[4] And, the number of cases of Alzheimer's disease is expected to escalate rapidly as the "baby boom" generation is reaching the age of elevated risk.[5]

Long-term care patients are dependent on others for their daily needs. More than three-quarters (76%) of such patients require assistance to walk. Two-thirds (66.64%) of patients suffer from incontinence of the bladder. More than one-third (35.6%) of such patients require assistance with eating.[6] Of the five essential daily living activities (getting in and out of bed, bathing, eating, dressing and using the bathroom), on average, long-term care residents require assistance in 4.1.[7]

Due to the increasing needs of residents in long-term facilities, the overall nursing staff time per resident per day has increased by almost nine percent from 2007 to 2012.[8] Nurse staffing levels is often cited as a key indicator of quality of nursing facility care, typically expressed in terms of hours of staff time per resident per day. However, the increased care needs of long-term care residents have not been met with increased staffing levels to support the care needed.

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[4] *Id*. at 10.

[5] Alzheimer's Association, *Generation Alzheimer's: The Defining Disease of the Baby Boomers* (2011), available at http://act.alz.org/site/DocServer/ALZ_BoomersReport.pdf?docID=521.

[6] AHCA 2012 Report at 46, Table A3.

[7] *Id*. at 11.

[8] *Id.* at 12-13, Figure 1.5.

Staffing studies conducted by the American Health Care Association and the Centers for Medicare and Medicaid found that while nursing home residents need an average of 4.10 hours of daily care per resident, the average hours actually provided are 3.67.[9] Nurses, who bear responsibility for administering and monitoring the effects of medications, constitute a minority of the staff available. A University of California study found that in 2005, registered nurses ("RNs") provided on average 38 minutes of care per patient per day, but by 2010, this number had dropped to 30 minutes of care.[10] In 2012, the American Health Care Association found the average direct care provided by RNs per day is only 25.2 minutes per patient.[11] The limited and diminishing amount of nurses' time available for each patient demands that their time be used as effectively and efficiently as possible, and saving even a few minutes daily per resident on medication administration can be beneficial.

The time savings also results in cost savings for patients, their families, long-term care facilities and the health system as a whole. TRECS has found that if each nursing-facility patient's medications were reduced by one, more than $1

[9] *Id.* at 13, Figure 1.5.

[10] Charlene Harrington, Ph.D. et al., *Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2005 Through 2010*, 61, Table 25, (Dep't of Social and Behavior Sciences, Uni. of Cal. Oct. 2011), available at http://thenewsoutlet.org/media/documents/Nursing-Homes/Funding/Harrington-nursing-home-staffing-report.pdf.

[11] AHCA 2012 Report, at 13, Figure 1.5.

billion would be saved in the first year alone.[12] The reduction in dosages also reduces the opportunities for errors. Given the complex, cumbersome and confusing process necessary to administer pharmaceuticals in long-term care facilities, including administration by different nurses on different days and shifts, even minor simplifications may have vast benefits.[13]

Long-term care facilities are facing increasing needs without a corresponding increase in resources. Any time savings can lead to a greater quality of care for patients—the foremost concern.

3. Family Caregivers Will Be Significantly Benefited By Single Dosages

Unpaid caregivers provide a significant portion of the care required for patients with Alzheimer's disease and the burden of that care weighs heavily on the caregivers. According to the Alzheimer's Association, 85% of help provided to older adults in the United States is from family members.[14] Unpaid caregivers,

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[12] The TRECS Institute, *Findings and Recommendations from the Industry's Best Minds on the Topic of Rethinking the Pharmaceutical Paradigm in Long-Term Care: An Invitation-Only Summit, The Wharton School* (Mar. 23, 2007), available at http://www.thetrecsinstitute.org/downloads/pharmacy_report.pdf.

[13] *See Id*. at 6 ("Current LTC Pharmacy Communication Process" diagram demonstrating the complexity of the communication process of administering pharmaceuticals to patients in long-term care facilities).

[14] Alzheimer's Association, *2014 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia* ("Alzheimer's Association 2014 Facts and Figures Report") 30, Volume 10, Issue 2, available at

usually immediate family members, provided an estimated 17.7 billion hours of unpaid care to Alzheimer's patients in 2013, valued at over $220.2 billion.[15] The average number of hours of care provided by each caregiver is 21.9 hours per week and 1,139 hours per year.[16] A 2011 Caregiver Action Network survey found that, on average, the most involved family caregivers of patients with Alzheimer's disease spend 43% of their time per week providing care. Most caregivers (62%) also have a full or part-time job.[17] And 30% of caregivers for Alzheimer's patients also have dependent children under the age of 18 who live with them.[18] On average, caregivers spend, 4.1 years in a caregiving role.[19]

Caregiving tasks for patients with dementia, such as Alzheimer's disease, include helping the person take medications correctly, either via reminders or direct administration, and helping the person adhere to treatment

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http://www.alz.org/downloads/Facts_Figures_2014.pdf (The $220.2 billion figure is based on an hourly rate of $12.45).

[15] *Id.* at 30, 33; S.A. at 15 (District Court opinion also noted that the burden on caregivers for providing that care imposed more than $9 billion in additional health care costs on the caregivers themselves).

[16] *Id*. at 33.

[17] Caregiver Action Network, *Alzheimer's Disease Family Caregiver Survey Key Findings* ("CAN Family Caregiver Survey Key Findings") (2011), available at http://www.caregiveraction.org/_doc/pdf/CAN%20Survey%20Fact.pdf.

[18] Alzheimer's Association 2014 Facts and Figures Report, at 31.

[19] CAN Family Caregiver Survey Key Findings.

recommendations.[20] These tasks are in addition to the numerous other types of care that family caregivers provide on a daily basis, such as helping with instrumental activities of daily living (providing transportation, household chores, shopping and managing finances), helping with personal activities of daily living (bathing, dressing, eating, walking and going to the bathroom), managing behavioral symptoms (aggression, depression, agitation, anxiety and wandering), finding support services, making arrangements, hiring and supervising others who provide care and assuming additional responsibilities, including communication with other family members about care plans and decision-making.[21] Thus, the primary caregiver is typically responsible not only for ensuring the patient takes his or her medications and compliance with treatment and prescriptions, but also the numerous other tasks associated with caregiving.

The burdens of caregiving have real consequences for family caregivers. As the patient's symptoms worsen, family caregivers may experience increased emotional stress, depression, impaired immune system response, health impairments, lost wages due to disruptions in employment and depleted income.[22]

Compliance is even more challenging for family caregivers than for professional organizations. Family caregivers often have jobs, dependent children

[20] Alzheimer's Association 2014 Facts and Figures Report, at 31.

[21] *Id*.

[22] *Id*. at 34.

living with them and other obligations that interfere with a second administration of Namenda every single day. Because Namenda allows patients with Alzheimer's disease to perform daily tasks for a longer period of time, an increase in compliance is likely to reduce the burdens on family caregivers, providing further time savings as the patient is able to perform those tasks.

It also can be more difficult for family caregivers to provide a second pill later in the day to Alzheimer's patients who experience "sundowning," which the District Court stated is "the tendency for some patients with Alzheimer's disease to become more confused, anxious, paranoid, [and] restless later in the day than earlier in the day." S.A. at 36. As a consequence, there are additional caregiver difficulties associated with ensuring the patient takes a drug later in the day. *Id.*

Due to the strain placed on family caregivers and their struggle to administer pills to difficult patients with memory loss late in the day while balancing competing family and work obligations, the reduction from a twice-daily pill to a once-daily are substantial for family caregivers.

II. THE DISTRICT COURT FAILED TO APPROPRIATELY CONSIDER THE BENEFITS OF SWITCHING FROM TWICE-DAILY DOSAGES TO A SINGLE DOSAGE

The District Court gave insufficient recognition to the benefits of the innovation presented by Namenda XR. Allowing the lower court's categorical

prioritization of the switch to generic medications over the benefits of improved versions of medications to stand would discourage innovation in the medical field.

The benefits of a single dosage for patients with Alzheimer's disease are clear and described above.

The District Court correctly found there is an "exponential difference" between taking medicine once-daily, rather than twice-daily, citing expert Dr. Barry Reisberg, who works at the Alzheimer's Disease Center of the New York University Langone Medical Center and testified that this "exponential difference" is "very much compounded" for patients with memory problems. S.A. at 35. The District Court found that other medical experts who testified "echoed" this testimony. *Id*. Witnesses who testified on behalf of the State of New York agreed that Namenda XR has patient benefits and may be preferred by some patients and caregivers. Berndt 11/12/14 Hr'g Tr. 454:13-455:16, 449:1-3; Lah 11/10/14 Hr'g Tr. 95:2-95:7. However, despite the District Court's recognition of the "exponential difference" for a patient to switch from the Namenda IR to XR, it found that the benefits of switching "are often marginal" and "not a significant benefit for patients already taking other twice-daily medications." S.A. at 54. Such a finding is not consistent with the experience of the nurses and family caregivers who administer Namenda. The District Court did not give appropriate weight to the full evidence before it and relied more on the perspective of generic

drug companies, rather than the patients and caregivers who are most likely to gain from a switch to a once-daily dosage.

The District Court incorrectly found there is damage to *consumers* if the market opportunity for generic drug companies is reduced. S.A. at 89-96. Mandating that Defendants-Appellants sell an older product on particular terms to ensure that consumers do not switch to a more convenient product reduces the consumer welfare question to the simple question of what product is cheaper, rather than properly weighing the quality of life benefits offered by the innovation.

The District Court relied upon testimony that, all else being equal, doctors would be reluctant to switch a patient's prescription if the patient was managing well under the patient's current prescriptions. S.A. at 56, 73, 87, 90-91. This answers the wrong question. In the case of switching from Namenda IR to Namenda XR, the patient's medication is not changing, only its administration is changing to be more manageable. Changing to a generic version of Namenda IR would also result in minor changes, such as the pill color and imprint of the brand name.[23] Thus, the Court's concern about change is equally applicable to the remedy sought by the State of New York.

[23] *See* U.S. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations* (34th ed.) at iv, available at http://1.usa.gov/1ypXL8s.

The District Court found purported harm may result for patients and their caregivers by switching from Namenda IR to Namenda XR as the change may be disruptive. S.A. at 90-92. Based on the experience of Caregiver *Amici* with patients who have switched to Namenda XR, Caregiver *Amici* do not agree that the switch is disruptive or causes patients harm. In any event, any theoretical harm that may result would almost certainly be outweighed by the benefits provided, as discussed above. The District Court's conclusion fails to adequately weigh expert testimony to the contrary. Ms. Polivka-West, an Alzheimer's disease expert who appeared on behalf of Defendants, provided testimony that "the benefits of going from a twice a day to a once a day far outweigh any concerns that there may be change in the routine. For a person with Alzheimer's, there is no routine. It's just what is familiar. You try to keep them in a familiar environment. They don't have recall, they don't have the memory . . . no short-term memory." Polivka-West 11/13/14 Hr'g Tr. 628:7-21. This testimony is consistent with the experience of the nurses and family caregivers on whose behalf this brief is filed. The benefits of the reduction of time spent administering the drug, the increase in compliance and the lessened burden on caregivers all substantially outweigh any hypothetical effect of the change from the immediate release to extended release version of the same medication.

A. Courts Should Not Discourage Innovation that Provides Benefits to Patients and Other Health Care Stakeholders

Brand pharmaceutical companies invest substantial sums of money into creating new and improved medications, including improved delivery mechanisms and dosages to ease the burden on patients. These incremental improvements can lead to far more significant breakthroughs in the future. And, to encourage future innovation, the pioneer pharmaceutical company must be able to maximize its return; it should not be forced to assist potential competitors in ensuring that cheap copies of the prior generation of the drug are available. *Verizon*, 540 U.S. at 407 ("The opportunity to charge monopoly prices—at least for a short period—is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth."). This is the nature of technology and innovation. While life-saving medications may be too far ahead in the future for today's patients with Alzheimer's disease and their caregivers, *life-enhancing* medications are available today. The courts should encourage improvements to be made to pharmaceuticals and not interfere with such innovation. The lower court's opinion sends the message that the judiciary is concerned with the rights of generic drug manufacturers to make money at the expense of today and tomorrow's patients with Alzheimer's disease and caregivers. This Court should reverse the District Court's decision and dissolve its injunction.

CONCLUSION

For the reasons set forth above, the judgment of the District Court should be overruled.

Dated: January 15, 2015

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(d) and 32(a)(7)(B)-(C), the undersigned counsel certifies as follows:

1. This brief complies with the type-volume limitation for an amicus brief under Fed. R. App. P. 32(a)(7)(B) (setting the maximum length for a party's principal brief at 14,000 words) and Fed. R. App. P. 29(d) (setting the maximum length of an amicus brief at one-half the maximum length for a party's principal brief) because this brief contains, according to the word count of the word processing system used to prepare this brief, 4,525 words, excluding those portions 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 style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2010 in 14-point Times New Roman font.

Dated: January 15, 2015

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CERTIFICATE OF SERVICE

It is hereby certified that on January 15, 2015, the foregoing brief was electronically filed with the Clerk of the Court by using the Court's ECF system. Counsel for the Appellants and counsel for the Appellee are registered in this case on ECF and will be served with the brief via the ECF system.

It is also hereby certified that six hard copies of the foregoing Brief for *Amici* The American Association for Long Term Care Nursing, The Caregiver Action Network and The TRECS Institute were sent via Hand Delivery to:

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