No. 18-540

IN THE

Supreme Court of the United States

LESLIE RUTLEDGE, IN HER OFFICIAL CAPACITY AS ARKANSAS ATTORNEY GENERAL,

Petitioner,

v.

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

BRIEF OF *AMICUS CURIAE* AIDS HEALTHCARE FOUNDATION IN SUPPORT OF PETITIONER

LAURA BOUDREAU
Counsel of Record
TOM MYERS
AIDS HEALTHCARE FOUNDATION
6255 W. Sunset Boulevard, 21st Floor
Los Angeles, CA 90028
(323) 860-5200
laura.boudreau@aidshealth.org

Counsel for Amicus Curiae

March 2, 2020

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

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INTEREST OF *AMICUS CURIAE*[1]

Amicus is the AIDS Healthcare Foundation (AHF). AHF, a California public benefit corporation founded in 1987 and now the largest HIV/AIDS organization in the United States, has the mission of ending the HIV/AIDS epidemic by providing cutting edge medicine and advocacy, regardless of ability to pay. Among other services, AHF operates 68 outpatient HIV medical clinics in 16 States, the District of Columbia and Puerto Rico, and 55 HIV specialty pharmacies. AHF currently has over 56,000 Americans in its care.

AHF also works on behalf of people with HIV/AIDS throughout the country to remove barriers to receiving proper care and treatment for HIV/AIDS through various advocacy techniques including litigation, public policy development, education, and community engagement.

AHF submits this brief in support of Petitioner Leslie Rutledge in her capacity as Attorney General of the State of Arkansas in order to ensure a proper understanding of the provision of pharmacy services to people living with HIV/AIDS and the impact of pharmacy benefit manager (PBM) prescription drug pricing and reimbursement actions on the public health.

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[1] Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part. The brief was authored solely by the attorneys appearing on the cover page. Further, no counsel for a party, and no party, made a monetary contribution intended to fund the preparation or submission of the brief. Pursuant to Rule 37.3(a), *amicus* obtained the written consent of counsel of record for each party to submit this brief.

SUMMARY OF ARGUMENT

Arkansas' law regulating pharmacy reimbursement by pharmacy benefits managers (PBMs) is an exercise of traditional state responsibility and obligation to protect the public health and prevent the spread of infectious diseases like HIV/AIDS. The law seeks to ensure that pharmacies are reimbursed at at least the wholesale cost of the drugs dispensed, rather than lose money on dispenses. This will ensure that pharmacies have the necessary resources to provide critical health care services.

This law is in an area of traditional state regulation and consistent with prior Court holdings including *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995), is not preempted by ERISA.

INTRODUCTION

A. Ending the HIV/AIDS Epidemic in the United States Requires Pharmacy Services That Help Infected People Stay Adherent To A Medication Regimen.

HIV/AIDS is an infectious disease, and individual States have a strong and traditional interest and obligation to take adequate steps to protect the public health from infectious diseases. *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). Without proper care and treatment, HIV/AIDS is fatal. Moreover, treating HIV/AIDS is extremely costly. People with HIV/AIDS require a lifetime of medical care, seeing doctors 4-6 times per year, undergoing multiple tests and monitoring annually, and adhering to medication regimens that can cost upwards of $36,000 per year, with yearly price increases averag-

ing 6%.[2] HIV/AIDS infection, which attacks the body's immune system, can lead to other opportunistic diseases and infections, such as pneumonia and various cancers, which also are costly to treat. It is estimated that that the lifetime medical costs for an individual who becomes infected with HIV at age 35 is $326,500, with 60% of those expenses attributable to the costs of antiretroviral medication.[3]

The key to effectively treating people with HIV/AIDS is getting them linked to care, then retaining them in medical care, and most importantly getting them adherent to a daily medication regimen. The ultimate goal and effect of medication adherence is to reduce the amount of HIV in a person to such a small amount that its presence is virtually undetectable to standard tests. People who achieve this state are known as "virally suppressed." For people who are adherent to a medication regimen and virally suppressed, HIV/AIDS can be a chronic but manageable disease, rather than a fatal one. They are able to work, take care of their families, and have an approximately normal life span.

Just as important, people who are virally suppressed are rendered virtually noninfectious – there is so little of the virus in the body, it is extremely difficult to transmit. Medication adherence thus not only keeps people healthy, it prevents new infections from

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[2] *See* Nicole C. McCann, et al., "HIV Antiretroviral Therapy Costs in the United States, 2012-2018," JAMA Intern Med. (Feb. 3, 2020), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2759735

[3] Tiarney D. Ritchwood, et al, "Trends in health-care expenditure among people living with HIV/AIDS in the United States: evidence from 10 Years of nationally representative data," 16 Int. J. Equity Health 188 (2017), *available at* https://doi.org/10.1186/s12939-017-0683-y

occurring.[4] Getting people with HIV/AIDS adherent to a medication regimen, and rendering them noninfectious, is the key to stopping new infections and ending this epidemic. Getting people with HIV/AIDS adherent to a medication regimen and virally suppressed is a core pillar of the federal National HIV/AIDS Strategy, which seeks to increase the percentage of people virally suppressed to 80%.[5]

Unfortunately, today most Americans with HIV/AIDS are not adherent to a medication regimen, are not virally suppressed, and are potentially still infectious. As a result, there are estimated to be 38,700 new HIV infections every year.[6] To address this, additional resources must be spent to help people adhere to their medication regimen.

B. Pharmacy Services Play A Crucial Role In Treating And Preventing The Spread Of HIV/AIDS.

To help ensure that their patients are able to adhere to whatever medication regimens they have, all pharmacists, and especially those working with potentially fatal disease populations like HIV/AIDS, do much more than merely ensure that the right number of the

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[4] Centers for Disease Control and Prevention, "HIV Treatment as Prevention," *available at* https://www.cdc.gov/hiv/risk/art/index.html (Last visited Feb. 27, 2020)

[5] White House Office of National Aids Policy, *National HIV/AIDS Strategy: Updated to 2020,* p. 12 (July 2015), *available at* https://files.hiv.gov/s3fs-public/nhas-update.pdf

[6] Centers for Disease Control and Prevention, "Estimated HIV Incidence and Prevalence in the United States 2010–2016," HIV Surveillance Supplemental Report, p. 20 (Feb. 2019), *available at* https://www.cdc.gov/hiv/ pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-24-1.pdf

right type of pills are put into a bottle and given to the customer. AHF's pharmacy teams provide a number of vital services that help people stay adherent to their regimen and stay in care. These services include:

1. In-person patient assessment based on the medication regimen and goals (outcomes). This assessment, developed with the patient, includes reviewing and identifying any barriers to care and adherence, and recommending and facilitating steps to remove them.
2. Packaging specifically designed to help patients remember to take their medication.
3. Synchronized dispensing of routine medications so patient can receive all their medications at the same time each month.
4. Regular in-person wellness contacts to be sure that medications are working properly, adherence is maintained, and to verify if any changes in therapy are needed or have occurred.
5. Regular assessments to be sure the goals of the therapy are being met and to review any barriers to meeting those goals.

These very necessary comprehensive adherence services, which require the expenditure of additional resources to provide, result in a much better outcome for AHF's clients. While just 45% of all Americans who have HIV/AIDS are virally suppressed,[7] fully 69% of AHF's clients have achieved viral suppression.

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[7] There are approximately 1,140,000 Americans living with HIV/AIDS. Estimated HIV Incidence and Prevalence in the United States 2010–2016, p. 47 (*supra* note 6). Approximately 514,519 have achieved viral suppression. Centers for Disease Control and Prevention, Monitoring Selected National HIV

ARGUMENT

I. THE DISTORTED MARKET POWER AND ANTICOMPETITIVE PRACTICES OF PBMS RESULT IN PRACTICES THAT HARM PUBLIC HEALTH.

The anticompetitive practices of PBMs, which act as middlemen, gatekeepers, and go-betweens among pharmaceutical companies, pharmacies, and insurers (including government insurers) have been well-documented. Given their immense size and market power – the three largest PBMs control approximately 80% of the market[8] – PBMs can exercise enormous economic leverage over pharmacies by virtually unilaterally setting pharmacy prescription drug reimbursement rates, often below the wholesale cost of the drug, setting up pharmacy networks to include or exclude certain pharmacies, engaging in price reimbursement discrimination between outside pharmacies and pharmacies, like CVS, which are part of the same PBM entity, and steering patients to their own pharmacies.

The results of these practices are predictable. The number of independently operated pharmacies is declining, including an alarming decline in rural pharmacies.[9]

Prevention and Care Objectives by Using HIV Surveillance Data: United States and 6 Dependent Areas, 2017, HIV Surveillance Supplemental Report, p. 47 (June 2019), *available at* https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-24-3.pdf.

[8] Cole Werble, Health Policy Brief: Pharmacy Benefit Managers Health Affairs, p.2 (Sept. 14, 2017), *available at* https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.

[9] Abiodun Salako, et al., Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018, Center for Rural Health Policy Analysis, Rural Policy Brief No. 2018-2 (July 2018),

In addition, pharmacies, even chain pharmacies, are cutting back on services, instead focusing solely on filling prescriptions – just putting pills into bottles – as quickly, voluminously, and cheaply as possible, with little or no consideration for the public health.[10]

II. THE ARKANSAS LAW AT ISSUE SEEKS TO MITIGATE THE PUBLIC HEALTH HARMS OF PBM PRACTICES.

The statute at issue here, Ark. Code Ann. 17-92-507, seeks to ensure that PBMs reimburse pharmacies at at least the wholesale cost of the drugs and to protect against below-cost reimbursements. This is a vital step in protecting the public health and combatting infectious diseases.

The drug regimen adherence services AHF provides, which keep people with HIV/AIDS in care, adherent to a drug regiment, and virally undetectable and non-infectious – all of which go far beyond just putting pills into bottles – cost money. If AHF were compelled to actually lose money by accepting below cost reimbursement, it could not provide those services. However, without these services, fewer people will take their

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available at https://www.public-health.uiowa.edu/rupri/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf; Paulina Firozi, *The Health 202: Here's Why Rural Independent Pharmacies Are Closing Their Doors*, Washington Post (Aug. 23, 2018), *available at* https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/08/23/the-health-202-here-s-why-rural-independent-pharmacies-are-closing-their-doors/5b7da33e1b326b7234392b05

[10] *See, e.g.*, Ellen Gabler, "How Chaos at Chain Pharmacies Is Putting Patients at Risk"*, New York Times* January 31, 2020, *available at* https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html?searchResultPosition=1

medications, making them sicker and increasing the likelihood of new infections.

By such actions, PBMs' pursuit of profit is putting the public health at risk. By compelling pharmacies to accept prescription reimbursement below cost, pharmacies like AHF do not have the resources to provide the services needed to keep people adherent to their medication regimens.

III. THE ARKANSAS LAW IS A TRADITIONAL EXERCISE OF STATE POWER TO PROTECT THE PUBLIC HEALTH AND PREVENT THE SPREAD OF INFECTIOUS DISEASES AND IS NOT PREEMPTED BY ERISA.

Arkansas' law is an effort to protect the public health and, in the case of specialty pharmacies like AHF, control the spread of infectious diseases. By ensuring that pharmacies are not compelled to fill prescriptions at a loss, the law seeks to ensure that pharmacies will have the resources to perform needed pharmacy services above and beyond merely putting pills in bottles, to improve the health of its citizens, and to slow the spread of new infections. The State has a substantial interest in the health of its citizens, and this law properly regulates this traditional area of state interest.

When subjecting a state law to preemption analysis, this Court starts with a presumption "that Congress did not intend to pre-empt areas of traditional state regulation." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985); *see also Hillsborough County, Fla. v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985) ("Where . . . the field that Congress is said to have pre-empted has been traditionally

occupied by the States 'we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (citations omitted).

It has long been understood that protecting and promoting the public health is a traditional area of state regulation. "The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'" *Metropolitan Life*, 471 U.S. at 756 (citations omitted). *See also Hillsborough County*, 471 U.S. at 715 (local ordinance regulating plasma donations not preempted by FDA regulation: "Through the challenged ordinances, Hillsborough County has attempted to protect the health of its plasma donors by preventing them from donating too frequently. . . . It also has attempted to ensure the quality of the plasma collected so as to protect, in turn, the recipients of such plasma.").

The Arkansas law at issue here is analogous to a New York State hospital reimbursement law that was found not to be preempted by ERISA in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995). There, the law required hospitals to bill surcharges to health maintenance organizations (HMOs) and to patients covered by commercial insurance, but not to patients insured by a non-profit Blue Cross/Blue Shield plan. *Id*. at 649.

The payment differentials were enacted for public health reasons, mainly to ensure that more people would have access to insurance coverage and medical care:

> The charge differentials have been justified on the ground that the Blues pay the hospitals promptly and efficiently and, more importantly, provide coverage for many subscribers whom the commercial insurers would reject as unacceptable risks. *Id.* at 658.

In other words, the non-profit Blues merited a cost break for covering the sickest, most vulnerable populations – an important public health purpose.

This Court found that even though the differentials may have some effect on decisions made by insurance buyers, including both individual and ERISA plans, the effects were indirect and did not "relate to" an employee benefit plan subject to ERISA preemption:

> Although there is no evidence that the surcharges will drive every health insurance consumer to the Blues, they do make the Blues more attractive (or less unattractive) as insurance alternatives and thus have an indirect economic effect on choices made by insurance buyers, including ERISA plans.
>
> An indirect economic influence, however, does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself; commercial insurers and HMO's may still offer more attractive packages than the Blues. *Id.* at 659-660.

The holding in *Travelers* applies here as well. Arkansas' law was enacted to address and regulate traditional areas of state responsibility. It establishes a reimbursement floor for pharmacies, for the purpose of ensuring access to pharmacies and necessary pharmacy services that improve health and protect against the spread of infectious disease – regulation that is

well within traditional state regulation and not preempted by ERISA. Further, it is a law of general application. Unlike in *Travelers*, all PBMs and commercial insurers that may contract with them are subject to it equally, so it is unclear that there is even an indirect economic effect on plan choice. As a result, the law in no way "bind[s] plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself."

CONCLUSION

Arkansas' law takes an important step to protect the public health. It is not preempted by ERISA and, if it is struck down, it will inevitably result in sicker Americans and increased infections. For the foregoing reasons and to protect the public health, *amicus* AIDS Healthcare Foundation respectfully request that this Court overrule the decision of the 8th Circuit and uphold the Arkansas law.

Respectfully submitted,

LAURA BOUDREAU
Counsel of Record
TOM MYERS
AIDS HEALTHCARE FOUNDATION
6255 W. Sunset Boulevard, 21st Floor
Los Angeles, CA 90028
(323) 860-5200
laura.boudreau@aidshealth.org

Counsel for Amicus Curiae

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