Case Nos. 1071439 & 1071440

IN THE SUPREME COURT OF ALABAMA

ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP,
DEFENDANTS/APPELLANTS,

V.

STATE OF ALABAMA,
PLAINTIFF/APPELLEE.

On Appeal from the Circuit Court of Montgomery County
(CV-2005-219.10 & .11)

BRIEF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF APPELLANTS

Local Counsel:

Gregory H. Hawley
White Arnold & Dowd P.C.
2025 Third Avenue North
Suite 500
Birmingham, AL 35203
Telephone: (205) 323-1888
Facsimile: (205) 323-8907
E-mail: ghawley@waadlaw.com

Of Counsel:

David A. Balto
1350 I Street, NW, Suite 850
Washington, DC 20005
Telephone: (202) 789-5424
E-mail: bradwasser@yahoo.com
Facsimile: (202)589-1819

John Rector
National Community Pharmacists Association
100 Daingerfield Road
Alexandria, VA 22314
Telephone: (703) 683-8200
E-mail: John.Rector@ncpanet.org
Facsimile: (703) 683-3619

Attorneys for *Amicus Curiae National Community Pharmacists*

Association

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STATEMENT OF THE CASE

Amicus curiae, the National Community Pharmacists Association ("NCPA"), herein adopts and incorporates by reference the Statement of the Case contained in the brief of AstraZeneca Pharmaceuticals, LP, and AstraZeneca LP ("AstraZeneca").

INTEREST OF AMICUS CURIAE NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

National Community Pharmacists Association ("NCPA"), founded in 1898 as the National Association of Retail Druggists, represents the pharmacist owners, managers, and employees of more than 24,000 independent community pharmacies across the United States, including 598 in the State of Alabama. The nation's independent pharmacies and their pharmacist owners are small business entrepreneurs and multifaceted healthcare providers who represent a vital part of the United States' healthcare delivery system. Unlike many chain drug stores and mass merchants, independent pharmacies operate in underserved areas across the country, including many rural communities in Alabama.

Independent pharmacies play a crucial role in drug distribution, dispensing more than 41% of all prescription drugs in the United States annually. On average, each independent pharmacy fills 61,087 prescriptions per year, for a total of 1.6 billion prescriptions filled by independent pharmacies in 2006. Independent pharmacies make up the majority of all pharmacies in more than half the states and U.S. territories.

NCPA's members are concerned about the lawsuit filed by the State of Alabama against AstraZeneca and more than seventy other pharmaceutical manufacturers. The State's allegations in these cases hinge on the assertion that the State overpaid pharmacies for filling the Prescriptions of low-income individuals under Medicaid.

NCPA believes that the judgment and verdict validating the State's claims, if permitted to stand, would have a crippling effect on the ability of pharmacies to participate in Medicaid and, as a result, on the ability of low-income individuals to obtain,

through Medicaid, access to prescription medications equal to the access other individuals enjoy.

SUMMARY OF ARGUMENT

NCPA believes that the State's claim of a broad, systemic fraud involving virtually every pharmaceutical manufacturer under Medicaid is untenable. The State's contention that it was unaware, or should not reasonably have been aware, of the meaning of well-established industry practices regarding average wholesale price ("AWP") and wholesale acquisition costs ("WACs") cannot be reconciled with real-world experience of pharmacists who deal with State Medicaid agencies on a regular basis.

The reality is that State Medicaid agencies have established reimbursement formulas in an effort to balance (i) the amount they reimburse pharmacies that dispense drugs to Medicaid patients, and (ii) the requirement - established by federal law - to set reimbursement sufficiently high to ensure participation in the Medicaid program by retail pharmacies. State agencies, including Alabama Medicaid, are fully aware

of these competing interests, and they reimburse pharmacies with full knowledge of the prices paid by pharmacies and the level of reimbursement necessary to ensure pharmacist participation in Medicaid. Further, NCPA agrees with AstraZeneca that the State's effort to rewrite its reimbursement formula to limit reimbursement to 9% below the price paid by pharmacies to acquire drugs, is contrary to federal law, which requires amendments to be submitted to the federal government for approval and that they ensure equivalent access to Medicaid patients.

As set forth below, NCPA's brief will address the rulings by the trial court relating to pharmacies that presented the jury with an inherently misleading picture of the Medicaid program. At its core, the trial court erred by ruling that a case in which the State claims fraud based upon alleged overpayments to pharmacies under Medicaid has nothing to do with pharmacies. R.1717 ("I'm not going to allow [evidence related to] pharmacists because its not about pharmacists"). NCPA believes that it was a mistake for the trial court to exclude testimony based upon its

source (pharmacies), when its substance was critically relevant to the jury's evaluation of the State's claims.

Independent pharmacists play a critical role in the success of Medicaid, and adequate reimbursement of their costs is essential to their continued participation in the program. Because pharmacies rely upon reimbursement payments from state Medicaid programs to compensate them for the costs of acquiring and dispensing drugs to low-income Medicaid patients, reimbursement must be at sufficient levels to justify the economic decision to participate in the Medicaid program.

Under the State's theory of liability, however, the State should have reimbursed pharmacies at a level significantly below (9% below) the State's estimate of what pharmacies themselves actually pay to acquire drugs from wholesalers. This reimbursement formula would cause pharmacies to lose money on every prescription they filled on behalf of a Medicaid recipient. Thus, implementation of the State's litigation theory, if permitted to stand, would force

many pharmacies to discontinue participation in the Medicaid program altogether, and would work to the detriment of low-income individuals who rely on Medicaid for access to essential prescription medications.

NCPA's brief seeks to explain the devastating impact that the State's theory would have on both independent pharmacies and, ultimately, on the indigent populations that they serve. If independent pharmacies are forced to opt out of participation in the Medicaid program, Medicaid beneficiaries would suffer as a result of decreased access to prescription drugs that would otherwise be available to them through Medicaid.

Testimony by pharmacists on this issue was essential to a fair assessment of the State's claims. It should come as no surprise that independent pharmacies are keenly aware of the costs to pharmacists of acquiring drugs and thus have information relevant to the issues in this case. Pharmacists, however, were prevented by the trial court from testifying that they repeatedly have shared that knowledge with state Medicaid agencies, including officials from Alabama

Medicaid. This evidence of the State's knowledge was relevant and critically important to the jury's assessment of the State's fraud claims.

Pharmacists are key participants in the Medicaid program, and there is no reason that they should be disqualified from providing relevant testimony about whether the State was defrauded and whether it overpaid pharmacies for dispensing drugs under Medicaid.

ARGUMENT

NCPA's brief will address (i) the role of pharmacies in the Medicaid program, (ii) the impact of the State's litigation position on the ability of pharmacies to participate in Medicaid, and (iii) the relevance of testimony by pharmacists to an assessment of the State's fraud claims.

I. THE ROLE OF RETAIL PHARMACIES IN THE MEDICAID PROGRAM.

Congress created Medicaid in 1965 to provide indigent people access to medical treatment and services. As the United States Supreme Court has explained, Medicaid was established "for the purpose of providing financial assistance to States that choose to

reimburse certain costs of medical treatment for needy persons." *Harris v. McRae*, 448 U.S. 297, 301 (1980).

Pharmacies occupy a central position in the administration of Medicaid's prescription drug program. If a state Medicaid program offers prescription drug benefits, the State must provide such benefits in a manner that comports with the Social Security Act. *See* 42 U.S.C. §§ 1396a(a)(10), 1396a(a)(54). When Congress established Medicaid, it determined that States themselves would not directly purchase prescription drugs or directly distribute prescription drugs to Medicaid recipients. Instead, pharmacies and other providers would undertake both of these tasks, and participating state Medicaid programs instead would be obligated to reimburse these providers for dispensing Medicaid prescriptions. In turn, the federal government pays a substantial portion (approximately 70% in Alabama) of the costs incurred by state Medicaid agencies.

Participation by pharmacies in the Medicaid program is voluntary. State Medicaid programs may base their pharmacy reimbursement rates on Estimated

Acquisition Cost plus a reasonable dispensing fee. *See* 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. § 447.331(b).[1] To ensure adequate participation by pharmacies, federal law further requires that pharmacy reimbursement payments be "sufficient to enlist enough providers so that care and services are available under the [Medicaid] plan at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A); *see also* 42 C.F.R. § 447.204.

II. THE STATE'S THEORY OF LIABILITY WOULD UNDERMINE PHARMACIST PARTICIPATION IN MEDICAID AND CAUSE HARM TO MEDICAID BENEFICIARIES.

In this case, the trial court issued a blanket order precluding the testimony of pharmacists. E.g., R.1717, 1912. That ruling denied the jury the ability to consider fully the State's implausible theory of damages, or to understand fully that the State's theory

[1] Federal regulations define Estimated Acquisition Cost as the "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.301. This figure is supplemented by a "dispensing fee," which is designed to compensate pharmacies for the costs they incur when filling prescriptions.

of damages would discourage pharmacy participation in Medicaid and thus result in harm to the indigent Medicaid beneficiaries who rely upon retail pharmacies for prescription medications.

At trial, the State's witness Edward Sauls put forth a compensatory damages theory based on the proposition that the State should have paid pharmacies less money for prescription drugs than the pharmacies actually paid to acquire the drugs in the first instance. R.1599-600. Mr. Sauls testified that the State overpaid pharmacies and that it should have been paying them 9% *less* than the rate at which the pharmacies paid to acquire the prescription drugs. *Id.* The State's compensatory damages theory ignores both economics and the Medicaid statute. Estimated Acquisition Cost has been determined by most states, including Alabama, to be AWP, not actual acquisition cost.

As for economics, commercial enterprises will not participate in a program that requires them to sell products at a price under the purchase price. Pharmacies are no different. They cannot succeed if

they are required to dispense prescription medications if they ultimately will receive 9% less than they paid for prescription medications. Indeed, many NCPA member pharmacies were experiencing considerable financial stress under the reimbursement rates that existed before Alabama Medicaid filed its suit. Allowing the State to argue that it overpaid these pharmacies because they should be reimbursed at a level 9% below their alleged costs of purchasing prescription drugs would have grave consequences for these pharmacies and the low-income patients that they currently serve. The trial court, however, excluded evidence that would have highlighted these facts for the jury. Specifically, the trial court prevented AstraZeneca from submitting data and analysis conducted by Dr. Eric Gaier about how much pharmacies were paid and their costs because it was "information that [AstraZeneca] got from pharmacies.". R.1912 ("I ruled that cannot come in"). That ruling was particularly unfair because the State was permitted to introduce evidence from wholesalers about the prices they charged to pharmacies for drugs. It was error to allow the State to base its damages claim on an

analysis of the prices charged by wholesalers to pharmacists, but then to exclude evidence of Dr. Gaier's analysis of the State's damages claim because it was based on data from pharmacists about the prices they pay wholesalers to purchase drugs. R.1913.

Likewise, John Rector, General Counsel for NCPA was prevented from informing the jury that "the economic situation facing independent pharmacies is challenging." Offer of Proof, Ex. E, 176, 184-85. Mr. Rector would have testified that if the State were to maintain its current dispensing fee and to lower its reimbursement rate to pharmacies for serving Medicaid beneficiaries to the actual acquisition cost (rather than setting its rate at 9% below acquisition cost), then many independent pharmacies with significant Medicaid populations, such as those serving rural communities, would find it difficult to stay in business. Written Proffer, Ex. E at 184-85, 190-98. If these pharmacies were to close, the Medicaid patients they serve would find it far more difficult to obtain the prescription medications on which they depend. *Id.* As a result, the State's theory of liability represents

nothing less than an attack on Medicaid's equal access provision. *See* 42 U.S.C. § 1396a(a)(30)(A).[2]

Further, although the State's compensatory damages model viewed the various companies that dispense prescription drugs as a monolithic entity, different pharmacies in fact operate in a wide variety of organizational and geographic constraints. When pharmacies purchase prescription drugs, for instance, it is important to understand that different types of pharmacies pay varying amounts for the same product. Chain pharmacies, which have substantial negotiating leverage, can generally acquire prescription drugs at a modest mark-up. In contrast, independent pharmacies,

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[2]Likewise, Danny Cottrell, a registered pharmacist in Brewton, Alabama, sought to testify that, if the State reimbursed pharmacies at acquisition cost, his pharmacy would lose money on every Medicaid transaction and would ultimately be unable to continue operating. Written Proffer, Ex. A at 103-04. Further, Danny Johnson, a registered pharmacist in Sylacauga, Alabama, would have testified that lowering the reimbursement rate would have caused his pharmacy to "either go out of business or be required to stop serving Medicaid patients . . . . I believe the same would be true for a number of other independent pharmacies located in Alabama." Written Proffer, Ex. C at ¶ 5; *see also* Written Proffer, Michael Vinson Dep., Ex. B. at 37 (testifying that pharmacies would lose money if Alabama Medicaid reimbursed them at actual acquisition cost and added only a dispensing fee).

which possess minimal purchasing power, pay larger mark-ups for prescription drugs. R.1765-67.

This discrepancy means that independent pharmacies are particularly reliant upon state reimbursements to ensure that they do not lose money when dispensing Medicaid prescriptions. The effects of the State's theory of compensatory damages would be particularly acute in rural parts of the State. Specifically, Mr. Rector would have testified that the larger the percentage of prescriptions that a pharmacy dispenses on behalf of Medicaid beneficiaries, the more important it is for the pharmacy to realize some profit on the sale of prescription drugs. Written Proffer, Ex. E at 176-77. For some independent pharmacies in rural Alabama, Medicaid customers comprise 50% to 60% of their clientele. *See* Written Proffer, Ex. B. 28-29.

Although the State argued that its lawsuit would vindicate the rights of Medicaid beneficiaries (R.1328-30), the reality is very different. The State's theory of compensatory damages would, in fact, adversely affect Medicaid beneficiaries. Pharmacies are constrained by market realities, and they would be

forced to abandon participation in the Medicaid program rather than lose money on every prescription they dispense for Medicaid beneficiaries. As a result of the State's theory, then, Medicaid beneficiaries would suffer increased difficulty in finding pharmacies willing to dispense their prescriptions. Consequently, the State would fail to meet their obligations under § 1396a(a)(30)(A).

III. THE TRIAL COURT IMPERMISSIBLY CONCLUDED THAT THE TESTIMONY OF PHARMACISTS WAS IRRELEVANT TO THE STATE'S CLAIM THAT IT OVERPAID PHARMACISTS UNDER MEDICAID.

Even though the State claimed that it had been defrauded and, as a result, had excessively reimbursed pharmacies under Medicaid, the trial court ruled that "I'm not going to allow the pharmacists because its not about pharmacists." R.1717. The pharmacist evidence that was excluded by the trial court was critically relevant to the core issues of knowledge, notice and reasonable reliance that are essential elements of the State's fraud claims.

1. Evidence Of The State's Knowledge Is Relevant And Admissible Where The State Alleges Fraud.

Under Alabama law, "relevant evidence is evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probably or less probable than it would be without the evidence." Ala. R. Evid. 401. Evidence is relevant when it "bears any logical relationship to the ultimate inference for which it is offered." *Aetna Life Ins. Co. v. Lavoie*, 470 So.2d 1060, 1078 (Ala. 1984); *Nat'l States Ins. Co. v. Jones*, 393 So.2d 1361, 1365 (Ala. 1980) (same). Put another way, "[w]hatever tends to shed light on the main inquiry . . . is, as a general rule, admissible evidence." C. Gamble, McElroy's Ala. Evid. § 21.01*(1)* (4th Ed. 1991). The State's fraud claims against AstraZeneca placed squarely in dispute, among other matters, the State's own knowledge regarding pharmaceutical pricing and whether the State's purported reliance on prescription drug prices as excluding discounts was reasonable. *See, e.g., Exxon Mobil Corp. v. Alabama Dep't of Conservation & Nat. Res.*, 986 So. 2d 1093, 1114 (Ala. 2007); *Liberty Nat. Life Ins. Co. v. Weldon*, 100 So. 2d

696, 718 (Ala. 1958) ("Knowledge may be established by circumstantial evidence even in the face of professions of ignorance."). The pharmacist witnesses proffered by AstraZeneca would have provided testimony directly relevant to each of these issues, and also would have explained that the State's theory of reimbursement would undermine the ability of pharmacies to continue dispensing drugs under Medicaid.

2. Evidence of What The State Knew or Should Have Known About The Prices Paid By Pharmacies Should Have Been Admitted.

AstraZeneca's pharmacist witnesses would have testified about the State's knowledge and reasonable reliance.

For example, Danny Johnson is a registered pharmacist and the owner of a pharmacy in Sylacauga, Alabama, which dispenses drugs to Medicaid patients. He would have testified that he has "served on [Alabama Medicaid Agency's] Pharmacy and Therapeutics Committee multiple times and have worked with numerous AMA personnel during my career in pharmacy. I have been personally present in meetings where the 'spread' [between AWP and actual acquisition cost] was discussed

in the presence of AMA personnel." Written Proffer, Ex. C at ¶ 10. Johnson would have further testified that the State knew "that AWP is not the real price" because under the State's reimbursement scheme, "AMA now reimburses at AWP [minus] 10% and there is no way that Alabama Medicaid would actually expect pharmacies to be paid less than the price at which they purchased the drug." Written Proffer, Ex. C at ¶ 8.

Similarly, the trial court excluded the testimony of Mike Vinson. Mr. Vinson, who owns a group of seven pharmacies in Montgomery, Alabama, would have testified that "since at least 1985 it has been well-known among industry actors involved in the sale and reimbursement of pharmaceuticals that AWP does not represent the actual average price that pharmacies pay to acquire drugs from wholesalers." Ex. B at 105-09. Instead, he "has been purchasing drugs from wholesalers at 15-18% off of AWP for approximately 15 to 20 years," *id.* at 76, 78-79, and during that time, Alabama Medicaid has had the right to review his invoices but has chosen not to review his invoices to drug wholesalers that reflect his acquisition costs. *Id.* at 76, 78-79. Mr. Vinson

would have told the jury that if the Medicaid reimbursement for his costs of purchasing drugs were lowered to his actual cost to purchase the drug, then (i) he would lose money on every prescription because the $5.40 dispensing fee is inadequate to cover his actual cost to dispense drugs, and (ii) he would no longer be able to serve Medicaid recipients. Ex. B. at 36-38, 93-96.

Finally, the trial court excluded the testimony of Mr. Rector from NCPA. Mr. Rector would have addressed the State's knowledge that AWP was not the price paid by pharmacies to purchase drugs. Mr. Rector would have testified, through his sworn deposition, that "[i]t would be hard to imagine" that an agency did not understand the true nature of AWP. Ex. D. at 209. Mr. Rector would have told the jury: "I would think, as a matter of due diligence, in an agency, that you would have to be aware of this kind of opinion and other related opinions." Ex. E. at 209. Mr. Rector further would have testified that "it was 'no secret' among state Medicaid agencies that AWP was not an actual

average of a pharmacy's cost to acquire a drug." Written Proffer, Ex. E., 174-75.

This testimony was relevant to the State's claims that it did not know (and was without reason to have known) that AWP was not the price paid by pharmacies to buy drugs. It was directly relevant to a core element of the fraud claim upon which the State bore the burden of proof. The trial court thus erred in excluding this evidence from trial.

CONCLUSION

The jury in this case was improperly denied evidence from pharmacists that was directly responsive to the State's claims of fraud. Indeed, the State's theory of liability would undermine the Medicaid program by discouraging participation by many of the retail pharmacies that provide prescription drugs to those who rely upon Medicaid. For the reasons stated above, the judgment below should be reversed.

STATEMENT REGARDING ORAL ARGUMENT

Oral argument is not requested.

This 15th Day of December, 2008.

Respectfully Submitted,

/s/ Gregory H. Hawley
Counsel for *Amicus Curiae*
National Community
Pharmacists Association

Gregory H. Hawley
White Arnold & Dowd P.C.
2025 Third Avenue North
Suite 500
Birmingham, AL 35203
Telephone:(205) 323-1888
Facsimile: (205) 323-8907
E-mail: ghawley@waadlaw.com

Of Counsel:

David A. Balto
1350 I Street, NW
Suite 850
Washington, DC 20005
Telephone:(202)789-5424
Facsimile: (202)589-1819
E-mail:bradwasser@yahoo.com

John Rector
National Community Pharmacists
Association
100 Daingerfield Road
Alexandria, VA 22314
Telephone:(703) 683-8200
Facsimile: (703) 683-3619
E-mail:John.Rector@ncpanet.org

CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing Brief of *Amicus Curiae*, National Community Pharmacists Association, has been served on this the 15th day of December, 2008, electronically and by depositing a copy of same in the United States mail, postage prepaid and properly addressed upon the following:

Jere L. Beasley
Jere@beasleyallen.com
W. Daniel Miles
Dee.Miles@beasleyallen.com
Clinton Carter
Clint.Carter@beasleyallen.com
Beasley, Allen, Crow,
Methvin, Portis & Miles
Post Office Box 4160
Montgomery, AL 36103-4160
(334) 269-2343

Caine O'Rear III
corear@handarendall.com)

Windy Blitzer
wbitzer@handarendall.com)
Hand Arendall L.L.C.
Post Office Box 123
Mobile, AL 36601
(251) 432-5511

Roger L. Bates
rbates@handarendall.com
Hand Arendall L.L.C.
1200 Park Place Tower
2001 Park Place North
Birmingham, AL 35203
(205) 324-4400

/s/ Gregory H. Hawley
Counsel for *Amicus Curiae*
National Community Pharmacists
Association

Gregory H. Hawley
White Arnold & Dowd P.C.
2025 Third Avenue North
Suite 500
Birmingham, AL 35203
Telephone: (205) 323-1888

Of Counsel:

David A. Balto
1350 I Street, NW
Suite 850
Washington, DC 20005
Telephone: (202) 789-5424
Facsimile: (202)589-1819
E-mail:bradwasser@yahoo.com

John Rector
National Community Pharmacists Association
100 Daingerfield Road
Alexandria, VA 22314
Telephone: (703) 683-8200
Facsimile: (703) 683-3619
E-mail:John.Rector@ncpanet.org