# NO. 22-3675

# IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

*Appellant*,

v.

ALAN MCCLAIN, IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF THE ARKANSAS INSURANCE DEPARTMENT, ET AL.,

*Appellees.*

On Appeal from the United States District Court for the Eastern District of Arkansas
Case No. 4:21-cv-864 (District Judge Billy Roy Wilson)

**BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE SUPPORTING APPELLANT AND REHEARING EN BANC**

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## INTEREST OF AMICUS CURIAE*

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus urging courts to properly construe 42 U.S.C. § 256b (Section 340B). *See Astra, USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023).

## INTRODUCTION & SUMMARY OF ARGUMENT

Reducing health care costs, including lowering the cost of prescription drugs for uninsured and low-income patients, is a laudable goal. Congress enacted the 340B Program while pursuing this worthwhile policy aim. Trying to extend the reach of the 340B Program to increase the benefits to patients, the Health Resources Services Administration issued an advisory opinion requiring 340B Program participants to deliver discounted drugs to an unlimited number of contract pharmacies. HRSA then issued violation letters ordering 340B

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* No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission.

Program participants to rescind policies that allegedly resulted in overcharging pharmacies.

But as the Third Circuit held, HRSA's actions stretched the 340B Program far beyond the statute's text. *Sanofi Aventis*, 58 F.4th at 703-06. In our system of government, federal agencies cannot draft the statutes they want; they must implement the statutes that Congress gives them. States must also comply with Congress's commands. Contrary to Appellees' arguments, the statutory text does not leave a gap that States may fill. Rather, the statutory language and structure shows that Congress wanted decisions about the 340B Program to be made at the national level. That is why in *Astra* the Supreme Court emphasized that the 340B Program must be governed "harmoniously and on a uniform, nationwide basis." 563 U.S. at 120. States may not interfere with that uniform regulation through their own lawsuits or statutory requirements. *See id.*

What HRSA failed to accomplish through regulatory overreach at the federal level, States are now trying to impose under the guise of state pharmacy regulation. Reading the writing on the wall while the lawsuits challenging HRSA's actions were pending, Arkansas enacted Act 1103.

Arkansas admits that the statute seeks to regulate the federal 340B Program. *See* Ark. Code Ann. § 23-92-601 (title); *id.* § 23-92-602(5).

This is a problem for pharmaceutical companies and the whole country. The 340B Program is very expensive and forces drug manufacturers to give away products at well below actual cost. Whatever the burdens imposed by federal law, drug manufacturers cannot—and should not—bear added burdens imposed by every State in the nation. And there is little question that, if the panel's decision here stands, other States will notice and pass laws imposing equal or greater burdens.

At least Congress considered the effects that the 340B Program would have on the pharmaceutical industry when deciding on the program's scope. But States have no incentive to do the same. Rather, they have the opposite incentive. There will be a race to the bottom to see which State can give its residents the cheapest drugs. That will slow innovation in the pharmaceutical space. This decreased innovation means that fewer new drugs that improve Americans' lives will come to market. In other words, some people will likely lose their lives if drug companies are forced to give away their products, at a loss, to all contract pharmacies.

Even if other States do not pass laws copying Act 1103, Arkansas's actions unfairly burden manufacturers. The panel's decision increases the regulatory burden on manufacturers as they must manage compliance programs for multiple regulatory regimes rather than just one federal regime. These broad ramifications of the panel's ruling therefore cry out for en banc review. The Court should grant the rehearing petition and ensure that pharmaceutical companies are motivated to innovate and patients can afford their drugs.

## ARGUMENT

### I. THE 340B PROGRAM HAS LARGE EFFECTS ON THE PHARMACEUTICAL MARKET.

Whether (and how) to expand the 340B Program's already heavy burdens on drug manufacturers is a question of national import that only Congress can answer. The 340B Program's economic impact is enormous. Ensuring that poor and underserved communities receive high-quality affordable healthcare is not cheap. In 2020, over $38 billion was spent on discounted drugs under the 340B Program. *See* Letter from Glen Voelker, Govt. Info. Specialist, HRSA, to Adam J. Fein, Drug Channels Institute (June 15, 2021), https://perma.cc/7STV-GYTG. "That figure is an astonishing 27% higher than its 2019 counterpart—and more than

quadruple the value of discounted purchases in 2014." Adam. J. Fein, *The 340B Program Soared to $38 Billion in 2020—Up 27% vs. 2019*, Drug Channels Institute (June 16, 2021), https://perma.cc/2AWB-RXAP. The price that 340B Program participants pay pharmaceutical companies for drugs, however, does not reflect the retail value of those drugs. In 2020, for example, the value of the drugs sold under the 340B Program was over $80 billion. *See* Rory Martin & Shiraz Hasan, *Growth of the 340B Program Accelerates in 2020*, IQVIA (Mar. 31, 2021), https://perma.cc/HF4Z-G7BK.

HRSA's audits have found that the increased use of contract pharmacy arrangements has produced a sharp rise in unlawful drug diversion and duplicate discounting. For audits conducted between fiscal years 2012 and 2019, there were over 1,500 findings of 340B Program non-compliance by covered entities. U.S. Gov't Accountability Off., GAO-21-107, *Drug Pricing Program*, 13 (Dec. 2020). For manufacturers, this spike in unlawful practices means that a sizable percentage of valuable inventory is being unfairly sold at a loss.

By expanding the channels for unlawful practices, Arkansas threatens to drive 340B Program costs higher still. For while HRSA

auditors may tally instances of unlawful drug diversion and duplicate discounting, the agency has not punished those violators. As the GAO report explains (at 15-16), "HRSA did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies . . . because the 340B statute does not address contract pharmacy use." In other words, HRSA believes that federal law allows covered entities to flout explicit statutory prohibitions with abandon. That's absurd.

At bottom, Act 1103 would allow Arkansas to transform the 340B Program from a sensible cost-saving measure into a misguided wealth-transfer scheme. Given the steep discounts the 340B Program provides, many covered entities and contract pharmacies will come to rely on manufacturers' supply of discounted drugs as an added revenue stream by selling those drugs at a steep profit.

A recent analysis found that "340B covered entities and their contract pharmacies generated an estimated $13 billion in gross profits on 340B purchased medicines in 2018." Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, Berkeley Rsch. Grp., 2 (Oct. 2020), https://perma.cc/8AU6-DKM8. Indeed, contract pharmacies' average profit margin on 340B Program drugs "is an

estimated 72 percent, compared with just 22 percent for non-340B medicines." *Id.* This is no small business.

Whether manufacturers should be forced to give away drugs at deep discounts so that covered entities and their for-profit vendors can generate operating revenue by reselling that product at market prices is a question that must be answered at the national level. No State may "forc[e] some people alone to bear public burdens which . . . should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960).

If the panel's decision is allowed to stand, Act 1103 will have profound economic and political consequences. This is not a decision that should be made on the state level. Rather, it is one that Congress must make. And Congress has spoken on the issue, deciding against Arkansas's approach. *See* S. Rep. No. 102-259, 2 (1992) (rejecting 340B Program language addressing drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with," covered entities). The Court should give effect to Congress's choice by granting the rehearing petition and reversing the District Court's order.

## II. REFUSING TO REHEAR THIS CASE WILL ENDANGER ALL AMERICANS' HEALTH.

If allowed to stand, the panel's decision will force manufacturers to increase prices on non-340B Program drugs or withdraw from the 340B Program (and therefore Medicare Part B and Medicaid) altogether. Either scenario will lead to fewer healthy Americans and a decreased quality of life.

### A. Other States May Copy Act 1103, Thereby Decreasing Incentives To Innovate.

Other States may react to this Court's upholding Act 1103 in one of two ways. First, it could lead to copycat statutes in every State. This would mean that the recently rejected HRSA interpretation will effectively be reinstated. Instead of Congress's passing legislation to amend federal law, States would be nullifying federal law. But John C. Calhoun lost that debate, and States cannot nullify federal laws. *See Whole Woman's Health v. Jackson*, 595 U.S. 30, 71 (2021) (Sotomayor, J., concurring and dissenting). As explained in the rehearing petition, this is reason enough to rehear the case en banc. The effects of allowing States to nullify the 340B statute would also be devastating.

One reason that pharmaceutical companies devote their limited resources to developing drugs is that they can recover more than their research and development costs when they develop life-saving and life-improving drugs. But Act 1103 puts pharmaceutical companies in a lose-lose position. A recent study shows just how expensive it is to bring new drugs to market. "Between 2009 and 2018, the FDA approved 355 new drugs and biologics." Oliver J. Wouters et al., *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018*, 323 J. Am. Med. Ass'n 844, 848 (2020). The average cost of getting each drug to market was $1,559,100,000. *See id.* That number, however, may underreport the costs of preclinical trials. Factoring in that potential underreporting, the average cost of bringing a single drug to market is between $1,782,200,000 and $2,194,100,000. *See id.* at 850.

Of course, averages are just that. The actual cost for bringing a drug to market varies widely. For example, it cost only $143,200,000 to bring crofelemer (an antidiarrhea drug) to market. Wouters, 323 J. Am. Med. Ass'n at 848. But it cost almost 52 times that amount—$7,424,200,000—to bring dupilumab (a drug for eczema) to market. *See id.* To put that latter figure in perspective, it cost the same to bring one drug to market

as Lyft's entire market capitalization. *See Lyft*, CompaniesMarketCap (Apr. 4, 2024), https://perma.cc/8J22-CS9G.

Despite the enormous costs of bringing drugs to market, the number of drugs that have become available has gone up over the past decade. *See* Congressional Budget Office, *Research & Development in the Pharmaceutical Industry*, 1 (Apr. 2021). This is because the amount that drug companies spend on research and development today "is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation." *Id.* The percentage of revenues spent on research and development has also doubled over the past two decades. *See id.* In other words, pharmaceutical companies see a reason to innovate in the current market.

The reason that drug companies are willing to increase their investment in research and development makes sense to any undergraduate economics major. Drug companies' "spending decisions depend on" the "[a]nticipated lifetime global revenues from a new drug," which, in turn, is influenced by "[p]olicies and programs that influence the supply of and demand for prescription drugs." CBO at 1. Government policies related to Medicare and Medicaid have a large effect on the

demand for prescription drugs in the United States. In other words, the drug companies believe that Medicare and Medicaid policies lead to prices and demand sufficient to develop more drugs than they did just a few decades ago.

But if other States copy Act 1103, the cost to participate in the 340B Program will skyrocket. Rather than providing discounted drugs only to a small group of hospitals and pharmacies, manufacturers will have to sell their products at a discounted rate to many contract pharmacies. The drug companies will not continue their current development pace if that happens. Rather, they may decrease research and development expenditures and thereby the number of drugs that enter the market. They may also raise the prices of drugs. Finally, they may pull out of the 340B Program, and those on Medicare and Medicaid will lack access to key drugs. Of course, the drug companies may also employ a combination of these strategies. These are all bad options for patients and for public health. The best way to stop these negative effects from materializing is granting the rehearing petition.

### B. Manufacturers Will Face Different Problems If Other States Do Not Copy Act 1103.

Even if other States do not copy Act 1103, the panel's decision will still cause problems for manufacturers. If left to stand, the panel's decision will mean that different rules apply in Arkansas than the rest of the country. And the panel decision gives the greenlight for other States to pass laws that, although different than Act 1103, still impose varied obligations on 340B Program participants.

The Supreme Court has "not hesitated to" find state laws preempted when they "risk subjecting" regulated parties "to conflicting state regulations." *FMC Corp. v. Holliday*, 498 U.S. 52, 59 (1990) (citing *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95-100 (1983)). This makes sense. One reason that Congress operates in certain areas—like the pharmaceutical space—is to ensure uniformity: a single regulator making nationwide rules. Imagine if every State in the country could force pharmaceutical companies to have differently formatted and worded labels for prescription drugs. Manufacturers would have to comply with 51 different labeling requirements at the time of production. The increased administrative costs for such a program would not be

borne just by the pharmaceutical companies. Rather, patients would also see the effect when drug prices spiked.

The same is true of administering the 340B Program. At least manufacturers can easily determine whether a request for discounted drugs is valid under uniform federal law. But if every State has different regulatory requirements, the pharmaceutical companies will have to hire more lawyers to understand those regulatory requirements and then hire specialists to ensure compliance on a state-by-state basis. This does not even include the increased substantive costs imposed by the differing regulations.

If 51 different regulatory regimes emerged, drug manufacturers would pass on the increased costs to patients. In essence, patients would be subsidizing pharmacies' bottom lines. The pharmacies could make more money because they received discounted drugs from the manufacturers. Yet patients would be paying more because of the increased prices necessary to compensate for the increased regulatory costs. Increased costs are bad for everyone except those running pharmacies. This Court should not allow that to happen.

At a minimum, allowing the panel decision to stand will cause great uncertainty for drug manufacturers. Which States will copy Act 1103, which will create their own regulatory requirements, and which will stick with the federal requirements? Regulatory uncertainty is bad for business. Businesses "crave certainty as much as almost anything: certainty is what allows them to make long-term plans and long-term investments." Alan Greenspan & Adrian Wooldridge, *Capitalism in America: A History* 258 (2018). When businesses lack certainty, they decrease their output. *Cf.* Senate Budget Committee, *Testimony of Chairman Ben Bernanke*, YouTube (Feb. 7, 2012), https://bit.ly/380rMXv (starting at 4:30) (economic growth slows when there is regulatory uncertainty). The only way to eliminate the uncertainty caused by the panel's decision is to grant the rehearing petition.

## CONCLUSION

This Court should grant the rehearing petition.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limits of Federal Rule of Appellate Procedure 29(b)(4) because it contains 2,598 words, excluding the parts exempted by Federal Rule of Appellate Procedure 32(f).

I also certify that this brief complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 32(a)(5) and (6) because it uses 14-point Century Schoolbook font.

Finally, I certify that the electronic version of this brief was scanned with Bitdefender Antivirus Plus and no virus was detected.

/s/ John M. Masslon II
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April 16, 2024

## CERTIFICATE OF SERVICE

I hereby certify that, on April 16, 2024, I served all counsel of record via the Court's CM/ECF system.

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