No. 24-1570

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellee,

vs.

ANDREW STOLFI, in his official capacity as Director of the Oregon Department of Consumer and Business Services,

Defendant-Appellant

On Appeal from the United States District Court
for the District of Oregon
No. 6:19-cv-01996-MO
Honorable Michael W. Mosman

BRIEF OF *AMICUS CURIAE* OREGON COALITION FOR AFFORDABLE PRESCRIPTIONS IN SUPPORT OF DEFENDANT-APPELLANT

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I. Statement of Interest of *Amicus Curiae*.

The Oregon Coalition for Affordable Prescriptions (OCAP) is a nonprofit advocacy organization made up of consumer groups, health care providers and plans, labor groups, community organizations and everyday Oregonians affected by high prescription drug prices. OCAP believes that prescription medications should be affordable and accessible to everyone who needs them. OCAP and its coalition of partners were key advocates for passage of Or. Laws 2018, Ch 7 (hereinafter "HB 4005") in 2018. Since then, OCAP has led successful efforts to build on HB 4005 to strengthen the state's efforts to contain prescriptions drug prices.

OCAP supports the position of Defendant-Appellant (hereinafter "Defendant" or "State") that the trial court erred in finding that HB 4005 violates the constitutional rights of prescription drug manufactures. That decision misstates the relevant legal standards and inaccurately characterizes the legislative goals for HB 4005. In this *Amicus* brief, OCAP will provide the court with additional legislative history and policy context for HB 4005 and subsequent legislation. Contrary to the court's conclusion, the reporting scheme created by HB 4005 has directly advanced the legislature's objective to better understand how prescription drug prices are established by manufacturers -- the first actor in the supply chain -- and reflected in the prices paid by Oregonians.

II. Rule 29(a)(4) Statement

Amicus Curiae, Oregon Coalition for Affordable Prescriptions, is registered as a nonprofit mutual benefit corporation with the State of Oregon and is not affiliated or supported by any publicly traded corporation. Accordingly, it does not need to submit a Rule 26.1 corporate disclosure statement.

This brief was prepared entirely by counsel for *Amicus Curiae*, Oregon Coalition for Affordable Prescriptions. No party or person, other than OCAP, has provided funding for this brief.

III. Conferral Certification

Upon conferral, Allon Kedom, Counsel for Plaintiff, indicates that Plaintiff has no objection to this request to appear as *Amicus Curiae*.

IV. Argument

A. Introduction

During the 2018 legislative session, Oregon legislators passed HB 4005 -- the prescription drug transparency law at issue in this appeal -- with strong bipartisan support.[1] The problem spurring the legislation was clear: unaffordable and ever-rising prescription drug prices, with little ability for consumers or policy makers to understand how prices are set, let alone any ability to negotiate for a

[1] HB 4005 was enacted in 2018 (Or Laws ch. 7, 2018), and is codified in ORS 656A.686 to 692. *Amicus* will refer to HB 4005 in this brief, as was done by the trial court and defendant.

lower price. The modest solution put forward in HB 4005: require prescription drug manufacturers to report to the state (the Department of Consumer and Business Services or "DCBS") factual information about factors influencing increases in the price of existing prescription drugs when significant (ten percent or more), or the initial price for certain new drugs. out certain drug prices and the factors leading to price increases over 10%. When enacting the law, lawmakers understood that they would not be directly lowering prescription drug prices. However, they believed that transparency might lead prescription drug manufacturers to think twice about price increases that could not be justified, help inform future policy, and empower consumers, including the state, to demand lower prices. In fact, to promote those goals, the Legislature required DCBS to analyze the data, prepare annual reports, hold a public hearing, and recommendations for additional legislation. HB 4005, Section 2(13). PhRMA then initiated this litigation.

The district court granted PhRMA's constitutional challenge and invalidated the entire law. The court's ruling ignores well-established precedent and, if allowed to stand, would undermine the ability of lawmakers to gather information and regulate industry, even in highly regulated sectors such as health care. Under the district court's First Amendment analysis, legislation requiring a company to disclose information the company deems "controversial," is unconstitutional

compelled commercial speech unless the legislature can prove that that the disclosure "directly advances" its legislative goals. Defendant ably addresses the flaws in the court's analysis and its arguments will not be repeated here. However, because the district court's holding relies, in part, on the conclusion that HB 4005's disclosure requirements "do not directly advance its legislative goals," *Amicus* write to rebut that conclusion.

The district court similarly erred in upholding PhRMA's facial "takings" challenge to that portion of HB 4005 incorporating existing public records law for trade secrets. Specifically, HB 4005, §2(10) (codified ORS 646A.689(10)) affirms that "trade secrets" are conditionally exempt from public disclosure as already provided under Oregon's public records laws. ORS 192.345. That is, under ORS 192.345(2), "trade secrets" (as defined) may not be disclosed "unless the public interest requires disclosure *in the particular instance*." (Emphasis added). Accordingly, whether information is truly a "trade secret," whether disclosure is required by the public interest, and whether any disclosure would constitute a "takings," necessarily requires a case-by-case analysis. As argued by Defendant, this defeats a facial challenge to the public interest exception.

In this brief, *Amicus* will not address the takings issue further, except to note that prescription drug manufacturers often claim that information is a "trade secret" when it is plainly not, to avoid or delay disclosure and regulatory oversight. ORS

192.345(2); Decl. of Cassandra Soucy, ER 138-139, ¶¶ 7-11; Prescription Drug Price Transparency Program Annual Report - 2023, pp. 48-49, https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf. This is a separate enforcement issue that remains, regardless of whether the public interest exception is found unconstitutional.

B. HB 4005's Reporting Scheme Furthers the State's Interests

In holding that HB 4005's reporting scheme violates PhRMA members' First Amendment rights, the district court found that "Oregon has failed to demonstrate that HB 4005 is narrowly tailored to advance its stated goals." In reaching this conclusion, the district court pointed to the fact that the law only burdens one actor out of many in the supply chain impacting drug prices, as well as the lack of evidence to show that reporting will advance its legislative goals. *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, No. 6:19-CV-01996-MO, 2024 WL 1177999, at *18 (D. Or. Mar. 19, 2024); ER 35-37. As discussed below, this analysis misstates the legislative goals of HB 4005 and ignores common sense. In addition, contrary to the trial court's findings, there is evidence that the rate of prescription drug price increases has slowed in recent years, after a number of states enacted prescription drug transparency laws.

1. HB 4005's Reporting Scheme Does Not Compel "Controversial Commercial Speech.

As a threshold matter, the district court erred in finding that HB 4005's reporting scheme compels commercial speech on a controversial topic and thus must pass intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York,* 447 U.S. 557, 100 S.Ct. 2343 (1980). As Defendant argues -- and the district court concedes -- HB 4005 requires prescription drug manufacturers to report purely factual information, including their own narrative description of the factors contributing to drug pricing. *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 2024 WL 1177999, at *15–16; ER 33. These regulatory disclosures of factual information are subject to rationale basis review. *See* Defendant-Appellant's Opening Brief at 17–18. Nonetheless, the district court concluded that the topic of drug pricing is "controversial" compelled commercial speech because HB 4005 requires "pharmaceutical companies to speak on a controversial topic and, in particular, justify why they fall on one side -- what Oregon deems the wrong side -- of that controversy." *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 2024 WL 1177999, at *16; ER 33-34. But just because there is political debate about the high costs of prescription drugs, does not make all disclosure requirements relating to drug pricing "controversial." If that were the case, then disclosure required by a myriad of consumer protection laws would be deemed "controversial." More fundamentally, HB 4005 does not require the

pharmaceutical companies to take sides or express an opinion. Indeed, what is the "right" and "wrong" side of the drug pricing controversy? All the law mandates is the disclosure of factual information to allow consumers and policy makers to make informed decisions. In addition, to avoid any argument that the state was looking for data to confirm its view that prescription drug manufacturers are "bad actors," HB 4005 expressly asks for the manufacturer to identify any other relevant factors impacting prices. HB 4005 § 2(3)(k) (codified at ORS 646A.689(3)(k)); OAR 836-200-0530(2)(h). Simply put, as Defendant thoroughly argues, HB 4005's regulatory scheme is unlike those laws found to compel speech on a controversial topic. *See* Defendant-Appellant's Opening Brief at 35–36. The district court erred in so holding.

2. HB 4005 Directly Advances the Legislature's Stated Goals.

Even assuming, however, that HB 4005's reporting requirements are subject to the more exacting "intermediate scrutiny," the district court erred in concluding that HB 4005 does not directly advance the legislative goals. There are two problems. First, the district court focused almost exclusively on whether there was evidence that HB 4005's reporting requirements decreased prescription drug prices. While the unaffordability of prescription drugs for many Oregonians certainly animated passage of HB 4005, legislators understood that transparency, by itself would not necessarily bring prices down. That is, contrary to the district

court's findings, the stated legislative goal was *not* to lower drug prices but rather provide Oregon prescription drug buyers with additional information about prescription drug prices in order to be better consumers and inform additional policymaking. That is an end to itself that has, in fact, been advanced.

Legislative history supports this conclusion. At House Committee on Health Care public hearings, legislators from both sides of the aisle emphasized that transparency by itself was "a very small step" but critically important given that consumers and policy makers alike "have no idea why price hikes are happening." Video Recording, House Committee on Health Care, HB 4005, Feb. 9, 2018, Minutes 32:08–32:19 (statement of Rep. A. Richard Vial); Video Recording, House Committee on Health Care, HB 4005, Feb. 5, 2018, Minutes 5:20–5:45, (statement of Rep. Rob Nosse). Rep. Rob Nosse, Co-Chief Sponsor for the bill explained further:

> With these transparency measures in place, consumers can educate themselves about why their medications cost so much, and, perhaps, we as legislators can begin to hold manufacturers accountable and better understand what is happening and allow this information to inform regulations that we might contemplate down the road.[2]

[2] Rep. Rosse and Rep. Kenny-Guyer also speculated that HB 4005 might create an incentive for drug manufacturers to not raise prices more than 10% in order to avoid the reporting requirements. Video Recording, House Committee on Health Care, HB 4005, Feb. 5, 2018, Minutes 23:01–23:58, (statement of Rep. Rob Nosse); Video Recording, House Committee on Health Care, HB 4005, Feb. 9, 2018, Minutes 30:36–31:00 (statement of Rep. Alissa Keny-Guyer).

The value of understanding how prescription drug manufacturers set prices was also emphasized by Senator Dennis Linthicum, former Republican Senator from District 9 (rural Southern Oregon) and Co-Chief Sponsor of the bill. In his verbal and written testimony, Sen. Linthicum made clear that he is generally a proponent of the free market and sympathetic to the challenges prescription drug makers face due to the complex regulatory environment. Video Recording, House Committee on Health Care, HB 4005, Feb. 5, 2018, Minutes 10:27–12:15 (verbal and written testimony of Sen. Dennis Linthicum). Nonetheless, as reflected in the charts in his written testimony showing the compounding increase in the price of insulin over his lifetime, Sen. Linthicum (a Type 1 Juvenile Onset, Insulin Dependent Diabetic), noted that competition does not appear to curb price hikes, nor does consumer price-consciousness, given the wildly different costs for insulin in different countries. *Id.* at Minutes 14:46–16:19. He also acknowledged the argument made by PhRMA that other actors in the supply stream may be responsible for current price increases. *Id.* at Minutes 17:10–21:20. Nonetheless, he testified that understanding how prescription drug prices are set must start with the prescription drug manufacturers. *Id.* They are "the first step, if you will, the No. 1 pin in the lane. * * * If the diagram looks like a skittle table, it is. The No. 1 pin, the one that starts the chain reaction going, is, unfortunately, the prescription drug manufactures." *Id.*

The second and related problem with the district court's analysis is that it ignores common sense. Because the stated legislative purpose was to collect information to better understand the factors driving prescription drug prices, that purpose was directly advanced by passage of the bill. As required by HB 4005, the Drug Price Transparency Program (within DCBS) has compiled and analyzed data provided by pharmaceutical companies, issued five annual reports, and developed policy proposals for the legislature based on its analysis. Copies of those reports can be found on the Prescription Drug Price Transparency website. https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx. A review of those reports demonstrates that, as the legislature contemplated, HB 4005 has allowed the Drug Price Transparency Program within DCBS to provide the public and legislators with accessible and useful information and policy recommendations. Regardless of whether that information results in a reduction or containment in prescription drug prices, the law has directly advanced the goal of increased understanding about how prescription drug manufacturers set prices.

3. Increased Transparency Correlates with Lower Prescription Drug Prices.

The district court held that the State of Oregon failed to meet its burden of proving with studies or anecdotal evidence that increased transparency around how prescription prices are set leads to lower prices. *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 2024 WL 1177999, at *17; ER 37. Again, *Amicus* agrees with Defendant

that it is unnecessary for Oregon to "prove" that HB 4005 has resulted in lower drug prices to survive constitutional scrutiny. In addition, *Amicus* agrees that there can be no question but that additional information helps level the playing field for consumers -- including the state -- during negotiations over drug prices. As anyone who has negotiated contracts and other agreements knows well, information is power. When one side has little to no information about what is driving costs, it is difficult to determine where there is room for movement or what a *reasonable* compromise might be. That information may or may not actually result in a better deal, depending on other factors, but it certainly helps.

In addition, while the effect of drug price transparency regulations on drug prices have not been well studied,[3] there is a correlation between the

[3] A 2021 review of published studies on the effect of prescription drug price transparency regulations found only two studies yielding conclusive results. Iris R. Joosse, et al., *Evidence of the Effectiveness of Policies Promoting Price Transparency -- A Systematic* Review, HEALTH POL'Y 134, Aug. 2023, at 3, https://www.sciencedirect.com/science/article/pii/S0168851022002822. Those results are striking, however. One of the reviewed studies examined a policy in South Africa requiring prescription drug manufacturers to report certain components of the prices they charge for medicines. *Id.* at 4. The government then published that information on a website. *Id.* The study found that these measures resulted in significant reductions in the price of prescription drugs -- between 2.45% and 9.12% for generic drugs, and 18.50% to 91.52% for originators (i.e., "brand name" drugs). *Id.*

implementation of drug price transparency regulations in various states and a moderation of price increases.

Vermont was the first state to pass a drug price transparency law in 2016. Johanna Butler, *Drug Price Transparency Laws Position States to Impact Drug Prices*, National Academy for State Health Policy (Jan. 10, 2022), https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices. Since then, 23 other states have passed such laws. *State Laws Passed to Lower Prescription Drug Costs: 2017–2024*, National Academy for State Health Policy (Jan. 13, 2023), https://nashp.org/state-tracker/state-drug-pricing-laws-2017-2024/ (last updated June 13, 2024) (select "Transparency" in the drop down menu). As noted by Butler, between 2016 and 2020, there was a 79% decline in the number of drugs reaching the state's per year price increase threshold. Similarly, the Oregon Drug Price Transparency Program reported that in 2020, the second year of operation, it saw 70% fewer reports of price increases than its first year. Prescription Drug Price Transparency Results and Recommendation -- 2020, p. 7, https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx. However, the number of new prescription drugs with high launch prices jumped. *Drug Price Increases Have Slowed, But New Analysis Shows Launch Prices Pushing Costs Into Orbit,* 46brooklyn (Oct. 15, 2019), https://www.46brooklyn.com/research/2019/10/11/three-two-one-launch-rfmyr.

More generally, since 2016, when transparency laws began to be enacted, prescription drug price increases have fallen steadily. The average percent price increase of brand name drugs in 2016 was 7.5%. *This Is The Way…To Analyze Changes in Brand Drug List Prices*, 46brooklyn (Jan. 23, 2024), https://www.46brooklyn.com/branddrug-boxscore (last updated June 2, 2024). By 2020 that number had fallen to 4.1%, and in 2024 the number was 0.6%. *Id.*

Looking at the price of all drugs, brand name and generic, shows a similar trend. In 2018, the proportion of all prescription drugs whose price increases exceeded inflation was 73.7%, whereas the proportion at or below inflation was only 26.3%. Arielle Bosworth, et al., *Changes in the List Prices of Prescription Drugs, 2017-2023*, U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (Oct. 6, 2023), https://aspe.hhs.gov/sites/default/files/documents/0cdd88059165eef3bed1fc587a0fd68a/aspe-drug-price-tracking-brief.pdf. By 2021 the proportion had flipped, with only 32.2% of price increases exceeding inflation and 67.8% at or below inflation. *Id.* And in 2023 the proportion was approximately even, as just over half of price increases exceeded inflation and just under half were at or below inflation. *Id.*[4]

[4] Notably, these downward trends in the growth of drug prices are despite the fact that the aggregate Consumer Price Index for medical care commodities fell only slightly over the same period, from 5.2% in May 2016 to 3.1% in May 2024. *12-Month Percentage Change, Consumer Price Index, Selected Categories*, U.S.

In short, while this data does not establish a causal connection between prescription drug price transparency laws and slower price increases, that inference can be drawn. It also makes sense. Prescription drug manufacturers may be choosing to set prices at a level that will avoid the heightened scrutiny and accountability required by state drug price transparency laws such as those in Oregon.

4. HB 4005 requires Prescription Drug Manufacturers and Insurers to Report Information Relating to Prescription Drug Pricing.

In finding that HB 4005 violates PhRMA's First Amendment rights, the district court held that HB 4005 is not narrowly tailored to achieve its stated goals because it is underinclusive. According to the trial court, while laws may be enacted piecemeal or step by step, Oregon failed to justify its decision to only require prescription drug manufacturers to provide information. *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 2024 WL 1177999, at *18, ER 37.

The court's analysis is premised on a faulty reading of the statute, ignores legislative history, and usurps legislative authority. As Defendant emphasizes -- and the trial court appears to recognize -- legislation is often adopted piecemeal for

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Bureau of Labor Statistics, https://www.bls.gov/charts/consumer-price-index/consumer-price-index-by-category-line-chart.htm (last viewed July 10, 2024) (select "Medical care commodities").

a variety of reasons -- political, practical, legal. Defendant-Appellant's Opening Brief at 39-41. It is not the court's job to second guess those decisions. In this case, Oregon legislators expressly recognized that HB 4005 was a modest first regulatory step designed to gather information necessary to make "smarter regulation." Video Recording, House Committee on Health Care, HB 4005, Feb. 5, 2018, Minutes 23:01–23:58, (statement of Rep. Rob Nosse). Indeed, HB 4005 expressly required DCBS to analyze the data and make recommendations to the legislature on additional legislative concepts to further the state's interest in prescription drug price affordability. HB 4005, §2(13) (codified at ORS 646A.689(14). Moreover, it makes sense to start with the prices charged by drug manufacturers because they are the first in line or, as Sen. Linthicium aptly noted, "the No. 1 pin." The prices they set impact everyone down the supply chain. It is unclear what additional justification the trial court expected.

The trial court's analysis also ignores the fact that HB 4005 requires health insurers -- another actor in the supply chain -- to provide information about prescription drug prices and the impact on premiums. HB 4005, §5 (codified in ORS 735.537. Thus, contrary to the district court finding, HB 4005 itself is not *exclusively* aimed at prescription drug manufacturers.

Finally, it is important to note that since HB 4005 was adopted in 2018, the Oregon legislature has enacted multiple laws -- supported by OCAP -- building on

HB 4005. For example, in 2019, it passed HB 2658 to require 60-day advance notice to DCBS of certain prescription drug price increases. House Bill (HB) 2658 (Or. 2019) (codified at ORS 646A.683). In 2021, it enacted SB 844 to establish the Prescription Drug Affordability Board. That Board is tasked with reviewing the affordability of certain prescription drugs, using data collected because of HB 4005. Senate Bill (SB) 844 (2021) (codified at ORS 656A.693–694). Finally, in 2023, the legislature passed SB 192, which requires Pharmacy Benefit Managers -- another actor in the supply chain often blamed by the pharmaceutical companies for high prescription drug prices -- to report information about rebates, fees, price protection payments and any other payments the pharmacy benefit manager received from manufacturers. That information is then aggregated and published. Senate Bill (SB) 192 § 2 (Or. 2023 Reg. Sess.) (Codified at ORS 735.537). SB 192 also expands which insurers need to file reports to include group health plans and tasks the Prescription Drug Affordability Board with developing a plan for establishing "upper payment limits" for those prescription drugs subject to affordability reviews. SB 192 §19 (codified at ORS 743.025). None of these requirements exist in isolation, as can be seen by a review of Prescription Drug Price Transparency Program webpage. *Prescription Drug Price Transparency,* Oregon Division of Financial Regulation, https://dfr.oregon.gov/drugtransparency /Pages/index.aspx (last viewed July 11, 2024).

V. Conclusion.

The Oregon Coalition for Affordable Prescriptions recognizes that the development, manufacture and distribution of prescription drugs is a complex process. The problem is that it is also opaque. Without the information gathered through HB 4005, consumers and policy makers have no way of knowing what factors contribute to the high (or increasing) costs of prescription drugs. That lack of understanding, in turn, makes it impossible to bargain effectively for lower prices or develop smart public policies to promote affordability. In 2018, Oregon legislators enacted HB 4005 as a first step to gain that knowledge. Subsequently, legislators built on HB 4005, for example, by expanding the entities filing reports to the state to include most health insurers and Pharmacy Benefit managers. Simply put, HB 4005 has been the building block of the State's ongoing efforts -- supported by OCAP -- to improve the affordability of prescription drugs for Oregonians.

As set forth in Defendant's brief, the district court applied the wrong legal standards and ignored legislative intent in ruling in favor of PhRMA and invalidating HB 4005 as a violation of PhRMA members' constitutional rights. HB 4005 is a straightforward reporting scheme that only requires PhRMA members to disclose factual information to DCBS; it does not compel them to express an opinion or take sides. HB 4005 has also has done exactly what

legislator's intended -- make the price setting decisions made by prescription drug manufacturers more transparent. Accordingly, *Amicus* OCAP joins Defendant in requesting that the trial court's judgment for plaintiffs be reversed, and remanded to the trial court with instructions to enter judgment in favor of defendant on the First Amendment and takings claims.

DATED this 12th day of July, 2024.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7), Federal Rules of Appellate Procedure, I certify that this brief is proportionately spaced, has a typeface of 14 points, and contains 3,903 words.

DATED this 12th day of July, 2024.

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that I electronically filed the foregoing document on July 12, 2024, with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the Appellate Electronic Filing system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

DATED this 12th day of July, 2024.

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