Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 1 of 31

#### No. 24-1570

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

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff-Appellee*,

v.

ANDREW STOLFI, IN HIS OFFICIAL CAPACITY AS DIRECTOR OF THE OREGON DEPARTMENT OF CONSUMER AND BUSINESS SERVICES, Defendant-Appellant.

On Appeal from the U.S. District Court for the District of Oregon No. 6:19-cy-01996 The Hon. Michael W. Mosman

BRIEF FOR THE STATES OF CALIFORNIA, ARIZONA, COLORADO, CONNECTICUT, DELAWARE, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, VERMONT, WASHINGTON, AND THE DISTRICT OF COLUMBIA AS AMICI CURIAE IN SUPPORT OF DEFENDANT-APPELLANT

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## TABLE OF CONTENTS

			Page
Introduction	n and	Interests of Amici Curiae	9
Argument			11
I.	•	g Price Transparency Laws Like HB 4005 Are ortant to Lowering the Cost of Prescription Drugs	11
	A.	High Prescription Drug Prices Harm Amici States	11
		High Prescription Drug Prices Threaten     Patient Access to Care	11
		2. High Prescription Drug Prices Increase the Financial Burden on States	15
	В.	Laws Promoting Drug Price Transparency Provide a Greater Understanding of Drug Spending and	
		Guide Policy Solutions	
Conclusion			25
Statement o	f Rela	ated Cases	28
Corporate D	Disclo	sure Statement	29
Certificate of	of Cor	mpliance	30
Certificate of	of Ser	vice	31

## **TABLE OF AUTHORITIES**

	Page
CASES	
Amgen Inc. v. Cal. Corr. Health Care Servs. 47 Cal. App. 5th 716 (2020)	21
STATUTES	
California Health & Saf. Code	
§ 127679(a)	21
§ 127676(b)	18
Colorado Revised Statute	
§ 10-16-1407	23
Maine Revised Statute, Title 22	
§ 8703	19
Maine Revised Statute, Title 5	22
§ 2042	
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§ 21-2C-13	23
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§ 126-BB:5	23
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§ 45:14-84.11	
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New York. Ins. Law	
§ 1111-a (2024)	10, 19

	Page
Oregon Revised Statute §§ 646A.680–69 § 646A.689(1)-(3)	
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REGULATIONS	
84 Fed. Reg. 20732 (2019)	14
CONSTITUTIONAL PROVISIONS	
First Amendment	11
Fifth Amendment	11
COURT RULES	
Federal Rule of Appellate Procedure 29(a)(2)	9
OTHER AUTHORITIES	
Adrienne M. Gilligan, Ph.D., Death or Debt? National Estimates of Financial Toxicity in Persons with Newly- Diagnosed Cancer, Am. J. of Med. (June 12, 2018), <a href="http://www.amjmed.com/article/S0002-9343(18)30509-6/abstract">http://www.amjmed.com/article/S0002-9343(18)30509-6/abstract</a>	14
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Page

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Cong. Budget Off., <i>Prescription Drugs: Spending, Use, and Prices</i> (Jan. 19, 2022), <a href="https://www.cbo.gov/publication/57050">https://www.cbo.gov/publication/57050</a>	13
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Dan Witters, <i>Millions in U.S. Lost Someone Who Couldn't Afford Treatment</i> , Gallup (Nov. 12, 2019), <a href="http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx">http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx</a>	12, 13
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Howard E. LeWine, M.D., Harvard Health Publ'g (Jan. 30, 2015), <i>Millions of adults skip medications due to high cost</i> <a href="https://www.health.harvard.edu/blog/millions-skip-medications-due-to-their-high-cost-201501307673">https://www.health.harvard.edu/blog/millions-skip-medications-due-to-their-high-cost-201501307673</a>	17

P	age
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taking-your-medicine.html	12
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position-states-to-impact-drug-prices/	18
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2021-2030: Growth To Moderate As COVID-19 Impacts Wane, Health Aff. (Mar. 28, 2022),	
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drug-affordability-review-initiatives/ (updated Jan. 4, 2024)	3, 24
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	Page
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Page
15
16, 17

Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 9 of 31

#### INTRODUCTION AND INTERESTS OF AMICI CURIAE

Amici Curiae States of Arizona, California, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Pennsylvania, Vermont, Washington, and the District of Columbia submit this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2). Amici States share a substantial interest in protecting the health and well-being of our residents and protecting access to affordable prescription drugs. Without such access, residents' medical conditions worsen, health outcomes decline, and even death can occur.

To ensure access to the prescription drugs on which millions of state residents depend, States throughout the Nation have adopted varied measures to hold pharmaceutical manufacturers accountable for increases in the price of prescription drugs. For example, some Amici States have created prescription drug affordability boards; others have enacted price transparency laws; still others have established spending targets and limits. Yet other Amici States stand to benefit from laws like Oregon's, using the information they make available to craft their own transparency laws and other prescription drug legislation. Through these laws, States can collect and analyze relevant data to inform solutions to contain the prices of drugs necessary to our residents' health.

As part of that effort, sixteen States—from Connecticut to Florida to Texas, Utah, and California—have adopted price transparency laws similar to Oregon House Bill 4005 (HB 4005), codified at O.R.S. §§ 646A.680–692. Under HB 4005, pharmaceutical manufacturers must report specified information about drugs when there is an increase in the drug's Wholesale Acquisition Cost—the manufacturer's list price for a drug before any discounts, rebates, or reductions in drug price. O.R.S. § 646A.689(1)-(3). Under this reporting requirement, manufacturers must report the net increase in the drug cost, factors contributing to the increase, direct costs incurred by the manufacturer, sales revenue and profits derived from the drug, and the ten highest prices paid by other countries for the drug in the previous calendar year. *Id.* at § 646A.689(2)-(3). This data helps "improve public health and safety by taking steps to address the spiraling health care costs for residents of this state." Id. at § 646A.680.

In short, price transparency laws like HB 4005 are important in the Amici States' effort to protect against harms caused by high drug costs, including to

<sup>&</sup>lt;sup>1</sup> This includes California, Connecticut, Florida, Maine, Minnesota, Nevada, New York, North Dakota, Louisiana, Texas, Utah, Vermont, Virginia, Washington, and West Virginia. Nat'l Acad. for St. Health Pol'y, *Prescription Drug Pricing Transparency Law Comparison Chart* (updated Dec. 7, 2023), <a href="https://nashp.org/state-tracker/prescription-drug-pricing-transparency-law-comparison-chart/">https://nashp.org/state-tracker/prescription-drug-pricing-transparency-law-comparison-chart/</a> (updated Dec. 7, 2023); N.J. Stat. Ann. § 45:14-82.1 to 82.10 (2023) (New Jersey); N.Y. Ins. Law § 1111-a (2024) (New York).

residents' health and to state finances. Amici States thus respectfully request that this Court reverse the district court's order granting summary judgment on the First Amendment claim.<sup>2</sup>

#### **ARGUMENT**

I. DRUG PRICE TRANSPARENCY LAWS LIKE HB 4005 ARE IMPORTANT TO LOWERING THE COST OF PRESCRIPTION DRUGS

High prescription drug prices harm States and their residents by obstructing access to the pharmaceuticals necessary to sustain the health and wellbeing of countless residents, including many of the States' most vulnerable populations. High prescription drug prices also increase the financial burden on States by requiring them, as key payers of healthcare services, to pay more for prescription drugs. Price transparency laws like HB 4005 protect against these harms by providing data about the drivers of price increases and informing policy solutions aimed at combatting the high cost of prescription drugs.

### A. High Prescription Drug Prices Harm Amici States

1. High Prescription Drug Prices Threaten Patient Access to Care

High prescription drug prices can disrupt patients' access to care, which can result in worsening medical conditions, declining health outcomes, and even

<sup>&</sup>lt;sup>2</sup> Amici States take no position in this amicus brief on the district court's analysis of the Fifth Amendment Takings Clause claim.

death.<sup>3</sup> "More than 13% of American adults—or about 34 million people—report knowing of at least one friend or family member in the past five years who died after not receiving needed medical treatment because they were unable to pay for it."<sup>4</sup>

In 2019, the per capita spending in the United States on prescription drugs was \$1,126 per person, while the per capita spending in other high-income countries averaged \$552.<sup>5</sup> That same year, per capita insurer payments for prescription drugs in the United States was 107 percent higher and per capita out-of-pocket spending was 86 percent higher than the average insurer payment among other "peer" countries.<sup>6</sup> Since 1980, the share of U.S. spending on prescription

<sup>&</sup>lt;sup>3</sup> Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. Times (April 17, 2017), <a href="https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html">https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html</a>; Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), <a href="https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx">https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx</a>.

<sup>&</sup>lt;sup>4</sup> Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), <a href="http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx">http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx</a>.

<sup>&</sup>lt;sup>5</sup> This includes spending by private insurance, government health programs, and out-of-pocket payments. Nisha Kurani et al., *How do prescription drug costs in the United States compare to other countries?*, Peterson-KFF Health System Tracker (Feb. 8, 2022), <a href="https://www.healthsystemtracker.org/chart-collection/how-do-prescription-drug-costs-in-the-united-states-compare-to-other-countries/#Per%20capita%20prescribed%20medicine%20spending,%20U.S.%20d ollars,%202004-2019.

<sup>&</sup>lt;sup>6</sup> *Id.* (including Germany, Canada, Japan, Switzerland, Austria, Belgium, Australia, United Kingdom, and Sweden).

drugs has nearly doubled, from 5 percent in 1980 to about 10 percent in 2018.<sup>7</sup> Estimates reflect that national spending for retail prescription drugs should reach \$567.1 billion by 2030, up from \$348.4 billion in 2020.<sup>8</sup> That \$200 billion increase represents a 57 percent increase in just one decade.

The increase in prescription drug costs has become a significant barrier to health care access. Through 2019, 22.9 percent of U.S. adults (about 58 million people) experienced "medication insecurity," the inability to pay for prescribed medication, at least once in the previous year. In a separate poll, "about three in ten adults report not taking their medicines as prescribed at some point in the past year because of the cost. This includes about one in five who report they have not filled a prescription or took an over-the counter drug instead (21%), and 12% who say they have cut pills in half or skipped a dose because of the cost." High

<sup>&</sup>lt;sup>7</sup> Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* (Jan. 19, 2022), <a href="https://www.cbo.gov/publication/57050">https://www.cbo.gov/publication/57050</a>.

<sup>&</sup>lt;sup>8</sup> John A. Poisal et al., *National Health Expenditure Projections*, 2021-2030: Growth To Moderate As COVID-19 Impacts Wane, Health Aff. (Mar. 28, 2022), <a href="http://healthaffairs.org/doi/10.1377/hlthaff.2022.00113">http://healthaffairs.org/doi/10.1377/hlthaff.2022.00113</a>.

<sup>&</sup>lt;sup>9</sup> Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), <a href="http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx">http://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx</a>.

<sup>&</sup>lt;sup>10</sup> Ashley Kirzinger et al., *Public Opinion on Prescription Drugs and Their Prices*, Kaiser Family Found. (Aug. 21, 2023), <a href="http://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/">http://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/</a>. *See* N.D. H.B. 1032, S. Hum. Servs. Comm., Test. of AARP N.D. Pres. at 2 (2021) ("In AARP's 2020 survey of North Dakota adults, almost 1 in 4 individuals did not fill

prescription costs disproportionately affect low-income residents and those with severe or chronic illnesses.<sup>11</sup> The reasons for this are clear. For example, of the 9.5 million newly diagnosed individuals with cancer over 50 years old, 42.4 percent depleted their entire life's assets within the first two years of treatment.<sup>12</sup>

States have a strong interest in addressing the price of drug products that are critical to their residents' quality of life. <sup>13</sup> The failure to take medications as prescribed exacerbates chronic conditions, increases residents' use of healthcare, and imposes greater health system costs. <sup>14</sup>

a prescription" in the prior two years, and of those individuals, 44 percent said this was due to the cost of the drug).

<sup>11</sup> See, e.g., Cal. S.B. 17, Rep. of S. Comm. on Health at 9 (Apr. 19, 2017) (noting the Western Center on Law and Poverty's statement that low-income patients in particular, "have a hard time affording their co-pays and other drug costs, and as a result, many people are forced to skip prescriptions, cut pills in half, or go without necessary care as a result of higher and higher drug costs"); *id.* at 7 (explaining that continued access to prescription drugs saves the lives of 360,000 Californians living with epilepsy); Nev. S.B. 539, S. Comm. Min. at 3 (May 26, 2017) (stating that diabetic patients' well-being is dependent on insulin-based drugs, which they cannot live without).

<sup>&</sup>lt;sup>12</sup> Adrienne M. Gilligan, Ph.D., *Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer*, Am. J. of Med. (June 12, 2018), http://www.amjmed.com/article/S0002-9343(18)30509-6/abstract.

<sup>&</sup>lt;sup>13</sup> Drug transparency laws empower consumers to make informed decisions about their health care by enabling them to compare prices and quality across different providers, leading to better health outcomes. *See* 84 Fed. Reg. 20732, 20744 (2019) ("Price Transparency enhances the information available in the market and allows markets to function more efficiently to the benefit of consumers.")

<sup>&</sup>lt;sup>14</sup> New England Healthcare Inst., *Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Medication Adherence for Chronic Disease* 

## 2. High Prescription Drug Prices Increase the Financial Burden on States

Beyond direct effects on Amici States' residents, high prescription drug costs also impose burdens on the public fisc because States are direct purchasers of such drugs.

States are significant payers of health care services. State dollars pay for prescription drugs used by state employees and their dependents, people housed by corrections, and Medicaid beneficiaries. For example, the Oregon Health Authority spent more than \$1.3 billion between January and December 2022 on prescription drugs for those enrolled in the Oregon Health Plan, the state's Medicaid and children's health insurance program. Further, the Oregon Public Employees' Benefit Board spent \$180 million for prescription drugs in 2022 for its 136,641 members and the Oregon Educators Benefit Board spent \$127 million on its

<sup>(</sup>Aug. 2009); A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans, U.S. Dep't of Health & Hum. Servs. (Sept. 2022), <a href="https://www.cms.gov/priorities/innovation/data-and-reports/2023/eo-rx-drug-cost-response-report">https://www.cms.gov/priorities/innovation/data-and-reports/2023/eo-rx-drug-cost-response-report</a>.

<sup>&</sup>lt;sup>15</sup> Ctrs. for Medicare & Medicaid Servs, *NHE Fact Sheet*, <u>https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet</u> (last modified Jun. 12, 2024).

<sup>&</sup>lt;sup>16</sup> Dep't of Consumer & Bus. Servs., *Prescription Drug Price Transparency Program results and recommendations* – 2023 at 17 (Dec. 1, 2023), <a href="https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf">https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf</a> (updated Mar. 29, 2024).

<sup>&</sup>lt;sup>17</sup> *Id*.

132,077 members for the 2021-2022 plan year. <sup>18</sup> In 2020, Oregon spent more on its Medicaid program than any other program, including its education, transportation, and public safety programs combined. <sup>19</sup> As of January 2023, 1.4 million people, more than one-third of Oregon's population, received Medicaid benefits. <sup>20</sup>

Similarly, in 2015-2016, California's Medicaid program spent over \$3.7 billion on outpatient prescription drugs, representing 4.2 percent of the California Department of Health Care Services' \$87 billion budget for 2015-2016.<sup>21</sup> And the California Public Employees' Retirement System ("CalPERS") reported in 2015 that total prescription drug costs for drugs obtained through mail order or at retail pharmacies through CalPERS plans was \$2.1 billion, an increase of about 10 percent from the previous year (\$1.9 billion).<sup>22</sup>

Vermont too is a significant payer for prescription drugs, having spent

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> Or. Sec'y of St., *Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies* at 5 (Aug. 2023), <a href="https://sos.oregon.gov/audits/Documents/2023-25.pdf">https://sos.oregon.gov/audits/Documents/2023-25.pdf</a>.

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> Cal. S.B. 17, Assemb. Floor Analysis at 7 (Sept. 6, 2017).

<sup>&</sup>lt;sup>22</sup> *Id*.

\$298.7 million for prescriptions for Medicaid members in fiscal year 2023, which was a 12 percent increase from the prior year.<sup>23</sup> Vermont paid an additional \$5.6 million in the same fiscal year through its Pharmaceutical Assistance Programs, which help Vermonters who do not qualify for Medicaid and are enrolled in Medicare pay for their Medicare Prescription Drug Plan and related costs.<sup>24</sup>

Further, not taking medications as prescribed can lead to higher health care costs due to avoidable hospitalizations.<sup>25</sup> This particularly affects States as direct

<sup>&</sup>lt;sup>23</sup> Vt. Agency of Human Servs. & Dep't of Vt. Health Access, *Report to The Vermont Legislature: Pharmacy Best Practices and Cost Control Program Report In Accordance with 33 V.S.A § 2001(c)* at 3 (Oct. 30, 2023), <a href="https://legislature.vermont.gov/assets/Legislative-Reports/DVHA-Pharmacy-Best-Practices-Cost-ControlFINAL-10.27.2023.pdf">https://legislature.vermont.gov/assets/Legislative-Reports/DVHA-Pharmacy-Best-Practices-Cost-ControlFINAL-10.27.2023.pdf</a>.

<sup>&</sup>lt;sup>24</sup> *Id.* at 7-8.

<sup>25</sup> Howard E. LeWine, M.D., *Millions of adults skip medications due to high cost*, Harvard Health Publ'g (Jan. 30, 2015), <a href="https://www.health.harvard.edu/blog/millions-skip-medications-due-to-their-high-cost-201501307673">https://www.health.harvard.edu/blog/millions-skip-medications-due-to-their-high-cost-201501307673</a> (explaining that "[n]ot taking medications as prescribed can cause . . . unnecessary complications related to a medical condition . . . bad outcome[s], like a heart attack or stroke and "increase medical costs if hospitalization or other medical interventions are needed."); Kenneth Finegold et al., *Report on the Affordability of Insulin*, U.S. Dep't of Health & Hum. Serv. (Dec. 16, 2022),

https://aspe.hhs.gov/sites/default/files/documents/b60f396f32e29a2a9469276d9ca8 0e4b/aspe-insulin-affordibility-rtc.pdf. See Vt. Agency of Human Servs. & Dep't of Vt. Health Access, Report to The Vermont Legislature: Pharmacy Best Practices and Cost Control Program Report In Accordance with 33 V.S.A § 2001(c) at 3 (Oct. 30, 2023), https://legislature.vermont.gov/assets/Legislative-Reports/DVHA-Pharmacy-Best-Practices-Cost-ControlFINAL-10.27.2023.pdf ("Increased medication adherence leads to the highest likelihood of benefit from medications, either to cure an illness or prevent adverse health events. It has been

payers of healthcare services. For example, as part of its 2022 report to Congress on the affordability of insulin, the U.S. Department of Health and Human Services discussed the effects of insulin non-adherence—which can result in amputations and ketoacidosis—and avoidable hospitalization costs. <sup>26</sup> High drug costs, and the resulting health harms to residents, thus burden state finances on multiple fronts. States have a strong interest in alleviating that burden.

## B. Laws Promoting Drug Price Transparency Provide a Greater Understanding of Drug Spending and Guide Policy Solutions

Developing policy solutions that protect against the considerable harms resulting from high prescription drug costs requires that States first understand the

estimated that non-optimized medication regimens have resulted in an estimated \$528.4 billion in avoidable US healthcare expenditures annually.").

<sup>&</sup>lt;sup>26</sup> Kenneth Finegold et al., *Report on the Affordability of Insulin*, U.S. Dep't. of Health & Hum. Serv. (Dec. 16, 2022), <a href="https://aspe.hhs.gov/sites/default/files/documents/b60f396f32e29a2a9469276d9ca80e4b/aspe-insulin-affordibility-rtc.pdf">https://aspe.hhs.gov/sites/default/files/documents/b60f396f32e29a2a9469276d9ca80e4b/aspe-insulin-affordibility-rtc.pdf</a>. The total costs for Medicare and Medicaid patients with amputations and ketoacidosis, including those resulting from insulin non-compliance, totaled "\$12.2 billion dollars, with about \$10.5 billion for Medicare patients, of which Medicare paid about 90 percent, and \$1.7 billion for Medicaid enrollees, which would be shared by both State and Federal governments." *Id.* 

cost and pricing of prescription drugs.<sup>27</sup> To that end, many States have promulgated price transparency laws to inform and guide those solutions.<sup>28</sup>

<sup>&</sup>lt;sup>27</sup> Interestingly, States like California and Oregon that have implemented drug price transparency laws have seen "fewer drug price increases [that] trigger reporting requirements" under States' price transparency laws, but initial "launch prices and overall spending on prescription drugs continue[] to rise." Johanna Butler, *Drug Price Transparency Laws Position States to Impact Drug Prices*, Nat'l Acad. for St. Health Pol'y (Jan. 10, 2022), <a href="https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/">https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/</a>. Understanding such trends in drug pricing can help legislators and government officials identify strategies to address the harm to States and their residents from high drug prices.

<sup>&</sup>lt;sup>28</sup> See, e.g., Cal. Health & Safety Code § 127676(b) (discussing the legislature's intent for California Senate Bill ("SB") 17 to provide accountability to the state through drug price transparency laws); Me. Rev. Stat. Ann. tit. 22, § 8703, (2019) (stating purpose "to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens"); Minn. Stat. Ann. § 62J.84, subd. 9 (2023) (describing that the goals of S.F. 1098 include "enhancing the understanding on pharmaceutical spending trends" and "assisting the state and other payers in the management of pharmaceutical costs"); N.J. Stat. Ann. § 45:14-82.11(i) (2023) (requiring that the data collected under P.L. 2023, c. 106 be used to develop recommendations "to advance the goal of more affordable and accessible prescription drugs for New Jersey residents," including recommendations for addressing any "affordability challenge for the State health care system"); N.Y. Ins. Law § 1111-a (2024) (stating as justification for the law that "[t]he prices charged for prescription drugs are a major threat to keeping health care affordable for New York employers and consumers"); Or. H.B. 4005 (2018) (noting that the legislature intended H.B. 4005 "to provide accountability for prescription drug pricing"); Va. H.B. 2007, Fiscal Impact Statement at 1 (2021) (stating that the information collected under H.B. 2007 would be used "to develop an annual online report that analyzes drivers of prescription drug prices"); Wash. Rev. Code Ann. § 43.71C.900 (2019) (addressing that "[i]t is essential to understand the drivers and impact of [prescription drug] costs, as transparency is the first step toward cost containment and greater consumer access to needed prescription drugs").

Price transparency laws like HB 4005 help States identify drugs causing affordability challenges to consumers and payers, as well as better understand pricing across a complex supply chain. <sup>29</sup> For example, launched in 2018 under HB 4005, the Oregon Prescription Drug Price Transparency Program ("Program") "provide[s] accountability for prescription drug pricing through transparency of specific cost and price information from pharmaceutical manufacturers and health insurers." Under HB 4005, pharmaceutical manufacturers must file reports related to new drugs and price increases that exceed a certain threshold. <sup>31</sup> Health insurers also must report information about prescription drug pricing and its effect on insurance premiums. <sup>32</sup> The Program publishes an annual report of findings and recommendations based on data obtained under HB 4005. <sup>33</sup>

<sup>&</sup>lt;sup>29</sup> See The Health Strategies Consultancy LLC, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, Kaiser Family Found. (Mar. 2005), <a href="http://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf">http://www.kff.org/wp-content/uploads/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf</a> (describing the U.S. commercial pharmaceutical supply chain, which includes the roles of pharmacies, pharmacy benefit managers, wholesalers, manufacturers, and insurers).

<sup>&</sup>lt;sup>30</sup> Dep't of Consumer & Bus. Servs., *Prescription Drug Price Transparency*, https://dfr.oregon.gov/drugtransparency/Pages/about.aspx.

 $<sup>^{31}</sup>$  *Id*.

 $<sup>^{32}</sup>$  *Id*.

<sup>&</sup>lt;sup>33</sup> Dep't of Consumer & Bus. Servs., *Prescription Drug Price Transparency*, <a href="https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx">https://dfr.oregon.gov/drugtransparency/Pages/annual-reports.aspx</a>.

Based on information obtained through HB 4005, the Program recently offered recommendations on how to increase transparency across other aspects of the pharmaceutical supply chain and reduce prescription drug costs for consumers. One such recommendation was enhanced reporting requirements for manufacturer patient assistance programs (including manufacturer "coupons" and other payments that reduce a patient's out-of-pocket costs to fill a prescription).<sup>34</sup>

Another was requiring insurers and pharmacy benefits managers to report their use of "copay accumulator" programs (the practice in which an insurer will not count third-party payments such as manufacturer coupons against a consumer's annual cost-sharing limit).<sup>35</sup> The Program also recommended an expansion of bulk prescription drug purchasing to leverage purchasing power.<sup>36</sup> Those recommendations flow directly from the information collected under HB 4005.

Similarly, in 2017, California enacted its own drug price transparency law, Senate Bill ("SB") 17, to help "shin[e] a light on drugs that are having the greatest impact on our health care dollar." *Amgen Inc. v. Cal. Corr. Health Care Servs.*, 47 Cal. App. 5th 716, 723 (2020). Under SB 17, "a manufacturer shall report . . . all of

<sup>&</sup>lt;sup>34</sup> Dep't of Consumer & Bus. Servs., *Prescription Drug Price Transparency Program results and recommendations* – 2023 at 63-65 (Dec. 1, 2023), <a href="https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf">https://dfr.oregon.gov/drugtransparency/Documents/20231207-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2023.pdf</a>.

 $<sup>^{35}</sup>$  *Id*.

<sup>&</sup>lt;sup>36</sup> *Id.* at 65.

the following information for each drug for which" there is an increase in the wholesale acquisition cost as specified in the statutory scheme, including "[a] description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug and the amount of the increase, including, but not limited to, an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug" and "[a] description of the change or improvement in the drug, if any, that necessitates the price increase." Cal. Health & Saf. Code § 127679(a). Using data obtained under SB 17, the California Department of Managed Health Care evaluates the impact that prescription drug costs have on health plan premiums.<sup>37</sup> Health plans paid nearly \$8.7 billion for prescription drugs in 2017, accounting for 13.1 percent of the total health plan premium that year.<sup>38</sup> While specialty drugs accounted for just over one percent of the total number of drugs prescribed, they represented over half of the health plans' total annual spending on prescription drugs.<sup>39</sup> The California Research Bureau also provided a report to the legislature on the implementation of SB 17. The Bureau recommended expanding drug price increase reporting requirements to other entities within the pharmaceutical supply

<sup>&</sup>lt;sup>37</sup> Dep't of Managed Health Care, *Prescription Drug Cost Transparency Report (SB 17)* (Dec. 2018), <a href="http://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf">http://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf</a>. <sup>38</sup> *Id.* at 1, 4, 15.

 $<sup>^{39}</sup>$  *Id.* at 15.

chain (such as pharmacy benefit managers, wholesale distributors, and pharmacies) and collaborating with other government agencies to maximize purchaser power to lower drug costs.<sup>40</sup>

Further, at least nine States, including Oregon, have implemented prescription drug affordability review initiatives, including the creation of prescription drug affordability boards ("PDAB"), independent bodies empowered by States to analyze the high cost of drugs and suggest ways to lower spending. <sup>41</sup> Using data procured through price transparency laws and from other sources, PDABs have used a variety of methods to lower drug costs. <sup>42</sup> For instance, PDABs in Maine and New Hampshire are authorized to set spending targets for prescription drugs and make policy recommendations to meet those targets. <sup>43</sup> PDABs in Colorado,

<sup>&</sup>lt;sup>40</sup> Ngan L. Tran, *Prescription Drug Pricing and Cost Transparency in California*, Cal. Rsch. Bureau, Cal. State Libr., 58 (Oct. 2022), <a href="https://www.library.ca.gov/wp-content/uploads/crb-reports/Prescription\_Drug\_Pricing\_and\_Cost\_Transparency\_in\_California-Oct\_2022v3.pdf">https://www.library.ca.gov/wp-content/uploads/crb-reports/Prescription\_Drug\_Pricing\_and\_Cost\_Transparency\_in\_California-Oct\_2022v3.pdf</a>.

<sup>&</sup>lt;sup>41</sup> Nat'l Acad. for St. Health Pol'y, *Comparison of State Prescription Drug Affordability Review Initiatives* (Mar. 31, 2022), <a href="https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/">https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/</a> (updated Jan. 4, 2024) (including Colorado, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New York, Oregon, and Washington).

<sup>&</sup>lt;sup>42</sup> Nat'l Acad. for St. Health Pol'y, *States Take Diverse Approaches to Drug Affordability Boards* (Feb. 12, 2021), <a href="https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/">https://nashp.org/states-take-diverse-approaches-to-drug-affordability-boards/</a>.

<sup>&</sup>lt;sup>43</sup> See, e.g., 5 M.R.S. § 2042 (2019) (authorizing the Maine PDAB to determine spending targets for certain prescription drugs and make recommendations to meet those spending targets); RSA 126-BB:5 (2020)

Maryland, Minnesota, and Washington are authorized to conduct affordability reviews of certain prescription drugs and establish an upper payment limit on the amount that a payer can reimburse for purchase of a drug. <sup>44</sup> Finally, the Massachusetts Executive Office of Health and Human Services and New York's Medicaid program directly negotiate with drug makers for supplemental rebates on prescription drugs. <sup>45</sup> Much of this is possible due to the information obtained from drug transparency laws like HB 4005.

In sum, laws promoting drug price transparency, including HB 4005, provide a greater understanding of drug spending and guide policy solutions to bring down costs. And in turn, States can better protect the health and wellbeing of their residents—a fundamental state function. States have used data obtained through drug price transparency laws to recommend and implement policy solutions across other aspects of the pharmaceutical supply chain. These efforts include working

(authorizing the New Hampshire PDAB to determine annual spending targets for prescription drugs and make recommendations to meet those spending targets).

<sup>&</sup>lt;sup>44</sup> See C.R.S.A. § 10-16-1407 (2021) (authorizing the Colorado PDAB to conduct prescription drug affordability reviews and establish an upper payment limit for certain drugs); Md. Health-General Code § 21-2C-13 (2019) (establishing process and criteria for the Maryland PDAB to set an upper payment limit on prescription drugs); Minn. Stat. § 62J.92 (2023) (authorizing the Minnesota PDAB to conduct prescription drug affordability reviews and establish an upper payment limit for certain drugs); Rev. Code Wash. § 70.405.050 (2022) (authorizing the Washington PDAB to conduct upper payment limits for certain drugs).

<sup>&</sup>lt;sup>45</sup> Nat'l Acad. for St. Health Pol'y, *Comparison of State Prescription Drug Affordability Review Initiatives* (Mar. 31, 2022), <a href="https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/">https://nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/</a> (updated Jan. 4, 2024).

Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 25 of 31

with other State or governmental entities for bulk purchasing, establishing spending targets and spending limits on high-priced drugs, and negotiating for supplemental rebates. A ruling from this Court prohibiting Oregon from implementing HB 4005 would threaten the drug price transparency laws of other States and may hinder States' ability to obtain drug pricing information and protect access to healthcare.

#### **CONCLUSION**

The district court's order granting summary judgment to Plaintiff-Appellee Pharmaceutical Research and Manufacturers of America should be reversed.

Dated: July 12, 2024 Respectfully submitted,

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Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 27 of 31

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### STATEMENT OF RELATED CASES

The States are not aware of any related cases, as defined by Ninth Circuit Rule 28-2, that are currently pending in this Court and are not already consolidated here.

Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 29 of 31

### CORPORATE DISCLOSURE STATEMENT

As governmental parties, amici are not required to file a certificate of interested persons. Fed. R. App. P. 26.1(a).

## UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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Case: 24-1570, 07/13/2024, DktEntry: 23.1, Page 31 of 31

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I certify that on July 12, 2024, I electronically filed the foregoing document with the Clerk of the Court of the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that all other participants in this case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: July 12, 2024

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