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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

EUGENE DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. LOU SAVAGE, in his official capacity as Acting Director of the Oregon Department of Consumer and Business Services, Defendant.	Case No. 6:19-cv-01996 **COMPLAINT** Declaratory and Injunctive Relief (42 U.S.C. § 1983 and 28 U.S.C. §§ 2201, 2202)

INTRODUCTION

1. In this action, Plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), on behalf of itself and its members, seeks to prevent unconstitutional enforcement of two recent Oregon laws, House Bill No. 4005, 2018 Or. L. Ch. 7 (the "Disclosure Law," attached as Exhibit A) and House Bill No. 2658, 2019 Or. L. Ch. 436 (the "Advance Notification

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Law," attached as Exhibit B). Separately and together, these laws impose nationwide restraints on the list price of biopharmaceutical manufacturers' products and intentionally bind every other state in the nation to Oregon's policy choices regarding prescription drug pricing. The laws also compel pharmaceutical manufacturers to turn over a host of competitively sensitive, trade-secret information—including manufacturers' reasons for price increases—and then threaten to disclose that sensitive information to the public.

2. Specifically, the Disclosure Law requires wide-ranging disclosures whenever a pharmaceutical manufacturer either increases a product's federally defined national list price—known as the "wholesale acquisition cost" or "WAC"—by at least 10 percent compared to the prior calendar year, or introduces a new prescription drug that costs more than $670 for a one-month supply. For each product meeting those thresholds, the manufacturer must make multiple disclosures to Oregon's Department of Consumer and Business Services, including a narrative description of all "factors that contributed to the price increase" and also must provide competitively sensitive, trade-secret-protected information about the costs of manufacturing, marketing, and distributing the product. The Disclosure Law then mandates that the Department publish all this information—even a manufacturer's trade secrets—on its website, so long as the Department deems such public disclosure to be in the "public interest."

3. The Advance Notification Law compels pharmaceutical manufacturers to make additional disclosures and also imposes nationwide direct restraints on prices. Under the Advance Notification Law, if a manufacturer plans to increase a brand-name product's WAC such that, on the effective date of the increase, the WAC will have increased by at least 10 percent or $10,000 over the preceding twelve months, the manufacturer must provide notice to

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the Department and then wait 60 days before implementing any increase in the product's WAC. Because under federal law the WAC is uniform nationwide, the law's 60-day notice requirement prevents the manufacturer from raising its WAC in any state for 60 days after notice is given. Further, the law not only bars the manufacturer from increasing the price, but also requires it to disclose to the State—and potentially for the State then to disclose to the public—competitively sensitive information such as the date and amount of the proposed increase, and whether the increase "is necessitated by a change to or improvement in the prescription drug."

4. The Disclosure Law and Advance Notification Law are unconstitutional on four grounds.

5. *First*, both laws violate the dormant Commerce Clause by restricting drug prices nationwide. The Disclosure Law's intrusive disclosure requirements and its threat to strip trade-secret protection are tied to the federally defined and national WAC. The Advance Notification Law likewise imposes a nationwide ban on increases in the WAC for qualifying drugs for 60 days after a manufacturer notifies the State that it intends to increase the product's WAC above the statutory threshold. The dormant Commerce Clause prohibits such attempts by one state to foist its policies onto other states.

6. For example, the Supreme Court in *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority*, 476 U.S. 573 (1986), struck down an analogous state ban on price changes. The New York law challenged there required distillers to file a monthly price list and to affirm that the listed in-state prices were no higher than those charged in other states. The law thus imposed a temporary nationwide ban on decreasing prices below those in New York. The

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Supreme Court held that New York could not regulate price changes outside the state. Oregon cannot do so either.

7. *Second*, both the Disclosure Law and the Advance Notification Law violate the First Amendment by compelling speech. Both laws require pharmaceutical manufacturers to communicate to the State—and often to the public—subjective information about their pricing decisions in a manner that endorses the State's preferred message. In particular, the Advance Notification Law forces manufacturers to declare that they plan to increase the WAC of a prescription drug in 60 days, even if they wish to provide less notice or none. As part of this process, the Advance Notification Law endorses only one potential justification for a price increase—a "change or improvement" in the drug—and compels manufacturers to state whether they can invoke that justification, no matter what other well-grounded reasons a manufacturer may have. The Disclosure Law not only compels manufacturers to disclose commercially sensitive, trade-secret information, but also requires them to create a narrative description of the factors that led to the price increase or the initial launch price.

8. In compelling this speech, the Disclosure Law and the Advance Notification Law impermissibly discriminate based on speaker, content, and viewpoint. They discriminate based on the speaker by singling out pharmaceutical manufacturers and forcing them to speak about price increases. They discriminate based on content and viewpoint by formulating implicit and explicit messages—that manufacturers alone are responsible for the prices that patients and others pay for prescription drugs, that manufacturers owe the State an explanation for their pricing decisions, and that only changes or improvements to a drug can justify increases to the

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WAC beyond what the State deems appropriate—and by forcing manufacturers to endorse and convey those messages.

9. *Third*, both laws also conflict with, and are therefore preempted by, federal law governing trade secrets. Recognizing that protection of trade secrets is critical to U.S. businesses, Congress enhanced existing state-law safeguards by enacting the Defend Trade Secrets Act of 2016 ("DTSA"). The DTSA sets a federal baseline for trade-secret protection, which extends to sensitive and confidential advertising, cost, marketing, pricing, and production information. The Disclosure Law and the Advance Notification Law do not merely fall below the federal baseline. They compel disclosure of these valuable trade secrets, threaten to extinguish their value by publishing them to the world, and effectively nullify federal protections in the DTSA, thereby undermining innovation and competition in the American pharmaceutical industry.

10. *Fourth*, both laws' threatened abrogation of trade-secret protection also effects an unconstitutional taking of property without *any* compensation—let alone "just compensation"—and thus violates the Fifth Amendment's Takings Clause. The laws threaten to deprive affected manufacturers of trade-secret protection for their confidential information, forcing disclosure to the State and potentially requiring dissemination on the Internet, including to third-party payers and competitors. Before the Disclosure Law and the Advance Notification Law, these materials qualified as trade secrets under the laws of every state, including Oregon. Trade secrets are property; the Disclosure Law and Advance Notification Law destroy the value of that property without just compensation.

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11. PhRMA thus seeks a declaration that the Disclosure Law and the Advance Notification Law violate the dormant Commerce Clause, infringe First Amendment rights, are preempted by federal trade-secret law, and take manufacturers' intellectual property without compensation in violation of the Takings Clause. PhRMA also seeks an injunction prohibiting Defendant from implementing or enforcing either law.

PARTIES

12. PhRMA is a non-profit corporation organized under Delaware law, with its headquarters in Washington, D.C. PhRMA serves as the pharmaceutical industry's principal public policy advocate, representing the interests of its members before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. Among other objectives, PhRMA seeks to advance public policies that foster continued medical innovation and to educate the public about the process for discovering and developing new drugs. PhRMA members are leading research-based pharmaceutical and biotechnology companies in America, devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives.[1]

13. Defendant Lou Savage is the Acting Director of the Oregon Department of Consumer and Business Services ("DCBS" or "the Department") and is sued in his official capacity only. As Acting Director of DCBS, Defendant Savage is responsible for the implementation and execution of the Disclosure Law and the Advance Notification Law.

[1] A full list of PhRMA members is available at http://www.phrma.org/about/members.

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JURISDICTION AND VENUE

14. PhRMA's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

15. Venue is proper in this district under 28 U.S.C. § 1391(b) because PhRMA's claims arise in this judicial district and because Defendant resides and performs his official duties in this district.

16. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201, and this Court has the authority under 28 U.S.C. §§ 2201 and 2202 to grant PhRMA declaratory and injunctive relief from the Disclosure Law and the Advance Notification Law.

FACTUAL ALLEGATIONS

PhRMA Members Spend Enormous Sums on Research and Development

17. PhRMA members develop life-saving and life-enhancing medicines that are promoted, prescribed, and sold throughout the nation, including in Oregon. Pharmaceutical manufacturers, including PhRMA's members, invest huge sums in the research and development of new medicines. Between 2000 and 2018, the U.S. Food and Drug Administration ("FDA") approved more than 550 new drugs.[2] PhRMA members were responsible for much of this innovation. They are also responsible for 19 of the 59 novel drugs that FDA approved in 2018 and 15 of the 41 novel drugs approved to date in 2019.[3] FDA has recognized that novel drugs "frequently provide important new therapies for patients."[4]

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[2] Asher Mullard, *2018 FDA Drug Approvals*, Nature (Jan. 15, 2019), https://go.nature.com/2CmHeMp.

[3] *See* FDA, *Novel Drug Approvals for 2018*, https://bit.ly/382egAv; FDA, *Novel Drug Approvals for 2019*, https://bit.ly/37UXgMu.

[4] *Id.*

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18. The cost of developing innovative medicines is staggering. On average, a manufacturer spends 10 to 15 years—and approximately $2.6 billion—developing a single new medicine.[5] PhRMA members invest billions each year on research and development.[6] Further, the required investments in time and expense to research and develop a new drug are continually increasing.[7] Among many reasons for these increases, clinical drug development takes more time as the required research grows more and more complex, attrition rates during the research phase are high, and demands by regulatory authorities and payers are escalating.[8]

19. The low likelihood of securing FDA approval magnifies the risk. As of 2018, FDA approved only 14 percent of drug candidates that entered clinical testing.[9] For example, it has rejected 99 percent of proposed Alzheimer drugs.[10] According to an estimate focusing on the most prolific developers of new drugs, "95% of the experimental medicines that are studied

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[5] Joseph A. DiMasi, et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 (2016), https://bit.ly/33JtBCE.

[6] *See, e.g.*, PhRMA, *2019 Profile: Biopharmaceutical Research Industry* (2019), https://onphr.ma/2Rh5c50; Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Transl. Med. 105 (Apr. 27, 2017), https://bit.ly/33KBRlT (some pharmaceutical companies have invested over $10 billion per novel drug); Kim Thomas, *The Price of Health: The Cost of Developing New Medicines*, The Guardian (Mar. 30, 2016), https://bit.ly/2kliNY5 (noting that "[d]rugs typically take 12 years from the initial discovery stage to reach the market").

[7] Schuhmacher et al., *supra* note 6 (the average time for clinical development increased from 6.4 years between 2005-2009 to 9.1 years between 2008-2012; research and development costs have increased 8.6% over the past sixty years); Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, Chem. & Eng'g News (Nov. 20, 2014), https://bit.ly/2LnuH0D (study found that "developing a prescription drug that gains market approval [costs] $2.6 billion, a 145% increase" from 2003).

[8] *Id.*

[9] MIT Sloan School of Management, *Measuring the Risks and Rewards of Drug Development* (Jan. 31, 2018), https://bit.ly/2mtmjTL.

[10] Jeffrey L. Cummings, et al., *The Price of Progress: Funding and Financing Alzheimer's Disease Drug Development*, 4 Alzheimer's & Dementia: Translational Research & Clinical Interventions 330, 331 (2018), https://bit.ly/2mtqy1C.

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in humans fail to be both effective and safe."[11] Even for products that are approved and reach the market, manufacturers may not earn back the full costs of research and development. The increased focus on novel medicines for small patient populations makes it even harder to recoup the investment in research and development as well as the costs associated with clinical trial failures. Drug treatments are becoming increasingly personalized, taking into consideration a patient's "genetic, anatomical, and physiological characteristics."[12] More than 40 percent of new drugs approved by FDA in 2018, for example, were personalized medicines with labeling that notes specific biological markers to help guide prescribers' decisions.[13] Pharmaceutical researchers are now developing gene therapies that work by administering genetic material "to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use."[14] These targeted drugs are often critical in treating rare illnesses. But they cost more to develop and, in some cases, help only relatively few patients.

20. As biopharmaceutical companies build on new technologies and advances in scientific knowledge, they continue to develop groundbreaking therapies to combat and potentially to cure devastating diseases. Pharmaceutical researchers are currently developing almost 300 medicines and vaccines that use the immune system to combat cancer, homing in on "[a] novel treatment . . . for the potential to reverse brain damage suffered from a stroke," and

[11] Matthew Herper, *The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change*, Forbes (Aug. 11, 2013), https://bit.ly/2m6Y2m1.

[12] FDA, *Paving the Way for Personalized Medicine* 4 (Oct. 2013), https://bit.ly/2PdIjwq.

[13] Personalized Med. Coalition, *Personalized Medicine at FDA: A Progress and Outlook Report* 2, 4 (2018), https://bit.ly/2rPkjrx.

[14] FDA, *What is Gene Therapy?* (Jul. 25, 2018), https://bit.ly/2OL4MlC.

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"working on cutting-edge medicines for patients with mental illness."[15] As of December 2018, pharmaceutical companies were working on almost 300 novel cell and gene therapies, including over 100 that treat cancer.[16]

The Nationwide WAC and the Pharmaceutical Supply Chain

21. The Disclosure Law and Advance Notification Law regulate the price of pharmaceutical products. Understanding the pharmaceutical supply chain and how prices are set at different levels is critical to assessing the nationwide impact of the requirements and policies set forth in these laws. As the Oregon legislature has recognized, many entities besides biopharmaceutical manufacturers are involved in determining the costs that consumers pay for pharmaceutical products.[17]

22. Biopharmaceutical manufacturers primarily sell their prescription drugs to wholesalers. Three wholesalers—AmerisourceBergen, Cardinal Health, and McKesson Corporation—account for approximately 90 percent of all pharmaceuticals distributed in the United States.

23. The nationwide WAC is used as a benchmark price for contracts between manufacturers and their customers, such as wholesalers and other direct customers. Federal law defines the WAC as "the manufacturer's list price" to wholesalers or direct purchasers, "not

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[15] America's Biopharmaceutical Companies, *Medicines in Development 2018 Report: Cancer* 5–6; https://onphr.ma/2RdP0RN; America's Biopharmaceutical Companies, *Medicines in Development 2018 Report: Heart Disease & Stroke* 4, https://onphr.ma/2RqcgMq; America's Biopharmaceutical Companies, *Medicines in Development 2019: Mental Illness* 2, https://onphr.ma/2OLFhkj.

[16] America's Biopharmaceutical Companies, *Medicines in Development 2018 Report: Cell Therapy and Gene Therapy* 1, https://onphr.ma/33IN6LF.

[17] Joint Interim Task Force on the Fair Pricing of Prescription Drugs, *Report on Transparency Strategies for the Pharmaceutical Supply Chain* 1–6 (Nov. 2018), https://bit.ly/2sIu9vV.

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including prompt pay or other discounts, rebates or reductions in price." 42 U.S.C. § 1395w-3a(c)(6)(B); *see also* HHS, *Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency*, 84 Fed. Reg. 20,732, 20,739 (May 10, 2019) (describing the WAC as "a *single*, manufacturer-published price that excludes rebates and discounts," and a "generalizable list price that applies to *all* patients prior to the application of insurance coverage" (emphasis added)). Manufacturers set the WAC for their drugs based on individualized, proprietary, and subjective pricing methodologies.

24. Consistent with federal law, a drug's WAC is uniform across the United States and is publicly available.

25. Wholesalers sell drugs to healthcare providers (such as hospitals and doctors) and retailers (such as pharmacies) at prices that are also based on the product's WAC. These prices, which are subject to competitive negotiation, are not public.

26. Most patients who receive drugs directly from a pharmacy or a healthcare provider pay insurance premiums, deductibles, and co-payment amounts. The amounts that a patient pays are set independently by the patient's insurance company, not by any biopharmaceutical manufacturer.

Overview of the Disclosure Law

27. On February 28, 2018, the Oregon House of Representatives passed HB 4005, titled the "Prescription Drug Price Transparency Act." On March 2, the Oregon Senate passed the same bill. The Speaker of the House signed the bill on March 6. On March 12, the Senate President signed HB 4005 and then Governor Kate Brown signed it into law. The Disclosure

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Law took effect immediately; its reporting requirements for new and existing drugs became operative on March 15 and July 1, 2019, respectively. 2018 Or. L. Ch. 7 §§ 13, 15.

28. The Disclosure Law imposes numerous disclosure requirements on manufacturers of "a prescription drug that is sold in [Oregon] state." *Id.* § 2(1)(e). The law authorizes DCBS to "adopt rules as necessary for carrying out" its mandate. *Id.* § 2(12).

29. The Disclosure Law's reporting requirements apply to all prescription drugs for which "[t]he price was $100 or more for a one-month supply or for a course of treatment lasting less than one month," whenever "[t]here was a net price increase of 10 percent or more in the price of the prescription drug . . . over the course of the previous calendar year." *Id.* § 2(2). The law defines "price" as "the wholesale acquisition cost as defined in 42 U.S.C. § 1395w-3a(c)(6)(B)"—*i.e.*, the federally defined, uniform, national WAC.

30. Beginning on July 1, 2019, manufacturers must submit to the Department annual reports regarding qualifying prescription drugs. Those reports must include the following information:

- the name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;
- the length of time the prescription drug has been on the market;
- the factors that contributed to the price increase;
- the name of any generic version of the prescription drug available on the market;
- the research and development costs associated with the prescription drug that were paid using public funds;
- the direct costs incurred by the manufacturer to manufacture the prescription drug, to market the prescription drug, to distribute the prescription drug, and for ongoing safety and effectiveness research associated with the prescription drug;
- the total sales revenue for the prescription drug during the previous calendar year;

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- the manufacturer's profit attributable to the prescription drug during the previous calendar year;
- the introductory price of the prescription drug when it was approved for marketing by the FDA and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;
- the 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;
- any other information that the manufacturer deems relevant to the price increase; and
- the documentation necessary to support the information reported.

2018 Or. L. Ch. 7 § 2(3).

31. DCBS regulations require manufacturers to include in their reports "a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase." Or. Admin. Code 836-200-0530(2)(h).

32. For drugs subject to these reporting requirements, manufacturers also must disclose detailed information annually regarding all patient assistance programs they offer to consumers residing in Oregon, including:

- the number of consumers who participated in the program;
- the total value of the coupons, discounts, copayment assistance, or other reduction in costs provided to consumers in Oregon who participated in the program;
- for each drug, the number of refills that qualify for the program;
- if the program expires after a specified period of time, the period of time that the program is available to each consumer; and
- the eligibility criteria for the program and how eligibility is verified for accuracy.

2018 Or. L. Ch. 7 § 2(5).

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33. The Disclosure Law imposes additional reporting obligations on any manufacturer that launches a new prescription drug for which the price "exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program." *Id.* § 2(6).[18] Manufacturers of such drugs must report the following additional information to DCBS within 30 days after introducing the drug for sale:

- a detailed description of the marketing used in the introduction of the new prescription drug;
- the methodology used to establish the price of the new prescription drug;
- whether the FDA granted the new prescription drug a breakthrough therapy designation or a priority review;
- if the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;
- the manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and
- the research and development costs associated with the new prescription drug that were paid using public funds.

Id.

34. All disclosures must be made "in the form and manner prescribed by the department." *Id.* § 2(3), (6).

35. DCBS may request that manufacturers substantiate their required reports with "supporting documentation or additional information concerning the report." *Id.* § 2(7). And it "may use any prescription drug price information the Department deems appropriate to verify that manufacturers have properly reported price increases as required." *Id.* § 2(4).

[18] As of filing, the Medicare Part D specialty-drug threshold is $670 for a one-month supply of the drug. *See* Centers for Medicare & Medicaid Servs., *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* 232 (Apr. 2, 2018), https://go.cms.gov/343SSZk.

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36. The statute directs DCBS to "post to its website" the information required to be reported under § 2(3) (the drug pricing disclosures), § 2(5) (the patient-assistance-program disclosures), and § 2(6) (the new-drug disclosures). *Id.* § 2(9)(b). The Department also must post on its website all of the prescription drugs that meet the law's reporting thresholds and the names of the drugs' manufacturers. *Id.* § 2(9)(a).

37. The Disclosure Law contains an exception to the Internet-posting requirement if (1) the information is "conditionally exempt from disclosure under ORS 192.345 as a trade secret" *and* (2) "the public interest does not require disclosure of the information." *Id.* § 2(10)(a).[19] If the Department withholds any information from public disclosure pursuant to the trade-secret exception, then the Department must post to its website "a report describing the nature of the information and the [D]epartment's basis for withholding the information from disclosure." *Id.* § 2(10)(b). "A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information." *Id.* § 2(10)(c).

38. DCBS has adopted regulations governing the evaluation and publication of trade-secret information. *See* Or. Admin. Code 836-200-0540. To request that any information be exempted from disclosure, the manufacturer must file with its report a written explanation demonstrating that: "(A) The information is not patented; (B) The information is known only to certain individuals within the manufacturer's organization and used in a business the organization conducts; (C) The information has actual or potential commercial value; (D) The

[19] ORS 192.345 conditionally exempts "trade secrets" from disclosure under Oregon's public-records law and defines "trade secret" as "any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within an organization and which is used in a business it conducts, having actual or potential commercial value, and which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it."

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information gives the manufacturer an opportunity to obtain a business advantage over competitors who do not know or use it; and (E) The public interest does not require disclosure of the information." *Id.* § (1)(b). Manufacturers bear the "burden of proof to establish that information in a filing is conditionally exempt from disclosure as a trade secret." *Id.* § (2). A manufacturer seeking to challenge DCBS's determination has only 15 days to request reconsideration from DCBS's director. *Id.* §§ (3), (4). The regulations do not clarify what information "the public interest" requires to be disclosed.

39. Under a schedule of fines adopted by DCBS, manufacturers that fail to submit timely reports, provide required information, or respond in a timely manner to any request for supporting documentation or additional information may face fines of up to $10,000 per day, depending on the nature of the violation. 2018 Or. L. Ch. 7 § 3(2); *see* Or. Admin. Code 836-200-0560.

40. The Disclosure Law requires DCBS to "conduct a public hearing annually on prescription drug prices" and on "information reported to the department" by manufacturers. 2018 Or. L. Ch. 7 § 5(2).

Overview of the Advance Notification Law

41. On April 18, 2019, the Oregon House of Representatives passed HB 2658, titled "an act [r]elating to prescription drug costs." The Oregon Senate passed the same bill on June 6. The House concurred with the Senate amendments and repassed the bill on June 11. On June 12, the Speaker of the House signed HB 2658, and the Senate President signed the bill the next day. On June 20, Governor Brown signed HB 2658 into law. *See* 2019 Or. L. Ch. 436. The Advance

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Notification Law takes effect January 1, 2020. *See* ORS 171.022 (providing that enrolled bills by default take effect "on January 1 of the year after passage of the Act").

42. The Advance Notification Law imposes notice and justification requirements on manufacturers of "a prescription drug that is sold in [Oregon] state." 2019 Or. L. Ch. 436 § 2(1)(c). The law does not cover health care practitioners or drug repackagers. *Id.* § 2(1)(b)(B).

43. Beginning January 1, 2020, the Advance Notification Law will require that covered manufacturers provide the State with written notice at least 60 days before increasing the WAC of prescription drugs beyond a certain threshold. *Id.* § 2(2). The thresholds depend on whether the drug is a brand-name product or a generic product. *Id.* § 2(3)

44. For a "brand-name prescription drug," the manufacturer must provide 60 days' notice before "[a]n increase in the price . . . for which there will be, on the date that the increase goes into effect, a cumulative increase of 10 percent or more or an increase of $10,000 or more in the price of the brand-name prescription drug within a 12-month period beginning on or after July 1, 2019." *Id.* § 2(3)(a).

45. The Advance Notification Law adopts a more lenient regimen for a "generic prescription drug." The advance-notice requirement is triggered at a higher threshold: "[a]n increase . . . for which there will be, on the date that the increase goes into effect, a cumulative increase of 25 percent or more *and* an increase of $300 or more in the price of the generic prescription drug within a 12-month period beginning on or after July 1, 2019." *Id.* § 2(3)(b) (emphasis added).

46. The Advance Notification Law exempts some generic drugs entirely. Manufacturers need not provide notice before increasing the price of a retail prescription drug

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that is both (1) "manufactured by four or more companies" and (2) either (i) is marketed and distributed pursuant to an abbreviated new drug application; (ii) is an "authorized generic drug as defined by 41 C.F.R. 447.502"; or (iii) "entered the market before the year 1962 and was not originally marketed under a new drug application." *Id.* § 2(4).

47. When the Advance Notification Law's advance-notice requirement applies, the manufacturer must provide DCBS with information about the drug, including: "(a) The date that the increase will become effective; (b) The current price of the prescription drug; (c) The dollar amount of the planned increase in the price of the prescription drug; (d) A statement of whether the price increase is necessitated by a change to or improvement in the prescription drug and, if so, a description of the change or improvement; and (e) The year the drug became available for sale in the United States." *Id.* § 2(2).

48. While the text of the Advance Notification Law is vague as to whether DCBS will publicly disclose the information provided in the advance notice, there are reasons to expect that the State intends to make the information public. A Fiscal Impact Statement accompanying the Advance Notification Law explains that DCBS "will implement this measure using the administrative framework developed as a result of [the Disclosure Law]."[20] As discussed above, the Disclosure Law requires DCBS to post the reported information on its public website unless: (1) the information is "conditionally exempt from disclosure under [ORS] 192.345 as a trade secret" *and* (2) "the public interest does not require disclosure of the information." 2018 Or. L. Ch. 7 § 2(10)(a). The Advance Notification Law thus threatens manufacturers with public

[20] *See* Legislative Fiscal Office, *Fiscal Impact of Proposed Legislation* (Mar. 28, 2019), https://olis.leg.state.or.us/liz/2019R1/Downloads/MeasureAnalysisDocument/46450.

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disclosure of even their most sensitive trade-secret information whenever DCBS unilaterally deems such disclosure to be in "the public interest." *Id.*

CONSTITUTIONAL DEFECTS OF THE DISCLOSURE LAW AND THE ADVANCE NOTIFICATION LAW

The Disclosure Law and the Advance Notification Law Violate the Dormant Commerce Clause

49. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause "reflect[s] a central concern of the Framers that[,] . . . in order to succeed, the new Union would have to avoid the tendencies toward economic Balkanization that had plagued relations among the Colonies and later among the States under the Articles of Confederation." *Hughes v. Oklahoma*, 441 U.S. 322, 325 (1979).

50. The Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This is the "so-called 'dormant' aspect of the Commerce Clause." *Id.*

51. When a state "directly regulates" interstate commerce, the Supreme Court has "generally struck down the statute without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986); *see also Edgar v. MITE Corp.*, 457 U.S. 624, 640 (1982) (plurality op.) ("The Commerce Clause . . . permits only *incidental* regulation of interstate commerce by the States; direct regulation is prohibited."); *NCAA v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993) (statute that "directly regulates interstate commerce . . . violates the Commerce Clause per se").

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52. In *Brown-Forman*, the Supreme Court invalidated a state law that required distillers to submit monthly price schedules to New York and certify that they would not charge wholesalers in other states less than the scheduled prices. 476 U.S. at 576. The Court held that this requirement violated the dormant Commerce Clause because "[o]nce a distiller has posted prices in New York, it is not free to change its prices elsewhere in the United States during the relevant month." *Id.* at 582. The Court found that New York was impermissibly "project[ing]" its legislation into other states. *Id.* at 584.

53. The Fourth Circuit last year followed *Brown-Forman* in striking down, under the dormant Commerce Clause, a Maryland statute that sought to reduce prescription drug prices by precluding manufacturers from making "excessive" and "[un]justified" price increases for certain "essential" generic drugs. *Ass'n for Accessible Medicines v. Frosh* ("*AAM*"), 887 F.3d 664, 666, 673 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019). Even though the Maryland statute applied only to drugs "made available for sale" in Maryland, the Fourth Circuit held that the law impermissibly regulated commerce "wholly outside of the State's borders" because its "practical effect" was to regulate out-of-state wholesale transactions "upstream" from consumer retail sales. *Id.* at 672–73 (citing *Brown-Forman,* 476 U.S. at 580).

54. Just like the Maryland statute invalidated in *AAM* and the New York statute invalidated in *Brown-Forman,* Oregon's Disclosure and Advance Notification Laws directly regulate out-of-state prices. Indeed, the Oregon laws intrude more significantly than the law invalidated in *Brown-Forman*. The nationwide ban on price changes in *Brown-Forman* lasted one month. The Advance Notification Law's nationwide price freeze is twice as long, and the

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Disclosure Law's threatened abrogation of trade-secret protection upon price increases above a certain threshold discourages those increases indefinitely.

55. The reach of the Disclosure and Advance Notification Laws also extends further than the law struck down in *Brown-Forman*. In defending the law in that case, New York argued that it "addressed only . . . sales of liquor in New York." 476 U.S. at 583. By contrast, in tying the advance-notice obligation and mandated disclosures to increases in the WAC, the Disclosure and Advance Notification Laws regulate the federally defined *national* list price for pharmaceuticals. A manufacturer cannot increase the list price of its product in *any* state without triggering both (1) a mandatory 60-day national price freeze and (2) a compelled disclosure of information that includes trade secrets. The stated purpose of the legislation, moreover, was to control national drug prices: The legislature expressly designed the 60-day freeze and intrusive reporting requirements to discourage manufacturers from increasing prices to a level Oregon deems excessive. *See* 2019 Or. L. Ch. 436 § 1 (declaring a "legislative intent" of the law as "taking steps to address . . . spiraling health care costs").

56. The requirements under the Disclosure and Advance Notification Laws that manufacturers must explain their price increases constitute an additional burden on pricing nationwide. If a manufacturer of a qualifying drug wishes to increase the national WAC for the drug above the Oregon-imposed threshold, it must justify the increase. Any failure to provide DCBS with what it deems a sufficiently detailed explanation for increases in the national list price subjects the manufacturer to fines. The obvious purpose and effect of these requirements is to control prices, not just in Oregon, but nationally.

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57. Manufacturers cannot avoid triggering the Disclosure Law or the Advance Notification Law even by refusing to sell drugs in-state. Both laws apply to manufacturers of any drug "that is sold in" Oregon, 2018 Or. L. Ch. 7 § 2(1)(e); 2019 Or. L. Ch. 436 § 2(1)(c), whether or not the manufacturer itself directs sales toward the State. This kind of attempt to "extend [a state's] police power beyond its jurisdictional bounds" violates the Commerce Clause. *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 393 (1994); *see also AAM*, 887 F.3d at 672.

The Disclosure Law and the Advance Notification Law Violate the First Amendment

58. The Disclosure and Advance Notification Laws violate the First Amendment by compelling pharmaceutical manufacturers to speak about their pricing decisions. U.S. businesses generally have no obligation to explain their pricing decisions, and manufacturers would not do so in the manner required by these laws unless coerced. This, in itself, causes harm. "'Since *all* speech inherently involves choices of what to say and what to leave unsaid,'" it is fundamental to free speech "that one who chooses to speak may also decide 'what not to say.'" *Hurley v. Irish-Am. Gay, Lesbian, & Bisexual Grp. of Boston*, 515 U.S. 557, 573 (1995) (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal.*, 475 U. S. 1, 11, 16 (1986) (plurality op.)). "*All* speech" includes speech about prices. As the Supreme Court has repeatedly held, laws regulating "how sellers may communicate their prices" are subject to First Amendment scrutiny. *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017). In particular, the First Amendment protects the free "flow of prescription drug price information." *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976). As the Disclosure and Advance Notification Laws "regulat[e] the communication of prices rather than prices themselves," the

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laws on their face implicate core First Amendment values. *Expressions Hair Design*, 137 S. Ct. at 1151; *see also Italian Colors Rest. v. Becerra*, 878 F.3d 1165, 1175-76 (9th Cir. 2018).

59. The Disclosure and Advance Notification Laws, however, do not merely require PhRMA's members to speak when they would prefer to remain silent. The laws require them implicitly to endorse the State's political message—namely, that manufacturers' WAC increases are primarily or even solely responsible for increases in the prices that patients and others pay for prescription drugs. Requiring manufacturers to justify price increases over the State's thresholds implies that such increases are inherently pernicious; lesser increases and price reductions require no explanation. And the Advance Notification Law expressly identifies "a change or improvement in the drug" as the only adequate justification for increasing the WAC, thereby subordinating alternative rationales for such increases. The new laws thus force private companies to "endorse ideas they find objectionable," a prospect that is "always demeaning." *Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31*, 138 S. Ct. 2448, 2464 (2018). "[F]or this reason . . . a law commanding involuntary affirmation of objected-to beliefs [requires] even more immediate and urgent grounds than a law demanding silence." *Id.* (internal quotation marks omitted).

60. Courts apply heightened judicial scrutiny to speech regulations that target particular speakers, discriminate based on the content of regulated communications, or favor particular viewpoints. *See Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015); *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 564-66 (2011). The Disclosure and Advance Notification Laws discriminate on all three bases: speaker, content, *and* viewpoint.

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a) **Speaker-Based Discrimination**. Both of the new laws "on [their] face burden[] . . . disfavored speakers." *Sorrell*, 564 U.S. at 564 (overturning Vermont law that "disfavor[ed] specific speakers, namely pharmaceutical manufacturers," by imposing prohibitions only on them). Participants all along the supply chain—wholesalers, pharmacy benefit managers, group purchasing organizations, pharmacies, hospitals, and clinics—play a role in setting a patient's out-of-pocket cost for prescription drugs. Yet the Disclosure and Advance Notification Laws require only certain pharmaceutical manufacturers to "explain" their actions, with the obvious subtext that they have misbehaved, overcharged the public, or acted irresponsibly absent a "change or improvement" in the drug. Indeed, the Advance Notification Law takes the speaker-based discrimination further by burdening manufacturers of brand-name drugs more than manufacturers of generics.

b) **Content-Based Discrimination**. The Advance Notification Law discriminates based on content by forcing manufacturers to speak at a particular time, to a particular audience, with a particular message—namely, the disapproving subtext previously described. The Disclosure Law, by requiring manufacturers to report the reasons for price increases above the State's disapproval threshold, likewise requires communication, and implicit validation, of views that the manufacturers dispute and would not otherwise convey. Laws that "[m]andat[e] speech that a speaker would not otherwise make" are content based, because forcing a speaker to convey a message "necessarily alters the content of the speech." *Riley*, 487 U.S. at 795.

c) **Viewpoint-Based Discrimination**. The Disclosure and Advance Notification Laws discriminate on the basis of viewpoint because they impose burdens based on

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"the specific motivating ideology [and] the opinion or perspective of the speaker." *Reed*, 135 S. Ct. at 2230 (internal quotation marks omitted). A manufacturer may freely express its opinions—or remain silent—regarding *reductions* in drug prices, or even regarding increases in drug prices below the level the State deems excessive. But the manufacturer must speak when its price increases hit the prescribed threshold, and such compelled speech must take the form mandated by the State, which is designed to convey the State's message that the price increase is unjustified. The laws thus use speech regulation to advance the State's view that drug prices should be lower and that price increases exceeding 10 percent or $10,000 annually for brand-name drugs are improper.

61. Even if the Disclosure and Advance Notification Laws did not discriminate on their face against certain pharmaceutical manufacturers, they still would violate the First Amendment under the test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Under *Central Hudson*, the State must demonstrate that the regulation of speech "directly advances a substantial governmental interest" and "is not more extensive than is necessary to serve that interest." 447 U.S. at 566; *see also Sorrell*, 564 U.S. at 572 (*Central Hudson* requires a "fit between the legislature's ends and the means chosen to accomplish those ends"). Oregon has no legitimate interest, let alone a substantial one, in regulating drug prices nationwide. Nor does Oregon have a substantial interest in compelling disclosure of changes to the WAC and explanations for those changes; the WAC is but one link in the chain of pharmaceutical pricing. *See, e.g.*, *Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 965-67 (9th Cir. 2009), *aff'd*, 564 U.S. 786 (2011) (State has no legitimate reason to force retailers to affix misleading labels on their products).

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62. Indeed, the Disclosure Law flips the First Amendment on its head by forcing manufacturers who do not want their compelled justifications made public to prove that the "public interest"—a concept left vague and undefined—does "not require" dissemination. 2018 Or. L. Ch. 7 § 2(10)(a). Under the Constitution, it is *the State* that must prove that its speech restrictions are justified by a compelling governmental interest, *see Reed*, 135 S. Ct. at 2231-32, not the manufacturer that must prove the absence of any such interest.

63. But even if regulating pharmaceutical prices nationwide were a legitimate state interest, Oregon does not and cannot advance that interest by mandating speech about prices and then regulating that speech as a backdoor means to achieve its regulatory objectives. Compelling speech about pricing is not a legitimate alternative to regulating pricing directly. The Supreme Court has made clear that "if the First Amendment means anything, it means that regulating speech must be a last—not first—resort." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002).

64. Nor do Oregon's laws *directly* advance the State's interest in lowering healthcare costs. Instead, they purport to make prescription drug pricing more "transparent" in the hopes of shaming manufacturers who intend to increase the WAC of their products. Even assuming that transparency would lead to lower prices—a proposition the Federal Trade Commission has questioned[21]—the Disclosure and Advance Notification Laws cannot fulfill their stated mission,

[21] *See* Letter from James Cosgrove, Director of Health Care, Gov't Accountability Office, to Rep. Sander M. Levin, Ranking Member, House Comm. on Ways and Means 4 (Aug. 1, 2016), http://www.gao.gov/assets/680/678784.pdf; Cong. Budget Office, *Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals* 6 (June 5, 2008), https://bit.ly/2XFj4uf.

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as they do not require the same level of "transparency" from other participants in the pharmaceutical supply chain that have a substantial role in setting drug prices.

65. Indeed, even if these laws advanced a substantial state interest, they still would not survive scrutiny because the "fit between the legislature's ends and the means chosen to accomplish those ends" is no fit at all. *Sorrell*, 564 U.S. at 572 (internal quotation marks omitted). The laws impose burdens on a single actor in a complex distribution system, attempt to use transparency as a means of controlling nationwide list prices, and are unlikely to have the intended effect of lowering prescription drug prices.

66. Oregon cannot evade the *Central Hudson* test by invoking the more lenient standard set forth in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985), which applies to certain compelled speech. Courts apply *Zauderer* only to the most basic, "purely factual and uncontroversial information" that is "orthodox in commercial advertising." The disclosures compelled here are not part of commercial advertising, and they are neither factual nor uncontroversial. *See Nat'l Inst. of Family & Life Advocates v. Becerra* ("*NIFLA*"), 138 S. Ct. 2361, 2368-72 (2018) (declining to apply *Zauderer* to California's requirement that pregnancy clinics give notice that the State provides free or low-cost access to family planning services and abortion). To the contrary, they misleadingly suggest that *only* the manufacturer determines the costs that consumers and others pay for pharmaceutical products, and also misleadingly suggest that price increases can be legitimate only if they are based on a "change or improvement in the prescription drug." 2019 Or. L. Ch. 7 § 2(2)(d).

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The Disclosure Law and the Advance Notification Law Conflict with Federal Trade-Secret Law

67. Trade-secret laws play a key role in fueling the American economy. Legal protection for trade secrets "encourage[s] invention in areas where patent law does not reach, and . . . prompt[s] the independent innovator to proceed with the discovery and exploitation of his invention." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 485 (1974).

68. Every state in the nation protects trade secrets. Forty-eight states, including Oregon, have adopted (with slight variations) the Uniform Trade Secrets Act ("UTSA"), which codified the common law elements of misappropriation of confidential information. The UTSA defines a "trade secret" as "information, including a formula, pattern, compilation, program, device, method, technique, or process, that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." UTSA, § 1(4); *see* ORS 646.461(4). Courts in UTSA jurisdictions, including Oregon, routinely hold that confidential information concerning advertising, cost, marketing, pricing, and production constitutes a trade secret. *See, e.g.*, *Pfizer Inc. v. Oregon Dep't of Justice ex rel. Kroger*, 254 Or. App. 144, 294 P.3d 496, 499, 507 (2012) (protecting from disclosure pharmaceutical manufacturers' litigation exhibits regarding "marketing of [two] medications"); *Citizens' Util. Bd. of Oregon v. Oregon Pub. Util. Comm'n*, 128 Or. App. 650, 877 P.2d 116, 122 (1994) (protecting from disclosure utility's cost-accounting method); *accord, e.g.*, *In re Dana Corp.*, 574 F.3d 129, 152 (2d Cir. 2009) ("Confidential proprietary data relating to pricing, costs, systems, and methods are protected by [New York] trade secret law").

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69. In 2016, Congress enacted the Defend Trade Secrets Act, creating a federal private right of action for misappropriation of trade secrets "related to a product or service used in, or intended for use in, interstate or foreign commerce." Pub. L. No. 114-153, 130 Stat. 376 (2016) (codified at 18 U.S.C. § 1836(b)).

70. Congress enacted the DTSA because "trade secrets are increasingly becoming the foundation of businesses across the country, with one estimate placing the value of trade secrets in the United States at $5 trillion. . . . With so much at stake, it is absolutely vital . . . [to] include strong protections against theft of trade secrets." 162 Cong. Rec. H2028-01, H2033 (Apr. 27, 2016) (comments of Rep. Nadler). "By improving trade secret protection," Congress intended the DTSA to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3 (2016).

71. Although every state protects trade secrets, Congress intended the DTSA to provide businesses engaged in interstate commerce with a uniform remedy for misappropriation. Congress expressed concern that "state laws vary in a number of ways and contain built-in limitations that make them not wholly effective in a national and global economy." H.R. Rep. No. 114-529, at 4 (Apr. 26, 2016) (Judiciary Committee). "[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." 162 Cong. Rec. H2034 (comments of Rep. Jackson Lee). Thus, the DTSA allows businesses "to move quickly to Federal court . . . to stop trade secrets from winding up being disseminated and losing their value." H.R. Rep. No. 114-529, at 6; accord S. Rep. No. 114-220, at 3.

72. The federal definition of "trade secret" under the DTSA was modeled on the UTSA. Oregon trade-secret law was too—until the Disclosure and Advance Notification Laws.

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The Disclosure Law compels manufacturers to disclose to DCBS confidential and proprietary advertising, cost, marketing, pricing, and production information. And the Advance Notification Law compels manufacturers to disclose confidential information about future price increases. All of this information derives independent value from not being generally known to third parties and competitors, and it constitutes trade secrets under the DTSA.

73. Further, the Disclosure and Advance Notification Laws threaten to eliminate trade-secret protection for all disclosed information. A manufacturer seeking to avoid public dissemination of any reported information bears the burden of showing not only that the information is subject to trade-secret protection under the DTSA or UTSA, but also that (among other things) the "information is known only to certain individuals within the manufacturer's organization and used in a business the organization conducts." Or. Admin. Code 836-200-0540(1)(b). The DTSA's and UTSA's definitions of a trade secret contain no such categorical requirement. *See* ORS 646.461(4); 18 U.S.C. § 1839(3).

74. Even if the manufacturer convinces DCBS that the information meets those requirements—which go beyond those in the DTSA and UTSA—public dissemination is still required unless DCBS determines that "[t]he public interest does not require disclosure of the information." 2018 Or. L. Ch. 7 § 2(10)(a). Neither the Disclosure Law nor its implementing regulations define "the public interest." Indeed, the Oregon legislature in passing the Disclosure Law declared "a substantial public interest in the price and cost of prescription drugs," suggesting that DCBS may view the public interest as requiring publication of *all* compelled disclosures.

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75. Once published on the Internet or otherwise publicly disseminated under the authority of the Disclosure or Advance Notification Laws, the information no longer constitutes a trade secret under either the UTSA or the DTSA. *See, e.g.*, 18 U.S.C. § 1839. The destruction of trade-secret protection in Oregon will thwart the ability of manufacturers subject to the State's disclosure requirements to sue for misappropriation in any jurisdiction, including in federal court under the DTSA.

76. The threatened demise of trade secret protection for pricing information is itself an injury to PhRMA members. Concerns about the ability of competitors to obtain commercially sensitive information also threatens to affect whether and how companies collect and store such information internally; to undermine the companies' position in commercial negotiations; and to impede the conduct of their business. Oregon's laws make protection for trade secrets more uncertain, burdensome, and costly, undercutting the objective of the DTSA to protect the competitiveness of American industry.

77. Thus, both laws "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), and indeed jeopardize the trillion of dollars' worth of trade secrets that Congress enacted the DTSA to protect.

The Disclosure Law and the Advance Notification Law Violate the Takings Clause

78. The Fifth Amendment provides that "private property [shall not] be taken for public use, without just compensation." U.S. Const. amend. V. This proscription applies to the states through the Fourteenth Amendment.

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79. Government regulation of private property can constitute a taking. *See Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992). "Private property" includes not only tangible property, but also intangible property, such as trade secrets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002–04 (1984). A state's "failure to provide adequate protection to assure [a trade secret's] confidentiality, when disclosure is compelled . . . , can amount to an unconstitutional taking of property by destroying [the trade secret], or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors." *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (alteration omitted) (quoting *Wearly v. FTC*, 462 F. Supp. 589, 598 (D.N.J. 1978)).

80. Courts have recognized that regulatory takings may be categorical or noncategorical. *See Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005). A categorical taking occurs where a statute or regulation "denies all economically beneficial or productive use" of property. *Lucas*, 505 U.S. at 1015. By contrast, a noncategorical taking may occur where a regulation "fall[s] short of eliminating all economically beneficial use," *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001), yet still goes "too far" for purposes of the Takings Clause, *Lucas*, 505 U.S. at 1014–15 (quoting *Pa. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922)). To determine whether a noncategorical regulatory taking goes "too far," courts apply the three-part test articulated in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978). That test assesses: "[1] the character of the governmental action, [2] its economic impact, and [3] its interference with reasonable investment-backed expectations." *Ruckelshaus*, 467 U.S. at 1005.

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81. The Disclosure and Advance Notification Laws categorically take property rights without compensation, in violation of the Takings Clause. "With respect to a trade secret, the right to exclude others is central to the very definition of the property interest." *Ruckelshaus*, 467 U.S. at 1011. In the event that the state unilaterally deems the disclosed information as being in "the public interest," Oregon's laws strip trade-secret protection and mandate public disclosure of manufacturers' confidential advertising, cost, marketing, pricing, and production information on DCBS's website, irreversibly destroying any trade-secret protection for the information disclosed. The operation of the laws thus ensures that manufacturers lose any claim of confidentiality, the *sine qua non* of what makes a trade secret valuable. *See Ruckelshaus*, 467 U.S. at 1011–12; *see also* 162 Cong. Rec. H2034 ("[U]nlike patents, once this information is disclosed it instantly loses its value and the property right itself ceases to exist." (comments of Rep. Jackson Lee in support of DTSA)).

82. Even if the laws did not work a categorical taking by threatening destruction of manufacturers' property interests in their trade secrets, the laws would still constitute impermissible regulatory takings under *Penn Central*'s three-part test.

83. *First*, the "character" of Oregon's legislative actions weighs heavily against sustaining them. The laws prevent pharmaceutical manufacturers from "exclud[ing] others from their trade secrets," causing the trade secrets to "lose all value." *Phillip Morris, Inc. v. Reilly*, 312 F.3d 24, 41 (1st Cir. 2002) (en banc). "Therefore, if the [pharmaceutical manufacturers] comply with the requirements of [the Disclosure and Advance Notification Laws], their property right will be extinguished." *Id.* at 42. "[T]his is precisely what the Takings Clause is designed to prevent." *Id.* at 32.

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84. *Second*, eliminating trade-secret protection for confidential advertising, cost, marketing, pricing, and production information relating to drugs will have a devastating "economic impact" not only on manufacturers subject to the disclosure requirements, but also on the market for drugs. *See Penn Central*, 438 U.S. at 124. A manufacturer forced to disclose such information will be at a severe competitive disadvantage against competitors not subject to the laws, who could use the published disclosures to learn how the manufacturer allocates its resources and sets its prices for each qualifying drug. Similarly, the Disclosure and Advance Notification Laws prejudice affected manufacturers in their dealings with third-party payers, who will be able to use the manufacturers' pricing information against them in negotiations. These adverse effects are not confined to Oregon: A trade secret published in Oregon is subject to use (and abuse) nationwide; losing trade-secret protection anywhere means losing it everywhere.

85. *Third*, the laws interfere with manufacturers' reasonable "investment-backed expectation" that their confidential and proprietary information would remain secret. *See Penn Central*, 438 U.S. at 124. For many years Oregon has treated confidential advertising, cost, marketing, pricing, and production information as being entitled to trade-secret protection, without any exception for drug manufacturers. *See, e.g.*, ORS 192.345; *id.* 646.461(4); *Pfizer*, 294 P.3d at 507. Manufacturers thus had developed reasonable investment-backed expectations in the secrecy of this information, which no other state required them to disclose. The value of the lost trade secret protection is reflected in the erosion of the anticipated returns on their investments in researching, developing, and marketing their drugs.

86. The requirement that disclosure of the reported information be deemed in "the public interest" is a vague, arbitrary, and insufficient safeguard. *See Reilly*, 312 F.3d at 31

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(striking down law allowing disclosure of trade secrets where doing so would "further public health"). Neither the Disclosure Law nor its implementing regulations clarify what sort of disclosures will or will not be deemed in "the public interest." The Disclosure Law's declaration that there is "a substantial public interest in the price and cost of prescription drugs" suggests that the State presumptively will find the reported information to be in the "public interest," even if it constitutes a trade secret. Indeed, the Disclosure Law requires manufacturers to prove that the information is subject to trade-secret protection as a threshold matter, even before the agency makes a public-interest determination. To avoid the destruction of their property, therefore, manufacturers bear the burden of proving the trade-secret status of their information *and* of convincing DCBS that disclosure is not in the public interest.

87. Thus, whether construed as a categorical or noncategorical taking, Oregon's disclosure and advance-notice requirements destroy valuable trade secrets without any compensation, much less "just compensation," in violation of the Takings Clause.

The Disclosure Law and the Advance Notification Law Harm PhRMA Members

88. The Disclosure and Advance Notification Laws' reporting and advance-notice requirements have harmed and will continue to harm PhRMA's members.

89. In recent years, PhRMA members have taken price increases or have introduced new prescription drugs that have triggered the Disclosure Law's reporting requirements, and have taken price increases that will trigger the Advance Notification Law's 60-day advance notice requirement when it takes effect.

90. Indeed, several PhRMA members have already been forced to make the disclosures required under the Disclosure Law. PhRMA members market drugs with a WAC of

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at least $100 for a month-long course of treatment and for which the WAC increased by 10 percent or more during the relevant time period. These PhRMA members timely submitted reports to DCBS containing the information required under section 2 of the Disclosure Law.

91. In addition, PhRMA members also market drugs that have triggered the Disclosure Law's reporting requirements for new prescription drugs. Each of these drugs was "introduced for sale in the United States" at a WAC "that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program." 2018 Or. L. Ch. 7 § 2(6). These PhRMA members timely submitted reports to DCBS containing the information required under section 2 of the Disclosure Law. They would not have made these statements, to which they object, had the Disclosure Law not required them to do so in violation of their First Amendment rights.

92. Moreover, in light of the absence of adequate protection for confidential and proprietary trade secrets in the Disclosure Law, these PhRMA members risk that DCBS will publicly disclose the confidential information that they have provided and will provide under the Disclosure Law. Such public disclosure of proprietary business information would subject these PhRMA members to competitive disadvantage.

93. The Advance Notification Law equally harms PhRMA's members. For example, California's Office of Statewide Health Planning and Development issued a report in September 2019 asserting that many pharmaceutical companies, including PhRMA members, have made price increases within the past five years that exceed the 10-percent threshold established by the

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Disclosure and Advance Notification Laws.[22] Were the Advance Notification Law in force, those PhRMA members would have had to file advance notices in Oregon, which in turn would forbid them from raising the WAC of those products nationwide for at least 60 days.

94. In the future, some PhRMA members will increase the prices for their products to a level that would subject them to the reporting requirements of the Disclosure Law and the advance notice and justification requirements of the Advance Notification Law. In the absence of the Disclosure and Advance Notification Laws, PhRMA members who will trigger the reporting and justification requirements in the future would not make the required statements, to which the members object. And, in the absence of the Advance Notification Law, PhRMA members would not wait 60 days to implement planned pricing increases. In other instances, PhRMA members will be deterred from undertaking price increases at the levels that would trigger the advance notice and reporting and justification requirements. Moreover, PhRMA members fear that the State will publish the advance notices to the public. If this were to occur, such publication would destroy trade secret protection that applies to the timing of pricing decisions, which is highly confidential and competitively sensitive.

95. PhRMA's challenges to both statutes are presently ripe for review. The Disclosure Law is in effect, and PhRMA members have already filed required reports. The Advance Notification Law's extraterritorial price regulation takes effect on January 1, 2020, but incorporates price increases made any time after July 1, 2019. Thus, from the moment the

[22] *See* Cal. Health & Human Servs., *Prescription Drugs WAC Increases—5 Year History*, CHHS Open Data, https://data.chhs.ca.gov/dataset/0c693b50-6d23-46a0-a1ae-7c320fe23dff/resource/b57d3435-a56c-4f74-83b3-d54775a005a2/download/prescription-drug-5year-history-data-q1.xlsx; *see also* Victoria Colliver, *California's Drug Transparency Law Yields Early Surprises*, Politico (Mar. 25, 2018), https://politi.co/2I6LctT.

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Advance Notification Law takes effect, it will restrict pricing decisions made outside the State in violation of the Commerce Clause, and it will compel manufacturers to report and justify their prices in violation of the First Amendment. Compliance with these unconstitutional laws thus will require "immediate and significant change in the plaintiffs' conduct of their affairs." *Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967).

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Disclosure Law and Advance Notification Law Violate the Commerce Clause, Article I, section 8, clause 3 of the U.S. Constitution)

96. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

97. The Constitution grants Congress the power "[t]o regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. The Commerce Clause places an implicit restraint on state laws that improperly restrain national commerce.

98. The Disclosure and Advance Notification Laws violate the Commerce Clause by regulating drug pricing beyond Oregon's jurisdiction. Because the WAC is a national list price, the Disclosure and Advance Notification Laws will affect the entire country. They will also curtail lawful pricing activities conducted entirely outside Oregon by burdening that conduct with notice and reporting requirements, by threating to strip trade-secret protection, and by imposing substantial fines in Oregon.

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SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Disclosure Law and Advance Notification Law Violate the First Amendment to the U.S. Constitution)

99. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

100. The Disclosure and Advance Notification Laws violate the First Amendment because they compel certain pharmaceutical manufacturers to communicate publicly the State's designated message about their drug pricing decisions even when the manufacturers prefer to remain silent. The Disclosure and Advance Notification Laws force manufacturers to disseminate the State's messages that only changes or improvements in a drug can justify a price increase, and that manufacturers bear primary responsibility for increases in drug prices. PhRMA's members disagree with and would not otherwise endorse those messages, implicitly or explicitly.

101. The Disclosure and Advance Notification Laws discriminate on the basis of speaker, content, and viewpoint. They constitute impermissible efforts by Oregon to compel speech as a means of regulating nationwide drug prices that the State cannot regulate directly.

102. The Disclosure and Advance Notification Laws fail strict scrutiny because they are not narrowly tailored to advance any compelling state interest. They fail the *Central Hudson* test because they do not directly advance a substantial government interest and lack a sufficient fit. And they fail even under *Zauderer* because their compelled disclosures are neither factual nor uncontroversial.

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THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Disclosure Law and Advance Notification Law Are Preempted by the Federal Trade-Secret Law and the Supremacy Clause, Article VI, Clause 2 of the U.S. Constitution)

103. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

104. The Disclosure Law compels manufacturers to disclose to DCBS confidential and proprietary advertising, cost, marketing, pricing, and production information that derives independent value from not being generally known to third-party payers and competitors. The Advance Notification Law compels manufacturers to disclose to DCBS information about future price increases that is confidential and that derives independent value from not being generally known to third-party payers and competitors. These categories of information are "trade secrets" under the federal Defend Trade Secrets Act of 2016.

105. The Disclosure and Advance Notification Laws violate the Supremacy Clause by nullifying federal trade-secret protection for information that manufacturers are forced to disclose. The laws thus stand as an obstacle to the accomplishment and execution of the full purposes and objectives of the DTSA, and are therefore preempted.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The Disclosure Law and Advance Notification Law Work Takings Without Just Compensation in Violation of the Fifth and Fourteenth Amendments to the U.S. Constitution)

106. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

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107. The Fifth Amendment to the United States Constitution, applicable to the states through the Fourteenth Amendment, provides that "private property [shall not] be taken for public use, without just compensation."

108. The Disclosure and the Advance Notification Laws effect categorical takings of Plaintiff's members' intellectual property rights because they threaten public disclosure of their trade secrets, thereby negating the value of those trade secrets.

109. Alternatively, the Disclosure and Advance Notification Laws work regulatory takings under the three-part test set out in *Penn Central*. First, the laws have the "character" of a total interference with manufacturers' property rights in their trade secrets. *Penn Central*, 438 U.S. at 124–25. Second, eliminating trade-secret protection for drugs' confidential advertising, cost, marketing, pricing, and production information will have a devastating "economic impact" not only on manufacturers subject to the disclosure requirements, but also on the market for pharmaceuticals. *Id.* at 124. Third, manufacturers have invested in the research and development of pharmaceuticals with the reasonable "investment-backed expectation" that their confidential and proprietary information will remain a secret. *Id.* at 124, 127.

110. Thus, the laws' disclosure and advance-notice requirements destroy valuable trade secrets without any compensation, let alone just compensation, in violation of the Takings Clause. U.S. Const. amends. V, XIV.

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PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiff requests a judgment in its favor against Defendant as follows:

1. A declaration that the Disclosure Law (2018 Or. L. Ch. 7) and the Advance Notification Law (2019 Or. L. Ch. 436) are unconstitutional and void;
2. A permanent injunction preventing Defendant from implementing or enforcing the Disclosure Law (2018 Or. L. Ch. 7) or the Advance Notification Law (2019 Or. L. Ch. 436);
3. An award of attorneys' fees and costs, plus interest accruing thereon, in Plaintiff's favor at the maximum rate allowed by law; and
4. An award of such other and further relief as the Court may deem appropriate.

DATED: December 9, 2019.

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CHAPTER 7

AN ACT HB 4005

Relating to the price of prescription drugs; creating new provisions; amending ORS 743.018 and 750.055; and declaring an emergency.

Whereas the state has a substantial public interest in the price and cost of prescription drugs; and

Whereas the state is a major purchaser of prescription drugs through the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services and the Department of Corrections; and

Whereas the state also provides major tax expenditures for health care through the tax exclusion of employer-sponsored health insurance coverage and the deductibility of the excess medical costs of individuals and families; and

Whereas the Legislative Assembly intends by sections 2, 3 and 5 of this 2018 Act to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing; and

Whereas the Legislative Assembly intends by this 2018 Act to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including decisions that result in price increases; and

Whereas the Legislative Assembly intends by this 2018 Act to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates for prescription drugs consistent with existing state and federal law; now, therefore,

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 and 3 of this 2018 Act shall be known and may be cited as the Prescription Drug Price Transparency Act.

SECTION 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer

shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) Beginning March 15, 2019, 30 days or less after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 3. (1) A manufacturer that fails to report or provide information as required by section 2 of this 2018 Act may be subject to a civil penalty as provided in this section.

(2) The Department of Consumer and Business Services shall adopt a schedule of penalties, not to exceed $10,000 per day of violation, based on the severity of each violation.

(3) The department shall impose civil penalties under this section as provided in ORS 183.745.

(4) The department may remit or mitigate civil penalties under this section upon terms and conditions the department considers proper and consistent with the public health and safety.

(5) Civil penalties collected under this section shall be paid over to the State Treasurer and deposited in the General Fund to be made available for general governmental expenses.

SECTION 4. Section 5 of this 2018 Act is added to and made a part of the Insurance Code.

SECTION 5. (1) An insurer shall include with any filing under ORS 743.018 the following information regarding drugs reimbursed by the insurer under policies or certificates issued in this state:

(a) The 25 most frequently prescribed drugs;

(b) The 25 most costly drugs as a portion of total annual spending;

(c) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; and

(d) The impact of the costs of prescription drugs on premium rates.

(2) The Department of Consumer and Business Services shall conduct a public hearing annually on prescription drug prices, information reported to the department under section 2 of this 2018 Act and information described in subsection (1) of this section.

(3) The department shall regularly update the interim committees of the Legislative Assembly related to health on the information described in subsection (1) of this section.

(4) Subsection (1) of this section applies to an insurer that issues policies or certificates of health insurance for sale in this state that include a prescription drug benefit.

SECTION 6. Section 2 of this 2018 Act is amended to read:

Sec. 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than July 1, 2019, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) [*Beginning March 15, 2019, 30 days or less*] **No later than 30 days** after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid

Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 7. Section 2 of this 2018 Act, as amended by section 6 of this 2018 Act, is amended to read:

Sec. 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b) "Health care facility" has the meaning given that term in ORS 442.015.

(c) "Health care service contractor" has the meaning given that term in ORS 750.005.

(d)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or at the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient or other person.

(e) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(f) "New prescription drug" has the meaning prescribed by the Department of Consumer and Business Services by rule.

(g) "Patient assistance program" means a program that a manufacturer offers to the general public in which a consumer may reduce the consumer's out-of-pocket costs for prescription drugs by using coupons or discount cards, receiving copayment assistance or by other means.

(h) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(i) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) No later than [*July 1, 2019*] **March 15 of each year**, a manufacturer shall report the information described in subsection (3) of this section to the department regarding each prescription drug for which:

(a) The price was $100 or more for a one-month supply or for a course of treatment lasting less than one month; and

(b) There was a net increase of 10 percent or more in the price of the prescription drug described in paragraph (a) of this subsection over the course of the previous calendar year.

(3) For each prescription drug described in subsection (2) of this section, a manufacturer shall report to the department, in the form and manner prescribed by the department:

(a) The name and price of the prescription drug and the net increase, expressed as a percentage, in the price of the drug over the course of the previous calendar year;

(b) The length of time the prescription drug has been on the market;

(c) The factors that contributed to the price increase;

(d) The name of any generic version of the prescription drug available on the market;

(e) The research and development costs associated with the prescription drug that were paid using public funds;

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

(D) For ongoing safety and effectiveness research associated with the prescription drug;

(g) The total sales revenue for the prescription drug during the previous calendar year;

(h) The manufacturer's profit attributable to the prescription drug during the previous calendar year;

(i) The introductory price of the prescription drug when it was approved for marketing by the United States Food and Drug Administration and the net yearly increase, by calendar year, in the price of the prescription drug during the previous five years;

(j) The 10 highest prices paid for the prescription drug during the previous calendar year in any country other than the United States;

(k) Any other information that the manufacturer deems relevant to the price increase described in subsection (2)(b) of this section; and

(L) The documentation necessary to support the information reported under this subsection.

(4) The department may use any prescription drug price information the department deems appropriate to verify that manufacturers have properly reported price increases as required by subsections (2) and (3) of this section.

(5) A manufacturer shall accompany the report provided under subsection (2) of this section with the following information about each patient assistance program offered by the manufacturer to consumers residing in this state for the prescription drugs described in subsection (2) of this section:

(a) The number of consumers who participated in the program;

(b) The total value of the coupons, discounts, copayment assistance or other reduction in costs provided to consumers in this state who participated in the program;

(c) For each drug, the number of refills that qualify for the program, if applicable;

(d) If the program expires after a specified period of time, the period of time that the program is available to each consumer; and

(e) The eligibility criteria for the program and how eligibility is verified for accuracy.

(6) No later than 30 days after a manufacturer introduces a new prescription drug for sale in the United States at a price that exceeds the threshold established by the Centers for Medicare and Medicaid Services for specialty drugs in the Medicare Part D program, the manufacturer shall notify the department, in the form and manner prescribed by the department, of all the following information:

(a) A description of the marketing used in the introduction of the new prescription drug;

(b) The methodology used to establish the price of the new prescription drug;

(c) Whether the United States Food and Drug Administration granted the new prescription drug a breakthrough therapy designation or a priority review;

(d) If the new prescription drug was not developed by the manufacturer, the date of and the price paid for acquisition of the new prescription drug by the manufacturer;

(e) The manufacturer's estimate of the average number of patients who will be prescribed the new prescription drug each month; and

(f) The research and development costs associated with the new prescription drug that were paid using public funds.

(7)(a) After receiving the report or information described in subsections (2), (3), (5) or (6) of this section, the department may make a written request to the manufacturer for supporting documentation or additional information concerning the report. The department shall prescribe by rule the periods:

(A) Following the receipt of the report or information during which the department may request additional information; and

(B) Following a request by the department for additional information during which a manufacturer may respond to the request.

(b) The department may extend the period prescribed under paragraph (a)(B) of this subsection, as necessary, on a case-by-case basis.

(8) A manufacturer may be subject to a civil penalty, as provided in section 3 of this 2018 Act, for:

(a) Failing to submit timely reports or notices as required by this section;

(b) Failing to provide information required under this section;

(c) Failing to respond in a timely manner to a written request by the department for additional information under subsection (7) of this section; or

(d) Providing inaccurate or incomplete information under this section.

(9) Except as provided in subsection (10) of this section, the department shall post to its website all of the following information:

(a) A list of the prescription drugs reported under subsection (2) of this section and the manufacturers of those prescription drugs;

(b) Information reported to the department under subsections (3) and (5) to (7) of this section; and

(c) Written requests by the department for additional information under subsection (7) of this section.

(10)(a) The department may not post to its website any information described in subsection (9) of this section if:

(A) The information is conditionally exempt from disclosure under ORS 192.345 as a trade secret; and

(B) The public interest does not require disclosure of the information.

(b) If the department withholds any information from public disclosure pursuant to this subsection, the department shall post to its website a report describing the nature of the information and the department's basis for withholding the information from disclosure.

(c) A person may petition the Attorney General, as provided in ORS 192.411, to review a decision by the department to withhold information pursuant to paragraph (a) of this subsection.

(11) The department shall make available to consumers, online and by telephone, a process for consumers to notify the department about an increase in the price of a prescription drug.

(12) The department may adopt rules as necessary for carrying out the provisions of this section, including but not limited to rules establishing fees to be paid by manufacturers to be used solely to pay the costs of the department in carrying out the provisions of this section.

(13) No later than December 15 of each year, the department shall compile and report the information collected by the department under this section to the interim committees of the Legislative Assembly related to health. The report shall include recommendations for legislative changes, if any, to contain the cost of prescription drugs and reduce the impact of price increases on consumers, the Department of Corrections, the Public Employees' Benefit Board, the Oregon Health Authority, the Department of Human Services, the Oregon Educators Benefit Board and health insurance premiums in the commercial market.

SECTION 8. ORS 743.018 is amended to read:

743.018. (1) Except for group life and health insurance, and except as provided in ORS 743.015, every insurer shall file with the Director of the Department of Consumer and Business Services all schedules and tables of premium rates for life and health insurance to be used on risks in this state, and shall file any amendments to or corrections of such schedules and tables. Premium rates are subject to approval, disapproval or withdrawal of approval by the director as provided in ORS 742.003, 742.005, 742.007 and 743.019.

(2) Except as provided in ORS 743B.013 and subsection (3) of this section, a rate filing by a carrier for any of the following health benefit plans subject to ORS 743.004, 743.022, 743.535 and 743B.003 to 743B.127 shall be available for public inspection immediately upon submission of the filing to the director:

(a) Health benefit plans for small employers.

(b) Individual health benefit plans.

(3) The director may by rule:

(a) Specify all information a carrier must submit as part of a rate filing under this section; and

(b) Identify the information submitted that will be exempt from disclosure under this section because the information constitutes a trade secret and would, if disclosed, harm competition.

(4) The director, after conducting an actuarial review of the rate filing, may approve a proposed premium rate for a health benefit plan for small employers or for an individual health benefit plan if, in the director's discretion, the proposed rates are:

(a) Actuarially sound;

(b) Reasonable and not excessive, inadequate or unfairly discriminatory; and

(c) Based upon reasonable administrative expenses.

(5) In order to determine whether the proposed premium rates for a health benefit plan for small employers or for an individual health benefit plan are reasonable and not excessive, inadequate or unfairly discriminatory, the director may consider:

(a) The insurer's financial position, including but not limited to profitability, surplus, reserves and investment savings.

(b) Historical and projected administrative costs and medical and hospital expenses**, including expenses for drugs reported under section 5 of this 2018 Act**.

(c) Historical and projected loss ratio between the amounts spent on medical services and earned premiums.

(d) Any anticipated change in the number of enrollees if the proposed premium rate is approved.

(e) Changes to covered benefits or health benefit plan design.

(f) Changes in the insurer's health care cost containment and quality improvement efforts since the insurer's last rate filing for the same category of health benefit plan.

(g) Whether the proposed change in the premium rate is necessary to maintain the insurer's solvency or to maintain rate stability and prevent excessive rate increases in the future.

(h) Any public comments received under ORS 743.019 pertaining to the standards set forth in subsection (4) of this section and this subsection.

(6) The requirements of this section do not supersede other provisions of law that require insurers, health care service contractors or multiple employer welfare arrangements providing health insurance to file schedules or tables of premium rates or proposed premium rates with the director or to seek the director's approval of rates or changes to rates.

SECTION 9. ORS 750.055 is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 735.600 to 735.650.

(g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260 and section 2, chapter 771, Oregon Laws 2013.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act**.

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 10. ORS 750.055, as amended by section 21, chapter 771, Oregon Laws 2013, section 7, chapter 25, Oregon Laws 2014, section 82, chapter 45, Oregon Laws 2014, section 9, chapter 59, Oregon Laws 2015, section 7, chapter 100, Oregon Laws 2015, section 7, chapter 224, Oregon Laws 2015, section 11, chapter 362, Oregon Laws 2015, section 10, chapter 470, Oregon Laws 2015, section 30, chapter 515, Oregon laws 2015, section 10, chapter 206, Oregon Laws 2017, section 6, chapter 417, Oregon Laws 2017, and section 22, chapter 479, Oregon Laws 2017, is amended to read:

750.055. (1) The following provisions apply to health care service contractors to the extent not inconsistent with the express provisions of ORS 750.005 to 750.095:

(a) ORS 705.137, 705.138 and 705.139.

(b) ORS 731.004 to 731.150, 731.162, 731.216 to 731.362, 731.382, 731.385, 731.386, 731.390, 731.398 to 731.430, 731.428, 731.450, 731.454, 731.485, as provided in subsection (2) of this section, ORS 731.488, 731.504, 731.508, 731.509, 731.510, 731.511, 731.512, 731.574 to 731.620, 731.640 to 731.652, 731.730, 731.731, 731.735, 731.737, 731.750, 731.752, 731.804, 731.808 and 731.844 to 731.992.

(c) ORS 732.215, 732.220, 732.230, 732.245, 732.250, 732.320, 732.325 and 732.517 to 732.596, not including ORS 732.582.

(d) ORS 733.010 to 733.050, 733.080, 733.140 to 733.170, 733.210, 733.510 to 733.680 and 733.695 to 733.780.

(e) ORS 734.014 to 734.440.

(f) ORS 735.600 to 735.650.

(g) ORS 742.001 to 742.009, 742.013, 742.016, 742.061, 742.065, 742.150 to 742.162 and 742.518 to 742.542.

(h) ORS 743.004, 743.005, 743.007, 743.008, 743.010, 743.018, 743.019, 743.020, 743.022, 743.023, 743.028, 743.029, 743.038, 743.040, 743.044, 743.050, 743.100 to 743.109, 743.402, 743.405, 743.406, 743.417, 743.472, 743.492, 743.495, 743.498, 743.522, 743.523, 743.524, 743.526, 743.535, 743.550, 743.650 to 743.656, 743.680 to 743.689, 743.788 and 743.790.

(i) ORS 743A.010, 743A.012, 743A.014, 743A.020, 743A.034, 743A.036, 743A.040, 743A.044, 743A.048, 743A.051, 743A.052, 743A.058, 743A.060, 743A.062, 743A.063, 743A.064, 743A.065, 743A.066, 743A.068, 743A.070, 743A.080, 743A.082, 743A.084, 743A.088, 743A.090, 743A.100, 743A.104, 743A.105, 743A.108, 743A.110, 743A.124, 743A.140, 743A.141, 743A.148, 743A.150, 743A.160, 743A.168, 743A.170, 743A.175, 743A.185, 743A.188, 743A.190, 743A.192, 743A.250, 743A.252 and 743A.260.

(j) ORS 743B.001, 743B.003 to 743B.127, 743B.128, 743B.130, 743B.195 to 743B.204, 743B.220, 743B.222, 743B.225, 743B.227, 743B.250, 743B.252, 743B.253, 743B.254, 743B.255, 743B.256, 743B.257, 743B.258, 743B.280 to 743B.285, 743B.287, 743B.300, 743B.310, 743B.320, 743B.323, 743B.330, 743B.340, 743B.341, 743B.342, 743B.343 to 743B.347, 743B.400, 743B.403, 743B.407, 743B.420, 743B.423, 743B.450, 743B.451, 743B.452, 743B.453, 743B.470, 743B.475, 743B.505, 743B.550, 743B.555, 743B.601, 743B.602 and 743B.800 **and section 5 of this 2018 Act**.

(k) The following provisions of ORS chapter 744:

(A) ORS 744.001 to 744.009, 744.011, 744.013, 744.014, 744.018, 744.022 to 744.033, 744.037, 744.052 to 744.089, 744.091 and 744.093, relating to the regulation of insurance producers;

(B) ORS 744.605, 744.609, 744.619, 744.621, 744.626, 744.631, 744.635, 744.650, 744.655 and 744.665, relating to the regulation of insurance consultants; and

(C) ORS 744.700 to 744.740, relating to the regulation of third party administrators.

(L) ORS 746.005 to 746.140, 746.160, 746.220 to 746.370, 746.600, 746.605, 746.607, 746.608, 746.610, 746.615, 746.625, 746.635, 746.650, 746.655, 746.660, 746.668, 746.670, 746.675, 746.680 and 746.690.

(2) The following provisions of the Insurance Code apply to health care service contractors except in the case of group practice health maintenance organizations that are federally qualified pursuant to Title XIII of the Public Health Service Act:

(a) ORS 731.485, if the group practice health maintenance organization wholly owns and operates an in-house drug outlet.

(b) ORS 743A.024, unless the patient is referred by a physician, physician assistant or nurse practitioner associated with a group practice health maintenance organization.

(3) For the purposes of this section, health care service contractors are insurers.

(4) Any for-profit health care service contractor organized under the laws of any other state that is not governed by the insurance laws of the other state is subject to all requirements of ORS chapter 732.

(5)(a) A health care service contractor is a domestic insurance company for the purpose of determining whether the health care service contractor is a debtor, as defined in 11 U.S.C. 109.

(b) A health care service contractor's classification as a domestic insurance company under paragraph (a) of this subsection does not subject the health care service contractor to ORS 734.510 to 734.710.

(6) The Director of the Department of Consumer and Business Services may, after notice and hearing, adopt reasonable rules not inconsistent with this section and ORS 750.003, 750.005, 750.025 and 750.045 that are necessary for the proper administration of these provisions.

SECTION 11. (1) The Task Force on the Fair Pricing of Prescription Drugs is established.

(2) The task force consists of 18 members appointed as follows:

(a) The President of the Senate shall appoint:

(A) One member from the Senate who is a member of the majority party.

(B) One member from the Senate who is a member of the minority party.

(b) The Speaker of the House of Representatives shall appoint:

(A) One member from the House of Representatives who is a member of the majority party.

(B) One member from the House of Representatives who is a member of the minority party.

(c) The Governor shall appoint the following members:

(A) One representative from the Department of Consumer and Business Services;

(B) One representative from the Oregon Health Authority;

(C) One representative from the Oregon Health Policy Board; and

(D) Individuals representing:

(i) Pharmaceutical manufacturers;

(ii) Insurance companies offering health insurance in this state;

(iii) Pharmacy benefit managers;

(iv) Prescription drug wholesalers;

(v) Consumers;

(vi) Independent pharmacies;

(vii) Large retail pharmacy chains;

(viii) Hospitals;

(ix) Biopharmaceutical companies based in Oregon;

(x) Coordinated care organizations; and

(xi) Medical providers.

(3) The task force shall develop a strategy to create transparency for drug prices across the entire supply chain of pharmaceutical products, including but not limited to manufacturers, insurers, pharmacy benefit managers, distributors, wholesalers and retail pharmacies.

(4) A majority of the voting members of the task force constitutes a quorum for the transaction of business.

(5) Official action by the task force requires the approval of a majority of the voting members of the task force.

(6) The task force shall elect one of its members to serve as chairperson.

(7) If there is a vacancy for any cause, the appointing authority shall make an appointment to become immediately effective.

(8) The task force shall meet at times and places specified by the call of the chairperson or of a majority of the voting members of the task force.

(9) The task force may adopt rules necessary for the operation of the task force.

(10) The task force shall submit a report in the manner provided by ORS 192.245, and may include recommendations for legislation, to the interim committees of the Legislative Assembly related to health no later than November 1, 2018. The report must contain a cost-effective and enforceable solution that exposes the cost factors that negatively impact prices paid by Oregonians for pharmaceutical products.

(11) The Legislative Policy and Research Director shall provide staff support to the task force.

(12) Members of the Legislative Assembly appointed to the task force are nonvoting members of the task force and may act in an advisory capacity only.

(13) Members of the task force who are not members of the Legislative Assembly are not entitled to compensation or reimbursement for expenses and serve as volunteers on the task force.

(14) All agencies of state government, as defined in ORS 174.111, are directed to assist the task force in the performance of the task force's duties and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the task force consider necessary to perform their duties.

SECTION 12. Section 11 of this 2018 Act is repealed on December 31, 2020.

SECTION 13. (1) Sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act become operative on January 1, 2019.

(2) The Department of Consumer and Business Services shall take all steps necessary before January 1, 2019, to carry out the provisions of sections 1 to 5 of this 2018 Act and the amendments to ORS 743.018 and 750.055 by sections 8 to 10 of this 2018 Act on and after January 1, 2019.

(3) The amendments to section 2 of this 2018 Act by section 6 of this 2018 Act become operative on March 15, 2019.

(4) The amendments to section 2 of this 2018 Act by section 7 of this 2018 Act become operative on July 2, 2019.

SECTION 14. Notwithstanding any other law limiting expenditures, the limitation on expenditures established by section 1 (5), chapter 372, Oregon Laws 2017, for the biennium ending June 30, 2019, as the maximum limit for payment of expenses from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by the Department of Consumer and Business Services, for the Division of Financial Regulation, is increased by $425,022 for carrying out sections 2, 3 and 5 of this 2018 Act.

SECTION 15. This 2018 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2018 Act takes effect on its passage.

Approved by the Governor March 12, 2018
Filed in the office of Secretary of State March 13, 2018
Effective date March 12, 2018

CHAPTER 436

AN ACT HB 2658

Relating to prescription drug costs.

Be It Enacted by the People of the State of Oregon:

SECTION 1. The legislative intent of section 2 of this 2019 Act is to improve public health and safety by taking steps to address the spiraling health care costs for residents of this state.

SECTION 2. (1) As used in this section:

(a) "Drug" has the meaning given that term in ORS 689.005.

(b)(A) "Manufacture" means:

(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and

(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.

(B) "Manufacture" does not include the preparation or compounding of a drug by an individual for the individual's own use or the preparation, compounding, packaging or labeling of a drug:

(i) By a health care practitioner incidental to administering or dispensing a drug in the course of professional practice;

(ii) By a health care practitioner or under the practitioner's authorization and supervision for the purpose of or incidental to research, teaching or chemical analysis activities and not for sale;

(iii) By a health care service contractor for dispensing to a subscriber or delivery to a health care facility or outpatient clinic owned or operated by the health care service contractor or an affiliate of the health care service contractor;

(iv) By a centralized repackaging operation for distribution to subscribers of health care service contractors or to pharmacies, health care facilities or outpatient clinics whether or not operated by or affiliated with a health care service contractor; or

(v) By a health care facility for dispensing to a patient of the health care facility.

(c) "Manufacturer" means a person that manufactures a prescription drug that is sold in this state.

(d) "Prescription drug" means a drug that must:

(A) Under federal law, be labeled "Caution: Federal law prohibits dispensing without prescription" prior to being dispensed or delivered; or

(B) Under any applicable federal or state law or regulation, be dispensed only by prescription or restricted to use only by health care practitioners.

(e) "Price" means the wholesale acquisition cost as defined in 42 U.S.C. 1395w-3a(c)(6)(B).

(2) At least 60 days before a prescription drug manufacturer increases the price of a prescription drug, as described in subsection (3) of this section, the prescription drug manufacturer shall report to the Department of Consumer and Business Services, in the form and manner prescribed by the department, all the following information about the prescription drug:

(a) The date that the increase will become effective;

(b) The current price of the prescription drug;

(c) The dollar amount of the planned increase in the price of the prescription drug;

(d) A statement of whether the price increase is necessitated by a change to or improvement in the prescription drug and, if so, a description of the change or improvement; and

(e) The year the drug became available for sale in the United States.

(3) Subsection (2) of this section applies to:

(a) An increase in the price of a brand-name prescription drug for which there will be, on the date that the increase goes into effect, a cumulative increase of 10 percent or more or an increase of $10,000 or more in the price of the brand-name prescription drug within a 12-month period beginning on or after July 1, 2019.

(b) An increase in the price of a generic prescription drug for which there will be, on the date that the increase goes into effect, a cumulative increase of 25 percent or more and an increase of $300 or more in the price of the generic prescription drug within a 12-month period beginning on or after July 1, 2019.

(4) Subsection (2) of this section does not apply to a prescription drug that is a retail drug, manufactured by four or more companies, that is:

(a) Marketed and distributed pursuant to an abbreviated new drug application, approved under 21 U.S.C. 355(j);

(b) An authorized generic drug as defined by 41 C.F.R. 447.502; or

(c) A drug that entered the market before the year 1962 and was not originally marketed under a new drug application.

Approved by the Governor June 20, 2019
Filed in the office of Secretary of State June 24, 2019
Effective date January 1, 2020

JS 44 (Rev. 09/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Pharmaceutical Research and Manufacturers of America

(b) County of Residence of First Listed Plaintiff District of Columbia
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
MB Law Group, LLP
117 SW Taylor St., Ste. 200
Portland, OR 97204
503-914-2015

DEFENDANTS
Lou Savage, in his official capacity as Acting Director of the Oregon Department of Consumer and Business Services

County of Residence of First Listed Defendant Marion
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*
Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
42 U.S.C. § 1983; 28 U.S.C. §§ 2201, 2202.
Brief description of cause:
Plaintiff seeks a declaratory judgment that Oregon House Bills 4005 and 2658 are unconstitutional.

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE 12/09/2019

SIGNATURE OF ATTORNEY OF RECORD s/ Jonathan M. Hoffman, OSB No. 754180

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____