No. 24-1570

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiff-Appellee,

v.

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

Appeal From the United States District Court
for the District of Oregon
No. 6:19-cv-01996-MO
(Hon. Michael W. Mosman, District Judge)

PLAINTIFF-APPELLEE'S BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Pharmaceutical Research and Manufacturers of America states that it has no parent corporations and no publicly held corporations own 10 percent or more of its stock.

Dated: September 4, 2024.

/s/ *Allon Kedem*
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STATEMENT REGARDING ORAL ARGUMENT

Appellant Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully submits that the issues in this case warrant oral argument. The appeal raises constitutional questions of substantial importance arising under the First Amendment and the Takings Clause, and the judgment below included the invalidation of a state statute on constitutional grounds.

INTRODUCTION

In 2018, Oregon's Legislative Assembly passed a sweeping new law, House Bill No. 4005, designed to fundamentally shift the market for prescription drugs statewide. HB 4005 targets confidential and proprietary information that pharmaceutical manufacturers use to make cost, marketing, pricing, and production decisions. The law forces them to provide these trade secrets to the State in the form of periodic reports they must create to justify drug-price increases. *Only* manufacturers are subject to this Reporting Requirement. The law also requires the State's Department of Consumer and Business Services to publish manufacturers' confidential information on its website whenever the agency deems publication to be in "[t]he public interest." ORS § 646A.689(2)(10)(a)(B). This Public-Interest Exception affords competitors, and the public at large, insight into manufacturers' most sensitive business information. HB 4005 is unconstitutional on two separate grounds.

First, HB 4005's Reporting Requirement violates the First Amendment by requiring pharmaceutical manufacturers (but no other participants in the prescription-drug market) to submit reports

justifying their pricing decisions. Because the law compels speech—drawing speaker- and content-based distinctions—it must undergo strict scrutiny—a standard the State does not even claim to satisfy.

Instead, the State defends its law as merely requiring "routine disclosures," like filing a tax return. Appellant's Opening Brief (AOB) 19. But as the Legislative Assembly declared (and the State sometimes admits), the audience for the reports is not the State alone, but *all* "purchasers, both public and private, as well as pharmacy benefit managers." AOB 23 (quoting HB 4005, preamble). There is nothing "routine" about forcing businesses to disclose their internal business strategies and then publishing them on the internet.

Nor can the law be defended under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), which ensures that *commercial advertisements* fully inform consumers about what they are buying. That doctrine applies to speech about characteristics of goods and services offered for sale, not a company's internal decision-making. Even where the doctrine applies, it requires the government to substantiate the need for compelled disclosures with actual evidence; here, Oregon offers none.

Indeed, the State cannot even settle on a consistent rationale for the law.

Second, HB 4005's Public-Interest Exception violates the Fifth Amendment by taking drug manufacturers' property without "just"—or any—compensation. Manufacturers have well-established and long-recognized property rights in their trade secrets, which retain value only if they remain confidential. But publication of a manufacturer's sensitive information under the Public-Interest Exception "publicly discloses the secret," causing the manufacturer's "property right [to be] extinguished." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984).

Whether viewed as a categorical or regulatory taking, the result is the same: Every application of the Public-Interest Exception will completely destroy (and hence take) a manufacturer's trade secret. HB 4005 thus inflicts the precise harm that the Fifth Amendment was adopted to prevent—forcing private property owners to shoulder the burden of the government's public-policy choices. The district court was accordingly correct to declare that invocation of the Public-Interest Exception must be accompanied by just compensation.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331 over PhRMA's claims arising under the Constitution and 42 U.S.C. § 1983, and jurisdiction to grant declaratory relief under 28 U.S.C. § 2201. The court entered partial judgment under Federal Rule of Civil Procedure 54(b). E.R.-40-41. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES PRESENTED

1. Does HB 4005's Reporting Requirement, which compels manufacturers to justify their drug-pricing decisions, violate the First Amendment?

2. Does HB 4005's Public-Interest Exception, which mandates public disclosure of manufacturers' trade-secret information, work a taking under the Fifth Amendment?

STATUTORY AND REGULATORY PROVISIONS

Per Circuit Rule 28-2.7, PhRMA includes relevant provisions in an addendum.

STATEMENT OF THE CASE

A. PhRMA's Members Spend Billions Developing Innovative Medicines

PhRMA is a trade association whose members develop cutting-edge medicines used by patients throughout the nation. Last year, FDA approved 55 new drugs, and PhRMA members were responsible for many of them.[1] Pharmaceutical manufacturers invest billions annually to research and manufacture these new products.[2]

The cost of all this innovation is staggering. On average, a manufacturer will spend nearly $3,000,000,000 developing one new medicine.[3] Some pharmaceutical companies have invested over $10,000,000,000 per new drug.[4] And the required investments are increasing.[5]

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[1] U.S. Food & Drug Admin., *Novel Drug Approvals for 2023*, https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023.

[2] PhRMA, *Biopharmaceuticals in Perspective* 33 (2019), https://onphr.ma/2wy2lMP; Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Transl. Med. 105, 105 (2016), https://bit.ly/33KBRlT.

[3] 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/30UAIdg.

[4] Schuhmacher, *supra*, at 3-4.

[5] *Id.*

The difficulty of securing FDA approval magnifies the risks to manufacturers. Only one compound in 5,000 that enters preclinical testing will achieve FDA approval.[6] Among the small share of investigational medicines that enter clinical trials, only 12% ever achieve FDA approval; of those, only 20% will ever generate revenues that exceed the average cost of developing a medicine.[7]

To recoup their investments, manufacturers calibrate prices and market their products using proprietary methods to balance competing concerns. Foremost among these are promoting patients' access to life-changing medicines, while at the same time generating capital necessary to continue scientific innovation. Because the marketplace is increasingly competitive, manufacturers depend on strong protections for their confidential business methods, which themselves require significant resources to develop.

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[6] Sandra Kraljevic et. al., Accelerating Drug Discovery, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004), https://bit.ly/2Y2gwEK.

[7] DiMasi, *supra*, at 25-26; John A. Vernon et al, *Drug Development Costs When Financial Risk is Measured Using the FAMA-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010) https://bit.ly/4cMpQ2.

B. Oregon House Bill 4005

On February 28, 2018, Oregon's Legislative Assembly passed the Prescription Drug Price Transparency Act, 2018 Or. L. Ch. 7, commonly known as HB 4005, codified at ORS §§ 646A.680-692. The law imposes numerous requirements on a manufacturer of any "prescription drug that is sold in [Oregon]." § 646A.689(1)(e).

1. HB 4005's Reporting Requirement

HB 4005 requires pharmaceutical manufacturers to report certain information when introducing a new drug or when the price of an existing drug increases above a certain threshold. ORS § 646A.689(3). For existing drugs, HB 4005's reporting requirements apply whenever "[t]he price was $100 or more for a one-month supply or for a course of treatment lasting less than one month," if the drug's net price increased by 10% or more over the preceding calendar year. § 646A.689(2). The law defines "price" to mean the drug's "wholesale acquisition cost as defined in 42 U.S.C. § 1395w-3a(c)(6)(B)"—that is, the drug's federally defined, national list price (often referred to as its WAC). § 646A.689(1)(h)(B)(i).

HB 4005 is administered by the State's Department of Consumer and Business Services (DCBS). For each covered prescription drug,

manufacturers must submit to DCBS annual reports that include the following information:

> (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 …; and
>
> (L) The documentation necessary to support the information reported under this subsection.

§ 646A.689(3). Similar requirements apply to newly launched drugs. § 646A.689(6).

All reports must be made "in the form and manner prescribed by [DCBS]." § 646A.689(3),(6). DCBS has promulgated regulations requiring manufacturers to include "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" in their reports. OAC 836-200-0530(2)(h). Manufacturers that fail to comply with the Reporting Requirement may face fines of up to $10,000 per day. ORS § 646A.692(2); *see* OAC 836-200-0560.

The Reporting Requirement for new drugs became operative on March 15, 2019, and for existing drugs on July 1, 2018. Or. L. Ch. 7

§§ 13(3), 15. According to DCBS, manufacturers, including PhRMA members, have submitted more than 1,900 reports since 2019.[8]

2. HB 4005's Public-Interest Exception

HB 4005 directs DCBS to "post to its website" all of the information that manufacturers are required to report. ORS § 646A.689(9)(b). DCBS also must post on its website all drugs that meet the law's reporting thresholds and the names of the drugs' manufacturers. § 646A.689(9)(a).

The internet-posting requirement applies unless (1) the relevant information is "conditionally exempt from disclosure under ORS § 192.345 as a trade secret," *and* (2) DCBS determines that "the public interest does not require disclosure of the information." § 646A.689(10)(a). The referenced statute contains protection for trade secrets under Oregon's Public Records Law. It broadly defines a "trade secret" to include information which is "known only to certain individuals within an organization and which is used in a business it

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[8] Or. Dep't of Consumer and Bus. Servs., *Prescription Drug Price Transparency Program Results and Recommendations – 2023* (*Annual Report*), at 8 (Dec. 1, 2023) (updated Mar. 29, 2024), https://bit.ly/3TcTes9.

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." § 192.345(2).

HB 4005 thus creates a blanket exception to existing state-law protections for manufacturers' trade secrets. Under this exception, which is known as the Public-Interest Exception, DCBS *must* publish these trade secrets whenever DCBS deems publication to be in the "public interest." § 646A.689(10)(a); *see* E.R.-138 (DCBS official stating that DCBS is "*required* to post that information on its website" whenever doing so would be in public interest) (emphasis added).

DCBS has adopted regulations to implement this provision. *See* OAC 836-200-0540. To request that information be exempted from disclosure, the manufacturer must file, along with its report, a written explanation demonstrating the following:

> (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 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*.

OAC 836-200-0540(1)(b) (emphasis added). The regulations do not clarify what information the "public interest" requires to be disclosed. If DCBS decides to publish information claimed to be a trade secret, a manufacturer has 15 days to request reconsideration from DCBS's Director. OAC 836-200-0540(3)-(4).

C. Proceedings Below

On December 9, 2019, PhRMA challenged both HB 4005 and a separate state law, House Bill No. 2658, 2019 Or. L. Ch. 436, which is known as the Advance Notification Law. E.R.-192-93, 233. The Advance Notification Law requires manufacturers to provide 60 days' notice before increasing the WAC of certain brand-name medicines. E.R.-207-08.

1. PhRMA brought four claims against HB 4005, alleging: (1) HB 4005 violates the dormant Commerce Clause by improperly regulating commerce outside of Oregon, E.R.-210-13; (2) HB 4005 is preempted by the federal Defend Trade Secrets Act, E.R.-219-22;

(3) HB 4005's Reporting Requirement unlawfully compels speech under the First Amendment E.R.-213-18; and (4) any invocation of the Public Interest Exception constitutes a taking under the Fifth Amendment, E.R.-222-26. PhRMA bought the same four claims against the Advanced Notification Law. E.R.-210-26.

PhRMA and the State jointly agreed to stay claims challenging the Advance Notification Law pending resolution of a similar challenge to a California law in *PhRMA v. David*, No. 2:17-CV-02573-MCE-KJN (E.D. Cal.). Following this Court's decision in *PhRMA v. Landsberg*, No. 21-16312, 2022 WL 2915588 (9th Cir. July 25, 2022) (Mem.), PhRMA voluntarily dismissed its Advance Notification Law challenge. E.R.-134-36.

2. PhRMA and the State cross-moved for summary judgment on claims against HB 4005. E.R.-141-89; S.E.R.-3-41. Following a hearing, the district court preliminarily ruled on the parties' cross-motions. E.R.-56-121. The court "grant[ed] summary judgment for plaintiffs on the takings claim." E.R.-119. The court denied summary judgment to both sides on the [dormant] commerce clause claim." *Id.* Finally, the court found "that, either as commercial speech on a

controversial topic, therefore triggering intermediate scrutiny, or as private speech, which would be intermediate scrutiny or higher, this speech – compelled speech violates the First Amendment." *Id.*

a. On February 16, 2024, following briefing by the parties on the proper scope of the judgment, the district court entered a declaratory judgment. E.R.-39-41, 245-46.

First, the district court "declare[d] that HB 4005's reporting requirement … violates the First Amendment to the United States Constitution and is, therefore, unenforceable." E.R.-40. The court further declared "that the publication of manufacturer's trade secrets under the Public Interest Exception … constitutes a taking of private property under the Fifth Amendment to the United States Constitution, and that any invocation of the Public Interest Exception by [the State] without simultaneously provided just compensation for that taking would accordingly violate the Fifth Amendment." E.R.-40. The court also dismissed PhRMA's preemption claim without prejudice and denied the parties' cross-motions in all other respects. E.R.-40-41.

Finding "no just reason for delay," the district court entered partial summary judgment on the claims that it had resolved. E.R.-40.

b. On March 19, 2024, the district court issued a written opinion supporting its declaratory judgment. E.R.-9-38.

At the outset, the district court concluded that PhRMA had shown "a realistic danger" that the exception would be invoked, injuring its members. E.R.-10. The court also determined that "a facial challenge to a statute under the Takings Clause may be considered ripe for adjudication if the enforcement of the statute would necessarily result in a taking of property by the government." E.R.-11. And "[h]ere, under the plain terms of the statute, a disclosure under the public-interest exception would result in the taking of a trade secret. DCBS has no discretion—if a trade secret would benefit the public interest, then it must disclose it." ER.-13.

On the merits, the district court first addressed PhRMA's First Amendment challenge to the Reporting Requirement, considering "whether HB 4005 regulates commercial or private speech." E.R.-31. The court viewed this as "a close question," ultimately concluding that

"the speech at issue here is best categorized as commercial speech." E.R.-31-32.

However, the district court rejected the State's argument that it should apply limited First Amendment scrutiny under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). For *Zauderer* to apply, the court explained, "the compelled commercial speech at issue must disclose purely factual and uncontroversial information." E.R.-32 (citation omitted). But HB 4005's compelled speech is *not* uncontroversial: It compels "pharmaceutical companies to speak on a controversial topic and, in particular, justify why they fall on one side—what Oregon deems the wrong side—of that controversy." E.R.-33-34. In sum, "HB 4005's reporting requirements, viewed in the context of drug prices and health care costs, concern controversial information and *Zauderer* does not apply." E.R.-34.

The district court accordingly applied intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557 (1980), to determine whether HB 4005 "directly advances a substantial government interest," and "is not more extensive than necessary to serve that interest." E.R.-35.

The court held that the State failed to satisfy its burden because it "cite[d] no studies or anecdotal evidence" to support its position and instead relied on "little more than speculation." E.R.-36-37.

On PhRMA's takings claim, the district court held that PhRMA had established that HB 4005's Public-Interest Exception takes manufacturers' property—their trade secrets—"every time it is invoked." E.R.-13. Applying factors articulated in *Penn Central Transportation Co. v. New York City*, 483 U.S. 104 (1978), the court determined that "all the factors support[ed] finding" that "the exercise of the public-interest exception works a regulatory taking." E.R.-16.

Because each application of the Public-Interest Exception destroys (takes) manufacturers' property, the district court explained, its invocation is a taking "[u]nless just compensation is provided." E.R.-17. The court accordingly found it appropriate to grant PhRMA "declaratory relief" requiring the State's invocation of the Public-Interest Exception to be accompanied by just compensation. *Id.*

Finally, the district court ruled on PhRMA's other claims. The court concluded that the Defend Trade Secrets Act does not preempt application of HB 4005. E.R.-23. And the court denied summary

judgment for both parties on the dormant Commerce Clause claim because it did not have sufficient evidence. E.R.-24-29.

SUMMARY OF ARGUMENT

I. HB 4005's Reporting Requirement violates the First Amendment by compelling manufacturers (and only manufacturers) to justify their pricing decisions. The law fails any level of heightened scrutiny.

Laws that compel speech are subject to strict scrutiny, as are laws that draw distinctions based on speaker or content. HB 4005 does all three, yet the State has never argued that HB 4005 is narrowly tailored to serve a compelling interest.

HB 4005 is not subject to intermediate scrutiny as commercial speech. The speech it compels does not propose—or even relate to—a commercial transaction. Nor do manufacturers have an economic motivation to file the compelled reports; they do it only because the law forces them.

Regardless, HB 4005 cannot survive intermediate scrutiny (and the State never argued below that it could). Under such scrutiny, the government must *prove* that its regulation directly advances a

substantial government interest. Here, the State cannot even settle on a consistent rationale for its law, much less explain how the law achieves it. And the State has offered *no* evidence that HB 4005 serves any governmental interest—let alone a substantial one.

The State defends the Reporting Requirement under *Zauderer*, a doctrine designed to ensure that advertisements adequately inform consumers about products and services offered for sale. The doctrine has never been applied to a law that compels speech about a company's internal reasons for making business decisions. In any event, *Zauderer* applies only where compelled speech is "purely factual and uncontroversial," but the reports at issue here are neither: The Reporting Requirement forces manufacturers to provide an *opinion* about factors contributing to drug-price increases, an inherently controversial topic. But even under *Zauderer*, the State must prove that the Reporting Requirement is both justified and not unduly burdensome. All the State offers here is "speculation." E.R.-37.

Finally, the State cannot justify the Reporting Requirement as compelling "routine disclosures" to support the government's essential operations, like filing a tax return. AOB 19. HB 4005's compelled

reports are published on the internet. And as the State (sometimes) admits, the law has the substantive purpose of "permit[ting] purchasers, both public and private, as well as pharmacy benefit managers to negotiate discounts and rebates for prescription drugs." AOB 23 (quoting HB 4005, preamble).

II. On its face, HB 4005's Public-Interest Exception takes manufacturers' property—their trade secrets—requiring just compensation under the Takings Clause.

Whether the Public-Interest Exception is viewed as a categorical taking or a regulatory taking, the result is the same. As the Supreme Court explained in *Ruckelshaus*, public disclosure of a trade secret destroys its value entirely—a factor "so overwhelming" that it renders the disclosure a taking on its face. 467 U.S. at 1005. Here, the Public-Interest exception results in the disclosure (hence, the destruction) of a manufacturer's trade secret every time it is invoked; indeed, the provision has no other function.

The State attempts to recast the forced disclosure of trade secrets as "information voluntarily submitted to a regulatory agency without an *express* promise of confidentiality." AOB 23. But the

Supreme Court (and other courts) reject the "peculiar proposition" that the government can "alter property rights" by changing the law to undermine a property-holder's expectations. *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 833 n.2 (1987). And PhRMA has standing to pursue a declaratory judgment that invoking the Public-Interest Exception amounts to a taking that must be accompanied by just compensation—the exact form of relief granted by the Supreme Court in recent takings cases.

STANDARD OF REVIEW

This court reviews *de novo* a ruling granting or denying summary judgment. *Branch Banking & Tr. Co. v. D.M.S.I., LLC*, 871 F.3d 751, 759 (9th Cir. 2017).

ARGUMENT

I. HB 4005's Reporting Requirement Violates the First Amendment

Just as the First Amendment forbids governmental censorship, it also "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006). The Reporting Requirement violates that command, by compelling manufacturers—and only manufacturers—to speak: They must create and submit to DCBS detailed reports regarding the factors affecting internal decision-making, including a narrative justification for price increases. The reports are then posted to the internet.

The Reporting Requirement is impermissibly designed to support the State's view that manufacturers are solely responsible for price increases. Those features render it unconstitutional: "[A] law commanding 'involuntary affirmation' of objected-to beliefs [requires] 'even more immediate and urgent grounds' than a law demanding silence." *Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31*, 585 U.S. 878, 893 (2018) (citation omitted). No immediate or urgent grounds exist here.

A. The Reporting Requirement Unconstitutionally Compels Private Speech

"At the heart of the First Amendment lies the principle that each person should decide for himself or herself the ideas and beliefs deserving of expression, consideration, and adherence." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994).

1. Laws that compel speech allow the government to "manipulate the public debate through coercion rather than persuasion," *id.*, inherently undermining "our democratic form of government," as well as "the search for truth," *Janus*, 585 U.S. at 893. Worse still, "[f]orcing free and independent individuals to endorse ideas they find objectionable is always demeaning," because it coerces them into "betraying their convictions." *Id.*; *see Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988) (forcing a speaker to convey a message "necessarily alters the content of the speech"). For these reasons, laws compelling speech generally receive the "most exacting" form of judicial review. *Turner Broad.*, 512 U.S. at 642; *accord Frudden v. Pilling*, 742 F.3d 1199, 1207 (9th Cir. 2014).

HB 4005 bears the hallmarks of government-compelled speech. The law requires manufacturers to provide DCBS with a detailed

report, ORS § 646A.689(3), which must include (among other information) "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," OAC 836-200-0530(2)(h). The State then publishes the reports on DCBS's website. ORS § 646A.689(9)(b). There can be no doubt that this speech is compelled. To state the obvious, no manufacturer would create these reports or submit them to DCBS unless required to do so; nor would manufacturers choose to have their information—much of it sensitive and confidential—disseminated on the internet.

2. HB 4005 faces heightened scrutiny for another reason: It strays far from the neutrality that the First Amendment requires for government regulation of private speech. For one thing, it targets a limited group—pharmaceutical manufacturers—and no other market participants. This singling out is contrary to the established rule that "government regulation may not favor one speaker over another." *Rosenberger v. Rector & Visitors of Univ. of Va.,* 515 U.S. 819, 828 (1995).

More fundamentally, HB 4005 represents "governmental control over the *content* of messages expressed by private individuals," something the First Amendment typically "does not countenance." *Turner Broad.*, 512 U.S. at 641 (emphasis added); *see Nat'l Inst. of Family & Life Advocates v. Becerra* (*NIFLA*), 585 U.S. 755, 766 (2018) (content-based regulations "are presumptively unconstitutional") (citation omitted). To determine whether a law is content-based, courts look at the law "on its face" and apply a "commonsense" test: "Government regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed." *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015). Statutes that "defin[e] regulated speech by particular subject matter" or "by its function or purpose" thus "are subject to strict scrutiny." *Id.* at 163-64. The information required by HB 4005—which focuses on a specific topic (drug pricing)—plainly is "defin[ed] … by [a] particular subject matter."

Moreover, the law concerns precisely the type of content-based restriction most anathema to First Amendment values: "discrimination among viewpoints." *Reed*, 576 U.S. at 168. Laws that

categorize private speech based on viewpoint "pose the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information or manipulate the public debate through coercion rather than persuasion. These restrictions raise the specter that the Government may effectively drive certain ideas or viewpoints from the marketplace." *Turner Broad.*, 512 U.S. at 641 (brackets and quotation marks omitted). A determination that the government is regulating private speech in a viewpoint-discriminatory manner is "all but dispositive." *Sorrell IMS Health Inc.*, 564 U.S. 552, 571 (2011).

The Reporting Requirement is designed to advance the State's erroneous view that manufacturers alone are responsible for the price of prescription drugs. Manufacturers are the *only* market participants required to justify their role in setting drug prices; other market participants face no comparable obligation. Oregon's tactic here is not subtle. A classic means of promoting a particular viewpoint is to "shape [an] expression by speaking on one subject while remaining silent on another. The message it disfavor[s] is not difficult to identify." *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*,

515 U.S. 557, 574 (1995). Thus, the law is "presumptively unconstitutional and may be justified only if the government proves that [it is] narrowly tailored to serve compelling state interests." *Reed*, 576 U.S. at 163.

3. "[I]t is the rare case in which a State demonstrates that a speech [law] is narrowly tailored to serve a compelling interest." *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 444 (2015) (quotation marks omitted). This is not such a rare case.

In fact, the State has never argued that HB 4005 would survive strict scrutiny. Below, the State *solely* argued that it should be assessed as commercial speech under *Zauderer*. On appeal, the State argues for the first time that HB 4005 should be upheld under rational basis review, or under *Central Hudson's* intermediate scrutiny, AOB 40-42. Even now, the State does not claim that it would satisfy strict scrutiny. Nor could it: HB 4005 would fail even intermediate scrutiny, see Part I.B.2, *infra*, so it necessarily fails strict scrutiny.

B. The Reporting Requirement Cannot Be Defended as a Regulation of Commercial Speech

The district court held that the disclosures required by HB 4005 are commercial in nature. They are not: They do not propose—or even

relate to—commercial transactions. The government may not force a private entity to speak, then defend its regulation on the ground that the entity's speech is merely commercial.

But even if the required disclosures were commercial, the district court correctly determined that they cannot survive intermediate scrutiny. Indeed, the State never argued below that they could. The State's defense of the Reporting Requirement falls far short of meeting its burden: The asserted justifications for the law are incoherent, and the State has not offered a shred of supporting evidence.

1. The speech compelled by the Reporting Requirement is not commercial speech

"Commercial speech is 'defined as speech that does no more than propose a commercial transaction.'" *Hunt v. City of L.A.*, 638 F.3d 703, 715 (9th Cir. 2011) (quoting *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001)). The Supreme Court has reaffirmed that definition numerous times. *See, e.g.*, *Harris v. Quinn*, 573 U.S. 616, 648 (2014) ("speech that does no more than propose a commercial transaction") (citation omitted); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002) (same); *United States v. Edge Broad. Co.*, 509 U.S. 418, 426 (1993) (same); *Edenfield v. Fane*, 507 U.S. 761, 767 (1993)

(same); *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989) (same); *see also IMDb.com Inc. v. Becerra*, 962 F.3d 1111, 1122 (9th Cir. 2020) (same). This makes sense, because such speech is "'linked inextricably' with the commercial arrangement that it proposes." *Edenfield*, 507 U.S. at 767 (citation omitted). At the core of commercial speech is a simple concept: "I will sell you the X [product] at the Y price." *Va. State Bd. of Pharm. v. Va. Citizens Consumer Council Inc.*, 425 U.S. 748, 761 (1976).

The State does not meaningfully claim that the detailed reports required by HB 4005 propose commercial transactions. The law forces manufacturers to create reports about the factors affecting drug-pricing decisions, including "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." OAC 836-200-0530(2)(h). This information, which concerns a manufacturer's *internal* decision-making, does not involve—much less propose—actual commercial transactions. And manufacturers do not create the reports to win customers; they do so only because the law compels them. The State's

argument thus simply ignores "the 'common-sense' distinction between speech proposing a commercial transaction … and other varieties of speech." *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455-56 (1978).

The State nevertheless contends (at 28-29) that the Reporting Requirement compels commercial speech under the test articulated in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983). At issue there were unsolicited mailings from a contraceptives-manufacturer, which informed potential customers about the "desirability and availability" of contraceptives generally, and also about the manufacturer's products "in particular." *Id.* at 62. To determine whether these mailings were commercial speech, the Supreme Court looked at three factors: (1) The mailings were "conceded to be advertisements"; (2) they "refer[red] to a specific product"; and (3) the manufacturer "ha[d] an economic motivation for mailing" them. *Id.* at 66-67. Although each factor standing alone would have been "insufficient," the Court held that "[t]he combination of *all* these characteristics … provide[d] strong support" for treating the mailings as commercial in nature. *Id.* at 66-67.

The *Bolger* test is appropriate only in cases "[w]here the facts present a close question." *Hunt*, 638 F.3d at 715. The test helps figure out whether speech that does *not* take the form of traditional advertising nevertheless may be "made in the context of commercial transactions." *Bolger*, 463 U.S. at 68. But where, as here, the speech in question is an involuntary response to governmental regulation—and is entirely unconnected to *any* particular commercial transaction—there is no "close question" that would justify application of the *Bolger* factors. *See IMDb.com*, 962 F.3d at 1122.

Even if *Bolger* applied here, it undercuts, rather than supports, the State's argument. For one thing, HB 4005's disclosures, which are not sent to potential customers, are nothing like advertisements. For another, manufacturers are motivated to submit them *only* by their need to comply with HB 4005. Manufacturers do refer to specific products in their notices (because the law forces them). But a "reference to a specific product does not by itself render [something] commercial speech." *Bolger*, 463 U.S. at 66. Otherwise, all public advocacy about a product would be commercial as well. The State identifies no comparable case in which speech was found to be

commercial merely because the government compelled the speaker to talk about a specific product.

To the contrary, every commercial-speech decision cited by the State illustrates just how different the speech at issue here is. In *Bolger*, the contraceptives-manufacturer mailed a variety of unsolicited advertisements to prospective customers in order to drum up business. 463 U.S. at 62. In *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), pharmacy benefit managers were promoting "more expensive brand name drug[s]" over "equally effective and cheaper generic drug[s]" in order to "collect a fee from the manufacturer for helping to increase the manufacturer's market share." *Id.* at 298. And *Hunt* involved boardwalk vendors who touted their wares to passersby. 638 F.3d at 708-09. All those cases involved a key feature absent here: "the core of [the speakers'] speech [wa]s directed to their products and why a consumer should buy them." *Id.* at 716.

The district court, in concluding that manufacturers' compliance with the Reporting Requirement could be seen as "economically motivated," relied on this Court's statement in *Ariix, LLC v.*

NutriSearch Corp. that "economic motivation is not limited simply to the expectation of a direct commercial transaction." 985 F.3d 1107, 1117 (9th Cir. 2021). But this Court's point was that the publishers of a supposedly neutral supplement guide might be economically motivated even though the guide did not directly offer products for purchase. *Id.* The Court thus explained that the publishers "published the Guide mainly to reap the financial benefits of a hidden marketing arrangement with [a third party]." *Id.* Under HB 4005, by contrast, manufacturers are merely complying with a regulatory command.

Nor can the speech be deemed commercial by invoking "common sense." E.R.-32. The State argues that the information required by HB 4005 "could be viewed as akin to information placed on the label of a retail product or disclosed in the course of contract negotiations." AOB 29. But a product's label is used by the retailer to entice potential customers. Information is disclosed during contract negotiations to facilitate the transaction. The information required by HB 4005 is wholly unlike this sort of "common sense" commercial information. Nor has the State identified any authority for treating regulatorily

compelled disclosures (as opposed to advertisements they may accompany) as commercial in nature.

2. The Reporting Requirement fails intermediate scrutiny

Because HB 4005 does not compel commercial speech, it must satisfy strict scrutiny. *See* Section I.A, *supra*. But even if this Court agrees with the district court that *Central Hudson* is the proper test to apply, it should agree with the district court that HB 4005 fails such scrutiny.

a. As an initial matter, any attempt by the State to argue that HB 4005 would survive intermediate scrutiny is waived. As the district court explained, "in its briefing and oral argument," the State argued only that HB 4005 would satisfy "rational basis review" (based on its mistaken view that the *Zauderer* standard is equivalent to a rational-basis test, see pp. 49-50, *infra*). E.R.-36 n.7. As a result, the State "did not squarely address the direct advancement and narrow tailoring requirements under *Central Hudson*." *Id.* Having "failed to raise [this argument] in the district court," the State "may not press [the] argument on appeal." *One Indus., LLC v. Jim O'Neal Distributing, Inc.*, 578 F.3d 1154, 1158 (9th Cir. 2009).

b. Regardless, the State's showing here falls short of satisfying intermediate scrutiny. Under *Central Hudson*, when the government wants to regulate commercial speech it must demonstrate that: (1) "the asserted governmental interest is substantial"; (2) "the regulation directly advances the governmental interest asserted"; and (3) the regulation is "narrowly drawn" and "not more extensive than is necessary to serve that interest" *Central Hudson*, 447 U.S. at 565-66. The State satisfies *none* of those requirements.

First, the State's justifications for the Reporting Requirement are inadequate on their face. The State claims that HB 4005 will "permit[] purchasers, both public and private, as well as pharmacy benefit managers to negotiate discounts and rebates for prescription drugs." AOB 23. But the State simultaneously insists that HB 4005 was *not* "intended to directly lower drug prices," and indeed that "any lack of connection to lower prices is *irrelevant*." AOB 25 (emphasis added).[9] A supposed desire to help "private" purchasers negotiate

[9] The State's argument also contradicts HB 4005's stated intent "to permit a manufacturer of a prescription drug to voluntarily make pricing decisions regarding a prescription drug, including decisions that result in price increases." HB 4005, preamble.

discounts also contradicts the State's insistence that "the reporting requirements compel speech directed at DCBS," rather than "at consumers." AOB 36. It *also* contradicts the State's argument that the required information is merely "designed to forward ordinary regulatory purposes." AOB 21 (citation omitted).

Even beyond these contradictions, the Reporting Requirement is a poor fit with the State's supposed goal of facilitating negotiations. The reports are not triggered by the prices paid by the State or by Oregonians, but instead by increases in the WAC—the *national* wholesale list price—which is significantly different than the prices paid by consumers. E.R-25. The State lacks power to regulate nationwide drug prices, moreover, and certainly cannot regulate speech as a backdoor means of achieving the same objective. *See Clairmont v. Sound Mental Health*, 632 F.3d 1091, 1100 (9th Cir. 2011).

The State's asserted interest in "provid[ing] accountability for prescription drug pricing," AOB 23 (quoting HB 4005, preamble), is no more substantial. The State never explains what it might mean to provide "accountability for prescription drug pricing," especially if the

lack of connection to lower prices is "irrelevant." Insofar as the State is merely claiming a general, amorphous interest in "transparency" about drug prices, *id.*, that certainly would not justify compelling "manufacturers to speak against their will," *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996); *see id.* (if educational interest were "alone sufficient, there is no end to the information that states could require manufacturers to disclose"). Indeed, a drug's wholesale list price is already public, and purchasers already know what retail prices they are being asked to pay.

Second, the State has not shown that the Reporting Requirement actually advances its asserted interests. To satisfy intermediate scrutiny, the State must "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. Here, the State has "demonstrate[d]" nothing.

As the district court noted, the State did not introduce *any* evidence showing that HB 4005 will achieve its purposes: "Oregon has not identified studies or evidence to show how the reporting requirements of HB 4005 will directly advance its legislative goals,

and the record it has created does nothing to advance such connection." E.R.-37. And because the State has "cite[d] to no studies or anecdotal evidence to support [its] assertions, … without more, they amount to little more than speculation." *Id.* Indeed, when asked how the law would "actually reduce the cost of prescription drugs," one state representative admitted: "I don't think we know yet." *Id.*(citation omitted). We still don't.

The State now asserts that it can satisfy its burden *solely* with "simple common sense." AOB 26 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001)) (citation omitted). But the cited case merely explains that common sense, considered with "history" and "consensus," can help supplement and provide context for "studies and anecdotes." *Lorillard Tobacco*, 533 U.S. at 555 (citation omitted). When the Supreme Court has invoked "common sense," it has *also* relied on actual "evidence." *Id.* at 557; *see id.* 558-61 ("studies," "specific findings," and other "data"); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995) ("106-page summary of [a] 2-year study," which included "data—both statistical and anecdotal"); *Burson v. Freeman*, 504 U.S. 191, 200-06 (1992) (more than a century of post-Founding

historical evidence from "all 50 states"). In doing so, the Court has reaffirmed that the government's "burden is *not* satisfied by mere speculation or conjecture," *Lorillard Tobacco*, 533 U.S. at 555 (emphasis added) (citation omitted), which is all the State offers here.

In any event, there is nothing common-sensical about the State's allusions to "transparency" and "accountability." Insofar as HB 4005 aims to facilitate *the State's* informed decision-making, there is no justification for requiring publication of the reports. Insofar as the law aims to inform *the public*, that goal is not advanced by a reporting requirement targeted solely at manufacturers. If genuinely committed to educating the public about drug prices, the State would have required *other* supply-chain participants to provide information about their own market activities, which affect actual prices. E.R.-25. Nor is it clear how the required information will help retail purchasers make purchasing decisions or negotiate discounts. The State leaves all these issues to "speculation." E.R.-37.

Third, the State cannot show that HB 4005 is not more extensive than necessary to meet its stated goals. Drug prices are set through "a complex supply chain," of which manufacturers are "only

one type" of participant. E.R.-37. Yet the State has never explained why HB 4005 compels *only* manufacturers to speak, making the law significantly "underinclusive given Oregon's own framing of the issue HB 4005 is aimed at addressing." *Id.* Finally, even if "there may be a justification for beginning its approach with this compulsion of this speech from these companies, [the State] does not elucidate that justification" either. E.R.-38.

C. HB 4005 Cannot Be Defended under *Zauderer*

The State argues that HB 4005 can be upheld under the lesser form of scrutiny that applies under *Zauderer*. But the *Zauderer* doctrine is designed to ensure that consumers are fully informed about the nature of what is being advertised to them. It has nothing to do with the disclosures required here. The State's argument ignores the justifications that underlie that doctrine, as well as how it has consistently been applied.

1. In *Zauderer,* the Supreme Court upheld a rule requiring lawyers who advertised their services on a contingency-fee basis to disclose that clients might nevertheless be liable for certain fees and costs. 471 U.S. at 633-34. The Court noted that the advertisements

were "commercial speech," and an advertiser's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id.* at 651. "Thus," the Court concluded, "warnings or disclaimers might be appropriately required in order to dissipate the possibility of consumer confusion or deception." *Id.* (punctuation altered). Later decisions of this Court have extended *Zauderer* to forced disclosures to consumers about "health and safety" characteristics of products or services being offered for sale. *CTIA-The Wireless Ass'n v. City of Berkeley* (*CTIA*), 928 F.3d 832, 844 (9th Cir. 2019).

Zauderer's rationale only justifies forcing a disclosure, however, if necessary to apprise consumers of the "terms under which [goods or] services will be available." 471 U.S. at 651. *Every* decision applying the doctrine that the State cites involved a law that compelled disclosure of the features of a good or service in connection with offering it for sale. *See id.* at 626 (client liability for litigation costs); *CTIA*, 928 F.3d 832 (risk of radiation exposure from cell phones); *Am. Beverage Ass'n v. City & Cty. of S.F.* (*ABA*), 916 F.3d 749 (9th Cir. 2019) (health dangers of added-sugar beverages); *Nationwide*

Biweekly Admin., Inc. v. Owen, 873 F.3d 716 (9th Cir. 2017) (refinancing solicitations not authorized by lender); *Nat'l Ass'n of Mfrs. v. SEC* (*NAM*), 800 F.3d 518 (D.C. Cir. 2015) (country-of-origin information for conflict minerals); *Rowe*, 429 F.3d 294 (pharmacy benefit managers' conflicts of interest); *Env'tl Def. Ctr., Inc. v. EPA*, 344 F.3d 832 (9th Cir. 2003) (hazards of improper waste disposal); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (risk of mercury in lightbulbs). As the State itself sums up, this Court "has yet to extend *Zauderer* to speech outside of strictly defined commercial transactions." AOB 32.

2. The speech compelled by HB 4005 is obviously different. Because the required drug-pricing reports do not accompany "advertising," a manufacturer's "constitutionally protected interest in *not*" speaking is far more than "minimal." *Zauderer*, 471 U.S. at 651; *see NAM*, 800 F.3d at 523 ("[T]he Supreme Court has refused to apply *Zauderer* when the case before it did not involve voluntary commercial advertising."). Indeed, HB 4005's reports are not commercial speech at all. *See* Section I.B.1, *supra*. And they neither "accompany[] a related product or service," *ABA*, 916 F.3d at 756, nor inform consumers about

the "intrinsic characteristics of the product [the compelled speaker] is selling," *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014). Instead, the disclosures concern manufacturers' *internal* decision-making. The State's own logic renders *Zauderer* inapplicable, and the State identifies no remotely comparable case applying it.

Even where *Zauderer* applies, moreover, it can justify forcing the disclosure of only "purely factual and uncontroversial information." 471 U.S. at 651. But disclosures compelled by HB 4005 are neither. A manufacturer's assessment of its *own* motivations for adjusting a drug's list price, and what "factors … contributed to the price increase," ORS § 646A.689(3)(c), is not factual; it inherently calls for expression of an opinion—one that forces manufacturers "to take sides in a heated political controversy" about the reasons for high prescription prices. *CTIA*, 928 F.3d at 848.

As the district court properly concluded, discussion of "drug prices and health care costs" is *inherently* "controversial." E.R.-34. By requiring manufacturers (and only manufacturers) to produce this information, the law forces them to "speak on a controversial topic and, in particular, justify why they fall on one side—what Oregon

deems the wrong side." E.R.-33. In the *Zauderer* cases cited by the State, by contrast, the required disclosures were genuinely factual and uncontroversial.[10]

This case is accordingly more analogous to *NAM*, in which mineral-traders were forced to announce whether their products were "conflict free"—a phrase defended by the government as "factual," but in reality just as loaded as HB 4005's disclosure requirement. 800 F.3d at 530. Here, where "[t]he pharmaceutical companies are the only entity involved in that controversy required to offer an explanation to the public," E.R.-34, their forced disclosures reinforce the State's message that manufacturers are the ones responsible for drug prices.

The State argues that the speech compelled by HB 4005 is uncontroversial because HB 4005 "compel[s] speech directed at DCBS, in an exercise of regulatory compliance." AOB 36. Again, that contradicts the State's argument that the law aims to help "public" purchasers and "pharmacy benefit mangers" negotiate discounts.

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[10] *CTIA*, 928 F.3d at 846-48 (radio-frequency exposure warnings were "literally true" and merely "short-hand description" of "safety warning" already required by FCC); *Owen*, 873 F.3d at 733 (warning that solicitation was not authorized by lender was factually correct and "[did] not imply that the solicitation is … unlawful or improper").

AOB 23 (citation omitted). Indeed, if the speech were "directed" only at DCBS, *Zauderer* would not apply in the first place. *See* 471 U.S. at 629 (doctrine addresses "whether a State may seek to prevent potential deception *of the public*") (emphasis added).

The State's argument thus fails on its own terms. The State ignores the fact that all the required information must, by law, be published on DCBS's website for the public to access—thus requiring manufacturers to enter the public fray on a highly contentious topic. See E.R.-109 (Court: "it's a subject people are mad about; right? [The State]: Sure.").

3. Finally, HB 4005 would fail even *Zauderer*'s lesser standard of scrutiny, under which the State "has the burden of proving that the [compelled speech] is neither unjustified nor unduly burdensome." *ABA*, 916 F.3d at 756. "Even under *Zauderer*," the government must show that the compelled disclosures "remedy a harm that is potentially real not purely hypothetical," and that the compulsion "extend[s] no broader than reasonably necessary." *NIFLA*, 585 U.S. at 776 (cleaned up).

The State's showing here falls far short. As noted above, the State never offers evidence to substantiate that forcing manufacturers to disclose and justify their decision-making about wholesale list prices meaningfully helps consumers change their negotiating practices. Nor does the State explain why only manufacturers are required to disclose their internal decision-making. *See* Section I.B.2, *supra*. The State's showing here thus "amount[s] to little more than speculation," E.R.-37, and compares unfavorably even to other *Zauderer* cases where the government "ha[d] not carried its burden to demonstrate that [the law's] requirement is not 'unjustified or unduly burdensome,'" *ABA*, 916 F.3d at 757; *see id.* (rejecting government's reliance on "expert" and research "study").

D. The State Cannot Invoke Rational-Basis Review

The State argues that the Reporting Requirement "amounts to the kind of regular governmental disclosures that are reviewed only under a rational-basis standard." AOB 17. According to the State, some disclosures compelled by the government are "require[d] for its essential operations." AOB 19 (quoting *Full Value Advisors, LLC v. SEC*, 633 F.3d 1101, 1109 (D.C. Cir. 2011)). The State maintains that

these "routine disclosures" are subject only to rational basis review. AOB 20. This argument fails on multiple levels.

Initially, the State has waived any argument that the required reports are merely "regular governmental disclosures" between "a regulated entity and its regulator." AOB 17-18. Below, the State argued *only* that the Reporting Requirement "passes the *Zauderer* test." S.E.R.-27 (section heading); *see* S.E.R.-29-30. Because the State did not raise this issue, the district court did not address it; the State may not raise it now.

Regardless, this new argument is without merit. As the D.C. Circuit explained in *Full Value Advisors*, some routine disclosures to the government are constitutionally unobjectionable—and necessary for its "essential operations"—such as where "the Government requires individuals to submit income tax information to the IRS." 633 F.3d at 1109 (quotation marks omitted). The court thus upheld a requirement for "active investing" hedge funds to disclose to the SEC their accumulation of stock in a publicly traded company. *Id.* at 1104. But in so ruling, the court repeatedly emphasized that "the Commission—not the public—[w]as [the hedge fund's] only audience."

Id. at 1108; *see id.* at 1109. And the Court emphasized the Commission's statutory obligation "to protect an institutional investor's confidential information." *Id.*[11]

Unlike those SEC disclosures and income tax returns, HB 4005's required reports are *not* kept confidential. To the contrary, they must be posted on the internet; and even manufacturers' confidential and proprietary information must be publicly posted if DCBS determines that doing so is in "the public interest." ORS § 646A.689(10)(a)(B); *see* Section II, *infra*. And as the State (sometimes) admits, the audience for them is not the State alone, but *all* "purchasers, both public and private, as well as pharmacy benefit managers." AOB 23 (citation omitted). Nor can the reports plausibly be described as "require[d] for [the government's] essential operations." *Full Value Advisors*, 633 F.3d at 1109. Indeed, the State has struggled even to articulate a consistent and coherent rationale for the reports, *see* Section I.B.2,

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[11] The State misleadingly states "the SEC was 'required to publicly disclose' reported information except in limited circumstances." AOB 21 (quoting 633 F.3d at 1108). Those supposedly limited circumstances, it fails to mention, included the very circumstances most directly at issue here: where a submitting entity was "entitled to confidential treatment" of its business information. 633 F.3d at 1108; *see id.* at 1104-05 (detailing confidentiality protections).

supra, and certainly has not explained how they could be "essential" to its ordinary operations.

More fundamentally, the State's argument would completely upend First Amendment law. According to the State, "a disclosure qualifies as … a routine regulatory disclosure"—and hence subject only to rational-basis review—"so long as it is made to a government agency, even if that agency has an obligation to publicly release the disclosed information." AOB 21. If that were true, the State could require *any* person (whether natural or artificial) to speak on *any* topic, so long as the ostensible audience was a governmental agency; and then the agency could turn around and post that compelled speech on the internet. *See id.* That would effectively erase constitutional protection against compelled speech.

No authority supports this proposition. The State relies heavily on *Rowe*, *see* AOB 20, but the First Circuit in fact applied the *Zauderer* test there. 429 F.3d at 309-10; *see id.* at 316 (Boudin, C.J., concurring). That test was appropriate, since the challenged law required pharmacy benefit managers (PBMs) to "disclose conflicts of interest" when "enter[ing] into contracts" with "health benefit providers." *Id.* at

299. And there, "[t]he disclosures made by the PBMs to the covered entities [we]re protected by confidentiality. None of the disclosures [we]re available to the public." *Id.* Here, the opposite is true.

Finally, the State relies heavily on statements from Chief Judge Boudin's opinion, but even those do not support its argument. Chief Judge Boudin called the disclosures at issue "routine," and said they were "designed to forward ordinary regulatory purposes," *id.* at 316, but he did not purport to embrace a new test for any forced disclosures that might meet that high-level description. Nor did he say that "[r]outine disclosures of that sort are subject only to 'the general rational basis test governing all government regulations under the Due Process Clause.'" AOB 20 (quoting 429 F.3d at 316). Rather, he said that the *Zauderer* test is "*akin to* the general rational basis test." 429 F.3d at 316 (emphasis added). He also explained that the test is designed to ensure "that an advertiser's rights are adequately protected." *Id.* (quoting *Zauderer*, 471 U.S. at 651). Unlike the PBMs soliciting business with benefit providers in *Rowe*, manufacturers who submit reports under HB 4005 cannot be described as "advertisers."

E. The District Court Properly Invalidated the Entire Reporting Requirement

Should this Court agree that the Reporting Requirement violates the First Amendment, the State asks the Court to limit the district court's judgment to one subsection of HB 4005 in particular: subsection (3)(c). AOB 42. This argument is waived and meritless.

1. "Oregon did not raise [a] severability argument in its briefs or at oral argument." E.R.-28 n.6. The State raised the argument for the first time "[i]n the briefing on the proposed declaratory judgment." *Id.* The district court accordingly found the argument waived and "declined to enter [the State's] proposed judgment and decline[d] to address these arguments in [its] Opinion." *Id.* That waiver finding was well within the court's discretion. *See Comite de Jornaleros de Redondo Beach v. City of Redondo Beach*, 657 F.3d 936, 951 n.10 (9th Cir. 2011) (en banc). The State does not argue that the court's determination was an abuse of discretion; indeed, the State ignores the waiver ruling altogether.

2. The entirety of HB 4005, not only Section (3)(c), fails heightened scrutiny. As explained below, by requiring manufacturers to submit reports on drug pricing, the law forces them "to enter into

an arena and say something on a subject people are mad about." E.R.-109. That rationale is *not* limited to the manufacturer's obligation under Section (3)(c) to speak about "factors that contributed to the price increase." HB 4005 § 2(3)(c). Though *some* of the required information is factual in nature, all of the information is still "being plugged into a highly controversial public debate," E.R.-76-77.

In addition, the State did not argue below that *any* part of the law would satisfy heightened scrutiny, nor did the State put forward evidence with respect to any part of the law. Even now, the State makes no effort to show how other aspects of the Reporting Requirement—that is, information required by other subparagraphs of subsection (3)—would pass intermediate scrutiny. AOB 42-43.

II. THE PUBLIC-INTEREST EXCEPTION TAKES MANUFACTURERS' TRADE SECRETS, REQUIRING JUST COMPENSATION

Oregon law affords legal protection to trade secrets, investing their owners with rights of "[i]ntangible personal property." ORS § 307.020(1)(a)(I). HB 4005 eliminates such protection for manufacturers' confidential information: Trade secrets *must* be posted on the internet—and hence destroyed—if "the public interest …

require[s]." § 646A.689(10)(a)(B). Every time this Public-Interest Exception is applied, it takes manufacturers' property without just compensation in violation of the Takings Clause. Accordingly, the district court properly declared that invocation of the exception requires the State to pay just compensation.

A. The Public-Interest Exception Takes a Manufacturer's Property

The Public-Interest Exception necessarily works a taking of private property because the law—each time it is applied—mandates public disclosure of a trade secret, destroying the secret's value. Whether such disclosures are properly considered categorical takings, or instead are assessed as regulatory takings, the result is the same: Absent just compensation, "the public-interest exception will amount to an unconstitutional taking every time it is invoked." E.R.-13.

1. The Fifth Amendment protects all forms of "private property," including "intangible property rights protected by state [or federal] law." *Ruckelshaus*, 467 U.S. at 1003. At issue in *Ruckelshaus* were "health, safety, and environmental data" that pesticide manufacturers were required to submit to EPA. *Id.* at 998. Manufacturers had given EPA their data, which were protected by

state trade-secret laws, under conditions designed "to ensure [their] secrecy." *Id.* But Congress added a new "public disclosure" provision authorizing EPA to publish the data to any competitor who agreed to pay a reasonable price for it. *Id.* at 992. Monsanto, a pesticide manufacturer, sued on the ground that disclosure of its data interfered with its "property interest protected by the Fifth Amendment." *Id.* at 1000.

The Supreme Court agreed. Drawing on authorities dating back to English common law, the Court explained that the "notion of 'property' … extends beyond land and tangible goods" and includes "[t]rade secrets"—long-recognized intellectual property that "ha[s] many of the characteristics of more tangible forms of property." *Id.* at 1002-03. Monsanto's trade secrets were accordingly "deserving of the protection of the Taking Clause." *Id.* at 1003. Numerous courts, both before and after *Ruckelshaus*, have similarly afforded constitutional protection to trade secrets. *See, e.g.*, *Philip Morris, Inc. v. Reilly*, 312 F.3d 24, 31-33 (1st Cir. 2002) (en banc) (ingredient list for tobacco products); *St. Michael's Convalescent Hosp. v. California*, 643 F.2d 1369, 1374 (9th Cir. 1981) (cost information of healthcare provider).

The value of a trade *secret*, as the name suggests, depends on its *secrecy*. "The right to exclude others is generally 'one of the most essential sticks in the bundle of rights,'" and for a trade secret "the right to exclude others is central to the very definition of the property interest." *Ruckelshaus*, 467 U.S. at 1011. Once disclosed "to others who are under no obligation to protect the confidentiality of the information," "[the] property right is extinguished." *Id.* at 1002.

When a law compels businesses to turn over proprietary information, and also authorizes the government to publish that information, the law has accordingly been deemed a taking requiring just compensation. Thus, in *Ruckelshaus*, the Supreme Court held that forcing Monsanto to disclose proprietary business data to its competitors had "destroy[ed]" the value of that data and amounted to a taking. *Id.* at 1012. And in *St. Michael's*, this Court held that even the government's "failure to provide adequate protection to assure [a trade secret's] confidentiality … can amount to [an] unconstitutional 'taking' of property by destroying it, or by exposing it to the risk of destruction by public disclosure or by disclosure to competitors." 643 F.2d at 1374 (brackets and citation omitted).

2. Takings jurisprudence distinguishes between "categorical" takings, in which governmental regulation "denies all economically beneficial or productive use" of property, *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992), and "regulatory" takings, which "fall short of eliminating all economically beneficial use," *Palazzolo v. Rhode Island*, 533 U.S. 606, 617 (2001). The former category always requires just compensation without further inquiry, while the latter obliges a court to evaluate "factors" such as "the regulation's economic effect on the [property-holder], the extent to which the regulation interferes with reasonable investment-backed expectations, and the character of the government action." *Id.* (citing *Penn Cent.*, 438 U.S. at 124).

Laws that compel the publication of trade secrets are properly considered "categorical" takings. For one thing, such laws "deprive [the] owner of *all* economically beneficial use of her property." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 538 (2005) (brackets and quotation marks omitted). As the Court has explained, "total deprivation of beneficial use is, from the [owner's] point of view, the equivalent of a physical appropriation." *Lucas*, 505 U.S. at 1017.

Moreover, the publication of trade secrets, like the invasion of real property, "eviscerates the owner's right to exclude others from … using her property—perhaps the most fundamental of all property interests." *Lingle*, 544 U.S. at 539; *see Kaiser Aetna v. United States*, 444 U.S. 164, 179-80 (1979) ("[T]he 'right to exclude,' so universally held to be a fundamental element of the property right, falls within this category of interests that the Government cannot take without compensation."). For both types of property—trade secrets and land—the value "is inextricably tied to both the demand of others for access and the legal enforceability of the owner's right to exclude." *Reilly*, 312 F.3d at 51 (Selya, J., concurring). There is accordingly "no principled reason to refrain from extending per se takings analysis to alleged takings of trade secrets." *Id.*; *see Nixon v. United States*, 978 F.2d 1269, 1284 (D.C. Cir. 1992) (rejecting attempt to exclude personal property from "the *per se* takings doctrine").

The Public-Interest Exception constitutes a taking under this categorical analysis. Like every other state, Oregon protects trade secrets, investing their owners with property rights enforceable through civil litigation. *See* Oregon Uniform Trade Secrets Act, ORS

§ 646.461 to .475; *cf.* § 307.020(1)(a)(I) (deeming "[t]rade secrets," for purposes of Oregon tax law, as a form of "[i]ntangible personal property"). HB 4005 uses a nearly identical definition of "trade secret." *Compare* § 646.461(4) (Oregon Uniform Trade Secrets Act), *with* § 192.345(2) (HB 4005). Both definitions apply to a wide variety of confidential business information that [1] "is known only to certain individuals," [2] has "actual or potential commercial value," and [3] affords its possessor "a business advantage over competitors who do not know or use it." § 192.345(2). Any data that qualifies as a trade secret under HB 4005, as a matter of law, is also a trade-secret under Oregon property law.

Since the Public-Interest Exception applies *only* to drug manufacturers' "trade secret[s]," § 646A.689(10)(a)(A), the exception will result in disclosure of a trade secret—otherwise protected under state law—every time DCBS invokes it. Put another way: The *only* information the State can publish under the Public-Interest Exception are trade secrets. That means it effects a categorical taking, since invocation of the provision necessarily destroys the secret's value completely. The State agrees that "if one defines the relevant property

here solely as the trade secret disclosed under the public-interest exception, then disclosure under that law destroys the entire value of the relevant property." AOB 52-53.

The State nevertheless argues that the "denominator parcel" here (*i.e.*, the property subject to the taking) is *not* the "trade secret being disclosed," but instead will vary depending on the particular pharmaceutical "product" to which the secret relates. AOB 54. But that argument is inconsistent with how courts assess trade-secret takings claims. In *Ruckelshaus*, for instance, the Supreme Court based its assessment on "Monsanto's property interest *in the trade secrets*" themselves—that is, in the "data submitted by Monsanto to the agency," which "constituted trade secrets under Missouri law"—without asking which particular pesticide the data described. 467 U.S. at 1012-13 (emphasis added). The Court also explained that, "[w]ith respect to a trade secret, the right to exclude others is central to the very definition of the property interest," again defining the property right in terms of the valuable secret. *Id.* at 1011. In *Reilly*, the First Circuit similarly treated the companies' "right to exclude others from their trade secrets" as *defining* the relevant right, such that disclosure

under the challenged law would cause "[manufacturers'] trade secrets [to] lose all value" and "their property right will be extinguished." 312 F.3d at 41-42. The same is true here.

The State also argues "the economic impact of disclosing any one piece of trade secret information may well be minimal when compared to the entire parcel of information necessary to derive any value from that information." AOB 56. But as noted, the "value" of secrecy is built into the very definition of the trade secret. ORS § 192.345(2). And *all* of that value is destroyed by publication, even if the manufacturer possesses other property (such as patent rights in the drug) that might affect the magnitude of the destruction. Thus, as the district court explained, the relative value of the secret is irrelevant: "[T]he trade secret that is revealed may not be the pharmaceutical company's most valuable secret, but it is nonetheless information that gains value through being generally unknown to the public. Disclosure necessarily destroys all of that value." E.R.-15.

3. Even if forced disclosure were merely a "regulatory" taking, it would *still* constitute a taking on its face.

In *Ruckelshaus*, the Supreme Court recited the familiar *Penn Central* factors, but ultimately focused only on one of them—the effect on manufacturers' investment-backed expectations—because "the force of this factor [was] so overwhelming." 467 U.S. at 1005. "Once the data that constitute a trade secret are disclosed to others," the Court explained, "the holder of the trade secret has lost his property interest in the data." *Id.* at 1011. In other words, because operation of the law led to the complete destruction of the property's value, the law on its face effected a taking. The Court accordingly held that Monsanto's data, if it qualified for trade-secret protection under state law, could not be published without compensation. *Id.* at 1013; *see Reilly*, 312 F.3d at 51 (Selya, J., concurring) (recognizing that *Ruckelshaus* established a categorial rule).

Here, the district court correctly determined that HB 4005's Public-Interest Exception effects a taking of private property "in all applications," just like in *Ruckelshaus* and *Reilly*. E.R.-13. As in those cases, publication here means the destruction of *all* "investment-backed expectations"—a "factor" that is "so overwhelming" as to render unnecessary any further inquiry. *Ruckelshaus*, 467 U.S. at

1005; *see Reilly*, 312 F.3d at 42 ("The Disclosure Act essentially destroys the tobacco companies' trade secrets."); *see also Hodel v. Va. Surface Mining & Reclamation Ass'n.* 452 U.S. 264, 295-96 (1981) ("The test to be applied in considering this facial challenge is fairly straightforward. A statute regulating the uses that can be made of property effects a taking if it denies an owner economically viable use of his [property].") (quotation marks omitted). Indeed, the taking here is even more aggressive than in those cases, where the statutes did not expressly strip legal protection from the information, and the government was permitted but not required to disclose it. *Ruckelshaus*, 467 U.S. at 992; *Reilly*, 312 F.3d at 29.

Nevertheless, consideration of the other two *Penn Central* factors only reinforces the conclusion that HB 4005 takes manufacturers' property. The "character of the governmental action" at issue here weighs heavily against its constitutionality. *Penn Central*, 438 U.S. at 124. Disclosure of trade secrets under the Public-Interest Exception is "not a mere 'consequential incidence' of a valid regulatory measure," *Armstrong v. United States*, 364 U.S. 40, 48 (1960), but in fact the exception's *sole* purpose and effect: to make

manufacturers' information available for "public use," U.S. Const., amend V. Thus, as the Supreme Court said in *Armstrong* of liens destroyed by the government, prior to the law's operation, property-holders "admittedly had compensable property. Immediately afterwards, they had none. This was not because their property vanished into thin air. It was because the Government for its own advantage destroyed the value of the [property]." 364 U.S. at 48.[12]

Eliminating trade-secret protection for manufacturers' confidential information will have a profound "economic impact," *Penn Central*, 438 U.S. at 124, not only on manufacturers subject to the disclosure requirements, but also on the national prescription-drug market. HB 4005 spans a wide array of sensitive business data, including: production, marketing, and distribution costs; pricing data; and sales revenue and profit data. ORS § 646A.689(3). These are some of businesses' most-sensitive data—used by manufacturers to make

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[12] The State argues that "assessing the nature-of-the-action factor here is difficult because the Public-Interest Exception does not permit disclosure absent a determination that such disclosure is affirmatively in the public interest." AOB 51. But the fact that a taking is for "public use" is the *starting point* for the takings analysis; if *not* for public use, the taking would be prohibited altogether.

strategic choices about how to recoup multi-billion-dollar investments. Courts uniformly recognize the value of this type of information. *See, e.g.*, *Nike, Inc. v. McCarthy*, 285 F. Supp. 2d 1242, 1245 (D. Or. 2003) ("confidential marketing and product information"), *aff'd*, 379 F.3d 576 (9th Cir. 2004); *IKON Office Sols., Inc. v. Am. Office Prods., Inc.*, 178 F. Supp. 2d 1154, 1169–70 (D. Or. 2001) ("pricing information and marketing strategy"); *Pelican Bay Forest Prods., Inc. v. W. Timber Prods., Inc.*, 443 P.3d 651, 658 (Or. Ct. App. 2019) ("customer information"). HB 4005 thus requires manufacturers to give their competitors an unprecedented window into their internal decision-making.

Loss of trade-secret protection could also put manufacturers at a disadvantage vis-à-vis "purchasers, both public and private, as well as pharmacy benefit managers," when "negotiat[ing] discounts and rebates for prescription drugs." HB 4005, preamble. Indeed, that was the point: HB 4005 expressly states that the purpose of forcing disclosure is to favor purchasers at the expense of manufacturers. *See id.* Whatever the merits of that goal, the State may not achieve it by "forcing [manufacturers] alone to bear [the] public burden." *First*

English Evangelical Lutheran Church v. L.A. Cnty., 482 U.S. 304, 318-19 (1987) (citation omitted). And all of these adverse effects extend well beyond Oregon. For trade secrets, public disclosure anywhere means disclosure everywhere. The Public Interest Exception thus nullifies manufacturers' rights under the property laws of all 50 States.

4. The State's contrary arguments lack merit. The State argues that PhRMA's members have no investment-backed expectations in the confidentiality of their trade secrets because they now have "notice" that their information is subject to the Public-Interest Exception, so their "voluntarily reporting such information will destroy any reasonable expectation of confidentiality." AOB 57. The district court explained why that argument fails: PhRMA's members "did not voluntarily hand over this information—in fact they disclosed under protest—they are entitled to that expectation despite knowing of the public-interest exception." E.R.-16.[13]

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[13] The State argues that manufacturers have been "on notice that *all* information submitted to the state has since 1987 been subject to a public-records law that also allowed disclosure of trade secrets when (continued . . .)

The State relies on *Ruckelshaus* to argue that a disclosure made to the government "without any express promise of confidentiality" is treated as voluntary. AOB 59. But *Ruckelshaus* said no such thing. Instead, *Ruckelshaus* said that Congress could require disclosure as a condition of obtaining a pesticide registration; the Court thus "found merely that the Takings Clause was not violated by giving effect to the Government's announcement that application for '*the right to* [*the*] *valuable Government benefit*' of obtaining registration of an insecticide." *Nollan*, 483 U.S. at 833 n.2 (quoting *Ruckelshaus*, 467 U.S. at 1007) (citation omitted).[14] But "allowing a manufacturer to simply sell its legal product" is *not* a "valuable government benefit" comparable to regulatory permit under "the complex regulatory scheme in *Monsanto*." *Reilly*, 312 F.3d at 47; *see id.* ("Massachusetts

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required by the public interest." AOB 59. But prior to HB 4005's enactment, manufacturers' trade secrets were protected by the Oregon Uniform Trade Secrets Act, which contains no public-interest exception. The State does not identify *any* manufacturer trade secrets *ever* disclosed under the public-records law prior to HB 4005.

[14] In *Ladd v. Law & Tech. Press*, 762 F.2d 809, 813 (9th Cir. 1985), this Court held that a copyright applicant could be required to give the government copies of the copyrighted work in order to "avail itself of the benefit" of copyright exclusivity. No comparable benefit exists here.

cannot condition the right to sell tobacco on the forfeiture of any constitutional protections the appellees have to their trade secrets."). The compelled disclosure under the Public-Interest Exception therefore "cannot be regarded as establishing the voluntary exchange that [the Supreme Court] found to have occurred in *Monsanto*." *Nollan*, 483 U.S. at 833 n.2 (citation omitted).[15]

Nor can the State nullify manufacturers' trade secrets on the ground that manufacturers participate in a "highly regulated industry 'that has long been the source of public concern and the subject of government regulation.'" AOB 60 (quoting *Ruckelshaus*, 467 U.S. at 1007). In *Ruckelshaus*, "Monsanto [did] not challenge[] the ability of the Federal Government to regulate the marketing and use of pesticides." 467 U.S. at 1007. Nor could it: The federal government had long treated "the ability to market pesticides in this country" as a

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[15] Justice Brennan's *Nollan* dissent echoes the State's argument here that the government can, by changing the law, "destroy [a property-owner's] reasonable expectation" about the scope of its property right. AOB 57; *see* 483 U.S. at 857-60. The majority expressly rejected this "peculiar proposition that a unilateral claim of entitlement by the government can alter property rights." 483 U.S. at 833 n.2.

discretionary "benefit." *Id.* The State has no comparable authority to forbid the sale of pharmaceutical products altogether.

Moreover, most PhRMA members do *not* sell their products directly within Oregon, yet HB 4005 applies to anyone who "manufactures a prescription drug that *is sold* in this state." ORS § 646A.689(1)(e) (emphasis added). As a result, even out-of-state sales to wholesalers can subject a manufacturer to the law's requirements, if those products are eventually resold in Oregon. A manufacturer would thus have to refrain from doing business *nationwide* to ensure that it was not subject to the Public-Interest Exception.

Finally, the result does not change even if the particular trade secret disclosed by DCBS "is not of significant economic value." AOB 55. As the district court explained, regardless of whether "the trade secret that is revealed [is] the pharmaceutical company's most valuable secret," its "[d]isclosure necessarily destroys that value" entirely. E.R.-15; *see Hodel*, 481 U.S. at 717-718 (finding regulatory taking of property interests ranging from $100 to several thousand dollars because the interests were "completely abolished").

B. PhRMA May Seek a Declaratory Remedy

Because every application of the Public-Interest Exception takes a manufacturer's trade secret, its invocation requires the State to pay just compensation. The district court's declaratory judgment says just that. E.R.-40. The State argues that PhRMA lacks standing to seek such a declaration, and that its members must first seek—and be denied—just compensation. The State's arguments run headlong into controlling precedent.

1. The Supreme Court defines "injury in fact" as the "invasion of a legally protected interest." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). A plaintiff who complains about "the government's allegedly unlawful regulation … of *someone else*" faces a "difficult" task, because the risk of injury will depend on "choices" that have yet to be made. *Id.* at 562. But where "the plaintiff is *himself* an object of the action (or forgone action) at issue … , there is ordinarily little question that the action or inaction has caused him injury." *Id.* at 561-62 (emphasis added). That is because forced compliance with "unlawful regulation" is itself legally cognizable harm. *Id.* at 562.

Here, where manufacturers are the *only* "object" of the Public-Interest Exception, the risk that their trade secrets will be disclosed is far more than merely "credible," *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979). Manufacturers have already asserted at least 10,500 trade-secret claims in reports submitted to DCBS, *Annual Report* 23, including claims from PhRMA's members, *see* C.R. 35-1 at 2. Like other cases where standing was upheld, moreover, "the State has not disavowed any intention of invoking" the challenged provision. *Babbitt*, 442 U.S. at 302; *see Italian Colors Rest. v. Becerra*, 878 F.3d 1165, 1173 (9th Cir. 2018) (upholding standing where "the Deputy Attorney General refused to stipulate that California will not enforce the statute"). To the contrary, the State has promulgated regulations *requiring* DCBS to disclose manufacturers' trade secrets whenever it deems publication to be in "[t]he public interest." OAC 836-200-0540(1)(b)(E). DCBS officials have similarly stated the agency is "*required* to post that information on its website" upon determining that doing so would be in the public interest. E.R.-

138 (emphasis added). There is thus a "very real threat of destructive disclosure" under the law. E.R.-17.[16]

The State relies on *Guggenheim v. City of Goleta*, 638 F.3d 1111, 1119 (9th Cir.2010), to argue that a facial takings challenge is inappropriate unless "the very enactment of the statute has reduced the value of the property or has effected a transfer of a property interest." AOB 45 (quoting 638 F.3d at 1119). *Guggenheim* upheld standing for trailer-park owners challenging rent-control ordinances because "[t]hey owned the land" when the ordinances were adopted. 638 F.3d at 1116. But the Court did not say that *only* property-owners whose property has already been transferred have standing; otherwise, pre-enforcement challenges (like the one at issue in *Reilly*, 312 F.3d at 29) would be impossible. Regardless, here, manufacturers owned their trade secrets when HB 4005 was enacted (and still do).

More generally, the State misconstrues *Guggenheim*, in which the property owners' facial challenge to two 2002 rent-control

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[16] When counsel for the State argued that any harm from the Public-Interest Exception was speculative because there had been "no instance" in which DCBS had invoked it, the district court asked "whether that fact is influenced by the pendency of this litigation." E.R.-80. Counsel responded: "I think it's possible." *Id.*

ordinances failed for reasons inapplicable here. Even though they "owned the mobile home park … during, before, and after adoption of" several different rent-control ordinances, they "d[id] not make" a challenge to the earliest ones (adopted in 1979 and 1987), despite the fact that the 2002 ordinances merely carried the prior regime forward. *Guggenheim*, 638 F.3d at 1119. That was fatal to their claim, "because the government action [t]here [wa]s a continuation of an old ordinance," about which they could have no "investment-backed expectations." *Id.* at 1120 (quotation marks omitted); *see id.* (calling this "the 'primary' factor"). In addition, because the challenged rent-control ordinances reduced the value of their property only partially, the property owners solely raised a regulatory challenge to "be evaluated under *Penn Central*." *Id.* at 1118. Here, by contrast, PhRMA challenged the Public-Interest Exception promptly; and the law takes *all* of the value of its members' trade secrets.

For similar reasons, it matters not that the harm of publication is "contingent" on a manufacturer reporting a trade secret to DCBS, and on DCBS "determin[ing] that disclosure is in the public interest." AOB 45. That argument "misunderstands how courts analyze facial

challenges." *City of Los Angeles v. Patel*, 576 U.S. 409, 418 (2015). For such a challenge, courts "consider only applications of the statute in which it actually authorizes or prohibits conduct," to see whether all such applications have the same constitutional infirmity. *Id.* Here, "every time it is invoked," the Public-Interest Exception results in the complete destruction of a trade secret. E.R.-13. Nor does the State identify any question about the law's operation rendering a facial challenge inappropriate.

2. The State argues that "equitable relief is generally unavailable" for a taking, AOB 62 (quoting *Knick v. Twp. Of Scott*, 588 U.S. 180, 201 (2019)) (emphasis omitted), and that a property-holder must attempt and fail to obtain just compensation before there is a violation of the Takings Clause. AOB 61-62. The State also argues that since "the amount of damages" will vary in any particular case, it was inappropriate for the district court to issue a "prospective declaratory judgment." AOB 64. As the court explained, however, that argument misconstrues "recent Supreme Court decisions." E.R.-11.

In *Knick*, the Supreme Court explained that "requests for injunctive relief" to *prevent* a taking are generally inappropriate where

"compensation is subsequently available." 588 U.S. at 198. That is because the Takings Clause does not *forbid* the government from taking private property; it just forbids takings "without just compensation." *Id.* at 199. "Given the availability of post-taking compensation, barring the government from acting will not ordinarily be appropriate." *Id.* at 202.

At the same time, the Court rejected the view that "there can be no uncompensated taking, and thus no Fifth Amendment claim actionable under § 1983, until the property owner has tried and failed to obtain compensation through [an] available state procedure." *Id.* at 194. Even if "later payment of compensation" may "remedy" a violation of the Takings Clause, the violation itself "occur[s] at the time of the taking." *Id.* at 193. When the government takes property without simultaneously paying just compensation, therefore, the "property owner may bring a Fifth Amendment claim under § 1983 at that time." *Id.* at 202.

Recognizing that uncompensated takings violate the Constitution, the Court explained, "simply allow[s] into federal court takings claims that otherwise would have been brought as inverse

condemnation suits in state court." *Id.* at 204. The Court thus remanded the plaintiff's request for declaratory relief. *Id.* at 206. Following *Knick*, the Supreme Court has granted declaratory relief to property-holders who have alleged uncompensated takings. *See Cedar Point Nursery v. Hassid*, 594 U.S. 139, 162 (2021) (declaring that an "access regulation grant[ing] labor organizations a right to invade [plaintiffs'] property … constitutes a *per se* physical taking"); *see also Pakdel v. City & Cnty. of San Francisco*, 594 U.S. 474, 479 (2021) (per curiam) ("Once the government is committed to a position" on the scope of a challenged law, "the dispute is ripe for judicial resolution.").

These cases foreclose the State's argument. Even assuming that PhRMA members would be able to seek after-the-fact compensation for the destruction of their trade secrets, "the violation is complete" if the government authorizes a taking without providing for compensation at the same time. *Knick*, 588 U.S. at 202. And that is precisely what the Public-Interest Exception does. The possibility that future litigation might be necessary to determine the *amount* of compensation for a disclosure is accordingly no reason to deny manufacturers a remedy on a fully ripe claim. *See id.* The district court

was therefore correct to declare that the State may not invoke the Public-Interest Exception to destroy manufacturers' trade secrets without contemporaneously providing adequate compensation.[17]

3. The State argues that the district court "*appeared to view* [its] prospective declaration about future government action to be *akin to injunctive relief*." AOB 61-62 (emphases added). That simply mischaracterizes the judgment. On PhRMA's takings claim, the court *solely* granted declaratory relief: It "DECLARE[D] that the publication of a manufacturer's trade secrets under the Public Interest Exception … constitutes a taking of private property," such that "any invocation of the Public Interest Exception by [the State] without simultaneously providing just compensation for that taking would accordingly violate the Fifth Amendment." E.R.-40. That declaration, which does not forbid DCBS from invoking the exception, was proper. The State cannot overturn a judgment properly limited to declaratory relief by

[17] The State never actually represents that adequate processes exist to compensate manufacturers whose trade secrets are published under the Public-Interest Exception.

falsely accusing the court that issued it of harboring unstated intentions to grant injunctive relief.

CONCLUSION

The district court's judgment should be affirmed.

Dated: September 4, 2024

Respectfully Submitted,

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DATED: September 4, 2024.

/s/ *Allon Kedem*
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CERTIFICATE OF SERVICE

On September 4, 2024, I caused the foregoing opposition to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate ACMS/ECF system. Participants in the case who are registered ACMS/ECF users will be served by the appellate ACMS/ECF system.

DATED: September 4, 2024.

/s/ *Allon Kedem*
ALLON KEDEM

STATUTORY ADDENDUM

Stautory Addendum

Amendment I to the United States Constitution provides:

> Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Amendment V to the United States Constitution provides:

> No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Oregon Revised Statutes § 646A.689 (ORS § 646A.689) provides (in relevant part):

Definitions; reporting requirements concerning drug manufacturing and pricing; penalty

* * *

(2) No later than 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.

* * *

(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.

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(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.

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