IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. **ANDREW STOLFI**, in his official capacity as Director of the Oregon Department of Consumer and Business Services, Defendant.	Case No. 6:19-cv-01996-MO **OPINION**

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MOSMAN, District Judge.

The parties filed cross-motions for summary judgment. As this Court ruled at oral argument, and for the reasons to follow, Pharmaceutical Research and Manufacturers of America ("PhRMA") is entitled to summary judgment on its Takings Clause and First Amendment

claims, and neither party is entitled to summary judgment on PhRMA's Commerce Clause claim. As clarified upon the entry of declaratory judgment and in this Opinion, Oregon is entitled to summary judgment on PhRMA's Supremacy Clause claim.

BACKGROUND

In 2018 the Oregon legislature enacted a law providing for "drug-pricing transparency." House Bill 4005, codified at O.R.S. 646A.680–692 ("HB 4005"). HB 4005 requires pharmaceutical manufacturers to report information about specific new prescription drugs and historical information about pricing for existing drugs to the Oregon Department of Consumer and Business Services ("DCBS").

> [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.

§ 2(2).

HB 4005 defines "price" as the wholesale acquisition cost ("WAC") as defined in 42 U.S.C. § 1395w-3a(c)(6)(B). That section, in turn, provides,

> The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

42 U.S.C. § 1395w-3a(c)(6)(B).

For each prescription drug described in subsection 2, a manufacturer must report 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 described in subsection (2)(b) of this section; and

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

§ 2(3). If a manufacturer fails to comply with HB 4005's reporting requirements, it is subject to a civil penalty "not to exceed $10,000 per day of violation." § 3(2).

DCBS is required to post the manufacturers' reported information on its website unless (1) the information is a trade secret under Oregon law and (2) the public interest does not require disclosure. § 2(10). The parties refer to this as the "public-interest exception."

According to Cassandra Soucy, the Drug Pricing Transparency Coordinator at DCBS, as of May 26, 2020, 1,112 reports had been filed under HB 4005. Declaration of Cassandra Soucy ("Soucy Decl."), ECF 30 ¶ 4. DCBS posted information that was not claimed as a trade secret to its website. *Id.* ¶ 5. As of May 2020, DCBS had not disclosed any information a drug manufacturer claimed as a trade secret, and manufacturers had asserted 4,865 such claims. *Id.*

As of August 2020, DCBS had not made a final decision about whether any trade secrets claimed by PhRMA members were trade secrets and whether the public interest would require disclosure of those trade secrets. Supplemental Declaration of Cassandra Soucy ("Supp. Soucy Decl."), ECF 39 ¶ 5.

Both parties moved for partial summary judgment. Plaintiff's Motion for Partial Summary Judgment ("Pl.'s MSJ"), ECF 25; Defendant's Combined Motion for Partial Summary Judgment and Opposition to Plaintiff's Moton for Partial Summary Judgment ("Def.'s MSJ & Opp. to Pl.'s MSJ"), ECF 29. On June 16, 2023, the parties filed a Stipulated Amendment to Complaint Removing Certain Claims Without Prejudice, ECF 60. The only claims pending are those addressed by the parties' motions for partial summary judgment. *Id.* This Court held oral argument on January 11, 2024 and ruled orally, holding that the public-interest exception violated the Takings Clause of the Fifth Amendment; the public-interest exception did not

violate the Supremacy Clause; there are disputes of fact as to whether HB 4005 violates the Commerce Clause; and HB 4005's reporting requirements violate the First Amendment. Plaintiff provided a proposed declaratory judgment, and the parties briefed their responses to that proposed judgment. This Court adopted Plaintiff's proposed declaratory judgment with a modification suggested by Oregon on the preemption claim.

LEGAL STANDARDS

A party is entitled to summary judgment if the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the burden of establishing the absence of a genuine dispute of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The court must view the evidence in the light most favorable to the non-movant and draw all reasonable inferences in the non-movant's favor. *Clicks Billiards, Inc. v. Sixshooters, Inc.*, 251 F.3d 1252, 1257 (9th Cir. 2001).

When parties file cross-motions for summary judgment, the court "evaluate[s] each motion separately, giving the nonmoving party in each instance the benefit of all reasonable inferences." *A.C.L.U. of Nev. v. City of Las Vegas*, 466 F.3d 784, 790–91 (9th Cir. 2006) (quotation marks and citation omitted). In evaluating the motions, "the court must consider each party's evidence, regardless under which motion the evidence is offered." *Las Vegas Sands, LLC v. Nehme*, 632 F.3d 526, 532 (9th Cir. 2011) (citation omitted).

DISCUSSION

Before addressing each of PhRMA's claims, two preliminary matters require discussion: standing and the standard for facial challenges.

A. Associational Standing

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies." U.S. Const., art. III, § 2. "The doctrine of standing gives meaning to these constitutional limits by identifying those disputes which are appropriately resolved through the judicial process." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014) (citation, footnote, brackets, and internal quotation marks omitted). For each claim, PhRMA needs to establish standing. *See Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) ("[A] plaintiff must demonstrate standing separately for each form of relief sought." (citations omitted)). In its Complaint, PhRMA notes that it brings this action "on behalf of itself and its members." ECF 1 ¶ 1.

PhRMA concedes that it lacks standing to bring its claims on its own behalf, but it contends it can sue in a representational capacity. An association has standing to sue on behalf of its members if (1) "its members would otherwise have standing to sue in their own right," (2) "the interests it seeks to protect are germane to the organization's purpose," and (3) "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). The second and third elements are satisfied—protecting pharmaceutical manufacturers from unconstitutional regulation is germane to PhRMA's purpose as a trade group of those manufacturers, and because PhRMA is pursuing a facial challenge, the participation of the individual members is unnecessary. As to the first element, like any Article III standing inquiry, an association must show that one of its members "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (citations omitted). For each of

PhRMA's claims, this Opinion begins by addressing whether PhRMA's members would have standing.

B. Facial Challenges

PhRMA brings facial challenges to the public-interest exception and reporting requirements of HB 4005. "A facial challenge is an attack on a statute itself as opposed to a particular application." *City of Los Angeles v. Patel*, 576 U.S. 409, 415 (2015). "[A] plaintiff can only succeed in a facial challenge by 'establish[ing] that no set of circumstances exists under which the [statute] would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449 (2008) (alteration in original) (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). Such constitutional challenges are considered the most difficult to mount successfully. *Willis v. City of Seattle*, 943 F.3d 882, 886 (9th Cir. 2019) (citation omitted).

C. Fifth Amendment Taking

HB 4005 requires PhRMA's members to submit trade secrets to DCBS, and, if DCBS determines that the disclosure of those trade secrets would benefit the public interest, it must disclose them. In PhRMA's view, this amounts to a threatened unconstitutional taking, because as soon as a trade secret is published it loses its value. Oregon responds that the public-interest exception has not yet been invoked, and Oregon has put in place procedural safeguards to ensure that pharmaceutical companies have an opportunity to be heard before a trade secret is disclosed.

1. PhRMA Has Standing to Bring Its Takings Claim

As noted at the outset, to establish standing, a plaintiff must show (1) an injury in fact, (2) a causal connection between the injury and the alleged conduct, and (3) redressability. An "injury in fact" must be "concrete and particularized" and "actual or imminent, not conjectural or

hypothetical." *Spokeo, Inc.*, 578 U.S. at 339 (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)).

Injury and Causation. "A plaintiff who challenges a statute must demonstrate a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement." *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979). When a plaintiff's course of conduct is "arguably affected with a constitutional interest" and "the injury is certainly impending," that is enough for the injury-in-fact requirement. *Id.* Trade secrets are a form of property. *See Carpenter v. United States*, 484 U.S. 19, 26 (1987); *see also Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–04 (1984). Therefore, the Fifth Amendment, applied to the states and judicial action, affords property protection for trade secrets. *See Chicago, B. & Q.R. Co. v. City of Chicago*, 166 U.S. 226 (1897). Public disclosure of a trade secret destroys its value. *See Hartley Pen Co. v. U.S. Dist. Ct.*, 287 F.2d 324, 328 (9th Cir. 1961) ("[T]he property in a trade secret is the power to make use of it to the exclusion of the world. If the world knows the process then the property disappears." (citation omitted)). If DCBS invoked the public-interest exception and posted a PhRMA member's trade secret online, then the statute would have caused the disclosure of the trade secret and uncompensated destruction of its value.

Redressability. PhRMA seeks a declaratory judgment[1] that the public-interest exception authorizes takings without just compensation, a constitutional violation. Oregon argues that this type of relief is not available for takings claims. In recent years, the Supreme Court has addressed the availability of declaratory and injunctive relief for takings claims in the context of ripeness, which this Court will address in the next subsection. For purposes of the *standing*

[1] PhRMA has abandoned any claims for injunctive relief. *See* ECF 44 at 3 ("PhRMA does not seek an injunction here.").

analysis, this Court asks whether, if granted, the relief sought would rectify the injury. That question is easily answered—yes. A declaratory judgment in PhRMA's favor would rectify the threatened injuries.

2. PhRMA's Takings Claim Is Ripe

To the extent there is a difference between constitutional standing and ripeness in the takings context,[2] it does not alter the analysis here. In pre-enforcement challenges, standing and ripeness often "boil down to the same question." *See Susan B. Anthony List*, 573 U.S. at 157 n.5. As a general matter, 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. *See Hodel v. Va. Surface Min. & Reclamation Ass'n, Inc.*, 452 U.S. 264, 295 (1981); *see also Suitum v. Tahoe Reg'l Plan. Agency*, 520 U.S. 725, 736 n.10 (1997) (explaining that a facial challenge in the takings context is usually ripe "the moment the challenged regulation or ordinance is passed").

A trio of more recent Supreme Court decisions address ripeness in takings cases. In *Knick v. Township of Scott*, the Court explained that "[a] property owner may bring a takings claim under § 1983 upon the taking of his property without just compensation by a local government." 139 S. Ct. 2162, 2179 (2019). "As long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Id.* at 2176.

[2] *See N. Mill St., LLC v. City of Aspen*, 6 F.4th 1216, 1229–30 (10th Cir. 2021) (holding that *Williamson County*'s ripeness test is prudential, not jurisdictional); *Pharm. Rsch. & Mfrs. of Am. v. Williams*, 64 F.4th 932, 950–51 (8th Cir. 2023) (Gruender, J., concurring) (concurring insofar as the majority opinion "does not decide the question of whether the availability of equitable relief implicates standing" for a takings claim); *Va. Hosp. & Healthcare Ass'n v. Kimsey*, No. 20-2176, 2022 WL 604049, at *4 & n.3 (4th Cir. Mar. 1, 2022) ("Whether the district court's grounds for dismissing the Takings and Preemption Claims were, as the court thought, Rule 12(b)(1) issues of Article III standing—or were instead Rule 12(b)(6) issues of the viability of those Claims—is a question that we acknowledge but need not resolve today.").

Two years later, the Supreme Court clarified in *Pakdel v. City & County of San Francisco* that "administrative 'exhaustion of state remedies' is not a prerequisite for a takings claim when the government has reached a conclusive position." 594 U.S. 474, 480 (2021) (per curiam). The Court reasoned that "[the finality] requirement ensures that a plaintiff has actually been injured by the Government's action and is not prematurely suing over a hypothetical harm. Along the same lines, because a plaintiff who asserts a regulatory taking must prove that the government regulation has gone too far, the court must first know how far the regulation goes. Once the government is committed to a position, however, these potential ambiguities evaporate and the dispute is ripe for judicial resolution." *Id.* at 479 (citation, brackets, and internal quotation marks omitted).

That same year, the Supreme Court decided *Cedar Point Nursery v. Hassid*, 594 U.S. 139 (2021). In that case, the plaintiff sought a preliminary injunction to prevent a physical taking, and the defendants moved to dismiss. *Id.* at 145–46. The lower courts denied the preliminary injunction motion and granted the motion to dismiss, but the Supreme Court reversed the Ninth Circuit's judgment and remanded. The Supreme Court did not explicitly address whether a preliminary injunction was appropriate or available to the plaintiff in *Cedar Point*. But at least one circuit court has viewed *Cedar Point* as a tacit endorsement of the principle that a plaintiff may have a ripe takings claim even prior to an actual physical taking occurring. *See Barber v. Charter Township of Springfield*, 31 F.4th 382, 389 (6th Cir. 2022). Given this reading of *Cedar Point*, and other guidance from the Supreme Court, the Sixth Circuit concluded that "a claim for injunctive relief is ripe if the government has reached a final decision that will enable a future physical taking." *Id.*

Here, 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. This is not a land use case in which there is some mechanism for the government to grant a variance that has not yet been finalized. Nor, on this record, is there a known mechanism for PhRMA's members to seek compensation. The law here, and how it will apply to the pharmaceutical companies, is set. PhRMA has therefore shown "*de facto* finality" sufficient for its claim to ripen. *Pakdel*, 594 U.S. at 479. This claim is ripe for review. *See Philip Morris, Inc. v. Reilly*, 267 F.3d 45, 52–54 (1st Cir. 2001), *on reh'g en banc*, 312 F.3d 24, 30 (1st Cir. 2002) (En banc "review does not include revisiting the issues of whether the tobacco companies' claims are ripe . . . .").

3. PhRMA Is Entitled to Summary Judgment on Its Takings Clause Claim

Having concluded that PhRMA's members, and so PhRMA, have standing, and the takings claim is ripe for adjudication, this Court next addresses the merits of the takings claim. Because this is a facial challenge, PhRMA must show that the public-interest exception would result in an unconstitutional taking in all applications.

Oregon argues that this claim fails because "PhRMA has not met its burden of proving that H.B. 4005 will 'take' trade secrets in *all* of its applications." Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 16. PhRMA responds that it need only prove that the *public-interest exception* will "take" trade secrets whenever invoked. Plaintiff's Reply and Opposition ("Pl.'s Reply & Opp. to Def.'s MSJ"), ECF 34 at 9–11. PhRMA's framing is correct. On this claim, it is only challenging the public-interest exception, so the question is whether the public-interest exception will amount to an unconstitutional taking every time it is invoked, not HB 4005 writ large.

In general, Supreme Court precedent distinguishes between two types of takings: physical takings and regulatory takings. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*,

535 U.S. 302, 323–24 (2002); *Reilly*, 312 F.3d at 33. The only Supreme Court case to address the appropriate categorization for a taking in the trade secret context is *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). There, the Court considered whether certain provisions of the Federal Insecticide, Fungicide, and Rodenticide Act constituted a taking. *Id.* at 990. Those provisions authorized the Environmental Protection Agency to disclose publicly some of the data submitted by companies applying for registration of pesticides. *Id.* The Court applied the regulatory takings test under *Penn Central Transportation Co. v. New York City*, 438 U.S. 104 (1978), to determine whether the statute worked a compensable taking of companies' trade secrets. *Id.* at 1004–14. Based on this precedent, this Court will analyze the public-interest exception under the regulatory takings scheme.

In *Ruckelshaus*, the Supreme Court identified several factors for courts to consider in determining whether a regulatory taking has occurred, including "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." *Id.* at 1005 (citations omitted). The following analysis addresses each of these factors in turn.

Character of the Governmental Action. In assessing the character of the governmental action, this Court considers how the government regulates and what that regulation does to the property interest—here, the pharmaceutical companies' trade secrets. *See Reilly*, 312 F.3d at 41 (citing *Hodel*, 481 U.S. at 716). This Court takes this to mean it should look at the way in which the taking fits into the regulatory scheme, and the regulatory impact on the property. The public-interest exception mandates disclosure of the companies' trade secrets when the public interest so requires. On its face, HB 4005 does not explain how DCBS determines when the public interest requires publication of a trade secret. Practically, "[t]his places an extremely low burden

on [Oregon],” *id.* at 44, which results in irrevocable individual loss. Further, “it is not at all clear that protecting the overall integrity of the [trade secrets] will interfere with [Oregon’s] goal[s].” *Id.* This factor supports finding the application of the public-interest exception to work a taking.

Economic Impact. The law regarding economic impact is fairly straightforward. The inquiry is whether the regulation “impair[s] the value or use of [the] property” according to the owners’ general use of their property. *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 83 (1980). Here, disclosure of a trade secret will destroy that trade secret’s value. To be sure, the 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. This factor favors finding that the public-interest exception works a taking.

Reasonable Investment-Backed Expectations. “Courts protect only reasonable expectations. Ideally, the relevant inquiry should recognize that not every investment deserves protection and that some investors inevitably will be disappointed.” *Reilly*, 312 F.3d at 36 (emphasis omitted). In *Ruckelshaus*, the Supreme Court focused solely on this last factor because “the force of this factor is so overwhelming, at least with respect to certain of the data submitted by Monsanto to EPA, that it disposes of the taking question regarding those data.” 467 U.S. at 1005. There, the Court made clear that, “[i]f, despite the data-consideration and data-disclosure provisions in the statute, Monsanto chose to submit the requisite data in order to receive a registration, it can hardly argue that its reasonable investment-backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission.” *Id.* at 1006–07. This result—that a company cannot claim it had a reasonable investment-backed expectation in secrecy when it submitted trade secrets to a government entity

knowing that the government may disclose those trade secrets—has been repeated in later cases. *See Reilly*, 312 F.3d at 38; *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 315 (1st Cir. 2005) (Boudin, C.J., and Dyk, J., jointly concurring and providing the controlling majority for the Takings Clause issue) ("There is no basis for forward-looking injunctive relief with respect to rebate contracts entered into after the statute's effective date.").

But in each of these cases, the entities voluntarily provided the trade secrets at issue. When that voluntariness is lacking, either because there is no quid pro quo, as there was in *Ruckelshaus*, or because disclosure is required, as in *Reilly*, then the regulatory takings factors, analyzed as a whole, point toward finding a taking or a threatened taking for purposes of a facial challenge. *See also Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 833 n.2 (1987) (explaining that in *Ruckelshaus* the Court found that the Takings Clause was not violated because trade secrets were exchanged for the right to a valuable government benefit). And here, voluntariness is lacking. PhRMA's members were simply obligated to disclose by Oregon's positive law. Thus, this Court finds that PhRMA's members have a reasonable investment-backed expectation that the state will maintain the secrecy of the information that qualifies for trade secret protection. Because the 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. Because all the factors support finding a regulatory taking, this Court finds that the exercise of the public-interest exception works a regulatory taking.

Availability of Declaratory Relief. "As long as an adequate provision for obtaining just compensation exists, there is no basis to enjoin the government's action effecting a taking." *Knick*, 139 S. Ct. at 2176. A recent case from the Eighth Circuit is instructive in interpreting what constitutes an "adequate provision" under state law. There, the court held that injunctive

and declaratory relief were available—and so, in that court's view, a takings claim was redressable—where the state's inverse condemnation procedure did not afford an adequate legal remedy. *Williams*, 64 F.4th at 946. The state law required drug manufacturers to provide insulin for free to residents who met certain criteria. *Id.* at 937. To receive just compensation for these repeated takings, manufacturers would be bound to litigate a multiplicity of suits so long as the law remained in effect, which the Eighth Circuit considered an inadequate remedy. *Id.* at 945. Relying on *Knick* and *Pakdel*, the Eighth Circuit reversed the district court's dismissal for lack of standing. *Id.* at 950.

Likewise here. Pharmaceutical companies are required to hand over trade secrets knowing that DCBS is under an obligation to disclose those trade secrets if the public interest so requires. As of May 2020, manufacturers had identified 4,865 trade secrets in their submissions to DCBS. Soucy Decl., ECF 30 ¶ 5. Unless just compensation is provided, a taking of private property for public use occurs with each mandated public disclosure. True, no such public disclosure has yet occurred. But PhRMA is left to guess whether that is due to this pending litigation or something else. In the meantime, the very real threat of destructive disclosure suffices for declaratory relief.

Even assuming some of the identified trade secrets do not qualify as such under the terms of the statute, pharmaceutical companies are still left in the same position as the plaintiffs in *Williams*: litigating a multiplicity of suits involving the same underlying takings. Oregon did not address the availability of a state compensation scheme until its reply, and it did not argue the adequacy of that scheme given these circumstances. *See* Defendant's Reply ("Def.'s Reply to

Pl.'s MSJ"), ECF 38 at 11–12.[3] "[T]he legal remedy of damages is not 'complete, practical and efficient,' because it requires a repetitive succession of inverse condemnation suits. An inverse condemnation action to reimburse a manufacturer for each discrete alleged taking is incapable of compensating the manufacturers for the repetitive, future takings that will occur under the Act's requirements. By contrast, equitable relief would protect manufacturers from those future harms." *Williams*, 64 F.4th at 945 (quoting *Terrace v. Thompson*, 263 U.S.197, 214 (1923)); *see also E. Enterprises v. Apfel*, 524 U.S. 498, 522 (1998) ("Based on the nature of the taking alleged in this case, we conclude that the declaratory judgment and injunction sought by petitioner constitute an appropriate remedy under the circumstances, and that it is within the district courts' power to award such equitable relief.").

D. Preemption

PhRMA argues that HB 4005's public-interest exception is preempted by the federal Defend Trade Secrets Act ("DTSA"), 18 U.S.C. §§ 1832–39. Oregon responds that it is not impossible to comply with both statutes, and that the public-interest exception does not frustrate the congressional purpose underlying the DTSA.

1. PhRMA Has Standing to Bring Its Preemption Claim

Because DCBS must disclose trade secrets that fall within the public-interest exception, there is the threat of possible disclosure of a trade secret, which could potentially constitute misappropriation under the DTSA. Along these same lines, misappropriation under the DTSA would impact a pharmaceutical company's property interest in its trade secret. In other words,

[3] This Court acknowledges that the briefing for this case was completed after *Knick* but before *Pakdel*. Nevertheless, Oregon did not respond to PhRMA's notice of supplemental authority addressing the Eighth Circuit's decision reversing the district court in *Williams*, *see* ECF 56, nor did it address the adequacy of the state's compensation scheme at oral argument on January 11, 2024.

the DTSA provides a civil cause of action for the loss of a trade secret, and if HB 4005 requires Oregon to disclose trade secrets despite the DTSA, then the pharmaceutical company has a concrete and particularized, though at this stage merely threatened, injury. This threatened enforcement of the public-interest exception, and concomitant injury despite a federal statute guarding against such injury, is sufficient for the injury-in-fact requirement. Likewise, there is no question that the public-interest exception would be the cause of the injury. And, according to PhRMA, severing the public-interest exception from HB 4005 would redress the injury. This Court is satisfied that PhRMA has standing to assert the preemption claim.

2. Oregon Is Entitled to Summary Judgment on the Preemption Claim

PhRMA argues that the public-interest exception is preempted by the DTSA. It relies on two types of conflict preemption. First, it argues that the disclosure mandated by the exception constitutes "misappropriation" of a trade secret under federal law, such that compliance with both statutes would be impossible. Second, it argues the public-interest exception is an obstacle to the full accomplishment of the DTSA's purposes and objectives because it nullifies the trade secrets that federal law protects. Pl.'s MSJ, ECF 25 at 22.

The DTSA authorizes the "owner of a trade secret that is misappropriated" to bring a civil action, 18 U.S.C. § 1836(b)(1), and grants the United States district courts original jurisdiction over such cases, 18 U.S.C. § 1836(c). Two provisions of the DTSA are relevant for the preemption analysis. First, the DTSA "does not prohibit or create a private right of action" in regard to "any otherwise lawful activity conducted by a governmental entity of . . . a State." 18 U.S.C. § 1833(a)(1). Second, the DTSA "shall not be construed to preempt or displace any other remedies, whether civil or criminal, provided by United States Federal, State, commonwealth, possession, or territory law for the misappropriation of a trade secret." 18 U.S.C. § 1838.

As for § 1833(a)(1), PhRMA argues that "[t]his sort of broadly worded saving clause 'does not bar the ordinary working of conflict preemption principles.'" Pl.'s MSJ, ECF 25 at 28 (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)). Instead, it goes on, "Congress typically uses such language, which is scattered throughout the U.S. Code, to indicate that federal law is not meant to 'dominate the field' exclusively." *Id.* (quoting *Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 492 (1987)). According to PhRMA, saving clauses like § 1833(a)(1) do not "override principles of conflict preemption, and the Supreme Court has repeatedly 'decline[d] to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.'" *Id.* (quoting *United States v. Locke*, 529 U.S. 89, 106 (2000)).

As for § 1838, PhRMA treats this as the linchpin of understanding the relationship between the DTSA and state-law schemes. It argues that this section shows that, "while Congress did not want to preempt trade secret *protections* provided by state law, Congress *did* want to preempt other, non-remedial forms of state law." Pl.'s MSJ, ECF 25 at 27.

There is a dearth of authority on the DTSA and its interaction with state laws. PhRMA points this Court to a situation from Nevada. There, a state law, SB 539, required drug manufactures to report information about reasons for certain price increases. Pl.'s Reply & Opp. to Def.'s MSJ, ECF 34 at 15. As here, PhRMA challenged the law, arguing that it violated the Takings Clause and the Supremacy Clause. *Id.* Nevada conceded that disclosure of trade secrets under that law would constitute 'misappropriation' for which a court may award relief pursuant to the DTSA, and it adopted regulations that prevented disclosure of trade secrets as defined by federal law. *Id.* PhRMA voluntarily dismissed its claims without prejudice.

For its part, Oregon cites a case from the District of Massachusetts, *Fast Enterprises, LLC v. Pollack*, Civil Action No. 16-CV-12149-ADB, 2018 WL 4539685 (D. Mass. Sept. 21, 2018), which involved a Massachusetts public records law. Plaintiff sued the Secretary and CEO of the Massachusetts Department of Transportation with the goal of enjoining her from disclosing its trade secrets pursuant to the public records law. The court concluded that it lacked subject matter jurisdiction. In particular, the court held that § 1833(a)(1), the saving clause, meant that a DTSA claim could not be maintained against a state performing lawful state activities.

i. Impossibility Preemption

PhRMA argues that it is impossible to comply with both the public-interest exception and the DTSA, and so the public-interest exception is preempted by federal law. Pl.'s MSJ, ECF 25 at 22–25. Federal law preempts state law when it is impossible to comply with both sets of laws. *See Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963). Impossibility preemption has been recognized as a "demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

Oregon responds that, "[i]n the speculative event that DCBS posts a PhRMA member's trade secrets online, it would not constitute misappropriation because it would only occur after the drug manufacturer was afforded robust due process to prevent disclosure pursuant to administrative rules promulgated under H.B. 4005." Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 12 (citations and emphasis omitted). This argument is unpersuasive—process alone does not keep disclosure from being misappropriation. *See* Pl.'s Reply & Opp. to Def.'s MSJ, ECF 34 at 15 ("Whatever 'process' the State chooses to undertake *before* disclosing a trade secret under the

public-interest exception, the fact remains that every such disclosure still qualifies as a misappropriation under the DTSA.").

But it is not clear that disclosure would be misappropriation under the DTSA. The DTSA defines misappropriation, in part, as disclosure of a trade secret of another without express or implied consent by a person who, at the time of disclosure, knew or had reason to know that the knowledge of the trade secret was acquired under circumstances giving rise to a duty to maintain the secrecy of the trade secret. 18 U.S.C. § 1839(5). DCBS is not under an absolute duty to maintain secrecy because HB 4005 permits disclosure in certain circumstances. Because disclosure under the public-interest exception would not constitute misappropriation under the DTSA, then it would be possible to comply with both sets of laws. Likewise, taken on its face, the saving clause in § 1833(a)(1) would prevent PhRMA's members from bringing a claim under the DTSA for the state's disclosure of its trade secrets. It is possible to comply with both statutes.

ii. Obstacle Preemption

Federal law also impliedly preempts state laws that pose an "obstacle" to the "full purposes and objectives" of Congress. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). In its obstacle preemption cases, the Supreme Court has held that state law impermissibly interferes with federal goals if it frustrates Congress's intent to adopt a uniform system of federal regulation; conflicts with Congress's goal of establishing a regulatory "ceiling" for certain products or activities; or impedes the vindication of a federal right. *See id.*; *Geier*, 529 U.S. at 875, 879; *Felder v. Casey*, 487 U.S. 131, 153 (1988).

The Supreme Court has cautioned that obstacle preemption does not justify a "freewheeling judicial inquiry" into whether state laws are "in tension" with federal objectives;

such a standard would undermine the principle that "it is Congress rather than the courts that preempts state law." *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011).

Here, the parties agree broadly that the objective of the DTSA is to provide a private cause of action and remedies for owners of trade secrets. *See* Pl.'s MSJ, ECF 25 at 27; Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 13–14. They diverge on the specifics—PhRMA sees the DTSA as promoting innovation and American jobs, whereas Oregon trains on the DTSA's focus on providing a remedy for those who have had their trade secrets stolen.

By its text, the DTSA protects against misappropriation of trade secrets—it creates a federal regime, which works in tandem with state trade secrets regimes, to ensure holders of trade secrets have recourse should their trade secrets be disclosed. And by its text, the DTSA does not appear to be intended to cabin the ability of states to impose reporting requirements. Therefore, Oregon is entitled to summary judgment on the preemption claim.

E. Dormant Commerce Clause

PhRMA argues that HB 4005 facially violates the dormant Commerce Clause because, by tying its reporting requirements to the federally defined WAC, it directly controls interstate commerce. Oregon responds that HB 4005 does not regulate or discriminate against extra-territorial commerce, and any impact HB 4005 has on out-of-state commerce is constitutionally permitted.

1. PhRMA Has Standing to Bring its Commerce Clause Claim

PhRMA has standing to assert its dormant Commerce Clause claim because, according to PhRMA, HB 4005 through its current operation is controlling commerce by imposing regulatory consequences on nationwide price changes. If PhRMA is correct, then the manufacturers are being regulated by an unconstitutional statute, and such regulation is a legally cognizable harm that a declaratory judgment can remedy. *See Lujan*, 504 U.S. at 562.

2. Neither Party Is Entitled to Summary Judgment on the Commerce Clause Claim

"The Constitution vests Congress with the power to 'regulate Commerce . . . among the several States.'" *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 368 (2023) (ellipsis in original) (quoting U.S. Const., art. I, § 8, cl. 3). The Supreme Court has held that the Commerce Clause "also 'contain[s] a further, negative command,' one effectively forbidding the enforcement of 'certain state [economic regulations] even when Congress has failed to legislate on the subject.'" *Id.* (alterations in original) (quoting *Okla. Tax Comm'n v. Jefferson Lines, Inc.*, 514 U.S. 175, 179 (1995)).

It is useful to note what PhRMA is *not* arguing. PhRMA does not argue that HB 4005 discriminates against out-of-state economic interests. *See* Pl.'s Reply & Opp. to Def.'s MSJ, ECF 34 at 22. PhRMA does not argue that HB 4005 has the practical effect of controlling commerce outside of Oregon. Pl.'s Resp. to Def.'s Notice of Suppl. Authority, ECF 58 at 1 ("PhRMA does not contend that the Disclosure Law has the practical effect of controlling out-of-state commerce." (emphasis omitted)). Instead, PhRMA argues that HB 4005 directly "controls commerce in all 50 States by imposing regulatory consequences on nationwide price moves" and that this "violate[s] the Commerce Clause per se." Pl.'s MSJ, ECF 25 at 31 (alteration in original) (quoting *Nat'l Collegiate Athletic Ass'n v. Miller*, 10 F.3d 633, 638 (9th Cir. 1993)).

This argument is similar to that made by PhRMA in *PhRMA v. David*. *See* ECF 43. There, SB 17, a California law, tied disclosure requirements for pharmaceutical manufacturers to the WAC, similar to HB 4005. In particular, SB 17 required the manufacturer of a prescription drug to notify certain purchasers at least 60 days before increasing the drug's federally defined WAC if (1) a course of therapy has a WAC of more than $40, and (2) the proposed increase would result in a cumulative increase of 16 percent or more over the two calendar years before the current year. Manufacturers were required to provide the date and amount of the planned

increase, as well as a statement as to whether a change or improvement in the drug necessitated the price increase and describing the change, if one occurred. PhRMA argued that SB 17 directly regulated commerce by tying state reporting requirements to the federally defined WAC.

The district court held that PhRMA was not entitled to summary judgment. It reasoned, "PhRMA relies on a general proposition that because the WAC is federally defined and must be uniform nationwide, SB 17 directly regulates out-of-state drug prices. However, this alone does not render SB 17 unconstitutional. There are genuine disputes of material fact as to whether providing advance notice of certain increases in a prescription drug's WAC results in either direct or extraterritorial regulation." *Pharm. Rsch. & Mfrs. of Am. v. David*, 510 F. Supp. 3d 891, 900 (E.D. Cal. 2021), *aff'd and remanded sub nom. Pharm. Rsch. & Mfrs. of Am. v. Landsberg*, No. 21-16312, 2022 WL 2915588 (9th Cir. July 25, 2022).

The Ninth Circuit affirmed:

> The district court correctly determined that "PhRMA claims SB 17 directly impacts out-of-state drug prices but what that impact may actually be remains unclear." While PhRMA argues that the advance notice provision freezes drug prices nationwide, WAC is a nationwide list price set by manufacturers for each drug that does not reflect the final transaction price. In its opposition to summary judgment, California presented expert testimony that changes in WAC are not directly tied to changes in a drug's final transaction price. Additionally, while PhRMA correctly notes that WAC is sometimes used in negotiations of drug prices in federal Medicare reimbursement and state Medicaid reimbursement programs, California's experts explained that the frequency of WAC's use in these reimbursement formulas and WAC's precise effects in calculating reimbursement amounts remains unclear. With regard to private contractual negotiations, the district court correctly found that PhRMA provides no "explanation or examples as to how these market transactions will be impacted, especially since such contracts involve negotiations on a wide array of factors, including rebates and discounts." And PhRMA fails to identify a single party unable to increase the WAC on a pharmaceutical drug due to SB 17's advance notice requirement.

Landsberg, 2022 WL 2915588, at *1. After the Ninth Circuit affirmed, PhRMA stipulated to dismissal with prejudice.

PhRMA argues that the district court's Commerce Clause conclusion rested on a factually and legally incorrect distinction between its case and *NCAA v. Miller*, 10 F.3d 633 (9th Cir. 1993). ECF 44. PhRMA continues to rely heavily on *NCAA v. Miller* for its dormant Commerce Clause argument.

NCAA v. Miller dealt with a Nevada statute that "require[d] any national collegiate athletic association to provide a Nevada institution, employee, student-athlete, or booster who is accused of a rules infraction with certain procedural due process protections during an enforcement proceeding in which sanctions may be imposed." 10 F.3d at 637 (footnotes omitted). Many of these procedures were not required by the NCAA's own enforcement program, and the statute allowed a Nevada state district court to enjoin any NCAA proceeding that violated the statute. *Id.* The statute also prohibited the NCAA from expelling its Nevada members. *Id.*

Individuals from the University of Nevada, Las Vegas ("UNLV"), who were charged with NCAA rules violations, asserted their right to have the proceedings comply with the Nevada statute. *Id.* The NCAA then sought declaratory and injunctive relief in federal court, arguing that the statute violated the Commerce Clause and the Contracts Clause. *Id.* "The district court found that the Statute violate[d] both the Commerce Clause and the Contracts Clause and enjoined its application to the NCAA's proceeding . . . ." *Id.*

On appeal, the Ninth Circuit agreed with the district court's conclusion but not its reasoning. The Ninth Circuit held that the statute violated the Commerce Clause per se because it directly regulated interstate commerce. *Id.* at 638. The statute "regulate[d] only interstate

organizations which are engaged in interstate commerce." *Id.* "In order to avoid liability . . . , the NCAA would [have been] forced to adopt Nevada's procedural rules for Nevada schools" for enforcement proceedings throughout the country. *Id.* The Ninth Circuit further noted that the statute's "extraterritorial reach also violate[d] the Commerce Clause because of its potential interaction or conflict with similar statutes in other jurisdictions." *Id.* "The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.* (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)).

Given the information available at this stage, this Court cannot determine the practical effect of HB 4005 on interstate commerce. Hypothetically, if a pharmaceutical manufacturer feared changing the WAC because of the Oregon reporting requirements, then Oregon could "control" out-of-state commerce. But *NCAA v. Miller* is not so on-point as to resolve the question as a matter of law. In *NCAA v. Miller*, Nevada was forcing organizations to institute certain procedural protections whenever it instituted a proceeding involving someone from Nevada. Given the nature of the NCAA's relationship with its member institutions, they would have been unlikely to grant UNLV such a special status, with its attendant competitive advantages. It was not far-fetched to assume that the Nevada statute would destroy the NCAA.[4] Here, Oregon is forcing companies to provide information whenever an essentially interstate figure increases. The companies can *do* whatever they choose, but there is a chance they must *tell* Oregon. *Compare Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664, 672–73, 675 (4th Cir. 2018) (striking down a Maryland price gouging law as violating the dormant Commerce

[4] It is worth noting that at the time of the Nevada litigation, UNLV was competing in men's basketball at the highest level, and won a national championship in 1990. This all happened under Coach Jerry "Tark the Shark" Tarkanian and amidst several NCAA investigations.

Clause because it "instruct[ed] prescription drug manufacturers that they are prohibited from charging an 'unconscionable' price in the initial sale of a drug, which occurs outside [the state's] borders"). But this record does not establish anything like the extraterritorial impact at issue in *NCAA v. Miller*.[5]

This Court's prior ruling on the Takings Clause claim also bears on this analysis. If pharmaceutical companies were forced to choose between handing over trade secrets with no assurance as to compensation and avoiding the Oregon market, then that Hobson's choice could bring HB 4005 more in line with the regulations in *NCAA v. Miller*. However, without that provision, this Court cannot conclude as a matter of law that HB 4005 violates the Commerce Clause. Having to report to Oregon could result in companies making different choices in other states, but PhRMA has not provided evidence of that result. Likewise, because the effect of HB 4005 is not known, Oregon is also not entitled to judgment as a matter of law.

F. First Amendment

At the outset, this Court notes that the parties assume that HB 4005's reporting requirements[6] regulate speech protected by the First Amendment. *See* Def.'s MSJ & Opp. to

[5] Because this Court finds that *NCAA v. Miller* does not control the outcome of this issue, it does not address whether *NCAA v. Miller* remains good law in light of *National Pork Producers*.

[6] In the briefing on the proposed declaratory judgment, Oregon suggested that PhRMA's First Amendment arguments reached only HB 4005 § 2(3)(c), which requires pharmaceutical companies to explain the factors that contributed to a price increase. *See* ECF 75. Oregon asked this Court to sever only that subsection from the statute. *Id.* Because Oregon did not raise this severability argument in its briefs or at oral argument, this Court declined to enter its proposed judgment and declines to address these arguments in this Opinion. *See Comite de Jornaleros de Redondo Beach v. City of Redondo Beach*, 657 F.3d 936, 951 n.10 (9th Cir. 2011) (en banc) (facial attack under the First Amendment) ("Because the City has waived any argument regarding severability by failing to raise it in its briefs or at oral argument, we do not consider it here." (citations omitted)).

Pl.'s MSJ, ECF 29 at 19–27. PhRMA argues that strict scrutiny applies because HB 4005 regulates private speech, and that the reporting requirements do not satisfy strict scrutiny. PhRMA further argues that even under rational basis review, the reporting requirements are facially unconstitutional. Oregon responds that the reporting requirements are subject only to rational basis review because they compel disclosure of commercial speech, and that the reporting requirements satisfy that level of scrutiny.

1. PhRMA Has Standing to Bring Its First Amendment Claim

PhRMA has standing to assert its First Amendment claim. PhRMA alleges that HB 4005's reporting requirements infringe on its members' First Amendment right to free speech by "compelling manufacturers—and only manufacturers—to speak." Pl.'s MSJ, ECF 25 at 31–38. Forced compliance with an "unlawful regulation" is itself a legally cognizable harm, which the court can remedy by declaring the regulation invalid. *Lujan*, 504 U.S. at 562. In other words, the injury is being forced to speak and, according to PhRMA, endorse Oregon's messaging, while other entities are not. HB 4005's reporting requirements cause that injury, and a decision that those requirements violate the First Amendment would redress the injury.

2. PhRMA Is Entitled to Summary Judgment on Its First Amendment Claim

The First Amendment imposes stringent limits on the government's authority either to restrict or compel speech by private citizens and organizations. *See Texas v. Johnson*, 491 U.S. 397 (1989); *Wooley v. Maynard*, 430 U.S. 705 (1977); *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943). To succeed on a facial challenge under the First Amendment, PhRMA must show that a "substantial number of [HB 4005's] applications are unconstitutional, judged in relation to [its] plainly legitimate sweep." *See Wash. State Grange*, 552 U.S. at 449 n.6 (citation and internal quotation marks omitted).

a. HB 4005's Reporting Requirements Regulate Commercial Speech

The parties disagree about the type of speech HB 4005 regulates. PhRMA argues that HB 4005 regulates companies' private speech, not commercial speech. Oregon responds that manufacturers need only disclose commercial speech. As explained below, this Court concludes that HB 4005's reporting requirements regulate commercial speech.

PhRMA provides a string of cases standing for the proposition that commercial speech is defined as "speech that does no more than pose a commercial transaction." Pl.'s Reply & Opp. to Def.'s MSJ, ECF 34 at 28 (citation omitted). According to PhRMA, because the disclosures required under HB 4005 do not pose a commercial transaction, the speech is not commercial. But a recent Ninth Circuit case, *Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107 (9th Cir. 2021), complicates the analysis. There, the Ninth Circuit explained that while commercial speech is usually defined, as PhRMA suggests, as speech that does no more than propose a commercial transaction, this definition is "just a starting point" and courts should "try to give effect to a common-sense distinction between commercial speech and other varieties of speech." *Id.* (citations and internal quotation marks omitted). In the Ninth Circuit, the "commercial speech analysis is fact-driven, due to the inherent difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category." *Id.* (quoting *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1272 (9th Cir. 2017)).

"[S]peech that does not propose a commercial transaction on its face can still be commercial speech." *Id.* (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66–68 (1983)). "Where the facts present a close question, 'strong support' that the speech should be characterized as commercial speech is found where [1] the speech is an advertisement, [2] the speech refers to a particular product, and [3] the speaker has an economic motivation." *Hunt v. City of Los Angeles*, 638 F.3d 703, 715 (9th Cir. 2011) (citations omitted). These are the "*Bolger*

factors." *Id.* "These so-called *Bolger* factors are important guideposts, but they are not dispositive." *Ariix, LLC*, 985 F.3d at 1116 (citations omitted).

Here, the speech is not an advertisement—the pharmaceutical companies are not trying to sell drugs through the HB 4005 disclosures. But the speech does refer to a particular product in that it centers on the drugs for which the disclosures are required. As for the third *Bolger* factor, the Ninth Circuit has explained that it "asks whether the speaker acted *primarily* out of economic motivation, not simply whether the speaker had any economic motivation." *Ariix, LLC*, 985 F.3d at 1116. "[E]conomic motivation is not limited simply to the expectation of a direct commercial transaction with consumers. Courts have found commercial speech even when it involves indirect benefits, such as benefits to employee compensation, improvements to a brand's image, general exposure of a product, and protection of licensees' interests. Importantly, the type of economic motivation is not the focus; rather, the crux is on whether the speaker had an adequate economic motivation so that the economic benefit was the primary purpose for speaking." *Id.* at 1117 (citations and footnote omitted). "[T]he question is context-specific and requires determining whether the speaker's purpose primarily turns on the economic benefit that the speaker receives from the speech." *Id.* at 1117 n.7.

Applying the *Bolger* factors, whether HB 4005 regulates commercial or private speech is a close question. The disclosure requirements are triggered by price changes and introductions of products to the market, and the content of the disclosures relates to costs and pricing. HB 4005 at its core deals with the economics of prescription pricing. The pharmaceutical companies are acting out of an economic motivation in that they are compelled to provide that economic information in order to participate in the market. But recognizing the option to participate in a market as an economic motivation for purposes of categorizing speech could result in state laws

that regulate all sorts of information receiving a lower level of scrutiny by virtue of being merely associated with a market.

Taking at face value *Ariix*'s instructions that neither the proposing-a-transaction test nor the *Bolger* factors are dispositive and that courts should "try to give effect to a common-sense distinction between commercial speech and other varieties of speech," 985 F.3d at 1115–16, this Court takes a wholistic approach to disclosures under HB 4005. Viewing the context of the disclosures as a whole, the speech at issue here is best categorized as commercial speech.

b. Intermediate Scrutiny Applies

As the Ninth Circuit recently explained, "The Supreme Court recognizes two levels of scrutiny governing compelled commercial speech. First, under *Central Hudson* [*Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980)], the Court applies intermediate scrutiny, which requires the government to directly advance a substantial governmental interest, and the means chosen must not be more extensive than necessary. Second, there is the lower standard applied in *Zauderer* [*v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)], which requires the compelled speech be reasonably related to a substantial government interest and not be unjustified or unduly burdensome." *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1275 (9th Cir. 2023) (citations and internal quotation marks omitted). "To qualify for review under *Zauderer*, the compelled commercial speech at issue must disclose 'purely factual and uncontroversial information.'" *Id.* at 1275 (quoting *Zauderer*, 471 U.S. at 651).

Oregon would have this Court apply *Zauderer* because, in its view, that standard necessarily applies to compulsions of commercial speech. Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 19–27. PhRMA would have this Court distinguish *Zauderer* and its progeny. Those cases, it argues, "involved a law that compelled disclosure of the features of a good or service in connection with offering it for sale." Pl.'s Reply & Opp. to Def.'s MSJ, ECF 34 at 32 (citations

omitted). Further, PhRMA argues, HB 4005 requires pharmaceutical companies to distribute controversial messages, making *Zauderer* inapplicable. *Id.* at 33.

This Court begins by addressing whether the disclosures mandated by HB 4005 concern "purely factual and uncontroversial information." First, HB 4005 generally asks for disclosures of purely factual information, such as the time the drug has been on the market and the name of any generics. The only non-factual information HB 4005 asks for is the pharmaceutical companies' narrative explanations justifying certain increases in price. But this is not the kind of non-factual information courts consider problematic under *Zauderer*—the government is not asking pharmaceutical companies to share the government's opinion, but their own explanations and opinions. Second, *Zauderer* requires that the disclosure be uncontroversial. The Ninth Circuit has articulated a nexus requirement between the potentially controversial aspects of the speech and the organization's opposition to the speech:

> We do not read the Court as saying broadly that any purely factual statement that can be tied in some way to a controversial issue is, for that reason alone, controversial. The dispute in [*National Institute of Family & Life Advocates v. Becerra*, 585 U.S. 755 (2018) ("*NIFLA*"),] was whether the state could require a clinic whose primary purpose was to oppose abortion to provide information about "state-sponsored services," including abortion. While factual, the compelled statement took sides in a heated political controversy, forcing the clinic to convey a message fundamentally at odds with its mission. Under these circumstances, the compelled notice was deemed controversial within the meaning of *Zauderer* and *NIFLA*.

CTIA – The Wireless Ass'n v. City of Berkeley, 928 F.3d 832, 845 (9th Cir. 2019); *see also Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1277 ("*NIFLA* tells us that the topic of the disclosure and its effect on the speaker is probative of determining whether something is subjectively controversial."). Here, HB 4005 requires pharmaceutical companies to speak on a controversial topic and, in particular, justify why they fall on one side—what Oregon deems the wrong side—

of that controversy. The pharmaceutical companies are the only entity involved in that controversy required to offer an explanation to the public. This Court finds that HB 4005's reporting requirements, viewed in the context of drug prices and health care costs, concern controversial information and *Zauderer* does not apply.

This Court notes that the analysis required under *Zauderer* is an uneasy fit for the facts here. Take *Zauderer* itself as an example. There, the state compelled an attorney to disclose information in addition to the advertising he was already engaging in. 471 U.S. at 651. The message required by the government was an addendum. And the same is true for many cases applying *Zauderer*'s rationale. *See, e.g.*, *CTIA*, 928 F.3d 832; *Am. Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749, 753 (9th Cir. 2019) (en banc); *Nationwide Biweekly Admin., Inc. v. Owen*, 873 F.3d 716 (9th Cir. 2017); *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518 (D.C. Cir. 2015); *Rowe*, 429 F.3d 294; *Env't Def. Ctr., Inc. v. EPA*, 344 F.3d 832 (9th Cir. 2003); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). A principle emerges from these applications: A factual, uncontroversial addition to already-occurring commercial communication is not so offensive to the freedom of speech to require an exacting level of scrutiny. For those situations, a level of scrutiny akin to rational basis will suffice.

As this case illustrates, however, compulsions of commercial speech are not always of the type addressed by *Zauderer*. Here, the pharmaceutical companies are not already engaged in commercial speech to which the disclosures compelled under HB 4005 are appended. *See Am. Beverage Ass'n*, 916 F.3d at 753. Nor are the companies operating storefronts in which the government requires the sharing or posting of certain information. *See CTIA*, 928 F.3d 832; *Am. Hosp. Ass'n v. Azar*, 468 F. Supp. 3d 372, 391 (D.D.C.) (explaining that *Zauderer* applied in part because the compelled disclosure was "directly relevant to the terms under which the services

will be available," namely payment rendered (quotation marks , citation, and alteration omitted)), *aff'd*, 983 F.3d 528 (D.C. Cir. 2020). Instead, by participating in the Oregon market, the pharmaceutical companies are required to share with Oregon, for public dissemination, information Oregon deemed relevant to prescription drug pricing. While Oregon does not dictate the content of the disclosed information, it does pose the questions the pharmaceutical companies must answer. This, too, counsels against applying *Zauderer* here.

c. HB 4005's Reporting Requirements Cannot Survive Intermediate Scrutiny

Having concluded that *Zauderer*'s lower level of scrutiny is inapplicable, this Court turns to *Central Hudson*. Under the *Central Hudson* standard, the government may compel a disclosure of commercial speech only if (1) it directly advances a substantial governmental interest, and (2) the restriction is not more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566. The fit between the legislature's ends and its means "need not be perfect nor the single best to achieve those ends, but one whose scope is narrowly tailored to achieve the legislative objective." *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1111 (9th Cir. 2004) (citation omitted). Oregon bears the burden of justifying its disclosure law. *See Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993); *Bolger*, 463 U.S. at 71 n.20. As the Supreme Court has made clear, "[t]his burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech 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 (citations omitted); *see also Ibanez v. Fla. Dep't of Bus. & Prof. Reg., Bd. of Acct.*, 512 U.S. 136, 143 (1994) ("The State's burden is not slight . . . .").

Oregon contends that HB 4005 serves "to provide accountability for prescription drug pricing to permit purchasers, both public and private, as well as pharmacy benefit managers, to

negotiate discounts and rebates for prescription drugs consistent with existing state and federal law." Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 23. Oregon further argues that it has a substantial interest "in providing Oregon prescription drug buyers with better information about the price of prescription drugs." Def.'s Reply to Pl.'s MSJ, ECF 38 at 17; *see also id.* at 18 (Reporting requirements under HB 4005 "reflect [Oregon's] attempt to provide accountability for prescription drug pricing and increase consumer knowledge of the prescription drug market." (citations omitted)).

Assuming that these are substantial interests, Oregon has nevertheless failed to show how HB 4005 will in fact directly advance them.[7] The requirement that a regulation directly advance the asserted interest is "critical," because without it, the government "could [interfere with] commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (citation omitted). To establish direct advancement, the government may refer "to studies and anecdotes pertaining to different locales altogether, or even . . . based solely on history, consensus, and simple common sense." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001) (citations and internal quotation marks omitted). Oregon claims that the "[s]elf-reported information from drug manufacturers about the various factors that contribute to rising drug prices" will result in increased transparency, which "can then be expected to enhance information available in the market and allow markets to function more efficiently, which would benefit consumers, including the state, which itself is a large purchaser of prescription drugs." Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 24. In its briefing before this Court, Oregon cites no studies or anecdotal

[7] As mentioned elsewhere, Oregon argued in its briefing and at oral argument that rational basis review applies because HB 4005 compels speech. Thus, Oregon did not squarely address the direct advancement and narrow tailoring requirements under *Central Hudson*.

evidence to support these assertions, and, without more, they amount to little more than speculation. *Cf. Am. Hosp. Ass'n v. Azar*, 468 F. Supp. 3d at 395 n.25 ("The agency's reliance on numerous studies here is hardly comparable to the pure speculation undergirding other agency actions that have been struck down under *Central Hudson*." (citations omitted)) (collecting cases).

Indeed, during the public hearings for HB 4005, when asked how the law would "actually reduce the cost of prescription drugs in Oregon," one state representative responded, "I don't think we know yet." ECF 31, Ex. 1 at 15–16. The representative went on, "I think we'll learn a lot as we watch this law play out. . . . And my hope would be is that we gain some understanding about why the cost of these medications go up, and then maybe we can make smarter regulation." *Id.* 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 a connection.

Likewise, Oregon has failed to demonstrate that HB 4005 is narrowly tailored to advance its stated goals. For instance, the law is underinclusive—it requires only one type of entity in a complex supply chain to provide justifications for price increases. To be sure, pharmaceutical companies have leeway under the text of the law to explain how other actors impact prices, but that leeway does not justify burdening the First Amendment rights of only PhRMA's members in service of acquiring information that may prove useful. Asking one actor among many to explain itself is underinclusive given Oregon's own framing of the issue HB 4005 is aimed at addressing: rising drug prices caused by a combination of factors. While Oregon may be correct that regulation can be piecemeal and preliminary without being unconstitutionally underinclusive, *see* Def.'s MSJ & Opp. to Pl.'s MSJ, ECF 29 at 24 ("[L]aws are not required to solve every part of

every problem to be valid."), it still fails to explain why the underinclusive nature of HB 4005's reporting requirements is nonetheless narrowly tailored. Put differently, while there may be a justification for beginning its approach with this compulsion of this speech from these companies, Oregon does not elucidate that justification.

Because HB 4005's reporting requirements cannot, on this record, survive intermediate scrutiny, this Court is satisfied that they likewise would not survive if analyzed as regulating private speech rather than commercial speech. *See NIFLA*, 585 U.S. at 773; *Yim v. City of Seattle*, 63 F.4th 783, 793 (9th Cir. 2023), *cert. denied sub nom. Yim v. Seattle*, 144 S. Ct. 693 (2024). The private speech framework would compel this Court to apply at least intermediate scrutiny, if not strict. *See Riley v. Nat'l Fed'n of the Blind of N.C., Inc*., 487 U.S. 781, 795 (1988); *McIntyre v. Ohio Elections Comm'n*, 514 U.S. 334, 348, 355 (1995); *Wooley v. Maynard*, 430 U.S. at 714. The preceding discussion addressing intermediate scrutiny would apply with full force.

CONCLUSION

For these reasons, and the reasons discussed at oral argument, PhRMA is entitled to summary judgment on its Takings Clause and First Amendment claims. Neither party is entitled to summary judgment on PhRMA's Commerce Clause claim. Oregon is entitled to summary judgment on PhRMA's Supremacy Clause claim.

IT IS SO ORDERED.

DATED this 19th day of March, 2024.

/s/ Michael W. Mosman
Michael W. Mosman
United States District Judge