No. 24-1570

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff-Appellee,

v.

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

Defendant-Appellant.

APPELLANT'S REPLY BRIEF

Appeal from the United States District Court
for the District of Oregon

ELLEN F. ROSENBLUM
Attorney General
BENJAMIN GUTMAN
Solicitor General
PEENESH SHAH
Assistant Attorney General
1162 Court St. NE
Salem, Oregon 97301-4096
Telephone: (503) 378-4402
Email: peenesh.h.shah@doj.oregon.gov

Attorneys for Appellant

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APPELLAN'TS REPLY BRIEF

INTRODUCTION

Plaintiff challenges disclosure requirements imposed on the highly regulated business of pharmaceutical manufacturing and distribution. It contends that those disclosure requirements impermissibly compel speech and inevitably constitute takings of property without compensation.

Plaintiff's arguments are as incorrect as they are extreme. Those arguments turn on a remarkably far-reaching view of the First and Fifth Amendments—a view that does not square with basic doctrinal limits, and one that would call into question longstanding, well-accepted commercial disclosure requirements.

Under the First Amendment, plaintiff contends that the challenged law compels speech by requiring drug manufacturers to report information about price increases. But that reporting requirement lacks a feature fundamental to the Supreme Court's decisions prohibiting compelled speech: a demand that people adopt or accommodate a *message* they would not otherwise express. Indeed, the lack of any compelled message is precisely why regulatory disclosures of this sort fit comfortably within the commercial-speech doctrine: They seek factual explanations about financial matters rather than opinions or messages on more value-laden subjects. Plaintiff's contrary analysis—seeking

to narrow the commercial-speech doctrine to regulations of advertisements or to exclude otherwise commercial speech that is adjacent to a controversial topic such as rising drug prices—is inconsistent with blackletter law.

It is also contrary to well-established practice. One example that should be familiar to many of plaintiff's members is the Security and Exchange Commission's Form 10-K, which requires companies to disclose information about the purposes of its executive compensation program—disclosures unconnected to advertisements but adjacent to a controversy over the pay of corporate executives. If plaintiff's argument here were accepted, Form 10-K would be unconstitutional. That cannot be so under settled law.

Plaintiff's takings argument under the Fifth Amendment fares no better. They challenge—on its face, because of the mere possibility of its application in as-yet entirely hypothetical situations—a provision allowing the public disclosure of trade secrets contained in regulatory reports when such disclosure is in the public interest. But binding Supreme Court precedent refutes plaintiff's contention that disclosure of a trade secret always amounts to a taking. To the contrary, in the only case to consider the issue, the Court held that no taking results from the disclosure of otherwise secret information voluntarily submitted to regulators in exchange for economic advantages, at least as long as the regulator offers no guarantee of confidentiality. That

conclusion followed from the Court's fact-specific application of its regulatory-takings rules—rules that are fundamentally incompatible both with a facial challenge and with plaintiff's *per se* takings argument.[1]

A. Plaintiff's free-speech arguments rest on an incorrect and extreme approach to First Amendment doctrine.

Plaintiff's free-speech analysis is incorrect because it misunderstands the existing frameworks for identifying impermissibly compelled speech, particularly in the context of commercial speech. And it is extreme because it contains no limiting principle that could accommodate many materially analogous, longstanding, and well-accepted regulations that would also be impermissible under plaintiff's analysis.

1. Plaintiff's argument misunderstands the existing frameworks for identifying impermissibly compelled speech, particularly in the context of commercial speech.

First, settled law does not support plaintiff's approach to regulatory disclosures. The Supreme Court has consistently held that a compelled-speech violation occurs only when the government is "telling people what they must say" or forcing them to "accommodate" a message different from their own.

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[1] For that and other reasons, the prospective relief that plaintiff seeks is generally unavailable in takings cases. (*See* AOB 61–63 (so arguing)).

Rumsfeld v. Forum for Acad. & Institutional Rights, Inc., 547 U.S. 47, 61, 63, 126 S. Ct. 1297 (2006) ("The compelled-speech violation in each of our prior cases, however, resulted from the fact that the complaining speaker's own message was affected by the speech it was forced to accommodate."); *see also Nat'l Inst. of Family & Life Advocates v. Becerra*, 585 U.S. 755, 766, 138 S. Ct. 2361 (2018) (holding that a plaintiff was likely to prevail on its free-speech challenge to a law that "compel[ed] individuals to speak a particular message"); *303 Creative LLC v. Elenis*, 600 U.S. 570, 596, 143 S. Ct. 2298 (2023) (invalidating law that "force[d] an individual to utter what is not in her mind about a question of political and religious significance" (internal quotation marks and brackets omitted)).

But drug manufacturers are not being told what to say or being forced to accommodate any message when they are required to report factual information about drug price increases. The reporting requirement here asks for no opinion or message, and no opinion or message is required to explain why, as a matter of historical fact, a particular manufacturer set a particular price as it did.

Because the reporting requirement focuses on purely factual information about financial matters, the district court was correct to conclude that any speech here is "best categorized as commercial speech" that should be analyzed under the permissive rules applicable to that category of speech. (ER-32).

Plaintiff rejects that part of the district court's ruling, but it is mistaken to insist that any speech compelled by the reporting requirement is not commercial because it does not propose a commercial transaction. (RAB 28–29). If the test for commercial speech were so limited, it would exclude many common regulatory disclosures, including those—"environmental spill reporting, accident reports by common carriers, SEC reporting as to corporate losses"—that the First Circuit has explained are as permissible under the lenient standard announced in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 105 S. Ct. 2265 (1985), which applies only to commercial speech. *See Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005). In light of *Rowe*'s analysis, the commercial-speech question in this case is "close" enough to warrant application of the multi-factor test developed in response to "the difficulty of drawing clear lines between commercial and non-commercial speech." *X Corp. v. Bonta*, __ F.4th __, 2024 WL 4033063, at *7 (9th Cir. Sept. 4, 2024) (discussing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 103 S. Ct. 2875 (1983)). Indeed, the district court's ruling here confirms that the question is at least close enough to allow reasonable minds to conclude that the speech at issue here is "best categorized as commercial speech." (ER-32). This court should therefore reject plaintiff's invitation to ignore the *Bolger* factors here. (RAB 31).

And those factors establish that the reporting requirement here pertains to commercial speech. Without doubt, the disclosures required under that law are not advertisements as contemplated in the first *Bolger* factor, but that factor is not dispositive because the purpose of the multi-factor *Bolger* test is to determine whether speech that does not "propose a commercial transaction"—a definition that already captures advertisements—is nevertheless commercial speech. On the other hand, plaintiff admits that the disclosures pertain to a particular product as contemplated in the second *Bolger* factor, (RAB 31), and that factor carries more weight because it serves the purposes of the multi-factor test by introducing an element not already captured in the proposes-a-commercial-transaction test: Not all statements pertaining to a product necessarily propose to sell that product.

As for the third *Bolger* factor, plaintiff suggests that manufacturers have no economic motivation when making the required reports because they are "merely complying with a regulatory command." (RAB 33). But they are complying with that command because it is necessary for them to market their products. Plaintiff seems to think that manufacturers have no choice but to provide the required disclosures, but that is no more true here than it is in cases involving warning labels, which plaintiff concedes are commercial speech that may permissibly be compelled even from businesses that would prefer not to

speak and even though such warnings do not "entice potential customers." (*See, e.g.*, RAB 33–34). In fact, plaintiff's members do have a choice—they can choose not to sell their products in Oregon if they are unwilling to comply with the reporting requirement. If they instead choose to stay in the Oregon market, it is because that is the more profitable option. After all, drug manufacturers are largely public corporations, and under the prevailing standards of corporate governance, they must maximize profits and shareholder value over any other goals—notwithstanding their unsupported platitudes about "promoting patients' access to life-changing medicines" and "continu[ing] scientific innovation." (RAB 6); *contrast Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 879 F.3d 101, 109 (4th Cir. 2018) (explaining that a, for a "non-profit organization," the "clearest motivation is not economic but moral, philosophical, and religious"); *see also Tanner v. McMurray*, 989 F.3d 860, 871 (10th Cir. 2021) ("Clearly, * * * a for-profit corporation acting to maximize shareholder value pursuant to its fiduciary duty" is not a "noble part-time public servant[.]").

Thus, in contrast with this court's analysis in *X Corp.*, two of the three *Bolger* factors here weigh in favor of commercial speech. *Compare* 2024 WL 4033063, at *8 (concluding that the compelled reports in that case "fail[ed] to satisfy at least two of the three *Bolger* factors").

More importantly, the speech here focuses on drug prices, which is purely financial information about commercial products. In *X Corp.*, by contrast, the compelled speech required reporting a business's operating definitions for what qualifies as hate speech, racism, extremism, radicalization, disinformation, or misinformation. *Compare* 2024 WL 4033063, at *3 (reproducing law challenged in that case). Indeed, the very nature of the business in *X Corp*. was the distribution of speech, closely tying the regulations at issue there to expressive conduct. But the business of drug manufacturing is not connected to expressive conduct, and the fundamentally economic information here—even narrative explanations for price increases—do not require any value judgments about such broadly and intensely political questions like those this court observed were implicated in *X Corp.* Merely explaining the reasons for a price increase does not require defining such "politically fraught," inherently subjective, and increasingly partisan labels as the ones involved in that case. *See id*. at *6, *8.

Put simply, the required disclosures here do not even approach the kind of speech that this court held to be inherently expressive and therefore non-commercial in *X Corp*. Indeed, plaintiff struggles to identify precisely what opinion or belief the reporting requirement here requires its members to adopt or express. It states that the law "forces manufacturers to provide an *opinion*

about factors contributing to drug-price increases," (RAB 19 (emphasis in original), but no opinion is required to explain why, as a matter of historical fact, a particular manufacturer set a particular price as it did. Some of those historical facts might be known solely to the manufacturer, but that does not make them opinions.

Plaintiff comes no closer to identifying any kind of expressive conduct when it argues that the law "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." (RAB 43 (quotation marks omitted)). That statement does not articulate precisely what opinion or "side" the reporting requirement forces plaintiff's members to express or adopt. Again, no opinion is required when merely identifying, as a matter of historical fact, the reasons for a particular pricing decision. And any general controversy about prescription drug prices does not make otherwise factual disclosures controversial: this court has already rejected the proposition that "any purely factual statement that can be tied in some way to a controversial issue is, for that reason alone, controversial." *CTIA - The Wireless Ass'n v. City of Berkeley, California*, 928 F.3d 832, 845 (9th Cir. 2019).

Perhaps the "side" plaintiff feels forced to take is the state's purported "view that manufacturers are solely responsible for price increases." (RAB 22).

But nothing in the reporting requirement requires manufacturers to say *anything* about prices ultimately paid by patients, let alone who is responsible for whatever factors supported a pricing decision. More importantly, nothing in the reporting requirement requires the manufacturers to adopt the view that plaintiff ascribes to the state. If a manufacturer raised its prices because of increased costs for ingredients, equipment, or personnel, it can say so. If it raised its prices to offset higher taxes or new regulatory compliance costs, it can say that too.

For all those reasons, the reporting requirement must be reviewed under the more lenient standards applicable to laws involving commercial speech. And whether under intermediate scrutiny or rational-basis review, that requirement is sufficiently connected to the Oregon legislature's primary goal of "provid[ing] notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing." H.B. 4005, ch. 7. That is a legitimate public goal because—as well explained in the amicus brief submitted by Oregon Coalition for Affordable Prescriptions (OCAP)—ample evidence establishes at least a correlation between greater transparency or accountability for drug prices and lower prices. (OCAP Amicus Br 10–13). To the extent this court requires

anecdotal evidence to support that fact, such evidence can be found in that amicus brief.

Finally, plaintiff is mistaken to contend that the state waived any argument that the reporting requirement may be upheld under intermediate scrutiny. (RAB 34). Regardless whether the district court was correct about which arguments the state "squarely" raised before that court, (*see* ER-36 n.7), the order on review squarely addressed the question whether the reporting requirement survives intermediate scrutiny. (ER-35–38). Thus, the state's arguments—which it does not here concede were as limited as the district court suggested in the cited footnote—were sufficient to alert the district court that it must rule on that issue. And because the district court's ultimate judgment rests on its resolution of that issue, that issue is properly before this court on appeal. *See Rath Packing Co. v. Becker*, 530 F.2d 1295, 1308–09 (9th Cir. 1975) (reaching the merits of an issue when the parties disputed the issue on appeal and "the judgment of the district court turned in large part on its resolution of [the] issue" even when the parties' arguments at the district court would not otherwise have been sufficient to preserve the issue for appeal).[2]

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[2] For all of the questions raised under plaintiff's First Amendment claim—regarding commercial vs. non-commercial speech and in applying *Zauderer* or any other test—the potential confidentiality of any compelled speech plays no part in the analysis under existing law. Questions about

Footnote continued…

2. Accepting plaintiff's argument would call into question materially analogous, longstanding, and well-accepted regulations.

Indeed, the reporting requirement must be permissible under settled law because that requirement is little different from many other longstanding, well-accepted, and routine commercial regulations, many of which would be subject to challenge under plaintiff's startlingly far-reaching analysis. Plaintiff disputes that the reporting requirement amounts to such a "routine" commercial financial disclosure, (*see* RAB 2), but many of its members annually submit materially analogous financial disclosures when filing Form 10-K with the Securities and Exchange Commission. (*See* ER-138–39 ¶¶ 7–8 (describing information publicly available on SEC filings, including form 10-K, submitted by plaintiff's members)). Among the many disclosures required on that form, corporations or registrants must "[d]iscuss the compensation awarded to, earned by, or paid to" its executives. 17 C.F.R. § 229.402(b)(1). And that discussion must "describe":

> (i) *The objectives of the registrant's compensation programs*;
>
> (ii) *What the compensation program is designed to reward*;
>
> (iii) Each element of compensation;

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confidentiality are relevant in this case only for purposes of the takings claim. Plaintiff's attempt to conflate the analysis is not well taken. (*See* RAB 48 n.11 (discussing confidentiality in context of free-speech claim)).

> (iv) *Why the registrant chooses to pay each element*;
>
> (v) How the registrant determines the amount (and, where applicable, the formula) for each element to pay;
>
> (vi) How each compensation element and the registrant's decisions regarding that element fit into the registrant's overall compensation objectives and affect decisions regarding other elements; and
>
> (vii) Whether and, if so, how the registrant has considered the results of the most recent shareholder advisory vote on executive compensation * * * in determining compensation policies and decisions and, if so, how that consideration has affected the registrant's executive compensation decisions and policies.

17 C.F.R. § 229.402(b) (emphases added). Further, just like the information that plaintiff here complains will "be published on DCBS's website for the public to access, (RAB 45), Form 10-K information is all published and available to the public on the S.E.C.'s website: *https://www.sec.gov/search-filings*.

But the subject of executive compensation is just as controversial as the subject of prescription drug prices that plaintiff contends it cannot be required to report information about.[3] If the reporting requirement here amounts to

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[3] *See, e.g.*, Allison Morrow, *A core frustration unites striking workers: Exorbitant CEO pay*, CNN, September 19, 2023, *https://www.cnn.com/2023/09/18/business/ceo-pay-unions-strike/index.html*; Joel Shulman, *When Is Executive Compensation Excessive? Elon Musk and Beyond*, Forbes, February 5, 2024, *https://www.forbes.com/sites/joelshulman/2024/02/05/when-is-executive-compensation-excessive-elon-musk-and-beyond/*.

impermissible compulsion of speech, the same would be true of the requirements of Form 10-K, and likely many other well-accepted and longstanding regulations integral to effective regulation of commercial activity.

Compelled disclosures of such economic information, however, do not violate the First Amendment—even when they require narrative descriptions and justifications like those discussed above. *See generally Full Value Advisors, LLC v. S.E.C.*, 633 F.3d 1101, 1108 (D.C. Cir. 2011) (explaining that a different S.E.C. disclosure requirement did "not raise the same constitutional concerns" as other kinds of compelled speech); *Rowe*, 429 F.3d at 316 (explaining that "routine disclosure of economically significant information designed to forward ordinary regulatory purposes" do not "require an extensive First Amendment analysis").

As suggested by the ease with which the First Circuit rejected the challenge in *Rowe*, that conclusion rests on myriad related rationales: that such speech does not require the speaker to endorse a position or affirm a belief about the purely economic information at issue, that it is in any event directed at a regulatory body rather than the public,[4] and that it is subject to more lenient

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[4] Plaintiff repeatedly insists that it is being impermissibly compelled to speak because the regulator here will disclose the reported information publicly. (*See, e.g.*, RAB 45). But the Supreme Court has recognized a difference between required disclosures to *regulators* and required disclosures

Footnote continued…

review because it is compelled commercial speech about purely factual information. (*See* AOB 31–33 (explaining the interaction and overlap of those various rationales)). Each of those rationales applies equally to the reporting requirement at issue here.

B. Plaintiff's takings arguments are foreclosed by precedent.

Plaintiff's arguments under the Fifth Amendment also reach too far to fit within existing law—particularly the Supreme Court's holding that, "as long as [the submitter] is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate Government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1007, 104 S. Ct. 2862 (1984).

Plaintiff's contrary arguments rest on a facile and maximalist view of trade secrets that does not square with well-accepted laws requiring the reporting of at least some information that would otherwise qualify as a trade

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to the *public*, even when the regulator will disclose the information to the public. *See Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 800, 108 S. Ct. 2667 (1988) ("For example, as a general rule, the State may itself publish the detailed financial disclosure forms it requires professional fundraisers to file. This procedure would communicate the desired information to the public without burdening a speaker with unwanted speech during the course of a solicitation.").

secret. If plaintiff's analysis were correct, then the Supreme Court would have erred long ago when it easily rejected a takings challenge to regulations requiring a business "to disclose upon the label the ingredients and their proportions" for a "proprietary food" made "under a secret formula." *Corn Products Ref. Co. v. Eddy*, 249 U.S. 427, 431–32, 39 S. Ct. 325 (1919).

Corn Products refutes plaintiff's reductive suggestion that compelled and uncompensated reporting of *any* trade secret is facially impermissible simply because disclosure of a secret destroys its value. By failing to consider the specific information at issue and how its holder derives value from its secrecy, plaintiff ignores the inherently fact-specific analysis required in a regulatory-takings case—an analysis that is incompatible with a facial challenge. *See Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 495, 107 S. Ct. 1232 (1987) (explaining that a regulatory-takings claim requires "ad hoc, factual inquiries" that "must be conducted with respect to specific property, and the particular estimates of economic impact and ultimate valuation relevant in the unique circumstances" (internal quotation marks omitted)).

Nor can plaintiff short-circuit that fact-specific analysis by insisting on a *per se* or "categorical" takings analysis. (*See* RAB 55–60). *Ruckelshaus* remains the only Supreme Court case to address an alleged taking of trade secrets. And the Court decided that case under its regulatory-takings

jurisprudence rather than as a categorical taking. *See Ruckelshaus*, 467 U.S. at 1005–07. This court must do the same.[5]

In *Ruckelshaus*, that analysis led the Court to rule almost entirely in the government's favor, concluding that the plaintiff generally lacked any reasonable investment-backed expectation of confidentiality in the secret information it submitted to the Environmental Protection Agency in exchange for permission to sell pesticides. 467 U.S. at 1006–10. By contrast, the Court ruled in the plaintiff's favor with respect to only a six-year window during which the government had "explicitly guaranteed" substantial confidentiality:

> This explicit governmental guarantee formed the basis of a reasonable investment-backed expectation. If EPA, consistent with the authority granted it by the 1978 [statutory] amendments, were now to disclose trade-secret data or consider those data in evaluating the application of a subsequent applicant in a manner not authorized by the [statutes] in effect between 1972 and 1978, EPA's actions would frustrate [the plaintiff's] reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it had submitted.

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[5] Even physical takings are not subject to the kind of simplistic analysis that plaintiff offers. (*See* RAB 57 (viewing the "right to exclude" as effecting a *per se* taking)). Sometimes, even an impairment of the right to physically exclude others will not support a takings claim. *See PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 84, 100 S. Ct. 2035 (1980) (explaining that the "appellants have failed to demonstrate that the 'right to exclude others' is so essential to the use or economic value of their property that the state-authorized limitation of it amounted to a 'taking'"). For that reason as well, plaintiff's claim requires consideration of more facts and circumstances than the simple publication of a trade secret in the abstract.

467 U.S. at 1011.

Plaintiff can point to no similar promise here. Instead, their claim largely overlaps with the claims that *Ruckelshaus* rejected by reasoning that "the Trade Secrets Act is not a guarantee of confidentiality to submitters of data," and that, "absent an express promise, [the plaintiff] had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA." *Id.* at 1008. Here, the vast majority of price increases that will be subject to the challenged requirements will occur in the future, and *all* affected price increases occurred after the challenged law was passed. Plaintiff's members cannot reasonably hold any investment-backed expectation that Oregon law will invariably protect any trade secrets later submitted to explain pricing—not when H.B. 4005 clearly states that such secrets will be disclosed if required by the public interest, just like other trade secrets submitted to the state since it first adopted the Uniform Trade Secrets Act. *See* ORS 192.345(2) (trade secrets are exempt from disclosure under the Oregon Public Records Law "unless the public interest requires disclosure in the particular instance.").[6]

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[6] Plaintiff is mistaken in its assertion that Oregon's enactment of the Uniform Trade Secrets Act "contains no public-interest exception." (RAB 66 n.13). When Oregon enacted that law in 1987, it contained the provision now found in ORS 646.473(3), precluding any trade-secret-misappropriation claim based on disclosure pursuant Oregon's Public Records Law. *See* 1987 Or. Laws ch. 537 § 8(3). By that time, Oregon's Public Records Law had long

Footnote continued…

Moreover, even in a case involving an express promise of confidentiality, the takings analysis remains fact-specific. For example, the secrets on which the plaintiff prevailed in *Ruckelshaus* were specific "research and test data" that it had submitted to the EPA after the law had briefly been amended to promise confidentiality. 467 U.S. at 1001–02. But the record in that case established that the manufacturer "had incurred costs in excess of $23.6 million in developing" that data. *Id*. at 989. Likewise, the record there established that such data is instrumental to the development of new products and the expansion of uses for existing products, as well as that the information would be valuable to competitors for similar reasons. *Id*.

The fact-specific showing of value in *Ruckelshaus* stands in contrast to plaintiff's general contentions here about the "sensitiv[ity]" of data used to "make strategic choices about how to recoup multi-billion-dollar investments." (*See* RAB 63–64). Plaintiff never attempts to identify even generally what kind of sensitive information (such as customer information, marketing strategy, or production costs) it views as a trade secret being taken by the challenged law. (*See* RAB 63 (identifying various kinds of "sensitive business data" without

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included a provision allowing the disclosure of trade secrets when in the public interest, as currently codified at ORS 192.345(2), but first enacted in 1973. *See* 1973 Or. Laws ch. 794 § 11.

explaining what specific data forms the basis for their takings claim)). If those generalized and unsubstantiated contentions are enough to support a facial takings challenge, then countless other longstanding and well-accepted laws will require reexamination.

Many common regulations, particularly in the financial industry, involve "sensitive" business data connected to "strategic choices" about investments. Even if such reports were being *compelled* and then disclosed despite an express promise of confidentiality, more facts would be required to support a claim that the trade secrets at issue were of the sort that could support a regulatory takings claim in *Ruckelshaus*, as opposed to the kind that could not support a regulatory takings claim in *Corn Products*.

And, of course, even that analysis ignores the most important fact in this case—like the plaintiff in *Ruckelshaus*, plaintiff's members here have a choice whether to submit information under the challenged law or instead to leave the heavily regulated industry in which they must comply with that law. (*See* AOB 59–61 (so arguing)). Resisting the state's authority to put drug manufacturers to such a choice, plaintiff suggests that, even if *Ruckelshaus* held that the federal government could regulate, burden, and condition the right to sell pesticides, a state "has no comparable authority to forbid the sale of pharmaceutical products altogether." (RAB 67–68). But pharmaceuticals are at

least as heavily regulated as pesticides. *See generally* 21 U.S.C. § 355 (providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" without approval by the Food and Drug Administration).

More troublingly, that argument grossly underestimates the states' plenary police powers. *See generally Gonzales v. Oregon*, 546 U.S. 243, 270, 126 S. Ct. 904 (2006) (observing that "the structure and limitations of federalism" allow the "States great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," including the "general regulation of medical practice" (internal quotation marks omitted)). Consistently with *Gonzales*, the state can and does decide *who* can sell pharmaceutical products in Oregon and under what conditions. Specifically, ORS chapter 689, along with numerous implementing regulations promulgated by the Oregon Board of Pharmacy, extensively regulates pharmacists, pharmacy technicians, drug stores and other aspects of the pharmaceutical industry. Thus, the state clearly may regulate the sale of pharmaceutical products, even to the point of prohibiting certain people or manufacturers from participating in the market.

For all those reasons, existing precedent precludes relief on plaintiff's takings claim.

CONCLUSION

The district court's judgment should be reversed, and this case should be remanded with instructions to enter summary judgment for defendant on the First Amendment and takings claims.

Respectfully submitted,

ELLEN F. ROSENBLUM
Attorney General
BENJAMIN GUTMAN
Solicitor General

/s/ Peenesh Shah
PEENESH SHAH
Assistant Attorney General
peenesh.h.shah@doj.oregon.gov

Attorneys for Defendant-Appellant
Andrew Stolfi, in his official capacity as
Director of the Oregon Department of
Consumer and Business Services

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7), Federal Rules of Appellate Procedure, I certify that the Appellant's Reply Brief is proportionately spaced, has a typeface of 14 points or more and contains 4,731 words.

DATED: October 10, 2024

/s/ Peenesh Shah

PEENESH SHAH
Assistant Attorney General
peenesh.h.shah@doj.oregon.gov

Attorneys for Defendant-Appellant
Andrew Stolfi, in his official capacity as
Director of the Oregon Department of
Consumer and Business Services

ELLEN F. ROSENBLUM
Attorney General
BENJAMIN GUTMAN
Solicitor General
PEENESH SHAH
Assistant Attorney General
1162 Court St.
Salem, Oregon 97301
Telephone: (503) 378-4402

Counsel for Appellant

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff-Appellee, v. ANDREW STOLFI, in his official capacity as Director of the Oregon Department of Consumer and Business Services, Defendant-Appellant.	U.S.C.A. No. 24-1570 STATEMENT OF RELATED CASES

Pursuant to Rule 28-2.6, Circuit Rules of the United States Court of Appeals for the Ninth Circuit, the undersigned, counsel of record for Appellee, certifies that he has no knowledge of any related cases pending in this court.

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Respectfully submitted,

ELLEN F. ROSENBLUM
Attorney General
BENJAMIN GUTMAN
Solicitor General

/s/ Peenesh Shah
PEENESH SHAH
Assistant Attorney General
peenesh.h.shah@doj.oregon.gov

Attorneys for Defendant-Appellant Andrew Stolfi, in his official capacity as Director of the Oregon Department of Consumer and Business Services

CERTIFICATE OF SERVICE

I hereby certify that on October 10, 2024, I directed the Appellant's Reply Brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Peenesh Shah

PEENESH SHAH
Assistant Attorney General
peenesh.h.shah@doj.oregon.gov

Attorney for Defendant-Appellant
Andrew Stolfi, in his official capacity as
Director of the Oregon Department of
Consumer and Business Services

SPH:bmg/976201684