FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff - Appellee*, v. ANDREW R. STOLFI, in his official capacity as Director of the Oregon Department of Consumer and Business Services, *Defendant - Appellant*.	No. 24-1570 D.C. No. 6:19-cv-01996-MO OPINION

Appeal from the United States District Court
for the District of Oregon
Michael W. Mosman, District Judge, Presiding

Argued and Submitted February 5, 2025
Portland, Oregon

Filed August 26, 2025

Before: Carlos T. Bea, Lucy H. Koh, and Jennifer Sung, Circuit Judges.

Opinion by Judge Koh;
Partial Concurrence and Partial Dissent by Judge Bea

SUMMARY*

First Amendment/Takings

The panel reversed the district court's summary judgment in favor of Plaintiff Pharmaceutical Researchers and Manufacturers of America ("PhRMA"), in PhRMA's action challenging Oregon House Bill No. 4005 ("HB 4005").

HB 4005 requires prescription drug manufacturers to report information related to certain prescription drugs to the Oregon Department of Consumer and Business Services ("DCBS"). In most circumstances, HB 4005 requires DCBS to post disclosed information on its website. However, HB 4005 expressly provides that DCBS may not publicly post any information designated as a "trade secret" unless disclosure is in the public interest. PhRMA brought facial claims against HB 4005, alleging in relevant part, that: (1) the reporting requirement violates the First Amendment and (2) any invocation of the public-interest exception constitutes an unconstitutional taking under the Fifth Amendment.

The panel reversed the district court's grant of summary judgment in favor of PhRMA on its First Amendment claim. The disclosures required by HB 4005, which involve product-specific economic information about prescription drugs that are available for purchase on the market, are properly categorized as commercial speech. The panel declined to reach the issue of whether the statute is subject

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

to intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), or a lower level of scrutiny under *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985), concluding that the statute survives the more stringent standard of intermediate scrutiny.

The panel reversed the district court's grant of summary judgment in favor of PhRMA on its Fifth Amendment takings claim. Although DCBS has never invoked the public-interest exception, PhRMA has standing and the takings claim is ripe for review. The panel then determined that it is appropriate to treat the claim as an alleged regulatory taking, rather than as a categorical, per se taking. Even assuming *arguendo* that a facial challenge can be made under the test for regulatory takings set forth in *Penn Central Transportation Co. v. New York City*, 438 12 U.S. 104 (1978), none of the *Penn Central* factors support PhRMA's facial takings claim.

Concurring in part and dissenting in part, Judge Bea concurred that PhRMA's facial takings challenge on the Fifth Amendment ground failed because Oregon's long-standing public interest exception in its state trade secret laws undermined the reasonableness of any expectation of absolute protection of trade secrets in Oregon. Judge Bea dissented because in his view, HB 4005's Pricing Strategy Disclosure Requirement compels non-commercial speech and cannot survive strict scrutiny under the First Amendment.

COUNSEL

Allon Kedem (argued), Elisabeth S. Theodore, Jeffrey L. Handwerker, Matthew L. Farley, and Robert S. Jones, Arnold & Porter Kaye Scholer LLP, Washington, D.C.; Jonathan M. Hoffman and David Cramer, MB Law Group LLP, Portland, Oregon; James C. Stansel, Melissa B. Kimmel, and Joanne H. Chan, Pharmaceutical Research and Manufacturers of America, Washington, D.C.; for Plaintiff-Appellee.

Peenesh Shah (argued) and Denise G. Fjordbeck, Assistant Attorneys General; Benjamin Gutman, Solicitor General; Ellen F. Rosenblum, Attorney General; Oregon Department of Justice, Salem, Oregon; for Defendant-Appellant.

Bryan Kao and Katelyn Wallace, Deputy Attorneys General; Karli Eisenberg, Supervising Deputy Attorney General; David Jones, Acting Senior Assistant Attorney General; Rob Bonta, California Attorney General; Office of the California Attorney General, Oakland, California; Kris Mayes, Arizona Attorney General, Office of the Arizona Attorney General, Phoenix, Arizona; Philip J. Weiser, Colorado Attorney General, Office of the Colorado Attorney General, Denver, Colorado; William Tong, Connecticut Attorney General, Office of the Connecticut Attorney General, Hartford, Connecticut; Kathleen Jennings, Delaware Attorney General, Office of the Delaware Attorney General, Wilmington, Delaware; Brian L. Schwalb, District of Columbia Attorney General, Office of the District of Columbia Attorney General, Washington, D.C.; Anne E. Lopez, Hawai'i Attorney General, Office of the Hawai'i Attorney General, Honolulu, Hawai'i; Kwame Raoul, Illinois Attorney General, Office of the Illinois Attorney General, Chicago, Illinois; Aaron M. Frey, Maine Attorney

General, Office of the Maine Attorney General, Augusta, Maine; Anthony G. Brown, Maryland Attorney General, Office of the Maryland Attorney General, Baltimore, Maryland; Andrea J. Campbell, Commonwealth of Massachusetts Attorney General, Office of the Commonwealth of Massachusetts Attorney General, Boston, Massachusetts; Dana Nessel, Michigan Attorney General, Office of the Michigan Attorney General, Lansing, Michigan; Keith Ellison, Minnesota Attorney General, Office of the Minnesota Attorney General, St. Paul, Minnesota; Aaron D. Ford, Nevada Attorney General, Office of the Nevada Attorney General, Carson City, Nevada; Matthew J. Platkin, New Jersey Attorney General, Office of the New Jersey Attorney General, Trenton, New Jersey; Raul Torrez, New Mexico Attorney General, Office of the New Mexico Attorney General, Santa Fe, New Mexico; Letitia James, New York Attorney General, Office of the New York Attorney General, New York, New York; Joshua H. Stein, North Carolina Attorney General, Office of the North Carolina Attorney General, Raleigh, North Carolina; Michelle A. Henry, Commonwealth of Pennsylvania Attorney General, Office of the Pennsylvania Attorney General, Harrisburg, Pennsylvania; Charity R. Clark, Vermont Attorney General, Office of the Vermont Attorney General, Montpelier, Vermont; Robert W. Ferguson, Washington Attorney General, Office of the Washington Attorney General, Olympia, Washington; for Amici Curiae States of California, Arizona, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Pennsylvania, Vermont, Washington, and The District of Columbia.

Margaret S. Olney, Bennett Hartman LLP, Portland, Oregon, for Amicus Curiae Oregon Coalition for Affordable Prescriptions.

Andrew R. Varcoe and Mariel A. Brookins, U.S. Chamber Litigation Center, Washington, D.C.; Jeffrey S. Bucholtz, King & Spalding LLP, Washington, D.C.; Matthew V.H. Noller, King & Spalding LLP, San Francisco, California; for Amicus Curiae The Chamber of Commerce of the United States of America.

OPINION

KOH, Circuit Judge:

In 2018, the Oregon Legislative Assembly passed the Prescription Drug Price Transparency Act, 2018 Or. Laws Ch. 7, also referred to as House Bill No. 4005 ("HB 4005"), codified at Or. Rev. Stat. §§ 646A.680-692. The law requires prescription drug manufacturers to, *inter alia*, report to the Oregon Department of Consumer and Business Services ("DCBS") information related to certain prescription drugs including, for example, current and past list prices, generic alternatives, and the length of time the drugs have been on the market. Or. Rev. Stat. § 646A.689(3). In most circumstances, HB 4005 requires DCBS to post disclosed information on its website. *Id.* § 646A.689(9). However, HB 4005 expressly provides that DCBS may not publicly post any information designated as a "trade secret" unless disclosure is in the public interest. *Id.* § 646A.689(10)(a).

This appeal concerns two facial challenges against HB 4005 brought by Plaintiff-Appellee Pharmaceutical

Research and Manufacturers of America ("PhRMA"). First, PhRMA alleges that HB 4005's reporting requirement, Or. Rev. Stat. § 646A.689(3), compels speech in violation of the First Amendment. Second, PhRMA alleges that HB 4005's "public-interest exception," Or. Rev. Stat. § 646A.689(10)(a), constitutes an uncompensated taking in violation of the Fifth Amendment. The district court entered summary judgment in favor of PhRMA on both claims and entered final declaratory judgment. For the reasons below, we reverse and remand to the district court for further proceedings consistent with this opinion.

I. BACKGROUND AND PROCEDURAL HISTORY

A. Statutory Background

In February 2018, the Oregon Legislative Assembly enacted HB 4005, commonly known as the Prescription Drug Price Transparency Act. In a preface to the bill, the legislature explained that "the state has a substantial public interest in the price and cost of prescription drugs," especially because the state acts as a "major purchaser of prescription drugs" and "provides major tax expenditures for health care through the tax exclusion of employer-sponsored health insurance coverage and the deductibility of the excess medical costs of individuals and families." HB 4005, ch. 7. In a statement of purpose, the legislature explained that HB 4005 is intended to "provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing" and "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." HB 4005, ch. 7.

i. The Reporting Requirement

The first provision at issue in this appeal, which the parties refer to as the "reporting requirement," requires pharmaceutical manufacturers to disclose to DCBS information related to the costs, revenues, and prices of certain prescription drugs.[1] The challenged reporting requirement applies only to drugs for which: (a) "[t]he price was $100 or more for a one-month supply or for a course of treatment lasting less than one month," and (b) "[t]here was a net increase of 10 percent or more in the price of the prescription drug . . . over the course of the previous calendar year." Or. Rev. Stat. § 646A.689(2). For these drugs, HB 4005 requires manufacturers to "report to [DCBS], in the form and manner prescribed by [DCBS]" 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;

[1] For the purposes of HB 4005, a "manufacturer" is defined as "a person that manufactures a prescription drug that is sold in [Oregon]." Or. Rev. Stat. § 646A.689(1)(e). "Price" is defined as the drug's wholesale acquisition cost, *i.e.*, the drug's federally defined, national list price. *Id.* § 646A.689(1)(i); 42 U.S.C. § 1395w-3a(c)(6)(B).

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

(f) The direct costs incurred by the manufacturer:

(A) To manufacture the prescription drug;

(B) To market the prescription drug;

(C) To distribute the prescription drug; and

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

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

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

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

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

(k) Any other information that the manufacturer deems relevant to the price increase . . . ; and

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

Id. § 646A.689(3) (hereinafter, "HB 4005's reporting requirement").[2]

Following HB 4005's enactment, DCBS promulgated implementing regulations requiring manufacturers to include, among other disclosures, "[t]he factors that contributed to the price increase, including a narrative description and explanation of all major financial and nonfinancial factors that influenced the decision to increase the wholesale acquisition cost of the drug product and to decide on the amount of the increase." Or. Admin. R. 836-200-0530(2)(h).[3]

ii. The Public-Interest Exception

The second provision at issue in this appeal, which the parties refer to as the "public-interest exception," relates to the public disclosure of certain information reported to DCBS by manufacturers. As a default, HB 4005 requires DCBS to post information disclosed by manufacturers publicly on the DCBS website. Or. Rev. Stat.

---

[2] Similar reporting requirements also apply to certain new prescription drugs introduced above a certain price threshold. Or. Rev. Stat. § 646A.689(6). However, PhRMA's motion for summary judgment discussed only the reporting requirement for existing drugs, and the district court's declaratory judgment was limited to the reporting requirement for existing drugs, Or. Rev. Stat. § 646A.689(3).

[3] Although the partial dissent would find several subsections of HB 4005's reporting requirement unconstitutional, the partial dissent agrees that multiple other subsections, specifically § 646A.689(3)(a), (b), (g), (i), and (j), do not violate the First Amendment. Partial Dissent at 80-81.

§ 646A.689(9). However, HB 4005 provides that DCBS may not post to its website information disclosed by manufacturers if: (1) "[t]he information is conditionally exempt from disclosure under [Or. Rev. Stat. § 192.345] as a trade secret; and (2) "[t]he public interest does not require disclosure of the information." *Id.* § 646A.689(10)(a). For purposes of HB 4005, a trade secret is defined to include "any formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information which is not patented, which is known only to certain individuals within an organization and which is used in a business it conducts, having actual or potential commercial value, and which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it." *Id.* § 192.345; *see id.* § 646A.689(10)(a).

As of May 2020, manufacturers had asserted 4,865 trade secret claims in the 1,112 reports submitted to DCBS. PhRMA represents that, according to an annual report published by DCBS, the number of trade secrets claimed by manufacturers had risen to more than 10,500 as of December 2023. Since HB 4005 was enacted in 2018, DCBS has not disclosed any information claimed as a trade secret.

B. Procedural History

Plaintiff PhRMA is a trade association whose members include pharmaceutical and biotechnology manufacturers. On December 9, 2019, PhRMA sued in federal court under 42 U.S.C. § 1983, naming as defendant the director of DCBS, acting in his official capacity (hereinafter, the "State"). PhRMA brought four facial claims against HB 4005, alleging that: (1) HB 4005 violates the dormant Commerce Clause, (2) HB 4005 is preempted by the federal Defend Trade Secrets Act, 18 U.S.C. §§ 1832-1839, (3) HB

4005's reporting requirement violates the First Amendment, and (4) any invocation of HB 4005's public-interest exception constitutes an unconstitutional taking under the Fifth Amendment.[4] PhRMA initially sought both injunctive relief and declaratory relief, but later abandoned any claim for injunctive relief.

PhRMA and the State filed cross-motions for partial summary judgment. In PhRMA's summary judgment motion, PhRMA's First Amendment arguments addressed only Or. Rev. Stat. § 646A.689(3)(c), which requires manufacturers to provide the "factors that contributed to the price increase," and its implementing regulation, Or. Admin. R. 836-200-0530(2)(h).

At a hearing in January 2024, the district court made an oral preliminary ruling on the parties' cross-motions. The court granted summary judgment to PhRMA on its First Amendment and Fifth Amendment takings claims, granted summary judgment to the State on PhRMA's preemption claim, and denied summary judgment to both sides on the dormant Commerce Clause claim. In its preliminary oral ruling on the First Amendment claim, the district court concluded that HB 4005's reporting requirement was unconstitutional without referencing any specific subsection of HB 4005. However, the court had before it only the

[4] In its complaint, PhRMA also challenged Oregon's Advance Notification Law, House Bill No. 2658, 2019 Or. Laws Ch. 436, which requires manufacturers to provide 60 days' notice before increasing the price of certain medications. PhRMA voluntarily dismissed its challenges to the Advance Notification Law, following the resolution of a challenge to a similar California law. *See generally Pharm. Rsch. & Manufacturers of Am. v. David*, No. 2:17-cv-02573 (E.D. Cal.).

parties' argument as to one subsection: Or. Rev. Stat. § 646A.689(3)(c).

Following the district court's oral preliminary ruling, the parties submitted briefing on the proper scope of the judgment. Although PhRMA had only made summary judgment arguments as to Or. Rev. Stat. § 646A.689(3)(c), PhRMA requested a judgment declaring the entirety of HB 4005's reporting requirement facially unconstitutional. In response, the State argued in its declaratory judgment briefing that subsection 646A.689(3)(c) should be severed from the remainder of the statute.

In February 2024, the district court entered a declaratory judgment. *Pharm. Rsch. & Manufacturers of Am. v. Stolfi*, No. 6:19-CV-01996, 2024 WL 1144401 (D. Or. Feb. 16, 2024) ("*Declaratory Judgment*"). In relevant part, the court declared that HB 4005's reporting requirement violates the First Amendment and is therefore unenforceable. *Id.* Although the district court had previously provided no analysis of any subsection of HB 4005's reporting requirement other than § 646A.689(3)(c) and provided no analysis of any subsection of HB 4005 in the declaratory judgment, it declared the entirety of § 646A.689(3) unconstitutional. As the district court later explained in its written opinion, although the district court acknowledged the State's argument that PhRMA's First Amendment summary judgment briefing addressed only § 646A.689(3)(c), the court declined to sever this subsection from the statute because it concluded that the State had waived any severability argument by failing to address severability in its opposition to PhRMA's summary judgment motion, which only challenged § 646A.689(3)(c). The court further declared that the publication of trade secrets under the public-interest exception,

§ 646A.689(10)(a), constitutes a taking under the Fifth Amendment, and that any invocation of the exception without simultaneously providing just compensation for that taking would accordingly violate the Fifth Amendment. *Id.*

In March 2024, the district court issued a written opinion supporting its declaratory judgment. *Pharm. Rsch. & Manufacturers of Am. v. Stolfi*, 724 F. Supp. 3d 1174 (D. Or. 2024) ("*Summary Judgment Opinion*"). As to PhRMA's First Amendment claim, the court first concluded that, "[v]iewing the context of the disclosures as a whole, the speech at issue here is best categorized as commercial speech." *Id.* at 1197-99. The district court next considered which of the two levels of scrutiny governing commercial speech—intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), or the more permissive standard set forth in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985)—should be applied to PhRMA's claim. *Id.* at 1199-200. The court explained that, for *Zauderer* to apply, the speech at issue "must disclose 'purely factual and uncontroversial information.'" *Id.* at 1199 (quoting *Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263, 1275 (9th Cir. 2023)). The court determined that "the only non-factual information HB 4005 asks for is the pharmaceutical companies' narrative explanations justifying certain increases in price," but explained that "this is not the kind of non-factual information courts consider problematic under *Zauderer*." *Id.* Nonetheless, the court determined that because HB 4005 required manufacturers to "speak on a controversial topic and, in particular, justify why they fall on one side . . . of that controversy," *Zauderer* review was inappropriate. *Id.* at 1200. Applying *Central Hudson*, the district court held that

HB 4005's reporting requirement failed intermediate scrutiny, concluding both that the State had failed to show how HB 4005 would directly advance its legislative goals, and that the State had failed to establish that HB 4005 was narrowly tailored to advance these goals. *Id.* at 1200-02. Again, the district court's analysis did not address any subsections of HB 4005's reporting requirement except § 646A.689(3)(c).

As to PhRMA's Fifth Amendment takings claim, the district court first concluded that PhRMA has standing to bring the claim, *id.* at 1186, and that the claim was ripe for review, *id.* at 1187-88. Turning to the merits, the court then determined that it was appropriate to treat PhRMA's claim as a regulatory taking, rather than a per se physical taking, and apply the regulatory takings test set forth in *Penn Central Transportation Co. v. New York City*, 438 U.S. 104 (1978). *Id.* at 1188-89. Applying the three factors articulated in *Penn Central*, the court determined that "all the factors support finding a regulatory taking" and thus concluded that any invocation of the public-interest exception constitutes an unconstitutional taking. *Id.* at 1189-90. Finally, the court held that declaratory relief was an appropriate remedy, explaining that "[u]nless just compensation is provided, a taking of private property for public use occurs with each mandated public disclosure." *Id.* at 1190-91.

In its declaratory judgment, the district court declared the entirety of HB 4005's reporting requirement unconstitutional under the First Amendment and declared any invocation of the public-interest exception unconstitutional under the Fifth Amendment. Finding "no just reason for delay," the court entered partial final judgment on these claims under Federal Rule of Civil

Procedure 54(b). *Declaratory Judgment*, 2024 WL 1144401 at *1. The State timely appealed.

II. JURISDICTION AND STANDARD OF REVIEW

We have jurisdiction to review the district court's partial final judgment under 28 U.S.C. § 1291. We review the district court's summary judgment rulings de novo. *Branch Banking & Tr. Co. v. D.M.S.I., LLC*, 871 F.3d 751, 759 (9th Cir. 2017). Under Federal Rule of Civil Procedure 56, a court "shall grant 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).

III. DISCUSSION

A. First Amendment Claim

We first address PhRMA's facial First Amendment challenge. For the reasons below, we hold that HB 4005's reporting requirement is best categorized as commercial speech and survives applicable First Amendment scrutiny.

i. Determining the Applicable Level of Scrutiny

a. Government Reporting Requirements

The State argues that HB 4005 merely requires manufacturers to report specific information to a government agency, which then makes that information available to the public unless it is a confidential trade secret. *See* Or. Rev. Stat. § 646A.689(3). And, as the State points out, statutes and regulations that require regulated entities and individuals to report information to a government agency are a common feature of modern government. *See, e.g.*, 26 U.S.C. § 6033 (requiring tax-exempt organizations

to report internal financial information to the Internal Revenue Service ("IRS")); 17 C.F.R. § 229.402(b) (requiring corporations to submit information regarding executive compensation to the Securities and Exchange Commission ("SEC")); 40 C.F.R. §§ 705.10, 705.15 (requiring manufacturers of certain chemical substances to report information regarding chemical use and processing to the Environmental Protection Agency ("EPA")); 21 C.F.R. §§ 803.1, 803.20 (requiring medical device manufacturers to report adverse medical events related to their products to the Food and Drug Administration ("FDA")); *see also Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 316 (1st Cir. 2005) (controlling concurrence) (referring to the "thousands" of commonplace reporting requirements "on the books"). For ease, we refer to such laws as "government reporting requirements." Notably, it is also commonplace for statutes and regulations to authorize or require agencies to make the information that must be disclosed under such reporting requirements available to the public. *See, e.g.*, 26 U.S.C. § 6104(a) (requiring the IRS to make certain information in reports from tax-exempt organizations available to the public); 40 C.F.R. § 705.30(h) (authorizing the EPA to publicize chemical processing information); 21 C.F.R. § 803.9 (authorizing the FDA to publicly disclose information in medical device reports).

Government reporting requirements are distinguishable from laws that require a private individual or entity to communicate information directly to another private individual or entity or the general public. *See, e.g.*, *Am. Beverage Ass'n v. City & County of San Francisco*, 916 F.3d 749, 753-54 (9th Cir. 2019) (en banc) (ordinance requiring health warning on advertisements for sugar-sweetened beverages); *Nat'l Ass'n of Wheat Growers*, 85 F.4th 1263,

1266 (9th Cir. 2023) (law requiring businesses to provide carcinogen warnings if products expose consumers to glyphosate); *CTIA—The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 837-38 (9th Cir. 2019) (ordinance requiring retailers to provide warnings to customers about federal radio-frequency radiation exposure guidelines for cell phone users). For ease, we refer to laws that compel certain information to be communicated directly from one private entity to another as "direct disclosure requirements."

Laws that require disclosures of information, including both government reporting requirements and direct disclosure requirements, are subject to First Amendment scrutiny. *See NetChoice, LLC v. Bonta*, 113 F.4th 1101, 1117 (9th Cir. 2024) ("[T]he forced disclosure of information . . . triggers First Amendment scrutiny."). However, such laws may be subject to different levels of scrutiny: rational basis review, intermediate scrutiny, or strict scrutiny.

For direct disclosure requirements, the analytical path for determining the applicable level of scrutiny is fairly well-settled. A direct disclosure requirement that "compel[s] individuals to speak a particular message" or "alter[s] the content" of protected speech is generally viewed as a content-based "compelled speech" requirement subject to strict scrutiny, unless the content of the direct disclosure requirement qualifies as "commercial speech," which is entitled to less constitutional protection. *Compare Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018); *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988), *with Cent. Hudson*, 447 U.S. at 562-63, *and Zauderer*, 471 U.S. at 651; *cf. Env't Def. Ctr., Inc. v. EPA*, 344 F.3d 832, 849 (9th Cir. 2003) (recognizing that government "may not constitutionally require an individual to disseminate an ideological message" but concluding that

an EPA rule "requiring a provider of storm sewers . . . to educate the public about the impacts of stormwater discharge on water bodies and . . . the hazards of improper waste disposal falls short of compelling such speech"). If the direct disclosure requirement regulates "commercial speech," then courts apply either intermediate scrutiny, *see Cent. Hudson*, 447 U.S. at 564-66, or a lower level of scrutiny akin to rational basis review, *see Zauderer*, 471 U.S. at 651. *Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1266, 1275.

For government reporting requirements, however, the correct analytical path is less clear. The parties advocate for two different approaches for determining the applicable level of scrutiny. Under PhRMA's preferred approach, all government reporting requirements are, for First Amendment purposes, the legal equivalent of direct disclosure requirements and should be analyzed the same way. That is, government reporting requirements are categorically viewed as content-based "compelled speech" requirements that are presumptively subject to strict scrutiny. It is important to recognize that, under this approach, government reporting requirements as a general rule are subject to strict scrutiny—and the *only* exception is for reports that qualify as "commercial speech" entitled to less constitutional protection.[5] For ease, we refer to this approach as the "presumptively strict approach."

[5] It is also important to recognize, in evaluating the merits of PhRMA's preferred analytical approach, that a content-based, compelled speech requirement that does not qualify as a commercial speech regulation is "presumptively unconstitutional" and must be struck down unless it withstands strict scrutiny. *See Nat'l Inst. of Fam. & Life Advocs.*, 585 U.S. at 766.

The State argues for a different approach for determining the applicable level of scrutiny. The State's alternative does not categorically equate government reporting requirements with direct disclosure requirements; nor does it categorically equate government reporting requirements with "compelled speech" requirements presumptively subject to strict scrutiny. However, if a government reporting requirement mandated that a covered entity or individual make a political or ideological statement, then it would be viewed as compelled speech that is presumptively subject to strict scrutiny.[6] *See United States v. Sindel*, 53 F.3d 874, 878 (8th Cir. 1995) ("A First Amendment protection against compelled speech . . . has been found only in the context of governmental compulsion to disseminate a particular political or ideological message."); *cf. Full Value Advisors, LLC v. SEC*, 633 F.3d 1101, 1108 (D.C. Cir. 2011) ("First Amendment concerns are paramount when the Government compels a speaker to endorse a position contrary to his beliefs, or to 'affirm[] a belief and an attitude of mind' he opposes." (alteration in original) (quoting *W. Va. Bd. of Educ. v. Barnette*, 319 U.S. 624, 633 (1943))). Thus, under the State's alternative approach, a government reporting requirement *may* be subject to strict scrutiny, but that is not presumptively the correct standard of review. For ease, we refer to this alternative as the "potentially strict approach."

[6] Of course, government reporting requirements are also potentially subject to heightened or strict scrutiny under various other constitutional doctrines. *See, e.g.*, *Cal. Bankers Ass'n v. Shultz*, 416 U.S. 21, 57-76 (1974) (considering First, Fourth, and Fifth Amendment challenges to a government reporting requirement); *Ams. for Prosperity Found. v. Bonta*, 594 U.S. 595, 602, 611-19 (2021) (considering a freedom of association challenge to a government reporting requirement).

In our view, there are several compelling reasons to follow the State's potentially strict approach. For one, as the State notes, two of our sister circuits have taken this approach in cases addressing First Amendment challenges to government reporting requirements. In doing so, they have explicitly rejected the argument that government reporting requirements necessarily compel speech—and therefore are presumptively subject to strict scrutiny—simply because they mandate the disclosure of specific information.

In *United States v. Sindel*, 53 F.3d 874 (8th Cir. 1995), the Eighth Circuit considered a First Amendment challenge to IRS Form 8300, which requires taxpayers to report information related to cash transactions, including "the name, address, tax identification number, and other information about each payor and each person on whose behalf payment is made." *Id.* at 875. The court rejected the argument that Form 8300 "compel[s] speech," holding that although the "protection against compelled speech" applies "in the context of governmental compulsion to disseminate a particular political or ideological message," Form 8300 "requires [the plaintiff] only to provide the government with information which his clients have given him voluntarily, not to disseminate publicly a message with which he disagrees." *Id.* at 878.

In *Full Value Advisors, LLC v. SEC*, 633 F.3d 1101 (D.C. Cir. 2011), the D.C. Circuit considered a First Amendment challenge to an SEC regulation requiring institutional investment managers to report quarterly to the SEC "the names, shares, and fair market value of the securities" over which the managers exercise control. *Id.* at 1104. This information was made publicly available unless managers sought and received an individual exemption from the SEC. *Id.* at 1104-05. Because exemption requests might require

managers to, for example, "provide a description of their investment strategy and explain why disclosure would be detrimental," the plaintiff argued that the regulation compelled it to speak in violation of the First Amendment. *Id.* at 1105-06. However, the court applied a level of scrutiny "akin to the general rational basis test," and concluded that the regulation satisfied this standard. *Id.* at 1109 (citation omitted).[7] Like the Eighth Circuit in *Sindel*, the D.C. Circuit rejected the plaintiff's argument that the required reports to the SEC were "a form of compelled speech," holding that the regulation was not "a veiled attempt to 'suppress unpopular ideas or information or manipulate the public debate through coercion rather than persuasion.'" *Id.* at 1108-09 (quoting *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994)).

A First Circuit case, *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), is also instructive. *Rowe* involved a direct disclosure requirement, not a government reporting requirement: the challenged state law required pharmacy benefit managers to disclose conflicts of interest and certain financial information to third parties with which they entered into contracts. *Id.* at 299. Nonetheless, the First Circuit's reasons for rejecting the plaintiff 's argument that the challenged disclosure requirement should be viewed as "compelled speech" suggest that it, too, would use the potentially strict approach

[7] Although the plaintiff in *Full Value Advisors* challenged subsections of the SEC regulation at issue that required public disclosures of its investment positions, the D.C. Circuit determined that this issue was not ripe for review and cabined its analysis to disclosures made only to the SEC. 633 F.3d at 1106-07, 1110.

to analyze a government reporting requirement. As the First Circuit explained:

> [The plaintiff's] First Amendment claim is completely without merit. So-called "compelled speech" may under modern Supreme Court jurisprudence raise a serious First Amendment concern where it effects a forced association between the speaker and a particular viewpoint. *See, e.g.*, *Wooley v. Maynard*, 430 U.S. 705 (1977) (requiring all New Hampshire drivers to display "Live Free or Die" on their license plates); *Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241 (1974) (requiring newspapers to afford political candidates a right to reply to editorial critiques). What is at stake here, by contrast, is simply routine disclosure of economically significant information designed to forward ordinary regulatory purposes—in this case, protecting covered entities from questionable [pharmacy benefit manager] business practices. There are literally thousands of similar regulations on the books—such as product labeling laws, environmental spill reporting, accident reports by common carriers, SEC reporting as to corporate losses and (most obviously) the requirement to file tax returns to government units who use the information to the obvious disadvantage of the taxpayer. The idea that these thousands of routine regulations require an extensive First Amendment analysis is mistaken. *Zauderer*, 471 U.S. 626, makes

> clear "that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." *Id.* at 651. This is a test akin to the general rational basis test governing all government regulations under the Due Process Clause. The test is so obviously met in this case as to make elaboration pointless.

Id. at 316 (controlling concurrence).

Although *Sindel* and *Full Value Advisors* did not address laws that specifically required the government to make reported information available to the public,[8] the Supreme Court's reasoning in *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980), and *Riley v. National Federation of the Blind of North Carolina, Inc.*, 487 U.S. 781 (1988), suggests that public dissemination of regulatory information collected by the government should not necessarily change the analytical framework. *Cf. NetChoice*, 113 F.4th at 1117-19 (rejecting the state's argument that a confidential government reporting requirement cannot unconstitutionally compel speech and subjecting the requirement to strict scrutiny).

In *Village of Schaumburg*, the Supreme Court struck down a local ordinance that required charitable organizations—in order to be eligible for a permit to engage in solicitation—to use a certain amount of their solicitation

[8] Even where a statute or regulation does not specifically provide for the public disclosure of reported information, that information may be made available to the public through federal or state public records laws. *See, e.g.*, 5 U.S.C. § 552 (Freedom of Information Act).

proceeds towards their charitable missions. 444 U.S. at 623-24. The Court held that this requirement did not withstand strict scrutiny and was not sufficiently tailored to the Village's asserted interest in fraud prevention. *Id.* at 636-37. It explained that "[t]he Village's legitimate interest in preventing fraud can be better served by measures less intrusive than a direct prohibition on solicitation," including through Illinois's existing financial disclosure requirements for charitable organizations. *Id.* at 637-38. Those state reporting requirements required charitable organizations to submit to the state a registration statement detailing "a variety of information about the organization and its fundraising activities," and these reports were "open to public inspection." *Id.* at 830 n.5 & 837 n.12.

In *Riley*, the Supreme Court considered the constitutionality of a direct disclosure requirement: the challenged North Carolina statute required fundraisers to disclose to potential donors the percentage of funds they had turned over to charities in the previous year when soliciting charitable donations. 487 U.S. at 786. The Court concluded that the direct disclosure requirement "alter[ed] the content" of fundraisers' speech during charitable solicitations, and it therefore applied strict scrutiny. *Id.* at 795, 798. [9] In

[9] In *Riley*, the state argued that, even if charitable solicitations generally are fully protected speech, the challenged statute "regulate[d] only commercial speech" because the information the fundraiser was compelled to disclose to potential donors "relate[d] only to the professional fundraiser's profit from the solicited contribution." *Id.* at 795. The Supreme Court assumed without deciding that speech related to the fundraiser's "financial motivation for speaking . . . in the abstract is indeed merely 'commercial,'" but held that it lost "its commercial character when it [wa]s inextricably intertwined with" fully protected charitable solicitations—and such "intertwining" is what the challenged direct disclosure law effectively required. *Id.* at 795-96.

concluding that the statute was not adequately tailored, the Court explained that "more benign and narrowly tailored options [were] available." *Id.* at 800. Most relevant here, the Court explained that "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." *Id.* In other words, at the same time that the Court held that a direct disclosure requirement—a law mandating disclosure of controversial financial information in the context of solicitation—was a "compelled speech" requirement subject to strict scrutiny, the Court strongly implied that a government reporting requirement was not—even if it would require fundraisers to report the same controversial financial information and disseminate it to the public.[10] *See also id.* at 795 ("[W]e do not suggest that States

[10] In *American Target Advertising, Inc. v. Giani*, 199 F.3d 1241 (10th Cir. 2000), the Tenth Circuit applied *Riley*'s reasoning to evaluate a First Amendment challenge to a Utah statute that, in relevant part, required professional fundraising consultants to meet certain registration and disclosure requirements. *Id.* at 1248. The statute required fundraisers to provide the state's consumer protection agency with, among other things, "a satisfactory statement of the factual basis for the projected percentage [of contributions] and projected anticipated revenues provided to the charitable organization, and if a flat fee is charged, documentation to support the reasonableness of such flat fee." Utah Code § 13-22-9(1)(b)(vii)(D). Similar to the regulatory regime created by HB 4005, the state made these fundraiser reports available to the public. *See Am. Target Advert., Inc. v. Giani*, 23 F. Supp. 2d 1303, 1307 (D. Utah 1998). The Tenth Circuit recognized that charitable solicitations are protected speech but determined that the statute was a content-neutral regulation of that speech, and was therefore subject to only intermediate scrutiny. *Am. Target Advert.*, 199 F.3d at 1247. Citing *Riley*, the court concluded

must sit idly by and allow their citizens to be defrauded. . . . North Carolina may constitutionally require fundraisers to disclose certain financial information to the State, as it has since 1981." (citing *Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 967 n.16 (1984))).

To be clear, a law requiring a regulated entity to express or endorse a political or ideological message would still be subject to strict scrutiny under the State's potentially strict approach. But the potentially strict approach would provide an analytical framework that would distinguish between government reporting requirements that "effect[] a forced association between the speaker and a particular viewpoint" and those involving only "routine disclosure of economically significant information designed to forward ordinary regulatory purposes" which typically will not "require an extensive First Amendment analysis." *Rowe*, 429 F.3d at 316 (controlling concurrence); *see also id.* ("The idea that these thousands of routine [government reporting] regulations require an extensive First Amendment analysis is mistaken.").

Another advantage of using the potentially strict approach to determine the applicable level of scrutiny is that it does not require us to evaluate, as a threshold question, whether the government reporting requirement should be categorized as a regulation of "commercial speech" by applying tests that were developed in a very different factual

---

that the registration and disclosure requirements were narrowly tailored to the state's substantial interest in fighting fraud. *Id.* at 1248. Notably, the court did not treat the registration and disclosure requirements as "compelled speech" subject to strict scrutiny, instead applying intermediate scrutiny, even though the requirements impacted fully protected charitable solicitations, not lesser-protected commercial speech.

context. The commercial speech doctrine has primarily evolved in the context of regulations of commercial entities' advertising, including laws that restricted advertising, *see Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 62-63, 66-68 (1983); *Cent. Hudson*, 447 U.S. at 558-60, 561-63; and laws that required advertisements to contain specific disclosures (*i.e.*, direct disclosure requirements), *see Zauderer*, 471 U.S. at 633, 637-38.

Because the commercial speech doctrine originated in this advertising context, the traditional legal tests for determining whether speech is "commercial" reflect this paradigm. The Court set forth these tests in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983). There, the Court considered a federal law that restricted the mailing of unsolicited advertisements for contraceptive devices. *Id.* at 61-62. The plaintiff, a manufacturer of contraceptives, sought to mail unsolicited advertisements, including informational pamphlets promoting its products but also discussing venereal disease and family planning. *Id.* at 67-68. It challenged the application of the federal statute to its proposed mailings on First Amendment grounds. *Id.* at 63. The plaintiff argued that the restricted speech was not commercial (and therefore fully protected) because the proposed mailings included non-commercial, educational information. *Id.* at 65-66.

In determining that the plaintiff's proposed mailings were "properly characterized as commercial speech," the Court explained that the "core notion of commercial speech [is] 'speech which does no more than propose a commercial transaction.'" *Id.* at 66-67 (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)) (cleaned up). The Court also identified three, non-dispositive factors that reflected the commercial

nature of the informational pamphlets in particular: (1) the pamphlets were "conceded to be advertisements," (2) they referred to particular products, and (3) the plaintiff had an "economic motivation" for mailing the pamphlets. *Id.* at 66-67.

The tests articulated in *Bolger* were designed to determine the appropriate level of scrutiny to apply to laws that regulate voluntary speech from a regulated commercial entity to a public audience. They are therefore inapt for determining what level of scrutiny to apply to speech in an entirely different context—mandatory reports from the regulated entity to the government, which the government may then make available to the public. The submission of information to the government pursuant to a government reporting requirement typically does not "*propose* a commercial transaction," even if it involves the disclosure of information directly related to commercial transactions. *Id.* at 66 (emphasis added). It also does not neatly fit two of the factors identified in *Bolger*: A report to the government is not an "advertisement," and regulated entities and individuals typically produce these reports out of legal obligation, not economic motivation. *Id.* at 66-67.

Because of this conceptual mismatch, applying these tests strictly in the context of government reporting requirements produces counterintuitive results. *Cf. Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 535 (D.C. Cir. 2015) (Srinivasan, J., dissenting) (explaining why "confining *Zauderer* to advertisement or product labels gives rise to highly curious results"). It would be odd to subject speech in a consumer-facing advertisement to *less* scrutiny than speech in an annual report filed with a state regulatory body simply because it better fits the doctrinal tests for defining commercial speech. Consider, for example, if HB 4005

required manufacturers to prominently display information about price increases in direct-to-consumer television advertisements, rather than in annual reports filed with DCBS. In that circumstance, the traditional "definitions" of commercial speech would likely be satisfied, and yet, disclosure of this information by the State in DCBS reports, rather than by a manufacturer in an advertisement, is a less burdensome disclosure obligation. *See Riley*, 487 U.S. at 800-01. That is, "[i]t would be strange . . . if the same compelled . . . disclosure—providing the same information about the same product—commanded more demanding First Amendment scrutiny if it appeared in a single yearly report" instead of in every television advertisement. *Nat'l Ass'n of Mfrs.*, 800 F.3d at 535 (Srinivasan, J., dissenting). This counterintuitive result underscores that, as a general matter, it makes little sense to determine the appropriate level of scrutiny to apply to government reporting requirements using the traditional definitions of commercial speech.[11]

[11] The combination of the presumptively strict approach with the partial dissent's view of *Bolger*'s commercial speech standard would also produce results that are inconsistent with the Supreme Court's reasoning in *Riley*. Recall that in *Riley*, the Court concluded that the challenged direct disclosure requirement failed strict scrutiny in part because there was a less restrictive alternative: the state could "constitutionally" serve its governmental interests by requiring professional fundraisers to file "detailed financial disclosure forms" specifying the percentage of charitable donations retained by the fundraiser and then "publish[ing]" those forms. 487 U.S. at 795, 800. Under the presumptively strict approach, that government reporting requirement would be subject to strict scrutiny unless the reported information qualified as commercial speech under *Bolger*. But mandatory reports to the government about how professional fundraisers profit from charitable donations do not "propose a commercial transaction," they are not "advertisements," and

In two recent cases, our court has applied strict scrutiny to evaluate government reporting requirements. However, as explained below, neither of those cases require us to adopt PhRMA's presumptively strict approach. In *NetChoice, LLC v. Bonta*, 113 F.4th 1101 (9th Cir. 2024), we considered a challenge to a California law that required "online businesses" to prepare reports "identifying, for each offered online service, product, or feature likely to be accessed by children, any risk of 'material detriment to children that arise from the data management practices of the business.'" *Id.* at 1109, 1116 (quoting Cal. Civ. Code § 1798.99.31). Every covered business was also required to assess "factors related to 'harm' prior to offering a new online service, product, or feature that is likely to be accessed by children." *Id.* at 1116.

Consistent with the potentially strict approach, we first addressed the question whether the challenged "DPIA report requirement" compelled speech, and we concluded that it "clearly compels speech by requiring covered businesses to opine on potential harm to children." *Id.* at 1117. We further explained that the reporting requirement "invites First Amendment scrutiny because it deputizes covered businesses into serving as censors for the State" by requiring business to make subjective decisions on whether or not material is "potentially harmful to children." *Id.* at 1118. That is, because the government reporting requirement mandated the covered entity to make a subjective opinion

---

they are not produced out of an "economic motivation." *Bolger*, 463 U.S. at 66-67. Further, the Court in *Riley* described the financial disclosures at issue as "unfavorable" to the fundraisers. 487 U.S. at 800. Therefore, under the presumptively strict approach and the partial dissent's view of *Bolger*, the less restrictive and "constitutional" alternative identified by the *Riley* Court would be unconstitutional unless it withstood strict scrutiny.

statement on a political issue, we concluded it was properly analyzed as a compelled speech requirement.[12] Next, we determined the appropriate level of scrutiny to apply. *Id.* at 1119. Because we had determined that the DPIA reporting requirement was a compelled speech requirement, it would be subject to strict scrutiny unless it regulated only "commercial speech . . . subject to a lesser standard than strict scrutiny." *Id.* at 1119-20. In resolving that issue, we again noted that the challenged requirement compelled covered entities to "opine on potential speech-based harms to children . . . disconnected from any economic transaction," and we concluded that "the subjective opinions compelled by [the law] are best classified as non-commercial speech" and therefore applied strict scrutiny. *Id.* at 1119-21.

NetChoice very briefly considered the fact that the challenged law was a government reporting requirement, and it did so only in rejecting the state's argument that the First Amendment is "wholly inapplicable" to government reporting requirements.[13] *Id.* at 1117-18. In other words,

[12] The partial dissent suggests that the *NetChoice* panel did not view the DPIA report requirements as compelling any political or ideological messages, seemingly because the panel never used the words "political" or "ideological." Partial Dissent at 104-05. But the *NetChoice* panel made quite clear that it viewed the DPIA reporting requirement as "requir[ing] businesses to go beyond opining about their products or services to opine on highly controversial issues of public concern." 113 F.3d at 1120.

[13] *NetChoice* relied on *Americans for Prosperity Foundation v. Bonta*, 594 U.S. 595 (2021), for this proposition. We note that *Americans for Prosperity Foundation* considered the First Amendment right to association, not the compelled speech doctrine. That case concerned a challenge to a California law that required charitable organizations to submit Schedule B of IRS Form 990 to the state. *Id.* at 602. (Schedule B

NetChoice neither considered whether, nor conclusively held that, government reporting requirements are categorically compelled speech requirements presumptively subject to strict scrutiny.

Next, in *X Corp. v. Bonta*, 116 F.4th 888 (9th Cir. 2024), we considered a challenge to a different California law, California's Assembly Bill 587 ("AB 587"), that required large social media companies to report to the state, among other things, whether and how they define several categories of content for purposes of their terms of service, including: hate speech or racism, extremism or radicalization, disinformation or misinformation, harassment, and foreign political interference. *Id.* at 894. But in *X Corp.*, unlike in *NetChoice*, we did not begin by expressly considering whether the challenged government reporting requirement compelled speech, and we did not answer that question by determining whether it required the covered entity to make subjective, political or ideological opinion statements. *Compare NetChoice*, 113 F.4th at 1116-18, *with X Corp.*, 116 F.4th at 899-900. Instead, we skipped over that question and started our analysis by asking whether the required "Content Category Reports" were commercial speech. *Id.* at 901. Then, we concluded that AB 587 did not regulate commercial speech because it required companies "to recast [their] content-moderation practices into language prescribed by the State, implicitly opining on whether and how certain controversial categories of content should be

---

requires organizations to disclosure the names and addresses of significant donors. *Id.*) The Supreme Court concluded that the law violated First Amendment associational rights. *Id.* at 611-19. There is no indication, however, that the Court viewed any aspect of the reporting requirement as a content-based compelled speech requirement subject to strict scrutiny.

moderated." *Id.* at 901. And we therefore applied strict scrutiny. *Id.* at 903.

In both *NetChoice* and *X Corp.*, our application of strict scrutiny ultimately turned on the subjective and political or ideological nature of the information that the regulations required. Specifically, in both cases, we concluded that the government reporting requirement at issue forced regulated entities to opine on fraught political issues, such as what online content is "harmful to children" or what content constitutes "hate speech or racism." *See NetChoice*, 113 F.4th at 1117-18; *X Corp.*, 116 F.4th at 901-02. We therefore applied the rule that laws that regulate speech based on its expressive content, by "compel[ling] speakers to utter or distribute speech bearing a particular message," are subject to strict scrutiny. *Turner Broad.*, 512 U.S. at 642.

Using the potentially strict approach would have led to the same conclusion in both cases. That is, using the potentially strict approach, we would still conclude that the government reporting requirements at issue in *NetChoice* and *X Corp.* must be subject to strict scrutiny because they compelled private entities to make subjective, ideological opinion statements to the government by identifying what online content is "harmful to children" or what content constitutes "hate speech or racism." *See* 113 F.4th at 1117-18; 116 F.4th at 901-02. Because laws that require speakers to disseminate ideological messages are subject to strict scrutiny—whether in a government report or an advertisement—we would apply that standard. *See Turner Broad.*, 512 U.S. at 642. However, we would reach this conclusion without applying the inapt commercial speech standards along the way. Rather, we would cut to the chase: because the government reporting requirements at issue in those cases mandate the "report" of political or ideological

statements, they are subject to strict scrutiny—regardless of whether they otherwise look like commercial speech regulations under *Bolger*.

PhRMA reads *X Corp.* as effectively adopting the presumptively strict approach. That is, it reads *X Corp.* as supporting the broad proposition that, because government reporting requirements mandate the disclosure of specific information, they are categorically content-based, compelled speech regulations subject to strict scrutiny unless they qualify as regulations of "commercial speech." We are not persuaded by this reading of *X Corp.* for several reasons.

First, as explained above, our application of strict scrutiny in *X Corp.* turned on the fact that AB 587 required social media companies to "speak a particular message" by "opining on whether and how certain controversial categories of content should be moderated." *Id.* 899-901 (citation omitted). *X Corp.* did not expressly hold that *all* government reporting requirements are compelled speech requirements subject to strict scrutiny unless they regulate commercial speech. Indeed, reading *X Corp.* in this way would create considerable tension with the decisions of our sister circuits and with the Supreme Court's reasoning in *Riley* and *Village of Schaumburg*, which suggests that many government reporting requirements are not subject to strict scrutiny, regardless of whether they can be categorized as regulations of commercial speech. Second, and relatedly, *X Corp.* also did not reach the question of what level of scrutiny should apply if a government reporting requirement does not qualify as a "commercial speech" regulation but does not compel the regulated entity to make subjective political or ideological statements. *See, e.g.*, *United States v. Kirilyuk*, 29 F.4th 1128, 1134 (9th Cir. 2022) ("[C]ases are not precedential for propositions not considered." (internal

quotation marks and citation omitted)). Third, *X Corp.* did not consider the potential consequences of presumptively treating all government reporting requirements as compelled speech requirements subject to strict scrutiny.

Although, in our view, using the potentially strict approach followed by our sister circuits would be more doctrinally sound and avoid unintended consequences, we do not need to fully resolve whether *X Corp.* requires us to use the presumptively strict approach in this case, because both approaches lead us to the same conclusion. As explained further below, using the presumptively strict approach, we conclude that HB 4005's reporting requirement qualifies as a commercial speech regulation subject to either intermediate scrutiny or lower scrutiny under *Zauderer*, and that it withstands intermediate scrutiny. HB 4005 is distinguishable from the laws challenged in *X Corp.* and *NetChoice* because it does not compel the covered entities to make subjective political or ideological statements. For that same reason, HB 4005 would not be subject to strict scrutiny under the potentially strict approach discussed above.[14]

b. Commercial Speech

Under the presumptively strict approach, to determine the level of scrutiny applicable to HB 4005's reporting requirement, we must first consider whether HB 4005's reporting requirement is properly categorized as commercial speech. As discussed, the "core notion of commercial speech [is] 'speech which does no more than propose a commercial

[14] PhRMA's First Amendment challenge focuses on its argument that HB 4005's reporting requirement unconstitutionally compels speech. It does not argue HB 4005's reporting requirement should be subject to strict scrutiny for any other reason.

transaction.'" *Bolger*, 463 U.S. at 66 (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 762) (cleaned up); *accord United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001). Courts also consider the three so-called "*Bolger* factors": (1) whether the speech is an advertisement, (2) whether the speech refers to a particular product, and (3) whether the speaker has an economic motivation. *Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107, 1116 (9th Cir. 2021) (citing *Hunt v. City of Los Angeles*, 638 F.3d 703, 715 (9th Cir. 2011)).[15]

[15] The partial dissent suggests that these tests limit commercial speech to content "akin to something people would otherwise disclose in proposing commercial transactions." Partial Dissent at 86. However, "in the commercial context . . . [the government] often requires affirmative disclosures that the speaker might not make voluntarily." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 492 & n.1 (1995) (Stevens, J., concurring) (categorizing "Surgeon General's Warning' labels on cigarettes" as commercial speech). Indeed, it is entirely common for courts to conclude that regulatory disclosures related to a specific product are commercial speech, even where the specific information disclosed is directly *contrary* to the speaker's economic interest and therefore would not be disclosed absent regulation. *See, e.g.*, *Am. Beverage Ass'n*, 916 F.3d at 755-56 (health warning on advertisements for sugar sweetened beverages); *Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1275 (carcinogen warnings for business whose products expose consumers to glyphosate); *CTIA*, 928 F.3d at 841-42 (warnings about radio-frequency radiation exposure guidelines for cell phone users); *Am. Meat Inst. v. U.S. Dep't of Agri.*, 760 F.3d 18, 21 (D.C. Cir. 2014) (en banc) (country of origin labeling on the packaging of meat products). And in any case, the partial dissent's assumption that the "pricing strategies" that manufacturers must disclose under HB 4005—*i.e.*, the "factors that contributed to the price increase[s]" of pharmaceutical drugs, Or. Rev. Stat. § 646A.689(3)(c)— are "not akin to anything people would otherwise disclose in proposing commercial transactions" is unfounded. Partial Dissent at 86. Companies routinely provide explanations for price

Courts treat these legal tests "as just a starting point, however, and instead try to give effect to a 'common-sense distinction' between commercial speech and other varieties of speech." *X Corp.*, 116 F.4th at 900 (quoting *Ariix*, 985 F.3d at 1115); *see also Ariix*, 985 F.3d at 1116 (explaining that the *Bolger* factors "are important guideposts, but they are not dispositive").[16] 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." *X Corp.*, 116 F.4th at 900 (quoting *First Resort, Inc. v. Herrera*, 860 F.3d 1263, 1272 (9th Cir. 2017)).

Our Circuit has characterized speech as commercial "even if not a clear fit" with these legal tests where the speech nonetheless "communicates the terms of an actual or potential [commercial] transaction." *Id.* at 901. We have, for example, applied the commercial speech doctrine to regulations requiring landlords to provide contact information for tenants' rights organizations before initiating buyout negotiations for condominium conversions, *see S.F. Apartment Ass'n v. City and County of San*

---

increases in proposing commercial transactions. *See, e.g.*, Daniella Genovese, *Egg Surcharge Hits Diners' Wallets*, Fox Bus. (Feb. 7, 2025 13:32 ET), https://www.foxbusiness.com/lifestyle/egg-surcharge-hits-diners-wallets-experts-say-consumers-should-fear-menu-price-hikes-more (featuring a photo of a menu with a disclaimer explaining a temporary surcharge "due to the nationwide rise in cost of eggs"); Utpal M. Dholakia, *If You're Going to Raise Prices, Tell Customers Why*, Harv. Bus. Rev. (June 29, 2021) (describing a United Airlines message to customers explaining its decision to raise the price of its United Club membership).

[16] Indeed, in *Bolger* itself the Supreme Court emphasized that it did not "mean to suggest that each of the characteristics present in this case must necessarily be present in order for speech to be commercial." 463 U.S. at 67 n.14.

Francisco, 881 F.3d 1169, 1174, 1176-77 (9th Cir. 2018); and to regulations requiring retailers to provide warnings about federal radio-frequency radiation exposure guidelines for cell phone users, *see CTIA*, 928 F.3d at 841-42. Similarly, in *Environmental Defense Center, Inc. v. EPA*, we applied the Supreme Court's reasoning in *Zauderer* in rejecting a compelled speech challenge to an EPA regulation that required municipal storm sewer providers to educate the public about the dangers of improper waste disposal. 344 F.3d at 849-51. We explicitly concluded that the "policy considerations" underlying the commercial speech doctrine applied in that context because the regulation required "market-participant" storm sewer providers to "inform the public how to dispose safely of toxins." *Id.* at 851 n.27.

Although the compelled disclosures in these cases did not "propose a commercial transaction," we applied the commercial speech doctrine because they nonetheless provided parties to "actual or potential" commercial transactions with information about those transactions.[17] *X Corp.*, 116 F.4th at 901; *see also NetChoice, LLC v. Paxton*, 49 F.4th 439, 446, 485-86 (5th Cir. 2022), *rev'd on other grounds sub nom. Moody v. NetChoice, LLC*, 603 U.S. 707 (2024) (applying the commercial speech doctrine to evaluate a state law requiring social media platforms to publish information related to their content-moderation policies); *NetChoice, LLC v. Att'y Gen., Fla.*, 34 F.4th 1196, 1206-07, 1223 (11th Cir. 2022), *rev'd on other grounds sub nom. Moody*, 603 U.S. 707 (same).

[17] Notably, none of these decisions applied the factors identified in *Bolger*. 463 U.S. at 66-68; *see generally S.F. Apartment Ass'n*, 881 F.3d at 1176-80; *CTIA*, 928 F.3d at 841-49; *Env't Def. Ctr.*, 344 F.3d at 849-51.

The reports required by HB 4005 likewise communicate the terms of potential commercial transactions. Specifically, the reports communicate product-specific economic information about prescription drugs that are available for purchase on the market. *See* Or. Rev. Stat. § 646A.689(2), (3). Much of the information required by HB 4005's reporting requirement is basic marketing information that manufacturers already disclose to the federal government and/or the public. *See, e.g.*, *id.* § 646A.689(3)(a), (i) (current and past list prices); *id.* § 646A.689(3)(b) (time drug has been on the market); *id.* § 646A.689(3)(d) (generic alternatives); *id.* § 646A.689(3)(g) (sales revenue); *id.* § 646A.689(3)(j) (prices in other countries); *see also* U.S. Food & Drug Admin., *Orange Book Preface* (Mar. 27, 2025), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (providing background on the FDA's "Orange Book" report, which publicizes therapeutic equivalence evaluations of generic drugs to "serve as public information . . . in the area of drug product selection"); Or. Rev. Stat. § 689.515 (permitting generic substitution based on therapeutic equivalence evaluations made by the FDA). Indeed, the partial dissent agrees that much of this "general marketing information" "compels factual and uncontroversial information and probably does not violate the First Amendment." Partial Dissent at 80-81. The remaining information required by HB 4005's reporting requirement is economic information that is no less tethered to commercial transactions. *See* Or. Rev. Stat. § 646A.689(3)(e), (f) (costs incurred by manufacturers); *id.* § 646A.689(3)(c), (k) (factors contributing to price increases); *id.* § 646A.689(3)(h) (profit information).

HB 4005's reporting requirement thus improves the "free flow of commercial information" for all drug

purchasers—both public and private. *Va. State Bd. of Pharmacy*, 425 U.S. at 765. Not only does HB 4005's reporting requirement provide drug pricing information to the State (itself a major drug purchaser in Oregon), but it also ensures private consumers have access to this information via public reports prepared by DCBS. *See* Or. Rev. Stat. § 646A.689(9). Indeed, the explicit purpose of HB 4005 is to provide market participants with information to facilitate future commercial transactions between drug manufacturers and market participants. *See* HB 4005, ch. 7 ("[T]he Legislative Assembly intends by this [Act] to permit purchasers, both public and private, as well as pharmacy benefit managers, to negotiate discounts and rebates for prescription drugs.").

Treating product-specific government reporting requirements as commercial speech makes sense in this case. Part of the reason that the First Amendment protects commercial speech is that such speech furthers the "consumer's interest in the free flow of commercial information." *Va. State Bd. of Pharmacy*, 425 U.S. at 764; *see also Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249-50 (2010) ("First Amendment protection for commercial speech is justified in large part by the information's value to consumers . . . ."); *Cent. Hudson*, 447 U.S. at 561-62 ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information."). Notably, outside the context of commercial transactions, the information required by HB 4005 has no independent expressive meaning. *Cf. Zauderer*, 471 U.S. at 651 (noting that the "interests at stake" in regulating commercial transactions "are not of the same order" as those where a speech regulation "prescribe[s] what

shall be orthodox in politics, nationalism, religion, or other matters of opinion" (quoting *Barnette*, 319 U.S. at 642)). Where, as here, a government reporting requirement is closely tethered to the sale of a product and "assists consumers and furthers the societal interest in the fullest possible dissemination of information," it is properly categorized as commercial speech. *Cent. Hudson*, 447 U.S. at 561-62.[18]

The partial dissent argues that certain subsections of HB 4005's reporting requirement—namely, those that it views as related to "pricing strategy"[19]— require manufacturers to disclose information that "go[es] further" than communicating the terms of a potential transaction because the reports require manufacturers to express "opinions about and reasons for" their drug prices. Partial Dissent at 81-82,

[18] Contrary to the partial dissent's assertions, we have not "articulate[d] a new legal test" for government reporting requirements. Partial Dissent at 95. Nor have we "discard[ed]" the *Bolger* factors. Partial Dissent at 79, 85. Rather, we have simply recognized that some aspects of the commercial speech doctrine are more instructive in this context than others. Our fact-cabined analysis reflects the reality that 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." *X Corp.*, 116 F.4th at 900 (quoting *First Resort*, 860 F.3d at 1272). Additionally, although the partial dissent characterizes our analysis as lacking a "limiting principle," Partial Dissent at 113, we highlight the close tether between the speech compelled by HB 4005 and commercial pharmaceutical transactions. Speech, such as this, that is incidental to a commercial transaction is not far removed from the "core" of commercial speech, *i.e.*, speech that "propose[s] a commercial transaction." *United Foods*, 533 U.S. at 409.

[19] The partial dissent agrees that other basic marketing information required by HB 4005 is "factual and uncontroversial commercial information." Partial Dissent at 80-81.

91-95 (quoting *X Corp.*, 116 F.4th at 901).[20] We disagree. The economic-focused reports at issue here are a far cry from the "politically fraught" definitions at issue in *X Corp.* 116 F.4th at 902. The law under review in *X Corp.*, AB 587, required social media companies to identify what they believed to be "Hate speech or racism," "Extremism or radicalization," "Disinformation or misinformation" and "Foreign political interference," which is an intensely political exercise. *Id.* at 896. HB 4005's reporting requirement simply does not compel manufacturers to express any analogous normative view about their drug pricing,[21] nor does it require manufacturers to define their drug pricing in value-laden, state-prescribed language.[22]

[20] Indeed, the partial dissent seems to imagine that HB 4005 requires manufacturers to report a detailed, play-by-play recount of internal discussions about pricing. Partial Dissent at 91-94, 98-100. However, the State represented at oral argument that DCBS would consider the following straightforward list of factors to be a satisfactory response to Or. Rev. Stat. § 646A.689(3)(c): "supply cost increases, research costs, and investor return."

[21] Unlike the information required by HB 4005, the speech compelled by AB 587 had independent expressive meaning outside the context of any commercial transaction. What constitutes "hate speech," for example, is a matter of public debate and concern outside the context of a social media company's terms of service (or, indeed, any commercial transaction). By contrast, it would make little sense to divorce the speech compelled by HB 4005, such as a pharmaceutical manufacturer's distribution costs, Or. Rev. Stat. § 646A.689(3)(f)(3), from specific product sales.

[22] The partial dissent asserts that reports required under HB 4005 "recast drug manufactures' pricing strategies into language prescribed by Oregon" because requiring manufacturers to report on various costs "impl[ies] that any increase in drug prices can be fairly justified only by increases in costs." Partial Dissent at 91. But under this view, laws

Rather, HB 4005 requires manufacturers to report product-specific, economic information about their products such as current and past list prices, generic alternatives, and the length of time the drugs have been on the market. *Compare* Or. Rev. Stat. § 646A.689(3), *with X Corp.*, 116 F.4th at 894, *and NetChoice*, 113 F.4th at 1109, 1119-20.

PhRMA similarly argues that HB 4005's reporting requirement calls for "opinion[s] . . . about the reasons for high prescription prices." But no opinion is required for a manufacturer to disclose, as a matter of historical fact, the factors the company considered in setting its drug price. Contrary to PhRMA's arguments, HB 4005's reporting requirement does not "reinforce the State's message that manufacturers are the ones responsible for drug prices." Indeed, manufacturers are free to explicitly *reject* any such message and explain (to DCBS, market participants, and the public at large) the full range of factors that drive their pricing decisions. If, for example, a manufacturer raises the

---

requiring nutrition labels on food products would also be subjected to strict scrutiny simply because they require reporting based on categories prescribed by the state. *Contra Am. Beverage Ass'n*, 916 F.3d at 756. Moreover, even setting aside that the "factors that contributed to [a] price increase" are reported separately from these costs here, *see* Or. Rev. Stat. § 646A.689(3)(c), (e), (f), if consumers were to find an "implicit" message in the State's decision to request cost information from manufacturers, any such message would be attributable to the State. Just as consumers understand that the categories of information disclosed on nutrition labels (*e.g.*, added sugars, trans fats, protein) are selected by the government, it is clear here that the categories of information disclosed under HB 4005 are selected by the State. Of course, the "State can express [its] view[s] through its own speech," *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578 (2011), and nothing about HB 4005 prevents a manufacturer from defining and disseminating its own message about drug pricing.

price of a drug to mitigate rising manufacturing costs, fund future research and development, offset a tax hike, or comply with new regulatory requirements, it remains entirely free to explain the impact of these economic pressures on the drug's price. *See* Or. Rev. Stat. § 646A.689(3)(k) (requesting "[a]ny other information that the manufacturer deems relevant to the price increase"); Or. Admin. R. 836-200-0530(2)(h) (requiring manufacturers include "a narrative description and explanation of all major financial and nonfinancial factors" contributing to a price increase).

And although drug pricing decisions may implicate controversial public policy issues, this fact is insufficient to transform the required reports into noncommercial speech. *See Bolger*, 469 U.S. at 68 ("We have made clear that advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech." (quoting *Cent. Hudson*, 447 U.S. at 563 n.5)); *Bd. of Trs. v. Fox*, 492 U.S. 469, 475 (1989) ("[C]ommunications can constitute commercial speech notwithstanding the fact that they contain discussions of important public issues." (internal quotation marks and citation omitted)); *Valle Del Sol Inc. v. Whiting*, 709 F.3d 808, 819 (9th Cir. 2013) (concluding that restrictions on solicitation speech of day laborers implicated commercial speech because, although "[t]he act of soliciting work as a day laborer may communicate a political message, . . . the primary purpose of the communication is to advertise a laborer's availability for work and to negotiate the terms of such work"). In this way, HB 4005's reporting requirement is similar to the hypothetical government reporting requirement that the Court tacitly approved of in *Riley*. There, the Court suggested that North Carolina could require

professional fundraisers to submit financial reports that disclosed the percentage of solicitation funds actually turned over to charities within the last 12 months—and then disseminate those financial reports to the public. *Riley*, 487 U.S. at 800. As here, exposing how much money professional fundraisers take from charitable donations could be considered "controversial" to the extent that it reflects fundraisers' profit-motivated decisionmaking, and publication of this information arguably went against the fundraisers' economic interests.[23]

That HB 4005 calls for the reporting of some information that may reflect internal decisionmaking also does not dissuade us from categorizing the reporting requirement as commercial speech.[24] Many routine financial regulations

[23] The partial dissent attempts to reconcile its reasoning with *Riley* by reframing the required disclosure in *Riley* as communicating the "price of [a professional fundraiser's] services." Partial Dissent at 111-12. But there is no difference in kind between requiring a professional fundraiser to publicly disclose "the average percentage of gross receipts actually turned over to charities by the fundraiser for all charitable solicitations conducted in North Carolina within the previous 12 months," *Riley*, 487 U.S. at 786, and requiring a pharmaceutical manufacturer to disclose the factors that contributed to a price increase. Both regulations essentially require the covered entity to (indirectly) explain to customers what it is they are paying for, even if the covered entity would prefer not to provide such clarity.

[24] PhRMA's focus on the disclosure of "internal decisionmaking" attempts to inject concerns about confidentiality into the First Amendment analysis. But PhRMA cites no authority for the proposition that confidentiality has a role to play in our First Amendment analysis. In any event, HB 4005 does not broadly compel the public disclosure of confidential information. A manufacturer may designate the information as a trade secret in its report to DCBS, and the State may only disclose protected trade secret information under the public-interest exception.

require the reporting of similar internal economic analysis. *See, e.g.*, 17 C.F.R. § 229.402(b) (requiring corporations to describe the "objectives of the [corporation's executive] compensation programs" including "[w]hat the compensation program is designed to reward" and "[w]hether and . . . how the [corporation] has considered the results of the most recent shareholder advisory vote on executive compensation" in publicly disclosed SEC filings); *Rowe*, 429 F.3d at 299, 307, 310, 316 (controlling concurrence) (analyzing a regulation requiring pharmacy benefit managers to identify and disclose "conflicts of interest" and "financial and utilization information" to health benefit providers as commercial speech). The mere fact that a reporting requirement compels regulated entities to disclose information reflecting the company's internal decisionmaking does not strip that speech of its fundamentally commercial character.[25]

Having concluded that HB 4005's reporting requirement is properly categorized as commercial speech, our next step would normally be to determine whether the statute is subject to intermediate scrutiny under *Central Hudson*, or qualifies for a lower level of scrutiny under *Zauderer*.[26] *See*

Or. Rev. Stat. § 646A.689(10)(a). The State has not done so since the law was enacted in 2018.

[25] Although the degree to which a compelled disclosure reflects a company's internal strategies might bear on whether speech is "purely factual" for purposes of determining if *Zauderer* review is appropriate, 471 U.S. at 651, it does not bear on whether a reporting requirement regulates commercial speech.

[26] For HB 4005, application of the commercial speech doctrine to determine the appropriate level of scrutiny does not produce a doctrinally

Nat'l Ass'n of Wheat Growers, 85 F.4th at 1275. We need not decide this issue, however, because we conclude that HB 4005's reporting requirement survives even the more stringent standard, intermediate scrutiny under *Central Hudson*. *See INS v. Bagamasbad*, 429 U.S. 24, 25 (1976) ("As a general rule courts . . . are not required to make findings on issues the decision of which is unnecessary to the results they reach.").

ii. Application of Intermediate Scrutiny

For HB 4005's reporting requirement to survive intermediate scrutiny under *Central Hudson*, the State must establish that the law "'directly advance[s]' a 'substantial' governmental interest, and [that] the means chosen [are] not . . . 'more extensive than necessary.'" *Nat'l Ass'n of Wheat*

---

indefensible result. However, there are other longstanding government reporting requirements that would be subject to strict scrutiny under the presumptively strict approach—even if we treated the *Bolger* factors as a "just a starting point" (as *Bolger* instructs) and focused on whether the report "communicates the terms of an actual or potential [commercial] transaction." *X Corp.*, 116 F.4th at 900-01. Consider, for example, IRS Form 990, which requires *noncommercial* entities, including non-profit charitable organizations, to disclose information about their missions and "program service accomplishments," as well as detailed financial information (such as their revenues, sources of revenues, spending, and most highly compensated employees). *See Form 990*, Internal Rev. Serv., https://www.irs.gov/pub/irs-pdf/f990.pdf; *see also Form 990*, Library of Cong. Rsch. Guide, https://guides.loc.gov/nonprofit-sector/form-990. Further, the 990 is a public document that can be accessed in a variety of ways, including on government websites. *See, e.g.*, *Tax Exempt Organization Search Tool*, Internal Rev. Serv., https://www.irs.gov/charities-non-profits/search-for-tax-exempt-organizations. Under the presumptively strict approach, this longstanding reporting requirement would likely be subject to strict scrutiny simply because it "compels" noncommercial entities to disclose noncommercial information.

Growers, 85 F.4th at 1275 (quoting *Cent. Hudson*, 447 U.S. at 564-66).

First, we conclude that the State's asserted interests in HB 4005's reporting requirement are "substantial." *Cent. Hudson*, 447 U.S. at 566. When the Oregon Legislative Assembly passed HB 4005, it highlighted the State's "substantial public interest in the price and cost of prescription drugs," and explained that HB 4005 is specifically designed to: (1) "provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability for prescription drug pricing," and (2) "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." HB 4005, ch. 7.

Although "consumer curiosity" alone is generally insufficient as a substantial state interest, *see Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 115 n.6 (2d Cir. 2001), the State's asserted interests here are not limited to transparency for its own sake. Rather, the State's transparency goals are intended to ensure the "preservation of a fair bargaining process" in negotiations related to drug purchasing. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996); *see also id.* at 502 ("It is the State's interest in protecting consumers from 'commercial harms' that provides 'the typical reason why commercial speech can be subject to greater governmental regulation than noncommercial speech.'" (quoting *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 426 (1993))); *Bolger*, 463 U.S. at 69 (highlighting the "substantial individual and societal interests in the free flow of commercial information" (internal quotation marks and citation omitted)).

The pharmaceutical drug market is characterized by significant informational asymmetries. *See* Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 Yale J.L. & Tech. 61, 70-77 (2020) (explaining that in the pharmaceutical market, "perverse incentives, along with externalities and information asymmetries, operate to blunt the natural competitive forces society might otherwise enjoy"). The State has a substantial interest in reducing those asymmetries, facilitating informed commercial transactions, and improving the efficiency of the pharmaceutical market. *See S.F. Apartment Ass'n*, 881 F.3d at 1177 (recognizing San Francisco's asserted interests in the "fairness of buyout negotiations" between landlords and tenants and the "reduct[ion] [in] the likelihood that tenants will accept 'unfair' buyout agreements" as substantial); *cf. Edenfield v. Fane*, 507 U.S. 761, 769 (1993) ("For purposes of [the *Central Hudson*] test, there is no question that [the State's] interest in ensuring the accuracy of commercial information in the marketplace is substantial."). This is particularly true given the State's role as a direct purchaser of pharmaceutical drugs and a major payer in the health care system, and given the magnitude of the State's expenditures on prescription drugs. *See* Brief for the State of Cal., et al. as Amici Curiae, at 15 (noting the Oregon Health Authority spent more than $1.3 billion in 2022 on prescription drugs for those enrolled in Oregon's Medicaid and children's health program).

Second, we conclude that HB 4005's reporting requirement "directly advances" these substantial interests. *Cent. Hudson*, 447 U.S. at 566. To meet the "direct advancement" requirement, the State must demonstrate that "the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S.

at 771. However, even "in a case applying strict scrutiny," the State may "justify speech restrictions by reference 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) (internal quotation marks and citation omitted).

The district court concluded that the State had not established how HB 4005 would directly advance its asserted interests because the State had failed to point to data showing that HB 4005 would "actually reduce the cost of prescription drugs in Oregon." *Summary Judgment Opinion*, 724 F. Supp. 3d at 1202. It is true that, in its summary judgment briefing, the State failed to cite any empirical evidence linking drug pricing transparency laws to lower drug prices. But the State has never claimed that HB 4005's reporting requirement itself will directly lower drug prices.[27] Rather, the State's stated goal in enacting HB 4005 was to reduce information asymmetries in the pharmaceutical market and provide drug purchasers with leverage in negotiations with manufacturers. It is common sense that collecting and publishing information about drug pricing,

[27] Although HB 4005's stated legislative goal is not to lower drug prices, amici curiae have provided evidence showing a correlation between drug pricing transparency laws and reductions in drug price increases. For example, the Oregon Coalition for Affordable Prescriptions cites data from Vermont showing that in the four years after the State passed a drug price transparency law in 2016, there was a 79% decline in the number of drugs reaching the per-year price increase threshold that triggered the law's reporting requirements. Brief for the Or. Coalition for Affordable Prescriptions as Amici Curiae, at 12 (citing Johanna Butler, *Drug Price Transparency Laws Position States to Impact Drug Prices*, Nat'l Acad. for State Health Pol'y (Jan. 10, 2022), https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices).

costs, and pharmaceutical market conditions "directly advances" this goal. *Cf. Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 415 (D.C. Cir. 2012) ("The government interest—ensuring the accuracy of commercial information in the marketplace—is clearly and directly advanced by a regulation requiring that the total, final price [of commercial airfare] be the most prominent."); Medicare and Medicaid Programs; Regulation To Require Drug Pricing Transparency, 84 Fed. Reg. 20732, 20744 (May 10, 2019) ("Price transparency helps improve market efficiencies by helping consumers make informed choices and the disclosure of price information clearly and directly advances this interest.").

Third, we conclude that the State's chosen means of speech regulation here are not "more extensive than necessary to further the State's interest[s]." *Cent. Hudson*, 447 U.S. at 569-70. In its briefing before this court, PhRMA does not argue that a more limited disclosure would suffice or identify any specific subsection of HB 4005's reporting requirement that it asserts is unnecessary to advance the State's interests. Rather PhRMA's sole argument is that HB 4005's reporting requirement is impermissibly underinclusive because it applies only to pharmaceutical manufacturers, and does not require other supply chain participants to provide any drug pricing information. However, "[a]s a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied." *Zauderer*, 471 U.S. at 651 n.14; *see also Destination Ventures, Ltd. v. FCC*, 46 F.3d 54, 56 (9th Cir. 1995) ("The First Amendment does not require Congress to forgo addressing the problem at all unless it completely eliminates [the problem]."). Moreover, PhRMA's

"argument holds even less water here because the narrow tailoring requirement guards against over-regulation rather than under-regulation." *Metro Lights, LLC v. City of Los Angeles*, 551 F.3d 898, 911 (9th Cir. 2009).

Additionally, courts have repeatedly characterized the mechanism of disclosure here—wherein the State rather than a regulated entity makes disclosed information available to the public—as narrowly tailored. For example, in *Riley*, the Court concluded that the North Carolina statute at issue, which required fundraisers to directly disclose the percentage of funds they had turned over to charities, was not narrowly tailored because there were "more benign and narrowly tailored options." *Id.* at 800. Again, the Court explained that "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." *Id.*; *see also Buckley v. Valeo*, 424 U.S. 1, 68 (1976) (explaining that, in the context of campaign finance, "disclosure requirements certainly in most applications appear to be the least restrictive means of curbing the evils of campaign ignorance"); *Nat'l Ass'n of Wheat Growers*, 85 F.4th at 1283 (explaining that a more narrowly tailored alternative for a product warning would be for the state to "post information about glyphosate on its own website"); *Nat'l Fed'n of the Blind of Tex., Inc. v. Abbott*, 647 F.3d 202, 214 (5th Cir. 2011) ("[T]here is nothing stopping Texas from requiring [a regulated entity] to file financial disclosure forms, which Texas could publish without burdening the [entity] with unwanted speech."). Under the State's chosen means of regulation here, manufacturers remain free to disseminate their own

messages directly to consumers and to the public at large. *See Va. State Bd. of Pharmacy*, 425 U.S. at 770 ("[P]eople will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.").

Ultimately, *Central Hudson* review requires only "a reasonable fit between the means and ends of the regulatory scheme." *Lorillard*, 533 U.S. at 561. We conclude that HB 4005's reporting requirement is appropriately tailored and survives intermediate scrutiny.

iii. Severability

In this appeal, the State again argues that, even if PhRMA were to prevail, it is entitled only to a judgment severing and invalidating Or. Rev. Stat. § 646A.689(3)(c), which requires manufacturers to report the "factors that contributed to the price increase." Because we conclude that all subsections of HB 4005's reporting requirement are constitutional under the First Amendment, we do not reach this argument. We note, however, that when striking down a state statute as unconstitutional, "'the normal rule' is that 'partial, rather than facial, invalidation is the required course.'" *Project Veritas v. Schmidt*, 125 F.4th 929, 960 n.29 (9th Cir. 2025) (en banc) (quoting *Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 504 (1985)).

Here, PhRMA only addressed § 646A.689(3)(c) in its summary judgment briefing. As a result, the State's opposition to PhRMA's summary judgment motion only addressed § 646A.689(3)(c). Similarly, the district court only analyzed § 646A.689(3)(c) in its preliminary oral ruling. Nevertheless, PhRMA subsequently proposed a declaratory judgment invalidating the entirety of

§ 646A.689(3). Although the State then raised severability in its brief objecting to PhRMA's proposed declaratory judgment, the district court invalidated the entire reporting requirement because it considered the State's severability argument waived. *Summary Judgment Opinion*, 724 F. Supp. 3d at 1197 n.6. At no point did the district court ever provide substantive analysis on any subsection except § 646A.689(3)(c). Moreover, because PhRMA's motion for summary judgment only addressed § 646A.689(3)(c), the State had no reason to raise severability in its opposition to PhRMA's summary judgment motion. Thus, the State could not have waived the severability issue in its opposition to PhRMA's motion for summary judgment.

But even if the State had waived the argument, our en banc court recently expressed "doubt" that declining to consider severability based on waiver "would be the proper course," explaining that "the Supreme Court has previously faulted our court for failing to consider severability before invalidating an entire state statute." *Project Veritas*, 125 F.4th at 960 n.29 (citing *Brockett*, 472 U.S. at 507; *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328-31 (2006); *New York v. United States*, 505 U.S. 144, 186 (1992)). So even if some subsections of Or. Rev. Stat. § 646A.689(3) did not survive the applicable level of scrutiny, the appropriate next step would be to sever them.

* * *

In sum, assuming *arguendo* that HB 4005's reporting requirement is subject to intermediate scrutiny, we conclude that it is a permissible regulation of commercial speech. We thus hold that the State, not PhRMA, is entitled to summary judgment on PhRMA's First Amendment claim.

B. Fifth Amendment Takings Claim

We next turn to whether HB 4005's public-interest exception constitutes an unconstitutional taking of private property under the Fifth Amendment. For the reasons below, we hold that PhRMA is not entitled to summary judgment in this facial challenge.

"The Takings Clause of the Fifth Amendment states that 'private property [shall not] be taken for public use, without just compensation.'" *Knick v. Twp. of Scott, Pennsylvania*, 588 U.S. 180, 184 (2019) (alteration in original) (quoting U.S. Const. amend. V).[28] Here, PhRMA argues that the public-interest exception is a facial violation of the Takings Clause because, each and every time the exception is invoked, the State takes manufacturers' property—specifically, their trade secrets—without providing just compensation. The State advances two primary arguments: (1) that PhRMA's claim is nonjusticiable, and (2) that PhRMA cannot prevail on the merits of its facial claim.

i. Justiciability

Both parties acknowledge that, to date, DCBS has never invoked the public-interest exception and never publicly disclosed any of the thousands of purported trade secrets filed with DCBS under HB 4005. The State argues that, because DCBS has yet to invoke the exception, PhRMA's claim is nonjusticiable. The pre-enforcement posture of this facial challenge raises two issues: Article III standing and ripeness. We discuss each in turn.

---

[28] The Takings Clause applies against the States through the Fourteenth Amendment. *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 160 (1980).

a. Article III Standing

Here, PhRMA asserts associational standing on behalf of its member pharmaceutical and biotechnology manufacturers. "To satisfy associational standing requirements, an organization must demonstrate that (1) at least one of its members has suffered an injury in fact that is (a) concrete and particularized and (b) actual or imminent, rather than conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action; and (3) it is likely, not merely speculative, that the injury will be redressed by a favorable decision." *California Rest. Ass'n v. City of Berkeley*, 89 F.4th 1094, 1099 (9th Cir. 2024).[29] The State argues that PhRMA cannot establish this first prong, *i.e.*, that any of its members has suffered an injury in fact. We disagree.

The State argues that PhRMA cannot establish an injury in fact in its facial challenge because the law's enactment had no immediate effect on private property. This argument is unavailing. To establish injury in fact, "[a]n allegation of future injury may suffice if the threatened injury is 'certainly impending,' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411, 414 n.5 (2013)); *see also In re Zappos.com, Inc.*, 888 F.3d 1020, 1026 (9th Cir. 2018). Standing alone, the fact

[29] Associational standing also requires that "the interests [the organization] seeks to protect are germane to the organization's purpose" and that "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Associated Gen. Contractors of Am., San Diego Chapter, Inc. v. Cal. Dep't of Transp.*, 713 F.3d 1187, 1194 (9th Cir. 2013). The State does not dispute that PhRMA has established these elements of associational standing, and we agree.

that the public-interest exception has never been invoked does not persuade us that the alleged harm here is, as the State argues, "purely speculative." Indeed, in a hearing before the district court, when the State was asked whether DCBS's decisions not to invoke the public-interest exception have been "influenced by the pendency of this litigation," counsel stated that this was "possible." Where, as here, "the State has not disavowed any intention of invoking the [challenged] provision," manufacturers face a "credible threat" of public disclosure of their trade secrets. *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298, 302 (1979). Importantly, PhRMA's theory of standing does not rest on a "speculative multi-link chain of inferences" about possible future events, *In re Zappos.com*, 888 F.3d at 1026, nor does it depend on the independent actions of third parties, *see Washington v. U.S. Food & Drug Admin.*, 108 F.4th 1163, 1175 (9th Cir. 2024). Rather, PhRMA's theory rests on a single determination by DCBS that disclosure of a claimed trade secret is in the "public interest." *See* Or. Rev. Stat. § 646A.689(10)(a). Once that determination is made, disclosure under HB 4005 is mandatory. *See id.* § 646A.689(9) (explaining that unless the public-interest exception applies, DCBS "*shall* post to its website" information disclosed by manufacturers (emphasis added)). We thus conclude that the risk of future injury is sufficiently nonspeculative to establish injury in fact.

The remaining Article III standing requirements are also satisfied. The risk of future harm faced by PhRMA's members is self evidently "fairly traceable" to the conduct being challenged—the invocation of the public-interest exception.

Redressability is also satisfied here. In considering Article III redressability, the focus is primarily on "the

connection between the alleged injury and requested judicial relief." *Wash. Env't Council v. Bellon*, 732 F.3d 1131, 1146 (9th Cir. 2013). PhRMA's requested relief here is a declaratory judgment recognizing that any invocation of the public-interest exception without simultaneously providing just compensation would violate the Fifth Amendment. A declaratory judgment in PhRMA's favor would redress manufacturers' injuries by making a "definitive determination of the legal rights of the parties." *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937); *see also MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126-27 (2007); *Seattle Pac. Univ. v. Ferguson*, 104 F.4th 50, 62 (9th Cir. 2024). In other words, even though a declaratory judgment itself would not provide immediate relief to PhRMA's members, the preclusive effect of the judgment would provide manufacturers relief by binding the State in any subsequent lawsuits seeking compensation for unconstitutional takings under the challenged provision. *Cf. Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982) ("[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his *every* injury.").

To be sure, in this context there is significant overlap between constitutional standing and ripeness issues. But, for Article III standing purposes, it suffices to conclude that the preclusive effect of a declaratory judgment in PhRMA's favor would redress manufacturers' alleged injuries.

b. Ripeness

We also conclude that PhRMA's takings claim is ripe for review. "[T]he ripeness inquiry contains both a constitutional and a prudential component." *Thomas v.*

Anchorage Equal Rts. Comm'n, 220 F.3d 1134, 1138 (9th Cir. 2000) (quoting *Portman v. County of Santa Clara*, 995 F.2d 898, 902 (9th Cir. 1993)). The constitutional component of the ripeness inquiry focuses on whether the issues presented are "definite and concrete, not hypothetical or abstract." *Id.* (quoting *Ry. Mail Ass'n v. Corsi*, 326 U.S. 88, 93 (1945)). Here, this inquiry "coincides squarely with standing's injury in fact prong," *id.*, and for the reasons discussed above, *see supra* Section III.B.i.a, we conclude that PhRMA's claim meets constitutional ripeness requirements.

Turning to prudential ripeness, in the context of a takings claim, the key question is whether the plaintiff has "received a 'final decision regarding the application of the [challenged] regulations to the property at issue' from 'the government entity charged with implementing the regulations.'" *Suitum v. Tahoe Reg'l Plan. Agency*, 520 U.S. 725, 734 (1997) (quoting *Williamson Cnty. Reg'l Plan. Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 186 (1985)). "[O]ur analysis is guided by two overarching considerations: 'the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.'" *Thomas*, 220 F.3d at 1141 (quoting *Abbott Laby's v. Gardner*, 387 U.S. 136, 148 (1967)).

Generally, in the takings context, "[o]nce the government is committed to a position . . . the dispute is ripe for judicial resolution." *Pakdel v. City & County of San Francisco*, 594 U.S. 474, 479 (2021). It is true that the State has yet to define the circumstances under which "[t]he public interest . . . require[s] disclosure." Or. Rev. Stat. § 646A.689(10)(a). However, PhRMA has chosen to litigate this case as a facial challenge and seeks a declaration stating that every disclosure under the public-interest exception—

regardless of why that disclosure was made—constitutes an unconstitutional taking. Resolving this facial claim does not involve probing fact-specific DCBS public-interest determinations, and thus there is no finality issue that renders this claim unripe. *Guggenheim v. City of Goleta*, 638 F.3d 1111, 1117 (9th Cir. 2010) (en banc) ("Facial challenges are exempt from [prudential finality requirements] because a facial challenge by its nature does not involve a decision applying the statute or regulation."); *see also Suitum*, 520 U.S. at 736 n.10 ("[F]acial challenges to regulation are generally ripe the moment the challenged regulation or ordinance is passed, but face an uphill battle since it is difficult to demonstrate that mere enactment of a piece of legislation deprived the owner of economically viable use of his property." (cleaned up)).

To be sure, whether any individual invocation of the public-interest exception constitutes an unconstitutional taking is a fact-specific, individualized inquiry. *See infra* Section III.B.ii. But we conclude that this issue is properly addressed as part of the merits of PhRMA's facial claim. No additional factual development is necessary for this court to decide whether every invocation of the exception constitutes a taking. Because the "issue presented is fit for judicial resolution," *Abbott Laby's*, 387 U.S. at 153, we see no reason to withhold a decision on the merits.

ii. Merits of the Takings Clause Claim

Because we conclude that PhRMA's facial takings claim is justiciable, we next turn to the merits.

As a threshold matter, we note that manufacturers have a protectable property interest in their claimed trade secret information to the extent that the information is "cognizable as a trade-secret property right under [state] law."

Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003-04 (1984); *see also Carpenter v. United States*, 484 U.S. 19, 26 (1987) ("Confidential business information has long been recognized as property."); *St. Michael's Convalescent Hosp. v. California,* 643 F.2d 1369, 1374 (9th Cir. 1981); *CDK Glob. LLC v. Brnovich*, 16 F.4th 1266, 1282 (9th Cir. 2021). Here, Oregon law recognizes a property interest in trade secrets, *see* Or. Rev. Stat. § 307.020(1)(a)(I) (defining trade secrets as intangible personal property for property tax purposes); *State ex rel. Sports Mgmt. News v. Nachtigal*, 921 P.2d 1304, 1309 (Or. 1996) (recognizing that Oregon's Uniform Trade Secrets Act "protect[s] the property interests of the holder of [a] trade secret"), and thus trade secrets submitted to DCBS constitute protectable property under the Fifth Amendment.[30]

a. Legal Standard

We next turn to the proper legal standard for evaluating PhRMA's takings claim. The Supreme Court has articulated two categories of takings under the Fifth Amendment. *See Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147-49 (2021). Where the government "physically acquires private property for a public use," a "per se" taking has occurred. *Id.* at 147-48. But where the government "instead imposes regulations that restrict an owner's ability to use his own

[30] We note that the definition of a "trade secret" incorporated by reference in HB 4005 is not identical to the definition in Oregon's Uniform Trade Secrets Act. *Compare* Or. Rev. Stat. § 192.345(2) (HB 4005 definition), *with id.* § 646.461(4) (Oregon Uniform Trade Secrets Act definition). However, the parties have not suggested that there is any material difference in these definitions, and the State does not dispute that trade secrets submitted under HB 4005 are property protected by the Fifth Amendment.

property," courts "appl[y] the flexible test developed in *Penn Central*." *Id.* at 148.

PhRMA does not assert that HB 4005 involves a "physical" taking but nonetheless argues that the public-interest exception should be considered a per se, "categorical" taking because it "denies [manufacturers] all economically beneficial or productive use" of their property. *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1015 (1992). This argument is unpersuasive for three reasons.

First, in the only Supreme Court case addressing an alleged taking of trade secrets, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984), the Court categorized the alleged taking as a regulatory taking and looked to the *Penn Central* factors. *Id.* at 1005-06. Second, it is far from clear that *Lucas*'s categorical approach extends beyond real property to intangible personal property. *Lucas* involved a land-use regulation and the Supreme Court framed the inquiry as whether the governmental action "denies an owner economically viable use *of his land*." 505 U.S. at 1016 (emphasis added). Indeed, *Lucas* explicitly distinguished land from personal property, explaining that "in the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [a plaintiff] ought to be aware of the possibility that new regulation might even render his property economically worthless." *Id.* at 1027-28. Third, even if *Lucas*'s categorical approach were applicable to intangible personal property, it is far from clear that every disclosure made under the public-interest exception will "den[y] *all* economically beneficial . . . use" of a manufacturer's trade secret in all cases. 505 U.S. at 1015 (emphasis added); *see also Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 330 (2002) ("Anything less than a 'complete elimination of value,' or a

'total loss,' . . . require[s] the kind of analysis applied in *Penn Central*." (quoting *Lucas*, 505 U.S. at 1019 n.8)). As discussed below, the economic impact of a disclosure will likely vary case by case, depending on the trade secret at issue and the extent of the information actually disclosed by DCBS. *See infra* Section III.B.ii.b.2.

We therefore categorize PhRMA's claim as a potential regulatory taking governed by the standards articulated in *Penn Central*.

b. Application of *Penn Central*

We begin by highlighting again that PhRMA has chosen to litigate this case as a facial challenge. Because "'[c]laims of facial invalidity often rest on speculation' about the law's coverage and its future enforcement" and "'threaten to short circuit the democratic process' by preventing duly enacted laws from being implemented in constitutional ways," the Supreme Court has "made facial challenges hard to win." *Moody v. NetChoice, LLC*, 603 U.S. 707, 723 (2024) (quoting *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450-51 (2008)); *see also Pennell v. City of San Jose*, 485 U.S. 1, 10 (1988); *Suitum*, 520 U.S. at 736 n.10; *Willis v. City of Seattle*, 943 F.3d 882, 886 (9th Cir. 2019).

Indeed, given the fact-intensive nature of the *Penn Central* framework, this court has repeatedly noted that "[i]t is not clear that a facial challenge can be made under *Penn Central*." *Laurel Park Cmty., LLC v. City of Tumwater*, 698 F.3d 1180, 1188 (9th Cir. 2012); *see also Guggenheim*, 638 F.3d at 1118 & n.32; *MHC Fin. Ltd. P'ship v. City of San Rafael*, 714 F.3d 1118, 1126 n.3 (9th Cir. 2013). As in these previous cases, we "assume, without deciding, that a facial challenge can be made under *Penn Central*." *Guggenheim,*

638 F.3d at 1118. However, we stress that PhRMA faces an "uphill battle," *Suitum*, 520 U.S. at 736 n.10, and "cannot succeed on [its] facial challenge unless [it] 'establishes that no set of circumstances exists under which the law would be valid,' or [it] shows that the law lacks a 'plainly legitimate sweep,'" *Moody*, 603 U.S. at 723 (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)) (cleaned up).

When considering whether a regulation constitutes a taking under *Penn Central*, courts generally consider three factors: (1) the regulation's interference with reasonable investment-backed expectations, (2) the economic impact of the regulation, and (3) the character of the government action. 438 U.S. at 124. We conclude that, under this "ad hoc," fact-specific framework, PhRMA is not entitled to summary judgment on this facial challenge. *Id.* at 124.

1. Reasonable Investment-Backed Expectations

"A 'reasonable investment-backed expectation' must be more than a 'unilateral expectation or an abstract need.'" *Monsanto*, 467 U.S. at 1005 (quoting *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155, 161 (1980)). Moreover, "[a]s a general matter, 'in the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [a property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless.'" *CDK Glob.*, 16 F.4th at 1282 (quoting *Lucas*, 505 U.S. at 1027-28). Here, we conclude that the disclosure of trade secrets under the public-interest exception will not, in every instance, upset reasonable investment-backed expectations.

First, reasonable expectations are necessarily tempered in areas "that ha[ve] long been the source of public concern

and the subject of government regulation." *Monsanto*, 467 U.S. at 1007; *see also Maine Educ. Ass'n Benefits Tr. v. Cioppa*, 695 F.3d 145, 154 (1st Cir. 2012) ("As a baseline proposition, [plaintiff's] expectations are substantially diminished by the highly regulated nature of the industry in which it operates."); *Rowe*, 429 F.3d at 316 (controlling concurrence) (concluding that pharmacy benefit managers "should . . . have expected the possibility" of disclosure of trade secrets given the "heavily regulated nature of the healthcare industry"). The pharmaceutical industry is unquestionably an industry with a long history of government regulation. *See, e.g.*, Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, 770-71 (prohibiting drug labels from being false or misleading and requiring labels to list presence and amount of certain ingredients). Importantly, regulation has not been limited to health and safety concerns. Increasingly, state and national governments have enacted regulations that directly address transparency in the pharmaceutical market. *See, e.g.*, 29 C.F.R. § 2590.715-2715A3(b); Vt. Stat. Ann. tit. 18, §§ 4633-4637; Cal. Health & Safety Code §§ 127675-12785; Minn. Stat. Ann. § 62J.84; N.J. Stat. Ann. §§ 45:14-82.1-82.11; N.Y. Ins. Law § 111-a. As a starting point, then, manufacturers ought to be aware of the heightened possibility that regulations may be enacted requiring disclosure of the exact type of information that may be commonly claimed as a trade secret under HB 4005.

Second, "the regulatory regime in place at the time the claimant acquires the property at issue helps to shape the reasonableness of . . . expectations." *Palazzolo v. Rhode Island*, 533 U.S. 606, 633 (2001) (O'Connor, J., concurring); *see also Ark. Game & Fish Comm'n v. United States*, 568 U.S. 23, 38 (2012) (explaining that "the property owner's

distinct investment-backed expectations" are "often informed by the law in force in the State in which the property is located"). Oregon law has precluded trade secret misappropriation claims based on the public disclosure of trade secrets where "the public interest requires disclosure" since the State first adopted the Uniform Trade Secrets Act in 1987. *See* 1987 Or. Laws Ch. 537 § 8(3) (Oregon Uniform Trade Secrets Act, now codified at Or. Rev. Stat. § 646.473(3)); 1973 Or. Laws Ch. 794 § 11 (Oregon's Public Records Law, now codified at Or. Rev. Stat. § 192.345(2)). The State's general practice of disclosing trade secrets in furtherance of the public interest further diminishes manufacturers' reasonable expectations of strict confidentiality in all cases.

Third, concluding that manufacturers have reasonable expectations of strict confidentiality of trade secrets submitted to the State under HB 4005 would be in significant tension with *Monsanto*, 467 U.S. 986. In *Monsanto*, the Supreme Court considered whether the EPA's disclosure of trade secret data submitted by Monsanto, a pesticide manufacturer, under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") constituted an unconstitutional taking. *Id.* at 990. The Court analyzed Monsanto's takings claim during three different time periods defined by two amendments to the statutory scheme.

Under FIFRA, which was first adopted in 1947, all pesticides must be registered with the federal government before their sale in interstate commerce. *Id.* at 990-91. Registration applications include various confidential information, including the formula for the pesticide and various health, safety, and environmental data. *See id.* at 991-93. As originally enacted, the statutory scheme was "silent with respect to EPA's authorized use and disclosure

of data submitted to it in connection with an application for registration." *Id.* at 1008. In 1972, Congress undertook comprehensive amendments to FIFRA and added a new provision related to the public disclosure of data submitted to EPA by pesticide manufacturers in support of a registration application. Under the new provision, pesticide manufacturers could designate disclosed information as a trade secret. *Id.* at 992. If so designated, EPA was prohibited from publicly disclosing this information. *Id.* In 1978, in part to clarify ambiguities in this regulatory scheme, Congress enacted additional amendments. *Id.* at 993. The 1978 amendments permitted the public disclosure of all health, safety, and environmental data—even if data was claimed as a trade secret. *Id.* at 995-96.[31]

The Court determined that EPA's disclosure of data between the 1972 and 1978 amendments could constitute a taking as "disclosure conflicts with the explicit assurance of confidentiality . . . contained in the statute during that period." *Id.* at 1013. However, the Court held that Monsanto could have had no reasonable expectation of strict confidentiality for information disclosed to EPA either before 1972 or after 1978, and thus the disclosure of data submitted by Monsanto during this time could not constitute an unconstitutional taking. Before 1972, when the statutory scheme was silent as to the disclosure of trade secret information, the Court explained that:

> [T]he [federal] Trade Secrets Act is not a guarantee of confidentiality to submitters of

[31] Other types of trade secret information (*e.g.*, manufacturing and quality control processes) were exempted from the disclosure requirement. *Id.* at 996 & n.5.

> data, and, absent an express promise, Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA. In an industry that long has been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest.

Id. at 1008-09. As to data submitted after 1978, the Court concluded that:

> If, despite the . . . 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. . . . [A]s long as Monsanto 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.

Id. at 1006-07.

HB 4005's public-interest exception is materially indistinguishable from the third time period at issue in *Monsanto*, *i.e.*, post-1978 amendments. HB 4005 explicitly authorizes the disclosure of trade secrets submitted to the State if disclosure is in the public interest. If manufacturers choose to run the risk of public disclosure of their trade secrets to do business in the highly regulated pharmaceutical industry, they "can hardly argue that [their] reasonable investment-backed expectations are disturbed when [the State] acts to . . . disclose the data in a manner that was authorized by law at the time of the submission." *Monsanto*, 467 U.S. at 1006-07.

The district court concluded that *Monsanto* was inapposite because there, pesticide manufacturers "voluntarily provided the trade secrets at issue," whereas here there is "no quid pro quo." *Summary Judgment Opinion*, 724 F. Supp. 3d at 1190. However, just as in *Monsanto*, the benefit provided to manufacturers is the ability to sell a highly regulated product in a government-regulated market. In *Monsanto*, the Supreme Court explained that in "those situations where [Monsanto] deems the [trade secret] data to be protected from disclosure more valuable than the right to sell in the United States," it can "decide to forgo registration in the United States and sell a pesticide only in foreign markets." 467 U.S. at 1007 n.11. Here, manufacturers have a similar choice. If they decide the value of protecting their trade secrets from potential disclosure to be more valuable than the right to sell in Oregon, they can decide to forego pharmaceutical sales in

the state and limit their product sales to other states and foreign markets.

PhRMA argues that such a choice is illusory and allowing a manufacturer to sell a legal product is not a valuable government benefit comparable to the regulatory permit at issue in *Monsanto*. This argument is not entirely without support. In *Horne v. Department of Agriculture*, the Supreme Court concluded that a regulation requiring "the [plaintiffs] to turn over 47 percent of their raisin crop[] in exchange for the 'benefit' of being allowed to sell the remaining 53 percent" was not a "similar voluntary exchange" to the exchange in *Monsanto*. 576 U.S. 350, 366 (2015); *see also Nollan v. California Coastal Comm'n*, 483 U.S. 825, 833 n.2 (1987) (distinguishing *Monsanto* on the basis that "the right to build on one's own property—even though its exercise can be subjected to legitimate permitting requirements—cannot remotely be described as a 'governmental benefit'").

However, we conclude that this case is much closer to *Monsanto* than to *Horne*. Access to highly regulated markets has not historically been conceived as a constitutional right. *See, e.g.*, *Corn Prods. Ref. Co. v. Eddy*, 249 U.S. 427, 431 (1919) ("[A] manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold."); *Nat'l Fertilizer Ass'n v. Bradley*, 301 U.S. 178, 182 (1937). The "valuable government benefit" of permitting a manufacturer to sell products in the highly regulated pesticide market is no different in kind than the "valuable government benefit" of permitting a manufacturer to sell products in a highly regulated pharmaceutical market. *Monsanto*, 467 U.S. at 1007. The claim at issue in *Horne*, where plaintiffs challenged the *physical* taking of a raisin crop, involved a

materially different market and a materially different government action. Indeed, in *Horne*, the Court explicitly noted that a law requiring raisin growers to physically turn over a portion of their crop was factually distinct from "[a] case about conditioning the sale of hazardous substances on disclosure of health, safety, and environmental information related to those hazards." 576 U.S. at 366.

Finally, manufacturers' reasonable expectations may differ significantly depending on the specific trade secret information and the public interest at issue in a given disclosure. A wide variety of information can be protected as a trade secret under Oregon law. *See* Or. Rev. Stat. § 192.345(2) (defining a trade secret to include, but not be limited to a "formula, plan, pattern, process, tool, mechanism, compound, procedure, production data, or compilation of information"). Manufacturers' reasonable confidentiality expectations will vary depending on how similar information has been historically regulated under preexisting state and federal law. Especially where a claimed trade secret is related to a drug's health and safety information, confidentiality expectations may be particularly diminished given the long history of government disclosure requirements for this type of information. *See, e.g.*, *Corn Prods.*, 249 U.S. at 431-32 ("The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth."); 15 U.S.C. § 2613(d)(3) (providing for the disclosure of data submitted under the Toxic Substances Control Act where "necessary to protect health or the environment against an unreasonable risk of injury to health or the environment").

Ultimately, given the facial nature of PhRMA's claim and the broad sweep of trade secret protection, we cannot say that every disclosure of a trade secret under HB 4005 will upset reasonable investment-backed expectations. We thus conclude that this factor does not support PhRMA's facial takings claim. We note that in *Monsanto*, the Supreme Court concluded that "the force of this factor is so overwhelming . . . that it disposes of the taking question." 467 U.S. at 1005. However, given the inherently fact-specific nature of the regulatory takings inquiry, we also address the additional *Penn Central* factors.

2. Economic Impact of the Regulation

In evaluating the economic impact of a challenged regulation under *Penn Central*, courts assess the extent to which the regulation "will unreasonably impair the value or use of [the plaintiff's] property." *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 83 (1980). In other words, "[w]e 'compare the value that has been taken from the property with the value that remains in the property.'" *Bridge Aina Le'a, LLC v. Land Use Comm'n*, 950 F.3d 610, 630-31 (9th Cir. 2020) (quoting *Colony Cove Props., LLC v. City of Carson*, 888 F.3d 445, 450 (9th Cir. 2018)). Here, because the economic impact of the public-interest exception may vary based on the extent of the disclosure, we conclude that this factor also does not support PhRMA's facial takings claim.

PhRMA argues that each time that DCBS publicly discloses a trade secret under the public-interest exception, the trade secret is rendered entirely worthless because the value of a trade secret lies in its confidentiality. This argument is not entirely without merit. HB 4005 incorporates the definition of a trade secret as information

with commercial value "known only to certain individuals within an organization . . . which gives its user an opportunity to obtain a business advantage over competitors who do not know or use it." Or. Rev. Stat. § 192.345; *see id.* § 646A.689(10)(a). As explained by the Supreme Court in *Monsanto*, "[i]f an individual discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished." 467 U.S. at 1002; *see also 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 [trade secret] then the property disappears." (citation omitted)).

However, it is far from clear that *every* invocation of the public-interest exception will necessarily disclose the information that provides the trade secret owner with its "competitive edge." *See Monsanto*, 467 U.S. at 1012. As defined in HB 4005, trade secret protection extends to *any* information that is valuable and secret enough to afford an economic advantage over competitors, including "compilation[s] of information." Or. Rev. Stat. § 192.345. If, in the context of a compilation trade secret, the State were to disclose only a portion of the data making up the claimed trade secret, it is plausible that the trade secret could retain much, if not all, of its economic value. *See Imperial Chem. Indus. Ltd. v. Nat'l Distillers & Chem. Corp.*, 342 F.2d 737, 742 (2d Cir. 1965) (collecting cases for the proposition that "a trade secret can exist in a combination of characteristics and components, each of which, by itself, is in the public domain, but the unified process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret"). In other words, to

hold the public-interest exception unconstitutional on its face, we would have to conclude that HB 4005 mandates broad disclosure of *all* the data making up a claimed trade secret in every case. However, in this pre-enforcement challenge, it is entirely plausible that DCBS could make a determination that a more limited disclosure is all that the public interest requires.

To be sure, many trade secrets implicated by HB 4005 may constitute a single piece of data, and disclosure of that data may entirely extinguish the value of the trade secret. But in this facial challenge, PhRMA cannot "establish[] that *no* set of circumstances exists under which the law would be valid." *Moody*, 603 U.S. at 723 (emphasis added) (quoting *Salerno*, 481 U.S. at 745). "[PhRMA] chose to litigate th[is] case[] as [a] facial challenge[], and that decision comes at a cost." *Id*. Therefore, this factor does not support PhRMA's takings claim.

3. Character of the Government Action

Finally, "the 'character of the governmental action'—for instance whether it amounts to a physical invasion or instead merely affects property interests through 'some public program adjusting the benefits and burdens of economic life to promote the common good'—may be relevant in discerning whether a taking has occurred." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 539 (2005) (quoting *Penn Cent.*, 438 U.S. at 124). This case clearly falls into the latter category. *See CDK Glob.*, 16 F.4th at 1282 ("Regulations commonly require regulated entities to disclose certain information. . . . [N]o one conceives of such requirements as physical takings."); *see also MHC Fin.*, 714 F.3d at 1128 (concluding that a rent control ordinance was "much more an 'adjust[ment of] the benefits and burdens of

economic life to promote the common good' than it is a physical invasion of property" (quoting *Penn Cent.*, 438 U.S. at 124)).

Moreover, because the "determination that governmental action constitutes a taking, is, in essence, a determination that the public at large, rather than a single owner, must bear the burden of an exercise of state power in the public interest," the Supreme Court has "recognized that this question 'necessarily requires a weighing of private and public interests.'" *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 492 (1987) (quoting *Agnis v. Tiburon*, 447 U.S. 255, 260-61 (1980)). Here, the public-interest exception does not permit disclosure of trade secret information unless and until DCBS makes an affirmative determination that disclosure is in the public interest. To be sure, the balance of private and public interests will differ depending on the nature of the public interest claimed by DCBS and the trade secret information at issue. But assessed facially, we cannot conclude that "no set of circumstances exist" where a significant public interest would clearly outweigh a manufacturer's private interest in a trade secret. *See Keystone*, 480 U.S. at 485 (concluding that "the character of the governmental action involved here leans heavily against finding a taking" where the government had "acted to arrest what it perceives to be a significant threat to the common welfare"); *see also CDK Glob.*, 16 F.4th at 1283 (concluding this factor did not support finding a regulatory taking where the state legislature determined "the statute promotes the common good through the advancement of consumer privacy and competition"). Thus, this factor also fails to support PhRMA's takings claim.

* * *

The proper weighing of the *Penn Central* factors varies from case to case, and courts have sometimes found individual factors to be dispositive. *Compare Hodel v. Irving*, 481 U.S. 704, 716 (1987) (concluding the "extraordinary" character of the regulation to be dispositive), *with Monsanto*, 467 U.S. at 1005 (concluding the lack of reasonable investment-backed expectations to be dispositive). Here, however, a weighing of the factors does not affect our analysis because none of the *Penn Central* factors support PhRMA's facial taking claim. We thus conclude that the State, not PhRMA, is entitled to summary judgment on the Fifth Amendment takings claim.

IV. CONCLUSION

For the foregoing reasons, the district court erred in granting summary judgment in favor of PhRMA on its First Amendment and Fifth Amendment claims and in entering final declaratory judgment. Accordingly, we reverse the district court's entry of final judgment and remand with instructions to enter summary judgment for the State on PhRMA's First Amendment and Fifth Amendment claims.

REVERSED AND REMANDED.

BEA, Circuit Judge, concurring in part and dissenting in part:

The First Amendment to our Constitution, applicable to the States through the Fourteenth Amendment, protects people's "right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). The question in this case is whether the government can, without passing strict scrutiny,[1] force an unwilling speaker to opine on an intensely debated and politically fraught subject because some potential listeners, including the government itself, can take advantage of that opinion for their own economic or political interests.[2]

My colleagues answer this question in the affirmative. They hold that an Oregon statute and its implementing regulation need not pass strict scrutiny when compelling drug manufacturers to disclose their internal pricing strategies because the purchasers of their drug products,

[1] Under strict scrutiny, a government regulation is "presumptively unconstitutional and may be justified only if the government proves that [the regulation is] narrowly tailored to serve compelling state interests." *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018).

[2] Where there is a willing speaker, the First Amendment protects both the speaker's right to speak and the listeners' right to listen. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756–57 (1976). Accordingly, courts have struck down regulations that abridge willing speakers' right to speak in the interest of their audiences' right to hear, as the Supreme Court did in *Virginia State Board of Pharmacy*. *See id.* at 763–65. In the same vein, courts have also upheld regulations that tackle inaccurate or misleading commercial speech by willing speakers to, for example, protect their audiences from possible deception. *See, e.g.*, *Zauderer v. Off. of Disciplinary Couns. of the Sup. Ct. of Ohio*, 471 U.S. 626, 650–53 (1985). This case does not involve such a willing speaker's speech.

including the State of Oregon itself, can take advantage of such information when negotiating prices against these drug manufacturers. Maj. Op. at 40–42.

In so holding, my colleagues discard the well-established legal tests articulated by the Supreme Court in *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983); disregard our Circuit's binding precedents in *X Corp. v. Bonta*, 116 F.4th 888 (9th Cir. 2024), and *NetChoice, LLC v. Bonta*, 113 F.4th 1101 (9th Cir. 2024); and deliver extensive dicta on how installing a novel analytical framework could help usher in a "modern government" that requires individuals and entities to turn in much private information. *See* Maj. Op. at 16–54.

My colleagues might be right that an attempt to impose wide-ranging reporting requirements is "a common feature of modern government," *id.* at 16, but it is the hallmark of our *lawful* government to demand such disclosures only within the confines of our Constitution. As the majority blurs and breaches these well-settled Constitutional boundaries, I respectfully dissent.[3]

I.

Pharmaceutical Research and Manufacturers of America ("PhRMA") challenged certain reporting requirements imposed by Oregon's Prescription Drug Price Transparency Act ("HB 4005") as violative of the First Amendment. Maj.

[3] I concur that the plaintiff-appellee's facial challenge on the Fifth Amendment ground fails because Oregon's long-standing public interest exception in its state trade secret laws undermines the reasonableness of any expectation of absolute protection of trade secrets in Oregon. Maj. Op. at 67. The plaintiff-appellee chose to litigate its Fifth Amendment claim as a facial challenge; "that decision comes at a cost." *Id.* at 75 (citation omitted).

Op. at 6–7. HB 4005 requires drug manufacturers to report, *inter alia*, detailed information about their pricing strategies for some prescription drugs to the Oregon Department of Consumer and Business Services ("DCBS") and instructs the DCBS to publish such information unless an exception applies. *Id.* (citing Or. Rev. Stat. § 646A.689(3), (9), (10)(a)). On appeal is the district court's declaratory judgment that invalidated Section 646A.689(3) of HB 4005 as offending the First Amendment.[4] *Id.* at 13 (citing *Pharm. Rsch. & Manufacturers of Am. v. Stolfi*, No. 6:19-CV-01996, 2024 WL 1144401 (D. Or. Feb. 16, 2024)).

A.

Section 646A.689(3) requires drug manufacturers to disclose two types of information. First, it demands disclosure of certain general marketing information for each prescription drug covered by HB 4005 ("General Marketing Information Disclosure Requirement"), including the length of time that the drug has been marketed, its introductory price, its price increases over time, its sales revenue, and its prices in other countries. Or. Rev. Stat. § 646A.689(3)(a), (b), (g), (i), (j). In my view, HB 4005's General Marketing Information Disclosure Requirement compels factual and uncontroversial commercial information and probably does not violate the First Amendment. *See Zauderer v. Off. of*

[4] Our review is not limited to Section 646A.689(3)(c) of HB 4005. *See* Maj. Op. at 12–15 (noting that PhRMA advanced arguments only against this one of many provisions under Section 646A.689(3)). It is the district court's judgment—not the statements in its opinion or the parties' arguments below—that we review on appeal. *See California v. Rooney*, 483 U.S. 307, 311 (1987). The district court's judgment declared the entire Section 646A.689(3) of HB 4005 unenforceable as violative of the First Amendment, so our review extends to the entire Section 646A.689(3).

Disciplinary Couns. of the Sup. Ct. of Ohio, 471 U.S. 626 (1985). So far, so good.

But Section 646A.689(3) demands much more. One should not be misled when the majority portrays HB 4005 as if it contained only this General Marketing Information Disclosure Requirement. *See* Maj. Op. at 7, 40, 43. This requirement is not the point of contention here.

What is really in dispute is Section 646A.689(3)'s additional requirement that drug manufacturers disclose their pricing strategies ("Pricing Strategy Disclosure Requirement"). Section 646A.689(3) obligates drug manufacturers to disclose, "in the form and manner prescribed by" the DCBS, all the "factors that contributed to the price increase[s]" of the drugs covered by HB 4005. Or. Rev. Stat. § 646A.689(3)(c). The state's implementing regulations clarify the statute's onerous requirements: drug manufacturers "must" include "narrative description[s] and explanation[s] of all major financial and nonfinancial factors that influenced the[ir] decision[s] to increase the [prices] of the [relevant] drug product[s] and to decide on the amount[s] of the increase[s]."[5] Or. Admin. R. 836-200-0530(2)(h) (2019). And Section 646A.689(3) further lists several factors that Oregon deems potentially relevant to drug prices and forces drug manufacturers to disclose information pursuant to these prescribed factors: research and development costs, manufacturing costs, marketing costs, distribution costs,

[5] While this appeal is pending, the DCBS amended its regulation, which now asks drug manufacturers to furnish this pricing strategy information "voluntarily." Or. Admin. R. 836-200-0530(2) (2025). As the mandatory language in Section 646A.689(3) of HB 4005 remains unchanged, this amendment of the DCBS's regulation affects neither the majority's analysis nor mine. *See, e.g.*, Maj. Op. at 44–45.

costs of safety and effectiveness research, the availability of generic substitutes, attributable profits, and so forth. Or. Rev. Stat. § 646A.689(3)(d), (e), (f), (h), (k); *see also id.* § 646A.689(l) (requiring drug manufacturers to produce documents to support the disclosed information).

In my view, HB 4005's Pricing Strategy Disclosure Requirement compels non-commercial speech and cannot survive strict scrutiny under the First Amendment.[6] My dissent thus focuses on HB 4005's Pricing Strategy Disclosure Requirement and the DCBS implementing regulation thereunder.[7]

B.

"It is well-established that the First Amendment protects 'the right to refrain from speaking at all'" and, accordingly, any "forced disclosure of information" "triggers First Amendment scrutiny." *NetChoice*, 113 F.4th at 1117 (quoting *Wooley*, 430 U.S. at 714). "When a state 'compels individuals to speak a particular message,' the state 'alters the content of their speech'" and engages in a content-based regulation. *X Corp.*, 116 F.4th at 900 (quoting *Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 585 U.S. 755, 766 (2018))

[6] Although the district court did not apply strict scrutiny when it invalidated Section 646A.689(3) of HB 4005 as violative of the First Amendment, we can affirm the judgment below on any ground supported by the record. *See Sec. Life Ins. Co. of Am. v. Meyling*, 146 F.3d 1184, 1190 (9th Cir. 1998). Oregon does not claim Section 646A.689(3) can survive strict scrutiny, so the only question is whether strict scrutiny applies in the first place.

[7] I would remand this case so that the district court could decide in the first instance whether HB 4005's Pricing Strategy Disclosure Requirement is severable from the remainder of Section 646A.689(3). *See* Maj. Op. at 54–55.

(cleaned up). Such a content-based regulation must withstand strict scrutiny unless it compels only commercial speech. *Id.* at 899–900. Hence, the First Amendment analysis in this case turns on whether the speech compelled by HB 4005's Pricing Strategy Disclosure Requirement ("Pricing Strategy Disclosures") constitutes commercial speech.

The "starting point" for this commercial speech inquiry is a "common-sense" one: Courts ask whether HB 4005's Pricing Strategy Disclosures do "no more than propose a commercial transaction." *Id.* at 900 (quoting *Ariix, LLC v. NutriSearch Corp.*, 985 F.3d 1107, 1115 (9th Cir. 2021), and *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001)). My colleagues perform essentially no analysis under this test; they recite it and move on. *See* Maj. Op. at 36–38. In my view, HB 4005's Pricing Strategy Disclosures are a far cry from a proposal for commercial transactions. After all, rational sellers do not propose commercial transactions by disclosing detailed rationales underlying their pricing decisions to potential buyers.

As a corollary of this "commercial transaction proposal" test, our Circuit has held that a compelled disclosure constitutes commercial speech if it "communicates the terms of an actual or potential transaction." *X Corp.*, 116 F.4th at 901. While the General Marketing Information Disclosures under HB 4005 may communicate transaction terms,[8] the

[8] The majority asserts that HB 4005 may lawfully compel drug manufacturers to identify the generic competitors of their drug products because this type of information constitutes common terms of commercial transactions. This is not the kind of commercial transactions with which I am familiar; to my knowledge, sellers usually do not inform

Pricing Strategy Disclosures convey far more than mere commercial terms. One need only ask oneself if a buyer of a Ford pickup truck would expect the dealer to tell him—as the terms of the potential transaction between them—*all the major* financial and nonfinancial factors that influenced the pickup's price, including, for example, the Ford Dearborn management's internal estimates of how competitors may price comparable pickups, its internal evaluation of competitors' business strengths, or its internal forecasts of tax credits and tariffs. Probably not.

Not denying this, the majority shifts the focus by stating in passing that HB 4005's Pricing Strategy Disclosures concern "economic information that is no less tethered to commercial transactions" than are actual terms of these transactions. Maj. Op. at 40; *see also id.* at 42 n.18 ("Speech, such as [the one compelled by HB 4005] . . . is not far removed from the 'core' of commercial speech, *i.e.*, speech that 'propose[s] a commercial transaction.'" (citation omitted)). But this vague standard of what is *closely* tethered to or what is not *far* removed from true commercial speech is not the "commercial transaction proposal" test that the Supreme Court and our Circuit have long applied.

Our inquiry should have ended here: Strict scrutiny should apply because HB 4005's Pricing Strategy Disclosure

---

potential buyers of cheaper alternatives competitive to the sellers' own products. The majority has reached this counterintuitive conclusion seemingly because the U.S. Food and Drug Administration and pharmacies have made such information publicly available. *See* Maj. Op. at 40. This reasoning misconceives our compelled speech doctrine. Just because a message is otherwise publicly available does not mean the government can freely force a person to be a carrier of that message.

Requirement compels non-commercial speech that does much more than just propose a commercial transaction.

If, however, one were to believe that HB 4005's Pricing Strategy Disclosure Requirement somehow presents "a close question" as to whether it compels non-commercial speech, the Supreme Court in *Bolger*, 463 U.S. at 66–67, has set forth some "important guideposts" to help us decide such a close case. *X Corp.*, 116 F.4th at 900 (discussing the "so-called *Bolger* factors"). *Bolger* teaches that "strong support" for finding speech to be commercial exists where the following factors are satisfied: (1) "the speech is an advertisement"; (2) "the speech refers to a particular product"; and (3) "the speaker has an economic motivation." *X Corp.*, 116 F.4th at 900 (quoting *Hunt v. City of L.A.*, 638 F.3d 703, 715 (9th Cir. 2011), which cited *Bolger*, 463 U.S. at 66–67). The first and third *Bolger* factors counsel against finding commercial speech here: HB 4005's Pricing Strategy Disclosures are not akin to advertisements, and no drug manufacturer has economic motivations to volunteer such disclosures, else PhRMA would not have brought this case.

This, again, should have ended our inquiry, even were ours a close case. But the majority simply recounts the *Bolger* factors and fails to apply them meaningfully.

Worse, the majority declares that the "commercial transaction proposal" test and the *Bolger* factors are not a "neat[] fit" and thus "inapt" for determining the proper level of First Amendment scrutiny where, as here, a law mandates companies to report information to the government and directs the government to publish the reported information. Maj. Op. at 29. According to the majority, a "submission of information to the government" "typically does not '*propose* a commercial transaction,'" even if the submission contains

only commercial speech. *Id.* (emphasis in original) (citation omitted). And it "would be odd" to apply less First Amendment scrutiny to a mandated display of a price increase in a consumer-facing advertisement than to a compelled disclosure of the same information in a government-facing report. *Id.* at 29.

That, if true, would indeed be odd. But the majority misunderstands the relevant doctrinal tests. Our precedents instruct us to consider whether the content of the speech compelled in a government submission is akin to something people would otherwise disclose in proposing commercial transactions. The inquiry focuses on the content, not the format, of the compelled speech.[9] Under our precedents, HB 4005's Pricing Strategy Disclosure Requirement compels non-commercial speech not because drug manufacturers' submissions to the DCBS serve no function of proposing commercial transactions, but because detailed pricing strategies are not akin to anything people would otherwise disclose in proposing commercial transactions, as discussed above. By the same logic, speech that communicates such quintessential transaction terms as a price increase—the type of information that HB 4005's General Marketing Information Disclosure Requirement compels—would constitute commercial speech wherever it appears, be it a consumer-facing advertisement or a government-facing report. Commercial speech does not lose its commercial

[9] Of course, the fact that certain speech already appears in the format of a product advertisement is evidence that the speech is something people would disclose in proposing commercial transactions. Hence the first *Bolger* factor. And if certain speech refers to a specific product, that factor is evidence that the speech might be something people would deliver in proposing commercial transactions. Hence the second and third *Bolger* factors.

nature because it is made in a government submission rather than in the process of proposing a transaction.

Therefore, our doctrinal tests, if understood correctly, are not inapt here.

II.

In fact, our doctrinal tests are very much apt in this case, as they were in *X Corp.* *See* 116 F.4th at 899–903. Like this case, *X Corp.* involved a law that required companies to report information to the government and directed the government to publish the reported information. Reviewing that law under the First Amendment, the *X Corp.* panel did not find it necessary to abandon the "commercial transaction proposal" test or the *Bolger* factors. *See* 116 F.4th at 902 (reprimanding the district court for its deviation from the doctrinal tests for discerning commercial speech). Rather, the *X Corp.* panel, unlike the majority here, deemed these well-established legal tests a proper fit and applied them faithfully.

A.

In *X Corp.*, X Corp., the owner of the social media platform X (formerly known as Twitter), sought a preliminary injunction against the enforcement of California State Assembly Bill 587 ("AB 587"). *Id.* at 894. Broadly speaking, AB 587 required large social media companies, including X Corp., to submit reports to the California Attorney General, (1) disclosing social media companies' terms of services and any existing content moderation policies ("TOS"), and (2) identifying from those TOSs specific terms, policies, and practices, if any, that address several content categories prescribed by the State of California, including hate speech, racism, misinformation,

radicalization, and so forth ("TOS Category Report"). *See id.* at 895–97 (quoting Cal. Bus. & Prof. Code § 22677). AB 587 then directed the Attorney General to publish these reports. Cal. Bus. & Prof. Code § 22677(c).

Regarding the TOS Category Reports in particular, Section 22677(a)(3) of AB 587 required social media companies to report whether and, if so, how they defined the content categories listed by California. *Id.* at 896. Section 22677(a)(4)(A) also required social media companies to report their content moderation policies, if any, that addressed these content categories pursuant to the social media companies' own definitions. *Id.* And Section 22677(a)(5) further required social media companies to report the high-level statistics as to how they had been moderating these content categories, if they had moderated them at all (e.g., the total number of flagged items of content in each category). *Id.* at 896–97. Under this disclosure regime, as the *X Corp.* panel observed, "[n]o matter how a social media company chooses to moderate [the content on its platform], the company will face backlash from its users and the public." *Id.* at 899 n.8. "That is true even if the company decides not to define the enumerated [content] categories, because [it] will draw criticism for under-moderating [its] [social media platform]." *Id.*

The district court denied X Corp. a preliminary injunction, holding that X Corp. was unlikely to prevail because both the TOSs and the TOS Category Reports constituted commercial speech and, accordingly, their compelled disclosure likely did not violate the First Amendment. *X Corp. v. Bonta*, No. 2:23-CV-01939, 2023 WL 8948286, at *1–2 (E.D. Cal. Dec. 28, 2023). With respect to the TOSs, the district court found that they were "part of a commercial transaction and appear[ed] to satisfy

the *Bolger* factors." *Id.* at *1. As to the TOS Category Reports, the district court found that they did "not so easily fit the traditional definition of commercial speech." *Id.* at *2. Sound familiar? Much like the majority here, the district court in *X Corp.* nonetheless held that the TOS Category Reports constituted commercial speech, without conducting any meaningful analysis under the doctrinal commercial speech tests. *See id.*; *see also X Corp.*, 116 F.4th at 902.

We reversed the district court's ruling on the TOS Category Reports. *X Corp.*, 116 F.4th at 904. We held that, while social media platforms' TOSs "m[ight] be commercial speech," the TOS Category Reports were "different in character and kind" because they would reveal social media companies' "opinions about and reasons for" their TOSs. *Id.* at 901.

Specifically, the *X Corp.* panel first found that the TOS Category Reports did "not satisfy the usual definition of commercial speech—i.e., speech that does no more than propose a commercial transaction." *Id.* (cleaned up) (citations omitted). The panel further reasoned that the TOS Category Reports "fail[ed] to satisfy at least two of the three *Bolger* factors": The compelled disclosures were not advertisements, and social media companies did not have any economic motivation in disclosing the TOS Category Reports. *Id.* (citations omitted). Therefore, after faithfully applying these doctrinal tests, the *X Corp.* panel concluded that the TOS Category Reports compelled non-commercial speech.

Additionally, the *X Corp.* panel distinguished social media companies' TOS Category Reports from their TOSs:

> [T]he [TOS] Category Reports are not commercial speech. They require a company to recast its content-moderation practices in language prescribed by the State, implicitly opining on whether and how certain controversial categories of content should be moderated. As a result, few indicia of commercial speech are present in the Content Category Reports.
>
> . . .
>
> . . . [T]he [TOS] Category Reports go further [than merely communicating the terms of actual or potential transactions]: they express a view *about* those terms by conveying whether a company believes certain categories should be defined and proscribed.
>
> . . .
>
> . . . The [TOS] Category Report provisions would require a social media company to convey the company's policy views on intensely debated and politically fraught topics, including hate speech, racism, misinformation, and radicalization, and also convey how the company has applied its policies. . . .

Id. at 901–02 (emphasis in original). For all these reasons, the *X Corp.* panel held that the TOS Category Reports

amounted to non-commercial speech and, accordingly, AB 587 likely failed strict scrutiny. *Id.* at 903.

B.

So too is the case here. While drug prices—like social media platforms' TOSs—are terms of commercial transactions, the detailed breakdown of and the internal rationales for these prices—like the TOS Category Reports—do much more than just propose a commercial transaction, and they do not resemble advertisements or anything that drug manufacturers would have an economic motivation to disclose.

Additionally, HB 4005's Pricing Strategy Disclosures go further than merely communicating the pricing terms for actual or potential transactions: They recast drug manufacturers' pricing strategies in language prescribed by Oregon and force drug manufacturers to voice their views as to how drugs are and should be priced.

"Our lodestars in deciding what level of scrutiny to apply to a compelled statement must be the nature of the speech taken as a whole and the effect of the compelled statement thereon." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). Here, HB 4005's Pricing Strategy Disclosure Requirement prescribes language that focuses primarily on costs, implying that any increase in drug prices can be fairly justified only by increases in costs, rather than other factors such as drug manufacturers' insights and

foresights regarding the relevant market demands and competitive dynamics.[10] *See* Or. Rev. Stat. § 646A.689(3).

Of course, drug manufacturers can offer explanations other than costs for their pricing decisions. *See* Or. Rev. Stat. § 646A.689(3)(c), (k); Or. Admin. R. 836-200-0530(2)(h) (2019). In doing so, however, drug manufacturers would have to divulge their overall pricing strategies, which are driven by not only cold numbers but also a host of qualitative judgments. Thomas T. Nagle & Georg Müller, THE STRATEGY AND TACTICS OF PRICING: A GUIDE TO GROWING MORE PROFITABLY 21, 172 (7th ed. 2024) ("There is no substitution for managerial experience and judgment when setting prices. . . . [P]rice setting usually . . . balances costs, customer value, strategic goals, and potential competitive responses."). A pharmaceutical company's pricing strategy may reveal its subjective assessment of customer demands, *id.* at 26–55, its marketing and communication strategies,[11] *see id.*, at 56–76, 158–63,

[10] The majority argues that this implied message would be attributed only to Oregon because the public knows drug manufacturers are forced by HB 4005. *See* Maj. Op. at 43–44 n.22. This argument, if it were to carry the day, would uproot our compelled speech doctrine under the First Amendment, as any message compelled by the government would henceforth be deemed attributable only to the government.

[11] Granted, companies may sometimes find it advantageous to communicate publicly certain rationales behind their pricing decisions. *See* Nagle & Müller, *supra*, at 170–72; *see also* Maj. Op. at 36–37 n.15. That some companies have elected or have been encouraged to engage in such a communication strategy every now and then does not license Oregon to compel similar speech in all circumstances. More importantly, HB 4005's Pricing Strategy Disclosures are different in character from disclosures typically involved in such a voluntary communication strategy. HB 4005's Pricing Strategy Disclosure

and even its opinion on issues of public concern. In fact, failure to consider public concern is a textbook mistake:

> Take the example of a pharmaceutical company that purchased an old prescription drug and hiked the price many-fold. The price change may have been considered economically rational—after all, the drug had few substitutes and consequently demand was very inelastic. Yet what the company failed to consider was the power of community-held norms of fairness in the decision and the resulting backlash against it and the entire pharmaceutical industry in general by an outraged public.

Id. at 154.

A drug manufacturer might consider at what level a price spike would spark public outcry and thereby cap any price increase below that level. In the relevant internal discussions, employees might opine on a myriad of controversial topics: whether a free market should allow drug manufacturers to set prices as they see fit; to what extent public sentiments against drug manufacturers are justified; and whether the government has adequate political

---

Requirement requires drug manufacturers to disclose *all the major* financial and nonfinancial factors that influenced their pricing decisions, thereby denying drug manufacturers the freedom to tailor what to disclose and what to withhold about their pricing decisions. *See, e.g.*, Maj. Op. at 36–37 n.15 (citing Utpal M. Dholakia, *If You're Going to Raise Prices, Tell Customers Why*, HARV. BUS. REV. (June 29, 2021), which advised companies to consider crafting "vivid and compelling stor[ies] for why the price[s] [are] being increased that focus[] on customer value").

will and power to quell a given price increase. HB 4005's Pricing Strategy Disclosure Requirement would compel disclosure of all these nuanced views regarding how drugs are and should be priced. As such, HB 4005's Pricing Strategy Disclosure Requirement does not simply compel "product-specific, economic information." Maj. Op. at 44.

Moreover, HB 4005's Pricing Strategy Disclosures would prompt drug manufacturers to express their broader views on the intensely debated and politically fraught topic of allegedly inflated prescription drug prices. PhRMA argues that HB 4005 seeks to reinforce Oregon's message that drug manufacturers are responsible for the allegedly inflated drug prices in our country, as HB 4005 did not require other participants in the pharmaceutical industry—pharmacy benefit managers, for instance—to make similar disclosures. In rejecting this argument, the majority envisions that drug manufacturers are free to refute Oregon's political message by opining that other market participants may have contributed to drug price increases. *See id.* at 44–45. In other words, the majority acknowledges that HB 4005's Pricing Strategy Disclosure Requirement will probably drag drug manufacturers into a public debate as to who is to blame for the allegedly inflated drug prices.

Therefore, HB 4005's Pricing Strategy Disclosures convey drug manufacturers' "opinions about and reasons for" their drug prices.[12] *X Corp.*, 116 F.4th at 901. To

[12] Relying on Oregon's purported representations at oral argument, the majority maintains that the "DCBS would consider the following straightforward list of factors to be a satisfactory response to Or. Rev. Stat. § 646A.689(3)(c): 'supply cost increases, research costs, and investor return.'" *Id.* at 43 n.20. To begin with, we review the

follow *X Corp.*, we must treat HB 4005's Pricing Strategy Disclosure Requirement as compelling non-commercial speech and subject it to strict scrutiny.

C.

Departing from *X Corp.*'s teaching, the majority articulates a new legal test. To decide whether a regulatory disclosure constitutes commercial speech, my colleagues ask two questions: (1) whether the disclosure would improve the "free flow of commercial information"; and (2) whether the disclosure is "incidental to a commercial transaction." Maj. Op. at 40, 42 n.18.

Given that any disclosure, almost by definition, would improve the free flow of information, the majority's new test depends on just its second question. To answer that question, the majority determines whether a forced

constitutionality of HB 4005 as legislated, not as how counsel hypothesized it should be read. More importantly, Oregon conceded only that a straightforward list of factors such as supply cost increases, research costs, and investor return would suffice "if [it in fact] explains the price increase." Oral Arg. at 2:41-3:33. What if it does not explain the price increase? Suppose a drug manufacturer decides to raise the price for its domestically manufactured drugs because, in its opinion, its competitors are likely to suffer significant tariffs for their foreign-manufactured generic substitutes. Does HB 4005 compel the drug manufacturer to disclose this rationale and the underlying opinions and analyses by demanding the disclosure of "all major financial and nonfinancial factors" that influenced drug manufacturers' pricing decisions? Or. Admin. R. 836-200-0530(2)(h) (2019); *see also* Or. Rev. Stat. § 646A.689(3)(c), (k); *id.* § 646A.689(l) (requiring drug manufacturers to produce supporting documents). Of course, it does. In fact, Section 646A.689(3)(c)'s very function is to capture nuanced financial and nonfinancial considerations other than, for example, research costs, of which other HB 4005 sections including Sections 646A.689(3)(e) and 646A.689(3)(f)(D) already demand disclosure.

disclosure "has no independent expressive meaning" outside the context of commercial transactions. *Id.* at 41; *see also id.* at 42 n.18.

But even under the majority's newly minted test, HB 4005's Pricing Strategy Disclosures constitute non-commercial speech. As detailed above, drug manufacturers' pricing strategies can be influenced by many factors, including drug manufacturers' views on issues of public concern such as how drugs should be priced and who should be held responsible for the allegedly inflated drug prices. The majority does not explain why such views have no independent expressive meaning outside the drug sale context.

Not only that, but the majority's test and reasoning effectively overrule *X Corp.*, 116 F.4th 888, which is impermissible in our Circuit, *see Miller v. Gammie*, 335 F.3d 889, 899 (9th Cir. 2003). To illustrate this point, let's apply the majority's test and reasoning to *X Corp.* 116 F.4th 888. In *X Corp.*, how social media companies chose to define and moderate different content on their platforms had little independent expressive meaning outside of their social media services. The number of items of content concerning hate speech that X Corp. had flagged—one part of a typical TOS Category Report under AB 587, *id.* at 896–97—carried little standalone expressive meaning other than describing X Corp.'s content moderation practices in its social media services.

The majority argues that, the speech compelled by HB 4005 in this case would not exist absent commercial transactions, whereas in *X Corp.*, "[w]hat constitute[d] 'hate speech,' for example, [was] a matter of public debate and concern outside the context of a social media company's

terms of service (or, indeed, any commercial transaction)." Maj. Op. at 43 n.21. The majority misreads AB 587. AB 587 compelled social media companies to disclose how they had defined and moderated such content categories as hate speech for purposes of running their social media platforms, not what *should* constitute hate speech in the abstract or in the public forum. *See X Corp.*, 116 F.4th at 896–97. In fact, the TOS Category Reports compelled by AB 587 were derived from social media companies' TOSs, which were largely "directed to [their] potential consumers" and might "presumably play a role in [these consumers'] decision of whether to use the platform." *Id.* at 902 n.10. As such, the TOS Category Reports would not come into existence absent social media companies' provision of their services.

Therefore, the TOS Category Reports would have amounted to commercial speech under my colleagues' novel test and myopic reasoning, contrary to what the *X Corp.* panel concluded less than a year ago. As this panel lacks the authority to overrule such published opinions of this Court as *X Corp.*, I cannot join my colleagues. *See Miller*, 335 F.3d at 899.

D.

To distinguish *X Corp.*, the majority advances three arguments. *First*, the majority argues that, while issues such as hate speech are "intensely political," prescription drug prices are not. Maj. Op. at 43. Why? As far as I can tell, the majority cites nothing but its own common sense. *See id.* at 38.

But it is unclear whether the majority's common sense aligns with our country's when it comes to what is or is not politically charged. *See, e.g.*, *Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best*

Prices in the World for Prescription Drugs, THE WHITE HOUSE (July 31, 2025), https://www.whitehouse.gov/fact-sheets/2025/07/fact-sheet-president-donald-j-trump-announces-actions-to-get-americans-the-best-prices-in-the-world-for-prescription-drugs/ (announcing that the executive branch sent "letters to leading pharmaceutical manufacturers outlining the steps they must take to bring down the prices of prescription drugs in the United States. . . ."); Sarah Fioroni, *Five Things to Know: Healthcare and the U.S. Election*, GALLUP (Sept. 30, 2024), https://news.gallup.com/poll/651386/five-things-know-healthcare-election.aspx (reporting that 47% of the respondents in a September 2024 preelection healthcare subject survey ranked "reducing drug costs" as "the single most or among the most important issues determining their votes" in the 2024 presidential election). First Amendment protections cannot depend on a judge's self-determined and unelaborated common sense regarding what is "intensely political" and what is not.[13]

Second, the majority asserts that, while AB 587 called for social media companies' opinions, HB 4005 simply

[13] That prices and costs are economic concepts does not automatically mean that HB 4005's Pricing Strategy Disclosures are nonpolitical. Suppose Congress passes a law requiring companies to disclose whether and, if so, how tariffs have contributed to the prices they charge. Does this hypothetical law necessarily compel only commercial speech simply because prices and tariffs are economic concepts? I am not so sure. *See* Wyatte Grantham-Philips & Josh Boak, *Amazon Is Not Planning to Break Out Tariff Costs Online as White House Attacks Potential Move*, THE ASSOCIATED PRESS (Apr. 29, 2025), https://apnews.com/article/amazon-tariff-prices-trump-white-house-859856963226 3872a6c04f7ef330c0fd. In my view, a person's speech is not automatically subject to a lower level of scrutiny simply because it involves economic concepts.

requires drug manufacturers to disclose, "as a matter of historical fact," their considerations in setting drug prices. Maj. Op. at 44. This assertion is incorrect as to both AB 587 and HB 4005. AB 587 directed social media companies to disclose, as a matter of historical fact, whether their TOSs defined and moderated such content categories as hate speech, what their definitions of those content categories encompassed, and how their moderation practices addressed those content categories. *X Corp.*, 116 F.4th at 896–97. To be clear, AB 587 did not require social media companies to express any "normative" view in "value-laden" language. Maj. Op. at 43. If a social media company's TOSs did not address any of the content categories prescribed by AB 587, an answer of "not applicable" under that category would suffice, and no additional narratives or explanations were necessary. *X Corp.*, 116 F.4th at 901 n.9. Notwithstanding this ostensible call for only factual disclosures, the *X Corp.* panel struck down AB 587 because it forced social media companies to opine "implicitly" on whether and how certain content categories should be defined and proscribed. *Id.* at 901.

The same reasoning applies here. Even assuming HB 4005's Pricing Strategy Disclosure Requirement covers only what factors, as a matter of historical fact, drug manufacturers considered in setting their prices, that requirement still compels drug manufacturers to opine *implicitly* on how their drugs should be priced, as discussed above. What's more, HB 4005's Pricing Strategy Disclosure Requirement demands not only a recount of historical facts, but also "narrative[s]" and "explanation[s]" of what drug manufacturers "deem[]" to have "contributed to the price increase[s]" of the relevant drugs. Or. Rev. Stat. § 646A.689(3)(c), (k); Or. Admin. R. 836-200-0530(2)(h)

(2019); *see also Narrative*, BLACK'S LAW DICTIONARY (12th ed. 2024) (defining a "narrative" to mean "[a]n account or description of a *selected* set of events, facts, experiences, or the like; a story" (emphasis added)); *Explanation*, BLACK'S LAW DICTIONARY (12th ed. 2024) (defining an "explanation" to mean a statement made in the "activity or process of expounding, *interpreting*, or making something intelligible" and/or the "*interpretation or meaning given* to something by someone who expounds it" (emphases added)). This means drug manufacturers must voice the reasons which, in their judgment and interpretation, caused the relevant drug price increases. As such, the majority cannot distinguish *X Corp.* by portraying HB 4005's Pricing Strategy Disclosure Requirement as more factual than AB 587's TOS Category Report provisions—if anything, Oregon calls for more opinions and judgments than did California.

Finally, the majority asserts that treating HB 4005's Pricing Strategy Disclosures as commercial speech is at odds with our case laws regarding retail product warnings. Maj. Op. at 37–38 n.15, 43–44 n.22. Like the *X Corp.* panel, I disagree. 116 F.4th at 901. Granted, our Circuit has treated certain retail product warnings as commercial speech, even though the traditional legal tests for finding commercial speech could sometimes suggest otherwise. *Id.* But retail product warnings constitute a "limited" exception inapplicable here. *Id.* Retail product warnings describe the products being sold to the public or communicate the terms of the relevant transactions, whereas HB 4005's Pricing Strategy Disclosures—much like AB 587's TOS Category Reports—"go further" by at least "implicitly" conveying drug manufacturers' "opinions about and reasons for" their

drug prices. *Id.* Therefore, cases regarding retail product warnings are inapposite.

III.

The majority has much more to say beyond disposing of the case before us. In dicta, the majority formulates a novel framework for future speech compulsion cases under the First Amendment. I address these dicta lest they become precedential in our Circuit. *United States v. Johnson*, 256 F.3d 895, 914 (9th Cir. 2001) (en banc) (Kozinski, J., concurring).

The majority first distinguishes "government reporting requirements" (i.e., laws that require entities and individuals to report information to the government and direct the government to publish such reported information) from "direct disclosure requirements" (i.e., laws that compel communication of certain information directly from one individual or private entity to another). Maj. Op. at 17–18. The majority then argues that, while "direct disclosure requirements" are presumptively subject to strict scrutiny unless the commercial speech exception applies, "government reporting requirements" need to pass strict scrutiny only when they compel political or ideological statements. *Id.* at 18–21. My colleagues call this new framework a "potentially strict" approach, as opposed to the "presumptively strict" approach that I have discussed so far. *Id.* at 19–20. With this new framework, my colleagues would like to skirt the commercial speech inquiry where, as here, a government reporting requirement is at issue. *Id.* at 27–28.

Perhaps unsure about this fresh framework, my colleagues elaborate it only in dicta.[14] Though rather lengthy—almost twice the length of the majority's discussion of strict scrutiny's inapplicability in this case, *compare id.* at 16–36, *with id.* at 36–48—these dicta are not well-reasoned, a requirement for dicta to become precedential in our Circuit. *See Johnson*, 256 F.3d at 914. In my view, these dicta contravene the binding precedents of our Circuit and lack support in the other cases that the majority discusses.[15]

A.

Of course, most conspicuous is the absence of the majority's novel framework in *X Corp.* *See* 116 F.4th 888. My colleagues admit that absence. Maj. Op. at 33–34. But they argue that their framework would nevertheless lead to the same conclusion as came the *X Corp.* panel. *Id.* at 34. This argument does not change the fact that our *X Corp.* panel never endorsed the majority's framework, explicitly or implicitly.

Moreover, the majority's new framework contradicts another binding precedent in our Circuit: *NetChoice*, 113

[14] *See* Maj. Op. at 36 ("Although, in our view, using the potentially strict approach followed by our sister circuits would be more doctrinally sound and avoid unintended consequences, we do not need to fully resolve whether *X Corp.* requires us to use the presumptively strict approach in this case, because both approaches lead us to the same conclusion.").

[15] I also note that HB 4005's Pricing Strategy Disclosure Requirement, as discussed above, compels drug manufacturers to opine on an "intensely debated and politically fraught" subject, *X Corp.*, 116 F.4th at 902, so it should be subject to strict scrutiny even under the majority's "potentially strict" approach.

F.4th 1101.[16] In *NetChoice*, a trade association of online businesses sued the California Attorney General, seeking to invalidate as violative of the First Amendment the California Age-Appropriate Design Code Act ("CAADCA"), a statute aimed at protecting children's privacy and influencing online products' designs to this end. *Id.* at 1108. At issue was CAADCA's reporting requirement (i.e., Data Protection Impact Assessment Report, or "DPIA report"), which compelled online businesses to identify risks of "material detriment to children" and to create a timed plan mitigating these risks. *Id.* at 1109–10 (quoting Cal. Civ. Code § 1798.99.31(a)(1), (a)(2)). Although the CAADCA, like HB 4005, imposed a government reporting requirement, the *NetChoice* panel analyzed the DPIA report requirement using the traditional "commercial transaction proposal" test and the *Bolger* factors. *Id.* at 1119–20. After concluding that the DPIA report requirement forced online businesses to "do far 'more than propose a commercial transaction'" and that the requirement satisfied none of the *Bolger* factors, *id.* (citations omitted), the *NetChoice* panel applied strict scrutiny and held that the DPIA report requirement fell "well short of satisfying strict First Amendment scrutiny," *id.* at 1121, 1122.

Despite this reasoning and holding, my colleagues believe *NetChoice* supports their framework because the *NetChoice* panel engaged in a threshold inquiry before determining whether the DPIA reports constituted

[16] *NetChoice* and *X Corp.* were argued on the same day before the same panel, and both opinions were authored by Judge Milan D. Smith. *Compare X Corp.*, 116 F.4th 888, *with NetChoice*, 113 F.4th 1101. The *NetChoice* opinion preceded the *X Corp.* opinion by about half a month; there is no reason to believe *X Corp.* departed from *NetChoice* in any meaningful way.

commercial speech. That threshold inquiry, in the majority's view, was whether the DPIA report requirement mandated the covered online businesses to make an opinion statement "on a political issue." Maj. Op. at 32.

But the majority is mistaken. The *NetChoice* panel simply inquired, as a threshold matter, whether the DPIA report requirement compelled speech *or conduct*, a traditional threshold inquiry for any case concerning the Free Speech Clause of the First Amendment. *See, e.g.*, 113 F.4th at 1117 ("Nor can we, as the State suggests, ignore that the DPIA [report] requirement compels speech simply because other parts of the CAADCA may primarily or exclusively regulate non-expressive conduct. The primary effect of the DPIA [report] provision is to compel speech, distinguishing it from statutes where the compelled speech was 'plainly incidental to the [law's] regulation of conduct.'"); *id.* at 1118 (reasoning that, even if the DPIA report requirement compelled the conduct of mitigating risks to children, the DPIA report requirement still triggered strict First Amendment scrutiny because it "deputize[d] covered businesses into serving as censors for the State," thereby interfering with these businesses' "editorial choices" and forcing them to determine "what material is potentially harmful to children"). Nowhere did the *NetChoice* panel apply or approve the majority's new framework. *See id.* at 1116–18.

What's more, had the majority's framework controlled the *NetChoice* panel, it would have concluded that the DPIA report requirement did not compel any political or ideological messages and thus need not pass strict scrutiny, opposite to what *NetChoice* held. The *NetChoice* panel never described the DPIA reports as "political" or "ideological." *See generally* 113 F.4th 1101. My colleagues

appear to admit as much, Maj. Op. at 32 n.12, and they fail to explain why they believe opinions about what harms children, which the DPIA report requirement compelled, amounted to political or ideological messages, whereas opinions about drug pricing in this case do not.[17] *See id.* at 34.

Therefore, the majority's new framework conflicts with the Ninth Circuit's binding precedents.

B.

The majority instead resorts to two cases from other Circuits, both predating our decisions in *X Corp.* and *NetChoice*: *Full Value Advisors, LLC v. S.E.C.*, 633 F.3d 1101 (D.C. Cir. 2011), and *United States v. Sindel*, 53 F.3d 874 (8th Cir. 1995). *See* Maj. Op. at 21–22. Neither of these cases is binding upon us; nor are they persuasive. I discuss them in turn.

In *Full Value Advisors*, Full Value Advisors, LLC, an institutional investment manager, challenged one of the Securities Exchange Act's disclosure requirements because it allegedly compelled speech in violation of the First

[17] My colleagues note that "the *NetChoice* panel made quite clear that it viewed the DPIA reporting requirement as 'requir[ing] businesses to go beyond opining about their products or services to opine on highly controversial issues of public concern.'" Maj. Op. at 32 n.12 (quoting *NetChoice*, 113 F.3d at 1120). Obviously, a controversial issue of public concern is not necessarily a political or ideological issue, so this quote from *NetChoice* does not support the majority's new legal framework. More importantly, the *NetChoice* panel made the relevant statement when it explained why the DPIA report requirement did not simply refer to a particular product under the second *Bolger* factor. *NetChoice*, 113 F.3d at 1120. Thus, this quote highlights the fact that *NetChoice* did not apply or approve my colleagues' novel framework. Quite the opposite, the *NetChoice* panel performed the traditional *Bolger* analysis.

Amendment. 633 F.3d at 1104. Specifically, Section 13(f)(1) of the Act required institutional investment managers to file quarterly reports with the SEC, disclosing the names, shares, and fair market values of the securities that the managers controlled ("Quarterly Reporting Requirement"). *Id.* (citing 15 U.S.C. § 78m(f)(1) and 17 C.F.R. § 240.13f-1(a)(1)). The SEC was required to publish this reported information unless an exemption applied. *Id.* 1104–05 (citing 15 U.S.C. § 78m(f)(2), (f)(3)). To request an exemption, an investment manager had to "submit enough information" to the SEC for it to "make an informed judgment as to the merits of the request" ("Exemption Application Requirement"). *Id.* at 1105.

The D.C. Circuit held that the Exemption Application Requirement did not violate the First Amendment.[18] *Id.* at 1109. Observing that the SEC, "not the public," was the "only audience" of investment managers' exemption applications, the court reasoned that "[c]ompelling disclosure to the [SEC] alone so the [SEC] may determine whether [an exemption is] warranted is a rational means of achieving" the goal of protecting institutional investors' confidential information. *Id.* at 1108.

Full Value Advisors stands for the unremarkable proposition that a party seeking relief before an adjudicator must offer—if needed, on a confidential basis—sufficient evidence to convince the adjudicator, "as in the case of compulsion to give evidence in court." *W. Virginia State Bd. of Educ. v. Barnette*, 319 U.S. 624, 645 (1943) (Murphy, J., concurring). This proposition has little relevance to this

[18] The D.C. Circuit did not opine as to whether the Quarterly Reporting Requirement violated the First Amendment, since Full Value Advisors's First Amendment claim in that regard was unripe. *Id.* at 1106–07.

case, which does not involve the compelled production of evidence in an adjudicatory setting.

In any event, the D.C. Circuit cabined its holding in *Full Value Advisors* to the context of confidential submissions for securities regulation. *See* 633 F.3d at 1109. As Justice Breyer once opined, securities regulation "involves 'a different balance of concerns' and 'calls for different applications of First Amendment principles.'" *Id.* (quoting *Nike, Inc. v. Kasky*, 539 U.S. 654, 678 (2003) (Breyer, J., dissenting from the dismissal of certiorari as improvidently granted)). This call for different applications of First Amendment principles undergirded the D.C. Circuit's opinion in *Full Value Advisors* but is inapplicable in this case. Therefore, *Full Value Advisors* cannot lend support to the majority's new framework.

Let's then turn to *Sindel*, another case on which the majority relies. In *Sindel*, the government sued attorney Richard Sindel to enforce an IRS summons that requested missing information from the IRS Form 8300 that Sindel filed to report certain cash transactions relating to his legal services. 53 F.3d at 875–76. The government argued that Sindel, pursuant to the instructions in IRS Form 8300, should have provided identifying information regarding the payors of the underlying cash transactions. *Id.* The Eighth Circuit held that "the First Amendment protection against compelled speech d[id] not prevent [the] enforcement of the summons." *Id.* at 878. The court reasoned that "[t]here is no right to refrain from speaking when 'essential operations of government may require it for the preservation of an orderly society[]—as in the case of compulsion to give evidence in court.'" *Id.* (quoting *Barnette*, 319 U.S. at 645 (Murphy, J., concurring)). Because the IRS summons in that case required "Sindel only to provide the government with

information which his clients ha[d] given him voluntarily, not to disseminate publicly a message with which he disagree[d]," the Eighth Circuit held that the summons compelled neither Sindel's nor his client's speech. *Id.* at 877–78.

Assuming *Sindel* was correctly decided, it is distinguishable. Compelling drug manufacturers to disclose their internal pricing strategies is in no way analogous to requiring citizens to provide the government with certain basic transaction information to facilitate the essential governmental operations of tax collection and illegality detection. The majority does not attempt to (and could not reasonably) argue that learning and publishing drug manufacturers' detailed pricing strategies constitute the "essential operations" of the Oregon government "for the preservation of an orderly society." *Id.* at 878.

To the extent *Sindel* seems to suggest that a speech compulsion claim under the First Amendment may arise only where the government forces a person to "disseminate publicly a message with which he disagrees," this suggestion conflicts with the law in our Circuit. *Id.* In *X Corp.*, AB 587 asked what constituted hate speech, in social media companies' views, but AB 587 did not impose any hate speech definition of its own. 116 F.4th at 896–97. In *NetChoice*, the DPIA report requirement urged online businesses to ascertain whether their operations could harm children, but the DPIA report requirement itself did not define what should be deemed harmful to children. 113 F.4th at 1109–10. Both AB 587 and the DPIA report requirement were transparency measures. In neither case did the challenged law ask any person to disseminate any views with which he disagreed. And yet, in both cases, strict

scrutiny applied. Thus, *Sindel* is not persuasive in our Circuit.

Therefore, neither *Full Value Advisors* nor *Sindel* is applicable here. Nor did they espouse the analytical framework that the majority now advocates.[19]

C.

The majority also posits that two Supreme Court cases are, if not in direct support, at least not inconsistent with its new framework: *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980), and *Riley*, 487 U.S. 781. *See* Maj. Op. at 24–27. As both cases are distinguishable for the same reason, I discuss them together.

In *Schaumburg*, Citizens for a Better Environment ("CBE"), a nonprofit organization, "requested permission to solicit contributions in the Village" of Schaumburg. 444

[19] The majority also relies on *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (1st Cir. 2005), a case involving a direct disclosure requirement, not a government reporting requirement. Maj. Op. at 22–24. At issue in *Rowe* was Maine's Unfair Prescription Drug Practices Act ("UPDPA") that regulated pharmacy benefit managers ("PBM"). 429 F.3d at 298. The UPDPA required the PBMs to act as fiduciaries for their health benefit provider clients in Maine and, accordingly, adhere to certain fiduciary duties including disclosing to the clients their conflicts of interest, self-dealing, and financial arrangements with third parties. *Id.* at 299. "None of the disclosures [were] available to the public." *Id.* Pharmaceutical Care Management Association ("PCMA") alleged that the UPDPA's disclosure requirement violated the First Amendment, but the First Circuit disagreed. *Id.* at 316 (controlling concurrence). Contrary to the majority's new framework, *Rowe* did not distinguish government reporting requirements from direct disclosure requirements. *Id.* And unlike HB 4005 here, the UPDPA simply imposed a fiduciary duty upon the PBMs in certain contractual setup, and the resulting factual disclosure requirement was just a derivative to such a fiduciary duty. *See id.* at 299.

U.S. at 624–25. The Village denied CBE's request because CBE could not demonstrate it would use 75% of received contributions for charitable purposes as required by the Schaumburg Village Code. *Id.* at 625. CBE thus sued the Village, claiming that the 75% requirement violated the First Amendment. *Id.* The Supreme Court agreed, holding that this 75% requirement did not withstand strict scrutiny. *Id.* at 636.

My colleagues recognize that *Schaumburg* concerned the curtailment of charitable solicitation speech—a type of speech that is fully protected by strict First Amendment scrutiny—not any compelled disclosures of charitable usage percentages. *See* Maj. Op. at 24. To find support for their framework, however, my colleagues seize on the following language from the Supreme Court's discussion of why the 75% requirement was not narrowly tailored under strict scrutiny:

> The Village's legitimate interest in preventing fraud can be better served by measures less intrusive than a direct prohibition on solicitation. . . . Efforts to promote disclosure of the finances of charitable organizations [] may assist in preventing fraud by informing the public of the ways in which their contributions will be employed.

444 U.S. at 637–38.

Riley was also about percentages of charitable usage. 487 U.S. at 795. At issue there was the North Carolina Charitable Solicitations Act's requirement that "professional fundraisers disclose to potential donors, before an appeal for

funds, the percentage of charitable contributions collected during the previous 12 months that were actually turned over to charity." *Id.* Assuming, without deciding, that the charitable usage disclosure compelled by the Act constituted commercial speech, the Supreme Court held that the timing of this disclosure, which had to be made before a fundraiser's solicitation for funds, rendered it "inextricably intertwined with otherwise fully protected speech," i.e., charitable solicitation. *Id.* at 796. Strict scrutiny thus applied. *Id.* at 798.

Reading *Riley*, my colleagues again focus on the Supreme Court's discussion as to why this charitable usage disclosure requirement was not narrowly tailored:

> [M]ore benign and narrowly tailored options are available. 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.

Id. at 800.

According to my colleagues, *Schaumburg* and *Riley* suggest that the Supreme Court would agree with their new framework, which treats government reporting requirements and direct disclosure requirements differently and abandons the commercial speech doctrine in cases involving government reporting requirements. Maj. Op. at 24–27. In my view, this interpretation of *Schaumburg* and *Riley* is unconvincing because it depends on the false premise that

the charitable usage disclosures hypothesized in *Schaumburg* and *Riley* constituted non-commercial speech that would warrant strict scrutiny if compelled by direct reporting requirements.

But the information regarding the percentages of donations that are used for charity constitutes commercial speech, for it communicates the prices—a quintessential transaction term—that nonprofit organizations charge for their services managing and dispensing donations. Disclosing how much of the received donations that a nonprofit organization passes on to intended charities tells the public the amount of donations that the nonprofit organization retains for itself; that is, the price of its services. It is analogous to the commission fees that people pay for brokerage services in the securities transaction context. Those commissions fees are distinct from the value of the securities that brokers help people transact, and disclosing those commission fees simply communicates the prices of the brokerage services. Understood as such, the Supreme Court in *Schaumburg* and *Riley* suggested only that the government could require charitable organizations to display the price tags of their services more prominently. By contrast, HB 4005's Pricing Strategy Disclosure Requirement does not merely require drug manufacturers to broadcast their price increases. Rather, it forces a full disclosure of drug manufacturers' pricing strategies, i.e., the "opinions about and reasons for" their drug prices. *X Corp.*, 116 F.4th at 901. *Schaumburg* and *Riley* cannot rescue HB 4005's Pricing Strategy Disclosure Requirement from strict scrutiny.

IV.

We have never applied anything other than strict scrutiny to the kind of speech that HB 4005's Pricing Strategy Disclosure Requirement compels. As the Supreme Court has cautioned, we must be "reluctant to mark off new categories of speech for diminished constitutional protection." *Nat'l Inst. of Fam. & Life Advocs.*, 585 U.S. at 767 (citation omitted).

In this case, my colleagues break new ground because society has an "interest in the fullest possible dissemination of information." Maj. Op. at 41 (citation omitted). The governmental power countenanced by this reasoning "has no clear limiting principle." *United States v. Alvarez*, 567 U.S. 709, 723 (2012) (Kennedy, J.) (plurality opinion) ("Our constitutional tradition stands against the idea that we need Oceania's Ministry of Truth." (citing G. Orwell, Nineteen Eighty-Four (1949) (Centennial ed. 2003))). I am not prepared to countenance a government that can compel an unwilling speaker to speak simply because the government and some others, for their own economic or political interests, would like to hear.

My colleagues also suggest that we subject government reporting requirements to a more lenient level of First Amendment scrutiny than we do for direct disclosure requirements. *See* Maj. Op. at 16–20. I fear this suggestion would encourage the government to circumvent strict First Amendment scrutiny by converting various kinds of existing and prospective direct disclosure requirements to government reporting requirements. I am not prepared to condone such a loophole either.

Following *X Corp.* and *NetChoice*, we must subject HB 4005's Pricing Strategy Disclosure Requirement to strict

scrutiny because it compels drug manufacturers to engage in non-commercial speech on an intensely debated and politically fraught topic: prescription drug prices. Oregon does not claim HB 4005's Pricing Strategy Disclosure Requirement survives strict scrutiny. Therefore, I dissent from the majority's disposition of PhRMA's First Amendment claim.

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate electronic filing system or, if you are a pro se litigant or an attorney with an exemption from the electronic filing requirement, file one original motion on paper.

Petition for Panel Rehearing and Petition for Rehearing En Banc (Fed. R. App. P. 40; 9th Cir. R. 40-1 to 40-4)

(1) Purpose

A. Panel Rehearing:

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - A material point of fact or law was overlooked in the decision;
  - A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Rehearing En Banc

- A party should seek en banc rehearing only if one or more of the following grounds exist:
  - Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
  - The proceeding involves a question of exceptional importance; or

- The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing or rehearing en banc must be filed within 14 days after entry of judgment. Fed. R. App. P. 40(d).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(d). The deadlines for seeking reconsideration of a non-dispositive order are set forth in 9th Cir. R. 27-10(a)(2).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- See Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-4.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- An answer, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or answer must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- Attorneys must file the petition electronically via the appellate electronic filing system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-8000.

Petition for a Writ of Certiorari

- The petition must be filed with the Supreme Court, not this Court. Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov.

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send a letter **in writing within 10 days** to:
    - Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Maria Evangelista, maria.b.evangelista@tr.com);
    - **and** electronically file a copy of the letter via the appellate electronic filing system by using the Correspondence filing category, or if you are an attorney exempted from electronic filing, mail the Court one copy of the letter.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 10. Bill of Costs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form10instructions.pdf

9th Cir. Case Number(s)

Case Name

The Clerk is requested to award costs to *(party name(s))*:

I swear under penalty of perjury that the copies for which costs are requested were actually and necessarily produced, and that the requested costs were actually expended.

Signature **Date**

*(use "*s/[typed name]*" to sign electronically-filed documents)*

COST TAXABLE	**REQUESTED** *(each column must be completed)*			
DOCUMENTS / FEE PAID	No. of Copies	Pages per Copy	Cost per Page	TOTAL COST
Excerpts of Record*			$	$
Principal Brief(s) *(Opening Brief; Answering Brief; 1st, 2nd , and/or 3rd Brief on Cross-Appeal; Intervenor Brief)*			$	$
Reply Brief / Cross-Appeal Reply Brief			$	$
Supplemental Brief(s)			$	$
Petition for Review Docket Fee / Petition for Writ of Mandamus Docket Fee / Appeal from Bankruptcy Appellate Panel Docket Fee				$
			TOTAL:	$

***Example:** Calculate 4 copies of 3 volumes of excerpts of record that total 500 pages [Vol. 1 (10 pgs.) + Vol. 2 (250 pgs.) + Vol. 3 (240 pgs.)] as:*
No. of Copies: 4; Pages per Copy: 500; Cost per Page: $.10 (or actual cost IF less than $.10);
TOTAL: 4 x 500 x $.10 = $200.

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

Egg surcharge hits diners' wallets: Experts say consumers should fear menu price hikes more

Daniella Genovese

Consumers are being hit with temporary surcharges due to the ongoing egg shortage in the U.S. food system. But experts told FOX Business that these surcharges are the lesser of two evils when compared to overall menu price increases.

Michelle Korsmo, the CEO of the National Restaurant Association (NAR), said that these surcharges are a temporary measure and can be removed from menus when macroeconomic conditions improve.

"When a restaurant operator adds a surcharge to their menu in a situation like this, it's generally because they are optimistic that it will be resolved quickly and because they want to be transparent with their customers about their rising costs," Korsmo told FOX Business.

For instance, the Waffle House, a Southern breakfast food chain, added a temporary 50 cent-per-egg surcharge to all of its menus on Monday.

WAFFLE HOUSE, OTHER COMPANIES ADD EGG SURCHARGE AMID SHORTAGE

The company blamed the ongoing egg shortage caused by highly pathogenic avian influenza (HPAI) — or bird flu — for the dramatic increase in egg prices, saying that "consumers and restaurants are being forced to make difficult decisions."

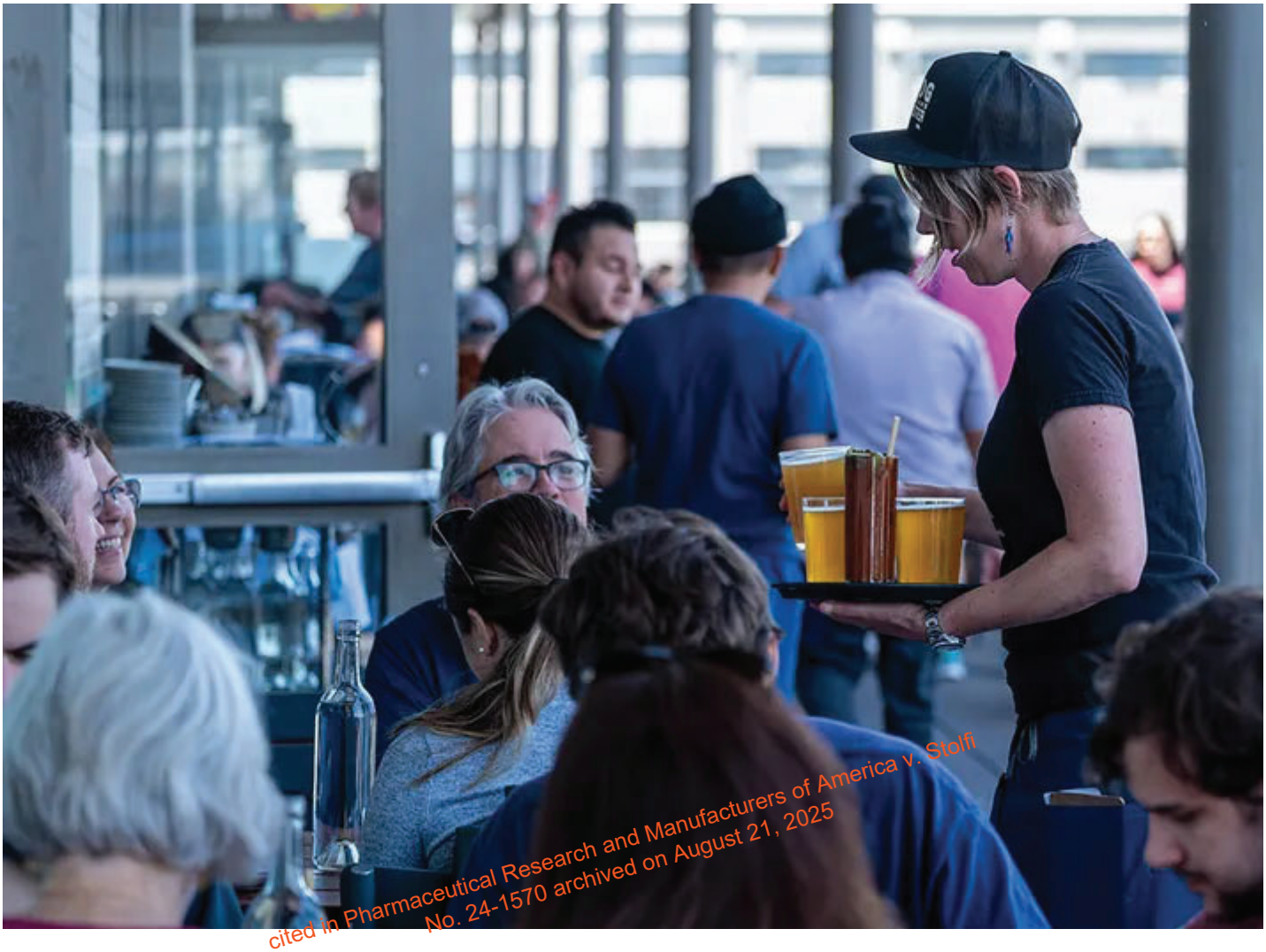
While the company didn't specify when the charge would be removed, it said that it will adjust or remove the surcharge when market conditions allow.

A menu in a Waffle House restaurant in Houston displays a sticker advising customers of a 50 cent price hike per egg "due to the nationwide rise in the cost of eggs" on Thursday. (Gianrigo Marletta/ AFP via Getty Images / Getty Images)

Changing the price on a menu will often add to an operator's costs. It also doesn't give them the opportunity to have the same transparency with customers about why the price is changing, Korsmo added.

TRUMP'S PROPOSED TARIFFS COULD DRIVE UP FOOD PRICES, EXPERTS SAY

"I think that most of the time, what we see with other types of inflation... it never really comes back down as low as it was in a pre-inflationary period, which is where we just get this kind of ongoing sense of a tougher economy," Korsmo said.



Customers are seen at a restaurant at the Ferry Building in San Francisco on May 31, 2024. (David Paul Morris/Bloomberg via Getty Images / Getty Images)

Sylvain Charlebois, professor and senior director of the Agri-Food Analytics Lab, highlighted that surcharges can be adjusted or removed as costs fluctuate, whereas menu price changes are more permanent and noticeable.

"Customers tend to react more negatively to visible price hikes than to separate fees, even if the net cost remains the same," said Charlebois. "While consumers may dislike extra fees, surcharges provide transparency by itemizing specific costs, such as supply chain disruptions, labor expenses or credit card processing fees."

GET FOX BUSINESS ON THE GO BY CLICKING HERE

Forrest Leighton, senior vice president of marketing at customer intelligence platform Chatmeter, told FOX Business that many restaurant customers are questioning the value of higher-priced menu items.

Chatmeter helps restaurants analyze customer feedback to inform decisions around menu items, prices, and operations. Its data shows that the number of pricing-related reviews calling restaurants "overpriced" rose more than 40% in 2024, while the number mentioning the word "cheap" dropped over 10%.

However, surcharges can provide customers with transparency around why the price is going up,

which helps make it more palatable, Leighton said, adding that loyal customers are less likely to walk away from a price increase they deem to be temporary and beyond the brand's control, which surcharges often are.

Diners are seen on the outdoor patio of a restaurant in Atlanta on Sept. 16, 2024. (Elijah Nouvelage/Bloomberg via Getty Images / Getty Images)

Max Chodorow, one of the owners of Jean's in New York City, told FOX Business that he wished he could add a surcharge, but legally, he can't in the city.

"Our costs are constantly growing, and there's only so much we can raise prices with consumer psychology," Chodorow said.

He said that a surcharge is easier to implement because people primarily react to sticker shock of the menu price. The only surcharge that restaurants are allowed to apply in New York state is an auto gratuity on parties over a certain size or special events, and it needs to be disclosed to the customer along certain guidelines, according to Chodorow.

They are not allowed to do anything with the fee "beyond pass it directly to tipped employees," he said.

Orange Book Preface

Center for Drug Evaluation and Research

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations

PREFACE TO FORTY FIFTH EDITION

The publication, Approved Drug Products With Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an approval that has not been withdrawn for safety or effectiveness reasons. Inclusion of products in the Orange Book is independent of any current regulatory action being taken administratively or judicially against a drug product. In addition, the Orange Book contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of healthcare costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

Background of the Publication. To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach). Because of the number of requests in the late 1970s for FDA assistance in preparing both positive and negative formularies, it became apparent that FDA could not serve the needs of each state on an individual basis. The Agency also recognized that providing a single list based on common criteria would be preferable to evaluating drug products on the basis of differing definitions and criteria in various state laws. As a result, on May 31, 1978, the Commissioner of the Food and Drug Administration sent a letter to officials of each state announcing FDA's intent to provide a list of all

prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products.

The Orange Book was distributed as a proposal in January 1979. It included only currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of Section 505 of the FD&C Act and FDA regulations at that time.

The therapeutic equivalence evaluations in the Orange Book reflect FDA's application of specific criteria to the multisource prescription drug products listed in the Orange Book and approved under Section 505 of the FD&C Act. These evaluations are presented in the form of code letters that indicate the basis for the evaluation made. An explanation of the codes appears in the Introduction.

A complete discussion of the background and basis of FDA's therapeutic equivalence evaluation policy was published in the Federal Register on January 12, 1979 (44 FR 2932). The final rule, which includes FDA's responses to the public comments on the proposal, was published in the Federal Register on October 31, 1980 (45 FR 72582). The first publication of the Orange Book in October 1980, concurrent with finalization of the rule, incorporated appropriate revisions. Each subsequent edition has included new approvals and made appropriate changes in data.

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments amended the FD&C Act to establish, among other things, the 505(b)(2) and 505(j) approval pathways. The Hatch-Waxman Amendments require that FDA, among other things, make publicly available a list of approved drug products with monthly supplements. The Orange Book and its monthly Cumulative Supplements satisfy this requirement. The Addendum to this publication identifies drugs that have qualified under the FD&C Act for periods of exclusivity and provides patent information concerning the approved drug products in the Orange Book. The Addendum also provides additional information that may be helpful to those submitting an NDA under Section 505(b) of the FD&C Act or an ANDA under Section 505(j) of the FD&C Act to the Agency.

The Agency intends to use this publication to further its objective of obtaining input and comment on the publication itself and related Agency procedures. Therefore, if you have comments on how the publication can be improved, please send them to the Central Document Room, Attn: Director, Division of Orange Book Publication and Regulatory Assessment (DOBPRA), Office of Generic Drug Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266. Comments received are publicly available to the extent allowable under the Freedom of Information Act and FDA regulations.

1.0 INTRODUCTION

1.1 Content and Exclusion

The Orange Book is composed of four parts: (1) approved prescription drug products with therapeutic equivalence evaluations (Prescription Drug Product List); (2) approved Over-the-Counter (OTC) drug products (OTC Drug Product List); (3) Drug Products with Approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research List; and (4) a cumulative list of approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined that they were withdrawn from sale for safety or effectiveness reasons, or have had their approvals withdrawn for other than safety or effectiveness reasons subsequent to being discontinued from marketing (Discontinued Drug Product List).[1] This publication also includes Appendices of information from prescription and OTC drug products lists:

(1) Appendix A, which is an alphabetical list of proprietary names, if one exists (brand name or trade name), and the name of the active ingredient.

(2) Appendix B, which is an alphabetical list of applicant names which have been abbreviated for this publication.

(3) Appendix C, which is an alphabetical list of uniform terms.

The *Addendum* contains patent and exclusivity information for the products contained in the Prescription Drug Product, OTC Drug Product, Discontinued Drug Product, and the Drug Products with Approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research Lists. The publication may include additional information that the Agency deems appropriate to disseminate.

Prior to the 6th Edition, the publication had excluded OTC drug products and drug products with approval under Section 505 of the FD&C Act administered by the Center for Biologics Evaluation and Research. The Hatch-Waxman Amendments required the Agency to begin publishing an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and effectiveness and for which NDAs are required.

Under the FD&C Act, some drug products are given tentative approvals. The Agency will not include drug products with tentative approvals in the Orange Book because a drug product that is granted tentative approval is not an approved drug product. Tentative approval lists by month are available on FDA's website Drugs@FDA. When the tentative approval becomes a final approval through a subsequent action letter to the applicant, the Agency will list the drug product and the date of approval in the appropriate approved drug product list. In addition, we note that Section 505(x) of the FD&C Act affects the date of approval for certain drug products subject to scheduling under the Controlled Substances Act. For these drug products subject to scheduling, the Agency will list the drug product on FDA's website Drugs@FDA upon approval under Section 505(c) of the FD&C Act, and will

list the drug product in the Orange Book upon the date of approval as determined under Section 505(x).

The Orange Book identifies the application holder of a drug product and does not identify distributors or repackagers.

1.2 Therapeutic Equivalence-Related Terms

Pharmaceutical Equivalents. Pharmaceutical equivalents are drug products in identical dosage forms and route(s) of administration that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where the residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.[2] They may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, within certain limits, labeling.

Pharmaceutical Alternatives. Pharmaceutical alternatives are drug products that contain the identical therapeutic moiety, or its precursor, but not necessarily in the same amount or dosage form, or the same salt or ester (e.g., tetracycline hydrochloride, 250 mg capsules vs. tetracycline phosphate complex, 250 mg capsules; quinidine sulfate, 200 mg tablets vs. quinidine sulfate, 200 mg capsules).[3] Each such drug product individually meets either the identical or its own respective compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates.[4] Different dosage forms and strengths within a product line by a single manufacturer are pharmaceutical alternatives, as are extended-release products when compared with immediate-release or standard-release formulations of the same active ingredient.

Therapeutic Equivalents. Approved drug products are considered to be therapeutic equivalents if they are pharmaceutical equivalents for which bioequivalence has been demonstrated, and they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.[5]

FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength,

quality, purity, and identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they may meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations. The concept of therapeutic equivalence applies only to drug products containing the identical active ingredient(s) and does not encompass a comparison of different therapeutic agents used for the same condition (e.g., meperidine hydrochloride vs. morphine sulfate for the treatment of pain). Any drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent to the applicant's drug product even if the applicant's drug product is single source or coded as non-equivalent (e.g., **BN**). Distributors or repackagers of an applicant's drug product are not identified in the Orange Book.

FDA considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/ time, certain aspects of labeling (e.g., the presence of specific pharmacokinetic information), and storage conditions. When such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a specific product be dispensed as a medical necessity. With this limitation, however, FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product can be expected to have the same clinical effect and safety profile as the prescribed product when administered to patients under the conditions specified in the labeling.

Strength. Strength refers to the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: (1)(a) the total quantity of drug substance in mass or units of activity in a dosage unit or container closure (e.g., weight/unit dose, weight/volume or weight/weight in a container closure, or units/volume or units/weight in a container closure); and/or, as applicable, (b) the concentration of the drug substance in mass or units of activity per unit volume or mass (e.g., weight/ weight, weight/volume, or units/volume); or (2) such other criteria the Agency establishes for determining the amount of drug substance contained in, delivered, or deliverable from a drug product if the weights and measures described in clause (1)(a) do not apply (e.g., certain drug-device combination products for which the amount of drug substance is emitted per use or unit time).[6] Note that if the criteria the Agency establishes for determining and expressing the amount of drug substance in a product evolves over time, the Agency generally does not intend to revise the expressions of strength for drug products already included in the Orange Book, but rather intends to apply the criteria prospectively to drug products added to the Orange Book.

Although the strength of drug products in the Orange Book is generally expressed in terms of the

amount of drug substance (active ingredient) in the drug product, it is sometimes expressed in terms of the amount of the active moiety.[7] For example, certain drug products included in the Orange Book include a designation of "EQ" next to their expression of strength. This "EQ" designation generally is used in connection with salt drug products to indicate that the strength of such drug product is being expressed in terms of the equivalent strength of the active moiety (e.g., "EQ 200 MG BASE"), rather than in terms of the strength of the active ingredient.

Bioavailability. Bioavailability is the rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of drug action. For drug products that are not intended to be absorbed into the bloodstream, bioavailability may be assessed by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or active moiety becomes available at the site of drug action.[8]

Bioequivalence. Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.[9] Section 505(j)(8)(B) of the FD&C Act describes certain conditions under which a test drug and reference listed drug (RLD)(see Section 1.4) shall be considered bioequivalent:

(i) (i) the rate and extent of absorption of the [test] drug do not show a significant difference from the rate and extent of absorption of the [reference] listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) (ii) the extent of absorption of the [test] drug does not show a significant difference from the extent of absorption of the [reference] listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the [reference] listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

Where these above methods are not applicable (e.g., for drug products that are not intended to be absorbed into the bloodstream), other scientifically valid in vivo or in vitro test methods to demonstrate bioequivalence may be appropriate.

For example, bioequivalence may sometimes be demonstrated using an in vitro bioequivalence standard, especially when such an in vitro test has been correlated with human in vivo bioavailability data. In other situations, bioequivalence may sometimes be demonstrated through comparative clinical trials or pharmacodynamic studies.[10]

1.3 Further Guidance on Bioequivalence

FDA's regulations and guidance documents provide additional information regarding bioequivalence and bioavailability, including methodologies and statistical criteria used to establish the bioequivalence of drug products.[11]

1.4 RLD and Reference Standard

An RLD is the listed drug [12] identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA.[13] FDA's general practice is to designate as RLDs drug products that have been approved for safety and effectiveness under Section 505(c) of the FD&C Act. For an ANDA based on an approved suitability petition (a petitioned ANDA), the RLD generally is the listed drug referenced in the approved suitability petition.[14]

A reference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval.[15] FDA generally selects a single reference standard that ANDA applicants must use in in vivo bioequivalence testing. Ordinarily, FDA will select the RLD as the reference standard. However, in some instances, the RLD and the reference standard may be different. For example, where the RLD has been withdrawn from sale for reasons other than safety or effectiveness, FDA may select an ANDA that is therapeutically equivalent to this RLD as the reference standard.[14]

FDA identifies RLDs in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists. Listed drugs identified as RLDs represent drug products upon which an applicant can rely in seeking approval of an ANDA. FDA intends to update periodically the RLDs identified in the Prescription Drug Product, OTC Drug Product, and Discontinued Drug Product Lists, as appropriate.

If FDA has not designated an RLD for a drug product the applicant intends to duplicate, the potential applicant may submit a controlled correspondence to the Office of Generic Drugs to ask FDA to designate an RLD for that drug product. Section 1.7, *Therapeutic Equivalence Evaluations Codes (products meeting necessary bioequivalence requirements)*, explains the character coding system (e.g., **AB, AB1, AB2, AB3**...) for multisource prescription drug products listed under the same heading with two or more RLDs.

FDA also identifies reference standards in the Prescription Drug Product and OTC Drug Product Lists. Listed drugs identified as reference standards represent FDA's best judgment at this time as to the appropriate comparator for purposes of conducting any in vivo bioequivalence studies required for approval.

A potential applicant should consult Agency guidance related to referencing approved drug products in ANDA submissions for information on submitting a request for selection of a reference standard.

FDA may, on its own initiative, select a new reference standard when doing so will help to ensure that applications for generic drugs may be submitted and evaluated, e.g., in the event that the listed drug currently selected as the reference standard has been withdrawn from sale.

If an applicant has a question related to the appropriate reference standard, it is recommended that an applicant submit a controlled correspondence to the Office of Generic Drugs.

1.5 General Policies and Legal Status

The Orange Book contains public information and advice. It does not mandate the drug products that are purchased, prescribed, dispensed, or substituted for one another, nor does it, conversely, mandate the products that should be avoided. To the extent that the Orange Book sets forth FDA's evaluations of the therapeutic equivalence of drug products that have been approved, it contains FDA's advice to the public, to practitioners, and to the states regarding drug product selection. These evaluations do not constitute determinations that any product is in violation of the FD&C Act or that any product is preferable to any other. Therapeutic equivalence evaluations are a scientific judgment based upon evidence, while generic substitution may involve social and economic policy administered by the states, e.g., reducing the cost of drugs to consumers. To the extent that the Orange Book identifies drug products approved under Section 505 of the FD&C Act, it sets forth information that the Agency is required to publish and that the public is entitled to under the Freedom of Information Act. Exclusion of a drug product from the Orange Book does not necessarily mean that the drug product is in violation of Section 505 of the FD&C Act, that such a product is not safe or effective, or that such a product is not therapeutically equivalent to other drug products. Rather, the exclusion may be based on the fact that FDA has not evaluated the safety, effectiveness, and quality of the drug product.

1.6 Practitioner/User Responsibilities

Professional care and judgment should be exercised in using the Orange Book. Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of FDA, to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. However, these products may differ in other characteristics that are not required by statute or regulation to be the same, such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time, and, in some instances, labeling. If products with such differences are substituted for each other, there is a potential for patient confusion, e.g., due to differences in color or shape of tablets, inability to provide a given dose using a partial tablet if the proper scoring configuration is not available, or decreased patient acceptance of certain products because of flavor. There may also be patient-specific allergic reactions in rare cases due to a coloring or a preservative ingredient.

FDA evaluation of therapeutic equivalence in no way relieves practitioners of their professional responsibilities in prescribing and dispensing such products with due care and with appropriate information to individual patients. In those circumstances where the characteristics of a specific product, other than its active ingredient, are important in the therapy of a particular patient, the practitioner's prescribing of that product may be appropriate. Pharmacists must also be familiar with the different characteristics of therapeutically equivalent products, e.g., expiration dates/times and labeling directions for storage of the different products (particularly for reconstituted products), so they can properly advise patients when one product is substituted for another.

Multisource and single-source drug products. In the Orange Book, FDA has evaluated for therapeutic equivalence only multisource prescription drug products approved under Section 505 of the FD&C Act, which in most instances means those pharmaceutical equivalents available (i.e., not on the Discontinued Drug Product list) from more than one manufacturer. For such products, a therapeutic equivalence code generally is included and product information is highlighted in bold face and underlined. Those products with approved applications that are single source (i.e., there is only one approved product available for that active ingredient, dosage form, route of administration, and strength) are also included in the Orange Book, but no therapeutic equivalence code is included with such products. Any drug product in the Orange Book repackaged and/or distributed by the applicant or some other person authorized by the applicant (e.g., an authorized generic) is considered to be therapeutically equivalent to the applicant's drug product, even if the applicant's drug product is single source or coded as non-equivalent (e.g., **BN**). Distributors or repackagers of an applicant's drug product are not identified in the Orange Book. The details of therapeutic equivalence codes and the policies underlying them are discussed in Section 1.7, *Therapeutic Equivalence Evaluations Codes*.

Products in the Orange Book are identified by the names of the holders of approved applications (applicants) who may not necessarily be the manufacturer of the product. There are numerous entities other than the applicant that may be involved in the development, manufacturing, and/or marketing of a product. Products listed in the Orange Book are identified by the applicant's name (firm name on the Form FDA 356h in the application). Where the applicant's name does not appear on the label, a person wishing to relate a specific product to the applicant name in the Orange Book may refer to FDA's NDC Directory[16] and match its search terms to information on the label, such as the NDC Code if available.

Every product in the Orange Book is subject at all times to regulatory action. From time to time, approved products may be found in violation of one or more provisions of the FD&C Act. In such circumstances, the Agency may commence appropriate enforcement action to correct the violation, if necessary, by securing removal of the product from the market by voluntary recall, seizure, or other enforcement actions. Such regulatory actions are, however, independent of the inclusion of a product in the Orange Book. The main criterion for inclusion of a product is that it has

an NDA or ANDA that has been approved and that has not been withdrawn for safety or effectiveness reasons. FDA believes that retention of a violative product in the Orange Book will not have any significant adverse health consequences, because other legal mechanisms are available to the Agency to prevent the product's actual marketing. FDA may, however, change a product's therapeutic equivalence rating if the circumstances giving rise to the violation change or otherwise call into question the Agency's assessment of whether a product meets the criteria for therapeutic equivalence.

1.7 Therapeutic Equivalence Evaluations Codes

Generally, prescription drug products that the Agency considers multisource have been assigned a therapeutic equivalence code. The coding system for therapeutic equivalence evaluations is designed to allow users to determine quickly whether the Agency has evaluated a particular approved prescription drug product (e.g., a particular strength of an approved drug that is not on the Discontinued Drug Product List) as therapeutically equivalent to other pharmaceutically equivalent prescription drug products (first letter) and to provide additional information on the basis of FDA's evaluations (second letter). With some exceptions (e.g., therapeutic equivalence evaluations for certain 505(b)(2) applications), the therapeutic equivalence evaluation date is the same as the approval date.

The two basic categories into which multisource drugs have been placed are indicated by the first letter of the relevant therapeutic equivalence code as follows:

A Drug products that FDA considers to be <u>therapeutically equivalent</u> to other pharmaceutically equivalent products, i.e., drug products for which:

there are no known or suspected bioequivalence problems. These are designated AA, AN, AO, AP, or AT, depending on the dosage form; or

actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. These are designated **AB**.

B Drug products that FDA at this time,nsiders <u>not to be therapeutically equivalent</u> to other pharmaceutically equivalent products, i.e., drug products for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence. Often the problem is with specific dosage forms rather than with the active ingredients. These are designated **BC, BD, BE, BN, BP, BR, BS, BT, BX,** or **B***.

Individual drug products have been evaluated as therapeutically equivalent in accordance with the definitions and policies outlined below:

"A" CODES

Drug products that are considered to be therapeutically equivalent to other

pharmaceutically equivalent products

"A" products are those for which there are no known or suspected bioequivalence problems or for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence. Drug products designated with an "A" code fall under one of two main policies:

for those active ingredients or dosage forms for which no in vivo bioequivalence issue is known or suspected, the information necessary to show bioequivalence between pharmaceutically equivalent products is either presumed and considered self-evident (based on other information in the application for some dosage forms (e.g., solutions)), or satisfied by a showing that an acceptable *in vitro* approach is met. A therapeutically equivalent rating is assigned to such products so long as they are manufactured in accordance with Current Good Manufacturing Practice regulations and meet the other requirements of their approved applications (these are designated **AA, AN, AO, AP**, or **AT**, depending on the dosage form, as described below); or

for those Drug Efficacy Study Implementation (DESI) drug products containing active ingredients or dosage forms that have been identified by FDA as having actual or potential bioequivalence problems, and for post-1962 drug products presenting a potential bioequivalence problem, an evaluation of therapeutic equivalence is assigned to pharmaceutical equivalents only if the approved application contains adequate scientific evidence establishing through in vivo and/or in vitro studies the bioequivalence of the product to a selected reference product (these products are designated as **AB**).

There are some general principles that may affect the substitution of pharmaceutically equivalent products in specific cases. Prescribers and dispensers of drugs should be alert to these principles so as to deal appropriately with situations that require professional judgment and discretion.

There may be labeling differences among pharmaceutically equivalent products that require attention on the part of the health professional (e.g., pharmaceutically equivalent powders to be reconstituted for administration as oral or injectable liquids may vary with respect to their expiration time or storage conditions after reconstitution). FDA's determination that such products are therapeutically equivalent is applicable only when each product is reconstituted, stored, and used under the conditions specified in its labeling.

The Agency may use notes in this publication to point out special situations, such as potential differences between two drug products that have been evaluated as bioequivalent and otherwise therapeutically equivalent, when they should be brought to the attention of health professionals. These notes are contained in Section 1.8, Description of Certain Special Situations. For example, in certain instances, there may be variations among therapeutically equivalent products in their use or in conditions of administration. When such variations may, in the Agency's opinion, affect prescribing or substitution decisions by health professionals, a note may be added to Section 1.8.

For example, occasionally a situation may arise in which changes in a listed drug product after its approval (for example, a change in dosing interval) may have an impact on the substitutability of already approved generic versions of that product that were rated by the Agency as therapeutically equivalent to the listed product. When such changes in the listed drug product are considered by the Agency to have a significant impact on therapeutic equivalence, the Agency will change the therapeutic equivalence ratings for other versions of the drug product unless the manufacturers of those other versions of the product provide additional information to assure equivalence under the changed conditions. Pending receipt of the additional data, the Agency may add a note to Section 1.8, or, in rare cases, may even change the therapeutic equivalence rating.

In some cases (e.g., Isolyte® S w/ Dextrose 5% in Plastic Container and Plasma Lyte® 148 and Dextrose 5% in Plastic Container), closely related products are listed as containing the same active ingredients, but in somewhat different amounts. In determining which of these products are pharmaceutically equivalent, generally the Agency has considered products to be pharmaceutically equivalent with labeled strengths of an ingredient that do not vary by more than 1%.

Different salts, esters or other noncovalent derivatives (such as a complex, chelate, or clathrate) of the same active moiety are regarded as different active ingredients. For the purpose of this publication, products containing such different active ingredients are considered pharmaceutical alternatives and, thus, are not therapeutically equivalent. Anhydrous and hydrated entities, as well as different polymorphs, are considered to be the same active ingredient and are expected to meet the same standards for identity to be considered pharmaceutical equivalents and therapeutic equivalents.

The codes in this book are not intended to preclude healthcare professionals from converting pharmaceutically different concentrations into pharmaceutical equivalents using accepted professional practice.

Preservatives and other inactive ingredients may differ among some therapeutically equivalent drug products. These differences do not affect FDA's evaluation of therapeutic equivalence except in cases where these components may influence bioequivalence or routes of administration.

The specific sub-codes for those drugs evaluated as therapeutically equivalent and the policies underlying these sub-codes follow:

AA Products in conventional dosage forms not presenting bioequivalence problems

Multisource drug products coded as *AA* contain active ingredients and are in dosage forms that are not regarded as presenting either actual or potential bioequivalence problems or drug quality or standards issues. However, all oral dosage forms must, nonetheless, meet an appropriate in vitro bioequivalence standard that is acceptable to the Agency in order to be approved.

AB, AB1, AB2, AB3... Products meeting necessary bioequivalence requirements

Multisource drug products listed under the same heading (i.e., identical active ingredients(s), dosage form, and route(s) of administration) and having the same strength (see Section 1.2, *Therapeutic Equivalence-Related Terms, Strength*) generally will be coded AB if data and information are submitted demonstrating bioequivalence.

In certain instances, a number is added to the end of the AB code to make a three-character code (i.e., **AB1, AB2, AB3**, etc.). Three-character codes generally are assigned only in situations when more than one RLD of the same strength has been designated under the same heading. If a study is submitted that demonstrates bioequivalence to an RLD, the generic drug product will be given the same three-character code as the RLD it was compared against. For example, Adalat® CC and Procardia XL®, extended-release tablets, are listed under the active ingredient nifedipine. These drug products, listed under the same heading, are not bioequivalent to each other. Adalat® CC and Procardia XL® have been assigned ratings of **AB1** and **AB2**, respectively. Generic drug products deemed by FDA to be bioequivalent to Adalat® CC and Procardia XL® have been approved. As a result, the generic drug products bioequivalent to Adalat® CC have been assigned a rating of **AB1** and those bioequivalent to Procardia XL® have been assigned a rating of **AB2** (the assignment of an **AB1 or AB2** rating to a specific product does not imply product preference). Even though drug products of distributors and/or repackagers are not included in the Orange Book, they are considered therapeutically equivalent to the applicant's drug product if the applicant's drug product is rated either with an **AB** or three-character code or is single source in the Orange Book. Drugs coded as **AB** under a heading are considered therapeutically equivalent only to other drugs coded as **AB** under that heading. Drugs coded with a three-character code under a heading are considered therapeutically equivalent only to other drugs coded with the same three-character code under that heading.

AN Solutions and powders for aerosolization

Uncertainty regarding the therapeutic equivalence of aerosolized products arises primarily because of differences in the drug delivery system. Solutions and powders intended for aerosolization that are marketed for use in general-use delivery systems are considered to be pharmaceutically and therapeutically equivalent and are coded **AN**. Those products that are compatible only with a specific delivery system or those products that are packaged in and with a specific delivery system are coded **BN**, unless they have met an appropriate bioequivalence standard and are otherwise determined to be therapeutically equivalent. Solutions or suspensions in a specific delivery system will be coded **AN** if the bioequivalence standard is based upon in vitro methodology. If bioequivalence needs to be demonstrated by in vivo methodology, then the drug products will be coded **AB**.

AO Injectable oil solutions

The absorption of drugs in injectable (parenteral) oil solutions may vary substantially with the type of oil employed as a vehicle and the concentration of the active ingredient. Injectable oil solutions are

therefore considered to be pharmaceutically and therapeutically equivalent only when the active ingredient, its concentration, and the type of oil used as a vehicle are all identical.

AP Injectable aqueous solutions and, in certain instances, intravenous non-aqueous solutions

It should be noted that even though injectable (parenteral) products under a specific listing may be evaluated as therapeutically equivalent, there may be important differences among the products in the general category, Injectable; Injection. For example, historically some injectable products that are rated therapeutically equivalent are labeled for different routes of administration. In addition, some products evaluated as therapeutically equivalent may have different preservatives or no preservatives at all. Injectable products are available as solutions (e.g., concentrated sterile solutions for dilution or sterile solutions ready for injection) or powders for reconstitution (e.g., a lyophilized powder for injection). Solutions and powders for reconstitution are considered different dosage forms, and thus not pharmaceutical equivalent drug products, but may be considered pharmaceutical alternative drug products. Therefore, they are not rated as therapeutically equivalent (AP) to each other even if these pharmaceutical alternative drug products are designed to produce the same concentration prior to injection and are expected to have similar clinical effects and safety profile under the conditions of use described in the labeling. Consistent with accepted professional practice, it is the responsibility of the prescriber, dispenser, or individual administering the product to be familiar with a product's labeling to assure that it is given only by the route(s) of administration stated in the labeling. Historically, the dosage form of a parenteral product was listed as “injectable” while the product physically was generally either a solution or powder. Thus, different products listed with the historical term “injectable” do not necessarily have the same dosage form.

Certain commonly used large volume intravenous products in glass containers are not included in the Orange Book (e.g., dextrose injection 5%, dextrose injection 10%, sodium chloride injection 0.9%) since these products are on the market without FDA approval and FDA has not published conditions for marketing such parenteral products under approved NDAs. When packaged in plastic containers, however, FDA regulations require approved applications prior to marketing. Approval then depends on, among other things, the extent of the available safety data involving the specific plastic component of the product. All large volume parenteral products are manufactured under similar standards, regardless of whether they are packaged in glass or plastic. Thus, FDA has no reason to believe that the packaging container of large volume parenteral drug products that are pharmaceutically equivalent would have any effect on their therapeutic equivalence.

Consistent with the definition of strength included in Section 1.2, Therapeutic Equivalence-Related Terms, the strength of a parenteral solution generally is identified by both the total drug content and the concentration of drug substance in a container approved by FDA. In the past, the strength of

parenteral solutions in the Orange Book has not been fully displayed. Rather, the strength of parenteral solutions in the Orange Book has been displayed in terms of concentration, expressed as x mg/milliliter (mL).[17] Generally, the amount of dry powder or lyophilized powder in a container is identified as the strength, expressed as x mg/vial.

However, FDA subsequently realized that the format of the Orange Book with respect to parenteral solutions should be changed to reflect that each strength of a drug is considered to be a separate listed drug. The Orange Book generally displays the strength of new approvals of parenteral solutions. Previously (i.e., prior to 2003), we would have displayed only the concentration of an approved parenteral solution, e.g., 1 mg/mL. For example, if this application had a 125 mL and 250 mL container approved, we would now display two product strengths, listing both total drug content and concentration of drug substance in the relevant approved container, e.g., 125 mg/125 mL (1 mg/mL) and 250 mg/250 mL (1 mg/mL).

AT Topical products

There are a variety of topical dosage forms available for dermatologic, ophthalmic, otic, rectal, and vaginal administration, including creams, gels, lotions, oils, ointments, pastes, solutions, sprays, suppositories, and inserts. Even though different topical dosage forms may contain the same active ingredient and potency, these dosage forms are not considered pharmaceutically equivalent. Therefore, they are not considered therapeutically equivalent. All solutions and DESI drug products containing the same active ingredient in the same topical dosage form for which a waiver of in vivo bioequivalence has been granted,or the application contains adequate scientific evidence establishing through an in vitro approach the bioequivalence of the product to a selected reference product, and for which chemistry and manufacturing processes are adequate to demonstrate bioequivalence, are considered therapeutically equivalent and coded **AT**. Pharmaceutically equivalent topical products that raise questions of bioequivalence and for which a waiver of in vivo bioequivalence has not been granted, including all post-1962 non-solution topical drug products, are coded **AB** when supported by adequate in vivo bioequivalence data, and BT in the absence of such data.

"B" CODES

Drug products that FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products.

"B" products, for which actual or potential bioequivalence problems have not been resolved by adequate evidence of bioequivalence, often have a problem with specific dosage forms rather than with the active ingredients. Drug products designated with a "B" code fall under one of three main policies:

the drug products contain active ingredients or are manufactured in dosage forms that have been

identified by the Agency as having documented bioequivalence problems or a significant potential for such problems and for which no adequate studies demonstrating bioequivalence have been submitted to FDA; or

the quality standards are inadequate or FDA has an insufficient basis to determine therapeutic equivalence; or

the drug products are under regulatory review.

The specific coding definitions and policies for the **"B"** sub-codes are as follows:

B* Drug products requiring further FDA investigation and review to determine therapeutic equivalence

The code **B*** is assigned to products previously assigned an **A** or **B** code when FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

BC Extended-release dosage forms (capsules, injectables and tablets)

Extended-release tablets are formulated in such a manner as to make the contained drug substance available over an extended period of time following ingestion.

Although bioavailability studies have been conducted on these dosage forms, they may be subject to bioavailability differences, primarily because applicants developing extended-release products for the same active ingredient rarely employ the same formulation approach. FDA, therefore, does not consider different extended-release dosage forms containing the same active ingredient in equal strength to be therapeutically equivalent unless equivalence between individual products in both rate and extent has been specifically demonstrated through appropriate bioequivalence studies. Extended-release products for which such bioequivalence data have not been submitted are coded BC, while those for which such data are available have been coded **AB**.

BD Active ingredients and dosage forms with documented bioequivalence problems

The **BD** code denotes products containing active ingredients with known bioequivalence problems and for which adequate studies have not been submitted to FDA demonstrating bioequivalence. Where studies showing bioequivalence have been submitted, the product has been coded **AB**.

BE Delayed-release oral dosage forms

Where the drug may be destroyed or inactivated by the gastric juice or where it may irritate the gastric mucosa, the use of “enteric” coatings is indicated. Such coatings are intended to delay the release of

the medication until the tablet has passed through the stomach. Drug products in delayed-release dosage forms containing the same active ingredients may be subject to significant differences in absorption. Unless otherwise specifically noted, the Agency considers different delayed-release products containing the same active ingredients as presenting a potential bioequivalence problem and codes these products **BE** in the absence of in vivo studies showing bioequivalence. If adequate in vivo studies have demonstrated the bioequivalence of specific delayed-release products, such products are coded **AB**.

BN Products in aerosol-nebulizer drug delivery systems

This code applies to drug solutions or powders that are marketed only as a component of, or as compatible with, a specific drug delivery system. There may, for example, be significant differences in the dose of drug and particle size delivered by different products of this type. Therefore, the Agency does not consider different metered aerosol dosage forms containing the same active ingredient(s) in equal strengths to be therapeutically equivalent unless the drug products meet an appropriate bioequivalence standard; such products are coded **AB**.

BP Active ingredients and dosage forms with potential bioequivalence problems

FDA's bioequivalence regulations (21 CFR 320.33) contain criteria and procedures for determining whether a specific active ingredient in a specific dosage form has a potential for causing a bioequivalence problem. It is FDA's policy to consider an active ingredient meeting these criteria as having a potential bioequivalence problem even in the absence of positive data demonstrating inequivalence. Pharmaceutically equivalent products containing these active ingredients in oral dosage forms are coded **BP** until adequate bioequivalence data are submitted, after which such products are coded **AB**. Injectable suspensions containing an active ingredient suspended in an aqueous or oleaginous vehicle have also been coded **BP**. Injectable suspensions are subject to bioequivalence problems because differences in particle size, polymorphic structure of the suspended active ingredient, or the suspension formulation can significantly affect the rate of release and absorption. FDA does not consider pharmaceutical equivalents of these products bioequivalent without adequate evidence of bioequivalence; such products would be coded **AB**.

BR Suppositories or enemas that deliver drugs for systemic absorption

The absorption of active ingredients from suppositories or enemas that are intended to have a systemic effect (as distinct from suppositories administered for local effect) can vary significantly from product to product. Therefore, FDA considers pharmaceutically equivalent systemic suppositories or enemas bioequivalent only if in vivo evidence of bioequivalence is available. In those cases where in vivo evidence is available, the products are coded AB. If such evidence is not available, the products are coded **BR**.

BS Products having drug standard deficiencies

If the drug standards for an active ingredient in a particular dosage form are found by FDA to be deficient so as to prevent an FDA evaluation of either pharmaceutical or therapeutic equivalence, all drug products containing that active ingredient in that dosage form are coded **BS**. For example, if the standards permit a wide variation in pharmacologically active components of the active ingredient such that pharmaceutical equivalence is in question, all products containing that active ingredient in that dosage form are coded **BS**.

BT Topical products with bioequivalence issues

This code applies mainly to post-1962 dermatologic, ophthalmic, otic, rectal, and vaginal products for topical administration, including creams, gels, lotions, oils, ointments, pastes, solutions, sprays, suppositories, and inserts not intended for systemic drug absorption. Topical products evaluated as having acceptable clinical performance, but that are not bioequivalent to other pharmaceutically equivalent products or that lack sufficient evidence of bioequivalence, will be coded **BT**.

BX Drug products for which the data are insufficient to determine therapeutic equivalence

The code **BX** is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in this document. In these situations, the drug products are presumed to be therapeutically inequivalent until the Agency has determined that there is adequate information to make a full evaluation of therapeutic equivalence.

1.8 Description of Certain Special Situations

Certain drugs listed in the Orange Book present special situations that merit further discussion. The following are descriptions of certain examples of those special situations:

Amino Acid and Protein Hydrolysate Injections. These products differ in the amount and kinds of amino acids they contain and, therefore, are not considered pharmaceutical equivalents. For this reason, these products are not considered therapeutically equivalent. At the same time, the Agency believes that it is appropriate to point out that where nitrogen balance is the sole therapeutic objective and individual amino acid content is not a consideration, pharmaceutical alternatives with the same total amount of nitrogen content may be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

Gaviscon®. Gaviscon® is an OTC product that has been marketed since September 1970. The active ingredients in this product, aluminum hydroxide and magnesium trisilicate, were reviewed by the Agency's OTC Antacid Panel and were considered to be safe and effective ingredients (Category I)

by that Panel. However, the tablet failed to pass the antacid test that is required of all antacid products. The Agency, therefore, placed the tablet in Category III for lack of effectiveness. A full NDA with clinical studies was submitted by Marion Laboratories, Inc., and approved by FDA on December 9, 1983. Gaviscon®'s activity in treating reflux acidity is made possible by the physical-chemical properties of the inactive ingredients, sodium bicarbonate and alginic acid. Therefore, all ANDAs that *cite Gaviscon® tablets as the RLD must contain the inactive ingredients sodium bicarbonate and alginic acid*. A full NDA will be required to support the effectiveness of the drug product if different inactive ingredients are to be substituted for sodium bicarbonate or alginic acid or if different proportions of these ingredients are to be used.

Levothyroxine Sodium.[18] Because there are multiple RLDs for levothyroxine sodium tablets and some RLD applicants have conducted studies to establish their drugs' therapeutic equivalence to other RLDs, FDA has determined that its usual practice of assigning two- or three-character therapeutic equivalence codes may be potentially confusing and inadequate for these drug products. Looking at the Orange Book listing alone for a product identified as an RLD or reference standard, it may be difficult to determine to which therapeutic equivalence code the RLDs and/or reference standard designation corresponds. For example, Unithroid 0.3 mg strength has been assigned the therapeutic equivalence codes AB1, AB2, and AB3 and it is identified as the RLD and reference standard, but it is unclear that the RLD and reference standard designations are associated with the AB1 therapeutic equivalence code.

Accordingly, FDA provides the following chart, which identifies (1) an RLD for each therapeutic equivalence code in the Orange Book and (2) and the reference standard products in the Active Section of the Orange Book.[19]

Therapeutic equivalence has been established between products that have the same AB+number therapeutic equivalence code (i.e., AB1, AB2, AB3 or AB4).

More than one therapeutic equivalence code may apply to some products. One common therapeutic equivalence code indicates therapeutic equivalence between products. For example, Unithroid has been assigned therapeutic equivalence codes AB1, AB2, and AB3, and therefore, Unithroid tablets are considered therapeutically equivalent to other levothyroxine sodium products of the same strength with these therapeutic equivalence codes.

TE Code	Proprietary Name	Applicant	Strength	Appl No	RLD	RS
AB1	UNITHROID	STEVENS J	0.3 MG	N021210	RLD	RS
AB2	SYNTHROID	ABBVIE	0.3 MG	N021402	RLD	RS

TE Code	Proprietary Name	Applicant	Strength	Appl No	RLD	RS
AB3	LEVOXYL	KING PHARMS	0.2 MG	N021301	RLD	RS
AB4	THYRO-TABS	ALVOGEN INC	0.3 MG	N021116	RLD	-
AB4	LEVOTHYROXINE SODIUM [20]	MYLAN	0.3 MG	A076187	-	RS

Patent Certification(s) and Reference Standard for ANDAs Duplicating a Drug Product Approved in a Petitioned ANDA. To submit an ANDA for a generic drug that is not the same as its RLD because it has one different active ingredient in a fixed-combination drug product, or has a different route of administration, dosage form, or strength than that of the RLD, an applicant first must obtain permission from FDA through what is known as a suitability petition pursuant to Section 505(j)(2)(C) of the FD&C Act. A petitioned ANDA relies on the RLD described in the suitability petition. An ANDA seeking approval of a drug that is the same as a drug product approved in a petitioned ANDA should use as its RLD, the RLD that served as the basis for the approved suitability petition, and use the drug product approved in the petitioned ANDA as its reference standard for conducting an in vivo bioequivalence study required for approval. However, the RLD for any such ANDA is generally the listed drug referenced in the approved suitability petition. The ANDA must include appropriate patent certification(s) and an exclusivity statement with respect to the RLD that served as the basis for the approved suitability petition[21] (This concept also generally applies to an ANDA applicant that utilizes a reference standard that is not an RLD, as such an application must include appropriate patent certification(s) and an exclusivity statement with respect to the RLD).

Waived exclusivity. If an NDA submitted under Section 505(b) of the FD&C Act qualifies for exclusivity under the FD&C Act, the exclusivity is generally listed in the Patent and Exclusivity Information Addendum of the Orange Book. If a drug product has qualified for this exclusivity, FDA will not accept for review and/or will not approve, as applicable, other applications blocked by the relevant exclusivity. If the listed drug is also protected by one or more patents, the approval date for an ANDA or 505(b)(2) application that relies on the listed drug will be determined based on an analysis of the applicant's patent certification(s) or statement(s) for each relevant patent and the effect of relevant exclusivity listed in the Orange Book. However, the holder of the NDA may waive its exclusivity as to any or all applications that might otherwise be blocked by such exclusivity. If an NDA holder waives its exclusivity, qualified applications may be accepted for review and/or approved, as applicable. An NDA for which the holder has waived its exclusivity as to all applications will be coded with a "W" in the Patent and Exclusivity Section of the Orange Book. The applicant whose product might otherwise be blocked by this exclusivity should indicate in the exclusivity statement in its application that the holder of the listed drug has waived its exclusivity.

1.9 Therapeutic Equivalence Code Change for a Category of Multisource Drug Products

The Agency will use the following procedures when, in response to a petition or on its own initiative, it is considering a change in the therapeutic equivalence code for approved multisource drug products. Such changes will generally occur when the Agency becomes aware of new scientific information affecting the therapeutic equivalence of an entire category of multisource drug products in the Orange Book (e.g., information concerning the active ingredient or the dosage form), rather than information concerning a single drug product within the category. These procedures will be used when a change in therapeutic equivalence code is under consideration for all drug products found in the Prescription Drug Product List under a specific active ingredient and dosage form. The change may be from the code signifying that the drug does not present a bioequivalence problem (e.g., **AA**) to a code signifying an actual or potential bioequivalence problem (e.g., **BP**), or vice versa. This procedure does not apply to a change of a particular product code (e.g., a change from **BP to AB** or from **AB to BX**).

Before making a change in a therapeutic equivalence code for an entire category of multisource drug products as described above, the Agency will announce in the Introduction to the Cumulative Supplement that it is considering the change and will invite comments. Comments, along with scientific data, may be sent to the Director, Office of Bioequivalence, Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Central Document Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

The comment period will generally be 60 days in length, and the closing date for comments will be listed in the description of the proposed change for each drug entity.

The most useful type of scientific data submitted to support comments is generally an in vivo bioavailability/bioequivalence study conducted on batches of the subject drug products. Comments including scientific data from an in vivo bioavailability/bioequivalence study should present a full description of the analytical procedures and equipment used, a validation of the analytical methodology, including the standard curve, a description of the method of calculating results, and a description of the pharmacokinetic and statistical models used in analyzing the data. Anecdotal or testimonial information is the least useful to the Agency, and submission of comments based on such information is discouraged. However, when there is supporting published or unpublished scientific literature, copies should be submitted with comments.

1.10 Change of the Therapeutic Equivalence Evaluation for a Single Product

The procedure described in Section 1.9 does not apply to a change in a single drug product code. For example, a change in a single drug product's code from **BP to AB** as a result of the submission of an acceptable bioequivalence study ordinarily will not be the subject of notice and comment in the Cumulative Supplement. Likewise, a change in a single drug product's code from **AB to BX** (e.g., as a result of new information raising a significant question as to bioequivalence) does not require notice and comment. The Agency's responsibility to provide the public with the Agency's most current

information related to therapeutic equivalence may require a change in a drug product's code prior to any formal notice and opportunity for the applicant to be heard. The publication in the Federal Register of a proposal to withdraw approval of a drug product will ordinarily result in a change in a product's code from **AB to BX** if this action has not already been taken.

We recognize that certain drug products approved in 505(b)(2) applications might not have therapeutic equivalence codes, and that FDA may undertake therapeutic equivalence evaluations with respect to such drug products. A person seeking to have a therapeutic equivalence rating for a drug product approved in a 505(b)(2) application may petition the Agency through the citizen petition procedure (see 21 CFR 10.25(a) and 21 CFR 10.30).[22]

1.11 Discontinued Drug Product List

The drug products in the Discontinued Drug Product List of the Orange Book (Discontinued Drug Product List) for which a determination has been made that the products were not withdrawn for safety or effectiveness reasons have been annotated with a footnote following the product strength: "**Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**". The determinations listed in the Orange Book are only reflective of determinations made since 1995 and published in the Federal Register. The identification of these drug products in the Discontinued Drug Product List should avoid the submission of multiple citizen petitions requesting a determination for the same drug product.

Generally, approved products are added to the Discontinued Drug Product List when the applicant notifies the Division of Orange Book Publication and Regulatory Assessment (DOBPRA) of the products' not-marketed status. Products may also be added to the Discontinued Drug Product List if annual reports or other submissions to the Agency indicate the product is not being marketed or as a result of other Agency administrative actions.[23] Changes to the Orange Book are not affected by the drug registration and listing requirements of Section 510 of the FD&C Act.

1.12 Changes to the Orange Book

Every effort is made to ensure the Annual Edition is current and accurate. Applicants are requested to inform DOBPRA of any changes or corrections, including any change in ownership or a product's marketing status that would result in the product being moved to the Discontinued Drug Product List. FDA notes that under Section 506I(a) of the FD&C Act, application holders must notify the Agency in writing 180 days prior to withdrawing a drug product from sale, or if 180 days is not practicable, not later than the date of withdrawal from sale. Furthermore, Section 506I(b) of the FD&C Act requires that application holders notify the Agency in writing within 180 days of approval of a drug product if such drug product will not be available for sale within 180 days of approval. A request to include a newly approved product in the Discontinued Drug Product List, rather than parts 1 or 2 of the Orange

Book (as discussed in Section 1.1), must be submitted to DOBPRA by the end of the month in which the product is approved to ensure that the product is not included in the Active Section of the next published Orange Book update. The Prescription Drug Product List and the OTC Drug Product List are collectively referred to as the "Active Section."

In addition, DOBPRA generally will act on requests to change a proprietary name for a listed drug only after approval of a supplement for the relevant change in proprietary name. To the extent that conventions for describing product identification information (i.e., active ingredients, dosage forms, routes of administration, product names, applicants, strengths) evolve over time, the Agency generally does not intend to revise such information for drug products already listed in the Orange Book, but rather intends to apply the change prospectively to drug products as they are added to the Orange Book.

You can contact DOBPRA by email at orangebook@fda.hhs.gov.

1.13 Availability of the Edition

The Annual Edition and current monthly Cumulative Supplement are available in a Portable Document Format (PDF) at the Orange Book home page by clicking on Publications.

---

[1] Generally, newly approved products are added to the Active Section of the Orange Book (i.e.,the Prescription Drug Product List or the Over-the-Counter Drug Product List), depending on the dispensing requirements (prescription or OTC) or approval authority, unless the Division of Orange Book Publication and Regulatory Assessment is otherwise notified before publication. See Section 1.12.

[2] 21 CFR 314.3(b).

[3] See 21 CFR 314.3(b).

[4] 21 CFR 314.3(b).

[5] 21 CFR 314.3(b).

[6] 21 CFR 314.3(b).

[7] Active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent bonds (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance. 21 CFR 314.3(b).

[8] 21 CFR 314.3(b).

[9] 21 CFR 314.3(b).

[10] 21 CFR 320.24.

[11] We note that prior to the 36th edition of the Orange Book, the Preface to the Orange Book included a section entitled "Statistical Criteria for Bioequivalence." Please see FDA's regulations and guidance documents for additional information regarding bioequivalence and bioavailability. See generally 21 CFR part 320. See FDA Drugs guidance Web page at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs and FDA Drugs guidance (Product-Specific Guidances for Generic Drug Development) Web page at https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development.

[12] A "listed drug" is a new drug product that has been approved under Section 505(c) of the FD&C Act for safety and effectiveness or under Section 505(j) of the FD&C Act, which has not been withdrawn or suspended under Section 505(e)(1) through (5) or Section 505(j)(6) of the FD&C Act, and which has not been withdrawn from sale for what FDA has determined are reasons of safety or effectiveness. Listed drug status is evidenced by the drug product's identification in thecurrent edition of FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations" (the list) as an approved drug. A drug product is deemed to be a listed drug on the date of approvalfor the NDA or ANDA for that drug product (21 CFR 314.3(b)).

[13] 21 CFR 314.3(b).

[14] 21 CFR 314.94(a)(3)(i).

[15] 21 CFR 314.3(b).

[16] https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory.

[17] The strengths of certain parenteral drug products, including contrast agents, may be expressed as a percentage.

[18] In previous editions of the Orange Book, FDA provided a chart outlining therapeutic equivalence codes for all 0.025 mg levothyroxine sodium drug products in the Active Section of the Orange Book. FDA has decided, for ease of review, to revise the chart to identify the NDAs for the reference listed drugs for each therapeutic equivalence code (i.e., AB1, AB2, AB3, and AB4), and their corresponding reference standards, which are identified in 0.2 and 0.3 mg strengths.

[19] The chart is current as of the date of publication of the annual edition. See the most current monthly cumulative supplement for updates to this information available at https://www.fda.gov/media/72973/download. Please consult the Active Section for information on other strengths.

[20] Alvogen, Inc.'s tablets (NDA 021116) (previously known as Levothroid) previously was listed in the Discontinued Drug Product List section of the Orange Book. It is the RLD for therapeutic equivalents identified with the AB4 code. During this time, Mylan's levothyroxine product (ANDA 076187) was selected as the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. It remains the reference standard for ANDA applicants to use to establish bioequivalence to Thyro-Tabs. If an ANDA that uses Mylan's levothyroxine product asits reference standard is approved, the ANDA will receive an AB4 rating. The ANDA applicant also may obtain an AB rating for its product to the other reference listed drugs (i.e., Unithroid, Synthroid, and Levoxyl) by submitting supplements that demonstrate that the generic product is bioequivalent to these other reference listed drugs and satisfies all other therapeutic equivalence criteria with respect to these reference listed drugs. See Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA to Teri Nataline, Principal Consultant, Lachman Consultant Services, Inc., Docket No. FDA-2015-P-0403 (May 27, 2016).

[21] If after approval of a suitability petition and before approval of an ANDA submitted pursuant to the approved petition, a drug product is approved in an NDA for the change described in the petition, the suitability petition and the listed drug identified in the petition can no longer be the basis of submission for such ANDA. Under these circumstances, an applicant seeking approval for a drug product with the change approved in the suitability petition must submit anew ANDA that identifies the drug product approved under such NDA as the RLD and comply with applicable regulatory requirements. See 21 CFR 314.93(f)(2).

[22] Section 3222 of the Food and Drug Omnibus Reform Act of 2022 (enacted December 29, 2022) amended the FD&C Act by adding a new provision to Section 505(j)(7)(A). Section 505(j)(7)(A)(v)(I) sets forth certain conditions under which FDA considers therapeutic equivalence evaluation requests in an application for an eligible drug submitted or approved pursuant to Section 505(b)(2) of the FD&C Act.

[23] See, e.g., Section 506I(d) of the FD&C Act.

Form **990**

Department of the Treasury
Internal Revenue Service

Return of Organization Exempt From Income Tax

Under section 501(c), 527, or 4947(a)(1) of the Internal Revenue Code (except private foundations)

Do not enter social security numbers on this form as it may be made public.

Go to *www.irs.gov/Form990* for instructions and the latest information.

OMB No. 1545-0047

2024

Open to Public Inspection

A For the 2024 calendar year, or tax year beginning , 2024, and ending , 20

B Check if applicable:
- ☐ Address change
- ☐ Name change
- ☐ Initial return
- ☐ Final return/terminated
- ☐ Amended return
- ☐ Application pending

C Name of organization

Doing business as

Number and street (or P.O. box if mail is not delivered to street address) | Room/suite

City or town, state or province, country, and ZIP or foreign postal code

D Employer identification number

E Telephone number

G Gross receipts $

F Name and address of principal officer:

H(a) Is this a group return for subordinates? ☐ Yes ☐ No

H(b) Are all subordinates included? ☐ Yes ☐ No

If "No," attach a list. See instructions.

H(c) Group exemption number

I Tax-exempt status: ☐ 501(c)(3) ☐ 501(c) ( ) (insert no.) ☐ 4947(a)(1) or ☐ 527

J Website:

K Form of organization: ☐ Corporation ☐ Trust ☐ Association ☐ Other

L Year of formation:

M State of legal domicile:

Part I Summary

Activities & Governance

1 Briefly describe the organization's mission or most significant activities:

2 Check this box ☐ if the organization discontinued its operations or disposed of more than 25% of its net assets.

3	Number of voting members of the governing body (Part VI, line 1a)	3	
4	Number of independent voting members of the governing body (Part VI, line 1b)	4	
5	Total number of individuals employed in calendar year 2024 (Part V, line 2a)	5	
6	Total number of volunteers (estimate if necessary)	6	
7a	Total unrelated business revenue from Part VIII, column (C), line 12	7a	
b	Net unrelated business taxable income from Form 990-T, Part I, line 11	7b	

Revenue

		Prior Year	Current Year
8	Contributions and grants (Part VIII, line 1h)		
9	Program service revenue (Part VIII, line 2g)		
10	Investment income (Part VIII, column (A), lines 3, 4, and 7d)		
11	Other revenue (Part VIII, column (A), lines 5, 6d, 8c, 9c, 10c, and 11e)		
12	Total revenue—add lines 8 through 11 (must equal Part VIII, column (A), line 12)		

Expenses

13	Grants and similar amounts paid (Part IX, column (A), lines 1–3)		
14	Benefits paid to or for members (Part IX, column (A), line 4)		
15	Salaries, other compensation, employee benefits (Part IX, column (A), lines 5–10)		
16a	Professional fundraising fees (Part IX, column (A), line 11e)		
b	Total fundraising expenses (Part IX, column (D), line 25)		
17	Other expenses (Part IX, column (A), lines 11a–11d, 11f–24e)		
18	Total expenses. Add lines 13–17 (must equal Part IX, column (A), line 25)		
19	Revenue less expenses. Subtract line 18 from line 12		

Net Assets or Fund Balances

		Beginning of Current Year	End of Year
20	Total assets (Part X, line 16)		
21	Total liabilities (Part X, line 26)		
22	Net assets or fund balances. Subtract line 21 from line 20		

Part II Signature Block

Under penalties of perjury, I declare that I have examined this return, including accompanying schedules and statements, and to the best of my knowledge and belief, it is true, correct, and complete. Declaration of preparer (other than officer) is based on all information of which preparer has any knowledge.

Sign Here

Signature of officer | Date

Type or print name and title

Paid Preparer Use Only

Preparer's name | Preparer's signature | Date | Check ☐ if self-employed | PTIN

Firm's name | Firm's EIN

Firm's address | Phone no.

May the IRS discuss this return with the preparer shown above? See instructions ☐ Yes ☐ No

Part III **Statement of Program Service Accomplishments**

Check if Schedule O contains a response or note to any line in this Part III . . . . . ☐

1 Briefly describe the organization's mission:

2 Did the organization undertake any significant program services during the year which were not listed on the prior Form 990 or 990-EZ? . . . . . ☐ **Yes** ☐ **No**

If "Yes," describe these new services on Schedule O.

3 Did the organization cease conducting, or make significant changes in how it conducts, any program services? . . . . . ☐ **Yes** ☐ **No**

If "Yes," describe these changes on Schedule O.

4 Describe the organization's program service accomplishments for each of its three largest program services, as measured by expenses. Section 501(c)(3) and 501(c)(4) organizations are required to report the amount of grants and allocations to others, the total expenses, and revenue, if any, for each program service reported.

4a (Code: _____) (Expenses $ _____ including grants of $ _____) (Revenue $ _____)

4b (Code: _____) (Expenses $ _____ including grants of $ _____) (Revenue $ _____)

4c (Code: _____) (Expenses $ _____ including grants of $ _____) (Revenue $ _____)

4d Other program services (Describe on Schedule O.)
(Expenses $ including grants of $) (Revenue $)

4e Total program service expenses

Part IV Checklist of Required Schedules

			Yes	No
1	Is the organization described in section 501(c)(3) or 4947(a)(1) (other than a private foundation)? *If "Yes," complete Schedule A*	1		
2	Is the organization required to complete Schedule B, Schedule of Contributors? See instructions	2		
3	Did the organization engage in direct or indirect political campaign activities on behalf of or in opposition to candidates for public office? *If "Yes," complete Schedule C, Part I*	3		
4	**Section 501(c)(3) organizations.** Did the organization engage in lobbying activities, or have a section 501(h) election in effect during the tax year? *If "Yes," complete Schedule C, Part II*	4		
5	Is the organization a section 501(c)(4), 501(c)(5), or 501(c)(6) organization that receives membership dues, assessments, or similar amounts as defined in Rev. Proc. 98-19? *If "Yes," complete Schedule C, Part III*	5		
6	Did the organization maintain any donor advised funds or any similar funds or accounts for which donors have the right to provide advice on the distribution or investment of amounts in such funds or accounts? *If "Yes," complete Schedule D, Part I*	6		
7	Did the organization receive or hold a conservation easement, including easements to preserve open space, the environment, historic land areas, or historic structures? *If "Yes," complete Schedule D, Part II*	7		
8	Did the organization maintain collections of works of art, historical treasures, or other similar assets? *If "Yes," complete Schedule D, Part III*	8		
9	Did the organization report an amount in Part X, line 21, for escrow or custodial account liability; serve as a custodian for amounts not listed in Part X; or provide credit counseling, debt management, credit repair, or debt negotiation services? *If "Yes," complete Schedule D, Part IV*	9		
10	Did the organization, directly or through a related organization, hold assets in donor-restricted endowments or in quasi-endowments? *If "Yes," complete Schedule D, Part V*	10		
11	If the organization's answer to any of the following questions is "Yes," then complete Schedule D, Parts VI, VII, VIII, IX, or X, as applicable.			
a	Did the organization report an amount for land, buildings, and equipment in Part X, line 10? *If "Yes," complete Schedule D, Part VI*	11a		
b	Did the organization report an amount for investments—other securities in Part X, line 12, that is 5% or more of its total assets reported in Part X, line 16? *If "Yes," complete Schedule D, Part VII*	11b		
c	Did the organization report an amount for investments—program related in Part X, line 13, that is 5% or more of its total assets reported in Part X, line 16? *If "Yes," complete Schedule D, Part VIII*	11c		
d	Did the organization report an amount for other assets in Part X, line 15, that is 5% or more of its total assets reported in Part X, line 16? *If "Yes," complete Schedule D, Part IX*	11d		
e	Did the organization report an amount for other liabilities in Part X, line 25? *If "Yes," complete Schedule D, Part X*	11e		
f	Did the organization's separate or consolidated financial statements for the tax year include a footnote that addresses the organization's liability for uncertain tax positions under FIN 48 (ASC 740)? *If "Yes," complete Schedule D, Part X*	11f		
12a	Did the organization obtain separate, independent audited financial statements for the tax year? *If "Yes," complete Schedule D, Parts XI and XII*	12a		
b	Was the organization included in consolidated, independent audited financial statements for the tax year? *If "Yes," and if the organization answered "No" to line 12a, then completing Schedule D, Parts XI and XII is optional*	12b		
13	Is the organization a school described in section 170(b)(1)(A)(ii)? *If "Yes," complete Schedule E*	13		
14a	Did the organization maintain an office, employees, or agents outside of the United States?	14a		
b	Did the organization have aggregate revenues or expenses of more than $10,000 from grantmaking, fundraising, business, investment, and program service activities outside the United States, or aggregate foreign investments valued at $100,000 or more? *If "Yes," complete Schedule F, Parts I and IV*	14b		
15	Did the organization report on Part IX, column (A), line 3, more than $5,000 of grants or other assistance to or for any foreign organization? *If "Yes," complete Schedule F, Parts II and IV*	15		
16	Did the organization report on Part IX, column (A), line 3, more than $5,000 of aggregate grants or other assistance to or for foreign individuals? *If "Yes," complete Schedule F, Parts III and IV*	16		
17	Did the organization report a total of more than $15,000 of expenses for professional fundraising services on Part IX, column (A), lines 6 and 11e? *If "Yes," complete Schedule G, Part I.* See instructions	17		
18	Did the organization report more than $15,000 total of fundraising event gross income and contributions on Part VIII, lines 1c and 8a? *If "Yes," complete Schedule G, Part II*	18		
19	Did the organization report more than $15,000 of gross income from gaming activities on Part VIII, line 9a? *If "Yes," complete Schedule G, Part III*	19		
20a	Did the organization operate one or more hospital facilities? *If "Yes," complete Schedule H*	20a		
b	If "Yes" to line 20a, did the organization attach a copy of its audited financial statements to this return?	20b		
21	Did the organization report more than $5,000 of grants or other assistance to any domestic organization or domestic government on Part IX, column (A), line 1? *If "Yes," complete Schedule I, Parts I and II*	21		

Part IV Checklist of Required Schedules *(continued)*

			Yes	No
22	Did the organization report more than $5,000 of grants or other assistance to or for domestic individuals on Part IX, column (A), line 2? *If "Yes," complete Schedule I, Parts I and III*	22		
23	Did the organization answer "Yes" to Part VII, Section A, line 3, 4, or 5, about compensation of the organization's current and former officers, directors, trustees, key employees, and highest compensated employees? *If "Yes," complete Schedule J*	23		
24a	Did the organization have a tax-exempt bond issue with an outstanding principal amount of more than $100,000 as of the last day of the year, that was issued after December 31, 2002? *If "Yes," answer lines 24b through 24d and complete Schedule K. If "No," go to line 25a*	24a		
b	Did the organization invest any proceeds of tax-exempt bonds beyond a temporary period exception?	24b		
c	Did the organization maintain an escrow account other than a refunding escrow at any time during the year to defease any tax-exempt bonds?	24c		
d	Did the organization act as an "on behalf of" issuer for bonds outstanding at any time during the year?	24d		
25a	**Section 501(c)(3), 501(c)(4), and 501(c)(29) organizations.** Did the organization engage in an excess benefit transaction with a disqualified person during the year? *If "Yes," complete Schedule L, Part I*	25a		
b	Is the organization aware that it engaged in an excess benefit transaction with a disqualified person in a prior year, and that the transaction has not been reported on any of the organization's prior Forms 990 or 990-EZ? *If "Yes," complete Schedule L, Part I*	25b		
26	Did the organization report any amount on Part X, line 5 or 22, for receivables from or payables to any current or former officer, director, trustee, key employee, creator or founder, substantial contributor, or 35% controlled entity or family member of any of these persons? *If "Yes," complete Schedule L, Part II*	26		
27	Did the organization provide a grant or other assistance to any current or former officer, director, trustee, key employee, creator or founder, substantial contributor or employee thereof, a grant selection committee member, or to a 35% controlled entity (including an employee thereof) or family member of any of these persons? *If "Yes," complete Schedule L, Part III*	27		
28	Was the organization a party to a business transaction with one of the following parties? (See the Schedule L, Part IV, instructions for applicable filing thresholds, conditions, and exceptions):			
a	A current or former officer, director, trustee, key employee, creator or founder, or substantial contributor? *If "Yes," complete Schedule L, Part IV*	28a		
b	A family member of any individual described in line 28a? *If "Yes," complete Schedule L, Part IV*	28b		
c	A 35% controlled entity of one or more individuals and/or organizations described in line 28a or 28b? *If "Yes," complete Schedule L, Part IV*	28c		
29	Did the organization receive more than $25,000 in noncash contributions? *If "Yes," complete Schedule M*	29		
30	Did the organization receive contributions of art, historical treasures, or other similar assets, or qualified conservation contributions? *If "Yes," complete Schedule M*	30		
31	Did the organization liquidate, terminate, or dissolve and cease operations? *If "Yes," complete Schedule N, Part I*	31		
32	Did the organization sell, exchange, dispose of, or transfer more than 25% of its net assets? *If "Yes," complete Schedule N, Part II*	32		
33	Did the organization own 100% of an entity disregarded as separate from the organization under Regulations sections 301.7701-2 and 301.7701-3? *If "Yes," complete Schedule R, Part I*	33		
34	Was the organization related to any tax-exempt or taxable entity? *If "Yes," complete Schedule R, Part II, III, or IV, and Part V, line 1*	34		
35a	Did the organization have a controlled entity within the meaning of section 512(b)(13)?	35a		
b	If "Yes" to line 35a, did the organization receive any payment from or engage in any transaction with a controlled entity within the meaning of section 512(b)(13)? *If "Yes," complete Schedule R, Part V, line 2*	35b		
36	**Section 501(c)(3) organizations.** Did the organization make any transfers to an exempt non-charitable related organization? *If "Yes," complete Schedule R, Part V, line 2*	36		
37	Did the organization conduct more than 5% of its activities through an entity that is not a related organization and that is treated as a partnership for federal income tax purposes? *If "Yes," complete Schedule R, Part VI*	37		
38	Did the organization complete Schedule O and provide explanations on Schedule O for Part VI, lines 11b and 19? **Note:** All Form 990 filers are required to complete Schedule O	38		

Part V Statements Regarding Other IRS Filings and Tax Compliance

Check if Schedule O contains a response or note to any line in this Part V ☐

				Yes	No
1a	Enter the number reported in box 3 of Form 1096. Enter -0- if not applicable	1a			
b	Enter the number of Forms W-2G included on line 1a. Enter -0- if not applicable	1b			
c	Did the organization comply with backup withholding rules for reportable payments to vendors and reportable gaming (gambling) winnings to prize winners?		1c		

Part V Statements Regarding Other IRS Filings and Tax Compliance *(continued)*

				Yes	No
2a	Enter the number of employees reported on Form W-3, Transmittal of Wage and Tax Statements, filed for the calendar year ending with or within the year covered by this return	2a			
b	If at least one is reported on line 2a, did the organization file all required federal employment tax returns?	2b			
3a	Did the organization have unrelated business gross income of $1,000 or more during the year?	3a			
b	If "Yes," has it filed a Form 990-T for this year? *If "No" to line 3b, provide an explanation on Schedule O*	3b			
4a	At any time during the calendar year, did the organization have an interest in, or a signature or other authority over, a financial account in a foreign country (such as a bank account, securities account, or other financial account)?	4a			
b	If "Yes," enter the name of the foreign country See instructions for filing requirements for FinCEN Form 114, Report of Foreign Bank and Financial Accounts (FBAR).				
5a	Was the organization a party to a prohibited tax shelter transaction at any time during the tax year?	5a			
b	Did any taxable party notify the organization that it was or is a party to a prohibited tax shelter transaction?	5b			
c	If "Yes" to line 5a or 5b, did the organization file Form 8886-T?	5c			
6a	Does the organization have annual gross receipts that are normally greater than $100,000, and did the organization solicit any contributions that were not tax deductible as charitable contributions?	6a			
b	If "Yes," did the organization include with every solicitation an express statement that such contributions or gifts were not tax deductible?	6b			
7	**Organizations that may receive deductible contributions under section 170(c).**				
a	Did the organization receive a payment in excess of $75 made partly as a contribution and partly for goods and services provided to the payor?	7a			
b	If "Yes," did the organization notify the donor of the value of the goods or services provided?	7b			
c	Did the organization sell, exchange, or otherwise dispose of tangible personal property for which it was required to file Form 8282?	7c			
d	If "Yes," indicate the number of Forms 8282 filed during the year	7d			
e	Did the organization receive any funds, directly or indirectly, to pay premiums on a personal benefit contract?	7e			
f	Did the organization, during the year, pay premiums, directly or indirectly, on a personal benefit contract?	7f			
g	If the organization received a contribution of qualified intellectual property, did the organization file Form 8899 as required?	7g			
h	If the organization received a contribution of cars, boats, airplanes, or other vehicles, did the organization file a Form 1098-C?	7h			
8	**Sponsoring organizations maintaining donor advised funds.** Did a donor advised fund maintained by the sponsoring organization have excess business holdings at any time during the year?	8			
9	**Sponsoring organizations maintaining donor advised funds.**				
a	Did the sponsoring organization make any taxable distributions under section 4966?	9a			
b	Did the sponsoring organization make a distribution to a donor, donor advisor, or related person?	9b			
10	**Section 501(c)(7) organizations.** Enter:				
a	Initiation fees and capital contributions included on Part VIII, line 12	10a			
b	Gross receipts, included on Form 990, Part VIII, line 12, for public use of club facilities	10b			
11	**Section 501(c)(12) organizations.** Enter:				
a	Gross income from members or shareholders	11a			
b	Gross income from other sources. (Do not net amounts due or paid to other sources against amounts due or received from them.)	11b			
12a	**Section 4947(a)(1) non-exempt charitable trusts.** Is the organization filing Form 990 in lieu of Form 1041?	12a			
b	If "Yes," enter the amount of tax-exempt interest received or accrued during the year	12b			
13	**Section 501(c)(29) qualified nonprofit health insurance issuers.**				
a	Is the organization licensed to issue qualified health plans in more than one state? **Note:** See the instructions for additional information the organization must report on Schedule O.	13a			
b	Enter the amount of reserves the organization is required to maintain by the states in which the organization is licensed to issue qualified health plans	13b			
c	Enter the amount of reserves on hand	13c			
14a	Did the organization receive any payments for indoor tanning services during the tax year?	14a			
b	If "Yes," has it filed a Form 720 to report these payments? *If "No," provide an explanation on Schedule O*	14b			
15	Is the organization subject to the section 4960 tax on payment(s) of more than $1,000,000 in remuneration or excess parachute payment(s) during the year? If "Yes," see the instructions and file Form 4720, Schedule N.	15			
16	Is the organization an educational institution subject to the section 4968 excise tax on net investment income? If "Yes," complete Form 4720, Schedule O.	16			
17	**Section 501(c)(21) organizations.** Did the trust, or any disqualified or other person, engage in any activities that would result in the imposition of an excise tax under section 4951, 4952, or 4953? If "Yes," complete Form 6069.	17			

Part VI **Governance, Management, and Disclosure.** *For each "Yes" response to lines 2 through 7b below, and for a "No" response to line 8a, 8b, or 10b below, describe the circumstances, processes, or changes on Schedule O. See instructions.*

Check if Schedule O contains a response or note to any line in this Part VI . . . . . ☐

Section A. Governing Body and Management

				Yes	No
1a	Enter the number of voting members of the governing body at the end of the tax year . .	1a			
	If there are material differences in voting rights among members of the governing body, or if the governing body delegated broad authority to an executive committee or similar committee, explain on Schedule O.				
b	Enter the number of voting members included on line 1a, above, who are independent .	1b			
2	Did any officer, director, trustee, or key employee have a family relationship or a business relationship with any other officer, director, trustee, or key employee?	2			
3	Did the organization delegate control over management duties customarily performed by or under the direct supervision of officers, directors, trustees, or key employees to a management company or other person? .	3			
4	Did the organization make any significant changes to its governing documents since the prior Form 990 was filed?	4			
5	Did the organization become aware during the year of a significant diversion of the organization's assets? .	5			
6	Did the organization have members or stockholders?	6			
7a	Did the organization have members, stockholders, or other persons who had the power to elect or appoint one or more members of the governing body?	7a			
b	Are any governance decisions of the organization reserved to (or subject to approval by) members, stockholders, or persons other than the governing body?	7b			
8	Did the organization contemporaneously document the meetings held or written actions undertaken during the year by the following:				
a	The governing body?	8a			
b	Each committee with authority to act on behalf of the governing body?	8b			
9	Is there any officer, director, trustee, or key employee listed in Part VII, Section A, who cannot be reached at the organization's mailing address? *If "Yes," provide the names and addresses on Schedule O*	9			

Section B. Policies *(This Section B requests information about policies not required by the Internal Revenue Code.)*

				Yes	No
10a	Did the organization have local chapters, branches, or affiliates?	10a			
b	If "Yes," did the organization have written policies and procedures governing the activities of such chapters, affiliates, and branches to ensure their operations are consistent with the organization's exempt purposes?	10b			
11a	Has the organization provided a complete copy of this Form 990 to all members of its governing body before filing the form?	11a			
b	Describe on Schedule O the process, if any, used by the organization to review this Form 990.				
12a	Did the organization have a written conflict of interest policy? *If "No," go to line 13*	12a			
b	Were officers, directors, or trustees, and key employees required to disclose annually interests that could give rise to conflicts?	12b			
c	Did the organization regularly and consistently monitor and enforce compliance with the policy? *If "Yes," describe on Schedule O how this was done*	12c			
13	Did the organization have a written whistleblower policy?	13			
14	Did the organization have a written document retention and destruction policy?	14			
15	Did the process for determining compensation of the following persons include a review and approval by independent persons, comparability data, and contemporaneous substantiation of the deliberation and decision?				
a	The organization's CEO, Executive Director, or top management official	15a			
b	Other officers or key employees of the organization	15b			
	If "Yes" to line 15a or 15b, describe the process on Schedule O. See instructions.				
16a	Did the organization invest in, contribute assets to, or participate in a joint venture or similar arrangement with a taxable entity during the year?	16a			
b	If "Yes," did the organization follow a written policy or procedure requiring the organization to evaluate its participation in joint venture arrangements under applicable federal tax law, and take steps to safeguard the organization's exempt status with respect to such arrangements?	16b			

Section C. Disclosure

17 List the states with which a copy of this Form 990 is required to be filed

18 Section 6104 requires an organization to make its Forms 1023 (1024 or 1024-A, if applicable), 990, and 990-T (section 501(c)(3)s only) available for public inspection. Indicate how you made these available. Check all that apply.

☐ Own website ☐ Another's website ☐ Upon request ☐ Other *(explain on Schedule O)*

19 Describe on Schedule O whether (and if so, how) the organization made its governing documents, conflict of interest policy, and financial statements available to the public during the tax year.

20 State the name, address, and telephone number of the person who possesses the organization's books and records.

Part VII Compensation of Officers, Directors, Trustees, Key Employees, Highest Compensated Employees, and Independent Contractors

Check if Schedule O contains a response or note to any line in this Part VII . . . . . ☐

Section A. Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees

1a Complete this table for all persons required to be listed. Report compensation for the calendar year ending with or within the organization's tax year.

- List all of the organization's **current** officers, directors, trustees (whether individuals or organizations), regardless of amount of compensation. Enter -0- in columns (D), (E), and (F) if no compensation was paid.
- List all of the organization's **current** key employees, if any. See the instructions for definition of "key employee."
- List the organization's five **current** highest compensated employees (other than an officer, director, trustee, or key employee) who received reportable compensation (box 5 of Form W-2, box 6 of Form 1099-MISC, and/or box 1 of Form 1099-NEC) of more than $100,000 from the organization and any related organizations.
- List all of the organization's **former** officers, key employees, and highest compensated employees who received more than $100,000 of reportable compensation from the organization and any related organizations.
- List all of the organization's **former directors or trustees** that received, in the capacity as a former director or trustee of the organization, more than $10,000 of reportable compensation from the organization and any related organizations.

See the instructions for the order in which to list the persons above.

☐ Check this box if neither the organization nor any related organization compensated any current officer, director, or trustee.

(A) Name and title	(B) Average hours per week (list any hours for related organizations below dotted line)	(C) Position (do not check more than one box, unless person is both an officer and a director/trustee)						(D) Reportable compensation from the organization (W-2/ 1099-MISC/ 1099-NEC)	(E) Reportable compensation from related organizations (W-2/ 1099-MISC/ 1099-NEC)	(F) Estimated amount of other compensation from the organization and related organizations
		Individual trustee or director	Institutional trustee	Officer	Key employee	Highest compensated employee	Former			
(1)										
(2)										
(3)										
(4)										
(5)										
(6)										
(7)										
(8)										
(9)										
(10)										
(11)										
(12)										
(13)										
(14)										

Part VII **Section A. Officers, Directors, Trustees, Key Employees, and Highest Compensated Employees** *(continued)*

(A) Name and title	(B) Average hours per week (list any hours for related organizations below dotted line)	(C) Position (do not check more than one box, unless person is both an officer and a director/trustee)						(D) Reportable compensation from the organization (W-2/ 1099-MISC/ 1099-NEC)	(E) Reportable compensation from related organizations (W-2/ 1099-MISC/ 1099-NEC)	(F) Estimated amount of other compensation from the organization and related organizations
		Individual trustee or director	Institutional trustee	Officer	Key employee	Highest compensated employee	Former			
(15)										
(16)										
(17)										
(18)										
(19)										
(20)										
(21)										
(22)										
(23)										
(24)										
(25)										
1b **Subtotal**										
c **Total from continuation sheets to Part VII, Section A**										
d **Total (add lines 1b and 1c)**										

2 Total number of individuals (including but not limited to those listed above) who received more than $100,000 of reportable compensation from the organization

			Yes	No
3	Did the organization list any **former** officer, director, trustee, key employee, or highest compensated employee on line 1a? *If "Yes," complete Schedule J for such individual*	3		
4	For any individual listed on line 1a, is the sum of reportable compensation and other compensation from the organization and related organizations greater than $150,000? *If "Yes," complete Schedule J for such individual*	4		
5	Did any person listed on line 1a receive or accrue compensation from any unrelated organization or individual for services rendered to the organization? *If "Yes," complete Schedule J for such person*	5		

Section B. Independent Contractors

1 Complete this table for your five highest compensated independent contractors that received more than $100,000 of compensation from the organization. Report compensation for the calendar year ending with or within the organization's tax year.

(A) Name and business address	(B) Description of services	(C) Compensation

2 Total number of independent contractors (including but not limited to those listed above) who received more than $100,000 of compensation from the organization

Part VIII Statement of Revenue

Check if Schedule O contains a response or note to any line in this Part VIII . . . . . ☐

			(A) Total revenue	(B) Related or exempt function revenue	(C) Unrelated business revenue	(D) Revenue excluded from tax under sections 512–514
Contributions, Gifts, Grants, and Other Similar Amounts	1a	Federated campaigns 1a				
	b	Membership dues 1b				
	c	Fundraising events 1c				
	d	Related organizations 1d				
	e	Government grants (contributions) 1e				
	f	All other contributions, gifts, grants, and similar amounts not included above 1f				
	g	Noncash contributions included in lines 1a–1f . . . . . 1g $				
	h	**Total.** Add lines 1a–1f				
Program Service Revenue		Business Code				
	2a					
	b					
	c					
	d					
	e					
	f	All other program service revenue . .				
	g	**Total.** Add lines 2a–2f				
Other Revenue	3	Investment income (including dividends, interest, and other similar amounts)				
	4	Income from investment of tax-exempt bond proceeds				
	5	Royalties				
		(i) Real / (ii) Personal				
	6a	Gross rents . . 6a				
	b	Less: rental expenses 6b				
	c	Rental income or (loss) 6c				
	d	Net rental income or (loss)				
		(i) Securities / (ii) Other				
	7a	Gross amount from sales of assets other than inventory 7a				
	b	Less: cost or other basis and sales expenses . 7b				
	c	Gain or (loss) . . 7c				
	d	Net gain or (loss)				
	8a	Gross income from fundraising events (not including $ _____ of contributions reported on line 1c). See Part IV, line 18 . . . 8a				
	b	Less: direct expenses 8b				
	c	Net income or (loss) from fundraising events . . .				
	9a	Gross income from gaming activities. See Part IV, line 19 . 9a				
	b	Less: direct expenses 9b				
	c	Net income or (loss) from gaming activities				
	10a	Gross sales of inventory, less returns and allowances . . . 10a				
	b	Less: cost of goods sold . . . 10b				
	c	Net income or (loss) from sales of inventory				
Miscellaneous Revenue		Business Code				
	11a					
	b					
	c					
	d	All other revenue				
	e	**Total.** Add lines 11a–11d				
	12	**Total revenue.** See instructions				

Part IX Statement of Functional Expenses

Section 501(c)(3) and 501(c)(4) organizations must complete all columns. All other organizations must complete column (A).

Check if Schedule O contains a response or note to any line in this Part IX . . . . . ☐

Do not include amounts reported on lines 6b, 7b, 8b, 9b, and 10b of Part VIII.	(A) Total expenses	(B) Program service expenses	(C) Management and general expenses	(D) Fundraising expenses
1 Grants and other assistance to domestic organizations and domestic governments. See Part IV, line 21				
2 Grants and other assistance to domestic individuals. See Part IV, line 22				
3 Grants and other assistance to foreign organizations, foreign governments, and foreign individuals. See Part IV, lines 15 and 16				
4 Benefits paid to or for members				
5 Compensation of current officers, directors, trustees, and key employees				
6 Compensation not included above to disqualified persons (as defined under section 4958(f)(1)) and persons described in section 4958(c)(3)(B)				
7 Other salaries and wages				
8 Pension plan accruals and contributions (include section 401(k) and 403(b) employer contributions)				
9 Other employee benefits				
10 Payroll taxes				
11 Fees for services (nonemployees):				
a Management				
b Legal				
c Accounting				
d Lobbying				
e Professional fundraising services. See Part IV, line 17				
f Investment management fees				
g Other. (If line 11g amount exceeds 10% of line 25, column (A), amount, list line 11g expenses on Schedule O.)				
12 Advertising and promotion				
13 Office expenses				
14 Information technology				
15 Royalties				
16 Occupancy				
17 Travel				
18 Payments of travel or entertainment expenses for any federal, state, or local public officials				
19 Conferences, conventions, and meetings				
20 Interest				
21 Payments to affiliates				
22 Depreciation, depletion, and amortization				
23 Insurance				
24 Other expenses. Itemize expenses not covered above. (List miscellaneous expenses on line 24e. If line 24e amount exceeds 10% of line 25, column (A), amount, list line 24e expenses on Schedule O.)				
a _____				
b _____				
c _____				
d _____				
e All other expenses _____				
25 **Total functional expenses.** Add lines 1 through 24e				
26 **Joint costs.** Complete this line only if the organization reported in column (B) joint costs from a combined educational campaign and fundraising solicitation. Check here ☐ if following SOP 98-2 (ASC 958-720)				

Part X Balance Sheet

Check if Schedule O contains a response or note to any line in this Part X . . . . . ☐

			(A) Beginning of year		(B) End of year
Assets	1	Cash—non-interest-bearing		1	
	2	Savings and temporary cash investments		2	
	3	Pledges and grants receivable, net		3	
	4	Accounts receivable, net		4	
	5	Loans and other receivables from any current or former officer, director, trustee, key employee, creator or founder, substantial contributor, or 35% controlled entity or family member of any of these persons		5	
	6	Loans and other receivables from other disqualified persons (as defined under section 4958(f)(1)), and persons described in section 4958(c)(3)(B)		6	
	7	Notes and loans receivable, net		7	
	8	Inventories for sale or use		8	
	9	Prepaid expenses and deferred charges		9	
	10a	Land, buildings, and equipment: cost or other basis. Complete Part VI of Schedule D — 10a			
	b	Less: accumulated depreciation — 10b		10c	
	11	Investments—publicly traded securities		11	
	12	Investments—other securities. See Part IV, line 11		12	
	13	Investments—program-related. See Part IV, line 11		13	
	14	Intangible assets		14	
	15	Other assets. See Part IV, line 11		15	
	16	**Total assets.** Add lines 1 through 15 (must equal line 33)		16	
Liabilities	17	Accounts payable and accrued expenses		17	
	18	Grants payable		18	
	19	Deferred revenue		19	
	20	Tax-exempt bond liabilities		20	
	21	Escrow or custodial account liability. Complete Part IV of Schedule D		21	
	22	Loans and other payables to any current or former officer, director, trustee, key employee, creator or founder, substantial contributor, or 35% controlled entity or family member of any of these persons		22	
	23	Secured mortgages and notes payable to unrelated third parties		23	
	24	Unsecured notes and loans payable to unrelated third parties		24	
	25	Other liabilities (including federal income tax, payables to related third parties, and other liabilities not included on lines 17–24). Complete Part X of Schedule D		25	
	26	**Total liabilities.** Add lines 17 through 25		26	
Net Assets or Fund Balances		**Organizations that follow FASB ASC 958, check here ☐ and complete lines 27, 28, 32, and 33.**			
	27	Net assets without donor restrictions		27	
	28	Net assets with donor restrictions		28	
		Organizations that do not follow FASB ASC 958, check here ☐ and complete lines 29 through 33.			
	29	Capital stock or trust principal, or current funds		29	
	30	Paid-in or capital surplus, or land, building, or equipment fund		30	
	31	Retained earnings, endowment, accumulated income, or other funds		31	
	32	Total net assets or fund balances		32	
	33	Total liabilities and net assets/fund balances		33	

Part XI Reconciliation of Net Assets

Check if Schedule O contains a response or note to any line in this Part XI . . . . . ☐

1	Total revenue (must equal Part VIII, column (A), line 12)	1	
2	Total expenses (must equal Part IX, column (A), line 25)	2	
3	Revenue less expenses. Subtract line 2 from line 1	3	
4	Net assets or fund balances at beginning of year (must equal Part X, line 32, column (A))	4	
5	Net unrealized gains (losses) on investments	5	
6	Donated services and use of facilities	6	
7	Investment expenses	7	
8	Prior period adjustments	8	
9	Other changes in net assets or fund balances (explain on Schedule O)	9	
10	Net assets or fund balances at end of year. Combine lines 3 through 9 (must equal Part X, line 32, column (B))	10	

Part XII Financial Statements and Reporting

Check if Schedule O contains a response or note to any line in this Part XII . . . . . ☐

			Yes	No
1	Accounting method used to prepare the Form 990: ☐ Cash ☐ Accrual ☐ Other _____ If the organization changed its method of accounting from a prior year or checked "Other," explain on Schedule O.			
2a	Were the organization's financial statements compiled or reviewed by an independent accountant?	2a		
	If "Yes," check a box below to indicate whether the financial statements for the year were compiled or reviewed on a separate basis, consolidated basis, or both.			
	☐ Separate basis ☐ Consolidated basis ☐ Both consolidated and separate basis			
b	Were the organization's financial statements audited by an independent accountant?	2b		
	If "Yes," check a box below to indicate whether the financial statements for the year were audited on a separate basis, consolidated basis, or both.			
	☐ Separate basis ☐ Consolidated basis ☐ Both consolidated and separate basis			
c	If "Yes" to line 2a or 2b, does the organization have a committee that assumes responsibility for oversight of the audit, review, or compilation of its financial statements and selection of an independent accountant?	2c		
	If the organization changed either its oversight process or selection process during the tax year, explain on Schedule O.			
3a	As a result of a federal award, was the organization required to undergo an audit or audits as set forth in the Uniform Guidance, 2 C.F.R. Part 200, Subpart F?	3a		
b	If "Yes," did the organization undergo the required audit or audits? If the organization did not undergo the required audit or audits, explain why on Schedule O and describe any steps taken to undergo such audits	3b		

The Nonprofit Sector in the United States: A Resource Guide

Form 990

The 990 is the tax form the Internal Revenue Service (IRS) requires all 501(c)(3) tax-exempt charitable and nonprofit organizations to submit annually. The Form 990 is designed to increase financial transparency and includes revenue, expenditure, and income data in addition to information used to assess whether a nonprofit aligns with federal requirements for tax-exempt status. The forms are publicly accessible once they are processed, but note that there can be a 12-18 month delay from the end of the organization's fiscal year to the latest available online form.

This page offers resources for understanding and completing the Form 990 as well as information on how to locate a tax exempt organization's 990.

How to Read the Form 990

These sources offer guidance on reading, understanding, and applying Form 990 data. Each resource includes information on what data is requested and collected by the IRS and where to find that data. There are also instructions for adding additional forms and responding to appended sections.

- Demystifying the 990-PF (Candid)
- Highlights of IRS Form 990 (IssueLab | Candid)
- How to Read the IRS Form 990 & Find Out What it Means (Nonprofit Coordinating Committee of New York) (PDF, 962KB)
- Form 990 Resources and Tools (IRS)

Locating a Form 990 text

The 990 is a public document that you can search for on the websites for the Secretary of State or the Attorney General where the organization is incorporated. In addition, 990s are available from a variety of open source and subscription sources. You may also request them from an organization or from the IRS.

The following are freely available, open source sites, unless otherwise noted, where you can locate IRS Form 990s.
The subscription resources marked with a padlock are available to researchers on-site at the Library of Congress. If you are unable to visit the Library, you may be able to access these resources through your local public or academic library.

- 990 Finder (Candid)
  This database provided by Candid (formerly provided by the Foundation Center) provides information on grants foundations, corporate donors, and other grant-making nonprofits, broader in scope than many other online databases. It provides program details for grant making public charities, foundations and corporate donors in the U.S. This database allows you to search IRS 990 forms.
- Form 990 Resources and Tools (IRS)
  This page provides resources and tools for tax-exempt organizations relating to annual filing requirements and 990-series forms.
  A tax-exempt organization must file an annual information return or notice with the IRS, unless an exception applies.Most states rely on the Form 990 to perform charitable and other regulatory oversight and to satisfy state income tax filing requirements for organizations claiming exemption from state income tax.
- Foundation Center Historical Collection (Indiana Purdue University)
  The Foundation Center was created in 1956 during a period of particularly intense public scrutiny of foundations. Many foundation annual reports, Form 990s, historic information files and print directories are archived at the Indian Perdue University, which manages the collection.
- Nonprofit Explorer, Research Tax Exempt Organizations, (ProPublica)
  This resource is provided by ProPublica, an independent, nonprofit that produces investigative journalism in the public interest. Use this database to view summaries of tax returns from tax-exempt organizations and see financial details such as their executive compensation and revenue and expenses.
- Search for Tax Exempt Organizations (IRS)
  You can use this IRS database to check an organization's: Eligibility to receive tax-deductible charitable contributions and review information about the organization's tax-exempt status and filings.

- State Government Websites (IRS)
  This page lists state websites with information on doing business in the state, taxation, links for employers, and more.

Subjects: Business and Management, Company and Industry Information

Login to LibApps

Hosted by Springshare
Library of Congress Legal SpringShare Privacy Policy

IRS

Search for tax exempt organizations

The Tax Exempt Organization Search Tool

You can check an organization's:

- Eligibility to receive tax-deductible charitable contributions
- Review information about the organization's tax-exempt status and filings.

Search for Tax Exempt Organizations

About the Tax Exempt Organization Search Tool

The online search tool allows you to search for an organization's tax exempt status and filings in the following data bases:

- Form 990 series returns
- Form 990-N (e-Postcard)
- Pub. 78 data
- Automatic revocation of exemption list
- Determination letters

Tips for using the search tool

Expand/Collapse All

Choose a database

You can choose from a number of data sets in the dropdown list:

- Pub. 78 data
- Automatic revocation of exemption list
- Determination letters
- Form 990 series returns

- Form 990-N (e-Postcard)

Search by employer identification number (EIN) or organization name

The information on the organizations are produced from computer records and is subject to certain limitations, particularly in the format and arrangement of the entries.

Searching by EIN

- The dash after the first two digits is optional for entering the employer identification number (EIN)

Searching by organization's name

- Fields are not case-sensitive.
- Include the entire or part of the name in quotation marks. For example, to search for Anytown General Hospital, enter "Anytown General Hospital" or "Anytown General."
- Avoid common words such as "the" or foundation.
- Organizations are listed under the legal name or a "doing business as" name that are on file with the IRS. Common or popular names of an organizations are not on file.
- In the Publication 78 data, "doing business as" names of organizations are not listed.

Note: If you are not getting the result you want, try sorting by city, state or zip.

Search the auto-revocation list

To narrow your search, use the date format MM-DD-YYYY or select a data range on the calendar.

- For example, to find an organization whose revocation was posted on the 12th or 13th of the month, enter a search range of MM/11/YYYY to MM/14/YYYY.

Note: Date range searches are not inclusive.

If you find an organization listed on the Auto-Revocation List, it may have been reinstated by the IRS since the automatic revocation date. You can search Pub.78 data (for 501(c)(3) or other organizations eligible to receive deductible charitable contributions) or the exempt organizations business master file extract (for other 501(c) organizations) to find out if the organization's tax- exempt status has been reinstated. You may also review its determination letter posted on TEOS; a reinstated organization will have a determination letting referencing that it is being reinstated and with an effective date on or after the effective date of the revocation.

Searching organizations with foreign addresses

Due to the different structure of foreign addresses, data is sometimes found in an unexpected location.

- For example, the province or country in which the organization is located is sometimes in the city field in the auto-revocation database.
- If you see this in your search, try sorting your search differently.

You can search the following data sets

Expand/Collapse All

Form 990-series returns

You can review the list of organizations that have filed forms in the Form 990 series:

- Form 990
- Form 990–EZ
- Form 990–PF (501(c)(3) Private Foundations)
- Form 990–T (990–T returns for 501(c)(3) organizations only)

Note: JAWS users will need to request these files.

Latest data posting: **Feb. 7, 2025**

For more information about the Form 990 Series, see Form 990 resources and tools

Form 990–N (e-Postcard)

Form 990-N (e-Postcard) is an annual electronic notice most small tax-exempt organizations (annual gross receipts normally $50,000 or less) are eligible to file instead of Form 990 or Form 990-EZ.

Latest data posting: **March 10, 2025**

Pub. 78 data

Lists of organizations that can receive tax-deductible contributions.

- Users may rely on this list in determining deductibility of their contributions.
- If an organization uses a “doing business as” (DBA) name, that name will not be listed in the Pub. 78 Data. Only the organization’s official name submitted to the IRS is included in the data set.
- Some donees (i.e., churches, group ruling subordinates, and governmental units) eligible to receive tax-deductible charitable contributions may not be listed in Pub. 78 Data. For more information see, Other eligible donees.

Latest data posting: **March 10, 2025**

Auto-revocation list

By law, tax-exempt status is automatically be revoked if an organization does not file the required Form 990-series returns or notices yearly for 3 consecutive years. The automatic revocation date is historical. It is the organization's effective date of automatic revocation (the date for the filing of the third annual Return or notice), but doesn't necessarily reflect its current tax-exempt status.

An organization may have applied for reinstatement of its tax-exempt status after the automatic revocation date had posted. IRS will recognize the reinstatement of the organization's tax-exempt status if the application is approved. You can find out if the exemption status has been reinstated by reviewing the Pub. 78 Data (for 501(c)(3) organizations) or reviewing its determination letter, which would show an effective date on or after the automatic revocation date, with the online tool or the bulk data download files. You may also review the EO BMF Extract to check the organization's current exempt status.

Revocation date of certain organizations

Organizations that do not file a required annual information return or notice for three consecutive years automatically lose their tax-exempt status by operation of law. An automatic revocation is effective on the original filing due date of the third annual return or notice (the "Revocation Date"). Due to the COVID-19 emergency, this year the IRS extended the filing dates for these returns and notices due from April 1 through July 14 to July 15, 2020. Organizations eligible for this relief that failed to file for the two previous years and did not file by July 15 have automatically lost their tax-exempt status. Due to systemic limitations, these organizations appear on the auto-revocation list showing a Revocation Date between April 1 and July 14, 2020. However, the Revocation Date for these organizations is July 15, 2020. For more information on automatic revocation, including how to request reinstatement, see Automatic revocation - How to have your tax-exempt status reinstated.

Latest data posting: **March 10, 2025**

Determination letters dated on or after Jan. 1, 2014

IRS issues a determination letter recognizing an organization as tax-exempt under the sub-section for which it applied. An organization must apply and pay a user fee to receive a determination letter.

Note: JAWS users will need to request these files.

Latest data posting: **March 12, 2025**

Note: JAWS users will not be able to hear the determination letters or copies of Forms 990, 990-EZ, 990-PF or 990-T read aloud. The files are images of the actual letters or returns. To obtain one of these documents, you may:

- Request it directly from the organization,
- Complete and submit Form 4506-A, Request for Public Inspection or Copy of Exempt or Political Organization IRS Form, or
- Call TE/GE Customer Account Services at 877-829-5500 to request the document.

Download a data set

You can download and review the full data sets, see Tax exempt organization search bulk data downloads.

Cumulative data files

The exempt organizations business master file extract has information about organizations that have received a determination of tax-exempt status from IRS. This information is available by state and region for downloading.

Related

- Stay Exempt: Small to mid-size tax exempt organization workshop
- Suspensions pursuant to Code Section 501(p)
- Revocations of 501(c)(3) determinations

Page Last Reviewed or Updated: 20-Aug-2025

BLOG / 01-10-22

Drug Price Transparency Laws Position States to Impact Drug Prices

by Johanna Butler

Drug price transparency laws enable state policymakers to understand opaque drug pricing and payment systems to formulate appropriate policy solutions to high prices, while also creating the data infrastructure to effectively realize those policy solutions. Since Vermont passed the first state drug price transparency law in 2016, more than a dozen states (https://www.nashp.org/prescription-drug-pricing-transparency-law-comparison-chart/) have enacted and implemented similar laws.

State-level transparency legislation shines light on drug pricing by requiring manufacturers and other supply chain entities such as prescription drug benefit managers (PBMs), health plans, and wholesalers to provide information on drug pricing. Transparency programs also establish accountability around manufacturers' price increases or high launch prices. Since programs began collecting pricing data, states have seen fewer drug price increases trigger reporting requirements; however, launch prices and overall spending on prescription drugs have continued to increase.

Transparency laws can also create a foundation for additional strategies to lower drug costs. Policies like prescription drug affordability boards (PDABs), rely on having access to and expertise with drug pricing data. This blog provides an update on state drug price

transparency laws and their impact.

Current State Transparency Landscape

Vermont passed the first state drug price transparency law in 2016. Since then, 13 other states have passed transparency laws focused on drug manufacturers and other actors within the supply chain — CA, CT, ME, MN, NV, NH, ND, OR, TX, UT, VA, WA, and WV. Most state programs require reporting from manufacturers when they increase the wholesale acquisition cost (WAC) of a drug above a certain threshold or if they introduce a drug with a high launch price. Several states also require reporting from insurers and pharmacy benefit managers. A few states extend reporting to other supply chain actors — pharmacy service administrative organizations (WA) and wholesale distributors (ME, NV, VA).

Transparency programs vary state-by-state regarding which drugs are reported on, the level of data collected (in aggregate or on an individual drug level), and how data is published and analyzed by the state.

- Maine's transparency program offers one of the more robust approaches to drug price transparency. Maine collects and analyzes (https://mhdo.maine.gov/_pdf/MHDO%20Rx%20Transparency%20Report%20210209%20FINAL.pdf) data with the goal to identify each supply chain entity's average net income, including data on manufacturers, PBMs, insurers, pharmacies, and wholesale distributors. This allows the public and policymakers to "follow the money" through the supply chain.
- California's transparency program posts launch price information and five-year schedules of price increases reported by manufacturers to its website (https://data.chhs.ca.gov/dataset/prescription-drug-wholesale-acquisition-cost-wac-increases), creating one of the only freely available sources of WAC data.
- Oregon's transparency program (https://dfr.oregon.gov/drugtransparency/Pages/index.aspx) holds an annual public hearing that acts as a forum for sharing data analysis, discussion with stakeholders, and policy recommendations.
- Nevada took a unique approach with its transparency program (https://dhhs.nv.gov/HCPWD/DRUG_TRANSPARENCY/), first focusing reporting on diabetes drugs when its program was enacted in 2018 and then including asthma medications in 2019. In 2021, the state expanded its program to include all prescription drugs.

Impact of Transparency Programs

As states investigate and work to lower high drug costs, drug price transparency has become an important foundation and launch pad for efforts to lower costs. Data collected by state transparency programs can provide insights into the types of price increases and types of drugs driving high spending in a state. Pricing data can provide policymakers state-specific information to direct policy.

Moderated Price Increases Over Time

Since state transparency laws were first enacted, the number of price increases that trigger reporting based on state thresholds has decreased over time. Vermont's Medicaid program explained in its 2020 report (https://gmcboard.vermont.gov/sites/gmcb/files/documents/Merged_DVHA_Act193_2021Submission.pdf) that compared to 2016, there was a 79 percent decline in the number of drugs reaching the state's per year price increase threshold. The program report concludes that fewer manufacturers are excessively increasing the price of drugs. Similarly, Oregon's transparency program reported (https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2020.pdf) that compared to its first year of implementation in 2019, the program received 70 percent fewer reports for price increases in 2020. However, during that same time, Oregon saw a 15 percent increase in the number of drugs with high launch prices.

Vermont and Oregon's findings align with what drug pricing researchers have found — from 2016 to 2020 the amount of WAAC price increases (https://www.46brooklyn.com/branddrug-boxscore) have decreased but launch prices (https://www.46brooklyn.com/research/2019/10/11/three-two-one-launch-rfmyr) have continued to rise. Although the rate of price increases may be moderating, launch prices may still cause increased state spending on prescription drugs.

Accountability for High Launch Prices

Transparency programs can establish accountability around manufacturers' high drug price increases and high launch prices. For example, manufacturers of Semglee, the first generic insulin product deemed interchangeable by the U.S. Food and Drug Administration, recently announced it will price the new insulin product at almost $270 per vial, only $20 cheaper than Lantus, the brand-name biologic competitor. Based on this launch price, Semglee would trigger Virginia's reporting requirements under the state's 2021 transparency law which requires manufacturers to report information on the launch of biosimilar products that are not at least 15 percent below the cost of the reference biologic. While the law is not yet implemented, Virginia's program would be one of the most immediate tools to create some accountability for Semglee's high list price.

Data Infrastructure for Policy Solutions

In addition to establishing accountability, transparency programs can provide the necessary data infrastructure for the successful implementation of efforts to lower drug prices. Since 2020, several states (https://www.nashp.org/comparison-of-state-prescription-drug-affordability-review-initiatives/) have enacted prescription drug affordability boards (PDAB), entities with the authority to review high cost drugs and in some states set an upper payment limit to ensure no one pays more than that amount in the state. A first step for a PDAB to review high drug costs and potentially set payment limits is to gather the necessary drug pricing data — whether that's leveraging existing data sources or establishing manufacturer or insurer reporting like transparency programs. States without transparency laws already in place must include transparency requirements. For example, Colorado's PDAB law (https://leg.colorado.gov/sites/default/files/2021a_175_signed.pdf), enacted in 2021, requires insurers to report top-spend drugs to help inform which drugs the PDAB will review.

States that already have transparency programs in place however, are well-positioned to take steps to rein in high drug costs through a PDAB. Oregon's new PDAB law (https://olis.oregonlegislature.gov/liz/2021R1/Measures/Overview/SB844) leverages the state's existing drug price transparency program (https://dfr.oregon.gov/drugtransparency/Pages/index.aspx) to identify high-cost drugs that should be reviewed by the board. Each quarter the transparency program will provide the PDAB with a list of drugs with high price increases or high launch prices as well as a list of insulin products sold in the state in the previous year. Based on this information, the PDAB will identify nine drugs and one insulin product to review. Oregon's PDAB will be supported and housed in the same agency that manages the drug price transparency program, the Department of Business and Consumer Services, allowing the PDAB to capitalize on the drug pricing data expertise developed by the transparency program since it was enacted in 2018.

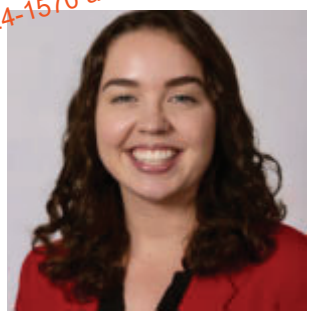
In these ways, transparency can be seen not only as a steppingstone to future action, but often a necessary building block to sustain other efforts. The data gathered and expertise developed by transparency programs could be applied to any number of drug pricing policies beyond PDABs — direct negotiations for supplemental Medicaid rebates, implementing reference rates, or prohibiting price gouging.

Federal Efforts on Transparency

While a variety of federal transparency efforts are in process, state transparency programs go beyond proposed or recently enacted language. The Build Back Better (https://budget.house.gov/build-back-better-act) Act that passed the House in November 2021 but continues to be debated in the Senate, would require pharmacy benefit managers to report

certain information related to spending, cost, utilization, and formulary placement to health plan sponsors. Additionally, the Centers for Medicare and Medicaid Services (CMS) recently published an interim final rule (https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending) requiring health plans to report certain information on the most costly drugs, most frequently utilized drugs, and drugs with the greatest year over year spending increases, among other data elements, to the Departments of Health and Human Services, Labor, and the Treasury. This interim final rule is similar to the insurer reporting requirements of many existing state transparency programs. For states that do not have transparency laws, this federal data, if shared with state leaders, could be helpful to identify top-spend drugs in each state and fuel other strategies to lower costs such as a PDAB. However, it's unclear to what extent the data could be accessed or used by states, though states are eager to coordinate with the federal government to enhance data-sharing on drug prices. Importantly, none of these initiatives focus on requiring reporting from manufactures — who actually set drug prices — leaving state officials to continue this important work.

To learn more about state transparency legislation, review the National Academy for State Health Policy's state strategy implementation tracker (https://nashp.org/prescription-drug-pricing-state-strategy-implementation/) or the Transparency Law Comparison Chart (https://www.nashp.org/prescription-drug-pricing-transparency-law-comparison-chart/).



(https://nashp.org/author/johanna-butler/)

Johanna Butler (https://nashp.org/author/johanna-butler/)

Policy Areas:

(https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/) Health Costs and Value (https://nashp.org/policys/health-costs-and-value/)

Topic: (https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/) Prescription Drug Pricing (https://nashp.org/topics/prescription-drug-pricing/)

Tags: (https://nashp.org/drug-price-transparency-laws-position-states-to-impact-drug-prices/) Drug Price Transparency (https://nashp.org/tag/drug-price-transparency/), Model Legislation (https://nashp.org/tag/model-legislation/)

RELATED CONTENT

affordability-board/)

BLOG / 03-31-25

District Court Dismisses Challenge to Colorado's Prescription Drug Affordability Board (https://nashp.org/district-court-dismisses-challenge-to-colorados-prescription-drug-affordability-board/)

(https://nashp.org/340b-drug-pricing-program-state-only-webinar/)

WEBINAR / 03-10-25

340B Drug Pricing Program State-Only Webinar (https://nashp.org/340b-drug-pricing-program-state-only-webinar/)

(https://nashp.org/state-legislatures-pursue-policies-to-address-high-health-care-prices/)

BLOG / 01-27-25

State Legislatures Pursue Policies to Address High Health Care Prices (https://nashp.org/state-legislatures-pursue-policies-to-address-high-health-care-prices/)

The WHITE HOUSE

FACT SHEETS

Fact Sheet: President Donald J. Trump Announces Actions to Get Americans the Best Prices in the World for Prescription Drugs

The White House

July 31, 2025

REDUCING DRUG PRICES FOR AMERICANS AND TAXPAYERS: Today, President Donald J. Trump sent letters to leading pharmaceutical manufacturers outlining the steps they must take to bring down the prices of prescription drugs in the United States to match the lowest price offered in other developed nations (known as the most-favored-nation, or MFN, price). The steps include:

- Calling on manufacturers to provide MFN prices to every single Medicaid patient.
- Requiring manufacturers to stipulate that they will not offer other developed nations better prices for new drugs than prices offered in the United States.
- Providing manufacturers with an avenue to cut out middlemen and sell medicines directly to patients, provided they do so at a price no higher than the best price available in developed nations.
- Using trade policy to support manufacturers in raising prices internationally provided that increased revenues abroad are reinvested directly into lowering prices for American patients and taxpayers.

The letters inform manufacturers that if they "refuse to step up," the federal government "will deploy every tool in our arsenal to protect American families from continued abusive drug pricing practices."

Letters were sent to AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, EMD Serono, Genentech, Gilead, GSK, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Regeneron, and Sanofi.

ENDING GLOBAL FREELOADING ON AMERICAN PHARMACEUTICAL INNOVATION:

President Trump is taking decisive action to rebalance a system that allows pharmaceutical manufacturers to offer low prices to other wealthy nations while charging Americans significantly higher prices.

- According to recent data, the prices Americans pay for brand-name drugs are more than three times the price other Organization for Economic Cooperation and Development nations pay, even after accounting for discounts manufacturers provide in the U.S.
- The United States has less than five percent of the world's population, yet roughly 75% of global pharmaceutical profits come from American taxpayers.
- Drug manufacturers benefit from generous research subsidies and enormous healthcare spending by the U.S. Government. Instead of passing that benefit through to American consumers, drug manufacturers then discount their products abroad to gain access to foreign markets and subsidize those discounts through high prices charged in America. Americans are subsidizing drug-manufacturer profits and foreign health systems, both in development and once the drugs are sold.

ONCE AGAIN DELIVERING ON PROMISES TO PUT AMERICAN PATIENTS FIRST:

Today's letters are an important step in President Trump's work to get Americans the best deal in the world on prescription drugs.

- On May 12, 2025, President Trump signed an Executive Order titled: "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" directing the Administration to take numerous actions to bring American drug prices in line with those paid by similar nations.
- Following the Order, the Administration engaged pharmaceutical manufacturers in discussions to achieve MFN pricing in the United States. Today's letters indicate that industry proposals have fallen short, and from this point forward, President Trump will only accept from drug manufacturers a commitment that provides American families immediate relief from vastly inflated drug prices and an end to the freeriding by European and other developed nations on American innovations.

President Trump has been relentless in his effort to address the unfair and outrageous prices Americans pay for prescription drugs:

- President Trump: “In case after case, our citizens pay massively higher prices than other nations pay for the same exact pill, from the same factory, effectively subsidizing socialism aboard [abroad] with skyrocketing prices at home. So we would spend tremendous amounts of money in order to provide inexpensive drugs to another country. And when I say the price is different, you can see some examples where the price is beyond anything — four times, five times different.”

FOUNDING FATHERS

Subscribe to The White House newsletter

Your email SIGN UP

Text POTUS to 45470 to receive updates

THE WHITE HOUSE

1600 Pennsylvania Ave NW
Washington, DC 20500

WH.GOV

GALLUP®

SEPTEMBER 29, 2024

Five Things to Know: Healthcare and the U.S. Election

BY **SARAH FIORONI**

Editor's Note: This research was conducted in partnership with West Health, a family of nonprofit and nonpartisan organizations focused on healthcare and aging.

WASHINGTON, D.C. -- Healthcare issues, especially those related to cost of and access to care, are an important top-of-mind policy area for many American voters. Yet, a new poll from West Health and Gallup shows that a majority of Americans say

healthcare is not receiving enough attention in the 2024 presidential campaign so far. The upcoming vice presidential debate presents a unique opportunity for the two campaigns to address these concerns and lay out their plans for healthcare policy.

The findings reported here are from a study fielded Sept. 9-16 via web using the Gallup Panel, with 2,398 respondents surveyed before the Sept. 10 presidential debate and 1,262 surveyed after it, for a total of 3,660 respondents. Attitudes reported here did not vary significantly for respondents interviewed before and after the debate.

1. Two in three Americans -- including majorities of both political parties -- say healthcare is not receiving enough attention during the presidential campaign so far.

Overall, 67% of U.S. adults say healthcare is not receiving enough attention during the 2024 presidential campaign, while 6% say it is getting too much attention and 27% the right amount. Democrats and independents are more likely than Republicans to say healthcare is not getting enough attention during the current presidential campaign. That said, more than half of Republicans (53%) agree that it is not getting enough attention.

Among the respondents who said they watched the presidential debate on Sept. 10, similar numbers (71%) report that the candidates did not spend enough time on healthcare-related issues during the debate. This attitude is held by 77% of

Democrats, 74% of independents and 57% of Republicans who watched the debate.

2. While independents are slightly more trusting of Harris than Trump when it comes to acting on key healthcare issues, about a third report not trusting either candidate.

Americans' levels of trust in the presidential candidates to tackle key issues related to cost and quality of healthcare fall along political party lines, with solid majorities of Republicans saying Donald Trump is more trusted to handle the issues and the vast majority of Democrats saying Kamala Harris is. Political independents are slightly more likely to report trusting Harris over Trump on these healthcare issues. This is especially true when it comes to improving access to care and insurance coverage as well as protecting or strengthening Medicare. On these two topics, independents are more than 10 points more likely to say they trust Harris over Trump.

About a third or more of independents report they don't trust either candidate across all the healthcare issues polled, suggesting that a significant portion of potential swing voters are cynical in how they feel about both candidates on healthcare.

3. Nearly half of Americans report that a candidate's position on lowering drug costs and mental healthcare policy are important issues in determining their vote in the upcoming

election.

A candidate's position on protecting Medicare and Social Security is the single most or among the most important healthcare-related issues in determining 63% of Americans' vote in the upcoming presidential election, while a candidate's position on lowering the cost of healthcare (57%) is close behind.

The importance of a candidate's position on mental healthcare (43%) is near the same level of importance as reducing drug costs (47%) as the single most or among the most important issues determining their vote. This mirrors Americans' broader dissatisfaction with this issue area, as 73% say the government is not doing enough to ensure the public has access to affordable mental healthcare.

4. Protecting Medicare and lowering drug costs are among the most important issues older Americans care about when determining their vote.

The importance of certain healthcare issues to a person's vote differs among older versus younger Americans. Americans 65 and older are much more likely than those 18 to 49 to say a candidate's positions on protecting Medicare and Social Security and lowering drug costs are among the most important issues or the single most important issue in determining their vote. Conversely, younger and older voters place about equal importance on a candidate's positions on lowering healthcare costs and their mental healthcare policies.

Democrats are more likely than Republicans and independents to say that various healthcare-related issues are at least among the most important when determining their vote in the upcoming election. Independents fall roughly between Republicans and Democrats when it comes to the importance of these issues.

Age differences are apparent within the party groups. On the issue of protecting Medicare and Social Security, 74% of Republicans over 65, and 68% of those 50 to 64, say this is the single most or among the most important issues determining their vote, compared with 40% of Republicans 18 to 49. Similarly, 94% of Democrats 65 and older, and 85% of those aged 50 to 64 say this is the single most or among the most important issues, compared with 58% of Democrats 18 to 49. Independents follow the same pattern.

5. Democrats are much more optimistic than Republicans and independents about improving access to affordable healthcare in the next five years.

The most recent numbers from the West Health-Gallup Healthcare Affordability Index show that just over half of the American public say they can pay for medicine or healthcare if they needed it today, declining from a high of 61% in 2022.

When asked how likely it is that access to affordable healthcare will improve in the next five years, Democrats express optimism, while Republicans and independents are pessimistic. Fifty-eight percent of Democrats believe access is very or somewhat

likely to improve, while majorities of Republicans (70%) and independents (64%) say improvement is not very or not at all likely.

Implications

Americans want more attention paid to lowering healthcare costs, an issue that has not had as much visibility in this presidential campaign compared with previous ones. This is especially true for Americans aged 65 and older. Majorities of older Republicans and older Democrats say a candidate's plan for protecting Medicare and Social Security is crucial to their vote choice.

The 65 and older population is a significant voting bloc in the U.S. In 2020, the population of Americans 65 and older reached a high of 55.8 million, accounting for roughly 17% of the population. That number is likely larger today, as the U.S. Census Bureau estimates by 2025, the 65+ population will reach 63.3 million.

Although other political issues may be overshadowing healthcare in the current election, Americans continue to have serious concerns about their ability to afford the healthcare they need. Data from this study show that more than two in three Americans (67%) are very or somewhat concerned that a major health event could lead to medical debt, including 62% of Republicans, 67% of independents and 71% of Democrats. Issues related to the cost and accessibility of healthcare directly impact the day-to-day life of every voter, regardless of their political party affiliation.

To stay up to date with the latest Gallup News insights and updates, follow us on X @Gallup.

Learn more about how the Gallup Panel works.

SURVEY METHODS

RELEASE DATE: September 29, 2024

SOURCE: Gallup https://news.gallup.com/poll/651386/five-things-know-healthcare-election.aspx

CONTACT: Gallup World Headquarters, 901 F Street, Washington, D.C., 20001, U.S.A

+1 202.715.3030

BUSINESS

Amazon is not planning to break out tariff costs online as White House attacks potential move

1 of 2 | The White House on Tuesday slammed plans by Amazon to show how much President Donald Trump's tariffs have raised prices on certain goods, calling it "a hostile and political act."

BY WYATTE GRANTHAM-PHILIPS AND JOSH BOAK

Updated 4:02 PM PDT, April 29, 2025

NEW YORK (AP) — Amazon says it's not planning to display added tariff costs next to product prices on its site — despite a report that sparked speculation the e-commerce giant would soon show the new import charges, and the White House's fiery comments denouncing the purported change.

The Trump administration's reaction appeared to be based on a misinterpretation of internal plans being considered by Amazon, rather than a final decision made by the company.

And even those talks were limited. Only Amazon's Haul service — its recently launched, low-cost storefront — "considered the idea" of listing import charges on certain products, company spokesperson Tim Doyle said in a statement sent to The Associated Press. But this "was never approved and is not going to happen."

Earlier Tuesday, Punchbowl News had reported that Amazon planned to start showing how much of each product's cost derived from tariffs "right next to" its total listed price, citing an anonymous source familiar with the matter.

0:00 / 47

AP AUDIO: Amazon is not planning to break out tariff costs online as White House attacks potential move

AP correspondent Ed Donahue reports Amazon clarifies its stand on posting tariff costs.

The Trump administration was quick to criticize news of the potential move. At a briefing with reporters earlier in the day, White House press secretary Karoline Leavitt accused Amazon of taking a "hostile and political act" — and further attacked the company by suggesting it had "partnered with a Chinese propaganda arm."

A source familiar with the matter, who spoke of the condition of anonymity, told The Associated Press that the president also called Amazon founder Jeff Bezos to complain about the reported plans Tuesday morning.

The administration seemed to change its tune following Amazon's clarifying statement.

"Jeff Bezos was very nice. He was terrific," President Donald Trump told reporters before leaving the White House for Michigan on Tuesday afternoon. "He solved a problem very quickly and he did the right thing. He's a good guy."

Bezos was one of a handful of powerful, ultra-wealthy tech titans who attended Trump's

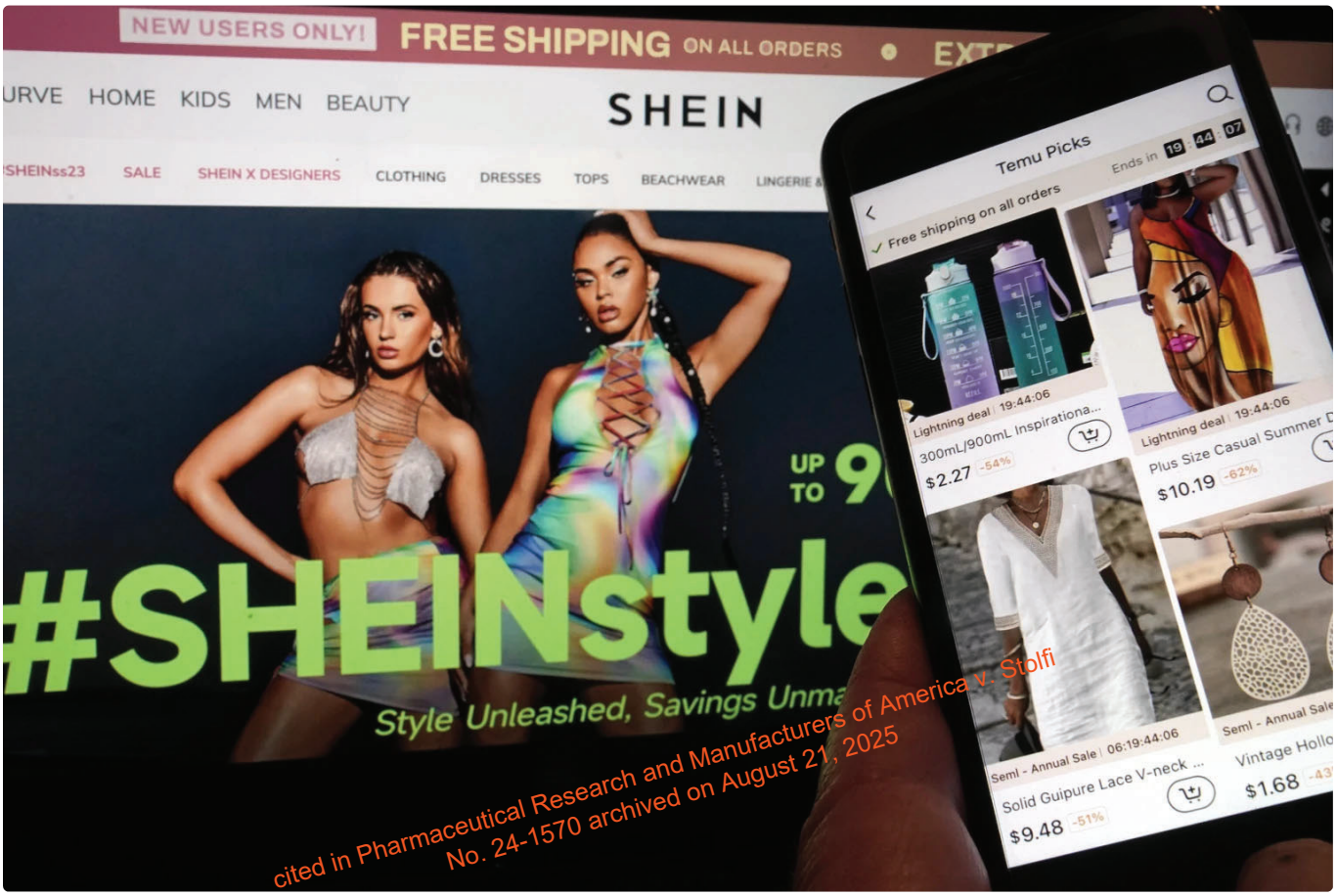
inauguration in January — filling some of the most exclusive seats right behind the president. But Trump's relationship with much of the corporate world has been tested since, as the tariff wars he's launched with nearly all of America's trading partners continue to plunge companies into uncertainty.

Trump's tariffs — and responding retaliation from targeted countries, notably China — threaten to increase prices for both consumers and businesses. Economists warn these import taxes will hike prices for a range of goods consumers buy each day and lead to worse inflationary pressure.

READ MORE:

Trump keeps contradicting himself on tariffs, making a fragile world economy nervous

Most Americans expect higher prices as a result of Trump's tariffs, a new AP-NORC poll finds



Temu and Shein will raise prices for US customers due to Trump's tariffs

There's a reason why the Trump administration responded the way it did to Tuesday's Amazon speculation, explains Rob Lalka, a professor of business at Tulane University's Freeman School — noting that such quick and harsh words from the White House signals concern about companies "redirecting customer frustration."

At the same time, volatile tariffs put a lot on the line for businesses like Amazon — and those companies may have to play ball, too, while trying to be transparent with customers. Many CEOs across industries have recently shared weaker outlooks due to the new — and at times on-again, off again — import taxes. And some big names have already raised prices while specifically pointing to the costs of tariffs, including Amazon rivals Temu and Shein.

Earlier this month, Temu and Shein said in separate but nearly identical notices that [illegible] operating expenses had gone up "due to recent changes in global trade rules and tariffs" —

both announcing price hikes to take effect last Friday (April 25).

Temu, owned by the Chinese e-commerce company PDD Holdings, now lists added "import charges" — which have reportedly doubled many items' prices, although those available in local warehouses currently appear to be exempt. Meanwhile, Shein, now based in Singapore, has a checkout banner that reads, "Tariffs are included in the price you pay. You'll never have to pay extra at delivery."

Tariffs may now be in the spotlight like they never were before — but companies have long itemized added costs to the things we purchase, Lalka notes, from city occupancy taxes on a hotel bill to rideshare apps like Uber breaking out local fees. And Amazon itself "already turned to this playbook" when it began collecting state sales taxes, he adds, although another line in your online shopping cart may be less apparent than potentially seeing total import taxes next to each product you scroll by.

It's a message regardless, he explains.

"Companies are always communicating something with us when whenever they are putting things in their receipt," Lalka said — adding that, while Amazon later confirmed it wasn't actually breaking out tariff prices, the idea didn't come from nowhere. "The reality is that politics are always being played."

Boak reported from Washington. AP writers Zeke Miller and Darlene Superville also contributed to this report.

WYATTE GRANTHAM-PHILIPS
Grantham-Philips is a business reporter who covers trending news for The Associated Press. She is based in New York.

JOSH BOAK
Boak covers the White House and economic policy for The Associated Press. He joined the AP in 2013.

MOST READ

1 Hurricane Erin picking up steam as it edges along the East Coast

2 Appeals court throws out massive civil fraud penalty against President Donald Trump

3 2 more beachfront homes near collapse as Hurricane Erin's waves pound North Carolina's Outer Banks

4 Trump's hot mic moment is the latest in a long global list

5 Is empathy a sin? Some conservative Christians argue it can be

SUGGESTED FOR YOU

$100 Trillion in Federal Land Could Soon Go Public

Advertisement: Investing Outlook

How Savvy Investors Pay for Healthcare in Retirement [Free Guide]

Advertisement: Fisher Investments

Moving Abroad: Finanical Checklist and Tips

Advertisement: Charles Schwab