UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

ABBVIE INC.; ALLERGAN, INC.; DURATA THERAPEUTICS, INC.; ABBVIE PRODUCTS, LLC; PHARMACYCLICS LLC; and ALLERGAN SALES, LLC, *Plaintiff*, *v.* PETER F. NERONHA, in his official capacity as ATTORNEY GENERAL OF RHODE ISLAND, and DAVID BERGANTINO, in his official capacity as Auditor General of the State of Rhode Island, *Defendant*.	Case No. 25-cv-388 Judge John J. McConnell, Jr.

BRIEF OF *AMICI CURIAE* THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, THE HOSPITAL ASSOCIATION OF RHODE ISLAND, AND THE AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANT

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INTEREST OF AMICI CURIAE[1]

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Rhode Island's legislative efforts to protect the 340B program.[2]

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences for their members, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

The **Hospital Association of Rhode Island** (**HARI**) is a statewide organization representing 17 hospitals and healthcare systems in Rhode Island. HARI assists member hospitals in effectively meeting the health care needs of Rhode Island through advocacy, representation, education, and services. HARI ensures that the needs and perspective of members are heard and addressed in state and national health policy development, legislative and regulatory debates, and system transformation matters. Together with its members, HARI works to ensure that all Rhode Islanders receive comprehensive, high-quality care.

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[1] The Defendants do not object to the filing of this brief. Plaintiffs take no position on the filing of this brief.

[2] Proposed *Amici* also certify that neither party's counsel authored the attached *amicus* brief in whole or part, and neither party nor its counsel nor any other person have contributed money to fund the preparation and/or submission of the brief.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice; advanced education and professional development; and served as a steadfast advocate for members and patients.

INTRODUCTION

Amici curiae AHA, 340B Health, HARI, and ASHP, have filed an *amicus* brief in another case pending before this Court challenging the same Rhode Island law, Chapter 288, (which Plaintiffs AbbVie Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products, LLC, Pharmacyclics LLC, and Allergan Sales, LLC (collectively, AbbVie) refer to as S. 114), *Novartis Pharms. Corp. v. Nehrona* (25-cv-387) (ECF No. 63). *Amici curiae* respectfully refer the Court to their *amicus* brief submitted in that case regarding the history of drug manufacturers' contract pharmacy restrictions and the manufacturers' past claims that those policies were permissible because: (1) they were *delivery* restrictions, and (2) the 340B statute had did not address *delivery* of 340B drugs.[3] *See Novartis. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703, 707 (3d Cir. 2023) (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence.").

[3] *E.g.*, Novartis Opening Brief at 4, *Novartis. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies.") (emphasis added); AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

Amici Curiae submit this *amicus* brief to describe the additional benefits of the 340B Program in Rhode Island, address the additional arguments presented by AbbVie in challenging Chapter 288, and direct the Court's attention to a recent Fifth Circuit decision that squarely rejects AbbVie's preemption and takings claims against an analogous state law. *AbbVie v. Fitch*, 24-60375, 2025 WL 2630900, at *14 (5th Cir. Sept. 12, 2025).

I. The 340b Program Benefits Local Rhode Island Hospitals.

340B Providers rely on savings from the 340B Program to provide critical care for some of the most vulnerable patients throughout the state of Rhode Island. For example, Rhode Island Hospital (RIH), which also supports Hasbro Children's hospital, serves a community where approximately 15% of residents and 30% of children live in poverty.[4] Several 340B Hospitals in the state, including Rhode Island Hospital (RIH) and Care New England Health System, serve any and all patients, regardless of their ability to pay. Furthermore, as *Amici* described in the amicus brief submitted in *Novartis v. Nehrona*, 25-cv-387 (Dkt. No. 29) at 5, RIH and other 340B Hospitals, including Care New England Health System spend tens of millions of dollars—if not hundreds of millions—in charity and uncompensated care each year.[5] Additionally, Care New England Health invests heavily in subsidized health services to address community needs, even when those programs operate at a financial loss, to ensure access to essential care such as neonatal intensive care, inpatient psychiatric care, chronic disease management, emergency and trauma services, and home health programs; in 2022 Care New England Health delivered

[4] United States Census Bureau, https://data.census.gov/table/ACSST1Y2024.S1702?q=poverty+rate+in+providence+rhode+island (last visited September 17, 2025).

[5] Care New England, 2024 Community Report, https://www.carenewengland.org/hubfs/-%20CNE/DEI/1-23_2024CommunityReport_DigitalBook.pdf (last visited September 17, 2024).

subsidized health services at a cost of $40.7 million.[6] These programs are necessary to the community. Care New England Health operates Woman & Infants Hospitals, where 50% of the births are covered by Medicaid.

Landmark Medical Center (LMC) provides critical services in Woonsocket, Rhode Island, where nearly one in five residences lives in poverty and the child poverty is over 30%.[7] The community is considered a "health care desert," and limited public transportation services isolate families and make it difficult to reach medical providers. LMC uses savings from the 340B Program to meet these community needs; for example, it provides transportation services to LMC and its associated cancer center, free medications; a food pantry for cancer patients, and "go food bags" for any patient without access to food.

340B Hospitals, provide these benefits under financial strain. For example, Care New England Health provides care to a significant number of patients who are covered by Medicaid; however, Medicaid does not cover the full cost of care to those patients, and, as a result, experienced a Medicaid "shortfall" of $28.9 million.[8] Care New England Health is able to provide those services in part because of the savings it receives from the 340B Program; however, contract pharmacy restrictions will significantly reduce the savings that are available to support these programs. RIH has already experienced a financial loss as a result of contract pharmacy restrictions, which puts the safety-net services it provides at risk.

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6 *Id.*

7 United States Census Bureau, https://data.census.gov/table?q=poverty+rate+in+Woonsocket+city,+Rhode+Island (last visited September 17, 2025).

8 Care New England, 2024 Community Report, https://www.carenewengland.org/hubfs/-%20CNE/DEI/1-23_2024CommunityReport_DigitalBook.pdf (last visited September 17, 2024).

II. Congress Did Not Create or Occupy a Field through the 340B Statute.

AbbVie first asserts a field-preemption theory, claiming that "every element of the [340B] program—from eligibility and pricing to compliance and enforcement—is governed by federal law." Compl. ¶ 138 (ECF No. 1). AbbVie's field preemption theory both misapplies the relevant standard and mischaracterizes the 340B statute and has thus been correctly rejected by the Eighth and Fifth Circuits (the only circuit courts to address challenges to similar state statutes), *PhRMA v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024); *AbbVie v. Fitch.,* 2025 WL 2630900, at *7 , and several district courts; *see e.g., AbbVie v. Skremetti*, No. 3:25-cv-00519, 2025 WL 1805271, at *13 (M.D. Tenn. June 30, 2025) (collecting cases).

Field preemption occurs only in narrow circumstances: "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. National Collegiate Athletic Association*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has "reject[ed] . . . the contention that pre-emption is to be inferred merely from the comprehensive character" of a federal statute. *Id.; see AbbVie v. Fitch.,* 2025 WL 2630900, at *6 ("Field preemption 'should not be inferred, however, simply because the agency's regulations are comprehensive.'" (quoting *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 149 (1986)). Rather, a statute preempts an entire field only if it "reflect[s] a congressional decision to foreclose any state regulation in the area," and thus "confer[s] a federal right to be free from any other" requirements in the same field. *Murphy*, 584 U.S. at 479 (citation omitted).

AbbVie relies entirely on the (supposed) comprehensiveness of the 340B statute to support its field preemption theory. But nowhere does AbbVie suggest that the 340B statute evinces Congress's intent to foreclose complementary state law. AbbVie notes that the 340B statute does not *affirmatively* "authorize state regulation," Compl. ¶ 141, but that argument flips preemption analysis upside down. Congress knows that, in many areas, it legislates against a backdrop of additional state regulation, and Courts presume that Congress generally *does not* intend to preempt state law. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see AbbVie v. Fitch.,* 2025 WL 2630900, at *5. That is especially true in "matters of health," given "the historic primacy of state regulation" in that area. *Medtronic, Inc.*, 518 U.S. at 485. Moreover, countless aspects of a drug company's contractual relationships with purchasers are governed by ordinary contract law, which of course is traditionally the province of states. *See, e.g.*, *AbbVie Endocrine Inc. v. Takeda Pharm. Co.*, 2021 WL 4302920, at *3 (Del. Ch. Sept. 22, 2021) (adjudicating breach-of-contract dispute involving drug-sale contract under state law). Nothing in the 340B statute suggests that Congress intended to oust states from their traditional role in regulating these areas, and AbbVie thus cannot meet its "burden of overcoming th[e] presumption" against preemption. *PhRMA v. Walsh*, 538 U.S. 644, 662 (2003).

AbbVie appears to attack the mere fact that Chapter 288 speaks directly to the federal 340B program and expressly invokes the 340B statute in defining its reach. *See* Pls.' Mot. for Prelim. Inj. (ECF No. 9) 10-11 (noting Chapter 288 definition of "340B drug"). But there is nothing improper about a state statute defining its reach by reference to federal law (and then imposing its own requirements)—or even a state statute whose "regulatory object" is a federal program. *See, e.g.*, *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607–08 (2011) (rejecting preemption

challenge to a state statute under which employers had to check their employees' *federal* immigration status using a specified *federal* database).

And, crucially, AbbVie is simply wrong that "every element," Compl. ¶138, of drug manufacturers' sales to 340B entities is dictated by the 340B statute. "Section 340B does not 'provide a full set of standards governing' discounted drugs for needy patients . . . Notably, it regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution." *AbbVie v. Fitch.,* 2025 WL 2630900, at *6 (collecting sources). In particular, as noted, courts have adopted the drug companies' arguments and held that the 340B statute is "silent about delivery conditions," *Novartis Pharms. Corp. v. Johnson*, 102 F.4th at 460. For precisely that reason, the Eighth Circuit, Fifth Circuit, and numerous district courts concluded the 340B statute is *not* comprehensive and rejected a field preemption challenge to a state contract pharmacy statute substantially similar to Chapter 288. *PhRMA v. McClain*, 95 F.4th at 1143; A*bbVie v. Fitch.,* 2025 WL 2630900, at *7; *see e.g., Abbvie v. Skremetti*, 2025 WL 1805271, at *13 (collecting cases).

AbbVie next attempts to argue that Chapter 288 is field preempted because it regulates price not delivery. However, "AbbVie's . . . argument is simply incorrect." *AbbVie v. Fitch.,* 2025 WL 2630900, at *7. Chapter 288 does not regulate the price of 340B drugs. The federal 340B statute dictates what price manufacturers must offer (the "ceiling price") and to whom (340B "covered entities"). Chapter 288 does not alter either requirement. As the Fifth Circuit correctly realized when addressing an analogous state law:

> By its plain text, H.B. 728 requires drug manufacturers to give custody of discounted drugs to contract pharmacies only insofar as they have partnered with covered entities to distribute the drugs to patients. It does not compel manufacturers to "offer" discounted drugs to contract pharmacies in the way that Section 340B compels them to "offer" these drugs to covered entities."

Id.; *see also id*. at *4 ("The record indicates that H.B. 728 does not impose on drug manufacturers a positive obligation to directly transfer or sell their drugs to anyone. Nor does it require them to sell larger quantities of their drugs at discounted prices than Section 340B requires …."). Simply put: "[Chapter 288] does not set or enforce discount pricing." *PhRMA v. McClain*, 95 F.4th at 1145; *see also PhRMA v. Murrill*, 2024 WL 4361597, at *9 (W.D. La. Sept. 30, 2024) ("[D]iscounts are set by the federal government, not the State of Louisiana or Act 358. Act 358 addresses only contract pharmacies, a matter that is not addressed in Section 340B.").

Chapter 288's core provision states only that a drug company may not discriminate against Rhode Island 340B hospitals based on their chosen delivery location. Chapter 288, which only addresses those restrictions, therefore regulates drug delivery and not drug pricing.

AbbVie nonetheless relies on the only decision to find otherwise, *PhRMA v. Morrissey*, to argue that Chapter 288 regulates price. 760 F. Supp. 3d 439, 455 (S.D. W. Va. Dec. 17, 2024). The *Morrisey* court found that an analogous state statute regulated price because of the "replenishment model," which the court described as permitting the pharmacy to replenish its own stock of drugs at the 340B price. *Id.* at 447-48. With that in mind, the court claimed that the operative question in that case was about "what price the pharmacy . . . will pay the manufacturer for the replenished drug upon distribution of the 340B eligible one." *Id.* However, that description fundamentally misunderstands the "replenishment model." The "replenishment model" is an inventory management system that tracks patient and drug data to ensure that 340B hospitals only pay the 340B price for drugs received by their eligible patients. *See, e.g.*, *AbbVie v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965, at *14 (S.D. Miss. July 22, 2024).

In the context of contract pharmacies, replenishment works as follows: The contract pharmacy buys drugs in bulk from a drug company at market price. Then, the hospital identifies

the patients who received drugs that are eligible for the 340B discount. Once the pharmacy has dispensed a full package of the drug to patients who have been identified as patients of that covered entity (say, a 340B hospital), back-end software determines that the 340B hospital should pay the 340B discounted price from that portion of the contract pharmacy's general supply to replace that package. By contrast, if a contract pharmacy dispenses a drug to a patient of a non-340B hospital, then the back-end inventory will not be replenished at the discounted price. If it worked any other way, the pharmacy would have to keep separate stocks of drugs: one for the covered entity and one for non-covered entities. It is more efficiently handled by treating the drugs as they are—fungible commodities—and handling the discount pricing on the back-end, not the front-end.

Most hospitals use the same type of inventory control method in their in-house pharmacies. 340B providers make an initial purchase of a drug at its full price and add that to their single inventory. Some of the purchased drugs may be used for 340B patients and some for non-340B patients. After the pharmacy has dispensed a full package of that drug to 340B patients, it replenishes (or re-stocks) the supply of that drug by purchasing a package of that drug at the 340B-discounted price.

Ultimately, by regulating the delivery of 340B drugs, Rhode Island is not requiring that manufacturers provide 340B pricing in situations where the federal statute does not. Nothing about that law alters the fact that the hospital is the only purchaser of 340B drugs. The contract pharmacy itself *never* purchases 340B discounted drugs and is never a "covered entity" entitled to receive a 340B discount. The law simply permits the purchaser—the 340B hospital—choose where the drugs it will be delivered—its own in-house pharmacy or a contract pharmacy.

Operating within the precise metes and bounds of the 340B statute—which is silent as to delivery—Rhode Island is protecting its in-state hospitals' flexibility to decide *where* they want

drugs that they have purchased to be delivered. If a Rhode Island hospital wants to buy a particular medication, the drug companies do not contest their obligation to ship that drug to the hospital's in-house pharmacy, even if that pharmacy uses the replenishment model. Chapter 288 simply mandates that those companies *also deliver* that drug to the pharmacies with which its in-state hospitals have contracts. Nothing in federal law forbids Rhode Island from making that policy decision.

III. Chapter 288 Is Not Preempted By HRSA's Rebate Program.

AbbVie's argument that Chapter 288 conflicts with HRSA's Rebate Pilot Program by prohibiting manufacturers from requesting and obtaining claims data, Pls.' MPI at 16, is a red herring. Since the inception of the 340B Program, manufacturers have complied with their obligations under the 340B Program by providing 340B drugs to covered entities at an upfront discount. However, in July 2025 the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services with responsibility to oversee the 340B Program, announced a pilot program to permit certain manufacturers to fulfill their obligations under the 340B statute by providing a rebate on a certain subset of drugs in the amount representing the difference between the list price of the drug and the discounted price of the drug (the Rebate Pilot Program). Under that pilot program, manufacturers of ten drugs subject to the Medicare Drug Price Negotiation Program,[9] which is operated by the Centers for Medicare and Medicaid (CMS), would be permitted, for one year, to provide 340B discounts in the form of rebates. This, in turn, will require 340B covered entities to provide manufacturers with a limited

[9] Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (CMS DPNP Guidance), 1 at https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf.

amount of claims data, some of which would overlap with what the drug companies have sought under their contract pharmacy restrictions.

The Pilot was introduced as only a "test" to better understand how a rebate model would operate,[10] and to date, HRSA has not approved a single application for a drug manufacturer to participate in the Pilot. Furthermore, the question of whether the 340B statute even permits HRSA to authorize manufacturers to effectuate 340B pricing through rebates is still being contested; in fact, the D.C. Circuit is currently considering this statutory question. *Novartis v. Kennedy*, 25-5177 (D.C. Cir.). As such, any preemption claim based on the Pilot is premature. It is black-letter law that "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of the state statute." *Rice v. Norman Williams Co*., 458 U.S. 654, 659 (1982); *see Dep't of Tax'n & Fin. of New York v. Milhelm Attea & Bros.*, 512 U.S. 61, 69 (1994).

However, even if the claim were suitable for review, there would be no conflict. Chapter 288 specifically permits manufacturers to collect claims data if it is "required by the Centers for Medicare and Medicaid Services." § 5-19.3-3(5). Though the Rebate Pilot Program is administered by HRSA, it is designed to work in tandem with the obligations set upon certain manufacturers by CMS. As such, Chapter 288 should be interpreted to permit the collection of claims data for drugs that are subject to the Rebate Pilot Program. In fact, Chapter 288 explicitly contemplates such an interpretation, stating that "nothing in this chapter is to be construed or applied to be in conflict with… applicable federal law and related regulations." § 5-19.3-9(b)(1). As such, should HRSA's Pilot continue, and should a manufacturer be granted permission to apply a rebate for one of the ten eligible drugs, this Court should construe any alleged conflict between Chapter 288 and the

[10] HRSA, *HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment*, https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program (last visited August 27, 2025).

Pilot as inapplicable for *only that one drug*. And, if any such potential conflict does arise as to those specific drugs; that limited conflict cannot justify striking down an entire state law. *E.g.*, *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449 (2008) ("[A] plaintiff can only succeed in a facial challenge by 'establish[ing] that no set of circumstances exists under which the Act would be valid,' *i.e.,* that the law is unconstitutional in all of its applications.") (quoting *U.S. v. Salerno*, 481 U.S. 739 (1987)); severability quote.

IV. Chapter 288 Does Not Violate the Takings Clause.

"A party challenging governmental action as an unconstitutional taking bears a substantial burden." *E. Enters. v. Apfel,* 524 U.S. 498, 523 (1998). But AbbVie would fail to state a Takings Clause claim under the most lenient of standards; in fact, when viewed under the proper legal framework AbbVie fails to even allege that its property is being taken. *AbbVie v. Fitch*, 2025 WL 2630900, at 9 (5th Cir. Sept. 12, 2025).

Takings Clause claims fall into two categories: (1) physical takings, which result from permanent physical occupation of private property; and (2) regulatory takings, which stem from government-imposed regulations restricting an owner's ability to use his own property. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Plan. Agency*, 535 U.S. 302, 322 (2002). AbbVie cannot show that its property will be "taken" under physical takings analysis and does not seek (nor could it) a preliminary injunction based on an allegation that Chapter 288 constitutes a regulatory taking.

A. Chapter 288 Will Not Result in a "Taking" of AbbVie's Property.

AbbVie's takings claims are meritless; and as the Fifth Circuit recently recognized with respect to an analogous state law, AbbVie cannot establish *either* a physical or regulatory taking. *See AbbVie v. Fitch.,* 2025 WL 2630900, at *4-5; *PhRMA. v. Murrill*, 2024 WL 4361597, at *14.

1. Chapter 288 Will Not Result In A "Physical" Taking

AbbVie's principal Takings Clause argument is that Chapter 288 results in a "physical" taking because it forces drug companies to transfer their prescription drugs to covered entities against under prices they would not otherwise offer. Pls.' MPI at 17.[11] But AbbVie misapprehends the governing Supreme Court precedent. When considered under the correct legal framework, there is no "forced transfer" so there can be no "physical taking."

The Supreme Court has made clear that the essential "element" of a "physical" takings claim is "required acquiescence." *FCC v. Florida Power Corp*., 480 U.S. 245, 252 (1987). By that, the Court has drawn a clear dividing line between 1) laws that "*require*" a property owner to "suffer the physical occupation of a portion" of his property, *Loretto v. Teleprompter Manhattan CATV Corp*., 458 U.S. 419, 440 (1982), and 2) situations where a property owner voluntarily chooses to engage in a commercial transactions with a third party *and then is subject to government regulation*, *see Florida Power Corp*., 480 U.S. at 252-253.[12] As the Court has put it, "it is the

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[11] AbbVie's assertion that Chapter 288 forces manufacturers to transfer drugs is not a factual allegation but is instead a legal conclusion couched as a factual allegation. The Court is not required to accept that assertion as true. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 527 (1992) (characterizing the conclusion that a rent control ordinance transfers interest from one private party to another as "an argument").

[12] *See also Cedar Point Nursey v. Hassid*, 594 U.S. 139, 157 (2021) ("Limitations on how a business generally open to the public may treat individuals on the premises are readily distinguishable from regulations granting a right to invade property closed to the public."); *CDK Global LLC v. Brnovich*, 16 F.4th 1266, 1282 (9th Cir. 2021) ("It is no answer that CDK may not wish to open its DMS to any particular authorized integrator. Once property owners voluntarily open their property to occupation by others, they cannot assert a per se right to compensation based

invitation … that makes the difference." *Id*. at 253. When there is no such "required acquiescence," there is no "physical" taking.

AbbVie's claim fails because there is no "required acquiescence" under Chapter 288. No matter how many times AbbVie uses the term "forced," it cannot escape the fact that it has chosen to enter the Rhode Island market to engage in commercial transactions with 340B hospitals. AbbVie admits that it will sell to Rhode Island 340B hospitals and will readily ship its drugs to a 340B hospital's in-house pharmacy, as it must do so if it chooses to participate in the 340B Program. Chapter 288 operates *after* AbbVie's decides to sell its drugs to 340B hospitals—namely, by ensuring that a Rhode Island 340B hospital can choose *where* it wants AbbVie to ship its drugs. All Chapter 288 does is regulate how a particular aspect of those transactions (delivery) must occur—much like dozens of other state laws regulating the particulars of relationships between buyers and sellers in commercial transactions. As such, because nothing *requires* AbbVie to enter the market to transfer drugs to Rhode Island 340B hospitals, nothing in Chapter 288 physically deprives AbbVie of its drugs within the meaning of the Takings Clause.

As the Fifth Circuit recently recognized when analyzing an analogous state law, statutes such as Chapter 288 do "not impose on drug manufacturers a positive obligation to directly transfer or sell their drugs to anyone [] [n] or [do they] require them to sell larger quantities of their drugs at discounted prices than Section 340B requires and thereby deprive them of sales at full market price." *AbbVie v. Fitch.,* 2025 WL 2630900, at *4. Instead, it "simply imposes on drug manufacturers a negative obligation of non-interference with covered entities' arrangements with contract pharmacies." *Id.; see PhRMA. v. Murrill*, 2024 WL 4361597, at *14 ("Because [Chapter

on their inability to exclude particular individuals." (quotation marks omitted)); *74 Pinehurst LLC v. New York*, 59 F.4th 557, 563 (2d Cir. 2023); *Building Owners and Managers Ass'n Intern. v. F.C.C.*, 254 F.3d 89, 98 (D.C. Cir. 2001).

288] does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it is not a taking for purposes of the Takings Clause."). Accordingly, AbbVie's "physical" takings theory must fail. *See AbbVie v. Fitch.,* 2025 WL 2630900, at *4; *AbbVie v. Fitch*, 2024 WL 3503965, at *19; *AbbVie v. Skremetti*, 2025 WL 1805271, at *19 ("State regulations on delivery do not amount to taking possession of [a drug manufacturer's] property or conveying it to a third party."); *see also Franklin Mem'l Hosp. v. Harvey*, 575 F.3d 121, 126 (1st Cir. 2009) (rejecting characterization of a state statute requiring hospitals to provide free care to low income patients as a "forced transfer").

The Supreme Court's decision in *Yee,* 503 U.S. 519, is instructive. The Court explained that when "a landowner decides to rent his land to tenants, the government may place ceilings on the rents the landowner can charge…. or require the landowner to accept tenants he does not like, without automatically having to pay compensation." *Id.* at 529. Given this holding, Chapter 288 is as much a "forced transfer," as it was a forced rental in *Yee*. Critically, AbbVie has decided to sell its drugs to Rhode Island 340B hospitals in exactly the same way the landowner decided to "rent his land to tenants." *Id*. So just as the Supreme Court held that the government may "require the landlord to accept tenants he does not like," *id*., Rhode Island may require AbbVie to accept delivery conditions it does not like. And just as *Yee* held that the law "merely regulate[d] the petitioners' use of their land by regulating the relationship between landlord and tenant," *id.* at 528, the law here merely regulates *the use* of 340B drugs by regulating the relationship between the drug company and the covered entity. Any regulation of the *use* of property, including when, where, how, and to whom a good is sold, must be evaluated as a "regulatory" taking—not as a "physical" taking. *Cedar Point*, 594 U.S. at 148; *Horne*, 576 U.S. at 361; *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1027–28 (1992); *Andrus v. Allard*, 444 U.S. 51, 67 (1979); *see*

also Bowles v. Willingham, 321 U.S. 503, 517–18 (1944); *Nebbia v. People of New York*, 291 U.S. 502, 532 (1934).

Finally, AbbVie is wrong that Chapter 288 forces drug manufacturers to transfer their drugs at discounted prices to entities not contemplated by the federal 340B program, as the Fifth Circuit recently explained. *AbbVie v. Fitch.,* 2025 WL 2630900, at *4. And even if true, it would still not constitute a physical taking. For starters, any drug company that chooses to participate in the 340B program must offer its drugs to 340B entities at or below a statutory ceiling price. *See* 42 U.S.C. § 256b(a). Having made the choice to enter the 340B program and thus to sell to its drugs Rhode Island's 340B hospitals, AbbVie has subjected itself to—at most—"use" regulations, including those governing drug delivery that take as given that federally-dictated 340B price. "Use" regulations like those imposed under Chapter 288 must be evaluated under the "regulatory" takings framework. AbbVie cannot satisfy that framework either.

More fundamentally, it is critical to observe that AbbVie does not even allege that its property is being "taken" at all. All AbbVie says is that Chapter 288 results in a "physical" taking because it forces drug companies to transfer their prescription drugs to covered entities under prices they would not otherwise offer. However, "AbbVie still receives payment of the full discounted amounts to which it is entitled under Section 340B." *AbbVie v. Fitch.,* 2025 WL 2630900, at *4. And, again, that is not a "physical" taking. *Cf. Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 322 (2002). ("The starting point for the court's analysis should have been to ask whether there was a total taking of the entire parcel; if not, then *Penn Central* was the proper framework."). At most, this alleged pricing "ceiling" is a "use" restriction of the kind that courts routinely analyze under the "regulatory" takings framework. *Yee*, 503 U.S. at 529. For this reason, too, AbbVie's "physical" takings argument must fail.

2. Chapter 288 Will Not Result in a "Regulatory" Taking

A "regulatory" taking occurs when a government regulation so severely interferes with an owner's right to use property as to be fairly characterized as having "taken" it. *Tahoe-Sierra*, 535 U.S. at 322. AbbVie's complaint includes just two paragraphs alleging, in the alternative, a "regulatory" takings under *Penn Central*. Compl. ¶¶ 172-73. That effort is half-hearted for a reason: AbbVie plainly cannot establish a taking under the *Penn Central* framework. *AbbVie v. Fitch.,* 2025 WL 2630900, at *5; *Astrazenca Pharms. LP v. Bailey*, No. 2:24-CV-04143-MDH, 2025 WL 644285, at *6 (W.D. Mo. Feb. 27, 2025); *PhRMA v. Murrill*, 2024 WL 4361597, at *15.

The *Penn Central* framework determines when a regulation has gone "too far." *Andrus*, 444 U.S. at 65 (citing *Penn Central Transportation Co. v. New York City*, 438 U.S. 104, 123-128 (1978)). "The major factors under the *Penn Central* inquiry are (1) the economic impact of the regulation on the claimant, (2) the extent to which the regulation has interfered with distinct investment-backed expectations, and (3) the character of the governmental action." *Maine Educ. Ass'n Benefits Tr. v. Cioppa,* 695 F.3d 145, 153 (1st Cir. 2012). None of these factors support a "regulatory" taking here.

First, AbbVie makes no specific allegations about the economic impact of Chapter 288. But even if AbbVie had alleged more, it would struggle to satisfy this factor. Generally speaking, laws meant to support the health, safety, morals, and general welfare of the entire community are generally upheld even if they destroy or adversely affect private property interests. *See Lucas,* 505 U.S. 1023. More specifically, the most that AbbVie could allege is that it has lost some modest value in its property by having to sell certain drugs at 340B prices, particularly where AbbVie still receives "a large percentage of the market price" for its 340B sales. *AbbVie v. Fitch*, 2025 WL 2630900, at *4 (5th Cir. Sept. 12, 2025). And, in any event, a reduction in the value of property is insufficient to demonstrate a taking. *Concrete Pipe & Prods. of California, Inc. v. Constr.*

Laborers Pension Tr. for S. California, 508 U.S. 602, 645 (1993) (holding that the "mere diminution in the value of property, however serious, is insufficient to demonstrate a taking" finding no "regulatory" taking where there was a 46 percent diminution in property value). And "the mere loss of some income because of regulation does not itself establish a taking*." Baptiste v. Kennealy*, 490 F. Supp. 3d 353, 389 (D. Mass. 2020) (quoting *Colony Cove Props., LLC v. City of Carson*, 888 F.3d 445, 451 (9th Cir. 2018)); *see also Village of Euclid v. Ambler Realty Co.*, 272 U.S. 365, 384 (1926) (rejecting a takings claim where the claimant's property was deprived of 75% of its value); *Hadacheck v. Sebastian*, 239 U.S. 394, 405 (1915) (rejecting a takings claim where the claimant's property was deprived of 92.5% of its value). Thus, had AbbVie even made allegations about economic impact, those allegations would fall far short of satisfying the first *Penn Central* factor.

AbbVie fares no better under the second *Penn Central* factor. What is important in judging reasonable expectations is the regulatory environment at the time of the acquisition of the property. As such, AbbVie's "expectations are substantially diminished by the highly regulated nature of the industry in which it operates." *Maine Educ. Ass'n Benefits Tr. v. Cioppa*, 695 F.3d 145, 154 (1st Cir. 2012) (citing *Franklin Mem'l Hosp. v. Harvey,* 575 F.3d 121, 128 (1st Cir.2009)). "This is particularly true where, as here, the extensive regulatory framework in place prior to the passage of the challenged legislation has consistently regulated the type of property interest for which [AbbVie] seeks constitutional protection." *Id.* Having chosen to do business in the highly-regulated pharmaceutical field, AbbVie cannot now complain that more regulations were unforeseeable, particularly when there was a well-known "gap" in how the 340B Program operated. *AbbVie v. Fitch*, 2025 WL 2630900, at *11 (citing Notice Regarding Section 602, 61 Fed. Reg. at 43550); *PhRMA v. Murrill*, 2024 WL 4361597, at *15 (contract pharmacy regulations

were foreseeable). And to make matters worse, AbbVie had long delivered its drugs to contract pharmacies; it only changed course in 2020. Given that historical record, AbbVie cannot claim that Chapter 288 interfered with its investment-backed expectations. *Maine Educ. Ass'n Benefits Tr. v. Cioppa,* 695 F.3d 145, 155 (1st Cir. 2012) ("key aspect of the investment-backed expectations inquiry is the claimant's awareness of the problem that spawned the challenged regulation.")

Finally, the third *Penn Central* factor considers 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.'" *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 539 (2005). Here, Chapter 288 plainly seeks to promote public welfare by adjusting those benefits and burdens. Its primary purpose is to advance the public good by ensuring that Rhode Island's 340B hospitals can help their patients to receive drugs at more convenient delivery locations, even if that imposes incidental burdens on drug companies. As such, the character of the government action cuts against AbbVie. *E.g.*, *AbbVie v. Fitch.,* 2025 WL 2630900, at *5 (holding that "the third *Penn Central* factor … weighs in the state's favor"); *Astrazenca Pharms. LP v. Bailey*, 2025 WL 644285, at *6.

B. AbbVie's Voluntary Participation In The 340B Program And The Highly-Regulated Pharmaceutical Market Forecloses A Takings Claim.

Even if AbbVie could demonstrate that Chapter 288 results in a taking (and it cannot for the reasons stated below), its claim would fail because AbbVie participates in both the 340B program *and* the Rhode Island's highly-regulated pharmaceutical market *voluntarily*. Either would be sufficient, but its voluntary participation in both decisively defeats its Takings Clause claim.

Where a property owner voluntarily participates in a government program "in exchange for the economic advantages" of joining that program, there can be no taking. *Ruckelshaus v.*

Monsanto, 467 U.S. 986, 1007 (1984). Likewise, governmental regulation affecting a plaintiff's property interests "does not constitute a taking of property where the regulated group is not required to participate in the regulated industry." *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *see, e.g.*, *Bowles,* 321 U.S. at 517; *Nat'l Lifeline Ass'n v. FCC*, 983 F.3d 498, 515 (D.C. Cir. 2020); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984).

As numerous courts have held,[13] these elemental Takings Clause principles defeat AbbVie's claim. Indeed, all three courts to consider this issue in the 340B context have rejected the Fifth Amendment challenges of pharmaceutical companies.[14] And in the healthcare context more generally, courts routinely reject Takings Clause claims where the plaintiff voluntarily participates in the program or activity that it claims is taking its property.[15]

AbbVie's awareness of the possibility of state regulation of contract pharmacies is especially damning. As other courts have held, those restrictions "should have been foreseeable to [AbbVie], as Section 340B has had a well-known 'gap' about how delivery must occur," *AbbVie*

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[13] *See AbbVie v. Fitch*, 2024 WL 3503965, at *17–19 (addressing voluntariness); *AbbVie v. Skremetti*, 2025 WL 1805271, at *19 (an analogous state law "does not require [a drug manufacturer] to sell its drugs in Tennessee at all; [drug manufacturers] voluntarily choose[] to participate in Medicare and Medicaid and to participate in the 340B program as a condition of that choice.").

[14] *Eli Lilly*, 2021 WL 5039566, at *21; *Sanofi-Aventis*, 570 F. Supp. 3d at 207–10; *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

[15] *See Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014), *cert. denied*, 575 U.S. 1008 (2015); *Minn. Ass'n of Health Care Facilities v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984); *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991); *Whitney v. Heckler*, 780 F.2d 963, 968–73 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875 (7th Cir. 1983); *Eli Lilly & Co. v. HHS*, 2021 WL 5039566, at *21; *Sanofi-Aventis U.S., LLC v. U.S. Dept. of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 207–10 (D.N.J. 2021), *rev'd on other grounds*, 58 F.4th 696 (3d Cir. 2023); *AbbVie v. Fitch*, 2024 WL 3503965, at *16–20.

v. Fitch, 2024 WL 3503965, at *19, particularly in light of drug companies' argument in favor of that cap, 340B hospital's longstanding use of contract pharmacies, and prior HRSA guidance relating to contract pharmacies. *AbbVie v. Fitch.,* 2025 WL 2630900, at *5 (citing Notice Regarding Section 602, 61 Fed. Reg. at 43550); *accord PhRMA v. Murrill*, 2024 WL 4361597, at *15 (rejecting Takings claim because "regulations requiring delivery and forbidding restrictions against delivery to contract pharmacies were foreseeable"). Tellingly, even though AbbVie is now apprised of Chapter 288 and similar statutes in other states, it continues to voluntarily participate in the 340B program and sell drugs to 340B hospitals in those other states.

To respond to this straightforward precedent about voluntary participation in the 340B program, AbbVie contends that it has not voluntarily accepted *state*-imposed obligations like those set forth in Chapter 288.[16] But even if that were a valid end-run around its voluntary decision to participate in a 340B program that contains numerous statutory gaps that can be filled by states—and it is not—AbbVie's participation in a regulated market remains indisputably voluntary. The law is clear that when a company voluntarily participates in a regulated market, there can be no Takings Clause violation, even if a State imposes additional conditions on participation. *See Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442,

[16] Even if the requirement of an additional state-law benefit had some basis in precedent—and it does not—manufacturers receive an important benefit from Rhode Island in exchange for compliance with Rhode Island law. Medicaid is a "cooperative federal-state program." *Bruns v. Mayhew,* 750 F.3d 61, 63 (1st Cir. 2014). And state Medicaid coverage of outpatient drugs (and only outpatient drugs are subject to the 340B Program) is largely optional, not mandatory. *See* 42 U.S.C. § 1396a(54); *see also Pharmaceutical Research and Mfrs. of America v. Walsh*, 538 U.S. 644, 665 (2003) ("We have made it clear that the Medicaid Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." (citation omitted)). Rhode Island's decision to cover such drugs confers a specific benefit on drug manufacturers. Rhode Island could revisit that decision, along with others that benefit other drug manufacturers, if they refuse to comply with its laws concerning delivery of 340B drugs. This is more than enough to meet the "additional-State-benefit" standard that the drug companies have invented.

446 (8th Cir. 1984). This is because "when an owner of property voluntarily participates in a regulated market, additional regulations that may reduce the value of the property regulated do not result in a taking." *Nat'l Lifeline Assoc.*, 983 F.3d at 515 (citing *Bowles*, 321 U.S. at 517 and *Garelick*, 987 F.2d at 916); *see also Se. Ark. Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016).

Health care (in general) and pharmaceuticals (in particular) are among the most heavily regulated markets—including at the state level. *PhRMA v. Stolfi*, No. 24-1570, 2025 WL 2448851, at *24 (9th Cir. Aug. 26, 2025) ("The pharmaceutical industry is unquestionably an industry with a long history of government regulation") (discussing both state and federal regulations). Rhode Island itself robustly regulates pharmaceuticals, as AbbVie should be well-versed because it has obtained (as it is required to) a Rhode Island Pharmacy License.[17] *Cf. Horne*, 576 U.S. at 366 (noting that *Monsanto*'s voluntariness principle arose in a case involving "a license to sell dangerous chemicals"). AbbVie's voluntary choice to participate in Rhode Island's highly-regulated pharmaceutical market is fatal to its Takings Clause claim, even if this Court concludes that its voluntary participation in the 340B program is not.

In the end, AbbVie and its sister drug companies want to have their cake and eat it too. They want to participate in the 340B Program and the highly-regulated pharmaceutical market without accepting the possibility that the economic advantages of doing so may carry the costs of regulation. The law has never countenanced AbbVie's impossible dream. *E.g.*, *Bowles*, 321 U.S. at 518 ("A member of the class which is regulated may suffer economic losses not shared by others. His property may lose utility and depreciate in value as a consequence of regulation.").

[17] *Licensee Lists,* State of Rhode Island, Department of Health, https://health.ri.gov/licensing/licensee-lists (last visited September 10, 2025).

C. Even if there were a taking, AbbVie's requested relief is not available.

Even if AbbVie could somehow establish that Chapter 288 will result in its property being taken, its takings claim would still fail because Chapter 288 serves a legitimate public purpose within Rhode Island's police power. *AbbVie v. Fitch.,* 2025 WL 2630900, at *5; *PhRMA v. McClain*, 95 F.4th at 1145. AbbVie seeks to enjoin Chapter 288 altogether—a form of equitable relief that "is generally unavailable" when the government takes private property for public use because the Constitution specifically provides a monetary remedy for such a taking: "just compensation." U.S. Const. Amdt. V; *Knick v. Township of Scott*, 588 U.S. 180, 201 (2019). For injunctive relief, AbbVie therefore must show not only that Chapter 288 results in a taking, but also that such a taking falls outside the "broad and inclusive" conception of "public use" that the Supreme Court has repeatedly reaffirmed under the Takings Clause. *Kelo v. City of New London*, 545 U.S. 459, 480–81 (2005). It cannot do so. Chapter 288 clearly serves a public use. *AbbVie v. Fitch.,* 2025 WL 2630900, at *5. As Fifth Circuit recently described an analogous state law, "[Chapter 288] was not 'enacted solely for the benefit of private parties,' but rather furthers 'important public interests.'" *Id.* (quoting *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 485–86 (1987)). State contract pharmacy statutes like Chapter 288 "assist[] in fulfilling the purpose of [the 340B program]," which Congress created "to support" covered entities that "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *PhRMA v. McClain*, 95 F.4th at 1145. That is plainly a "public purpose."

V. CHAPTER 288 IS NOT VOID FOR VAGUENESS

A regulation is void for vagueness if it is "so vague that it fails to give ordinary people fair notice of the conduct it punishes or so standardless that it invites arbitrary enforcement." *Johnson v. United States*, 576 U.S. 591, 595 (2015); *Knox v. Brnovich*, 907 F.3d 1167, 1182 (9th Cir. 2018).

That is simply not the case here, as three other district courts addressing analogous state statutes have already found. *PhRMA v. Murrill*, 2024 WL 4361597, at *10-11; *AbbVie v. Skremetti*, 2025 WL 1805271, at *22; *PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *15 (S.D. Miss. July 1, 2024).

That Chapter 288 does not include a definition of "interfere" does not render the statute unconstitutionally vague. *PhRMA v. Murrill*, 2024 WL 4361597, at *10-11; *AbbVie v. Skremetti*, 2025 WL 1805271 at *22; *PhRMA v. Fitch*, No. 1:24-cv-160-HSO-BWR, 2024 WL 3277365, at *15 (S.D. Miss. July 1, 2024). Drug "manufacturer[s]"—the only entities subject to H.B. 266's prohibitions—can readily assess what conduct is prohibited by the statute's terms, including the term "interfere." If necessary, dictionaries can help provide the necessary clarity.[18] So do countless criminal and civil statutes that prohibit "interference" without expressly defining the term.[19] And to the extent there is any doubt, courts may apply the doctrine of *noscitur a sociis*, under which "a word is known by the company it keeps," *Yates v. United States,* 574 U.S. 528, 543 (2015), meaning that the term "interference" can be considered in the context of the surrounding words "deny," "restrict," and "prohibit." *See* H.B. 266 § 4682(a).

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[18] Black's Law Dictionary defines "interference" as "[t]he act of . . . meddling in the affairs of others" or "[a]n obstruction or hindrance." *Interference*, Black's Law Dictionary (12th ed. 2024); *PhRMA v. Murrill*, 2024 WL 4361597, at *10-11. Merriam-Webster defines "interfere" as "to enter into or take a part in the concerns of others," "to interpose in a way that hinders or impedes[,]" or "to act reciprocally so as to augment, diminish, or otherwise affect one another[.]" *Interfere*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/interfering.

[19] For example, there are numerous uses of the term "interfere" in the U.S. Code. *E.g.*, 15 U.S.C. § 77kk(c) ("[I]t shall be unlawful for [specified entity] . . . to do any act directly or indirectly which would interfere with or obstruct or hinder or which might be calculated to obstruct, hinder, or interfere with the policy or policies of the said Department of State or the Government of the United States . . ."); 18 U.S.C. § 245(b); 29 U.S.C. § 158(a); 29 U.S.C. § 2615(a)(1); 42 U.S.C. § 3617; 47 U.S.C. § 333. Thus, finding the term "interfere" to render H.B. 2048 unconstitutionally vague would have vast repercussions throughout the various civil and criminal codes of Oklahoma and the nation.

Furthermore, AbbVie knows that these contracts relate to the delivery of 340B drugs to pharmacies, and in fact, devotes pages of its brief describing how those contracts operate. The Rhode Island Legislature specifically responded to drug manufacturers' efforts, since 2020, to restrict contract pharmacy arrangements. Courts must "interpret the relevant words not in a vacuum, but with reference to the statutory context, 'structure, history, and purpose.'" *Abramski v. United States*, 573 U.S. 169, 179 (2014) (internal citation omitted). Given this history and context, AbbVie knows exactly what the Chapter 288 seeks to prevent. Its feigned ignorance about the meaning of the term "interfere" cannot be taken seriously.[20]

[20] AbbVie also argues that the statute is unconstitutionally vague because it does not require any scienter requirement such as intentionally or otherwise. But the absence of a scienter requirement alone does not render a statute unconstitutional. *Hotel & Motel Ass'n of Oakland v. City of Oakland*, 344 F.3d 959, 973 (9th Cir. 2003); *United States v. Harris*, 705 F.3d 929, 932 (9th Cir. 2013) (a statute's "lack of a scienter element does not render it unconstitutionally vague").

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Nicholas J. Hemond, do hereby certify that on September 18, 2025, a true and correct copy of the foregoing document was filed electronically through the Court's CM/ECF system, is available for viewing and downloading from ECF system, will be sent electronically to counsel of record as registered participants identified on the Notice of Electronic Filing.

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