IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

JEFFREY LANDRY, in his official capacity as Attorney General of Louisiana,

Defendant.

No. _____

Judge: _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

PRELIMINARY STATEMENT

1. Under the 340B Drug Pricing Program, 42 U.S.C. § 256b, ("340B"), drug manufacturers are required to provide significant price discounts to 15 statutorily specified types of safety net healthcare providers ("covered entities"). Congress authorized the Secretary of Health and Human Services ("HHS") to investigate and address any alleged manufacturer non-compliance via a centralized enforcement scheme, which provides for audits and the imposition of civil monetary penalties. Congress also authorized HHS to resolve any disputes that arise between manufacturers and covered entities through a federally administered administrative dispute resolution process.

2. In *Astra, USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), the Supreme Court rejected Santa Clara County's attempt to supplement these comprehensive statutory enforcement provisions with common-law remedies. Despite that holding, Louisiana recently passed a law that expressly attempts to supplement the comprehensive federal statutory scheme by purporting to define (and expand) the types of entities to which manufacturers must provide 340B-discounted drugs; impose new state-law procedures and penalties to compel compliance; and delegate responsibility to the Louisiana Attorney General to enforce these requirements and penalties.

3. But under the Supremacy Clause of the United States Constitution, Louisiana cannot substitute its own new requirements for what the federal statute already provides. Louisiana cannot dictate as a matter of state law how 340B should operate. Under the federal Constitution, Louisiana has no authority to impose conditions on drug manufacturers' participation in an exclusively federal program.

4. Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA") brings this action in order to declare unlawful this improper state interference in the federal 340B

scheme and to enjoin the Louisiana Attorney General from enforcing Louisiana Revised Statute § 40:2884-2885 against PhRMA's members and as to the sale of their drugs under 340B.

5. That result follows from the relevant statutory schemes. Congress enacted the 340B Drug Pricing Program in 1992 so that specified types of safety-net healthcare providers could obtain discounted drugs for their uninsured, underinsured, and low-income patients.

6. 340B forms part of an integrated series of federal programs under which drug manufacturers who want their outpatient drugs to be reimbursed under Medicare Part B or the federal share of Medicaid must typically participate in 340B and offer substantial discounts on certain drugs to certain defined "covered entities."

7. Congress, however, appreciated the need to carefully limit the burdens it was imposing on the manufacturers forced to bear the cost of these subsidies so as not to overly discourage participation in those other federal programs.

8. To achieve that balance, Congress in 340B crafted a comprehensive federal scheme to govern the discounts. Among other provisions in 340B, Congress:

- Specifically enumerated the 15 exclusive categories of healthcare providers that qualify as covered entities with the right to receive discounted drugs;
- Prohibited covered entities from selling or transferring the discounted drugs to anyone other than their patients;
- Established a formula for pricing 340B-discounted drugs;
- Defined how the relevant federal agencies must administer 340B (*e.g.*, through contracts between the federal government and manufacturers, known as Pharmaceutical Pricing Agreements ("PPAs"));

- Detailed how 340B was to be enforced by providing specified penalties for noncompliance; and

- Established a federal adjudicative process—Administrative Dispute Resolution ("ADR")—to resolve questions about the applicability of 340B's requirements and 340B's bounds.

9. With the limited universe of carefully defined covered entities, combined with the statutory anti-transfer and pricing provisions, Congress created a closed system that strictly defined the entities with a right to obtain 340B-discounted drugs and restricted the conveyance of those drugs only to eligible patients of those entities. That closed system limits manufacturers' discounting obligations and was designed to ensure that benefits reach only the intended beneficiaries of the federal program—covered entities and their patients—and are not diverted for other purposes at the expense of manufacturers.

10. The administration and enforcement provisions established an exclusive system of federal management that is designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120. The Supreme Court has already explained that each aspect of 340B is integral to the functioning of the whole. *See id.*

11. As the Supreme Court has also explained, the federal statute's centralization of administration and carefully defined enforcement authority within HHS was designed to ensure that 340B's carefully defined manufacturer obligations did not unduly burden manufacturers, who could potentially leave 340B and, as a result, also withdraw from participating in Medicare Part B and Medicaid. *See also* Br. for the United States as *Amicus Curiae* Supporting Petitioners at *10, *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, No. 09-1273, 2010 WL 4717264 (U.S. Nov. 19, 2010) (federal enforcement scheme "intended to be exclusive").

12. Despite the Supreme Court's clear statements regarding the need for centralized, "harmonious," and "nationwide" administration of 340B, Louisiana has intruded into the federal scheme and imposed its own conditions on participation in 340B by enacting a new statute, Act 358. Louisiana Revised Statute §§ 40:2881-2886 ("Act 358" or the "Act"); *see* House Bill No. 548 (enacted as Act 358, noting "DRUGS/PRESCRIPTION: Provides relative to the 340B drug pricing program"). Act 358 purports to mandate, as a matter of state law, that manufacturers participating in 340B provide 340B-discounted drugs not only to covered entities, but also to any and all pharmacies that enter into a contract with a covered entity ("contract pharmacies") in Louisiana, without limitation or condition (the "forced sale provision"). La. Rev. Stat. § 40:2884(A). Act 358 also broadly prohibits manufacturers and distributors from "interfer[ing]" with a pharmacy contracted with a 340B entity (the "interference provision"). La. Rev. Stat. § 40:2884(B). In doing so, the Act purports to define the scope of a manufacturer's 340B obligations within Louisiana, and effectively adds contract pharmacies to the list of congressionally enumerated entities to which manufacturers must provide 340B-discounted drugs as a condition of participating in other federal programs.

13. Multiple federal courts, however, including most recently the U.S. Court of Appeals for the Third Circuit, have already concluded that manufacturers are not obligated under 340B to provide discounted drugs to every pharmacy that a covered entity may choose to contract with, and that manufacturers are entitled to impose conditions and limitations on a covered entity's use of contract pharmacies. *See, e.g.*, *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 704 (3d Cir. 2023) (holding that 340B's text "suggests that [Congress] had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a*

plethora of pharmacies" (emphasis added)); *Novartis Pharms. Corp. v. Espinosa*, No. 21-cv-1479, 2021 WL 5161783, at *5-7 (D.D.C. Nov. 5, 2021).

14. Louisiana's Act 358 thus seeks to do the very thing that federal courts have already determined even the federal government cannot do: force manufacturers to provide 340B-discounted drugs to contract pharmacies without limitation.

15. Act 358 compounds its intrusion into 340B by imposing its own state-law penalties and other remedies for non-compliance (the "state-law enforcement provision"), thereby circumventing the exclusive federal oversight and enforcement mechanisms established by Congress. La. Rev. Stat. § 40:2885.

16. Specifically, Act 358 dictates that the failure to provide 340B-discounted drugs to contract pharmacies serving Louisiana residents is a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, Louisiana Revised Statute 51:1401 *et seq*., and subjects a violator to any and all remedies and penalties provided for in that state law in an action brought by the Louisiana Attorney General, including injunctive relief, civil penalties, restitution, and revocation of relevant business licenses and the ability to do business in Louisiana. La. Rev. Stat. §§ 51:1407-1408.

17. These procedures and remedies differ dramatically from, and extend far beyond, the specific and defined procedures and remedies that the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d).

18. For these and other reasons, Act 358 is unconstitutional as it is preempted by federal law.

19. Act 358 also suffers from an additional constitutional defect: unconstitutional vagueness. Act 358's interference provision provides that "[a] manufacturer . . . shall not interfere

with a pharmacy contracted with a 340B entity." La. Rev. Stat. § 40:2884(B). But the Act nowhere defines what constitutes "interference."

20. That provision does not provide notice to manufacturers regarding what conduct is prohibited. After all, the immediately prior provision specifies that manufacturers or distributors "shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity[.]" La. Rev. Stat. § 40:2884(A). The interference provision of the Act appears intended to add further requirements, but does not provide any rule or standard to govern the prohibited conduct and is substantially incomprehensible.

21. The forced sale provision suffers from the identical defect: It provides that manufacturers and distributors "shall not deny, restrict, prohibit, *or otherwise interfere with*" contract pharmacies' purchasing and acquiring of 340B price drugs, but provides no guidance to regulated entities on what conduct would constitute such unlawful "interfer[ence]." La. Rev. Stat. § 40:2884(A).

22. PhRMA brings this lawsuit seeking a declaration that Sections 40:2884-2885 of Act 358 are preempted and void for vagueness, and requests injunctive relief barring Defendant from enforcing them against PhRMA and its members.

PARTIES

23. Plaintiff PhRMA is a trade association representing the nation's leading innovative biopharmaceutical research companies and advocating for policies that encourage the discovery and development of important new pharmaceutical products. PhRMA's members, which manufacture and sell pharmaceutical products, participate in the federal 340B program and will thus be forced to deliver their drugs at a steep discount to Louisiana pharmacies under Act 358.

Neither the claims asserted nor the relief sought in the Complaint requires the participation of any individual member of PhRMA.

24. Defendant Jeffrey Landry is the Attorney General of Louisiana, the chief law enforcement officer of the state. The Attorney General is given enforcement authority over the challenged legislation. La. Rev. Stat. § 40:2885 (making violation of Act 358 a violation of Louisiana's Unfair Trade Practice and Consumer Protection Law); La. Rev. Stat. §§ 51:1407-1408 (giving the Attorney General enforcement authority over violations of Louisiana's Unfair Trade Practice and Consumer Protection Law).

JURISDICTION AND VENUE

25. PhRMA's causes of action arise under 28 U.S.C. § 1331, 42 U.S.C. § 1983, and the United States Constitution. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3).

26. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

27. This Court has inherent equitable powers to enjoin the actions of state officials if they contradict the federal Constitution or federal law. *Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

28. Venue is proper in this district because this action challenges a Louisiana law which is applicable to the sale of PhRMA's members' drugs in this district, and thus Act 358 purports to directly restrict and restrain PhRMA members' conduct in selling and distributing drugs within this district. 28 U.S.C. § 1391(b)(2).

29. Substantial amounts of PhRMA's members' drugs are sold under the 340B program to covered entities in this district. For example, HHS's website reflects that there are nine covered entities in Lafayette, LA; eight in Shreveport, LA; five in Lake Charles, LA; and four in Monroe,

LA. *See* HRSA, Covered Entity Search Criteria, available at https://340bopais.hrsa.gov/CoveredEntitySearch/000077285. The same HHS website reflects that those covered entities maintain a substantial number of contract pharmacy arrangements, including with contract pharmacies in this district. Accordingly, Act 358 is likely to be enforced against PhRMA members in this district.

30. Venue is also proper in this district because the Defendant maintains an office in each of Alexandria, Lafayette, Monroe, and Shreveport, which are all located in this district. 28 U.S.C. § 1391(b)(1).

BACKGROUND

A. 340B

31. Congress established 340B in 1992 to "provide[] protection from drug price increases to specified Federally funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

32. To that end, 340B "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities," known as "covered entities," that provide healthcare to certain underserved populations. *Pharm. Rsch. & Mfs. of Am. v. HHS*, 43 F. Supp. 3d 28, 31 (D.D.C. 2014) (quoting *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011)).

33. 340B now accounts for approximately seven percent of all prescription-drug sales in the United States. Karen Mulligan, PhD, University of Southern California Leonard D. Schaeffer Center for Health Policy & Economics, *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments* (Oct. 14, 2021), available at https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/; *see also* Adam J. Fein, *The 340B Program Climbed to $44*

Billion in 2021—With Hospitals Grabbing Most of the Money, *Drug Channels* (Aug. 15, 2022) ("Fein 2021"), available at https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html (discounted purchases under 340B reached a record of $43.9 billion in 2021). By 2026, 340B is estimated to become the "largest federal drug program, exceeding gross drug purchases through Medicare Part D, Medicare Part B, and Medicaid." Berkeley Rsch. Grp., 340B Program at a Glance (2021), available at https://media.thinkbrg.com/wp-content/uploads/2021/12/09062840/340B_Forecast-Report-Infographic_2021.pdf

34. 340B is governed by a federal statutory framework, implemented by the Health Resources and Services Administration ("HRSA"), a federal agency within HHS.

35. Under 340B, participating manufacturers must offer to each "covered entity" (which is defined by the federal 340B statute) certain outpatient drugs (also specified by statute) at or below a price (again set by statute), if such drugs are offered to any other purchasers. 42 U.S.C. § 256b(a)(1).

36. Federal law defines "covered entity" for purposes of 340B to mean an entity that "is one of" 15 types of specifically enumerated categories of nonprofit healthcare providers, 42 U.S.C. § 256b(a)(4), and that meets other specifically enumerated requirements, including that the entity does not engage in an unlawful transfer of 340B-discounted drugs and does not submit a duplicate discount (*see infra* at 14). 42 U.S.C. § 256b(a)(5).

37. Federally Qualified Health Centers, children's hospitals, critical access hospitals, sole community hospitals (*i.e.*, hospitals that are geographically isolated from other hospitals, 42 U.S.C. § 1395ww(d)(5)(D)(iii)), and certain other clinics and hospitals are all specifically defined as "covered entities" eligible to enroll and participate in 340B. *Id.*; *see also Am. Hosp. Ass'n v.*

Azar, 967 F.3d 818, 820-22 (D.C. Cir. 2020). Retail pharmacies are not among the listed covered entities. Indeed, *no* pharmacies and *no* for-profit entities are enumerated at all.

38. Federal law defines "covered outpatient drug" for purposes of 340B to have "the meaning given such term[] in section 1927(k) of the Social Security Act [42 U.S.C. § 1396r-8(k)]," 42 U.S.C. § 256b(b)(1), which in turn generally defines this term (subject to exceptions) to mean drugs and biologics approved by the federal Food and Drug Administration ("FDA") to "be dispensed only upon prescription," *id.* § 1396r-8(k)(2)(A). Covered outpatient drugs do *not* include, *inter alia*, drugs or biological products provided "as part of, or as incident to and in the same setting as" inpatient hospital services, hospice services, dental services, physicians' services, or outpatient hospital services and "for which payment may be made . . . as part of payment for" these services "and not as direct reimbursement for the drug." *Id.* § 1396r-8(k)(3). In other words, 340B pricing is available for outpatient drugs that are separately payable from medical services, and not for inpatient drugs.

39. Federal law defines the "ceiling price" for purposes of 340B to mean "the maximum price that covered entities may permissibly be required to pay for the drug." *Id.* § 256b(a)(1). Federal law also provides that participating manufacturers shall "calculate[]" the ceiling price by determining the difference between the drug's "Average Manufacturer Price" and its Medicaid rebate amount, as both are determined under Section 1927 of the Social Security Act, the Medicaid Drug Rebate Program statute. *Id.* § 256b(a)(1); *see also* 42 C.F.R. § 10.10 ("Ceiling price for a covered outpatient drug"). In plain English, the ceiling price is the highest price a manufacturer may charge to 340B covered entities for a covered outpatient drug on 340B-eligible purchases. That ceiling price is deeply discounted compared to the drug's ordinary price.

40. Manufacturers must "offer" these "ceiling price" discounts to "covered entities," and only "covered entities" may receive these discounts under the express terms of federal law. *See* 42 U.S.C. § 256b(a)(1). For-profit hospitals and commercial businesses such as retail pharmacies are not entitled to receive 340B pricing. *See id.*

41. So long as a manufacturer offers the discounted drugs to a "covered entity," as the federal statute requires, it need not "deliver [those] goods wherever and to whomever the buyer demands." *Sanofi Aventis U.S. LLC v. United States Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703 (3d Cir. 2023).

42. Indeed, "Congress's use of the singular 'covered entity' in the [statute] suggests that it had in mind one-to-one transactions between a covered entity and a drug maker without mixing in a plethora of pharmacies." *Id.* And "[n]o other language in Section 340B requires delivery to an unlimited number of contract pharmacies." *Id.*

43. To the contrary, 340B forbids covered entities from "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). In other words, covered entities are expressly prohibited from providing 340B-discounted covered outpatient drugs to anyone but their own patients.

44. Congress has not expressly commanded pharmaceutical manufacturers to participate in 340B. *See Astra USA*, 563 U.S. at 117-18. Instead, generally for their drugs to be eligible for reimbursement under either Medicare Part B or the federal share of Medicaid (programs that provide elderly and financially needy patient populations access to affordable healthcare), manufacturers must participate in 340B. 42 U.S.C. § 1396r-8(a)(1), (5); *see also Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 580 (2012) (describing threat to withhold federal Medicaid funding from States as coercive—a metaphorical "gun to the head").

45. Manufacturers "opt into" 340B by signing a form federal contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113. That form contract is known as the Pharmaceutical Pricing Agreement, or PPA. *Id.* at 117. PPAs do not meaningfully vary between manufacturers, but "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 111, 118.

46. If HHS determines that a manufacturer breached its 340B obligations, HHS can terminate the PPA and remove the manufacturer from 340B. *See* 42 U.S.C. § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412-13 (Dec. 12, 1996). The manufacturer, in turn, typically will then be forced to withdraw from participating in Medicare Part B and Medicaid and their drugs will no longer be eligible to receive reimbursements under those programs, which would have a profound impact on many vulnerable patient populations and our healthcare system. *See* 42 U.S.C. § 1396r-8(a)(1), (a)(5), (b)(4)(B)(v).

47. Given the stakes for Medicare Part B and Medicaid and their patient populations, Congress chose to assign oversight and enforcement responsibilities exclusively to HHS in order to ensure the delicate balance that maintains manufacturer participation. HHS, in turn, has delegated 340B's oversight and enforcement to its component agency, HRSA. Neither the 340B statute nor any federal regulations promulgated under it authorize, envision, or create room for state regulation regarding these issues within or on top of 340B. Indeed, the Supreme Court made that clear in *Astra*, holding that the administration and enforcement provisions established an exclusive system of federal management that is designed to be "harmoniously" administered on a "nationwide basis," with HHS "hold[ing] the control rein." *Astra*, 563 U.S. at 120.

48. Congress has also carefully specified the exclusive mechanisms available for administering 340B disputes and violations: audit, ADR, and an enforcement scheme directed by

HHS. For instance, the statute specifies that manufacturers have a right to audit covered entities to ensure that the covered entity is complying with the 340B program's requirements. 42 U.S.C. § 256b(a)(5)(C). Manufacturers, in turn, are also subject to compliance audits. *Id.* § 256b(d)(1)(B)(v).

49. The imposition of penalties for violating 340B is also directly committed to HHS: HRSA evaluates manufacturers' compliance with the 340B statute's requirements and may seek to have HHS impose civil monetary penalties on manufacturers that purposefully charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs.

50. Specifically, HRSA may seek to have HHS impose civil monetary penalties of nearly $6,323 "for each instance of overcharging" a covered entity. Annual Civil Monetary Penalties Inflation Adjustment, 87 Fed. Reg. 15,100, 15,105 (Mar. 17, 2022) (final rule); *see also* 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. § 10.11(a). "Overcharging" refers to charging a covered entity a price above the applicable 340B "ceiling price." Congress has specified that these civil monetary penalties can attach to manufacturers only where they "knowingly and intentionally" overcharge. 42 U.S.C. § 256b(d)(1)(B)(vi)(III).

51. 340B also provides for resolving 340B disputes between manufacturers and covered entities via an ADR process to be established through "[r]egulations promulgated by the Secretary [of Health and Human Services]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 826-27 (2010) (codified at 42 U.S.C. § 256b(d)(3)) (amending the statute to require HHS to promulgate regulations establishing ADR).

52. These regulations must "designate or establish a decision-making official or body within [HHS] to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price . . . and

claims by manufacturers that violations of [statutory prohibitions on conduct like unlawful transfer to non-covered entities] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)).

53. These regulations also must be designed with such safeguards and "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously"—including required audits and discovery. 42 U.S.C. § 256b(d)(3)(B).

54. To ensure finality and repose, the statute provides that "administrative resolution of a claim or claims . . . shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* § 256b(d)(3)(C).

55. Covered entities must also comply with additional requirements under 340B. As explained above, covered entities are prohibited from "resell[ing] or otherwise transfer[ring] the drug to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B) (prohibiting unlawful transfers). And covered entities are also prohibited from seeking or causing unlawful "duplicate discounts or rebates" from manufacturers. 42 U.S.C. § 256b(a)(5)(A). Such "duplicate discounting" most often occurs when a covered entity obtains a drug at the 340B price and dispenses it to a Medicaid patient, and the manufacturer then also pays a Medicaid rebate to the state Medicaid agency on the same drug.

B. Contract Pharmacy Abuses And Resulting Litigation

56. As noted above, 340B requires that a manufacturer offer discounted prices only to a "covered entity." 42 U.S.C. § 256b(a)(1).

57. Retail pharmacies, including community-based pharmacies, are not "covered entit[ies]," so they are ineligible to receive 340B discounts.

58. But certain private, for-profit entities—including the largest national chain pharmacies—have in increasing numbers sought to leverage 340B as a tool to enhance their profitability in a way that Congress never intended. This is accomplished through complicated

contractual arrangements between a covered entity, a pharmacy, and typically other entities like a third-party administrator.

59. The core feature of these arbitrage arrangements is that the for-profit pharmacies end up obtaining drugs purchased at the 340B price. These contract pharmacies, however, serve not only patients of 340B covered entities, but the general public as well—despite the fact that 340B-covered outpatient drugs are permitted to be dispensed only to patients of 340B covered entities.

60. Between 2010 and 2018, the number of such contract pharmacy arrangements with covered entities exploded, increasing "more than fifteen-fold, from about 1,300 to approximately 20,000 [as of 2018]." U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 10 (June 2018) ("2018 GAO Report"), available at https://www.gao.gov/assets/gao-18-480.pdf. A more recent study put the increase at 4,228%, with now "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" participating in 340B as contract pharmacies. Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 4, Berkeley Rsch. Grp. (Oct. 2020), available at https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf. By 2020, each covered entity used an average of 22 contract pharmacies. *Id.* at 7. As a result, the number of actual claims for 340B discounts nationwide *tripled* between 2014 and 2019. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 billion in 2019; Now Over 8% of Drug Sales*, Drug Channels (June 9, 2020), available at https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html; *see also* Fein 2021 (discounted purchases under 340B increased $5.9 billion between 2020 and 2021 alone).

61. Several federal watchdogs, including the U.S. Government Accountability Office ("GAO") and HHS's own Office of the Inspector General ("OIG"), have warned that the growth of these arrangements exacerbates concerns about abuse and unlawful 340B discounting. *See* 2018 GAO Report at 44 ("The identified noncompliance at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."); *id.* at 45 ("The expansion of contract pharmacies . . . increases potential risks to the 340B Program, such as risks related to diversion and duplicate discounts.").

62. Here is how the system has evolved over recent years: Under the "replenishment model" now in widespread use by contract pharmacies, the pharmacies sell drugs from their general inventories to all individuals (both 340B covered entity patients and non-340B covered entity patients). *See Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. On Health, Educ. Labor, & Pensions*, 115th Cong., at 11 (2018) (testimony of Ann Maxwell, Assistance Inspector Gen. for Evaluation & Inspections, OIG) ("Maxwell Testimony"), as downloaded from https://www.govinfo.gov/content/pkg/CHRG-115shrg30195/pdf/CHRG-l 15shrg30l 95.pdf ("[M]any contract pharmacies dispense drugs to all of their customers—340B-eligible *or otherwise*—from their *regular* inventory." (emphasis added)). Pharmacies sell those drugs at an undiscounted price or a rate negotiated by the patient's insurer that is significantly higher than the 340B-discounted price.

63. Then, after subsequent data analysis using undisclosed algorithms, the contract pharmacies purport to retroactively identify patients with some relationship to a covered entity—patients who were not previously identified as 340B-eligible at the time the drug was dispensed.[1] These black-box algorithms likely result in contract pharmacies claiming discounts where the

[1] *See, e.g.*, 2018 GAO Report, at 2; Maxwell Testimony, at 11.

pharmacies' customers do not qualify for them under 340B. *See* HHS Office of Inspector General ("OIG"), Mem. Report: Contract Pharmacy Arrangements in the 340B Program OEI 05-13-00431, at 16 (Feb. 4, 2014), available at https://bit.ly/3eWKmBQ.[2]

64. After identifying the drugs that they have sold to purported patients of a covered entity, the pharmacies then purchase additional drugs at the 340B-discounted price—nominally in the name of the covered entities—to "replenish" the drugs sold previously to the purported patients. Again, this is done after the fact, without the benefit of data verifying that these newly identified 340B patient prescriptions were actually issued in connection with a patient visit to a covered entity.

65. Once those replenishment drugs are received, the cycle starts anew: the 340B-discounted drugs are again comingled in the pharmacy's general inventory and dispensed to any individual who walks in the door, regardless of covered entity patient status. Decl. of Krista M. Pedley, *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 at ¶ 11 (HRSA Director of Office of Pharmacy Affairs stating that under the replenishment system, contract pharmacies use stock replenished at 340B prices as "neutral inventory" that "may be dispensed to any subsequent patient").

66. This "replenishment" practice may not result in discounts for covered entity patients (*i.e.*, the people that Congress intended to benefit from 340B)—but it can enhance the

[2] HHS OIG has acknowledged this problem. It discussed the following hypothetical: a physician, who practices part-time at a covered entity hospital, gives a prescription to a patient at his private practice. *See* Maxwell Testimony, at 11. Although this prescription would likely not qualify for 340B, *see* 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015), one contract pharmacy said it would claim a 340B discount because it simply matches the name of the prescriber with those who work at a 340B covered entity *at all* (even if only part time), *see* Maxwell Testimony, at 11. This demonstrates how contract pharmacies can expand the definition of an eligible "patient" to cover additional, non-340B prescriptions.

profitability of the pharmacies and covered entities involved. *See* U.S. Gov't Accountability Off., GAO-20-108, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, at 5 (Dec. 2019), available at https://www.gao.gov/assets/gao-20-108.pdf (explaining that covered entities "purchase [340B-discounted] drugs at the 340B Program price for all eligible patients regardless of the patients' income or insurance status" and "receiv[e] reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs"); Roby Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, at 3, 12 (2022), available at https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf (concluding that "most 340B-eligible patients at contract pharmacies are not directly benefiting from 340B discounts" and that each stakeholder in the 340B Program, including contract pharmacies, are "profit[ing] from 340B revenue"). Both CVS and Walgreens have publicly disclosed, for example, that 340B profits are material to their finances. CVS Health Corp., Annual Report (SEC Form 10-K), at 22 (Feb. 8, 2023), available at https://bit.ly/3Sh3Dl1; Walgreens Boots Alliance, Inc., Annual Report (SEC Form 10-K), at 28 (Oct. 13, 2022), available at http://bit.ly/3kflVXh.[3]

[3] *See also* Anna Wilde Matthews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients*, WALL STREET JOURNAL (Dec. 20, 2022), available at https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899 (explaining that many hospitals do not pass on 340B discounts to their patients and that 340B appears to bolster profits in well-off areas more than helping hospitals in less-privileged neighborhoods); Katie Thomas & Jessica Silver-Greenberg, *How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits*, NEW YORK TIMES (Sept. 24, 2022), available at https://www.nytimes.com/2022/09/24/health/bon-secours-mercy-health-profit-poor-neighborhood.html (explaining how one hospital "nakedly capitaliz[ed] on" 340B to turn a profit).

67. Besides diverting discounts intended for vulnerable populations, the explosion in contract pharmacy arrangements has also led to an increase in unlawful transfers of drugs purchased at a 340B price. *See, e.g.*, 42 U.S.C. § 256b(a)(5)(B) (prohibiting transfer or sale to anyone "who is not a patient of the [covered] entity"); U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 28 (Sept. 2011), available at https://www.gao.gov/assets/gao-11-836.pdf ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies."). Indeed, approximately two-thirds of violations for unlawful transfers uncovered by HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

68. In prior guidance, the federal government made clear that an entity that dispenses 340B drugs should determine patient eligibility when filling a prescription in order to comply with the statute and prevent the possibility of unlawful transfers. *See* 61 Fed. Reg. 43,549, 43,556 (Aug. 23, 1996). But that is not happening under the prevailing "replenishment" model used today. Instead, data matching exercises—which are conducted long after a contract pharmacy has filled a particular prescription—guess at which prescriptions might have come from a covered entity thereby qualifying for discounted status, and are very likely overestimating the number that did.[4]

69. The use of contract pharmacies can also exacerbate unlawful "duplicate discounting." 42 U.S.C. § 256b(a)(5)(A)(i). Unlawful duplicate discounting forces the manufacturer to provide a discount on its drug twice-over—once on the front end as a 340B

[4] This is one reason why claims for 340B-discounted drugs have grown tremendously, while the number of patients treated by covered entities has not. *See* William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, PIONEER HEALTH, at 5 (Mar. 2022), available at https://bit.ly/3MShVog.

discount to the covered entity, and again on the back end in the form of a rebate to the state Medicaid agency.

70. GAO has found that duplicate discounting happens with outsized frequency when covered entities use contract pharmacies. *See, e.g.*, 2018 GAO Report at 45; *see generally* U.S. Gov't Accountability Off., GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020), available at https://www.gao.gov/assets/gao-20-212.pdf.

71. The explosion in contract pharmacy arrangements, along with the increased use of the replenishment model and documented problems with program integrity, led in part to certain PhRMA members independently adopting new policies directed at addressing the 340B abuses reported by federal watchdogs. *See, e.g.*, *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF 13 at 17-19.

72. In response, the General Counsel of HHS issued a legal opinion on December 30, 2020, purporting to interpret the 340B statute and declaring that "*to the extent* contract pharmacies are acting as *agents* of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." HHS, Off. of the Sec'y, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program, at 1 (Dec. 30, 2020) ("Advisory Opinion"), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (emphasis added); *AstraZeneca*, 2021 WL 2458063, at *6 ("[T]he [Advisory] Opinion is the first document in which HHS explicitly concluded that *drug manufacturers* are required *by statute* to provide 340B drugs to *multiple* contract pharmacies."). In May 2021, HRSA issued letter decisions to the manufacturers who

were implementing policies to address 340B abuses. HRSA asserted that the manufacturers were in violation of 340B's mandates and threatened them with penalties. *See* HRSA, 340B Drug Pricing Program, *HRSA Determines Six Pharmaceutical Manufacturers Are In Violation of the 340B Statute*, available at https://www.hrsa.gov/opa/index.html.

73. Litigation ensued. Multiple pharmaceutical manufacturers—including several PhRMA members—sued HHS, HRSA, and relevant government officials, in their official capacities, in federal courts across the country.

74. Although the suits raise a variety of claims, each manufacturer centrally contends that manufacturers are not required, as a matter of federal law, to accede to covered entities' demands that they provide, without limitation or condition, 340B-priced drugs to any and all of their purported "contract pharmacies"—and that the federal government is barred from trying to enforce that interpretation of 340B. *See Eli Lilly & Co. v. Becerra*, No. 1:21-cv-81 (S.D. Ind.); *AstraZeneca Pharms. LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00634-FLW-LHG (D.N.J.); *Novo Nordisk Inc. v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-00806-FLW-LHG (D.N.J.); *Novartis Pharms. Corp. v. Becerra*, No. 1:21-cv-01479 (D.D.C.); *United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-1686-DLF (D.D.C.); *cf. Pharm. Rsch. & Mfrs. Ass'n of Am. v. Becerra*, No. 21-cv-00198-PWG (D. Md.).

75. Courts have repeatedly rejected the position that manufacturers must supply 340B-discounted drugs to as many contract pharmacies as a covered entity wants without limitation—the same requirement that Act 358 purports to impose here.

76. Most recently, the Third Circuit rejected the assertion that 340B requires manufacturers to provide 340B-discounted drugs to a theoretically unlimited number of contract

pharmacies. *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 704 (3d Cir. 2023); *id.* at 703 ("Nowhere does Section 340B mention contract pharmacies."). To the contrary, the Third Circuit noted that "Congress's use of the singular 'covered entity' in the [statute's] 'purchased by' language suggests that it had in mind one-to-one transactions between a covered entity and a drug maker *without mixing in a plethora of pharmacies*." *Id.* (emphasis added); *id.* (340B does not "require[] delivery to an unlimited number of contract pharmacies"). It also expressly enjoined the federal government from imposing this requirement. *Id.* at 706 (barring the federal government "from enforcing against [plaintiffs] its reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies"); *id.* at 704 (noting that "'Congress knew how to' grant covered entities permission to contract with third parties for distribution . . . but did not" (quoting *State Farm Fire & Cas. Co. v. United States ex. rel. Rigsby*, 580 U.S. 36, 39 (2016))).

77. The U.S. District Court for the District of Columbia similarly found that nothing forbids drug manufacturers from imposing reasonable conditions regarding contract pharmacies as part of manufacturers' participation in 340B. *Novartis Pharms*, 2021 WL 5161783, at *7; *see also AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58-59 (D. Del. 2021) (340B statute does not require manufacturers to provide 340B-discounted drugs to an unlimited number of contract pharmacies).[5]

78. Louisiana has now attempted to impose on manufacturers, as a matter of state law, an obligation in a federal program that federal courts have already concluded does not exist.

[5] Two appeals remain pending. *See United Therapeutics Corp. v. Johnson*,No. 21-5304 (D.C. Cir.), *Novartis Pharms. v. Espinosa*, No. 21-5299 (D.C. Cir.) (consolidated); *Eli Lilly & Co. v. Becerra*, Nos. 21-3128, 21-3405 (7th Cir.).

C. Louisiana Enacts Act 358 To Impose State-Law Conditions On 340B

79. On June 12, 2023, Louisiana enacted Act 358 (formerly known as Louisiana House Bill 548).

80. Act 358 expressly provides that its regulatory object is the federal 340B program. *See* La. Rev. Stat. § 40:2882(1) ("'340B drug' means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 U.S.C. 256b and is purchased by a covered entity as defined in 42 U.S.C. 256b(a)(4).").

81. Act 358 does not specify any source for the state's purported authority to add requirements to a comprehensive federal healthcare program.

82. Act 358 enacts Louisiana Revised Statute § 40:2884(A), which instructs that "[a] manufacturer . . . shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services."

83. Act 358 defines "pharmacy" in reference to Louisiana Revised Statute 37:1164(38), which in turn defines "pharmacy" as "any place located within [Louisiana] where drugs are dispensed and pharmacy primary care is provided, and any place outside of [Louisiana] where drugs are dispensed and pharmacy primary care is provided to residents of" Louisiana. Act 358 further requires that "residents who are provided pharmacy care shall be physically located in" Louisiana. La. Rev. Stat. § 40:2882(5).

84. Act 358's text nowhere requires that drugs purchased at a 340B-discounted price that are provided to a pharmacy be dispensed only to patients of a covered entity, as provided for by 340B. On the contrary, Act 358 expressly requires that a manufacturer cannot restrict or

prohibit contract pharmacies from purchasing or obtaining drugs at a 340B price in any circumstance.

85. Act 358 also enacts Louisiana Revised Statute § 40:2884(B), which instructs that "[a] manufacturer . . . shall not interfere with a pharmacy contracted with a 340B entity." The Act does not define what constitutes interference. The scope of this provision is unclear. *See supra* at 4-6.

86. Act 358 also does not acknowledge HRSA's enforcement authority or the congressionally mandated safeguards for administrative dispute resolution under 340B. It also does not consider the limitations on enforcement power Congress deemed necessary to maintain the 340B program's delicate balance. *See supra* at 12-14.

87. Instead, Act 358 makes any violation of its provisions a violation of Louisiana's Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. § 51.1401 *et seq.* La. Rev. Stat. § 40:2885. Louisiana's Unfair Trade Practices and Consumer Protection Law gives enforcement authority to the Louisiana Attorney General over violations of that provision. La. Rev. Stat. §§ 51:1407-1408.

88. The remedies and penalties provided for in the Louisiana Unfair Trade Practices and Consumer Protection Law in an action brought by the Attorney General include injunctive relief, civil penalties, restitution, and revocation of relevant business licenses and the ability to do business in Louisiana. La. Rev. Stat. §§ 51:1407-1408.

89. These procedures and remedies differ dramatically from, and extend far beyond, the procedures and remedies that the federal government may pursue under 340B. *See, e.g.*, 42 U.S.C. § 256b(d).

90. The Louisiana Attorney General is likely to enforce the Act. On April 24, 2023, the Louisiana Attorney General publicly announced his support for House Bill 548 (now Act 358). *See* @AGJeffLandry, TWITTER (Apr. 24, 2023, 1:42 PM), available at https://twitter.com/AGJeffLandry/status/1650555777759817731.

91. Act 358 is to take effect on August 1, 2023, by operation of Louisiana Constitution article III, section 19.

CLAIMS FOR RELIEF

CLAIM I
(Declaratory/Injunctive Relief—Preemption Under the Supremacy Clause of the U.S. Constitution and The Federal 340B Statute)

92. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

93. Federal law is "the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

94. Act 358's forced sale, interference, and state-law enforcement provisions are preempted because they intrude upon the exclusive field created by 340B and, worse, do so in a way that directly conflicts with the federal statute's terms and in a manner that is likely to generate conflict between state and federal regulators.

95. Field preemption exists where (1) Congress's "framework of regulation [is] 'so pervasive'" that Congress has "left no room for the States to supplement it," or (2) where there is a "federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona v. United States*, 567 U.S. 387 399 (2012) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

96. Field preemption is especially likely where a state law "'diminish[es] the [federal government]'s control over enforcement' and 'detract[s] from the integrated scheme of regulation'

created by Congress." *Id.* at 402 (quoting *Wisc. Dep't of Indus. v. Gould Inc.*, 475 U.S. 282, 288-89 (1986)).

97. As the Supreme Court has recognized, Congress created a comprehensive federal program in 340B and centralized control of that program exclusively within HHS to safeguard the delicate balance Congress struck. *See Astra*, 563 U.S. at 110 (noting the "interdependent" nature of 340B with other federal programs). There is no room for state supplementation in this field. As previously discussed, Congress created the exclusively federal field here through enactment of 340B. *See supra* at 1-5, 12-13. And unlike other federal healthcare programs, where Congress has assigned the States significant roles in administering those programs, it chose not to do so here. *See, e.g.*, 42 U.S.C. § 1396a (Medicaid statute providing for state plans); 42 U.S.C. § 18031 (Affordable Care Act establishing states' ability to set up health benefit plan exchanges).

98. And the system crafted by Congress was not open-ended. Instead, Congress designed a pervasive and integrated scheme of regulation through creation of a closed system. Congress carefully defined the program's limited intended beneficiaries (enumerated covered entities), set the nature of the benefit (a set ceiling price), and provided limitations on that benefit (to whom covered entities may furnish discounted drugs). Congress spoke in exacting detail because 340B must maintain a delicate balance to ensure that the program achieves its purpose without becoming too onerous for manufacturers, reinforcing that this is an area of dominant federal concern. And, finally, Congress set out an exclusive federal enforcement scheme to maintain the program as a harmonious whole.

99. Act 358 nevertheless seeks to directly intrude on this carefully balanced federal program by expanding the category of entities who must receive 340B-discounted drugs and implementing its own enforcement regime. *See* La. Rev. Stat. § 40:2882 (defining "340B drug"

as "a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to [the 340B statute] and is purchased by a covered entity as defined in [the 340B statute]"). That is far more than 340B requires, permits, or contemplates. *Sanofi Aventis U.S. LLC*, 58 F.4th at 703; *see also id.* at 706 (Third Circuit enjoining the federal government from mandating what Louisiana is now attempting to do). Accordingly, Act 358 impermissibly intrudes on the field of the operation of 340B by imposing additional obligations and a separate enforcement scheme and is accordingly preempted.

100. Act 358 is also conflict preempted. Conflict preemption "is present when (1) 'compliance with both state and federal law is impossible,' or (2) state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Aldridge v. Miss. Dep't of Corr.*, 990 F.3d 868, 875 (5th Cir. 2021) (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100-01 (1989)). A conflict exists between the 340B statute and federal PPAs, on the one hand, and Act 358's compulsory sale and interference provisions, on the other, for several reasons.

101. *First*, 340B requires only that manufacturers "offer" 340B-discounted drugs to covered entities (*i.e.*, that they provide some meaningful path for covered entities to access these medications). *See* 42 U.S.C. § 256b(a)(1); *Sanofi Aventis U.S. LLC*, 58 F.4th at 703. Congress placed strict limits on the types of entities entitled to 340B pricing (contract pharmacies are not included). Congress also expressly prohibited any covered entity from reselling or otherwise transferring a drug bought at the 340B price to anyone other than its patients. 42 U.S.C. § 256b(a)(5)(B). Several PhRMA members have already noted in pending litigation that because a retail pharmacy is not a "patient of [a covered] entity," it is prohibited by federal statute from

receiving 340B-discounted drugs. *See, e.g.*, *Eli Lilly & Co.*, No. 1:21-cv-81 (S.D. Ind. May 10, 2021), ECF No. 89 at 29.

102. By mandating that manufacturers not just offer 340B-discounted drugs, but also provide those 340B-discounted drugs to any and all contract pharmacies that a covered entity chooses to contract with, the Louisiana statute dramatically expands manufacturers' obligations under the federal program. Indeed, Louisiana is now seeking to impose as a matter of state law what even the federal government has been enjoined from requiring of manufacturers under federal law, in connection with an exclusively federal program. *Sanofi Aventis U.S., LLC*, 58 F.4th at 706. Louisiana's efforts conflict with both the plain text of the statute's requirements, and Congress's desire to create a carefully circumscribed and federally managed closed system.

103. *Second*, the Louisiana statute's broad prohibition on "otherwise interfer[ing]" with a contract pharmacy's "acquisition of a 340B drug," La. Rev. Stat. § 40:2884(A); *see also id.* § 40:2884(B), appears to prohibit manufacturers from imposing the very conditions on providing 340B-discounted drugs to contract pharmacies that multiple federal courts have said are permissible. And that prohibition would also seem to stretch as far as to prevent manufacturers from using the very federal administrative process Congress designed to the extent the use of that process "interferes" with the pharmacies' ability to obtain 340B-discounted drugs.

104. *Third*, Act 358's state-law enforcement provision conflicts with the carefully calibrated system created by Congress to ensure 340B compliance and raises the specter of inconsistent adjudications. La. Rev. Stat. § 40:2885. Congress specified that a manufacturer may be held liable only when it "*knowingly and intentionally*" overcharges a covered entity. *Id.* § 256b(d)(1)(B)(vi)(III) (emphasis added). Act 358 contains no such limitation. Moreover, Louisiana cannot enforce Act 358 without determining whether an entity is "authorized to

participate in 340B drug pricing"—an issue determined exclusively under the federal 340B statute. *See* La. Rev. Stat. § 40:2882(2) (defining 340B entity by reference to the federal definition); 42 U.S.C. § 256b(a)(4).

105. *Fourth*, Act 358 frustrates the "accomplishment and execution of the full purposes and objectives of Congress," *Aldridge*, 990 F.3d at 875 (quoting *ARC*, 490 U.S. at 100-01), in various ways in addition to those described above. For example, by purporting to impose additional, onerous terms on 340B (including terms the Third Circuit has held not even the federal government can impose), Act 358 increases the cost of participation in the federal Medicare and Medicaid programs, without providing corresponding additional benefits.

106. For all of the foregoing reasons, Act 358's forced sale, interference, and state-law enforcement provisions are preempted and their enforcement should be enjoined. *See Villas at Parkside Partners v. City of Farmers Branch*, 726 F.3d 524 (5th Cir. 2013) (Preemption may be implied where federal law is "so pervasive . . . that Congress left no room for the States to supplement it or where there is a federal interest . . . so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," where "compliance with both federal and state regulations is a physical impossibility," or "where the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (internal quotation marks and citation omitted)); *Witty v. Delta Air Lines, Inc.*, 366 F.3d 380, 385 (5th Cir. 2004); *City of Morgan City v. S. La. Elec. Co-op. Ass'n*, 31 F.3d 319, 324 (5th Cir. 1994).

CLAIM II
(Declaratory/Injunctive Relief—Due Process Clause—Void for Vagueness)

107. PhRMA re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

108. The Fourteenth Amendment's Due Process Clause provides that no State may "deprive any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1.

109. "The Fourteenth Amendment's guarantee of Due Process proscribes laws so vague that persons 'of common intelligence must necessarily guess at [their] meaning and differ as to [their] application.'" *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir. 2001) (quoting *Smith v. Goguen*, 415 U.S. 566, 572 n.8 (1974)).

110. To meet that standard, a statute imposing a civil penalty must not "command[] compliance in terms so vague and indefinite as really to be no rule or standard at all" and must not be "substantially incomprehensible." *Ford Motor Co. v. Tex. Dep't of Transp.*, 264 F.3d 493, 507 (5th Cir. 2001) (quoting *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122 n.2 (5th Cir. 1991)); *cf. FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) ("Even when speech is not at issue, the void for vagueness doctrine addresses at least two connected but discrete due process concerns: first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.").

111. This applies with particular force where First Amendment interests are implicated. Indeed, "[w]hen a statute is capable of reaching First Amendment freedoms, the doctrine demands a greater degree of specificity than in other contexts." *Trimble v. City of New Iberia*, 73 F. Supp. 2d 659, 668 (W.D. La. 1999); *see also Fox*, 567 U.S. at 253-54 (stricter application of vagueness doctrine is appropriate where statute involves speech in order "to ensure that ambiguity does not chill protected speech"); *Goguen*, 415 U.S. at 573 (considering First Amendment implications in applying due process vagueness analysis); *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972)

("[W]here a vague statute abuts upon sensitive areas of basic First Amendment freedoms, it operates to inhibit the exercise of those freedoms." (internal quotations and citations omitted)).

112. Act 358 broadly states that "[a] manufacturer or distributor shall not *interfere* with a pharmacy contracted with a 340B entity." La. Rev. Stat. § 40:2884(B) (emphasis added). Act 358 does not define "interfere." *Cf. Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 786 (4th Cir. 2023) (affirming district court grant of summary judgment to plaintiffs where law prohibited "interfer[ing] with or [disturbing] in any way or in any place the students or teachers of any school or college in this States" and noting that "[i]t is hard to know where to begin with the vagueness problems with th[e] statute"); *United States v. Elliot*, No. 2:17-cr-33, 2018 WL 11478272, at *1, 3 (N.D. Ga. Aug. 8, 2018) (concluding regulation that prohibited "[a]ny act or conduct by any person which interferes with, impedes or disrupts the use of the project" was unconstitutionally vague as applied); *Corp. of Haverford College v. Reeher*, 329 F. Supp. 1196, 1208-09 (E.D. Pa. 1971) (collecting cases where prohibitions on interference were deemed unconstitutionally vague). By its own terms, the interference provision does not limit itself to conduct but also reaches speech. Act 358 may, for example, prevent a manufacturer from publicizing information about unlawful transfers occurring at particular contract pharmacies if that is said to "interfere" with the contract pharmacies. Likewise, the Act may prevent manufacturers from filing complaints in the context of the federal system that Congress created for administrative dispute resolution. Uncertainty as to the scope of prohibited conduct and speech under Act 358 is the precise problem with vague laws.

113. Nor is there a way for manufacturers to determine the scope of the application of Act 358's interference provision. It prohibits interference with a "pharmacy," which Act 358 defines, through cross-reference, to include "any place located within [Louisiana] where drugs are

dispensed and pharmacy primary care is provided, and any place *outside* of [Louisiana] where drugs are dispensed and pharmacy primary care is provided to residents of [Louisiana]" if the "residents who are provided pharmacy care [are] physically located in [Louisiana]." La. Rev. Stat. § 40:2882(5) (cross-referencing La. Rev. Stat. 37:1164(38) (emphasis added)). As a result, Act 358's interference provision might apply nationwide to all pharmacies depending on whether a resident of Louisiana is provided drugs from that pharmacy.[6]

114. Manufacturers have no way of determining *ex ante* where individuals being treated by a pharmacy will reside. Nor is there any mechanism available for manufacturers to determine the physical location of an individual when a pharmacy provides them drugs.

115. The forced sale provision suffers from a similar defect: It provides that manufacturers and distributors "shall not deny, restrict, prohibit, *or otherwise interfere with*" contract pharmacies' purchasing and acquiring of 340B price drugs, but provides no guidance to regulated entities on what conduct would constitute such unlawful "interfer[ence]." La. Rev. Stat. § 40:2884(A).

116. On its face, Act 358 is unconstitutionally vague. Act 358's interference and forced sale provisions fail to provide persons of ordinary intelligence a reasonable opportunity to understand when or how their speech and conduct violate the Act. And the vagueness inherent in Act 358's interference provision authorizes or encourages arbitrary and discriminatory enforcement.

[6] Indeed, it is conceivable that Act 358 could govern conduct occurring entirely outside of Louisiana's borders (for example, where an out-of-state manufacturer directs speech or conduct at a pharmacy located in Texas and pharmacy happens to provide care to a Louisiana resident), raising additional serious constitutional concerns. *See, e.g.*, *Edgar v. MITE Corp*, 457 U.S. 624 (1982).

117. For these reasons, Act 358 is invalid under the Due Process Clause of the Fourteenth Amendment.

PRAYER FOR RELIEF

PhRMA respectfully prays that this Court:

a. issue an order and judgment declaring that Louisiana Revised Statute § 40:2884-2885 is unconstitutional and violates federal law;

b. issue an order and judgment declaring that Louisiana Revised Statute § 40:2884-2885 does not require PhRMA's members to offer price discounts under 340B to contract pharmacies in Louisiana or contract pharmacies located outside of Louisiana that fall within the ambit of the statute;

c. enjoin the implementation and enforcement of Louisiana Revised Statute § 40:2884-2885 against PhRMA's members;

d. enjoin the implementation and enforcement of Louisiana Revised Statute § 40:2884-2885 as to the sale of PhRMA's members' drugs under 340B;

e. award PhRMA costs and reasonable attorneys' fees, as appropriate; and

f. grant any other relief the Court finds just and appropriate.

Dated: July 27, 2023

Respectfully submitted,

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JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Pharmaceutical Research and Manufacturers of America

(b) County of Residence of First Listed Plaintiff Washington, D.C.
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

(see attachment)

DEFENDANTS

Jeffrey Landry, in his official capacity as Attorney General of Louisiana

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
42 U.S.C. § 1983; 28 U.S.C. § 2201

Brief description of cause:
Plaintiff seeks an order and judgment declaring that Louisiana Revised Statutes §§ 40:2884-2885 are unconstitutional and violate federal law.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
July 27, 2023

SIGNATURE OF ATTORNEY OF RECORD
s/Jeffrey J. Gelpi

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

ATTACHMENT TO CIVIL COVER SHEET

PLAINTIFF:

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Attorneys: Unknown