

APPENDIX

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APPENDIX A

No. 24-60342

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff—Appellant,

versus

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*
Defendant—Appellee.

Appeal from the United States District Court for the
Southern District of Mississippi
USDC No. 1:24-CV-164

Filed: April 9, 2026

OPINION

Before KING, HO, and RAMIREZ, *Circuit Judges.*

PER CURIAM:*

* This opinion is not designated for publication. *See* 5TH CIR.
R. 47.5.

Novartis Pharmaceuticals Corporation appeals the denial of its motion to preliminarily enjoin the enforcement of a state law governing the distribution of drugs that are discounted under a federal program. It contends that the state law is preempted by federal law. We AFFIRM.

I

Section 340B of the Public Health Service Act requires drug manufacturers that participate in Medicaid and Medicare Part B, like Novartis, to offer covered outpatient drugs at discounted prices to specified “covered entities,” such as eligible nonprofit and public hospitals, community health centers, and clinics. 42 U.S.C. §§ 256b(a)(1), (a)(4). The Health Resources and Services Administration, which administers the Section 340B program, has interpreted the statute to permit covered entities to dispense 340B priced drugs to their patients through pharmacies with which they contract. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549, 43549 (Aug. 23, 1996); Notice Regarding 340B Drug Pricing Program— Contract Pharmacy Services, 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010). The statute prohibits covered entities from diverting discounted drugs by reselling or transferring them to nonpatients and from obtaining duplicate discounts through receipt of both Section 340B discounts and Medicaid rebates for the same drug. 42 U.S.C. §§ 256b(a)(5), (b)(2).

Many participating drug manufacturers adopted policies restricting covered entities’ use of contract pharmacies to dispense 340B priced drugs based on

concerns that the arrangements create opportunities for abuse of the Section 340B program and impose significant costs on drug manufacturers. In response, several states, including Mississippi, enacted laws regulating drug manufacturers' treatment of contract pharmacies. Mississippi's H.B. 728 prohibits drug manufacturers from "deny[ing], restrict[ing], prohibit[ing], or otherwise interfer[ing] with, either directly or indirectly, the acquisition . . . or delivery of" 340B priced drugs to contract pharmacies. MISS. CODE ANN. § 41-149-7 (2024).

Novartis sued the Attorney General of Mississippi for declaratory and injunctive relief and sought a preliminary injunction against the enforcement of H.B. 728 on grounds that it was preempted by federal law. The district court found that Novartis had not shown a substantial likelihood of success on the merits of its claim and denied the motion for a preliminary injunction. Novartis appealed.

II

We review the denial of a preliminary injunction for abuse of discretion, reviewing underlying legal determinations de novo and factual findings for clear error. *Anibowei v. Morgan*, 70 F.4th 898, 902 (5th Cir. 2023); *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 642 (5th Cir. 2025).

A party seeking a preliminary injunction must establish:

- (1) a substantial likelihood of success on the merits,
- (2) a substantial threat of irreparable injury if the injunction is not issued,
- (3) that the threatened injury if the

injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

AbbVie, 152 F.4th at 642 (quoting *Jones v. Tex. Dep't of Crim. Just.*, 880 F.3d 756, 759 (5th Cir. 2018)). When the government is a party, factors three and four merge. *Id.*

III

Novartis argues that because H.B. 728 “dramatically expands” the scope of Section 340B, the district court erred in finding that it failed to show a likelihood of success on the merits of its claim that under the Supremacy Clause, H.B. 728 is preempted by federal law.

The Supremacy Clause provides that the laws of the United States “shall be 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. “Congress may implicitly preempt state law in two ways: field preemption and conflict preemption.” *AbbVie*, 152 F.4th at 645. Field preemption occurs when Congress’s intent to exclusively occupy a field can be inferred from pervasive federal regulation or a dominant federal interest. *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Janvey v. Democratic Senatorial Campaign Comm., Inc.*, 712 F.3d 185, 200 (5th Cir. 2013). Conflict preemption occurs when a state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Arizona*, 567 U.S. at 399. In areas traditionally regulated by the states, courts

apply a presumption against preemption, requiring a clear and manifest congressional intent to displace state law. *Deanda v. Becerra*, 96 F.4th 750, 761 (5th Cir. 2024).

Novartis first argues that the district erred in applying the presumption against preemption because H.B. 728 does not regulate traditional state police powers. We recently rejected a pre-enforcement preemption challenge to H.B. 728 substantially similar to that of Novartis in *AbbVie*. *AbbVie* explained that H.B. 728 regulates the distribution of drugs to patients and the role of pharmacies in that process—areas of public health and consumer protection traditionally governed by the states. 152 F.4th at 646–47; *see also AbbVie, Inc. v. Murrill*, 166 F.4th 528, 539 (5th Cir. 2026) (applying *AbbVie* to a materially indistinguishable Louisiana law and rejecting the argument that the presumption against preemption did not apply because the Louisiana law regulates public health and consumer protection, areas traditionally within a state’s police powers). Because *AbbVie* found that H.B. 728 regulates areas traditionally governed by the states, the presumption against preemption applies, and the district court did not err in applying it.

Novartis next argues that the district erred by finding that H.B. 728 is not field preempted by federal law because Congress intended to occupy the field of the Section 340B program. *AbbVie* explained that Section 340B is a drug pricing program that regulates costs, eligibility, and compliance, but it does not govern “the distribution of [340B priced] drugs to patients and the role of pharmacies in such

distribution.” 152 F.4th at 647. Because Congress left those matters unaddressed, they remained subject to state regulation. *Id.* at 646–47. And in any event, because H.B. 728 regulates areas traditionally reserved for the states, the presumption against preemption applies, reinforcing *AbbVie*’s conclusion that Congress did not intend to exclusively occupy the field. *Id.* at 647.

Finally, Novartis argues that the district erred by not finding that H.B. 728 interferes with federal requirements. *AbbVie* found that H.B. 728 “does not compel manufacturers to ‘offer’ discounted drugs to contract pharmacies in the way that Section 340B compels . . . [manufacturers] to ‘offer’ these drugs to covered entities.” *Id.* at 647. Nor does “H.B. 728’s enforcement scheme . . . conflict with Section 340B’s enforcement scheme,” it noted, because the statutes do not regulate the same subject matter. *Id.* at 647–48. For these reasons, *AbbVie* held, H.B. 728 does not stand as an obstacle to Section 340B’s objectives. *Id.*

Novartis seeks to distinguish *AbbVie*, noting that it found insufficient record evidence to show that H.B. 728 permits diversion of discounted drugs in violation of Section 340B. Here, Novartis argues that H.B. 728 prohibits drug manufacturers from maintaining contract pharmacy policies that are permitted under federal law, which in turn forces them to extend discounts beyond what Section 340B requires. But *AbbVie* expressly found that H.B. 728 “does not compel manufacturers to ‘offer’ discounted drugs to contract pharmacies”; it only requires them to allow covered entities to receive 340B priced drugs through the pharmacies they use to distribute drugs. 152 F.4th

at 647 (citation modified). Because *AbbVie* rejected the same theories that Novartis advances here, it controls, and we are bound by that holding under our rule of orderliness. See *Murrill*, 166 F.4th at 539 (finding that “[*AbbVie*] controls” the preemption analysis for a materially identical Louisiana statute); *Jacobs v. Nat’l Drug Intel. Ctr.*, 548 F.3d 375, 378 (5th Cir. 2008) (“It is a well-settled Fifth Circuit rule of orderliness that one panel of our court may not overturn another panel’s decision, absent an intervening change in the law, such as by a statutory amendment, or the Supreme Court, or our *en banc* court.”).

Because Novartis failed to show a likelihood of success on the merits of its preemption claim, the district court did not abuse its discretion by denying a preliminary injunction. See *AbbVie*, 152 F.4th at 648.

AFFIRMED.

8a

APPENDIX B

No. 24-60342

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff—Appellant,

versus

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*
Defendant—Appellee.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:24-CV-164

Filed: May 5, 2026

JUDGMENT

Before KING, HO, and RAMIREZ, *Circuit Judges.*

This cause was considered on the record on appeal
and was argued by counsel.

IT IS ORDERED and ADJUDGED that the
judgment of the District Court is AFFIRMED.

IT IS FURTHER ORDERED that appellant pay to appellee the costs on appeal to be taxed by the Clerk of this Court.

The judgment or mandate of this court shall issue 7 days after the time to file a petition for rehearing expires, or 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, whichever is later. See FED. R. APP. P. 41(B). The court may shorten or extend the time by order. See 5TH CIR. R. 41 I.O.P.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*

Defendant.

Civil No. 1:24-cv-164-HSO-BWR

Filed: July 1, 2024

MEMORANDUM OPINION AND ORDER
DENYING MOTION [4] FOR
PRELIMINARY INJUNCTION

This matter comes before the Court on Plaintiff Novartis Pharmaceuticals Corporation’s (“Novartis” or “Plaintiff”) Motion [4] for Preliminary Injunction. Having considered the allegations set forth in Plaintiff’s Complaint [1], the parties’ Memoranda [5], [12], [27], and relevant legal authority, and having heard argument at a hearing held on June 27, 2024, the Court will deny the Motion [4].

I. BACKGROUND

Plaintiff's Motion [4] asks the Court to enjoin the enforcement of Mississippi's recently enacted "Defending Affordable Prescription Drug Costs Act," 2024 Miss. H.B. 728 ("H.B. 728"), which is set to take effect on July 1, 2024. House Bill 728 concerns a federal program referred to as Section 340B. *See* 42 U.S.C. § 256b. Under Section 340B, pharmaceutical manufacturers who participate in Medicaid and Medicare Part B must offer certain drugs at discounted prices to certain healthcare providers, called "covered entities," that generally provide care for the poor. *See infra*, Part I.A. In essence, H.B. 728 requires manufacturers to deliver drugs ordered through the 340B program to for-profit pharmacies called "contract pharmacies" with which covered entities have arrangements under which the pharmacy will dispense discounted drugs to the covered entity's patients.

Plaintiff claims that H.B. 728, in requiring it to deliver discounted drugs to an unlimited number of contract pharmacies, invalidly expands its obligation to provide discounted drugs to covered entities. *See id.* at 2, 6–7. It asserts that H.B. 728 is preempted by § 256b and various federal laws—such as patent laws—that provide regulatory exclusivities that enable manufacturers to reap high profits as incentives for innovation in pharmaceuticals. *See id.* at 1–3. Plaintiff therefore seeks a preliminary injunction to stay the enforcement of H.B. 728. Because it is unable to satisfy the necessary elements for such relief, Plaintiff's Motion [4] will be denied.

A. The Section 340B program

Section 340B requires pharmaceutical manufacturers that want the federal government to cover their drugs under Medicaid and Medicare Part B to provide discounts on their drugs to certain healthcare providers. 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5); *see Sanofi Aventis U.S. LLC v. United States Dep’t of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *judgment entered*, No. 21-3167, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). Those healthcare providers are “called ‘340B’ or ‘covered’ entities,” and “include public hospitals and community health centers, many of” which are “providers of safety-net services to the poor.” *Astra USA, Inc. v. Santa Clara Cnty., Cal.*, 563 U.S. 110, 113 (2011). The 340B Program “is superintended by the Health Resources and Services Administration,” (“HRSA”), “a unit of the Department of Health and Human Services,” (“HHS”). *Id.*

“Drug manufacturers,” such as Plaintiff, “opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement” (“PPA”) “used nationwide.” *Id.* These agreements “are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS.” *Id.* PPAs must “require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” § 256b(a)(1).

Through Section 340B, Congress leverages the federal government’s market power in healthcare—

Medicare and Medicaid cover “almost half the annual nationwide spending on prescription drugs,” *Sanofi Aventis*, 58 F.4th at 699 (citing Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (2022))—to aid covered entities in their mission to care for low-income Americans, *see id.* The statute enables covered entities “to give uninsured patients drugs at little or no cost.” *Id.* Covered entities also obtain “extra revenue from serving insured patients” because “they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount.” *Id.* (citing Gov’t Accountability Off., *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 17–18 (GAO-11-836, Sept. 2011)).

Section 340B contains two provisions that prohibit covered entities from abusing their ability to obtain discounted drugs. Covered entities cannot “resell or otherwise transfer” discounted drugs “to a person who is not a patient of the entity.” § 256b(a)(5)(B). Covered entities also cannot obtain “duplicate discounts or rebates,” meaning they cannot obtain Medicaid rebates under title XIX of the Social Security Act, *see* 42 U.S.C. § 1396 *et seq.*, for drugs that they purchase at a discount under Section 340B, *see* § 256b(a)(5)(A)(i).

To ensure covered entities do not resell discounted drugs or obtain duplicate discounts, the statute contains an auditing provision. It states:

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an

agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

§ 256b(a)(5)(C). And “[i]f the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing,” that the covered entity illegally resold discounted drugs or obtained duplicate discounts, “the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug . . . provided under the agreement between the entity and the manufacturer.” § 256b(a)(5)(D).

The Secretary can impose additional sanctions. Covered entities that the Secretary finds knowingly and intentionally resold discounted drugs must “pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under [§ 256(a)(5)(D)].” § 256b(d)(2)(B)(v)(I). Where the Secretary finds the covered entity's reselling “was systematic and egregious as well as knowing and intentional,” the Secretary can remove the covered entity from the program entirely. § 256b(d)(2)(B)(v)(II).

B. The dispensation of 340B drugs at contract pharmacies and related litigation

The issue in this case concerns a matter notably absent from the foregoing discussion: how discounted drugs under Section 340B are to be delivered to patients of covered entities. Between 1996 and March 2010, HRSA’s 1996 Guidance “acknowledged that section 340B ‘is silent as to permissible drug distribution systems,’ but it nonetheless sought to fill ‘gaps in the legislation’ and thereby ‘move the program forward.’” *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C. Cir. 2024) (quoting Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,549–50 (Aug. 23, 1996) (“1996 Guidance”). Given that “many covered entities use outside pharmacies to distribute drugs to their patients,” HRSA’s 1996 Guidance “stated that a covered entity without an in-house pharmacy may contract with a single outside pharmacy to dispense drugs at a single location.” *Id.* at 457 (citing 1996 Guidance at 43,555). The 1996 Guidance also required that, “in directing shipments to its contract pharmacy,” the covered entity “must retain title to the drugs and thus ‘be responsible’ for any diversion or duplicate discounts.” *Id.* (citing 1996 Guidance at 43,553).

In 2010, HRSA shifted course. HRSA’s 2010 Guidance took the position that “covered entities may contract with an unlimited number of outside pharmacies and may do so regardless of whether the entities have in-house pharmacies.” *Id.* (citing Notice Regarding 340B Drug Pricing Program—Contract

Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010) (“2010 Guidance”). In its view, this Guidance “would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients.” 2010 Guidance at 10,273. HRSA did not change its view that covered entities “must maintain title to and responsibility for the drugs.” *Novartis*, 102 F.4th at 457 (citing 2010 Guidance at 10,277). HRSA considered comments following the release of proposed guidelines in 2007, Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 72 Fed. Reg. 1,540 (Jan. 12, 2007), asserting that allowing covered entities to dispense Section 340B drugs through multiple contract pharmacies would enable diversion and duplicate discounts, see 2010 Guidance at 10,272–75. But it ultimately decided that covered entities could use multiple contract pharmacies if “they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition,” including that “[a]uditable records must be maintained to demonstrate compliance with those requirements.” *Id.* at 10,273.

In 2020, many pharmaceutical manufacturers sought to prevent covered entities from using multiple contract pharmacies to dispense Section 340B drugs by implementing policies “limit[ing] the number and kinds of contract pharmacies to which they would ship orders.” *Novartis*, 102 F.4th at 458. As Plaintiff argues in its Memorandum [5], pharmaceutical

manufacturers were and remain concerned about the model covered entities and contract pharmacies often use in dispensing and accounting for Section 340B drugs. *See* Memo [5] at 14–15. Plaintiff refers to that model as the “replenishment model.” *Id.* Put simply, under this model, a contract pharmacy first dispenses prescription drugs to all its customers from one supply of drugs, which it purchased at full price from the manufacturer. *Id.* According to Plaintiff, the pharmacy—or a third-party administrator—determines whether a customer was a covered-entity patient after it dispenses the drug “based on an opaque formula generally not shared with manufacturers.” *Id.* The pharmacy then informs the covered entity of the quantity of drugs it dispensed to the entity’s patients. *Id.* The covered entity then places an order of Section 340B drugs in that quantity as a “replenishment” of the drugs dispensed to covered-entity patients. *See id.*

As the D.C. Circuit recognized, “[m]anufacturers,” such as Plaintiff, “have argued that these arrangements lead to unlawful diversion and duplicate discounts.” *Novartis*, 102 F.4th at 458. Under the replenishment model, “[t]he covered entity [and] the pharmacy . . . often divvy up the spread between the discounted price and the higher insurance reimbursement rate.” *Id.* at 457. So, covered entities and contract pharmacies both have “a financial incentive to catalog as many prescriptions as possible as eligible for the discount.” *Id.* at 457–58.

In 2020, HHS, concerned about manufacturers’ policies limiting covered-entity patients’ access to medications, issued an advisory opinion stating that

pharmaceutical manufacturers are *required* to ship Section 340B drugs to an unlimited number of contract pharmacies. *See Sanofi Aventis*, 58 F.4th at 701 (citing HHS Off. Gen. Couns., *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* (Dec. 30, 2020), <https://perma.cc/L7W2-H597> (“2020 Advisory Opinion”)). “HHS reasoned that 340B drugs are ‘purchased by’ a covered entity no matter how they are distributed,” and so, “the ‘situs of delivery . . . is irrelevant.”’ *Id.* at 701 (citing 2020 Advisory Opinion at 1–3). Both the Third Circuit and the D.C. Circuit concluded, however, that Section 340B is silent about delivery, and that the federal statute’s requirement that manufacturers offer discounts to covered entities did not implicitly permit HHS to mandate that they comply with any delivery practice the covered entities desire. *See id.* at 703–06; *Novartis*, 102 F.4th at 460–63.

In response, states have begun to impose explicitly what HHS had purported to impose by guidance. For example, in 2021, Arkansas enacted Act 1103, which “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying the pharmacy access to a covered entity’s 340B drugs,” and “prohibits pharmaceutical manufacturers from interfering in a covered entity’s agreement with a contract pharmacy by denying 340B drug pricing to covered entities who use contract pharmacies for distribution.” *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) (citing Ark. Code Ann. § 23-92-604(c)). An association of pharmaceutical manufacturers sought an injunction against

enforcement of the Arkansas law on a theory that Section 340B preempts it. *Id.* at 1139–40. The Eighth Circuit, however, disagreed. *Id.* As to field preemption, the Eighth Circuit concluded that “the 340B Program is not so pervasive that Congress left no room for the States to supplement it,” given that the statute is “‘is silent about delivery’ of drugs to patients.” *Id.* at 1143 (quoting *Sanofi Aventis U.S. LLC*, 58 F.4th at 703) (other quotation marks and citation omitted). Concerning conflict preemption, because the Arkansas law “does not require manufacturers to provide 340B pricing discounts to contract pharmacies,” and “does not set or enforce discount pricing,” the Eighth Circuit found that “the delivery of a covered entity’s 340B drugs to contract pharmacies for dispensing creates no obstacle” to the statute’s purpose. *Id.* at 1145. In fact, the Eighth Circuit observed that the Arkansas law “assists in fulfilling the purpose of 340B,” in that it facilitates the distribution and dispensation of discounted 340B drugs. *Id.*

On April 12, 2024, the Governor of Mississippi signed H.B. 728, which had been enacted by the state legislature. Ex. [12-1] (H.B. 728). House Bill 728 provides that “[a] manufacturer or distributor 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.” H.B. 728 § 4. The law defines a “340B drug” as a covered outpatient drug “that has been subject to any

offer for reduced prices by a manufacturer pursuant to [Section 340B].” H.B. 728 § 2(a). A violation of H.B. 728 constitutes a violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 *et seq*, *see* H.B. 728 § 5, which provides for both civil and criminal penalties and is enforced by Mississippi’s Attorney General, *see* Miss Code Ann. §§ 75-24-9 (covering injunctive relief), 75-24-19 (covering civil penalties for violations of injunctions issued under § 75-24-9, and for knowing and willful violations of the statute), 75-24-20 (covering criminal penalties for knowing and willful violations).

C. Procedural history

On June 3, 2024, Plaintiff Novartis Pharmaceuticals Corporation filed a Complaint [1] in this Court seeking a declaratory judgment under 28 U.S.C. § 2201 that H.B. 728 is preempted by federal law. Compl. [1] at 24. It likewise sought temporary, preliminary, and permanent injunctive relief against the Attorney General of Mississippi, enjoining her from enforcing H.B. 728 against Plaintiff. *Id.* at 25. Plaintiff filed a Motion [4] for Preliminary Injunction on June 4, 2024, and argues that H.B. 728 is preempted under conflict and field preemption. *See generally* Memo [5]. Defendant, Mississippi Attorney General Lynn Fitch, (“Defendant”) responded on June 17, 2024, Resp. [11], and the American Hospital Association, 340B Health, the Mississippi Hospital Association, and the Rural Hospital Alliance filed an Amicus Brief [17] on June 18, 2024, in support of Defendant. The Court held a hearing on the Motion [4] on June 27, 2024.

II. DISCUSSION

A party seeking a preliminary injunction must show: “(1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable harm if the injunction does not issue, (3) that the threatened injury outweighs any harm that will result if the injunction is granted, and (4) that granting the injunction is in the public interest.” *Clark v. Commodity Futures Trading Comm’n*, 74 F.4th 627, 640–41 (5th Cir. 2023); see Fed. R. Civ. P. 65. Factors three and four, “[t]he balance-of-harms and public-interest factors[,] merge when the government opposes an injunction.” *Career Colleges & Sch. of Texas v. United States Dep’t of Educ.*, 98 F.4th 220, 254 (5th Cir. 2024) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). “A preliminary injunction is an extraordinary remedy and should be granted only if the movant has clearly carried the burden of persuasion with respect to all four factors.” *Allied Mktg. Grp., Inc. v. CDL Mktg., Inc.*, 878 F.2d 806, 809 (5th Cir. 1989).

Plaintiff cannot satisfy the first requirement because it has not demonstrated a “substantial likelihood of success on the merits.” *Clark*, 74 F.4th at 640. The Court will therefore deny the Motion [4] and need not reach the other elements.

A. Preemption generally

The Supremacy Clause of the United States Constitution provides that federal law “shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.” Art. VI, cl. 2. “Under this principle,

Congress has the power to preempt state law.” *Arizona v. United States*, 567 U.S. 387, 399 (2012).

When a party raises preemption, “[t]he purpose of Congress is the ultimate touchstone’ of [the] analysis.” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978)) (other citations and quotations omitted). Preemption may be “compelled whether Congress’ command is explicitly stated in the statute’s language or implicitly contained in its structure and purpose.” *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (internal quotation marks and citation omitted). But the Court cannot “assume[] lightly that Congress has derogated state regulation, but instead [should] address[] claims of pre-emption with the starting presumption that Congress does not intend to supplant state law.” *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995). And “[d]eference to our federalism counsels a presumption that areas of law traditionally reserved to the states . . . are not to be disturbed absent the clear and manifest purpose of Congress.” *In re Davis*, 170 F.3d 475, 481 (5th Cir. 1999) (en banc) (internal quotation marks and citations omitted).

Three categories of preemption exist: “when (1) a federal statute expressly preempts state law,” (“express preemption”); “(2) federal legislation pervasively occupies a regulatory field,” (“field preemption”); “or (3) a federal statute conflicts with state law,” (“conflict preemption”). *Deanda v. Becerra*, 96 F.4th 750, 760–61 (5th Cir. 2024) (citing *Arizona*, 567 U.S. at 398–400). Plaintiff does not contend that

the 340B Program, or federal drug laws that provide regulatory and patent exclusivity periods, expressly preempt Mississippi law. *See generally* Memo [5]. Rather, Plaintiff argues that the 340B Program implicitly preempts Mississippi law under conflict preemption and field preemption, *id.* at 22–28, and that Mississippi law conflicts with federal drug laws that provide regulatory and patent exclusivity periods, *id.* at 28–31.

B. Section 340B does not preempt H.B. 728 under conflict preemption

Conflict preemption arises “where ‘compliance with both state and federal law is impossible,’ or where ‘the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 377 (2015) (quoting *California v. ARC America Corp.*, 490 U.S. 93, 100, 101 (1989)) (other internal quotation marks omitted). “In either situation, federal law must prevail.” *Id.*

Plaintiff does not contend that compliance with both Mississippi and federal law is impossible. *See generally* Memo [5]. So, Plaintiff must show that Mississippi law “produce[s] a result inconsistent with the objective of the federal statute,” *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947), such that it “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Plaintiff must meet “a high threshold” to succeed on such a theory. *Barrosse v. Huntington Ingalls, Inc.*, 70 F.4th 315, 320 (5th Cir. 2023) (quoting *Chamber of Com. v. Whiting*, 563 U.S. 582, 607

(2011)), *cert. denied*, 144 S. Ct. 557 (2024). “Courts may not conduct ‘a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives [because] such an endeavor would undercut the principle that it is Congress rather than the courts that pre-empts state law.’” *Id.* (quoting *Whiting*, 563 U.S. at 607) (alteration in original).

In a case like this one, “[p]reemption analysis begins ‘with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’” *Deanda*, 96 F.4th at 761 (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008)). That is because a state law regulating health and safety falls within a state’s traditional police powers. See *Hillsborough Cnty., Fla. v. Automated Med. Lab’ys, Inc.*, 471 U.S. 707, 710, 716 (1985) (holding that a local regulation of blood donation centers, including “donor testing and recordkeeping requirements beyond those contained in the federal regulations,” was not preempted because the challenger did not “present a showing of implicit pre-emption of the whole field, or of a conflict between a particular local provision and the federal scheme, that [was] strong enough to overcome the presumption that state and local regulation of health and safety matters can constitutionally coexist with federal regulation”); *Elam v. Kansas City S. Ry. Co.*, 635 F.3d 796, 813 (5th Cir. 2011) (discussing how the Court should “begin with the assumption that Congress did not intend to supersede the historic police powers of the states to protect the health and safety of their citizens” (internal quotation marks and citation omitted)).

House Bill 728 plainly falls under the umbrella of a health and safety regulation. It prohibits manufacturers from refusing to deliver Section 340B drugs to contract pharmacies, presumably to maximize covered-entity patients' access to drugs for which the manufacturers have already agreed to provide a discount. The state statute therefore triggers the presumption against preemption. *See Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003) (plurality opinion of Stevens, J.) (applying “[t]he presumption against federal pre-emption of a state statute designed to foster public health” (citing *Hillsborough Cnty.*, 471 U.S. at 715–18), and rejecting a preemption claim challenging a Maine policy that subjected drug manufacturers’ pharmaceuticals to prior authorization procedures before providing state Medicaid coverage for them unless the manufacturers agreed to provide rebates to Maine residents beyond rebates the Medicaid Act provides for); *Wyeth v. Levine*, 555 U.S. 555, 578 (2009) (“[T]he FDA traditionally regarded state law as a complementary form of drug regulation.”); *McClain*, 95 F.4th at 1144 (holding that Section 340B does not preempt state law prohibiting manufacturers from precluding covered entities from making dispensation contracts with pharmacies in part because “[p]harmacy has traditionally been regulated at the state level, and we must assume that absent a strong showing that Congress intended preemption, state statutes that impact health and welfare are not preempted”).

Plaintiff argues that the law does not trigger this presumption, but the Court is unpersuaded. *See Reply* [27] at 2. Plaintiff cites *Lofton v. McNeil Consumer &*

Specialty Pharms., 672 F.3d 372 (5th Cir. 2012), to assert that “the Supreme Court has often declined to apply the presumption in its conflict-preemption analysis.” *Id.* *Lofton* merely states that “whatever value or relevance a presumption against preemption of state tort law should play is uncertain” given its observation that the Supreme Court’s “majority opinion in [*PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011)] made no reference to the ‘presumption’ in the course of upholding implied conflict preemption over state law claims for failure to maintain adequate warning labels for FDA-approved generic drugs.” 672 F.3d at 378. *Lofton*’s statements about the scope of the presumption against preemption do not mean that the presumption against preemption no longer applies.

Further, *Lofton*’s statement that “the primacy of the state’s police powers is not universal” is inapplicable here. *Id.* *Lofton* discussed state-law tort claims based on fraud on the FDA. *See id.* at 378–79. In that context, “the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.” *Id.* at 378 (citing *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 347 (2001)). House Bill 728 does not purport to prohibit fraud on a federal agency.

Applying the presumption against preemption here, the Court does not find that Section 340B exhibits a clear purpose to preempt state laws that would require manufacturers to deliver covered entities’ drugs to contract pharmacies for distribution. Section 340B does not explicitly mandate how delivery of discounted drugs is to occur. *See McClain*, 95 F.4th at

1142 (“[T]he 340B Program ‘is silent about delivery’ and distribution of pharmaceuticals to patients.” (quoting *Sanofi Aventis*, 58 F.4th at 703)).¹ Section 340B merely requires participating manufacturers to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price.” § 256b(a)(1).

Sanofi Aventis and *Novartis* concluded that, under the terms of Section 340B, HHS may not *require* manufacturers to ship drugs intended for covered-entity patients to any contract pharmacy the entity deals with. *Sanofi Aventis*, 58 F.4th at 703 (concluding that “Section 340B does not require delivery to an unlimited number of contract pharmacies”); *Novartis*, 102 F.4th at 460–63. But the same “[s]tatutory silence[],” *Sanofi Aventis*, 58 F.4th 699, that does not *implicitly mandate* that manufacturers deliver to any contract pharmacy does not, on the other hand, show that Congress clearly intended to preclude states from enacting their own public health regulations aimed at maximizing the availability of low-cost drugs for covered-entity patients, *see McClain*, 95 F.4th at 1145 (concluding that “the delivery of a covered entity’s 340B drugs to contract pharmacies for dispensing creates no obstacle” to Section 340B’s objectives). If

¹ Section 340B discusses distribution, directing the Secretary to “establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs,” and providing, “*If* a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.” § 256b(a)(8) (emphasis added). These provisions do not mandate how delivery is to occur.

anything, H.B. 728 arguably promotes Section 340B’s objective of ensuring covered-entity patients can conveniently access their medications. *See id.* at 1144–45 (explaining how Arkansas’s prohibition on manufacturers preventing covered entities from contracting with pharmacies for drug distribution “does not create an obstacle for pharmaceutical manufacturers to comply with 340B, rather it does the opposite: [the law] assists in fulfilling the purpose of 340B”).

The upshot of Plaintiff’s argument is that Congress deliberately left to pharmaceutical manufacturers the discretion to refuse to ship 340B discounted drugs to contract pharmacies simply because it was silent in the statute about delivery. *See* Reply [27] at 4 (citing *Novartis*, 102 F.4th at 460). Plaintiff is correct that federal law can preempt state law when Congress, or a federal agency implementing federal law, makes a policy choice that balances competing objectives in such a way that a state regulation aimed at the same subject matter upsets the balance that the federal government struck. *See* Memo [5] at 26 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000)). But that is not this case.

In *Geier*, the Court held that a Department of Transportation regulation, FMVSS 208, requiring automobile manufacturers to equip some, but not all, of their 1987 vehicles with passive restraints—such as airbags—preempted state tort law requiring airbags beyond what that regulation required. 529 U.S. at 864–65. But there, the Supreme Court found that “clear evidence of a conflict” existed between state tort law and the regulation. *Id.* at 885. The Court reached

this conclusion based on the agency's "contemporaneous explanation" of several "significant considerations" it had in mind in designing the regulation. *See id.* at 877–81. The regulation "deliberately provided [car manufacturers] with a range of choices among different passive restraint devices," so as to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 875.

Here, Plaintiff does not persuasively show, at least at this stage of the proceedings, how H.B. 728 creates a substantial obstacle to Section 340B's purposes, or what consideration Congress had in mind in not addressing delivery of 340B drugs. In other words, there is no clear evidence of an "actual," "significant" conflict. *Id.* at 884–85 (internal quotation marks and citation omitted). House Bill 728 does not require pharmaceutical manufacturers to offer 340B drugs below applicable ceiling prices, expand the definition of what a 340B healthcare provider is, or expand the remedies available to a covered entity when a manufacturer overcharges it for 340B drugs. House Bill 728 prohibits manufacturers from interfering with covered entities ordering delivery of Section 340B drugs to pharmacies for distribution—something Section 340B may not require, but does not implicitly preclude either.

To the extent that delivering discounted drugs to contract pharmacies raises the risk of diversion, Section 340B prohibits diversion and provides for comprehensive enforcement mechanisms. *See supra*, Part I.A. If Section 340B healthcare providers are

conspiring with pharmacies to divert discounted drugs, HHS can require the provider to compensate the manufacturer for its losses, § 256b(a)(5), and remove the provider from the program, § 256b(d)(2)(B)(v)(II). The Court is not prepared to find Section 340B likely preempts H.B. 728 on a theory that Congress’s remedial scheme under Section 340B is inadequate to deter violations of federal law. As written, H.B. 728 and Section 340B do not conflict.

Congress also increased enforcement mechanisms against diversion in the Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 7102, 124 Stat. 119 (enacted March 23, 2010), by adding § 256b(d), *id.* at 823–26, 18 days after the 2010 HRSA Guidance that advised that covered entities can use an unlimited number of contract pharmacies, Notice Regarding 340B Drug Pricing Program— Contract Pharmacy Services, 75 Fed. Reg. 10,272, 10,272–73 (Mar. 5, 2010). Thus, Congress was presumably aware of the potential for diversion through the use of an unlimited number of contract pharmacies, and it increased enforcement against diversion, yet remained silent about delivery—not to mention about preemption. And while “failures to enact legislation ‘are not reliable indicators of congressional intent,’” *Novartis*, 102 F.4th at 462 (quoting *Mead Corp. v. Tilley*, 490 U.S. 714, 723 (1989)), Plaintiff’s argument relies on an inference of preemptive intent from Congress’s silence as to delivery, so the Court considers legislative context relevant in interpreting that silence, *see Arizona*, 567 U.S. at 405–406 (discussing policy proposals Congress did not enact in analyzing preemption).

In addition, Plaintiff argues that “H.B. 728 erects a substantial obstacle to that centralized federal process” for enforcing Section 340B’s requirements “by creating its own enforcement pathway before state administrative agencies.” Memo [5] at 27. The Court disagrees: H.B. 728 addresses delivery and Section 340B does not, so adjudications under H.B. 728 will not interfere with federal enforcement of Section 340B’s compliance mechanisms. The Court therefore concludes that Plaintiff has not shown a substantial likelihood that it will succeed on the merits of its conflict-preemption claim.

C. Section 340B does not preempt H.B. 728 under field preemption

The Court is also unpersuaded that Section 340B preempts H.B. 728 under a theory of field preemption. Field preemption requires that Congress has passed such comprehensive legislation in an area that it has “occupied the field.” *Arizona*, 567 U.S. at 401. Congress’s intent to displace state law can be inferred from its enactment of a federal regulatory scheme “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.’” *Id.* at 399 (quoting *Rice*, 331 U.S. at 230). Field preemption “should not be inferred, however, simply because the agency’s regulations are comprehensive.” *R.J. Reynolds Tobacco Co. v. Durham Cnty., N.C.*, 479 U.S. 130, 149 (1986).

“Field preemption of state law is disfavored.” *Nat’l Press Photographers Ass’n v. McCraw*, 90 F.4th 770, 796 (5th Cir. 2024). The Fifth Circuit has emphasized

that “Courts should not infer field preemption in ‘areas that have been traditionally occupied by the states,’ in which case congressional intent to preempt must be ‘clear and manifest.” *Id.* (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). “And importantly, field preemption is not to be found where federal ‘regulations, while detailed, appear to contemplate some concurrent state regulation.” *Id.* (quoting *R.J. Reynolds Tobacco*, 479 U.S. at 149).

House Bill 728 implicates a traditional area of state regulation, triggering the presumption against preemption, *see supra*, Part II.B., and rendering inapplicable *Arizona*’s discussion of dominant federal interests, *see Arizona*, 567 U.S. at 399. Section 340B also does not control how manufacturers must deliver discounted drugs to patients of covered entities. *See supra*, Part II.B. Section 340B thus leaves room for states to impose their own regulations on delivery of Section 340B drugs to promote patients’ access to their medications. “[M]erely because [Section 340B is] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field.” *Hillsborough Cnty.*, 471 U.S. at 717. While federal law comprehensively regulates the determination of ceiling prices on Section 340B drugs and provides robust enforcement mechanisms that ensure covered entities and manufacturers comply with the statute’s requirements, *see supra*, Part I.A., Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs.

The Court is also not persuaded that field preemption is compelled by *Astra*'s holding that covered entities cannot bring overcharging claims as third-party beneficiaries to PPAs. *See Astra*, 563 U.S. at 117–19. *Astra* rejected an argument that, despite a covered entity's "inability to assert a statutory right of action" under Section 340B itself, "PPAs implementing the 340B Program are agreements enforceable by covered entities as third-party beneficiaries." *Astra*, 563 U.S. at 117. Because PPAs are essentially contracts whereby manufacturers opt into Section 340B, the Court reasoned that "[a] third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself." *Id.* at 118. Accordingly, "[t]he absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract's ceiling-price obligations instead." *Id.*

The Supreme Court's rejection of a right of action for covered entities under PPAs has minimal bearing on whether Section 340B preempts state law about the delivery of 340B drugs. And *Astra* did not apply any presumption in favor of such a right of action analogous to the presumption against preemption applicable here. *See Arizona*, 567 U.S. at 400 ("In preemption analysis, courts should assume that the historic police powers of the States are not superseded unless that was the clear and manifest purpose of Congress." (internal quotation marks and citations omitted)). The Court therefore concludes that Plaintiff

has not shown a substantial likelihood of success on the merits of its field preemption claim.

D. Federal laws that provide regulatory exclusivities do not preempt H.B. 728

Plaintiff next contends that H.B. 728 “is preempted by federal drug laws, including those governing regulatory exclusivity and patent protection periods.” Memo [5] at 28. The Court disagrees.

The patent laws and other regulatory exclusivities cited by Plaintiff, including the Food, Drug, and Cosmetic Act and Hatch-Waxman Act, create bargains whereby, “[i]n exchange for bringing new designs and technologies into the public domain through disclosure . . . an inventor receives a limited term of protection from competitive exploitation.” *Amgen Inc. v. Sanofi*, 598 U.S. 594, 604 (2023) (internal quotations and citations omitted). In considering preemption of state laws which potentially conflict with federal patent law, courts look to whether a state law “clashes with the objectives of the federal patent laws.” *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964)). Plaintiff asserts, and the Court assumes, that the same logic applies to preemption claims based on other federal regulatory exclusivities that incentivize innovation in pharmaceuticals; that is, that state laws capping prices on drugs that federal law insulates from competition interfere with the objectives of federal law. See Memo [5] at 30 (citing *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (concluding that, “[b]y penalizing high prices—and thus limiting the full exercise of the exclusionary

power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs”).

Section 340B does not impose discounts on drugs beyond those for which manufacturers have already agreed to provide discounts in order to participate in Medicare Part B and Medicaid. *See supra*, Part I.A. Because H.B. 728 does not purport to lower prices on any drugs not already discounted under Section 340B, it does not substantially interfere with the incentives created by patent laws or other federal laws establishing regulatory exclusivities. The Court therefore does not find that Plaintiff has shown a substantial likelihood of success on the merits of its preemption claim based on federal regulatory exclusivities.

III. CONCLUSION

Because Plaintiff has not shown a substantial likelihood of success on the merits as required to obtain a preliminary injunction, it is not entitled to such relief, and the Court need not address the remaining Rule 65 factors. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 23–24 (2008) (declining to address other preliminary injunction factors after finding against the plaintiffs on one such factor). To the extent the Court has not addressed any of the parties’ remaining arguments, it has considered them and determined they would not alter the Court’s conclusion.

**IT IS, THEREFORE, ORDERED AND
ADJUDGED THAT,** Plaintiff Novartis

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Pharmaceuticals Corporation's Motion [4] for Preliminary Injunction is **DENIED**.

SO ORDERED AND ADJUDGED, this the 1st day of July, 2024.

s/ Halil Suleyman Ozerden
HALIL SULEYMAN OZERDEN
UNITED STATES DISTRICT JUDGE

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APPENDIX D

No. 24-60342

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

NOVARTIS PHARMACEUTICALS CORPORATION,
Plaintiff—Appellant,

versus

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*
Defendant—Appellee.

Appeal from the United States District Court
for the Southern District of Mississippi
USDC No. 1:24-CV-164

Filed: May 5, 2026

ON PETITION FOR REHEARING EN BANC

Before KING, HO, and RAMIREZ, *Circuit Judges.*

PER CURIAM:

Treating the petition for rehearing en banc as a petition for panel rehearing (5TH CIR. R.40 I.O.P.), the petition for panel rehearing is DENIED. Because no member of the panel or judge in regular active service

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requested that the court be polled on rehearing en banc (FED. R. APP. P.40 and 5TH CIR. R.40), the petition for rehearing en banc is DENIED.

APPENDIX E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*

Defendant.

Civil No. 1:24-cv-164-HSO-BWR

Filed: June 3, 2024

VERIFIED COMPLAINT

Plaintiff Novartis Pharmaceuticals Corporation brings this Complaint against Defendant Lynn Fitch, in her official capacity as the Attorney General of the State of Mississippi, and alleges as follows:

PRELIMINARY STATEMENT

1. This is an action for temporary, preliminary, and/or permanent injunctive relief challenging the constitutionality of Mississippi's H.B. 728, which purports to dramatically expand the scope of a federal

law mandating the sale of covered outpatient drugs at a discounted price to “covered entities”—non-profit hospitals and clinics meeting specified statutory criteria.

2. The Supreme Court has held that state laws cannot be used to enforce the federal 340B statute, which requires drug manufacturers to provide deeply discounted prices on their covered outpatient drugs to qualifying covered entities. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110 (2011). That decision makes sense: The federal 340B Program is a unified federal regulatory scheme, carefully constructed by Congress, and governed by a comprehensive framework of federal statutes and regulations that collectively define the obligations imposed on regulated entities. Allowing states to tinker with the federal framework would undermine Congressional objectives.

3. H.B. 728 is deceptively called the “Defending Affordable Prescription Drug Costs Act.” But it does little to lower the costs of prescription drugs to patients. The Mississippi law requires manufacturers to provide the federal 340B discount to covered entities on an unlimited number of transactions involving for-profit pharmacies (known as “contract pharmacies”). Several federal courts (including the Third Circuit, the D.C. Circuit, and the District Court for the District of Columbia) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. Yet that is precisely what Mississippi’s H.B. 728 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law. H.B. 728 directly conflicts with Congress’s carefully

designed federal program and is therefore preempted by federal 340B law.

4. H.B. 728 further conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow types of private claims relating to 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet H.B. 728 purports to do exactly that.

5. The Mississippi law also is preempted by federal laws governing the timing of drug approvals, including federal patent laws and the Food, Drug, and Cosmetic Act (FDCA) as amended by the federal Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act). In these statutes, Congress spelled out a grand bargain: Brand name manufacturers are driven to research, develop, and bring to market pharmaceutical products on the promise that they will obtain federally protected, exclusive rights to sell their products at market prices for specified periods of time. Once those periods expire, generic manufacturers are permitted to rely upon the drug development work done by innovator manufacturers by obtaining streamlined approval of generic products. H.B. 728 requires Novartis to make its drugs that are not covered by the federal 340B framework available at heavily discounted prices before those federally protected

exclusivity periods have run, undermining the bargain carefully constructed by federal law. That frustrates the purposes of Congress.

6. Absent immediate judicial intervention enjoining H.B. 728, Novartis will suffer irreparable harm. Once the law becomes effective on **July 1, 2024**, Novartis will risk violating Mississippi law merely by continuing to implement a contract pharmacy policy that has already been expressly declared lawful by other federal courts applying the federal 340B law. If H.B. 728 is not enjoined, Novartis will continue to suffer severe irreparable harm and loss of its constitutional rights on an ongoing basis. Novartis therefore requests a preliminary injunction enjoining enforcement of H.B. 728 pending a decision on the merits.

7. For all of these reasons, Novartis brings this action seeking a declaration that H.B. 728 is unconstitutional and a temporary, preliminary, and/or permanent injunction barring Defendant from enforcing H.B. 728 against Novartis.

PARTIES

8. Plaintiff Novartis is a corporation organized in Delaware with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis's purpose is to reimagine medicine to improve and extend people's lives.

9. Defendant Lynn Fitch is the Attorney General for the State of Mississippi and is responsible for administering and enforcing the provisions of H.B. 728. Defendant Fitch maintains offices at 550 High Street, Suite 1200, Jackson, Mississippi 39205, and at

1141 Bayview Avenue, Suite 402, Biloxi, Mississippi 39530.

JURISDICTION AND VENUE

10. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States, and under 28 U.S.C. §§ 2201-02, in that there exists an actual justiciable controversy between the parties as to which Plaintiff requires a declaration of its rights by this Court and injunctive relief.

11. This Court also has inherent equitable powers to enjoin the actions of state officials that contradict the U.S. Constitution and federal law. *Ex parte Young*, 209 U.S. 123, 159-160 (1908); *United States v. South Carolina*, 720 F.3d 518, 526 (4th Cir. 2013).

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b)(1) and (2) because Defendant maintains offices in Jackson and Biloxi, Mississippi, which are in this district, and/or because a substantial part of the events or omissions giving rise to the claim occurred in this district. H.B. 728 purports to restrict Novartis's conduct in this district, and a substantial amount of Novartis's drug products are sold in this district. The challenged state law also applies to contract pharmacy arrangements in this district. H.B. 728 is therefore likely to be enforced against manufacturers in this district.

FACTUAL BACKGROUND

I. Statutory and Regulatory Background

13. Congress created the 340B Drug Pricing Program in 1992. The program requires participating pharmaceutical manufacturers to provide deep

discounts on certain drugs to specified types of healthcare providers—known as “covered entities”—as a condition of the availability of federal payments for such drugs under Medicaid and Medicare Part B. 42 U.S.C. § 256b.

14. At its core, the 340B Program requires a participating pharmaceutical manufacturer to charge a covered entity no more than the 340B ceiling price—a discounted price calculated under a prescribed statutory formula—for each unit of a covered outpatient drug. *Id.* §§ 256b(a)(1), (a)(4), (b)(1). A participating manufacturer “shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.” *Id.* § 256b(a)(1).

15. The 340B Program is overseen by the federal Department of Health and Human Services (HHS) and its sub-agency, the Health Resources and Services Administration (HRSA). To participate in the 340B Program, a manufacturer must enter a Pharmaceutical Pricing Agreement (PPA) with the federal government. 42 U.S.C. § 256b(a)(1).

16. The “applicable ceiling price,” or “340B price,” is a steeply discounted rate—as low as one penny—calculated under a prescribed statutory formula. *See* 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210, 1214-15 (Jan. 5, 2017); 42 U.S.C. § 256b(a)(2).

17. Congress intentionally limited the scope of sales that would trigger such a severe discount to those drugs “purchased by a covered entity.” 42 U.S.C.

§ 256b(a)(1). The statute carefully defined the term “covered entity” in a specific and exhaustive way, listing 15 types of entities that qualify for the discount. *Id.* § 256b(a)(4) (listing federal grantees, black lung clinics, family planning projects, and specified types of non-profit hospitals). The statute does not require that the 340B discount be given to entities not included within the definition of “covered entity.”

18. In the first several years of the program, covered entities dispensed 340B-purchased drugs exclusively through their own in-house pharmacies. But over time, covered entities sought to be able to dispense 340B-purchased drugs through contractual arrangements with third-party pharmacies (so-called “contract pharmacies”) as well. Under these arrangements, instead of drugs being shipped to the covered entity for dispensing by its in-house pharmacy, drugs are shipped to the contract pharmacy—often a large, national chain—for dispensing there.

19. Contract pharmacy arrangements, including those in Mississippi, traditionally involve a “virtual inventory” or “replenishment” model. Under this model, the contract pharmacy starts with an inventory of commercially purchased product and dispenses all units of the drug from this common inventory, regardless of whether the individual to whom a unit is dispensed is a patient of the covered entity. That is because the contract pharmacy itself typically has not determined at the time of dispensing whether the individual receiving the prescription is a “patient” of the covered entity. That determination is

made afterward. Where it believed, based on an opaque formula generally not shared with the manufacturer, that the individual is a covered-entity patient, the covered entity purchases a “replenishment” unit at the 340B price and directs shipment to the contract pharmacy—which commingles the 340B-purchased unit with commercially purchased units in its common inventory. The 340B replenishment unit is treated as it if had been purchased at the commercial price—and thus is available for dispensing to anyone, including a non-patient of the covered entity—even though it has in fact been purchased at the 340B price. *See Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 21, 2024) (“Slip Op.”), at 16-18; *See also HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 at 5 (Feb. 4, 2014), *available at* <https://oig.hhs.gov/oei/reports/oei05-13-00431.pdf>.

20. The statute provides for only two enforcement mechanisms. First, the statute provides for the imposition of civil monetary penalties (CMPs) on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the ceiling price. 42 U.S.C. § 256b(d)(1)(B)(vi)(III). HRSA has taken the position that implementation of this statutory remedy requires a referral to the HHS Office of Inspector General (OIG).

21. In addition, the statute required the Secretary of HHS to promulgate regulations establishing an ADR process to resolve specific categories of private disputes between covered entities and manufacturers

arising under the 340B Program. 42 U.S.C. § 256b(d)(3). The statute specifically describes two narrow claim categories that are funneled to administrative dispute resolution: (1) “claims by covered entities that they have been overcharged for drugs purchased under this section,” and (2) claims by manufacturers relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A). In promulgating ADR regulations, the agency has recently interpreted these provisions—rightly or wrongly—to include a claim “that a manufacturer has limited the covered entity’s ability to purchase covered outpatient drugs at or below the 340B ceiling price.” 89 Fed. Reg. 28,643, at 28,657 (Apr. 19, 2024).

22. There are no other enforcement mechanisms contemplated by the 340B statute.

II. HRSA’s Changing Position on Contract Pharmacies

23. Over time, HRSA’s position on contract pharmacies has evolved.

24. In 1996, the agency issued guidance announcing that the agency would not preclude covered entities lacking an in-house pharmacy from entering into a contractual relationship with a single outside pharmacy to dispense covered outpatient drugs to the covered entity’s patients. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

25. In 2010, HRSA issued revised guidance on contract pharmacy arrangements, stating that covered entities may be permitted to “use” an untold number of “multiple pharmacy arrangements”—with no limits on their physical location, and even if the

covered entity had its own in-house pharmacy—”as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition.” 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). HRSA’s 2010 Guidance thus purported to authorize covered entities to enter into a limitless number of contract pharmacy arrangements with any pharmacy located anywhere in the United States.

26. That decision had striking consequences. Over the ensuing years, the number of contract pharmacies receiving and distributing 340B drugs grew at a rapid clip. By 2018, the Government Accountability Office found that the number of contract pharmacies had ballooned from 1,300 in 2010 to nearly 20,000 by 2017. Government Accountability Off., *Drug Discount Program, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 36 (June 2018), <https://www.gao.gov/assets/gao-18-480.pdf>. This report echoed findings from the Department of Health and Human Services’ Office of Inspector General, which similarly documented dramatically increased use—and abuse—of 340B discounts through covered entities’ contract pharmacy relationships. HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, No. OEI-05-00431 at 9-10, 16 (2014), <https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

27. Neither covered entities nor their contract pharmacies are required to pass on 340B discounts to patients, and often they do not. Instead, covered entities and contract pharmacies are permitted to (and often do) pocket the discount themselves. Over

time, 340B expenditures have swelled as contract pharmacy arrangements, and the profits they generate for covered entities and contract pharmacies alike, proliferated. By 2020, sales of 340B units constituted an estimated 7% of the entire U.S. prescription drug market and 17% of all total U.S. branded outpatient drug sales. Karen Mulligan, *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>; Eleanor Blalock, *Measuring the Relative Size of the 340B Program: 2020 Update* (June 2022), available at <https://media.thinkbrg.com/wp-content/uploads/2022/06/30124832/BRG-340B-Measuring-Relative-Size-2022.pdf>. In 2022, discounted purchases under the 340B Program hit a record high of approximately \$54 billion—a more than 22% year-over-year increase. *Id.*; See also Adam J. Fein, *The 340B Program Reached \$54 Billion in 2022—Up 22% vs. 2021*, Drug Channels (Sept. 24, 2023).

III. Novartis’s Contract Pharmacy Policy and Resulting Litigation

28. Concerned about ever-increasing abuse through fast-multiplying contract-pharmacy arrangements, in late 2020, Novartis notified HRSA of its plans to implement a contract pharmacy policy. Beginning in November 2020, Novartis explained, it would recognize all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allow covered entities to seek

exemptions based on individual circumstances. Novartis's 40-mile limitation did not apply to covered entities that are federal grantees.

29. In early 2021, HRSA issued a violation letter to Novartis, contending that Novartis's policy violated the statute and demanding immediate compliance with HRSA's view that, at the unilateral direction of a covered entity, a manufacturer is obligated to deliver 340B drugs to any contract pharmacy, on pain of an enforcement action.

30. Upon receiving HRSA's violation letter, Novartis immediately challenged the agency action in the U.S. District Court for the District of Columbia. *See Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C.) (filed May 31, 2021). Novartis's challenge was heard alongside a later case brought by United Therapeutics, which had also received a violation letter. *See United Therapeutics Corp. v. Espinosa*, No. 1:21-cv-01686 (D.D.C.).

31. Following full briefing and argument, the District Court vacated HRSA's violation letters and issued a decision rejecting HRSA's purported requirement that manufacturers recognize an unlimited number of contract pharmacies as inconsistent with the language of the 340B statute. *Novartis Pharms. Corp. v. Espinosa*, No. 21-CV-1479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021). As the District Court explained, HRSA's enforcement letters rested on the contention that the 340B statute "prohibit[s] drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies," but that the 340B statute does no such thing. *Id.* at *9. In sum, the District Court

held that “[t]he statute’s plain language, purpose, and structure do not prohibit drug manufacturers from attaching any conditions to the sales of covered drugs through contract pharmacies.” *Id.*

32. On May 21, 2024, the D.C. Circuit affirmed, holding that the federal 340B statute’s “requirement to ‘offer’ drugs at a certain ‘price’ does not prohibit distribution conditions, much less require the offeror to accede to any distribution conditions, much less require the offeror to accede to any distribution terms demanded by the offeree.” *Novartis Pharms. Corp. v. Johnson*, Slip Op., at 16. The D.C. Circuit also noted that statutory silence on contract pharmacies does not mean that manufacturers are required to recognize an unlimited number of them. “Statutory silence implies that manufacturers may impose distribution conditions by contract, not that they are prohibited from doing so.” *Id.* at 14. The Court thus held that Novartis’s contract pharmacy policy does not violate the federal 340B statute, and affirmed the vacatur of HRSA’s violation letter.

33. In a parallel lawsuit brought by other drug manufacturers, the U.S. Court of Appeals for the Third Circuit likewise rejected the notion that Section 340B requires manufacturers to recognize an unlimited number of contract pharmacy arrangements. *See Sanofi Aventis U.S. LLC v. United States Dep’t of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023). The unanimous Third Circuit panel held unlawful HHS’s efforts to enforce its interpretation of Section 340B against drug manufacturers that imposed delivery conditions on sales to covered entities using contract pharmacies.

Id. at 699. In so doing, the Third Circuit held that “Section 340B does not require delivery to an unlimited number of contract pharmacies.” *Id.* at 703. It identified multiple structural indicators that not only confirmed this reading of Section 340B but further indicated that the omission reflected Congress’ intent that unlimited contract pharmacies not be required.

34. Critically, the Third Circuit noted that “[n]owhere does Section 340B mention contract pharmacies,” and inferred based on the language and structure of the statute that Congress’s decision to omit contract pharmacies from the list was not an unintentional gap, but was done intentionally. The Court noted, Congress “expressly contemplate[d] drug makers selling discounted drugs through contract pharmacies” in an adjacent provision of the same authorizing legislation relating to another (non-340B) program, but did not include similar language for the 340B program. *Id.* at 703-705.

35. The Third Circuit also rejected the argument that manufacturers are required to deliver their 340B drugs anywhere that covered entities wish, including to third party contract pharmacies, as “one giant leap from the text.” *Id.* at 704. To the contrary, “Congress’s use of the singular ‘covered entity’ in the ‘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.* Because the “drug makers’ restrictions on delivery to contract pharmacies [did] not violate Section 340B,” the Third Circuit “enjoin[ed] HHS from enforcing against them its reading of Section 340B as requiring

delivery of discounted drugs to an unlimited number of contract pharmacies.” *Id.* at 706.

36. Following both the D.C. District Court’s and the Third Circuit’s decisions, Novartis announced in April 2023 that it was revising its contract pharmacy policy, effective May 3, 2023. In keeping with both decisions, Novartis’s current policy permits hospital covered entities lacking an in-house pharmacy to select a single contract pharmacy location. Novartis also recognizes any arrangements a hospital covered entity might have with contract pharmacies that the covered entity fully owns and controls. Federal grantee covered entities continue to be exempt. *See* Ex. A (April 3, 2023 Letter to Covered Entities on 340B Contract Pharmacy Policy). Novartis’s revised policy mirrors one of the manufacturer policies that the Third Circuit found lawful, and has now also specifically been found lawful by the D.C. Circuit.

IV. Mississippi Enacts Its Own “340B” Legislation.

37. On April 12, 2024, Mississippi enacted H.B. 728, which states in relevant part that a manufacturer or distributor “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.” H.B. 728 § 4(1).¹

¹ Available at <https://billstatus.ls.state.ms.us/documents/2024/pdf/HB/0700-0799/HB0728SG.pdf>.

38. The law sweeps broadly: A manufacturer or distributor also “shall not interfere with a pharmacy contracted with a 340B entity.” H.B. 728 § 4(2).

39. A “340B drug” is defined as a covered outpatient drug “that has been subject to any offer for reduced prices by a manufacturer pursuant to [the federal 340B statute].” H.B. 728 § 2(a). In other words, a “340B drug” is a drug that is sold at a 340B discount.

40. A “340B entity” is defined to mean “an entity participating or authorized to participate in the federal 340B drug discount program, as described [in the federal 340B statute], including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.” *See* H.B. 728 § 2(b).

41. Putting these definitions together, the Mississippi statute requires manufacturers like Novartis to provide the 340B discount on transactions that involve contract pharmacies.

42. A manufacturer in violation of H.B. 728 faces penalties on numerous fronts.

43. A violation of H.B. 728 constitutes an unfair, abusive, or deceptive trade practice under the Mississippi Consumer Protection Act (MCPA), *see* Miss. Code Ann. § 75-24-1 *et seq.*, subject to a spate of specified enforcement actions and penalties. *See* H.B. 728 § 5.

44. The statute provides for a fine of \$10,000 per each knowing and willful violation or violation of an injunction. *See* Miss. Code Ann. § 75-24-19.

45. The law imposes criminal penalties as well: A person who knowingly and willfully violates the

MCPA is guilty of a misdemeanor and subject to a fine of up to \$1,000 for the first violation. That liability ratchets up for a second conviction. A person convicted of a second violation is guilty of a misdemeanor and also subject a fine of up to \$1,000 per violation and/or imprisonment for up to one year. Miss. Code Ann. §§ 75-24-20(a), (b). Upon a third or subsequent conviction for violating H.B. 728, the liability escalates further still, resulting in a felony offense, threatening a fine of up to \$5,000 per violation and imprisonment of up to five years. Miss. Code Ann. § 75-24-20(c).

46. Liability under H.B. 728 for would-be violators can mount quickly, not only because “[a] violation occurs each time a prohibited act is committed” under Mississippi’s law, H.B. 728 § 5, but also because, under Mississippi law, convictions of comparable criminal offenses *in states beyond Mississippi* matter for “purposes of determining if a violation ... is a first, second or third or subsequent offense”: The law provides that “[c]riminal convictions from other states for violations of substantially similar provisions . . . shall be counted.” Miss. Code Ann. § 75-24-20(d).

47. A violation of H.B. 728 also subjects a manufacturer to “any and all actions, including investigative demands, remedies, and penalties provided for” in the MCPA. H.B. 728.

48. The MCPA vests additional powers with the Mississippi Attorney General, including the issuances of subpoenas, subpoenas duces tecum, cease and desist orders, and conducting hearings to investigate and “[c]ompel the production of books, papers,

documents, and other evidence.” *See* Miss. Code. Ann § 75-24-27.

49. In short, the penalties for a violation of H.B. 728 are dire.

H.B. 728 IS UNLAWFUL

50. H.B. 728 violates the Supremacy Clause of the U.S. Constitution, under both field and conflict preemption principles.

51. It is of no moment that Mississippi’s statute says that “[n]othing in this section shall be construed or applied to be conflict with . . . applicable federal law and related regulation.” H.B. 728 § 6(2). Such a provision “cannot substantively operate to save an otherwise invalid statute.” *Community in Solidarity with the People of El Salvador v. FBI*, 770 F.2d 468, 474 (5th Cir. 1985).

Field Preemption

52. 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)). State statutes that diminish federal control over enforcement, and detract from a unified regulatory scheme that Congress has established, are especially likely to violate the Supremacy Clause under field preemption principles.

53. The 340B Program is just that sort of integrated federal regulatory scheme. It is a creature

of a federal statute in which Congress has set out comprehensive regulatory parameters and supplied an exclusively federal framework for enforcement and dispute resolution. The 340B statute carefully defines the types of entities that are entitled to receive the 340B discount, and provides its own enforcement pathways for violations of the statute, including civil penalty assessments, administrative appeal pathways, and audits initiated by the agency and/or manufacturers. *See* 42 U.S.C. §§ 256b(a) and (d)(3)(A)—(B). For that reason, the Supreme Court has held that the federal 340B program is to be administered—and enforced—solely by or through the federal government. State law claims seeking to separately enforce the 340B statute are preempted. *Astra*, 563 U.S. 110.

54. The federal 340B statute mentions states only in passing and even then only in a limited way. For example, the definition of covered entity includes hospitals that are “owned or operated by a unit of State or local government”; “State-operated AIDS drug purchasing assistance program[s] receiving” certain federal “financial assistance”; and “entit[ies] receiving [federal] funds” to treat sexually transmitted diseases or tuberculosis “through a State or unit of local government” are all federally defined covered entities. 42 U.S.C. §§ 256b(a)(4)(E), (K), (L)(i).

55. By purporting to create a separate, state-specific pathway that adjusts the contours of the federal 340B requirements—altering when the discount is owed, and overriding federal restrictions on who can enforce it—H.B. 728 runs afoul of the Supreme Court’s admonition that using state law to

enforce federal 340B requirements is “incompatible with the statutory regime.” *Astra*, 563 U.S. at 113. Congress has left “no room for the States to supplement it[s]” federal regulatory scheme. *Arizona*, 567 U.S. at 399.

56. Field preemption also exists when a federal interest is so dominant that it must be assumed the federal system precludes enforcement of state laws covering the same subject. The federal interests in overseeing and enforcing the 340B Program could hardly be more dominant. Congress directed HHS to create a comprehensive remedial scheme, which allows for federal enforcement as well as private ADR claims “to prevent overcharges and other violations of the discounted pricing requirements” and to govern disputes over 340B discount pricing. 42 U.S.C. §§ 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. Just as private lawsuits by state actors seeking to apply state common law to enforce 340B requirements are “incompatible with the [340B] statutory regime,” so too is a state statute purporting to do the same thing. *Astra*, 563 U.S. at 113.

Conflict Preemption

57. H.B. 728 also is preempted by the federal 340B statute under conflict preemption principles. State laws are preempted under conflict principles where they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Conflict preemption is also found when a state law “interferes with the methods by which the federal statute was designed to” achieve those purposes and objectives. *International Paper Co. v. Ouellette*, 479 U.S. 481, 492, 494 (1987).

Preemption by Federal 340E Statute

58. The Mississippi law is preempted by the federal 340B statute, in two ways.

59. First, H.B. 728 conflicts with federal law by purporting to unilaterally expand the universe of 340B-eligible sales well beyond those required by the statute itself. As the D.C. Circuit, the Third Circuit, the District Court for the District of Columbia, and the District Court for the District of Delaware recognized, the federal 340B statutory scheme does not require that a drug manufacturer honor unlimited contract pharmacy arrangements. *See Sanofi Aventis*, 58 F.4th at 703; *see also Novartis Pharms. Corp.*, 2021 WL 5161783, at *6. By Congressional design, whether to recognize covered entities' contract-pharmacy arrangements is purely a matter of manufacturer discretion. Yet H.B. 728 purports to require manufacturers to make their 340B drugs available in connection with an unlimited number of contract pharmacy arrangements, in conflict with federal law as interpreted by multiple courts.

60. In addition, H.B. 728 conflicts with the exclusive enforcement mechanism spelled out in the 340B statute. Congress made its intent plain: The federal 340B program must be enforced by a specialized federal administrative agency, and only that agency, through one of two centralized administrative processes: one driven by federal actors pursuing CMPs and other penalties, and the other driven by private claimants who file specified ADR claims before HRSA.

61. In *Astra*, county-operated 340B facilities filed a lawsuit against various drug manufacturers, alleging

that they were charging prices in excess of those permitted under the manufacturers' PPAs. 563 U.S. 110. The plaintiffs' claims were styled as third-party beneficiary claims for breach of contract under state law. The Court rejected the plaintiffs' attempt to manufacture a state law right of action for violations of the 340B statute, noting: "Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions. That control could not be maintained were potentially thousands of covered entities permitted to bring suits alleging errors in manufacturers' price calculations." *Id.* at 114.

62. As with the state common law remedy that the Supreme Court overturned in *Astra*, H.B. 728 erects a substantial obstacle to that centralized federal process by creating a separate enforcement pathway for covered entities outside of the federal enforcement process. Mississippi's law flouts the oversight scheme mandated by Congress and allows covered entities to bypass federal enforcement pathways. For all these reasons, H.B. 728 is unenforceable under the Supremacy Clause. *See Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 326 (2016).

Preemption by Federal Laws Governing Drug Exclusivity Periods and Patent Rights

63. Finally, H.B. 728 is preempted by federal laws governing patent protection and regulatory exclusivity periods for drug products. Congress has plenary authority under the U.S. Constitution to establish and oversee the patent laws, which provide a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. In 1984,

Congress enacted the “Hatch-Waxman” amendments to the FDCA, which among other things created a framework for patent litigation between brand manufacturers and generic manufacturers. Under the resulting framework, innovative manufacturers are “impelled to invest in creative effort” on the promise that they will obtain “a federally protected ‘exclusive right’ to sell their inventions for a limited period.” *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007) (“*BIO*”).

64. These patent exclusivity periods are distinctively federal and leave no room for state interference. “Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989); *Southeastern Pennsylvania Trans. Auth. v. Gilead Scis., Inc.*, 102 F. Supp. 3d 688, 703 (E.D. Pa. 2015) (“Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs.”).

65. State laws that cap or fix the prices at which patented drugs may be sold are preempted by federal patent law because they attempt to re-balance the carefully constructed federal statutory scheme that allocates rewards and incentives to innovator manufacturers. *See, e.g., Pharmaceutical Rsch. & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 60 (D.D.C. 2005), *aff’d sub nom. Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007) (“*BIO*”).

66. In *BIO*, the Federal Circuit held that a D.C. law that capped the price of patented pharmaceutical products was preempted by the federal patent laws. See *Biotechnology Indus. Org.*, 496 F.3d 1362. “Inventors are impelled to invest in creative effort by the expectation that, through procurement of a patent, they will obtain a federally protected ‘exclusive right’ to exclude others from making, using, or selling embodiments of their invention.” *Id.* at 1372. The Court noted that the legislative history of the Hatch-Waxman Act supports this goal: “Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.” *Id.* at 1373 (citing legislative history). The Court thus found that the “underlying determination about the proper balance between innovators’ profit and consumer access to medication, though, is exclusively one for Congress to make”—and a state may not “re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* at 1374. “By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs.” *Id.* The Court thus found the D.C. law preempted.

67. The same delicate balance underlies the federal exclusivity periods awarded to drugs as part of the drug approval process. Congress has spelled out a

grand bargain: Manufacturers are driven to research, develop, and bring to market pharmaceutical products through a rigorous New Drug Application pathway, which requires manufacturers to submit clinical trials showing safety and efficacy. Brand name manufacturers do so on the promise that they will obtain a federally protected, exclusive right to sell their products at market prices for a specified period of time after approval, known as a “regulatory exclusivity period.”

68. Congress thus directed the Food and Drug Administration (FDA) to recognize various periods of market exclusivity following approval of new drugs in order to reward manufacturers for innovation undertaken at considerable risk and expense. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii) (five years exclusivity for new chemical entities not previously approved by the FDA); *id.* § 355(c)(3)(E)(iii)-(iv), (j)(5)(F)(iii)-(iv) (three years exclusivity to reward additional clinical testing for new indications or to develop new dosages); *id.* § 355a (six months additional exclusivity for pediatric clinical testing); *id.* § 360cc (seven years exclusivity for “orphan drugs” used to treat rare diseases).

69. Once those exclusivity periods expire, generic manufacturers are permitted to utilize the drug development work done by innovator manufacturers in order to obtain streamlined approval of generic products—without the need to show safety or efficacy through clinical trials. The public reaps the benefit of immediate access to a new product during the innovator manufacturer’s exclusivity period, and cheaper products once those periods expire.

70. By requiring Novartis and other manufacturers of brand-name drugs to offer the steep 340B discount on sales made through contract pharmacy arrangements, even during the marketing exclusivity periods they are due under federal law, H.B. 728 impermissibly diminishes the reward that federal law confers on manufacturers, which in turn redounds to the benefit of patients who gain access to Novartis's life-saving and life-sustaining drug products.

V. H.B. 728 Will Cause Concrete and Imminent Harm to Novartis.

71. Novartis will be irreparably harmed unless this Court enjoins Defendant from enforcing H.B. 728.

72. First, if H.B. 728 is not enjoined, Novartis will be exposed to unconstitutional state-law obligations, and will risk violating Mississippi law by continuing with a policy that fully complies with federal law (as determined by multiple federal courts). A regulated entity may be irreparably injured in the face of the threatened enforcement of a preempted law. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992).

73. Failure to comply with the state law will also subject Novartis to state administrative enforcement proceedings that are themselves unlawful and unconstitutional. These state pathways deprive Novartis of its rights under the carefully crafted, federally defined terms of the 340B Program enforcement pathways. These deprivations of constitutional rights constitute irreparable injury for purposes of a preliminary injunction.

74. Novartis also faces the prospect of significant financial penalties for violations of H.B. 728. As noted above, the state statute contemplates civil and criminal penalties totaling of up to \$15,000 per violation, plus the potential for imprisonment. H.B. 728. Novartis thus risks exposure to fines totaling millions of dollars per year plus imprisonment. This money will divert resources away from Novartis' s research and development of new drug therapies for critical patient populations. Once lost, drug development research opportunities and market-leading opportunities can never be fully regained.

75. If Novartis tries to avoid these stringent fines and financial penalties by coming into compliance with the state statute, Novartis faces the loss of millions of dollars in unconstitutional state-mandated discounts per year. Novartis has no readily apparent way to recover these unlawfully mandated discounts once given. In fact, HRSA's position is that a manufacturer may only seek recovery through the federal ADR process only on claims relating to duplicate discounts and drug diversion. 42 U.S.C. § 256b(d)(3)(A).

76. Granting injunctive relief here would not harm Defendant, as it is well-established that states maintain no interest in enforcing a statute that violates federal law.

77. Injunctive relief also would serve the public interest. The public has a substantial interest in seeing that federal law is enforced and not countenancing state efforts to reset the metes and bounds of participation in federal healthcare programs.

CLAIM FOR RELIEF

COUNT I

(Declaratory/Injunctive Relief— Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2)

78. Novartis realleges, reasserts, and incorporates by reference herein each of the foregoing allegations as though set forth fully herein.

79. The Supremacy Clause of the U.S. Constitution provides that 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.

80. H.B. 728 is preempted by the federal 340B statute under both field preemption and conflict preemption principles.

81. First, H.B. 728 is preempted because it attempts to regulate in a field that Congress has fully occupied. In crafting the 340B statute, Congress created a comprehensive and self-contained federal regime—one that carefully defines the types of entities that are entitled to receive the 340B discount, and provides its own enforcement pathways for violations of the statute, including civil penalty assessments, administrative appeal pathways, and audits initiated by the agency and/or manufacturers. *See* 42 U.S.C. §§ 256b(a) and (d)(3)(A)—(B). Congress left no room for states to tinker with the parameters of the federal law. Nor is there space for states to add their own enforcement mechanisms to the two

exclusive enforcement pathways spelled out in the federal statute.

82. Field preemption also exists when a federal interest is so dominant that it must be assumed the federal system precludes enforcement of state laws covering the same subject. The federal interests in overseeing and enforcing the 340B Program could hardly be more dominant. Congress directed HHS to create an exclusive and comprehensive remedial scheme, which allows for federal enforcement as well as private ADR claims “to prevent overcharges and other violations of the discounted pricing requirements” and to govern disputes over 340B discount pricing. 42 U.S.C. §§ 256b(d)(1)(A), (d)(2)(A), (3); 42 C.F.R. §§ 10.3, 10.20. State statutes that seek to adjust and enforce the federal 340B law are “incompatible with the [340B] statutory regime.” *Astra*, 563 U.S. at 113.

83. H.B. 728 also is preempted because it imposes a substantial obstacle to the achievement of federal purposes and objectives under the 340B statute. The Mississippi law requires manufacturers to provide the federal 340B discount on an unlimited number of transactions involving contract pharmacies. Several federal courts (including the Third Circuit, the D.C. Circuit, and the District Court for the District of Columbia) have held that federal 340B law does *not* require manufacturers to recognize an unlimited number of contract pharmacies. Yet that is precisely what Mississippi’s H.B. 728 purports to mandate, greatly expanding the scope of the federal discounting obligation in conflict with federal law.

84. H.B. 728 also conflicts with the federal 340B enforcement process by purporting to create its own state-level 340B enforcement mechanism. Congress created two exclusive pathways to resolve disputes arising under the 340B statute: (i) direct enforcement by federal agencies, and (ii) an Administrative Dispute Resolution process that serves as the exclusive means for regulated entities to bring narrow types of private claims relating to 340B law. Congress gave no authority to the States to administer, interpret, or enforce any aspect of the 340B Program. Yet H.B. 728 purports to do exactly that.

85. Finally, by purporting to reduce the value of the exclusivity periods and patent terms that the FDCA and federal patent laws guarantee to qualifying drug manufacturers, H.B. 728 is preempted under conflict preemption principles because it interferes with the careful balance of rewards and incentives that Congress crafted—a framework in which States simply play no role.

PRAYER FOR RELIEF

For the foregoing reasons, Novartis prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that H.B. 728 is preempted by federal law and is thus null, void, and unenforceable;

B. Temporary, preliminary, and permanent injunctive relief vacating H.B. 728 and enjoining Defendant from implementing and/or enforcing H.B. 728 against Novartis or any of its affiliates, officers, agents, representatives, or contractors;

C. Temporary, preliminary, and permanent injunctive relief enjoining Defendant from seeking civil penalties, equitable relief, or any other remedy based on an alleged violation under H.B. 728 by Novartis or any of its affiliates, officers, agents, representatives, or contractors;

D. An order awarding Novartis attorneys' fees, costs, and expenses, as appropriate; and

E. Such other and further relief as the Court deems just and proper.

Dated: June 3, 2024

Respectfully submitted,

/s/ J. William Manuel

J. William Manuel (MS Bar No. 9891)

BRADLEY ARANT BOULT

CUMMINGS LLP

One Jackson Place

188 E. Capitol Street, Suite 1000

Jackson, MS 39201

Telephone: (601) 948-8000

Facsimile: (601) 948-3000

wmanuel@bradley.com

Catherine E. Stetson*

Susan M. Cook*

Marian Golden*

HOGAN LOVELLS US LLP

555 Thirteenth Street, NW

Washington, DC 20004

Telephone: (202) 637-5600

70a

cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com

**Pro Hac Vice Motion Forthcoming*

*Attorneys for Novartis
Pharmaceuticals Corporation*

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VERIFICATION

I, the undersigned, having read the allegations of the foregoing Verified Complaint, hereby declare under penalty of perjury and pursuant to 28 U.S.C. § 1746 that the factual allegations asserted in the Verified Complaint are true and correct.

Executed this 3rd day of June, 2024.

/s/ Odalys Caprisecca
Odalys Caprisecca

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APPENDIX F

**EXHIBIT A TO COMPLAINT –
CONTRACT PHARMACY LETTER**

Filed: June 3, 2024

NOVARTIS

Novartis Pharmaceuticals
Managed Markets Finance
One Health Plaza
East Hanover, NJ 07936
Telephone +1 862 778 8300

April 3, 2023

BY ELECTRONIC MAIL

Dear Covered Entity:

In follow-up to our previous communications on August 17, 2020, and October 30, 2020, we are providing an update on additional steps that Novartis is taking as part of its 340B Drug Pricing Program. After careful consideration, we have decided to adjust our contract pharmacy policy to more closely match the 340B **program's intended focus, while preserving the sustainability of this vital program.**

For hospital covered entities, beginning on May 1, 2023, Novartis will ship all units ordered at the 340B discounted price directly to covered entities. Novartis

will allow all covered entities without an in-house pharmacy to select one contract pharmacy location where Novartis will ship 340B discounted units.

In addition, Novartis will recognize any arrangements with contract pharmacies that are fully owned and controlled by a covered entity.

All federal grantee covered entities continue to be exempt from our contract pharmacy policy.

This change will not affect patient access to prescribed medicines **Nor will it affect a covered entity's ability** to continue to benefit from the 340B discount.

Novartis continues to support the core mission of the 340B program to increase access to outpatient drugs by uninsured, low-income, and other vulnerable patients. We will continue to work alongside other stakeholders to advocate for the transparency, oversight, and accountability reforms necessary for the 340B program to continue its mission as intended. As such, we continue to encourage all covered entities to **voluntarily upload their claims data to the ESP™ platform, in an effort to increase transparency**, mitigate instances of duplicative discounts, and otherwise help maintain the integrity and sustainability of this vital program.

For covered entities that do not have an in-house pharmacy and seek to designate a contract pharmacy location, please go to <https://www.340besp.com/> designations and complete the online form.

We look forward to working collaboratively with you to further strengthen the 340B program. If you have

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any questions, please contact us at
Novartis.340B@novartis.com.

Sincerely,

/s/ Odalys Caprisecca

Odalys Caprisecca

VP, Managed Markets Finance

Novartis Pharmaceuticals Corporation

One Health Plaza, East Hanover, NJ 07936-1080

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APPENDIX G

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

LYNN FITCH, *in her official capacity as Attorney
General of the State of Mississippi,*

Defendant.

Civil No. 1:24-cv-164-HSO-BWR

Filed: June 4, 2024

DECLARATION OF ODALYS CAPRISECCA

I, Odalys Caprisecca, declare under penalty of perjury
as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated herein are based upon my personal knowledge, including my experience in the pharmaceutical industry, my work at Novartis Pharmaceuticals Corporation (Novartis), and my review of the business records of the company. If called to testify, I could truthfully and competently testify to those facts.

2. I am the Vice President of Managed Markets Finance at Novartis, where I have been employed since 2021. More generally, I have more than 30 years of experience in the pharmaceutical industry. During that time, I have had various responsibilities for Pricing, Market Access, Trade Operations, Government Reporting, Commercial and Government Contracting, Contract Operations, Fair Market Value, Finance, and Governance.

3. In my current position, I am responsible for leading Novartis's Managed Markets Finance function with responsibility for Contract Operations, Government Reporting, Federal & State Programs, Medicaid, Gross To Net, Fair Market Value, and Governance.

4. Novartis is a pharmaceutical company devoted to improving and extending people's lives through medicine. The company uses science and technology to address society's most challenging healthcare issues, undertaking research to discover and develop breakthrough treatments. Novartis is committed to ensuring that its life-altering products and treatments are available to as many patients as possible. To that end, Novartis is a participant in the 340B Drug Pricing Program (340B program), which is intended to benefit uninsured, low-income, and other vulnerable patients. Novartis also works to ensure that patients can access its drug products through other means, including co-pay assistance, adherence programs, free samples, and free medication for certain patients.

5. Within Novartis's portfolio are pharmaceutical products focused on improving cardiovascular health,

treating patients with immunological or neurological conditions, and helping to heal those battling cancer. Novartis also is researching and developing new products that, once they come to market, will offer life-changing treatments for patients. These products in Novartis's pipeline include treatments in the disease areas of Oncology, Immunology, Neuroscience, Cardiovascular, Renal, and Metabolic.

6. In November 2020, Novartis implemented a contract pharmacy policy, pursuant to which Novartis voluntarily recognized all contract pharmacies within 40 miles of a covered entity—an area of more than 5,000 square miles—and allowed covered entities to seek exemptions based on individual circumstances. This 40-mile limitation did not apply to federal grantee covered entities.

7. In April 2023, Novartis announced an update to its contract pharmacy policy, effective May 2023. Novartis's current policy provides that units purchased by a covered entity at the 340B discounted price will be delivered only to the covered entity's in-house pharmacy—or, if the covered entity lacks an in-house pharmacy, to one designated contract pharmacy location. Federal grantee covered entities remain exempt. Novartis's current contract pharmacy policy was carefully crafted in light of the federal court decisions issued by the United States District Court for the District of Columbia and the United States Court of Appeals for the Third Circuit in the Administrative Procedure Act lawsuits filed against the Health Resources and Services Administration (HRSA), including the lawsuit filed by Novartis.

8. I understand that Mississippi has enacted legislation purporting to impose state-law obligations on manufacturers, like Novartis, that have placed certain limitations on the recognition of contract pharmacy arrangements. I further understand that Mississippi's law requires Novartis to recognize an unlimited number of contract pharmacy arrangements with respect to covered entities in the state, notwithstanding the court decisions mentioned above.

9. As a manufacturer of branded products, Novartis relies on the revenues generated from the sales of its patented drugs to recoup the high costs of developing those drugs. Novartis's ability to sell its products covered by patent or regulatory exclusivities at a non-340B price for transactions that do not fall within the requirements of the federal 340B statute is important to its ability to fully invest in pipeline products and continue to engage in therapeutic innovation with the goal of saving and bettering patient lives.

10. At present, Novartis has 67 innovator drug products with patent-protected or regulatory market exclusivity periods that have not yet expired. Novartis spent, on average, \$11 billion to research, develop, and bring to market new drug products in 2023—an investment that may be recouped only through these exclusivities protected by federal law.

11. Mississippi's law will require Novartis to transfer its pharmaceutical products at steeply discounted prices *before* the federally protected exclusivity periods have run, thereby reducing the benefits of federal protections afforded to those

products and undermining the bargain between brand name and generic drug manufacturers.

12. Because Mississippi's law requires Novartis to provide its drugs at steeply discounted 340B prices on transactions that do not fall within the requirements of the federal statute, Novartis will face the threat of millions of dollars in forced unnecessary discounts annually as a result of Mississippi's law. Novartis is already beginning to feel financial, operational, and compliance burdens created by Mississippi's statute and its potential sweeping application.

13. Once the 340B discounts are given, it is my understanding that there is no defined pathway or process for a covered entity or contract pharmacy to automatically refund to Novartis unlawfully received discounts if Mississippi's statute is subsequently invalidated.

14. The lost revenue will, in turn, negatively affect Novartis's ability to invest in its pipeline innovation products. For example, the lost revenue will negatively impact Novartis's drug development programs by reducing funds that Novartis uses for developing therapies for new indications and improving its existing drugs. That will be to the detriment of the public, and vulnerable patients in particular, who desperately need innovative drugs and new treatments. It will also hinder the company's ability to recruit and maintain talent and build relationships with the stakeholders necessary to develop pharmaceuticals that patients need. Any loss of revenue risks the potential for layoffs of experienced staff. Those harms are irreparable; once

research and development opportunities are lost or delayed, it is impossible to recoup the lost investment.

15. Mississippi's law threatens to impose a civil penalty of up to \$10,000 per violation in the event of a knowing and willful violation or violation of an injunction. H.B. 728; MS Code § 75-24-19. Mississippi's law also imposes substantial criminal penalties for non-compliance. A violation of Mississippi's law would subject violating entities to criminal penalties in the form of both a misdemeanor and a felony offense. Criminal penalties may also be imposed, of up to \$1,000 for per violation for the first two violations, and up to \$5,000 for the third and subsequent violations. MS Code § 75-24-20. "A violation occurs each time a prohibited act is committed." H.B. 728. None of these fines or penalties appear to be readily recoverable should the Mississippi law later be found invalid.

16. These actions and penalties pose a significant legal, operational, and reputational risk to Novartis. Labeling a company as in violation of trade practices laws undermines consumer trust and confidence in the company, directly communicating to the public that the company should not be trusted. Notwithstanding the lawfulness of Novartis's policy under federal law, the Mississippi statute would stigmatize Novartis and label it a wrongdoer. That damage would have long-lasting effects, even if Mississippi's law is subsequently held unconstitutional.

17. These state punishments, above and beyond those permitted by federal law, make participation in 340B dramatically more onerous for manufacturers,

including Novartis. Manufacturers have historically been able to rely on the federal government's oversight of 340B for uniformity and continuity. Mississippi's statute directly threatens that reliance and the balance struck by Congress by imposing greater potential punishment on manufacturers.

18. Novartis's harm is amplified considering that a number of other states, including Arkansas, Louisiana, West Virginia, Maryland, Kansas, and Minnesota, have recently adopted comparable, but differing, statutes. Novartis must contend with the difficulty of complying with a patchwork of potentially inconsistent regimes, all tied to federal 340B participation.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct

/s/ Odalys Caprisecca

Odalys Caprisecca

Executed on June 4, 2024 at East Hanover, NJ.

APPENDIX H
Constitutional, Statutory, and Regulatory
Provisions Involved

U.S. Const. art. VI, § 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

42 U.S.C. § 256b

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the “ceiling price”), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) “Rebate percentage” defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the “rebate percentage” is the amount (expressed as a percentage) equal to--

- (i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by
- (ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the “rebate percentage” shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) “Over the counter drug” defined

The term “over the counter drug” means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical

assistance under title XIX of the Social Security Act.

(4) “Covered entity” defined

In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social

Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary

relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs1 (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs1 (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent

purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

(1) In general

In this section, the terms “average manufacturer price”, “covered outpatient drug”, and “manufacturer” have the meaning given such terms in section 1927 (k) of the Social Security Act.

(2) Covered drug

In this section, the term “covered drug”--

(A) means a covered outpatient drug (as defined in section 1927(k) (2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph

(A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive

adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed \$5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly

update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5) (B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections² (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1) (B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

- (i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services 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 described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;
- (ii) establish such deadlines and procedures as may be necessary to ensure that claims

shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of

covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) 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.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.

42 C.F.R. § 10.21

§ 10.21 Claims.

(a) Claims permitted. All claims must be specific to the parties identified in the claims and are limited to the following:

(1) Claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHS Act, that the covered entity has violated section 340B(a)(5)(A) of the PHS Act, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHS Act, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity.

(b) Requirements for filing a claim.

(1) Absent extenuating circumstances, a covered entity or manufacturer must file a claim under this section in writing to OPA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision.

(2) A covered entity filing a claim described in paragraph (a)(1) of this section must provide the basis, including all available supporting documentation, for its belief that it has been overcharged by a manufacturer, in addition to any other documentation as may be requested by OPA. A covered entity claim against multiple manufacturers is not permitted.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts, in addition to any other documentation as may be requested by OPA.

(4) A covered entity or manufacturer filing a claim must provide documentation of good faith efforts, including for example, documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim.

(c) Combining claims.

(1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity consents to the jointly filed claim and meets the filing requirements.

(i) For covered entity joint claims, the claim must list each covered entity, its 340B ID and include documentation as described in paragraph (b) of this section, which demonstrates that each covered entity meets all of the requirements for filing the ADR claim.

(ii) For covered entity joint claims, a letter requesting the combining of claims must accompany the claim at the time of filing and must document that each covered entity consents to the combining of the claims, including signatures of individuals representing each covered entity and a point of contact for each covered entity.

(2) An association or organization may file on behalf of one or more covered entities representing their interests if:

(i) Each covered entity is a member of the association or the organization representing it and each covered entity meets the requirements for filing a claim;

(ii) The joint claim filed by the association or organization must assert overcharging by a single manufacturer for the same drug(s); and

(iii) The claim includes a letter from the association or organization attesting that each covered entity agrees to the organization or association asserting a claim on its behalf, including a point of contact for each covered entity.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the consolidated claim, meets the requirements for filing a claim, and the 340B ADR Panel determines that such consolidation is appropriate and

consistent with the goals of fairness and economy of resources. Consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests are not permitted.

(d) Deadlines and procedures for filing a claim.

(1) Covered entities and manufacturers must file claims in writing with OPA, in the manner set forth by OPA.

(2) OPA will conduct an initial review of all information submitted by the party filing the claim and will make a determination as to whether the requirements in paragraph (b) of this section are met. The OPA staff conducting the initial review of a claim may not be appointed to serve on the 340B ADR Panel reviewing that specific claim.

(3) Additional information to substantiate a claim may be submitted by the initiating party and may be requested by OPA. If additional information is requested, the initiating party will have 20 business days from the receipt of OPA's request to respond. If the initiating party does not respond to a request for additional information within the specified time frame or request and receive an extension, the claim will not move forward to the 340B ADR Panel for review.

(4) OPA will provide written notification to the initiating party that the claim is complete. Once the claim is complete, OPA will also provide written notification to the opposing party that the claim was submitted. This written notification will provide a copy of the initiating party's claim, and additional instructions regarding the 340B ADR

process, including timelines and information on how to submit their response in accordance with the procedures for responding to a claim as outlined in paragraph (e) of this section.

(5) If OPA finds that the claim meets the requirements described in paragraph (b) of this section, and once OPA receives the opposing party's response in accordance with the procedures outlined in paragraph (e) of this section, additional written notification will be sent to both parties advising that the claim will be forwarded to the 340B ADR Panel for review.

(6) If OPA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both parties stating the reasons that the claim did not move forward.

(7) For any claim that does not move forward for review by the 340B ADR Panel, the claim may be revised and refiled if there is new information to support the alleged statutory violation and the claim meets the criteria set forth in this section.

(e) Responding to a submitted claim.

(1) Upon receipt of notification by OPA that a claim is deemed complete and has met the requirements in paragraph (b) of this section, the opposing party in alleged violation will have 30 business days to submit a written response to OPA.

(2) A party may submit a request for an extension of the initial 30 business days response period and

OPA will make a determination to approve or disapprove such request and notify both parties.

(3) OPA will provide a copy of the opposing party's response to the initiating party and will notify both parties that the claim has moved forward for review by the 340B ADR Panel.

(4) If an opposing party does not respond or elects not to participate in the 340B ADR process, OPA will notify both parties that the claim has moved forward for review by the 340B ADR Panel and the 340B ADR Panel will render its decision after review of the information submitted in the claim.

107a

**HB 728 (As Sent to Governor) -
2024 Regular Session**

MISSISSIPPI LEGISLATURE

2024 Regular Session

To: Drug Policy

By: Representative Barton

House Bill 728

AN ACT TO BE KNOWN AS THE DEFENDING AFFORDABLE PRESCRIPTION DRUG COSTS ACT; TO PROVIDE DEFINITIONS FOR THE PURPOSE OF THE ACT; TO PROHIBIT HEALTH INSURANCE ISSUERS, PHARMACY BENEFIT MANAGERS AND OTHER THIRD PARTY PAYORS AND DRUG MANUFACTURERS AND DISTRIBUTORS FROM ENGAGING IN CERTAIN DISCRIMINATORY ACTIONS RELATING TO ENTITIES THAT ARE PARTICIPATING OR AUTHORIZED TO PARTICIPATE IN THE FEDERAL 340B DRUG DISCOUNT PROGRAM; TO PROVIDE THAT THE COMMISSION OF ANY ACT PROHIBITED BY THIS ACT IS CONSIDERED A VIOLATION OF THE CONSUMER PROTECTION ACT; TO AMEND SECTION 75-24-5, MISSISSIPPI CODE OF 1972, TO CONFORM TO THE PRECEDING PROVISION; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. Short title. This act may be cited as the “Defending Affordable Prescription Drug Costs Act”.

SECTION 2. Definitions. As used in this act, the following terms have the following meanings:

(a) “340B drug” means a drug that has been subject to any offer for reduced prices by a manufacturer pursuant to 42 USC 256b and is purchased by a covered entity as defined in 42 USC 256b(a)(4).

(b) “340B entity” means an entity participating or authorized to participate in the federal 340B drug discount program, as described in 42 USC 256b, including its pharmacy, or any pharmacy contracted with the participating entity to dispense drugs purchased through the 340B drug discount program.

(c) “Health insurance issuer” means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the Commissioner of Insurance, that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including an accident and sickness insurance company, a health maintenance organization, a preferred provider organization or any similar entity, or any other entity providing a health insurance plan as defined in Section 73-21-153.

(d) “Manufacturer” has the same meaning as defined in Section 73-21-73.

(e) “Pharmacy” has the same meaning as defined in Section 73-21-73.

(f) “Pharmacy benefit manager” has the same meaning as defined in Section 73-21-153.

SECTION 3. Prohibition of certain discriminatory actions related to reimbursement of 340B entities. (1) (a) With respect to reimbursement to a 340B entity for 340B drugs, a health insurance issuer, pharmacy benefit manager, other third-party payor, or its agent shall not do any of the following:

(i) Reimburse a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities or lower reimbursement for a claim on the basis that the claim is for a 340B drug.

(ii) Impose any terms or conditions on any 340B entity with respect to any of the following that differ from such terms or conditions applied to non-340B entities on the basis that the entity participates in the federal 340B drug discount program set forth in 42 USC 256b or that a drug is a 340B drug including, without limitation, any of the following:

1. Fees, charges, clawbacks, or other adjustments or assessments. For purposes of this item 1, the term “other adjustment” includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other entities that do not participate in the 340B drug discount program, including affiliate pharmacies of the health insurance issuer, pharmacy benefit manager, or other third-party payor.

2. Dispensing fees that are less than the dispensing fees for non-340B entities.
 3. Restrictions or requirements regarding participation in standard or preferred pharmacy networks.
 4. Requirements relating to the frequency or scope of audits of inventory management systems.
 5. Requirements that a claim for a drug include any identification, billing modifier, attestation, or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services or the Division of Medicaid for the administration of the Mississippi Medicaid program.
 6. Any other restrictions, conditions, practices, or policies that are not imposed on non-340B entities.
- (iii) Require a 340B entity to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing.
- (iv) Discriminate against a 340B entity in a manner that prevents or interferes with any patient's choice to receive such drugs from the 340B entity, including the administration of such drugs. For purposes of this subparagraph (iv), it is considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a health insurance issuer, pharmacy benefit manager, or other third-party

payor places any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity, including but not limited to requiring a claim for a drug to include any identification, billing modifier, attestation or other indication that a drug is a 340B drug in order to be processed or resubmitted unless it is required by the Centers for Medicare and Medicaid Services or the Division of Medicaid in administration of the Mississippi Medicaid program.

(v) Include any other provision in a contract between a health insurance issuer, pharmacy benefit manager, or other third-party payor and a 340B entity that discriminates against the 340B entity or prevents or interferes with an individual's choice to receive a prescription drug from a 340B entity, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B entity.

(vi) Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, pharmacy benefit manager, or other third-party payor.

(vii) Exclude any 340B entity from the health insurance issuer, pharmacy benefit manager, or other third-party payor network on the basis that the 340B entity dispenses drugs subject to an agreement under 42 USC 256b, or refusing to contract with a 340B entity for reasons other than those that apply equally to non-340B entities.

(2) Nothing in this act applies to the Mississippi Medicaid program as payor when Medicaid provides reimbursement for covered outpatient drugs as defined in 42 USC 1396r-8(k).

SECTION 4. Prohibition of certain discriminatory actions by a manufacturer or distributor related to 340B entities. (1) A manufacturer or distributor 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.

(2) A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

SECTION 5. Violations.The commission of any act prohibited by this act is considered a violation of the Consumer Protection Act, Sections 75-24-1 through 75-24-29, and subjects the violator to any and all actions, including investigative demands, remedies, and penalties provided for in those sections, except there shall be no right to bring a private action. A violation occurs each time a prohibited act is committed.

SECTION 6. Federal preemption. (1) Nothing in this act is to be construed or applied to be less restrictive than federal law for a person or entity regulated by this act.

(2) Nothing in this act is to be construed or applied to be in conflict with any of the following:

(a) Applicable federal law and related regulations.

(b) Other laws of this state if the state law is compatible with applicable federal law.

(3) Limited distribution of a drug required under 21 USC 355-1 is not to be construed as a violation of this act.

SECTION 7. Section 75-24-5, Mississippi Code of 1972, is amended as follows:

75-24-5. (1) Unfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce are prohibited. Action may be brought under Section 75-24-5(1) only under the provisions of Section 75-24-9.

(2) Without limiting the scope of subsection (1) of this section, the following unfair methods of competition and unfair or deceptive trade practices or acts in the conduct of any trade or commerce are * * * ~~hereby~~ prohibited:

(a) Passing off goods or services as those of another;

(b) Misrepresentation of the source, sponsorship, approval, or certification of goods or services;

(c) Misrepresentation of affiliation, connection, or association with, or certification by another;

(d) Misrepresentation of designations of geographic origin in connection with goods or services;

(e) Representing that goods or services have sponsorship, approval, characteristics,

ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;

(f) Representing that goods are original or new if they are reconditioned, reclaimed, used, or secondhand;

(g) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;

(h) Disparaging the goods, services, or business of another by false or misleading representation of fact;

(i) Advertising goods or services with intent not to sell them as advertised;

(j) Advertising goods or services with intent not to supply reasonably expectable public demand, unless the advertisement discloses a limitation of quantity;

(k) Misrepresentations of fact concerning the reasons for, existence of, or amounts of price reductions;

(l) Advertising by or on behalf of any licensed or regulated health care professional which does not specifically describe the license or qualifications of the licensed or regulated health care professional;

(m) Charging an increased premium for reinstating a motor vehicle insurance policy that was cancelled or suspended by the insured solely for the reason that he was transferred out of this

state while serving in the United States Armed Forces or on active duty in the National Guard or United States Armed Forces Reserve. It is also an unfair practice for an insurer to charge an increased premium for a new motor vehicle insurance policy if the applicant for coverage or his covered dependents were previously insured with a different insurer and canceled that policy solely for the reason that he was transferred out of this state while serving in the United States Armed Forces or on active duty in the National Guard or United States Armed Forces Reserve. For purposes of determining premiums, an insurer shall consider such persons as having maintained continuous coverage. The provisions of this paragraph (m) shall apply only to such instances when the insured does not drive the vehicle during the period of cancellation or suspension of his policy;

(n) Violating the provisions of Section 75-24-8;

* * * ~~and~~

(o) Violating the provisions of Section 73-3-38

* * * ~~;~~ and

(p) Violating any of the provisions of Sections 1 through 6 of this act.

SECTION 8. This act shall take effect and be in force from and after July 1, 2024.