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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company),

Plaintiffs,

v.

ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII,

Defendant.

Civil No. 1:25-cv-00230-SASP-WRP

PLAINTIFFS' TRIAL BRIEF

Judge: Hon. Judge Shanlyn A. S. Park

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INTRODUCTION

Pursuant to this Court's Pretrial Procedures § VII(N) and this Court's Order adopting the parties' proposed trial schedule, Dkt. 160, AbbVie submits this trial brief to provide "citations to case law and other authorities that [AbbVie] asserts should be applied" to decide this case. Pretrial Procedures § VII(N).[1]

On June 2, 2025, AbbVie filed suit challenging the constitutionality of Hawai'i's Act 143. Following the Court's Order in February 2026 Denying In Part the Attorney General's Motion to Dismiss, AbbVie issued numerous subpoenas to covered entities, contract pharmacies, and third-party administrators ("TPAs") to obtain the documents and testimony demonstrating how Act 143 operates on the ground and who really benefits from it. Five depositions and more than one thousand pages of produced discovery later, AbbVie is ready to put that evidence before the Court. The evidence will show precisely what the Attorney General has denied and what this brief previews below: that Act 143 does not help patients. Instead, it hands a windfall to covered entities, contract pharmacies, and their TPAs by overriding rights Congress and federal courts have already confirmed belong to AbbVie.

This case is about Hawai'i's attempt to rewrite the rules of admission to

[1] The parties have yet to exchange exhibit and witness lists but will do so under the operative schedule this Friday, October 16, and then meet and confer about any disputes on Wednesday, October 21. *See* Joint Statement, Dkt. 148. AbbVie will confer with counsel for Defendant regarding filing the pre-trial statement contemplated by Local Rule 16.4(b), including whether filing a joint statement would be preferable.

Medicaid and Medicare Part B for manufacturers, to benefit for-profit pharmacies and their TPAs. Under federal law, drug manufacturers like AbbVie who want to sell their medications to Medicaid and Medicare beneficiaries must participate in the federal 340B Program. The 340B Program requires AbbVie to offer its drugs to certain healthcare providers, called "covered entities" at significant discounts. 42 U.S.C. § 256b(a). The 340B Program thus operates as a bargain between the federal government and AbbVie. AbbVie offers discounted drugs to covered entities and, in exchange, Congress provides federal insurance coverage for manufacturers' drugs. For a long time, the 340B Program was a relatively small benefit for covered entities, which simply purchased medications for their patients at a discounted price.

Eventually, however, national pharmacy chains like CVS and Walgreens turned it into a buy-low, sell-high scheme through which hospitals nominally purchase the discounted drugs before giving them to commercial pharmacies to sell at full price. The pharmacies and pharmacy-owned TPAs take a massive chunk of the profit generated from obtaining inventory at the 340B discounted price and selling it to the pharmacy's customers at the full commercial price. Upon discovering this lucrative arbitrage opportunity, commercial pharmacies flooded 340B covered entities with offers to partner up. The 340B Program has exploded in size as a result and is now on track to overtake Medicare Part D as the largest federal healthcare program in the next few years. *See* Alliance for Integrity and Reform of

340B, *The Impact of Growth in 340B Contract Pharmacy Arrangements—Six Years Later*, at 8 (Oct. 2020), https://tinyurl.com/4zjautah.

In an effort to curb this abuse and the program's exponential growth, manufacturers like AbbVie began placing reasonable limits on their 340B offers to covered entities. Specifically, AbbVie allows each covered entity to choose one, and only one, commercial pharmacy to receive 340B-priced inventory, so long as the covered entity and pharmacy provide AbbVie documentation (called "claims data") proving that the discounted medicines are going only to the covered entity's patients and that the covered entity and pharmacy are complying with the federal 340B Program's strict regulations. [redacted], so AbbVie's claims-data requirement imposes no additional burden. Two courts of appeals have already held that policies like AbbVie's are lawful under the federal 340B Program. *See Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 703-04 (3d Cir. 2023); *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 455, 460 (D.C. Cir. 2024).

The State of Hawai'i did not like the fact that federal courts upheld AbbVie's policy under federal law because it meant that AbbVie would not be required to sell discounted drugs to covered entities and pharmacies participating in 340B arbitrage. So Hawai'i enacted 143 to override the Third and D.C. Circuits' decisions in *Sanofi*

and *Novartis*. Where AbbVie could previously limit its offer of 340B pricing to covered entities that agreed to the terms of AbbVie's policy, Act 143 now requires AbbVie to unconditionally sell an unlimited amount of 340B-priced drugs to covered entities and commercial pharmacies even if they reject the terms of AbbVie's (federally compliant) policy. Put differently, Hawai'i's law takes away AbbVie's right to decide when and on what terms it makes the 340B price available to covered entities and commercial pharmacies. At bottom, as the evidence at trial will confirm, Act 143 forces AbbVie to sell its property at penny prices even when it does not want to.

Just as important is what the evidence will show Act 143 does ***not*** do. The evidence will show that Act 143 does not save patients money on medication. Patients (or their insurers) always pay full price at the pharmacy counter, with or without Act 143. The evidence will show that Act 143 does not make any medication more accessible to any patient. No matter what, any patient can go to any pharmacy of his or her choosing and receive the same exact drugs. Nor does Act 143 have any effect on how those drugs arrive to the pharmacies in the first place. All drugs, whether purchased at the commercial price or the 340B price, arrive to hospitals and pharmacies in the same boxes and in the same trucks. The only thing that Act 143 changes is the price at which a pharmacy acquires its inventory. Without Act 143, a pharmacy would have to act like any other retail

business and purchase its inventory at a wholesale commercial price set by the manufacturer (i.e., AbbVie). When Act 143 is in effect, that same pharmacy can avoid AbbVie's wholesale price by placing an order in the name of a covered entity and obtain the same exact medication at the discounted 340B price. Indeed, the evidence will show that the only reason for pharmacies to work with covered entities at all is so that pharmacies can stock their shelves with discounted drugs and later sell those drugs to patients at the full commercial price, pocketing the spread.

In passing Act 143, Hawai'i violated the Constitution in at least three independent ways. ***First***, Act 143 violates the Supremacy Clause by rewriting the terms of a federal healthcare program and making it more burdensome for drug manufacturers to participate in Medicaid and Medicare Part B. ***Second***, Act 143 violates the Takings Clause by forcing AbbVie to hand over its property to private parties who resell to patients (or their insurers) at a huge profit and for no public purpose. ***Third***, Act 143 violates the Commerce Clause by intruding on Congress's exclusive power to regulate interstate commerce. This Court has already held that, if AbbVie's factual allegations prove true, the law is on AbbVie's side. MTD Order, Dkt. 81, at 31. Discovery has confirmed every one of those allegations, and trial will vindicate AbbVie's constitutional protections.

First, the evidence will show that Act 143 violates the Supremacy Clause. *M'Culloch v. Maryland*, 17 U.S. 316 (1819), and its progeny establish that states

may not target federal entities, officials, contractors, or anyone else with whom the federal government deals for regulation. Yet Act 143 does just that. It says that manufacturers participating in the 340B Program—and only those manufacturers—must unconditionally give their property away to hospitals and pharmacies. That rewrites the terms of manufacturers' participation in the 340B Program, Medicaid, and Medicare Part B by forcing them to make discounted sales federal law would otherwise permit them to reject.

Act 143 is both field and conflict preempted. It intrudes into a federal field by attaching itself to the federal 340B program, which is an exclusively federal creation. And it meddles with an area of dominant federal interest—the requirements attached to Medicare and Medicaid dollars. Act 143 conflicts with Congress's careful calibration of 340B requirements to ensure that participating in the 340B Program made sense for the manufacturers who were agreeing to offer significant discounts on their medications. Further, Act 143 disrupts an exclusive agency forum that Congress created for 340B disputes—a forum that the Supreme Court has already confirmed is the sole remedy for 340B violations.

Though some federal courts have held that similar contract pharmacy state laws are not preempted, *none* of those cases had the benefit of a full factual record. At trial, AbbVie will show that the underlying factual premises of those decisions are wrong. Covered entities do not maintain title to drugs held at their contract

pharmacies, *contra PhRMA v. McClain*, 95 F.4th 1136, 1142–44 (8th Cir. 2024); *AbbVie, Inc. v. Murrill*, 180 F.4th 747, 760 (5th Cir. 2026), nor are contract pharmacies agents of their covered entities, *contra AbbVie, Inc. v. Fitch*, 152 F.4th 635, 647 (5th Cir. 2025).

Second, the evidence will show that the Takings Clause prohibits states from forcing companies to sell their property without just compensation or for private use. Yet that is exactly what Act 143 requires. Under Act 143, AbbVie must sell "340B drugs"—regular medications at steeply discounted prices—to covered entities and contract pharmacies who do not agree to AbbVie's policy. Indeed, the text of Act 143 unambiguously prohibits AbbVie from "deny[ing]" the "acquisition" of its property. Haw. Rev. Stat. § 481N-2(a). That is just an inverse way of saying AbbVie must permit covered entities and contract pharmacies to acquire their drugs at bargain-bin discounts. But AbbVie would otherwise reject such sales, as federal law allows. Meaning, each compelled sale under Act 143 is a physical taking of AbbVie's property (its drugs) *without* just compensation. (Even if just compensation were available, there is no reason to believe the State of Hawai'i would waive sovereign immunity in order to pay it.) And even just compensation does not remedy a forced sale *for private* use. Yet the evidence will show that Act 143's forced sales benefit only private parties, including for-profit pharmacy chains and their own middlemen TPAs, not the public. The Takings Clause has never condoned such

private wealth transfers.

Third, the evidence will show that Act 143 violates the dormant Commerce Clause doctrine. Act 143 discriminates against interstate commerce by significantly burdening out-of-state manufacturers like AbbVie for the direct benefit of in-state covered entities and pharmacies. Moreover, the evidence will show that Act 143 regulates wholly out-of-state transactions. Act 143's requirement that manufacturers transfer their drugs to contract pharmacies includes no geographic limitations, and Hawai‘i covered entities often enter contract pharmacy arrangements with pharmacies located outside the state—sometimes as far away as Florida. For all these burdens on out-of-state commerce, the evidence will show that Act 143 creates minimal local benefits at the expense of huge damage to a nationwide drug-pricing regime.

AbbVie will prove each of these violations at trial. Following the presentation of the evidence, the Court should find for AbbVie and hold Act 143 unconstitutional.

FACTUAL BACKGROUND

A. The 340B Pricing Program.

In 1992, Congress enacted Section 340B of the federal Public Health Service Act, establishing the "340B Program." *See* 42 U.S.C. § 256b. To encourage participation in the program, Congress made manufacturers' ability to receive Medicare Part B and Medicaid funds conditional on their participation in the 340B

Program. *See Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 113 (2011).

Congress's chosen verb matters. Section 340B requires manufacturers to "***offer***"—and conspicuously does not say ***sell***—their products to each "covered entity … for purchase at or below the applicable ceiling price." 42 U.S.C. § 256b(a)(1). Had Congress intended to compel manufacturers to complete sales on demand, it knew how to say so—it did not. By requiring only an "offer," the statute leaves manufacturers free to propose reasonable terms and conditions as part of that offer, and free to decline to consummate a sale if a covered entity will not accept them. "Covered entities" include, among others, federally qualified health centers, disproportionate share hospitals ("DSH hospitals") and rural hospitals. *Id.* §§ 1396r-8(a)(5)(B), 256b(a)(4). The statutorily defined list does not include contract pharmacies or *any* for-profit entity. *Id.* § 256b(a)(4). And those "offers" cost manufacturers because the "ceiling price" is set by a statutory formula and is well below the normal commercial price for manufacturers' drugs, between 23.1 and 99.9% of the average market price for a given drug. Manufacturers' deal with Congress is contractual: manufacturers accept the deal by signing a "Pharmaceutical Pricing Agreement" ("PPA") contract with the United States Department of Health & Human Services ("HHS"). *Id.* § 256b(a)(1); *Astra*, 563 U.S. at 115.

Because access to such sharp discounts creates strong financial incentives, 340B contains guardrails to prevent abuse. First, the law explicitly prohibits covered

entities from "resell[ing] or otherwise transfer[ring]" drugs they purchased at a discount to anyone who is not a patient of the entity—a practice called "diversion." 42 U.S.C. § 256b(a)(5)(B). And second, covered entities may not cause manufacturers to pay a Medicaid rebate on a unit of drug they purchased at a 340B discount—a forbidden "duplicate discount." *Id.* § 256b(a)(5)(A)(i). Manufacturers, for their part, can be subject to administrative enforcement actions if a covered entity "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price"—"overcharging." 42 C.F.R. § 10.21(a)(1). Congress vested HHS and its subagency, the Health Resources and Services Administration ("HRSA"), with exclusive authority to enforce these guardrails and administer the 340B Program through audits and a federal Administrative Dispute Resolution ("ADR") process for the claims discussed above. *See Astra*, 563 U.S. at 120-22.

B. Contract Pharmacies and The Replenishment Model.

In 1996, HRSA issued non-binding guidance suggesting covered entities lacking an in-house dispensing pharmacy should be permitted to contract with a ***single*** outside pharmacy—think Long's or Walgreens—to sell drugs that the covered entity purchased at the 340B price. 61 Fed. Reg. 43,549, 43,550-55 (Aug. 23, 1996). To avoid potential unlawful diversion, HRSA assumed the covered entity would maintain title to drugs and the contract pharmacy would serve as an agent of the

covered entity—otherwise such arrangements would seemingly "transfer" drugs to non-patients for resale. *Id.*

That status quo was upended in 2010. HRSA opined that ***all*** covered entities—even those with their own in-house pharmacy—could contract with an ***unlimited*** number of pharmacies. 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010). Consequently, covered entities' use of contract pharmacies surged by more than ***12,000 percent***. That explosion has been driven by the prospect of sharing in the outsized profit margins on 340B-priced drugs. AbbVie's witnesses will explain how commercial pharmacies generate significant profits by sharing in the "spread" from selling 340B-priced drugs at ***full*** or higher prices to patients and/or seeking full commercial reimbursement from insurance plans when the covered entity actually purchased the drugs for pennies on the dollar.

The evidence will show that most Hawai'i contract pharmacies operate under what is known as the "replenishment model." *See* Ex. 2, Scheidler Dep. 67:3-4 (affirming that the replenishment model is used in Hawai'i); [redacted]. AbbVie's witnesses will explain that, under this model, the contract pharmacy fills all prescriptions using its own existing drug inventory to all individuals at the point of sale, irrespective of whether an individual is a patient of a covered entity. The pharmacy does not determine at the point-of-purchase whether the individual is eligible for the 340B

discount. Later, the pharmacy (often with the help of a TPA) feeds prescription-level information (called "claims data") through a black-box algorithm to determine which dispenses of drugs ***may*** have been to 340B-eligible patients. [redacted]. An order is then placed for additional quantities of that drug at the 340B price for the contract pharmacy. Once the contract pharmacy receives the replenishment order, the 340B-priced drugs are placed on the shelf and may be dispensed to any subsequent patient—340B-eligible or not. Manufacturers' drugs are available for purchase by and shipment to all qualified pharmacies, the only question being whether the pharmacy "replenishes" its stock of drugs at the commercial or 340B price.

Importantly, the evidence will show that contract pharmacies often take title to the 340B-priced drugs, and do not maintain (and in fact often expressly disclaim) an agency relationship with the covered entities. Though covered entities and commercial pharmacies reap windfalls from this process, uninsured and underinsured patients do not benefit. *Novartis*, 102 F.4th at 457-58 (explaining that the covered entity, pharmacy, and third-party administrator split "the spread between the discounted price and the higher insurance reimbursement rate," so each "has a financial incentive to catalog as many prescriptions as possible as eligible for the discount").

In 2020, drug manufacturers began adopting policies to restore the 340B

Program's integrity. AbbVie offers covered entities unlimited 340B-priced drugs for sale at or below the ceiling price, but AbbVie will not complete sales to covered entities if those drugs are destined for unlimited, third-party contract pharmacies (which may always purchase AbbVie's drugs at ordinary prices). Instead, consistent with the 1996 Guidelines, AbbVie will complete 340B sales only if the covered entity indicates that it will direct delivery to its in-house pharmacy or—if the covered entity does not have an in-house pharmacy—one contract pharmacy. *See* Ex. 4, Scheidler Decl., Ex. B (Dkt. 16-3) (340B Integrity Initiative, Mar. 29, 2023 Update) (providing that AbbVie will facilitate bill to/ship to orders of 340B priced medicines only if covered entity submits claims data and uses only one contract pharmacy within 40 miles of the covered entity parent site).

If a covered entity does not comply with this policy, AbbVie will not sell to that covered entity at the 340B price. Accordingly, there are no 340B-priced drugs to deliver, and the non-compliant covered entity never receives title. Rather, the pharmacy or covered entity can complete a purchase for the same drugs at the commercial price. Courts of Appeals have upheld materially identical policies as lawful and consistent with the 340B statute, holding manufacturers have the right to impose reasonable conditions on their offers under federal law. *Sanofi*, 58 F.4th at 703-04; *Novartis*, 102 F.4th at 460-61. Put another way, those courts held that manufacturers do not have an unlimited obligation to ***sell*** 340B-priced drugs on

whatever terms "any covered entity might find most convenient." *Novartis*, 102 F.4th at 461. Instead, manufacturers have only an obligation to ***offer*** the discount subject to covered entities' acceptance of manufacturers' other reasonable conditions; if covered entities reject those terms, manufacturers have no obligation to sell.

C. Hawai'i Act 143.

Act 143 steps in to outlaw AbbVie's federally lawful conditions and compel AbbVie to complete 340B-priced sales when it otherwise would not. It provides, "No manufacturer … shall deny, restrict, or prohibit, either directly or indirectly, the ***acquisition*** of a 340B drug by, or shipping ***or delivery*** of a 340B drug to, a pharmacy that is under contract with a 340B covered entity and is authorized under the contract to receive and dispense 340B drugs on behalf of the 340B covered entity …." Haw. Rev. Stat. § 481N-2(a) (emphasis added). Act 143 defines "340B drug" as "a prescription drug that is purchased by a 340B covered entity through the federal 340B drug pricing program … and is dispensed by a pharmacy." *Id.* § 481N-1. The law's preamble makes clear that it seeks to maximize the spread that covered entities can generate when using contract pharmacies. Dkt. 25-3, PageID.891.

ARGUMENT

AbbVie asserts claims under the Supremacy Clause, the Takings Clause, and the dormant Commerce Clause. To prevail on these claims at trial, AbbVie need

only establish the facts necessary to support its claims by a preponderance of the evidence. *In re Exxon Valdez*, 270 F.3d 1215, 1232 (9th Cir. 2001). In denying the Attorney General's motion to dismiss, the Court has already determined that AbbVie's remaining claims must succeed if its allegations prove true. MTD Order at 31. At trial, AbbVie will carry its burden to establish that Act 143 is unconstitutional.

I. ACT 143 VIOLATES THE SUPREMACY CLAUSE.

AbbVie will show that Act 143 is conflict and field preempted. ***First***, Act 143 is conflict preempted because it expands manufacturers' 340B obligations and establishes an overlapping state enforcement scheme for disputes that only HHS may adjudicate. ***Second***, Act 143 is field preempted because Section 340B comprehensively governs the 340B Program and leaves no room for state supplementation. Act 143 therefore violates the Supremacy Clause by targeting 340B participants for adverse regulation. AbbVie will show that Act 143 is preempted four times over.

A. Act 143 Conflicts With The 340B Program.

A state law is conflict preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012); *Geo Grp., Inc. v. Newsom*, 50 F.4th 745, 758 (9th Cir. 2022). AbbVie will show that Act 143 does so in at least

two ways. ***First***, Act 143 makes participation in the 340B Program more burdensome than federal law requires by mandating concessions from manufacturers beyond those Congress envisioned. ***Second***, Act 143 undermines the nationwide uniformity of 340B and Medicare enforcement.

1. Act 143 Changes the Terms of 340B Participation.

Congress's bargain was deliberate and precise: by participating in 340B in exchange for access to sales within Medicare and Medicaid, manufacturers agree to "offer" their drugs for purchase by covered entities at discounted prices. 42 U.S.C. § 256b(a)(1). Manufacturers may impose reasonable commercial conditions on that federally mandated offer, including by imposing restrictions on the use of contract pharmacies by covered entities. *See Novartis*, 102 F.4th at 455, 460. AbbVie has agreed to participate in the federal 340B program, *see* Ex. 5, Scheidler Decl., Ex. A (ECF 16-2) (Pharmaceutical Pricing Agreement) at 11, and therefore is required to offer its drugs for purchase by covered entities at 340B prices subject to reasonable commercial conditions AbbVie may impose.

Act 143 disrupts the balance Congress struck by requiring AbbVie to sell its drugs at the 340B price to a covered entity *even if the entity rejects the terms of AbbVie's 340B pricing offer*. *See* Haw. Rev. Stat. § 481N-2(a) (barring manufacturers from "deny[ing] … the acquisition of a 340B drug by … a pharmacy that is under contract with a 340B covered entity"). As a result, Hawai‘i nullifies

the right to condition sales granted by federal law contrary to the Supremacy Clause. *Golden State Transit Corp. v. City of Los Angeles*, 475 U.S. 608, 614 (1986) (federal law "precludes state and municipal regulation concerning conduct that Congress intended to be unregulated" (cleaned up)); *Me. Forest Prods. Council v. Cormier*, 51 F.4th 1, 10 (1st Cir. 2022) (state law preempted for "nullify[ing an] implicit federal right" granted to private parties).

Act 143 also drives up the cost of participating in 340B—a cost Congress never imposed and never intended. Every additional discount compelled by Act 143 forces AbbVie to forgo the difference between the commercial price it would receive under federal law and the discounted price Hawai'i requires. Tellingly, if AbbVie withdrew from 340B tomorrow, Hawai'i could not compel AbbVie to provide a single additional discount; Act 143's entire command depends on, and burdens, AbbVie's federal participation. Act 143, therefore, stands as "an obstacle to the accomplishment … of the full purposes and objectives of Congress." *Arizona*, 567 U.S. at 399. By increasing the burdens of 340B participation, Act 143 frustrates Congress's efforts to incentivize manufacturer participation while retaining leverage to negotiate other appropriate bargains from manufacturers. *See* Brief of the United States, *PhRMA v. Neronha*, 2026 WL 527776, at *15 (1st Cir. Feb. 25, 2026) (No. 26-1039) (state restrictions on offer conditions raise "the costs of participation" in 340B, which can lead "rational manufacturers … to withdraw"); *see Forest Park II*

v. Hadley, 336 F.3d 724, 731-33 (8th Cir. 2003) (finding preemption where state law prohibited a federal program participant from taking action that the federal government authorized "as an incentive" to participate).

The Attorney General defends Act 143 on the basis that it regulates delivery, not price, and therefore does not conflict with the federal 340B program. Opp'n to Mot. for PI, Dkt. 26, at 10-13. The Attorney General is wrong. AbbVie's evidence at trial will show that Act 143 regulates *pricing*, not delivery. By prohibiting AbbVie from imposing limits on covered entities' use of contract pharmacies as a condition of 340B sales, Act 143 forces AbbVie to sell drugs at 340B-discounted prices to covered entities on terms AbbVie would otherwise refuse. *See* Ex. 4, Scheidler Decl., Ex. B (ECF 16-3) (340B Integrity Initiative, Mar. 29, 2023 Update) (providing that AbbVie will facilitate bill to/ship to orders of 340B priced medicines only if covered entity use only one contract pharmacy within 40 miles of the covered entity parent site); [redacted].

The Attorney General also asserts that 340B covered entities in Hawai'i maintain an agency relationship with their contract pharmacies, and that title of 340B-priced drugs never passes to contract pharmacies. Opp'n to Mot. for PI at 13–14. The documentary record proves otherwise. [redacted]

[redacted][2] [redacted]

[redacted][3]

2. Act 143 Usurps Exclusive HRSA Enforcement Authority.

Act 143 also obstructs federal objectives because it "undermine[s] the [federal government's] efforts to administer … § 340B harmoniously and on a uniform, nationwide basis." *Astra*, 563 U.S. at 120. Congress vested exclusive enforcement of when and whether manufacturers are obligated to provide 340B pricing to HRSA. *Id.* at 117, 121-22. So, all allegations that "a manufacturer has ***limited*** the covered entity's ability ***to purchase*** covered outpatient drugs at or below the 340B ceiling

[2] [redacted]

[3] [redacted]

price," 42 C.F.R. § 10.21(a)(1) (emphases added), including complaints regarding "***restrictions***" by manufacturers "on certain covered entities[']' use of contract pharmacies," *340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 89 Fed. Reg. 28,643, 28,644 (Apr. 19, 2024) (emphasis added), must go to federal ADR.

Act 143, however, provides for private claims by covered entities against manufacturers for "restrict[ing] … the acquisition of a 340B drug." Haw. Rev. Stat. § 481N-2(a). Act 143 claims against AbbVie would require allegations that AbbVie "den[ied], restrict[ed], or prohibit[ed]" covered entities use of contract pharmacies to "acqui[re]" covered outpatient drugs at the 340B price. *Id.* Every Act 143 claim would thus turn on when and whether a covered entity was entitled to a 340B price and if AbbVie denied it. Disputes about when and whether manufacturers must provide 340B pricing belong in HRSA's ADR process, not in Hawai'i state court. *PhRMA v. Morrisey*, 760 F. Supp. 3d 439, 456-58 (S.D. W.Va. 2024); *AbbVie Inc. v. Drummond*, 808 F. Supp. 3d 1266, 1278-79 (W.D. Okla. 2025). Indeed, covered entities regularly bring federal ADR actions against manufacturers' policies. *See 340B ADR Decision Summaries*, HRSA (July 16, 2026), https://tinyurl.com/mrjb746k. "[W]hen two separate remedies are brought to bear on the same activity," conflict is "imminent" and the state remedy must give way. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 380 (2000) (citation

modified).

Act 143 may further conflict with Congress's intended 340B enforcement mechanisms by preventing manufacturers from obtaining claims data from covered entities. Claims data is necessary for manufacturers to vindicate their rights under the federal ADR framework because HRSA requires "documentation" giving rise to "reasonable cause" to suspect noncompliance by a covered entity before it will approve an audit, 61 Fed. Reg. 65,406, 65,409-10 (Dec. 12, 1996), which is itself a precondition to a manufacturer bringing an ADR claim against a covered entity, 42 U.S.C. § 256b(d)(3)(B)(iv).

Act 143 appears on its face to allow manufacturers to collect claims data. *See* Haw. Rev. Stat. § 481N-2(b) ("Nothing in this section shall … prohibit a manufacturer from requiring a 340B covered entity to provide claims data … provided that the claims data is necessary to investigate potential diversion [or] duplicate discounts[.]"). The Attorney General, however, has been less than clear about her interpretation of that provision. On one hand, the Attorney General has represented that "Act 143 enshrines and protects a manufacturer's ability to require claims data from a 340B covered entity." Ex. 14, June 10, 2026 Resp. to Pls.' 30(b)(6) Notice at 17 (Topic 12). On the other hand, the Attorney General has reserved her right to seek retroactive penalties for AbbVie's conduct during the litigation, *see id.* at 7 (Topic 2), even though AbbVie has *only* been enforcing the

claims-data component of its policy while this suit is pending. And in another currently pending challenge to Act 143, Defendant has opposed another manufacturer's claims-data arguments on the ground that "claims data is not necessary to conduct an audit,"[4] suggesting such a policy falls outside Act 143's statutory safe harbor. Def.'s Opp'n to Summ. J. Mot. in *PhRMA v. Lopez*, No. 1:25-cv-00292 (D. Haw.) Dkt. 146 at 25.

Given the lack of clarity as to whether AbbVie's claims-data requirement violates Act 143 and whether AbbVie's enforcement of its claims-data requirement would ever be used against AbbVie in a state enforcement action, AbbVie intends to put forth evidence that claims data is necessary to access federal ADR and that state laws prohibiting manufacturers' claims-data requirements frustrate the federal enforcement scheme.

[4] Importantly, by focusing on whether claims-data collection is "necessary" for audits, the Attorney General addressed the wrong question. If collection were necessary, and Act 143 prohibited it, then that would lead to "impossibility" preemption. *Arizona*, 567 U.S. at 399 ("compliance with both federal and state regulations is a physical impossibility"). But to show preemption AbbVie must only show that a bar on claims-data collection "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id.* Even if audits are theoretically possible without claims data, AbbVie's evidence will show that such bars make them much harder to initiate and thus foster and shield 340B abuse, the prevention of which is a clear objective of Congress's. *See* 42 U.S.C. § 256b(d)(2); [redacted].

B. Act 143 Intrudes Into The Federal 340B Field

1. Act 143 Targets 340B Participants For Additional Burdens.

Hawai‘i’s action violates the Supremacy Clause by singling out 340B Program participants for obligations and liabilities from which non-participating manufacturers are free. Manufacturers who do not participate in 340B are able, under Act 143, to decline counter-offers from their customers. *Moss v. Am. Int’l Adjustment Co.*, 86 Haw. 59, 63 (1997) (defining counter-offer as “[a] reply to an offer which purports to accept it but is conditional on the offeror’s assent to terms additional to or different from those offered” (quoting Restatement (Second) of Contracts § 59 (1981)). Under Act 143, 340B participants lose that right and must accept covered entities’ counter-offers for 340B pricing that omit material terms.

“[S]tate laws” cannot “discriminate against the Federal Government or those with whom it deals.” *United States v. Washington*, 596 U.S. 832, 838-39 (2022) (quotation marks omitted). And the United States “deals” with private entities in a variety of ways—for example, contracting with them, *see id.*, creating them, *M’Culloch*, 17 U.S. at 435-36, paying them pensions, *Dawson v. Steager*, 586 U.S. 171, 179 (2019), and leasing them property, *Phillips Chem. Co. v. Dumas Indep. Sch. Dist.*, 361 U.S. 376, 387 (1960). Most relevant here, states also may not target those who deal with the federal government via their participation in federal programs by imposing additional burdens or lessening their protections. *See*

Lawrence County v. Lead-Deadwood Sch. Dist. No. 40-1, 469 U.S. 256, 270 (1985); *Forest Park II*, 336 F.3d at 734 ("When, however, these state programs place additional requirements on federal program participants … they are preempted.").

Act 143 violates that rule. ***First***, it applies only to those manufacturers who elect to "deal with" the federal government by participating in 340B. The statute targets only those manufacturers that sell "340B drug[s]." Haw. Rev. Stat. § 481N-1, -2(a). Because only 340B-participating manufacturers sell 340B drugs, 42 U.S.C. § 256b(a)(1), the law regulates only 340B participants. Such targeting is forbidden. *Churchill Downs Tech. Initiatives Co. v. Mich. Gaming Control Bd.*, 162 F.4th 631, 639 (6th Cir. 2025) ("The Supreme Court has disapproved of states tailoring regulation to target federal schemes ….").[5]

Second, Act 143 does not just target 340B participants; it discriminates against them. A non-340B manufacturer retains the right to choose the terms on which it will sell its property, while a 340B manufacturer is forced to sell its drugs at a discount even when federal law would otherwise allow the 340B manufacturer to decline a sale. In *Washington*, for example, a state law imposed more onerous

[5] Courts have discussed this anti-targeting principle under different names. *See, e.g.*, *Geo Grp.*, 50 F.4th 745 (immunity and preemption); *PhRMA v. McCuskey*, 171 F.4th 675, 688–89 (4th Cir.), *reh'g en banc granted*, 176 F.4th 830 (4th Cir. 2026) (field preemption); *Churchill*, 162 F.4th at 639 (conflict preemption). At bottom, however, the rule is the same: states cannot target objects for special regulation because of federal status.

requirements on any "contractor or subcontractor, who was engaged in the performance of work, either directly or indirectly, for the United States." 596 U.S. at 839. Contractors for non–United States projects were free from those obligations. That law treated entities affiliated with the federal government worse than those that were not, so it could not stand. *Id.* And in *Boeing Co. v. Movassaghi*, a state law imposed uniquely stringent standards on the cleanup of a federal nuclear site in California by a federal contractor. 768 F.3d 832, 842 (9th Cir. 2014). That state law targeted a federal undertaking—thus discriminating against the federal government—and could not survive the Supremacy Clause. *Id.*

The same holds true here. The evidence will show that AbbVie is worse off financially as a result of Hawai'i's discrimination because AbbVie has to make discounted sales that a competitor who does not participate in the 340B program would not have to make. *See* Ex. 2, Scheidler Dep. 58:16-18. States cannot target topics for adverse regulation because of some connection to the federal government. As the United States has explained in analogous cases, state laws may not "impermissibly target[] and discriminate[] against manufacturers that participate in a federal program." Brief, *Neronha*, 2026 WL 527776, at *12. Because Hawai'i Act 143 does so, it cannot stand.

2. Section 340B Completely Occupies the Field of 340B Administration.

Act 143 is also preempted for invading an exclusive federal field. A field is

preempted when it is either occupied by a "framework of regulation 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." *Arizona*, 567 U.S. at 399 (emphasis added). Here, both are true.

First, 340B comes complete with a pervasive framework of rules governing covered drugs, ceiling prices, eligible entities, compliance obligations, and its own exclusive enforcement forum. *Astra*, 563 U.S. at 114, 120; 42 U.S.C. §§ 256b(a)(5)(C)-(D), (d)(1)(B)(v), (d)(3); 42 C.F.R. §§ 10.20 et seq. The statute "places" the federal government, not the states, "in the driver's seat of this important program." *Novartis Pharms. Corp. v. Kennedy*, 182 F.4th 1027, 1035 (D.C. Cir. 2026). And unlike cooperative federalism programs like Medicaid, Section 340B carves out no role for state participation.

"Section 340B did not merely set a floor to which States may add additional obligations. Instead, Congress struck a careful bargain" and "ousted States from [that] field"—specifically, any role in determining what obligations attach to manufacturers' participation in 340B. *McCuskey*, 171 F.4th at 692. Congress's mandate of limited, conditional 340B-priced sales occupies the field of when and whether discounts are required; Act 143, however, invades precisely that field, stripping away the conditions Congress allowed and compelling unconditional sales

to enrich state-preferred entities. Worse, Act 143 does not merely add to the federal scheme—it inverts it, turning a program designed to benefit patients through covered entities into a vehicle for enriching contract pharmacies and their TPAs. This "intrudes upon the federally occupied field of" 340B "qualifications that Congress has reserved for the agency, and impermissibly subjects federal law to supplementation by, and variation among, state laws." *Ventress v. Japan Airlines*, 747 F.3d 716, 722 (9th Cir. 2014) (citation modified); *AbbVie Inc. v. Wrigley*, 832 F. Supp. 3d 920, 937–38 (D.N.D. 2026).

Second, and independently, the federal interest in exclusive 340B enforcement is dominant within the meaning of Arizona. "[S]preading the enforcement burden … is hardly what Congress contemplated when it centralized enforcement in the government." *Astra*, 563 U.S. at 119. Given the complexity of the federal drug-pricing landscape, "adjudication of rights under [340B] must proceed with an eye towards any implications for the other" programs—precisely the kind of centralized, coordinated judgment that fifty separate state enforcement schemes would make impossible. *Id.* at 120. The United States has itself explained its dominant interest before the courts: "the federal interest in determining the costliness of Medicare and Medicaid participation could hardly be stronger." Brief, *Neronha*, 2026 WL 527776, at *21. Act 143 is exactly the kind of uncoordinated state intrusion that this dominant federal interest forecloses.

In light of the federal occupation of the field of 340B obligations, enforcement of Act 143 must be enjoined.

II. ACT 143 CONSTITUTES AN UNCONSTITUTIONAL TAKING.

The evidence will show that Act 143 effects an unconstitutional taking of AbbVie's private property. The Fifth Amendment to the Constitution commands "nor shall private property be taken for public use, without just compensation." U.S. Const. amend. V. ***First***, Act 143 effects a physical taking because, as the evidence will show, it forces AbbVie to sell property when AbbVie otherwise would not. Those compelled sales thus extinguish AbbVie's "rights to possess, use and dispose of" the drugs. *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982). Importantly, the Attorney General concedes that Act 143 is neither voluntary nor a part of the 340B Program. *See* Ex. 14, June 10, 2026 Irrog. to AG, No. 12 ("Participation in Act 143 is separate from participation in the 340B Program ….") . And AbbVie's evidence will show that Act 143 does not serve a constitutionally adequate public purpose. ***Second***, even if the Act did not effect physical takings, it so reduces AbbVie's ability to control and use its property that it effects a regulatory taking.

A. The Additional Discounted Sales Act 143 Compels Constitute Per Se Physical Takings.

The sales that Act 143 compels are physical takings. A physical taking occurs whenever "the government physically acquires private property for" its use or for

another private party. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147-48 (2021). Whenever a law "results in a physical appropriation of property, a *per se* taking has occurred." *Id.* AbbVie will prove that Hawai'i's law does so.

Act 143 instructs that AbbVie cannot "deny, restrict, or prohibit, either directly or indirectly, the ***acquisition*** of a 340B drug by … a pharmacy that is under contract with a 340B covered entity." Haw. Rev. Stat. § 481N-2(a) (emphasis added). Per the Attorney General, that command applies "pre-sale" to prevent manufacturers from "refus[ing] to offer[] a drug for sale at the 340B price." Ex. 14, June 10, 2026 Irrog. to AG, No. 8. While the Attorney General claims Act 143 only requires an "offer," the Act's plain language reduces to a forced sale: prohibiting a manufacturer from "deny[ing] … the acquisition of a 340B drug" is no different from mandating the sale of the drug at the 340B price. Thus, Act 143 requires AbbVie to sell its drugs at discounted prices, regardless of any contract-pharmacy policy, whenever covered entities ask. That is a compelled sale and a taking. *See Pung v. Isabella County*, 609 U.S. 30 (2026); *Horne v. Dep't of Agric.*, 576 U.S. 351, 361-62 (2015).

Importantly, federal law does not require AbbVie to complete these sales. AbbVie must only ***offer*** its drugs to covered entities at the 340B price, 42 U.S.C. § 256b(a)(1), but AbbVie need not ***sell*** its drugs at the 340B price under any circumstances. Instead, federal law authorizes AbbVie to include in its offer other

reasonable terms and conditions alongside the 340B price. *See Novartis*, 102 F.4th at 460; *Sanofi*, 58 F.4th at 703. When covered entities decline those other terms and conditions, AbbVie has no federal obligation to complete a 340B-discounted sale.

Absent Act 143, AbbVie simply would not consummate a sale in those circumstances where it is not required to by federal law or ordinary contracting principles—when covered entities do not accept all of the terms of its offer. Under its 340B Integrity Initiative, first enacted in 2020, AbbVie requires, as a condition of a sale at a 340B price, that hospital covered entities without in-house outpatient pharmacies designate only one contract pharmacy location within 40 miles of the covered entity to dispense drugs purchased at the 340B price. *See* Ex. 4, Scheidler Dep., Ex. B (ECF 16-3) (340B Integrity Initiative, Mar. 29, 2023 Update); [redacted]. If a covered entity were to reject this condition, AbbVie would not complete a sale under its policy. [redacted][6]

By prohibiting AbbVie from "deny[ing] … the ***acquisition*** of a 340B drug"

6 [redacted]

by a covered entity, Haw. Rev. Stat. § 481N-2(a) (emphasis added), Act 143 requires AbbVie to comply with an unlimited contract pharmacy condition and make sales it would otherwise refuse. *See* Ex. 14, June 10, 2026 Irrog. to AG, No. 6 ("acquisition encompasses purchases"). That is true even though Act 143 is phrased to negatively prohibit AbbVie from doing something rather than to affirmatively order it to do so. The law at issue in *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419 (1982), was similarly framed as a prohibition. There, the New York law provided that "a landlord may not 'interfere with the installation of cable television facilities upon his property or premises.'" *Id.* at 423. By punishing the property owner's interference with another's access, the law affirmatively compelled admission and extinguished the right to exclude. *Id.* at 436. That the state worded its law negatively ("No landlord shall … interfere with the installation ….") instead of positively ("All landlords shall grant access for installation.") was immaterial to what the Constitution demands. Here, Act 143 punishes AbbVie for exercising its property right not to sell on terms with which it does not agree; meaning, it compels AbbVie to sell on those terms, making it a physical taking of AbbVie's property (its drugs). *See Cedar Point*, 594 U.S. at 144 (holding that a law that penalized "interference" with third parties accessing a farm was a taking).

AbbVie's evidence will confirm that Act 143 operates as an affirmative command to sell drugs at a discount AbbVie would otherwise refuse to provide. [redacted]

[redacted]

Indeed, the head of AbbVie's 340B Center of Excellence attributed the "acceleration of 340B discounts" in Hawai'i to the passage of Act 143 in the middle of 2025. Ex. 2, Scheidler Dep. 58:16-18. Those transactions would not take place but for Act 143.

B. Act 143 Does Not Serve A Sufficient Public Purpose.

Act 143 serves no "public use" to justify the taking of AbbVie's property. U.S. Const. amend. V. As AbbVie's evidence will show, Act 143 confers benefits on private entities including private hospitals and their commercial pharmacy partners. "[T]ransfers intended to confer benefits on particular, favored private entities, and with only incidental or pretextual public benefits, are forbidden by the Public Use Clause." *See Kelo v. City of New London*, 545 U.S. 469, 490 (2005) (Kennedy, J., concurring). AbbVie will prove that Act 143 serves to benefit contract pharmacies and covered entities, not the public. [redacted]

[redacted]

At the outset, patients receive no benefit at the point of sale. [redacted]

Instead, Act 143 impacts only the price paid by the covered entity for AbbVie's drug. As AbbVie will show at trial, the increased sales forced by Act 143 generate profits for covered entities, contract pharmacies, and TPAs. [redacted]

[redacted]

Increased use of contract pharmacies drastically benefits the pharmacies themselves and their third-party administrators. [redacted]

Indeed, the increased revenue made possible by Act 143 is not used by these private entities for any public purpose. [redacted] And the evidence

indicates that increased 340B profits have minimal effects on charity care spending and patient outcomes. [redacted] Ultimately, Act 143 is not about lowering the cost of medication to patients or increasing access to those medications. It is about lining the pockets of private hospitals and pharmacies.

C. AbbVie Did Not Volunteer For Act 143's Additional Sales.

The Attorney General may try to elicit a concession at trial that AbbVie voluntarily opted into the federal 340B Program. That would prove nothing. The relevant question is not whether AbbVie volunteered for 340B; it is whether AbbVie volunteered for Act 143. It did not. A demand for private property is not a taking only if it is "a voluntary exchange for a governmental benefit." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1232 (D.C. Cir. 2023). But once a party has already received the benefit in full, the government cannot impose new demands for more property unless it offers some new "incremental benefit" in return. *Id.* at 1233. AbbVie already has everything the federal bargain promised: Medicaid and Medicare participation, guaranteed so long as AbbVie offers 340B pricing. Act 143 gives AbbVie nothing it did not already have in exchange for the additional, unconditional sales it demands. Under *Valancourt*, a demand backed by no new benefit is not voluntary—it is a taking.

More fundamentally, the voluntary participation doctrine works only on a sovereign-by-sovereign basis. That is, states cannot "rid[e] the coattails of a federal

benefit" and add a state-law demand for further property without adding a state benefit. *AbbVie, Inc. v. Brown*, 809 F. Supp. 3d 1341, 1362 (D. Utah 2025). Hawai'i is not "charging admission to a market of [Hawai'i's] own creation, but rather [Hawai'i is] demanding a ransom in exchange for continued access to [the federal] market." *Drummond*, 808 F. Supp. 3d at 1279. States cannot do so. Imagine it were otherwise: Hawai'i could confiscate medical supplies from any hospital that participates in federal Medicare or take any property subject to the protections of a federal patent. The Fifth Amendment is not so flimsy.

Importantly, Hawai'i has conceded this argument by admitting that "Act 143 is not a program, but rather a law that manufacturers such as AbbVie must abide by. Participation in Act 143 is separate from participation in the 340B Program …. Act 143 does not provide any separate benefits for a manufacturer's compliance." Ex. 14, June 10, 2026 Irrogs. to AG, No. 12. Thus, the Attorney General may not use the voluntary-participation doctrine to excuse its taking of AbbVie's property.

D. Alternatively, Hawai'i Act 143 Constitutes A Regulatory Taking.

Because Act 143 is a "physical appropriation" of AbbVie's property—it requires that AbbVie transfer its personal property to someone else against its will—the regulatory-takings doctrine does not apply. *Horne*, 576 U.S. at 363; *Loretto*, 458 U.S. at 425-26. But even assuming that this case does not involve a physical appropriation, AbbVie pleads in the alternative that Act 143 effectuates a partial

regulatory taking. *See Penn Central Transp. Corp. v. City of New York*, 438 U.S. 104, 124 (1978) (laying out three-factor test for regulatory taking: (1) the economic impact of the regulation, (2) the extent to which the regulation has interfered with investment-backed expectations, and (3) the "character of the governmental action").

AbbVie will prove each of the *Penn* Central factors at trial. In particular, AbbVie will show that Act 143 imposes significant financial losses on AbbVie and interferes with its reasonable investment backed expectations. *See* Ex. 2, Scheidler Dep. 57:16-24 (explaining "significant growth" in 340B discounts from 2020 to 2022 "reflects the growth of contract pharmacies"), *id.* 64:8-11 ("in every case when we have … exempted a state [from contract pharmacy policy] there's been an acceleration in the growth of the 340B discounts claimed and an increase in the dollar amount"). Further, Act 143 serves no valid government purpose because it deprives manufacturers of the full use and control of their property for the commercial benefit of private parties. [redacted]

III. ACT 143 VIOLATES THE DORMANT COMMERCE CLAUSE.

"A state law may run afoul of the dormant Commerce Clause by: (1) discriminating against interstate commerce; (2) effecting extraterritorial control on interstate commerce; or (3) unduly burdening interstate commerce." MTD Order at 22. AbbVie will show that Act 143 does all three.

First, Act 143 discriminates against interstate commerce. The central aim of Hawai‘i’s law is to “build[s] up ... domestic commerce” in the form of in-state covered entities and pharmacies at the expense of out-of-state manufacturers. *Nat’l Pork Producers Council v. Ross*, 598 U.S. 356, 369 (2023). As discussed, it forces manufacturers to provide drugs at significantly reduced prices to hospitals and pharmacies that would not otherwise be entitled to reduced prices under federal law. [redacted] Hawai‘i’s targeting of only those nationwide manufacturers who participate in a nationwide program for additional burdens for the benefit of in-state entities, would “amount[] to ‘simple economic protectionism’” that the Supreme Court affirmed to be an illegitimate legislative interest. *Nat’l Pork Producers*, 598 U.S. at 372.

Second, Act 143 effects extraterritorial control of commerce occurring entirely outside the boundaries of Hawai‘i. Where a state statute “regulates a commercial transaction that ‘takes place wholly outside of the State’s borders,’” it violates the dormant Commerce Clause. *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323 (9th Cir. 2015).

Act 143's requirement that manufacturers transfer their drugs to contract pharmacies includes no geographic limitations. And Hawai'i covered entities often enter contract pharmacy arrangements with pharmacies located outside the state. [redacted] In practice, Act 143 permits the Attorney General to regulate a Hawai'i covered entity that purchases drugs from a California wholesaler that got its drugs from an Illinois manufacturer that then provides the drugs to a pharmacy in Texas. The sale could take place entirely outside of Hawai'i yet still be under the guise of Act 143. This is the exact type of extraterritorial application the dormant commerce clause seeks to prohibit. *See Sam Francis Found.*, 784 F.3d at 1323; *see Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989).

Third, Act 143's burden on interstate commerce is excessive in relation to putative local benefits. Courts strike down "nondiscriminatory burdens on commerce … that … clearly outweigh the benefits of a state or local practice." *Dep't of Revenue of Ky. v. Davis,* 553 U.S. 328, 353 (2008). While Act 143 will benefit Hawai'i covered entities and contract pharmacies at the expense of out-of-

state manufacturers, AbbVie will show that the law does nothing to lower drug costs for patients or deliver improved care. [redacted] Indeed, AbbVie's contract pharmacy policy—which Act 143 directly targets— "has no impact on patient access to critical medication." Ex. 23, Scheidler Decl. (ECF 16-1) ¶ 7(b).

CONCLUSION

For the foregoing reasons, AbbVie should prevail at trial.

DATED: Honolulu, Hawai‘i, October 12, 2026.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Plaintiffs' Trial Brief was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Claire Wong Black
Claire Wong Black

Exhibit 1 (Filed Under Seal)

EXHIBIT 2

IN THE UNITED STATE DISTRICT COURT

STATE OF HAWAII

ABBVIE INC. (A Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC., (a Delaware corporation); ABBVIE PRODUCTS, LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), Plaintiffs, vs. ANNE E. LOPEZ, in her official Capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, vs. ANNE E. LOPEZ, in her official Capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, Defendant.	CASE NO. 1:25-CV-230-SARP-WRP 1:25-CV-292-SARP-WRP (Consolidated Cases)

ZOOM DEPOSITION OF
EDWARD SCHEIDLER

Taken on behalf of the Defendant, ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, at Honolulu, Hawaii, Commencing at 6:00 a.m., on June 9, 2026, pursuant to notice.

BEFORE:
SHEILA MOORE, RPR, RMR, CMRS, CRR, CSR No. 501

state very clearly up front in our policy every iteration of our policy, we state that this policy does not affect access and affordability for patients to medications. And that's something that commonly is misunderstood, misrepresented, misreported.

Again, it just goes against how we normally think about the distribution and our daily experience. All of us have been a patient at one time and we've visited a pharmacy, we've taken medication, and you're used to that experience where you go to the pharmacy, where you go to the doctor and they ask you could I have your insurance card, you give them the insurance card, they scan a copy, you fill out the little clipboard, you do your thing. They tell you, oh, you have Blue Cross Blue Shield under your benefit design, you owe a $10 co-pay, how would you like to satisfy that? And then they say, yes, this medication that your doctor's prescribed, you know, X, Y, Z, drug, it's actually covered by your program, so great news, et cetera, et cetera. There's a prior authorization, all of that.

So when all of that is occurring there is

Q. I want to go to this second table on this spreadsheet with the count of invoice number per year.

Do you have an estimate of how much these discounts translate to in dollar amounts?

A. Off the top of my head I don't. I'd be -- I'd be speculating.

I think the important thing is that it gives us a sense of the change and the impact because the discounts either at best are static from year over year, don't change, or they increase. So you can always -- you can tell that if the volume of invoices at the 340B price grows you're gonna have an increased amount of discounting that you're given and increased financial impact because the prices, the discounts only go in one direction; they continue to grow.

Q. So I see from 2020 to 2022, there's a pretty significant growth. 2020, it was 110. 2021, 492. And 2022, 1,404 invoices.

Do you have any idea as to why there's been such a huge growth in that number?

A. I do. So what you're seeing here, is from 2020 to 2025 there were a series of events. So 2020, 2021, 2022 really reflects the growth of contract pharmacies, and it was -- it's been accelerating. There's sort of a bowing-up curve. It's not even a

straight curve, it's a bowing up, and you see that very dramatically here.

We announced our first policy which was our data integrity initiative requiring claims submission for all contract pharmacies, and that drove an acceleration in contract pharmacy 340B-related discounts ahead of implementation of that policy. So that even pushed 2022 up higher.

And then that policy went in place, and initially covered entities did not submit the data, did not comply with the policy, so you see it drop. And that's what's reflected in 2023, and its stabilization in 2024.

And then 2025 reflects a return to growth as we began to exempt -- we had the -- the one contract pharmacy limitation in 2023 and 2024, and then in the middle of 2025 Hawaii passed its law and that showed an acceleration of 340B discounts.

So that really is the underlying dynamics in market events that go behind what you see here reflected in the -- in the activity on the chart.

Q. And when did you say this claims data policy went into effect?

A. It was in -- I believe it was February, March of 2022. First quarter, let's say the first quarter I

will incur in compliance costs for 2026?

A. I don't have that in front of me.

Q. Would you happen to have a -- any idea as to the grand total of how much AbbVie has incurred to comply with Act 143 from July 1st, 2025 to present?

A. I'd be speculating. There could be different factors that effect growth rates.

Big picture, as I've shared before, in every case when we have a exempted a state there's been an acceleration in the growth of the 340B discounts claimed and an increase in the dollar amount. I have no reason to expect that that would not be the case in Hawaii, but the size and scale of that I'd be speculating.

Q. If we were to -- if we were to go on recess today, would you be able to pull those figures?

A. Not in this short period of time. We want to make sure that we can do the right kind of analysis that would stand up to the rigueur of -- of a legal proceeding.

Q. Okay, thank you.

Let me jump over to topic 6, the replenishment model. I just wanted to make sure, are you ready?

A. I'm ready.

Q. Okay. What is your understanding of the

A. Especially -- it's almost exclusively used if there's a third-party pharmacy involved.

Q. Do you know if it's used in Hawaii?

A. Yes.

Q. Was the replenishment model always the model that was used in the 340B context?

A. You used the term always, so I'm not sure if it's always been used. The program's been around since 1992.

I am aware initially pharmacies would -- if you recall when the program started, contract pharmacies weren't even part of the program. So from '92 to '96 there were no contract pharmacies. '96 to 2010, certain covered entities could have one; not all would.

So when you -- when I've have spoken with pharmacists who used to work at a covered entity hospital, they would talk about 340B day where they would order from the wholesaler 340B-priced product, and then those totes or crates or whatever, those boxes, shipments, of the 340B-priced product would come, and they'd literally have segregated inventory with 340B-priced product and then regular product. That's no longer the case. Everything is now virtual inventory or whatnot.

Exhibit 3 (Filed Under Seal)

EXHIBIT 4

EXHIBIT B

abbvie

March 29, 2023

Dear 340B Covered Entity,

AbbVie is updating its 340B program integrity initiative. The updated initiative is designed to address persistent abuses of the 340B program, including diversion and inappropriate duplicate discounting. AbbVie's updated initiative will *not* block access to 340B priced medicines for any eligible covered entity and patients will continue to have uninterrupted access to AbbVie's medicines.

Effective April 17, 2023, AbbVie will decline to facilitate bill to/ ship to orders for all hospital covered entities for 340B-priced medicines. This limitation on bill to/ ship to orders in AbbVie's new policy is aligned to AbbVie's standard commercial sales conditions for non-340B customers. Accordingly, hospital covered entities will no longer be permitted to direct delivery of AbbVie's 340B priced medicines to contract pharmacies. AbbVie's 340B integrity initiative will continue to honor bill to/ ship to requests to contract pharmacies for grantee covered entities.

What is not changing? Patients will continue to have uninterrupted access to AbbVie medicines. All covered entities will continue to be able to purchase 340B priced medicines and have them delivered to locations properly registered as a 340B covered entity or child site on the HRSA database. Covered entities will be offered, and may purchase, as much AbbVie medicine at the 340B price as desired, provided it is shipped to the covered entity location. Grantee covered entities will still be permitted to utilize contract pharmacies.

What is changing for *hospital covered entities*? Starting April 17, 2023, except for the limited exceptions described below or in the attached FAQs, hospital covered entities will no longer be eligible to place bill to/ ship to replenishment orders of 340B priced medicines for contract pharmacies.

A hospital covered entity *without* an in-house outpatient pharmacy may designate one contract pharmacy location. AbbVie will facilitate bill to/ ship to orders of 340B priced medicines to that location only; provided that, (i) the covered entity submits limited claims data on 340B utilization for such contract pharmacy location and (ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative.

Even if your hospital covered entity had previously designated a contract pharmacy location under AbbVie's existing policy, you will need to access 340B ESP™ and designate one contract pharmacy location for AbbVie's updated policy. Please do so prior to April 9, 2023. For details on accessing the exceptions to this policy, please see the attached FAQs.

EXHIBIT B

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What is changing for *federal grantee covered entities*? There is **no change** for federal grantee[1] covered entities, such as community health centers, federally-qualified health centers and Ryan White clinics. Federal grantee covered entities will continue to be eligible to place bill to/ ship to replenishment orders of 340B priced drugs for their contract pharmacies.

AbbVie is committed to the intended purpose of the 340B program and believes that for the 340B program to fulfill its important mission of improving access to medicines for uninsured and vulnerable patients, the program integrity challenges must be addressed. We look forward to working collaboratively with you to further strengthen the 340B program.

Please reach out to 340bcommunications@abbvie.com if you have questions about our updated policy. For assistance with using 340 ESP™, please contact support@340BESP.com.

Best regards,



Chris Compisi
Vice President, US Market Access

[1] Grantees refers to entities eligible for the 340B program under 42 U.S.C. §256(b)(4)(A)-(K).

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FREQUENTLY ASKED QUESTIONS

Medicines Covered

Q: Which AbbVie medicines are subject to this updated contract pharmacy policy?
The policy applies to the list of products attached to this FAQ. AbbVie will inform covered entities of any changes to the product list. Both the AbbVie policy and the up-to-date list of AbbVie products can be found on 340B ESP™ www.340BESP.com.

Exception for Certain Products

Q: Am I still able to designate a contract pharmacy location for AbbVie medicines subject to a limited distribution network if my covered entity in-house pharmacy is not in the limited distribution network?
If your covered entity's in-house pharmacy is not within a limited distribution network for an AbbVie product, you may designate one of the specified contract pharmacy locations for receiving replenishment shipment of the product. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy location. Currently, this contract pharmacy designation is available for Duopa and Imbruvica. Please access 340B ESP™ at www.340BESP.com and navigate to the Entity Profile tab to make your selection. **Even if you had previously selected a designated one contract pharmacy location for Duopa or Imbruvica under AbbVie's previous policy, your covered entity must still access 340B ESP™ and select one designated pharmacy location for the limited distribution products under this updated policy. Your designated pharmacy location for limited distribution products must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023.** If you have questions about how to make this designation, please contact Second Sight Solutions at 888-398-5520 or support@340BESP.com.

Exception for Hospital Covered Entities *Without* an In-House Pharmacy

Q: What if my covered entity does not have an outpatient pharmacy at the location registered as a parent or child site on the 340B covered entity database?
If your covered entity does not have an in-house outpatient pharmacy capable of dispensing 340B priced products, your entity may designate a single contract pharmacy location and AbbVie will facilitate bill to/ ship to replenishment orders of 340B priced drugs to that contract pharmacy; *provided that*:

(i) the covered entity registers with 340B ESP™ and submits limited claims data on 340B utilization for such contract pharmacy, and
(ii) the one contract pharmacy is located within 40 miles of the HRSA registered covered entity parent site.

Q: How can my covered entity identify pharmacy locations within 40 miles of my parent hospital?
340B ESP™ will maintain a list of pharmacies within a 40 mile radius of the parent hospital registered on the HRSA 340B OPAIS database.

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Q: What if I am unable to identify an eligible pharmacy location for my designation? For example, what if there is no pharmacy location within 40 miles of my covered entity's parent site?
AbbVie is committed to ensuring that every covered entity has at least one pharmacy location where it can receive AbbVie's medicines at 340B prices. If you are unable to locate a pharmacy location within 40 miles, AbbVie will work with your covered entity to locate the nearest appropriate contract pharmacy location. Please reach out to 340 ESP™ if you encounter challenges in designating your one contract pharmacy location.

Designation of Permitted Contract Pharmacy Locations

Q: If my covered entity is eligible to designate a contract pharmacy location because it does not have an in-house pharmacy, how does my entity make its designation?
Covered entities that are eligible to designate a single contract pharmacy can do so by registering an account at www.340BESP.com and navigating to the Entity Profile tab. The 340B ESP™ platform is the only way a covered entity can designate its single contract pharmacy location under AbbVie's policy. **The one contract pharmacy location must be listed in 340B ESP™ by April 9, 2023 for the designation to take effect on April 17, 2023. Even if your covered entity has designated an exception for one contract pharmacy location under AbbVie's previous policy or is submitting claims data for the desired location, you must still access 340B ESP™ and select your designated contract pharmacy location for this updated policy. Please do so prior to April 9, 2023.** If you fail to designate your one contract pharmacy location by April 9, 2023, you may still make a designation after such date, but the designated contract pharmacy location will not be eligible for 340B priced orders by the effective date of AbbVie's updated policy.

Once during each 12-month period following the effective date of this policy, a covered entity may designate a different contract pharmacy location. Please note that such designations may take up to 10 business days to become effective.

Q: If I designate one contract pharmacy location to receive orders of medicines subject to this policy, should I also make a separate designation for a contract pharmacy location to receive AbbVie medicines subject to a limited distribution network?
Yes, you should separately designate one contract pharmacy location to receive medicines subject to a limited distribution network. AbbVie will facilitate bill to/ ship to orders to this designated pharmacy. Currently, this separate contract pharmacy designation is available for Duopa and Imbruvica. Accordingly, this pharmacy designation may be in addition to the one permitted contract pharmacy designation for other AbbVie medicines. Please access 340B ESP™ at www.340BESP.com to make this selection.

Q: My covered entity is affiliated with an outpatient pharmacy that is registered with HRSA as a contract pharmacy. How will AbbVie's policy impact this pharmacy location?
AbbVie will decline to facilitate bill to/ ship to orders for all contract pharmacies of hospital covered entities. Your covered entity should place orders for delivery to your covered entity's in-house pharmacy. Hospital covered entities that do not have an in-house pharmacy, may choose to designate

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an affiliated contract pharmacy as its designated contract pharmacy location, provided it complies with the data submission and distance requirements described herein.

Claims Data Submission Requirements

Q: What are the requirements for submission of claims data?
The claims data submission requirement applies to a hospital covered entity without an in-house pharmacy that designates one contract pharmacy location within 40 miles of the HRSA registered covered entity parent site. All specified claims data must be submitted within 45 days of the date of dispense to your covered entity's patient. Please submit claims data within the specified time period to ensure your designated contract pharmacy location remains eligible to receive 340B priced medicines. If purchases for the designated contract pharmacy location exceed conforming claims submitted according to this policy, this may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines.

The 340B ESP™ platform requires claims uploads on the 1st and 16th of every month. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform. Please see 340B ESP™ at www.340BESP.com for additional details on submitting claims data, including the limited set of required data fields.

Q: How will AbbVie use the 340B claims data that covered entities provide through 340B ESP™?
Contract pharmacy claims data uploaded by 340B covered entities will be used to identify and resolve certain ineligible rebates, including in Medicaid, Medicare Part D, TRICARE and commercial payer rebates, determine compliance with AbbVie's 340B integrity initiative and determine eligibility for placing certain replenishment orders under the policy.

Q: What happens if my organization is unable to provide claims data in conformance with AbbVie's policy?
Failure to provide claims data in conformance with the requirements of this policy may result in the designated contract pharmacy losing eligibility to receive 340B priced medicines. If you encounter challenges in submitting conforming claims data, please reach out to 340B ESP™ with questions. Please also ensure that your covered entity's contract pharmacy administrator is aware of these policy requirements and takes any appropriate steps to assist with the submission of claims data. Specified claims data must be submitted within 45 days of the date of dispense to the covered entity's patient. AbbVie will provide covered entities a 60-day grace period from the effective date of this policy to start submitting claims data for the designated contract pharmacy location.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process you can access a repository of webinars at www.340BESP.com/resources/webinars or call Second Sight Solutions at 888-398-5520. Any changes to AbbVie's policy will be available in the most up-to-date policy document on www.340BESP.com.

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AbbVie 340B Program Integrity Initiative Applicable Products

PRODUCT
CREON®
DEPAKOTE®
DUOPA®
GENGRAF®
HUMIRA®
IMBRUVICA®
KALETRA®
K-TAB®
LUPRON®
MAVYRET®
NIASPAN®
NIMBEX®
NORVIR®
ORIAHNN®
ORILISSA®
RINVOQ®
SKYRIZI®
SURVANTA®
SYNTHROID®
TRICOR®
TRILIPIX®
ULTANE®
VIEKIRA PAK®
ZEMPLAR®
ACTONEL®
ACULAR®
ACULAR® LS
ACUVAIL®
ALOCRIL®
ALPHAGAN® P
ANDRODERM®
ARMOUR® THYROID
ASACOL® HD
ATELVIA®
AVYCAZ®
BENTYL®
BOTOX®

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PRODUCT
BYSTOLIC®
CANASA®
CARAFATE®
CELEXA®
COMBIGAN®
CONDYLOX®
CRINONE®
DALVANCE®
DELZICOL®
DURYSTA®
ESTRACE®
FETZIMA®
FML®
FML FORTE®
GELNIQUE®
GENERESS® FE
INFED®
KADIAN®
KYBELLA®
LASTACAFT®
LATISSE®
LEXAPRO®
LINZESS®
LO LOESTRIN® FE
LUMIGAN®
MINASTRIN® 24 Fe
MONUROL®
NAMENDA® / NAMENDA XR®
NAMZARIC®
OCUFLOX®
OXYTROL®
OZURDEX®
POLYTRIM®
PRED FORTE®
PRED MILD®
PYLERA®
QULIPTA®
RAPAFLO®
RECTIV®
REFRESH®

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PRODUCT
RESTASIS®
SAPHRIS®
SAVELLA®
TAYTULLA®
TEFLARO®
UBRELVY®
URSO FORTE® / URSO 250®
VANIQA®
VIBERZI®
VIIBRYD®
VRAYLAR®
VUITY™
ZYMAXID®

EXHIBIT 5

EXHIBIT A

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:
The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

(1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C- 03I, Rockville, Maryland, 20857.

EXHIBIT A

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

PHARMACEUTICAL PRICING AGREEMENT

(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary") and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) **"Bundled Sale"** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

(d) **"Covered Drug"** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) **"Covered Entity"** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) **"Manufacturer"** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) **"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) **"Medicaid Rebate Program and Medicaid Rebate Agreement"** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) **"National Drug Code (NDC)"** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) **"Over the Counter Drug"** means a drug that may be sold without a

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327;
Expiration Date: 08/31/2019

prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) **"Quarter"** means a calendar quarter unless otherwise specified.

(l) **"Rebate Percentage"** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) **"the Secretary"** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) **"Unit of the Drug"** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) **"Wholesaler"** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP,

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c) to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327;
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IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the 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 section II(a) of the Agreement. Pursuant to section 340B(a) (4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of

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the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.

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(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane Mail
Stop 8W03A
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c) No provision in the Agreement shall prohibit the Manufacturer from charging a price

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for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

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Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: Rob Michael
(Signature)

Title: Vice Chairman and CFO Date: 5/31/2022

Phone Number: 847-938-0927 Ext.___ FAX Number: _____

e-Mail Address: robert.michael@abbvie.com

Manufacturer Labeler Code(s): 61168

Name of Manufacturer: Kythera Biopharmaceutical Inc (An AbbVie Company)

Manufacturer Address: 1 N Waukegan Rd
N. Chicago, IL 60064

Contact Person: April Gerzel

Title: Director, Public Payer Markets

Phone Number: 847-937-5979 Ext._____ FAX Number: _____

e-Mail Address: april.gerzel@abbvie.com

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Exhibit 6 (Filed Under Seal)

Exhibit 7 (Filed Under Seal)

Exhibit 8 (Filed Under Seal)

Exhibit 9 (Filed Under Seal)

Exhibit 10 (Filed Under Seal)

Exhibit 11 (Filed Under Seal)

Exhibit 12 (Filed Under Seal)

Exhibit 13 (Filed Under Seal)

ANNE E. LOPEZ 7609
Attorney General of Hawai‘i

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Attorneys for Defendant
ANNE E. LOPEZ in her official capacity as
ATTORNEY GENERAL OF THE STATE OF HAWAI‘I

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS, LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), Plaintiffs, vs.	CIVIL NO. 1:25-cv-230-SARP-WRP CIVIL NO. 1:25-cv-292-SARP-WRP (Consolidated Cases) **DEFENDANT'S INTERROGATORY RESPONSES TO PLAINTIFFS' NOTICE OF TAKING VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION PURSUANT TO RULE 30(B)(6) OF THE FEDERAL RULES OF CIVIL PROCEDURE**

ANNE E. LOPEZ in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAI‘I,

Defendant

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

vs.

ANNE E. LOPEZ in her official capacity as ATTORNEY GENERAL OF HAWAI‘I,

Defendant.

DEFENDANT'S INTERROGATORY RESPONSES TO PLAINTIFFS' NOTICE OF TAKING VIDEOTAPED DEPOSITION UPON ORAL EXAMINATION PURSUANT TO RULE 30(B)(6) OF THE FEDERAL RULES OF CIVIL PROCEDURE

Defendant Anne E. Lopez, in her official capacity as Attorney General of the State of Hawai‘i, by and through her undersigned counsel, and pursuant to Rules 26 and 33 of the *Federal Rules of Civil Procedure*, hereby responds and objects to Plaintiffs' Notice of Taking Videotaped Deposition Upon Oral Examination Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure [Designated Representative of Defendant Anne E. Lopez in her official capacity as Attorney General of the State of Hawai‘i], served on May 26, 2026, which are being treated

as a Request for Answers to Interrogatories pursuant to the conference of the parties held on June 4, 2026.

All responses set forth herein are subject to and without waiver of any of Defendant's Specific Objections. Defendant reserves the right to revise, correct, add to, supplement, or clarify any of her responses.

DATED: Honolulu, Hawai'i, _____.

/s/ *Christopher T. Han*
CHRISTOPHER J.I. LEONG
ASHLEY M. TANAKA
CHRISTOPHER T. HAN
NICHOLAS K.N. KIDO

Counsel for Defendant
ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAI'I

SPECIFIC RESPONSES AND OBJECTIONS

TOPIC 1:

Any way in which You understand AbbVie's Policy to violate Act 143.

Objections:

Defendant objects to this Topic as it is overly broad, seeks attorney work product, and violates the deliberative process privilege. Should the constitutionality of Act 143 be upheld and Defendant choose to pursue an enforcement action, this Topic would implicate impressions by the appropriate enforcement attorney.

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Act 143, now codified as *Haw. Rev. Stat.* ("HRS") Chapter 481N, prohibits a manufacturer from "deny[ing], restrict[ing], or prohibit[ing], either directly or indirectly, the acquisition of a 340B drug by, or shipping or delivery of a 340B drug to, a pharmacy that is under contract with a 340B covered entity and is authorized under the contract to receive and dispense 340B drugs on behalf of the 340B covered entity unless the receipt is prohibited by the United States Department of Health and Human Services." HRS § 481N-2(a).

Under AbbVie's policy, hospital covered entities with an in-house outpatient pharmacy are "no longer eligible to place bill to/ship to replenishment orders of

340B priced medicines for contract pharmacies." Exhibit B, Plaintiffs' Motion for Preliminary Injunction ("MPI"), Dkt. 16-3 at 2. For a hospital covered entity without an in-house outpatient pharmacy, AbbVie's policy allows the covered entity to designate one contract pharmacy location that is located within 40 miles of the HRSA registered covered entity parent site. *Id.*

These provisions violate Act 143 by (1) prohibiting the acquisition, shipping, and delivery of 340B drugs to contract pharmacies that are contracted with any covered entity with an in-house pharmacy, and (2) prohibiting the acquisition, shipping, and delivery of 340B drugs to additional contract pharmacies that are contracted with any covered entity that has already contracted with a contract pharmacy.

TOPIC 2:

> *How Act 143 may be enforced against manufacturers by the Attorney General, including any penalties manufacturers may face.*

Objections:

Defendant objects to this Topic to the extent that it is irrelevant, overly broad, seeks attorney work product, and violates the deliberative process privilege. Plaintiffs do not represent the interests of other manufacturers, so discovery on such potential enforcement actions against other third parties is irrelevant. *See PhRMA v. Lopez*, 1:25-cv-292; *AstraZeneca Pharmaceuticals LP v. Lopez*, 1:25-

cv-369. Moreover, this lawsuit is a facial challenge, as opposed to an as-applied challenge.

Should the constitutionality of Act 143 be upheld and Defendant choose to pursue an enforcement action, this Topic would implicate impressions, investigative thoughts, and strategies by the appropriate enforcement attorney.

This information is also available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Per HRS § 481N-4(a), the "attorney general may bring a civil action to enjoin a violation of section § 481N-2." HRS § 481N-4 provides the following penalties:

> (b) Any manufacturer, or any agent or affiliate of a manufacturer, that violates section 481N-2 shall be fined no less than $500 and no more than $2,500 for each violation. The fine shall be collected in a civil action brought by the attorney general on behalf of the State. The penalties provided in this section shall be cumulative to the remedies or penalties available under all other laws of the State. Each day that a violation of section 481N-2 occurs shall constitute a separate violation.
>
> (c) In an action brought by the attorney general, the court may award disgorgement and any other equitable relief that it considers appropriate.

The Attorney General's pre-suit investigative powers are prescribed in HRS § 28-2.5.

Inquiry into the Department's enforcement tactics and practices are inappropriate. *See e.g.*, *S.E.C. v. Rosenfeld*, 1997 WL 576021 (S.D.N.Y. Sept. 16, 1997); *E.E.O.C. v. Evans Fruit Co.*, No. CV-10-3033-LRS, 2012 WL 442025 (E.D. Wash. Feb. 10, 2012).

That said, I have not had an opportunity to formulate any enforcement plans due to the timing of this lawsuit. Act 143 was signed into law on May 30, 2025, and this suit followed mere days later on June 3, 2025. Two additional constitutional challenges, *PhRMA v. Lopez*, 1:25-cv-292 and *AstraZeneca Pharmaceuticals LP v. Lopez*, 1:25-cv-369, subsequently followed that year.

I do not intend to enforce Act 143 until the final resolution of these pending constitutional challenges, including any potential appeals. Should I prevail, I reserve the right to fully prosecute any violations by manufacturers during the pendency of these actions.

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TOPIC 3:

How Act 143 may be enforced against manufacturers by 340B Covered Entities, including any penalties manufacturers may face.

Objections:

Defendant objects to this Topic as it is unduly burdensome and overly broad. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

HRS § 481N-3 provides as follows:

> Any 340B covered entity that is injured in its business or property by a violation of section 481N-2 may bring a civil action to enjoin the violation. If a judgment is awarded in favor of the 340B covered entity, the 340B covered entity shall be awarded reasonable attorney's fees together with the costs of the suit.

As for the specifics of how any 340B Covered Entity may choose to enforce their claims, I do not know as the Department does not represent such third parties. Per HRS § 26-7, the Department's representation is limited "to the governor, legislature, and such state departments and officers as the governor may direct[.]"

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TOPIC 4:

The history of the 340B Program, including the operation of the replenishment model and the ADR process.

Objections:

Defendant objects to this Topic as it is vague and ambiguous, overly broad, and unduly burdensome. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources). Defendant is not the historian of the 340B Program, nor is she a participant in either the replenishment model or the ADR process.

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

The Department's understanding of the history of the 340B Program can be found in pleadings by my counsel. *See e.g.*, Defendant's Motion to Dismiss ("MTD"), Dkt. 25 at 2-7. This understanding is based on existing case law,[1]

[1] *See e.g.*, *AbbVie Inc. v. Fitch*, 2024 WL 3503965 (S.D. Miss. July 22, 2024) *aff'd sub nom. AbbVie Inc. et al. v. Fitch*, 2025 WL 2630900 (5th Cir. Sept. 12, 2025); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271 (M.D. Tenn. June 30, 2025); *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *Pharm. Rsch. & Manufacturers of Am. v. Murrill*, 2024 WL 4361597 (W.D. La. Sept. 30, 2024), *aff'd sub nom. AbbVie, Inc. v. Murrill*, 166 F.4th 528 (5th Cir. 2026).

publicly available documents,[2] and statements from individuals from local covered entities. *See e.g.*, Deposition of Jennifer Dacumos, Declaration of Jennifer Dacumos, Deposition of Eric King, Declaration of Eric King.

TOPIC 5:

> *Your understanding of whether and how Act 143 regulates delivery of 340B-priced drugs rather than the price at which those drugs are sold. Def.'s Mot. to Dismiss at 11, 15 (Dkt. 25).*

Objections:

Defendant objects to this Topic as to the extent it seeks attorney work product. This information is also available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Act 143 does not dictate the price of the drugs, as the price is set by the 340B statute. Act 143 regulates delivery by explicitly prohibiting any denials, restrictions, prohibitions, either directly or indirectly, the shipping or delivery of a 340B drug to a pharmacy under contract with a 340B covered entity in Hawai'i.

[2] *See e.g.*, MPI Exhibits, Articles referenced in the Complaint, Notices by the HRSA (e.g., 61 Fed. Reg. 43,549 (Aug. 23, 1996) & 74 Fed. Reg. 10,272 (Mar. 5, 2010)).

TOPIC 6:

Your understanding of the phrase "acquisition of a 340B drug" as used in Act 143, including all the ways it is distinct and different from "delivery" of a 340B drug.

Objections:

Defendant objects to this Topic to the extent it seeks attorney work product. This information is also available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

These terms are interpreted pursuant to their plain meaning.

"Acquisition" is defined as follows:

> 2. The gaining of possession or control over something; esp., the act of getting land, power, money, etc. <the acquisition of new paintings for the museum> <acquisition of the target company's assets>.
>
> 3. Something acquired; esp., something one has obtained by buying it or being given it <a valuable acquisition>.

ACQUISITION, Black's Law Dictionary (12th ed. 2024).

"Delivery" is defined as follows:

> 1. The formal act of voluntarily transferring something; esp., the act of bringing goods, letters, etc. to a particular person or place.

2. The thing or things so brought and transferred.

DELIVERY, Black's Law Dictionary (12th ed. 2024)

As seen above, acquisition encompasses purchases, whereas delivery contemplates the goods already being purchased.

TOPIC 7:

> *Any way in which You understand AbbVie's Policy to "deny, restrict, or prohibit…the acquisition of a 340B drug by" "a pharmacy that is under contract with a 340B covered entity" as used in Act 143.*

Objections:

Defendant objects to this Topic as being duplicative with Topic 1, seeks attorney work product, and violates the deliberative process privilege. Should the constitutionality of Act 143 be upheld and Defendant choose to pursue an enforcement action, this Topic would implicate impressions by the appropriate enforcement attorney.

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

See my response to Topic 1.

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TOPIC 8:

When You understand Act 143 to operate on 340B-discounted transactions, including whether Act 143 operates (1) when a manufacturer has offered drugs for sale at the 340B price (i.e., pre-sale), or (2) after an order for drugs at the 340B price has been placed (i.e. post-sale).

Objections:

Defendant objects to this Topic as being vague and ambiguous, seeks attorney work product, and violates the deliberative process privilege. Should the constitutionality of Act 143 be upheld and Defendant choose to pursue an enforcement action, this Topic would implicate impressions by the appropriate enforcement attorney.

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

The Department understands Act 143 to apply pre-sale, when a manufacturer offers (or refuses to offer) a drug for sale at the 340B price.

TOPIC 9:

Your understanding of whether and how Hawaii's Act 143 dictates the way Covered Entities', Contract Pharmacies', and/or Third-Party Administrators' must spend revenue from sales of drugs purchased at the 340B price.

Objections:

Defendant objects to this Topic as being irrelevant and unduly burdensome. This information is available to Plaintiffs from another source that is more

convenient, less burdensome, and less expensive (i.e., the text of Act 143 speaks for itself).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Act 143 does not impose any restrictions or requirements on how Covered Entities, Contract Pharmacies, and/or Third-Party Administrators must spend revenue from sales of drugs purchased at the 340B price. *See generally*, HRS Chapter 481N.

TOPIC 10:

> *Your understanding of how Act 143 impacts patients' access to medications, including Your understanding of how the purpose of Act 143 "is to provide patients in the State access to affordable medication through contract pharmacies, the practice of which was being limited by drug manufacturers such as Plaintiffs." Def.'s Mot. to Dismiss at 8 (Dkt. 25).*

Objections:

Defendant objects to this Topic as being unduly burdensome and seeking attorney work product. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

//

Response:

The Department's understanding stems from the preamble of Act 143. The Department does not maintain or possess its own data as to the impact of Act 143 on patients' access to medications. Any such information would be in the possession of third parties such as local covered entities.

The Department's understanding is that a manufacturer's practice of restricting the number of eligible contract pharmacies results in adverse consequences for the State, including restricting the number of locations from which patients can purchase 340B eligible medication and reducing the financial savings for covered entities, which are reinvested for essential community benefits such as financial assistance for low-income patients and free (or reduced cost) services.

TOPIC 11:

> *Any way in which You understand manufacturers to have potential federal defenses to Act 143 enforcement actions by the Attorney General or 340B covered entities, including but not limited to federal defenses related to diversion or duplicate discounting, 42 U.S.C. § 256b(a)(5)(A), (B), and including whether those defenses can be adjudicated by a Hawaii state court in an Act 143 enforcement action or how otherwise you understand manufacturers would litigate those defenses.*

Objections:

Defendant objects to this Topic to the extent it seeks attorney work product and violates the deliberative process privilege. Should the constitutionality of Act

143 be upheld and Defendant choose to pursue an enforcement action, this Topic would implicate impressions by the appropriate enforcement attorney. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Manufacturers do not have any federal defenses to Act 143, as Act 143 imposes separate requirements from the 340B statute. Act 143 does not govern diversion or duplication claims. Conversely, federal law does not impose any delivery restrictions, but Act 143 does.

TOPIC 12:

> *How AbbVie voluntarily participates in Act 143 via participation in the federal 340B Program, including Your understanding of any separate benefit provided by the State of Hawaii in exchange for AbbVie's compliance with Act 143. Def.'s Mot. to Dismiss at 19-20 (Dkt. 25).*

Objections:

Defendant objects to this Topic to the extent it seeks attorney work product. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

This question misstates the Department's position and misconstrues Act 143. Unlike the federal 340B Program, Act 143 is not a program, but rather a law that manufacturers such as AbbVie must abide by. Participation in Act 143 is separate from participation in the 340B Program, as Act 143 regulates an area that is silent in the 340B Program (i.e., delivery).

The Department understands AbbVie's participation in the 340B Program to be voluntary based on AbbVie's own allegations. *See* Complaint, ¶¶ 23-28 (alleging Plaintiffs to be signatories to the 340B Pharmaceutical Pricing Agreements).

Act 143 enshrines and protects a manufacturer's ability to require claims data from a 340B covered entity. *See* § HRS 481N-2(b). Otherwise, Act 143 does not provide any separate benefits for a manufacturer's compliance.

TOPIC 13:

> *How Act 143 serves a public use within the meaning of the Fifth Amendment, including whether and how any 340B revenue received by virtue of Act 143 by Covered Entities, Contract Pharmacies, and/or Third-Party Administrators serves a public use within the meaning of the Fifth Amendment.*

Objections:

Defendant objects to this Topic to the extent it is vague and ambiguous and seeks attorney work product. This information is available to Plaintiffs from

another source that is more convenient, less burdensome, and less expensive (including from publicly available sources).

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

Act 143 serves a public purpose, and thus public use, within the meaning of the Fifth Amendment by advancing public health in a manner similar to Mississippi's HB 728. *See* MTD at 19-20 (citing *AbbVie Inc. v. Fitch*, 2024 WL 3503965 at *20 (S.D. Miss. July 22, 2024)). The preamble of Act 143 provides "that the 340B program helps stretch limited resources, allowing hospitals to reinvest savings into essential community benefits." Act 143 at 1. The preamble also provides "that contract pharmacies are crucial in Hawaii, where geographic barriers make access to health care difficult for many residents." *Id.* at 2. As such, the Department's understanding is that the 340B revenue received by virtue of Act 143 by Covered Entities serves a public purpose by supporting community benefits, whereas Contract Pharmacies "play a vital role in ensuring that patients can access medications, especially in rural areas where many hospitals do not have an in-house pharmacy." *Id*. Act 143 does not account for Third-Party Administrators.

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TOPIC 14:

> *Your understanding of the relationship between covered entities and their contract pharmacies located outside the State of Hawaii, including how those arrangements increase patient access to patients of Hawaii covered entities.*

Objections:

Defendant objects to this Topic as being overly broad, unduly burdensome, and seeking attorney work product. This information is available to Plaintiffs from another source that is more convenient, less burdensome, and less expensive (including from publicly available sources). Defendant is not a participant in the arrangement described in the Topic, nor does she represent any of the entities described above.

/s/ *Christopher T. Han*
Counsel for Defendant

Response:

The Department's understanding is that Hawaii covered entities ship certain medication to contract pharmacies outside the State due to requirements from insurers. This understanding is based on Plaintiffs' Complaint[3] and statements from representatives from local covered entities (i.e., Jennifer Dacumos and Eric King).

//

[3] *See* Dkt. 1, ¶ 76 (Pioneer Institute Public Policy Research, *340B in Hawaii*).

The Department does not maintain or possess its own data as to the relationship between covered entities and their contract pharmacies located outside of the State of Hawai‘i, including how those arrangements increase patient access to patients of Hawaii covered entities. Any such information would be in the possession of third parties such as local covered entities.

VERIFICATION OF INTERROGATORY ANSWERS

I, Anne E. Lopez, declare under penalty of perjury that the foregoing responses are true and correct to the best of my knowledge.

Dated: Honolulu, Hawaii; Jun 9, 2026.

Anne E. Lopez

ANNE E. LOPEZ
Attorney General of the State of Hawai‘i

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII, *Defendant*.	Civil No. 1:25-cv-00230-SASP-WRP Judge Shanlyn A. S. Park **Declaration of Eric King**

DECLARATION OF ERIC KING

I, Eric King, declare as follows:

1. I am over the age of 21, have personal knowledge of the matters set forth in this Declaration, and am competent to testify to them. I submit this Declaration in support of Defendant's Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction.

2. I earned my Master of Business Administration from the University of Central Oklahoma in 2009. Since 2012 I have worked in the health care space, specifically in 340B compliance.

3. I am currently employed by The Queen's Health Systems (QHS) as its Director of the 340B Program, which I have held since January 2018.

4. In my role, I manage QHS's administration of the federal 340B drug program,

including oversight of QHS's contractual relationships with a range of pharmacies—retail chains, independent pharmacies, and specialty pharmacies (specialty pharmacies focus on high-cost, high-touch therapies for complex conditions such as cancer, multiple sclerosis, HIV, Hepatitis C, rheumatoid arthritis, and cystic fibrosis).

5. I oversee 340B Program compliance for multiple 340B-qualified covered entities in Hawaii, including:

a. The Queen's Medical Center, a Disproportionate Share Hospital

b. Queen's North Hawaii Community Hospital, a Disproportionate Share Hospital

c. Molokai General Hospital, a Critical Access Hospital

6. The hospitals mentioned above are non-profit, safety-net hospitals that provide health care and critical services to low-income and vulnerable populations, regardless of patients' ability to pay. The hospitals serve a disproportionately high number of Medicare and Medicaid beneficiaries.

7. Through a hypothetical example, Edward Scheidler seems to insinuate that covered entities save 99% per prescription through the 340B program. Although it is possible, it is not typical and fails to acknowledge that manufacturers themselves are the main drivers of 340B discount rates. Estimates vary, but the minimum 340B discount for a brand-name drug is just 23%. Everything above that is caused by manufacturers' own actions.

Replenishment

8. In general, contract pharmacy arrangements use a replenishment model. Not every arrangement works the same way—I can only speak to the specifics of contract pharmacy arrangements used by QHS hospitals—but at a basic level, under a replenishment model, when a patient is determined to be a 340B patient of a covered entity, the contract pharmacy's drug

inventory is replenished with a drug purchased directly by a covered entity at the 340B discount after a drug is dispensed. Most of the time, QHS covered entities purchase from drug wholesalers rather than directly from drug manufacturers.

9. For all contract pharmacy arrangements, including replenishment models, a covered entity may establish a relationship with a pharmacy or it may use a third-party administrator (TPA) to facilitate data capture, transfer, and reporting for a covered entity's contract pharmacy program.

10. Replenishment occurs in three steps. First, a contract pharmacy dispenses a drug in a certain amount to a patient. The patient may present in person with a prescription, or the covered entity may transmit the prescription to the pharmacy (e-prescribing). The dispensed drug comes from the contract pharmacy's general inventory.

11. For the second step, the 340B software notifies the covered entity and contract pharmacy that a replenishment order for a dispensed drug may be placed with the 340B drug wholesaler under the covered entity's 340B account. The National Drug Code (NDC) system assigns an 11-digit number to each drug product to identify its (1) labeler (manufacturer or distributor), (2) product details (strength, dosage form, formulation), and (3) wholesale package (size and type). For a replenishment order to go through, the product ordered must be an exact 11-digit match with the dispensed product identified by the software.

12. A single dispense does not usually trigger a replenishment order. Instead, the contract pharmacy or TPA will accrue 340B-eligible dispenses of a specific 11-digit NDC product toward a specific package size. For instance, while a patient might be prescribed 30 once-a-day tablets, the manufacturer may put 90 tablets in a bottle. Only after three, 30-tablet dispenses occur will a replenishment order be authorized. QHS covered entities receive accumulation reports to

track when a replenishment order is needed.

13. The replenishment order is typically placed on the covered entity's 340B account with a wholesaler—not directly with a drug manufacturer. The 340B account is in the covered entity's name and has its financial payment information. For example, The Queen's Medical Center has its own 340B account. The 340B account has a "bill to" address, which is the covered entity's address, and a "ship to" address, which is the contract pharmacy (or sometimes its warehouse). The wholesaler invoice shows the covered entity as the purchaser of the product under the "sold to" field. It is the covered entity that pays for and purchases the drug at the 340B discount price from the wholesaler. If there are any payment issues, the wholesaler would seek to collect payment from the covered entity—not from the contract pharmacy.

14. For efficiency and to prevent the pharmacy from having more inventory on hand that it needs, QHS authorizes its contract pharmacies to place 340B replenishment orders directly with the wholesaler on QHS's 340B accounts.

15. Regardless of the exact logistics, it is my understanding that the Health Resources and Services Administration (HRSA) views the covered entity as the legal purchaser and authorizer of the order. If any order is sent on behalf of a QHS covered entity, the QHS covered entity is aware of the replenishment order; typically, the QHS covered entity approves the submission to the wholesaler in advance to ensure accuracy.

16. For the third and final step, the drug at issue is shipped to the contract pharmacy. The contract pharmacy then places the drug on its shelf as part of its general inventory, available to be dispensed to a subsequent patient.

17. QHS covered entities have a responsibility to make sure that their contract pharmacies replenish inventory with 340B discounted drugs only when the drugs have been

provided to qualified 340B patients. QHS covered entities have systems in place to ensure this happens, including the TPA-aided analysis process described below.

18. Although certain processes are simplified for efficiency and convenience's sake, replenishment models do not operate on auto-pilot. The TPA software is programmed to hold eligible claims from adding new dispenses to the accumulator for a specific number of days to allow QHS to audit the claims. Using reports generated from the TPA software, contract pharmacy claims and their associated product accumulations are audited every month, including a 100% audit of non-Queen's contract pharmacies' claims, to ensure compliance with QHS 340B eligibility standards.

Additional oversight of contract pharmacies

19. In its contracts with contract pharmacies, QHS covered entities require all contract pharmacies to comply with federal 340B laws and regulations, including prohibitions on duplicative discounts, rebates, and unauthorized diversion of 340B drugs.

20. There are a variety of 340B-specific software programs that can be used to evaluate each dispense. The purpose of the software is to compare the information about the dispense to the covered entity's patient data to apply the entity's eligibility criteria and help the entity determine if the patient was eligible for a 340B discount. The covered entity receives a report of every 340B-eligible dispense so that it can oversee the software. QHS uses Macro Helix, Wellpartner, and 340B Complete software programs. HRSA also audits this process.

21. Each year, HRSA audits many covered entities along with their contract pharmacy arrangements. During my time at QHS, two QHS hospitals have undergone HRSA audits, and neither of the audits identified findings related to our contract pharmacy arrangements. In addition, QHS follows HRSA's guidance by engaging an independent third-party auditor to audit our

contract pharmacy relationships every year.

22. QHS also conducts monthly internal audits and commissions annual external audits to ensure compliance with all 340B program requirements. QHS covered entities promptly self-report any issues identified and resolve them in good faith with manufacturers. As part of these audits, QHS routinely reviews contract pharmacy claims and patient eligibility. Contrary to Mr. Scheidler's contentions, QHS covered entities, not their contract pharmacies, determine who eligible patients are. QHS covered entities never use a "once-a-patient-always-a-patient" model.

Drug manufacturer restrictions on contract pharmacies

23. Since 2020, pharmaceutical manufacturers have increasingly imposed restrictions on the delivery of 340B drugs to contract pharmacies. As of this writing, 38 manufacturers, including AbbVie, have implemented such restrictions and that number continues to rise year after year.

24. AbbVie has restricted contract pharmacy shipments since at least February 1, 2022. Since then, AbbVie has changed is policy no fewer than ten times. AbbVie's policy changes have resulted in breakdowns in communications and the use of additional resources. For example, AbbVie and other manufacturers used to email their policies directly to covered entities, but many no longer do so. As a result, QHS and its covered entities have had to spend time and resources to manually check the internet for these updates on a regular basis, sometimes weekly. These efforts divert critical personnel and funds away from patient care.

25. Tracking and responding to each manufacturer's 340B shipment policy imposes a substantial burden on QHS. A team including pharmacy personnel, compliance, and in-house and outside attorneys have been assembled to support this work. This team has spent countless hours tracking, assessing, and responding to manufacturers' unilateral policies.

26. Under AbbVie's current policy, covered entities in Hawaii are limited to one designated contract pharmacy. AbbVie requires that the pharmacy be within forty miles of the covered entity, and it refuses to ship 340B drugs to that pharmacy unless the entity submits patient-specific claims data to a third-party vendor chosen by AbbVie, which is another example of AbbVie creating more administrative work for covered entities and increasing their costs, all of which inhibits patient care. The vendor's data-upload software includes nonnegotiable, problematic terms and conditions. For example, the terms permit the vendor to revoke access to the software at any time and cap the vendor's liability damages at $10,000.

27. Due to AbbVie's requirement allowing only one contract pharmacy to receive 340B drugs, QHS has avoided contractual relationships with community and specialty pharmacies because of the inability to access 340B drugs. All of these decisions divert money away from patient care.

28. The limitations on delivery and distribution of 340B covered drugs imposed by AbbVie and other pharmaceutical manufacturers have had significant consequences for QHS covered entities. For example, not every pharmacy carries every drug. Some high-cost drugs are only available through "specialty pharmacies," which typically ship the patients' drugs by mail.

29. QHS itself operates as a specialty pharmacy in Honolulu, Hawaii, but because of AbbVie's 40-mile restriction, AbbVie refuses to ship 340B drugs to pharmacies that provide drugs to rural hospital locations. For example, a patient from our Queen's North Hawaii Community Hospital on the Big Island could still choose to have their drug dispensed through the QHS specialty pharmacy on Oahu, but rather than acquiring the drug at the 340B price, the QHS specialty pharmacy is forced to spend more on the drug through conventional channels, and QHS is denied the 340B savings that help pay for the many free community benefit programs QHS

provides such as vaccine clinics and medical aid stations at sporting events, as well as offset losses from providing essential care to Hawaii's uninsured and underinsured population, including those on Medicare and Medicaid.

30. By requiring QHS entities to each choose a single contract pharmacy, AbbVie and other manufacturers force QHS to make trade-offs. If a QHS entity chooses a local pharmacy, then it is not serving patients who need specialty drugs or who lack reliable transportation. If a QHS entity chooses a mail-order pharmacy, it is not serving patients who lack stable housing or otherwise may not be able to receive at-home delivery. If a specialty or home infusion pharmacy is chosen, QHS is not serving patients who are prescribed less costly, less specialized medications.

31. On average, QHS saves an estimated $60.5M per year using the 340B program. QHS uses these 340B savings to support a range of services aligned with the program's intent to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.[1]" For example, QHS has a wide-reaching financial assistance policy that offers a 76% discount to patients with income less than 400% of the federal poverty level, and a 100% discount to patients under 250% of the federal poverty level. Queen's 2024 Community Health Needs Assessment describes the other unmet health needs in our communities and the strategies QHS has adopted to address them.

32. The restrictions imposed by AbbVie and other manufacturers directly affect patient care and services, specifically for patients located in rural communities and patients who require access to specialty drugs.

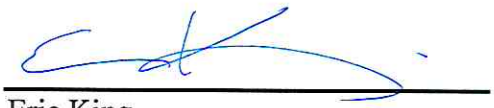
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[1] Health Resources & Services Administration, *340B Drug Pricing Program* (https://www.hrsa.gov/opa) (last visited July 10, 2025).

33. I am aware that Hawaii recently enacted Act 143 (formerly HB 712) to address manufacturer-imposed restrictions on 340B drug delivery. QHS strongly supports Act 143 as a necessary corrective measure.

I declare under penalty of perjury that the foregoing is true and correct.

Dated the 18 of July, 2025



Eric King
Director, 340B Program
The Queen's Health Systems
1301 Punchbowl Street | Honolulu, HI 96813

Exhibit 16 (Filed Under Seal)

Exhibit 17 (Filed Under Seal)

Exhibit 18 (Filed Under Seal)

Exhibit 19 (Filed Under Seal)

Exhibit 20 (Filed Under Seal)

Exhibit 21 (Filed Under Seal)

Exhibit 22 (Filed Under Seal)

EXHIBIT 23

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

ABBVIE INC. (a Delaware corporation); ALLERGAN, INC. (a Delaware corporation); DURATA THERAPEUTICS, INC. (a Delaware corporation); ABBVIE PRODUCTS LLC (a Georgia limited liability company); PHARMACYCLICS LLC (a Delaware limited liability company); ALLERGAN SALES, LLC (a Delaware limited liability company), *Plaintiffs*, v. ANNE E. LOPEZ, in her official capacity as ATTORNEY GENERAL OF THE STATE OF HAWAII. *Defendants*.	No. 1:25-cv-00230 Judge Shanlyn Park

DECLARATION OF EDWARD SCHEIDLER

I, Edward Scheidler, declare as follows in support of Plaintiff's Motion for a Preliminary Injunction in the above-captioned action:

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am the Head of the 340B Center of Excellence at AbbVie Inc. ("AbbVie"). I have worked at AbbVie since 2004 and been responsible for AbbVie's 340B Program since 2017. My responsibilities include regularly engaging

with the purchasers of AbbVie's pharmaceutical products concerning AbbVie's participation in the federal 340B Program, including with respect to AbbVie's relationships with commercial pharmacies (many of which are so-called "contract pharmacies"). I am familiar with the conditions of participation in federal health care programs, such as Medicare and Medicaid.

3. AbbVie Inc. and the other Plaintiffs named in *AbbVie, Inc. et al. v. Lopez*, No. 1:25-cv-00230, are currently parties to Pharmaceutical Pricing Agreements ("PPAs") executed with the United States Department of Health and Human Services ("HHS"). I understand the terms of the PPAs to be set by statute and non-negotiable. A true and correct copy of an executed PPA is attached hereto as Exhibit A as an example. *See* Ex. A (Pharmaceutical Pricing Agreement). The entity who executed the PPA at Exhibit A later merged into Plaintiff, Allergan Sales, LLC, a subsidiary of AbbVie Inc. (The PPAs relevant to the other six Plaintiffs are virtually identical by terms and obligations imposed.)

4. On April 17, 2023, AbbVie implemented an initiative under which AbbVie continued to offer "each covered entity" the ability to "purchase" its covered outpatient drugs "at or below the applicable ceiling" price set by statute but clarified that it would no longer indiscriminately accept requests to transfer or otherwise ship 340B discounted drugs to an unlimited number of contract pharmacies serving hospital covered entities. A true and correct copy of the April 17 initiative is

attached as Exhibit B. True and correct copies of subsequent updates to the policy language, issued on April 30, 2024 and February 27, 2025, are attached as Exhibit C and D, respectively. *See* Ex. B, Ltr. from C. Compisi to 340B Covered Entities (March 29, 2023); Ex. C, Ltr. from C. Compisi to 340B Covered Entities (April 30, 2024); Ex. D, Ltr. from E. Scheidler to 340B Covered Entities (Feb. 27, 2025). AbbVie's policy in no way affects patient access to drugs. AbbVie is committed to ensuring that each hospital covered entity has at least one pharmacy location where it can receive shipments of discounted AbbVie medicines, and out of which it can dispense AbbVie's 340B-discounted drugs to qualifying patients.

5. Under AbbVie's current policy, AbbVie facilitates the shipment of orders of 340B-priced medicines to one contract pharmacy location if the hospital covered entity does not have an in-house pharmacy, submits limited claims data on 340B utilization for that contract pharmacy, and the contract pharmacy is located within 40 miles of the HRSA registered covered entity. If a hospital covered entity is unable to identify an eligible contract pharmacy within 40 miles, AbbVie will work with the covered entity to identify a suitable alternative. Federal Grantees[1] may place orders for direct delivery to an unlimited number of contract pharmacies as long as the Grantee covered entity registers with 340B ESP™—a web-based platform made

[1] "Grantee" covered entity types are listed in 42 U.S.C. § 256b(4)(A)–(K).

available to covered entities at no cost—and submit claims data. Under this policy, AbbVie continues to make its products available at 340B-discounted prices in unlimited quantities to *all* covered entities, and certain contract pharmacies. AbbVie has stopped providing 340B-discounted drugs to an unlimited number of contract pharmacies for hospital covered entities.

6. In my role at AbbVie, I have acquired deep knowledge of and experience with the functioning of all facets of the 340B Program, including covered entities' use of contract pharmacies, the conditions of participation set out in the federal PPA, how the program operates in practice, and how it affects AbbVie's business. In particular, I am familiar with the "replenishment model" that contract pharmacies use to cause covered entities to place orders for 340B-discounted drugs as well as the mechanisms by which 340B discounts are applied. In the course of my job, I have regular conversations with contract pharmacies and covered entities regarding the 340B Program, and I work with them to address any disputes that may arise, or clarifications requested, regarding AbbVie's 340B policies.

7. I have reviewed Hawaii's Act 143 and understand it to be similar to legislation enacted in at least seventeen other states, the constitutionality of which is currently being challenged by pharmaceutical manufacturers in federal courts. I wish to clarify and expand on several points based on my experience and my understanding of the Hawaii bill and its context:

a. Act 143 repeatedly uses the language "340B drug." *See* Act 143 § 2-1, -2(a), (b). To clarify: there is no such thing as a "340B drug." There are only drugs—identical in composition and quality—offered for purchase at different price points, including at the 340B-ceiling price. Just as no one refers to a "WAC drug" or a "GPO drug" or a "Purchase Discount drug," the label "340B drug" is a misnomer.[2] The product does not change; only the commercial terms of the transaction vary. Act 143's language presumes a (faulty) distinction where none exists.

b. AbbVie's policy has no impact on patient access to critical medication. AbbVie's policy in no way restricts or limits any pharmacy's ability to order drugs—AbbVie will deliver its drugs (provided they are not in shortage) to any pharmacy, anywhere. A Hawaiian can present a prescription at any pharmacy and receive the medication; no customer must travel a significant distance to fill a prescription. AbbVie is in no way limiting the availability of medications in Hawaii or elsewhere. Whether a patient can obtain

[2] The Wholesale Acquisition Cost (WAC) is the list price set by manufacturers for sales to wholesalers. Group Purchase Organizations (GPOs) negotiate discounted prices on behalf of healthcare providers. "Purchase discounts" refer to other negotiated or volume-based discounts available in commercial contracts. These terms reflect pricing mechanisms—not distinct or different types of drugs.

a prescription medication is instead dependent on whether (1) the pharmacy chooses to stock the drug and (2) the patient's health insurance plan will cover it. For these reasons, the availability of 340B *pricing* has no bearing on patient access or a drug's availability.

c. For covered entities employing the replenishment model described below, the geographic location of the hospital has no effect on the amount paid by customers. A customer from Hilo, HI would pay full commercial price (i.e., whatever would be stipulated under that patient's insurance plan—hence why a pharmacy or doctor's office always asks for an insurance card first) for a drug whether she went to a local drugstore around the corner or a CVS in Honolulu, HI.

8. Under the "replenishment model," contract pharmacies dispense drugs to 340B and non-340B patients out of their general inventories. They do not maintain physically segregated inventories of 340B-priced drugs. Nor do most contract pharmacies attempt to determine prior to sale whether the patient is eligible for a 340B-discounted drug. In other words, in almost all instances, contract pharmacies order AbbVie-manufactured drugs and dispense them to their customers at full price without knowledge as to whether, at the time of dispensing, that patient is a 340B-eligible patient.

9. Pharmacies purchase AbbVie products for their general inventories at market prices. After a particular quantity of a particular drug is dispensed to pharmacy customers, the pharmacy (either itself or through a Third-Party Administrator "TPA" with which it contracts) determines which *prior* dispensing events should be linked with 340B eligibility. This determination is typically made via the contract pharmacy's own criteria, without any involvement from the covered entities. The contract pharmacy's criteria may include prior patients, who no longer receive the 340B-discounted drugs at the pharmacy but are included under a "once-a-patient-always-a-patient" approach, so the covered entity and its pharmacies are able to maximize the arbitrage profits from the 340B Program. Some covered entities and contract pharmacies sometimes work together to set the criteria for 340B "patient" eligibility. For example, I am aware that some contract pharmacies use a "set it and forget it" process, whereby they agree on certain criteria with the TPA at the time of contracting and never revisit those criteria. Conversely, sometimes covered entities change their "patient definition" and reprocess, retroactively, historical data to determine additional eligible dispensing events for those time frames based on *new* criteria.

10. After identifying the purported 340B-eligible transactions, the contract pharmacy (typically through a TPA) instructs the covered entity associated with the patient to place an order of *additional* quantities of that drug at the discounted 340B

price to "replenish" the contract pharmacy's inventory of non-340B-discounted drugs. However, I am not aware of any instances where the covered entity directly places replenishment orders for a contract pharmacy dispense. Rather, in my experience, the order is typically generated and submitted by the contract pharmacy (either itself or through a TPA) using a third-party covered entity's purchasing account information. I am aware of at least one situation where a contract pharmacy placed a replenishment order with AbbVie; and when AbbVie later asked the covered entity about this order, the covered entity stated that it did not know that a replenishment order had been placed.

11. It is through this mechanism that AbbVie must extend the 340B discount on units given to contract pharmacies to replace inventory purchased at non- discounted prices that may—if the TPA's algorithm works correctly—have been dispensed to patients of a covered entity.

12. When a contract pharmacy places an order on behalf of a covered entity, AbbVie usually does not ship its 340B-discounted "replenishment" drugs to the covered entity.[3] While the covered entity makes the purchase, replenishment product is shipped directly from the wholesaler to the contract pharmacy. Within the industry, this practice is referred to as a "Bill To/Ship To" order. This means the

[3] AbbVie does ship drugs to covered entity-owned pharmacies, as well as covered entities' in-house pharmacies.

wholesaler bills the covered entity but ships to the contract pharmacy. These shipments of 340B-priced drugs to contract pharmacies are not based on orders needed for specific 340B-eligible patients based on actual or projected future need.

13. I do not understand covered entities to maintain legal title to AbbVie drugs while they are held in a contract pharmacy's general inventory prior to being identified, post-sale, as 340B-linked drugs. Instead, at the time of sale to a patient, a unit of drugs is owned by the contract pharmacy itself.

14. I understand that, as a result of the replenishment model, patients continue to pay full price at the point of sale or dispensing, or their insurer or other payment plan does. Note then that when that drug is "replenished" at the 340B discounted price, that creates a difference between the full price paid by customers at the pharmacy counter and the discounted price AbbVie offers to covered entities, known as "spread." The contract pharmacy and covered entity split that spread pursuant to the terms of the agreements between them, usually some percentage is retained by the pharmacy. This phenomenon has been well-documented in multiple sources, ranging from the U.S. Department of Health and Human Services Inspector General to newspaper reporters for major outlets.[4]

[4] *See* HHS Office of Inspector General, OEI-05-13-00431, Mem. Report: Contract Pharmacy Arrangements in the 340B Program (2014) ("HHS Report"), at 2, https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp (finding that "some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies"); Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, WALL ST. J. (Sept. 10, 2020), https://www.wsj.com/articles/the-federal-program-that-keeps-insulin-prices-

15. To provide an example of the replenishment model in practice, I will describe the process via a hypothetical sale of "Drug A," premised on data in AbbVie's internal invoicing system for 340B orders. I assume Drug A has a commercial price of $100 per unit, and is subject to a discount rate of 99% under AbbVie's PPA. That 99% difference yields a per-unit 340B price of $1.00. In other words, the difference between the commercial price and 340B-price is $99.00. A CVS Pharmacy in Honolulu, HI orders 10 units of Drug A at the $100.00 commercial price, per unit, for a total of $1,000 in cost. The CVS Pharmacy then resells the product at a mark-up price of $120.00 per unit of Drug A.

a. Over the next month, ten customers receive prescriptions for Drug A, have them filled at the CVS Pharmacy, and pay $120 per unit either out-of-pocket (i.e., a $25 copayment) or via private insurance

high-11599779400 (explaining that "almost half the U.S. pharmacy industry now profits from the 340B Program, which is designed as a narrow support to certain hospitals," while patients "don't benefit" and "are expected to pay . . . full out-of-pocket costs," even though manufacturers have "practically given the product away"); Rory Martin & Kepler Illich, *Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?*, IQVIA, at 12, https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies.pdf ("The 340B Drug Discount Program as it exists today is a complex system of arbitrage . . . in which most vulnerable patients at contract pharmacies do not get drug discounts."); Lin JK, et al., *Assessment of US Pharmacies Contracted with Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics*, JAMA Health Forum (2022), at 2, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530 (finding that contract pharmacy growth from 2011–2019 was concentrated in affluent and predominantly White neighborhoods and that the share of 340B pharmacies in socioeconomically disadvantaged and primarily non-Hispanic Black and Hispanic/Latino neighborhoods declined).

coverage for which they pay a premium. The CVS receives, in total $1,200 from the 10 customers who purchased Drug A, recouping both the initial commercial price and $200 in profit. (I assume some level of mark-up by the CVS over the commercial acquisition cost when transacting with customers at the pharmacy counter.)

b. Later, the TPA of CVS Pharmacy (usually it is Wellpartner, owned by CVS), calculates how many of those ten units of Drug A they believe were dispensed to a 340B patient of a specific Covered Entity under contract with that particular CVS location. Neither I, nor anyone at AbbVie, have any insight into or understanding of how this determination is made or what factors are considered. I understand, generally, that these determinations are often not accurate. Their criteria for determining whether a customer was a 340B patient can include factors like the identity of the prescriber or how long ago the patient last received a prescription from a 340B-eligible covered entity. As explained above, I understand that some contract pharmacies have a "once-a-patient-always-a-patient" model, which includes any customer who has *ever* received a prescription from a 340B covered entity or prescriber.

c. In our example, let us assume that the CVS Pharmacy and its TPA determine five of the ten customers who purchased Drug A were 340B-eligible patients. The CVS Pharmacy and its TPA then notify the covered entity to order five units of Drug A for the CVS Pharmacy to "replenish" the five full-priced units of Drug A that the CVS Pharmacy previously purchased and dispensed to 340B patients.

d. As explained above, those five 340B patients have already paid full price (or their insurer has) for their unit of Drug A at the $120 price. I do not understand that contract pharmacies retroactively reimburse patients for the 340B-eligible price after the fact. If they did, AbbVie's policy would not in any way prohibit a covered entity's election to undertake that practice.

e. AbbVie or its wholesaler receive the covered entity's order for five units of Drug A and ships them to the CVS Pharmacy in the same package or on the same pallet as commercially-purchased units of Drug A and other drugs being sent to the CVS Pharmacy via a commercial order.

f. There is no way to discern which units of Drug A are the five units sold at the 340B price. They are not packaged differently, labeled

differently, or shipped separately or in a different kind of box (either by color, labeling, or other demarcation). One received by the contract pharmacy, they are placed into the general inventory and dispensed to any customer who walks in the door, 340B-eligible or otherwise. The only difference between a unit of Drug A shipped for "replenishment" and other units of Drug A *is the price* AbbVie receives for the shipment of its drugs. Placing 340B replenishment orders has no effect on how AbbVie drugs are transported or delivered.

g. The CVS receives the five units of Drug A at the 340B price and, as a matter of accounting, adjusts the previous paid price for those five units down to the cost of the 340B price, $1.00. The CVS then splits the differential, $495, between itself and the covered entity at some percentage. If we assume it is 70/30 in favor of the covered entity, then CVS keeps $148.50 and pays the covered entity $346.50. The patient who paid the full $120 (or their $25 copayment) receives no discount.

16. It is my understanding that AbbVie has no obligation to contract pharmacies under the 340B Program. I do not understand contract pharmacies, like CVS, to be agents of covered entities in Hawaii or elsewhere.

17. When AbbVie changed its 340B contract pharmacy policy, a large commercial specialty pharmacy customer requested a meeting with AbbVie to discuss "its" 340B discount. AbbVie refused to meet with this pharmacy, explaining that it is not entitled to place orders at the 340B price, and that it needed to reach out to its respective covered entities if it had concerns with those entities' access to 340B discounts.

18. In addition to the "replenishment model," I understand that some covered entity stakeholders are converting to what is known as a "credit," "non-inventory replenishment," or "inventory synchronization model." Under this emerging model, contract pharmacies attempt to create a credit against their non-340B WAC-priced orders when they identify covered entity "patients" at contract pharmacies. At the very least, the emergence of this model evidences that 340B discounts are sometimes provided without even the suggestion that covered entities maintain legal title or that contract pharmacies function as legal agents subject to the dictates of covered entities.

19. Additionally, I am also aware that some contract pharmacies and covered entities use a "*pre*-plenishment model." Under that model, a covered entity and contract pharmacy predict, based on average data, how many prescriptions of a particular drug they think are likely in a given month and order those drugs ahead of time to "pre-plenish" the contract pharmacy's stock. That practice is (1) unmoored

from any actual 340B eligible dispensing event, and (2) misunderstands the reality that often times prescriptions are not filled or are filled elsewhere, making any such "prediction" of how many 340B-eligible customers are likely to come in nearly impossible.

20. I understand that Hawaii, like several other states, has enacted legislation purporting to impose state-law obligations on manufacturers, like AbbVie, as a condition of their participation in the federal 340B Program. I further understand that Hawaii's law, Act 143, requires AbbVie to cooperate with an unlimited number of contract pharmacy arrangements.

21. As a manufacturer, AbbVie relies on revenues generated from sales of its drugs to recoup the high costs of developing new, better drugs. While AbbVie willingly complies with its obligations under the federal 340B Program to help provide low-cost drugs to at-risk patients, AbbVie's ability to sell its products at non-340B prices for transactions that fall outside the requirements of the federal 340B statute is important to its ability to invest in developing new drugs with the goal of improving patients' lives.

22. Requiring cooperation with unlimited numbers of contract pharmacy arrangements in Hawaii, as I understand Hawaii's Act 143 to require, would have a significant effect on the volume of AbbVie drugs subject to 340B pricing. When AbbVie first revised its 340B policy to prohibit sales to unlimited contract

pharmacies in April 2023, AbbVie experienced a significant reduction in the volume of drugs for which 340B pricing was requested. Notably, the policy did not change or otherwise affect the way 340B-priced drugs are delivered or shipped to contract pharmacies.

23. Because Act 143 requires AbbVie to provide its drugs at steeply discounted 340B prices to an unlimited number of contract pharmacy arrangements, AbbVie will face the threat of millions of dollars in forced unnecessary discounts each year as a result of Act 143 For example, AbbVie's cost of complying with similar laws in Mississippi and Missouri cost around $33.1 million and $35 million, respectively last year. AbbVie estimates that the projected cost of compliance with Act 143 will be approximately $23 million in 2025. And, as more states like Hawaii adopt similar laws, AbbVie's injury grows into the hundreds of millions.

24. Once 340B discounts are given, it is my understanding that there is no way for a covered entity or contract pharmacy to automatically refund AbbVie for unlawfully received discounts if Hawaii's statute is subsequently invalidated.

25. This lost revenue will negatively impact AbbVie's business model and affect its ability to invest in future products. This will in turn impact the public and vulnerable patients who desperately need innovative drugs and new treatments. These harms are irreparable because once research and development opportunities are lost or delayed, it is impossible to recoup that lost investment.

26. Act 143 threatens to impose significant monetary penalties in the case of a violation, including up to criminal penalties. These penalties pose a significant legal, operational, and reputational risk to AbbVie.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct; in witness whereof, I have caused my signature to be hereunto affixed.

Executed on this 18th day of June 2025.

By: 

Edward Scheidler