

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.

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

Defendant.

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PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA,

Plaintiff,

vs.

ANNE E. LOPEZ, IN HER OFFICIAL  
CAPACITY AS ATTORNEY GENERAL  
OF HAWAI'I,

Defendant.

CIV. NOS. 25-00230-SASP-WRP and  
25-00292 SASP-WRP  
(CONSOLIDATED)

ORDER GRANTING IN PART AND  
DENYING IN PART DEFENDANT'S  
MOTIONS TO DISMISS

**ORDER GRANTING IN PART AND DENYING IN  
PART DEFENDANT'S MOTIONS TO DISMISS**

Under the federal Section 340B Program, codified at 42 U.S.C. § 256b, drug  
manufacturers that participate in Medicaid and Medicare Part B must offer heavily discounted

drugs to certain healthcare facilities (“covered entities”) that serve predominantly uninsured and low-income individuals. In recent years, several states have enacted legislation to, among other things, limit drug manufacturers’ ability to apply distribution conditions on their 340B offers to covered entities. In 2025, Hawai‘i followed suit and enacted Act 143, codified at Hawaii Revised Statutes (“HRS”) Chapter 481N. Act 143 took effect on July 1, 2025. Thereafter, two drug manufacturers, Plaintiffs AbbVie Inc., Durata Therapeutics, Inc., AbbVie Products, LLC, Pharmacyclics, LLC, Allergan Sales, LLC (collectively “AbbVie”), and Pharmaceutical Research and Manufacturers of America (“Pharma”) (collectively “Plaintiffs”), filed separate civil actions in this Court seeking to invalidate the law on grounds that Act 143 is unconstitutional in several respects. Their cases were ultimately consolidated.<sup>1</sup>

Now before this Court is Defendant Attorney General of the State of Hawai‘i Anne E. Lopez’s (“the State”) Motions to Dismiss against AbbVie and Pharma (collectively “Motions to Dismiss”).<sup>2</sup> [ECF Nos. 25 and 48, respectively.]

After careful consideration and for the reasons discussed herein, the Court GRANTS IN PART and DENIES IN PART the State’s Motions to Dismiss.

## **I. RELEVANT BACKGROUND<sup>3</sup>**

### **A. The Section 340B Program**

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<sup>1</sup> All references to the record are to the consolidated docket: 1:25-cv-00230-SASP-WRP, unless otherwise indicated.

<sup>2</sup> The operative pleadings are AbbVie’s Complaint, ECF No. 1, filed on June 2, 2025 in 1:25-cv-00230-SASP-WRP (“AbbVie Complaint”); and Pharma’s Complaint, ECF No. 1, filed on July 11, 2025 in 1:25-cv-00292-SASP-WRP (“Pharma Complaint”).

<sup>3</sup> This section is not intended to be a comprehensive summary of all the facts, but rather, a broad overview of the relevant background information. Other facts pertinent to this Court’s decision are summarized below to the extent they are applicable.

Enacted by Congress in 1992,<sup>4</sup> Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, is a drug-pricing program that, as a condition of participating in Medicare Part B and Medicaid, “imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities” referred to as “covered entities.” *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011); *see* 42 U.S.C. § 256b(a)(1), (4). The Section 340B Program defines “covered entity” to include fifteen subsets of healthcare providers. *See* 42 U.S.C. § 256b(a)(4). Covered entities are the only institutions permitted to purchase discounted drugs through the Section 340B Program. *Id.* § 256b(a)(1). The list of covered entities includes federally qualified health centers, Native Hawaiian health centers, rural referral centers, and federal-or state-funded hospitals and community health centers that primarily serve low-income patients. *See id.* § 256b(a)(4). In securing discounted drugs for covered entities, the Section 340B Program was created “to ensure that uninsured and low-income individuals can access the medications they need and to ensure that medical providers serving these individuals receive crucial subsidies.” *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 639 (5th Cir. 2025) (citations omitted).

The Section 340B Program is administered by the Secretary of Health and Human Services (“HHS”), which has delegated its authority to the Health Resources and Services Administration (“HRSA”). *See Astra USA, Inc.*, 563 U.S. at 113–14. To opt into the Section 340B Program, drug manufacturers must sign a Pharmaceutical Pricing Agreement (“PPA”): a “uniform agreement[] that recite[s] the responsibilities [that the Section 340B Program] imposes.” *Id.* at 113. “The [Section] 340B Program ‘has three basic parts: (1) a cap on drug

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<sup>4</sup> Congress first enacted the Section 340B Program as part of the Veterans Health Care Act of 1992, and later amended it in 2010 as part of the Affordable Care Act. Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967; Pub. L. No. 111-148, tit. VII.B, §§ 7101–02, 124 Stat. 119, 821–27 (both codified at 42 U.S.C. § 256b).

makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms' for both covered entities and drug manufacturers." *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1141 (8th Cir. 2024) (quoting *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023)).

First, the Section 340B Program requires that participating drug manufacturers offer covered outpatient drugs to covered entities at or below a "ceiling price." See 42 U.S.C. § 256b(a)(1). In so mandating, the statute establishes a formula for calculating ceiling prices, *id.* § 256b(a)(2), and defines covered drugs. *Id.* § 256b(a)(3), (b)(2).

Second, the Section 340B Program includes requirements for covered entities. See 42 U.S.C. § 256b(a)(5). Among them, "[c]overed entities are prohibited from requesting the 340B discount for drugs that also qualify for a Medicaid rebate (referred to as a double discount), 42 U.S.C. § 256b(a)(5)(A), may not resell or otherwise transfer the discounted drugs to anyone who is not a patient of the covered entity (referred to as diversion), *id.* § 256b(a)(5)(B), and must allow the Secretary and manufacturers to audit their records according to procedures established by the Secretary, *id.* § 256b(a)(5)(C)." *Pharm. Rsch. & Mfrs. of Am. v. Frey*, No. 1:25-cv-00469-JCN, 2026 WL 184504, at \*1 (D. Me. Jan. 23, 2026).

Third, the Section 340B Program includes multiple compliance, enforcement, and dispute resolution mechanisms. For example, "[i]f the Secretary finds that a covered entity has engaged in double-discounting or diversion, the entity shall be liable to the manufacturer for the discounts it received improperly." *Id.* at \*2 (citing 42 U.S.C. § 256b(a)(5)(D)). The Secretary may also impose additional sanctions on a covered entity for diversion violations under certain enumerated circumstances, 42 U.S.C. § 256b(d)(2)(B)(v), and may impose monetary sanctions on drug manufacturers for overcharging a covered entity. *Id.* § 256b(d)(1)(B)(vi). The Section

340B Program also provides an administrative dispute resolution process which permits covered entities to submit claims against drug manufacturers for being overcharged, and drug manufacturers to submit claims for diversion or double discount violations by covered entities. *Id.* § 256b(d)(3).

## **B. Contract Pharmacy Arrangements**

Since the Section 340B Program’s enactment, “covered entities have contracted with outside pharmacies, referred to as ‘contract pharmacies,’ for the distribution and dispensation of 340B drugs.” *McClain*, 95 F.4th at 1139.

In August 1996, HRSA issued a final non-binding guidance notice (“1996 Guidance”) regarding the Section 340B Program and contract pharmacy arrangements. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996). Therein, HRSA observed that “[t]he statute is silent as to permissible drug distribution systems,” and that “[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself.” *Id.* at 43549. HRSA stated that a covered entity that lacked an in-house pharmacy could contract with *an individual outside pharmacy* to provide services to the covered entity’s patients. *Id.* at 43555 (“Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice.”). In response to public comments that the use of contract pharmacy services would result in an unauthorized expansion of the Section 340B Program, HRSA noted that its guidelines “create no new law and create no new rights or duties.” *Id.* at 43550.

In March 2010, HRSA issued a final non-binding guidance notice (“2010 Guidance”) regarding the Section 340B Program and contract pharmacy arrangements, replacing

its earlier 1996 Guidance regarding the same. Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10272, 10277 (Mar. 5, 2010). Therein, HRSA changed course from its earlier guidance encouraging covered entities to contract with a singular outside pharmacy, and stated that covered entities could contract with *multiple outside pharmacies*, regardless of whether the covered entity had its own in-house pharmacy, “as long as they comply with guidance developed to help ensure against diversion and duplicate discounts,” among other established policies. *Id.* at 10273, 10277–79 (“In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies[.]”). HRSA again observed that its 2010 Guidance “neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law.” *Id.* at 10273.

Plaintiffs allege that since 2010, covered entities have dramatically increased their use of contract pharmacies. [AbbVie Compl. ¶ 57; *see also* Pharma Compl. ¶ 62.] According to AbbVie, use of contract pharmacies have reportedly risen “12,000% between 2010 and 2024.” [AbbVie Compl. ¶ 57.] AbbVie also alleges that “[s]imilarly, the number of covered entities participating in the [Section 340B] [P]rogram jumped from around 15,000 in 2010 to more than 50,000 by 2020.” [AbbVie Compl. ¶ 58.] Plaintiffs appear to attribute the growth of contract pharmacy arrangements with the “prospect of sharing in the outsized profit margins on manufacturer-subsidized 340B-discounted drugs.” [AbbVie Compl. ¶ 57; *see also* Pharma Compl. ¶¶ 60–62.] Plaintiffs contend that the exponential boom in contract pharmacy arrangements exacerbates the potential risk of abuse of the Section 340B Program via double discounting and diversion. [See AbbVie Compl. ¶¶ 57–58, 66–67, 73–74, 81; Pharma Compl. ¶¶ 63, 65, 80–82.] Specifically, Plaintiffs contend that the “replenishment model”—a retroactive

process of claiming and tracking 340B discounts, used by a majority of contract pharmacies— has contributed significantly to increased abuse of the Section 340B Program, allegedly at the expense of the communities the program was intended to serve. [See AbbVie Compl. ¶¶ 63–74, 77–78, 80–82; Pharma Compl. ¶¶ 63–67, 70, 72, 74–75, 77–78, 80–82.]

The replenishment model works as follows: (1) The pharmacy purchases a quantity of a drug at market price and maintains it in common inventory; (2) the pharmacy dispenses drugs from the common inventory whenever a customer arrives with a prescription without regard to whether the customer is a patient of a covered entity; (3) an administrator later reviews claims data to analyze which transactions were for covered drugs to a patient of a covered entity and thus eligible for the discount; and (4) after enough qualifying transactions have occurred, the covered entity orders more units of the drug at the discounted price to replenish the units dispensed to patients of the covered entity.

*Novartis Pharms. Corp. v. Frey*, Nos. 1:25-cv-00407-JCN and 1:25-cv-00416-JCN, 2025 WL 2813787, at \*3 (D. Me. Sept. 23, 2025). [See AbbVie Compl. ¶¶ 63–66; Pharma Compl. ¶¶ 64–67.]

### C. HRSA Prohibition on Drug Manufacturer Limits

In an attempt to combat the alleged abuses associated with increased contract pharmacy arrangements and widespread use of the replenishment model, AbbVie and “certain [Pharma] members” joined other drug manufacturers in adopting independent policies to limit the use of contract pharmacies by covered entities. [See Pharma Compl. ¶ 85; AbbVie Compl. ¶¶ 85–87, 89.]

In December 2020, the HHS Office of the General Counsel issued an advisory opinion (“2020 Advisory Opinion”) stating that the Section 340B Program unambiguously “requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner.” See *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 458

(D.C. Cir. 2024). [See AbbVie Compl. ¶ 93; Pharma Compl. ¶ 86.] Litigation over the 2020 Advisory Opinion ensued. [AbbVie Compl. ¶ 93.]

In June 2021, the District Court of Delaware held that the 2020 Advisory Opinion was legally flawed, at least in part, because the Section 340B Program is silent with respect to contract pharmacy arrangements, and therefore does not unambiguously prohibit manufacturers from imposing distribution conditions, nor mandate covered entities' ability to contract with an unlimited number of outside pharmacies. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 58–62 (D. Del. 2021) (“[T]he Court concludes that there is more than one permissible interpretation of the 340B statute. Because the [2020 Advisory Opinion] wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities’ permissible use of an unlimited number of contract pharmacies, the Opinion is legally flawed.” (footnote omitted)). “Two days later, while that court was still considering what relief to afford, HHS withdrew its [2020 Advisory Opinion.]” *Johnson*, 102 F.4th at 458.

During the pendency of the litigation over the 2020 Advisory Opinion, in May 2021, HRSA issued violation letters to drug manufacturers that implemented policies to address 340B abuses—including AbbVie and some Pharma members—stating that the manufacturers’ independent policies violated the Section 340B Program and had resulted in overcharges. [See AbbVie Compl. ¶ 94; Pharma Compl. ¶ 87.] Litigation followed. [See Pharma Compl. ¶ 87.]

“Most of the district courts to consider the legality of the violation letters vacated the letters, and two circuit courts ruled in favor of the manufacturers.” *Pharm. Rsch. & Mfrs. of Am.*, 2026 WL 184504, at \*3. The Third Circuit and the District of Columbia (“D.C.”) Circuit held, among other things, that the Section 340B Program is silent about delivery, and therefore the statute does not explicitly require drug manufacturers to distribute discounted drugs to an

unlimited number of contract pharmacies. *See Sanofi Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696, 703–07 (3d Cir. 2023); *Johnson*, 102 F.4th at 460, 464. [*See AbbVie Compl.* ¶¶ 97–100; *Pharma Compl.* ¶¶ 92–95.]

In purported response to decisions like those of the Third and D.C. Circuits, several States, including Hawai'i, have enacted laws seeking to, among other things, prohibit drug manufacturers from limiting the use of contract pharmacies by covered entities. *Pharm. Rsch. & Mfrs. of Am.*, 2026 WL 184504, at \*4 (“Approximately twenty states, . . . have enacted laws in response to the court decisions finding that HRSA lacked statutory authority to prohibit the manufacturers’ policies.”). [*See AbbVie Compl.* ¶¶ 101, 104; *Pharma Compl.* ¶¶ 100, 103–04.]

#### **D. Act 143**

In May 2025, Hawai'i enacted Act 143, to protect covered entities’ partnerships with contract pharmacies in the State. 2025 Haw. Sess. Laws Act 143, §§ 1–3 at 329–32. The statute requires, among other things, participating drug manufacturers to deliver drugs discounted under the Section 340B Program to contract pharmacies. *See HRS* § 481N-2(a). Act 143 took effect on July 1, 2025. 2025 Haw. Sess. Laws Act 143, § 3 at 332.

Act 143 includes, in relevant part, the following prohibitions:

(a) No manufacturer, or any agent or affiliate of a 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 unless the receipt is prohibited by the United States Department of Health and Human Services.

(b) Nothing in this section shall deny, restrict, or prohibit a manufacturer from requiring a 340B covered entity to provide claims data for the manufacturer’s 340B drugs dispensed through a

contract pharmacy arrangement; provided that the claims data is necessary to investigate potential diversion, duplicate discounts, or whether a transaction is eligible for a rebate under applicable arrangements between a drug manufacturer and a third-party payor; provided further that any request for claims data by a manufacturer shall be limited to claims submitted no more than three years prior to the date of the request. Any claims data provided pursuant to this subsection shall be shared in a manner that is fully compliant with the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, and any other applicable privacy laws. Nothing in this subsection shall be construed to supersede or conflict with any applicable federal laws, rules, or regulations governing the 340B program.

HRS § 481N-2 (a)–(b).

Act 143 also requires drug manufacturers to report annually to the hospital trade association in the State certain information regarding the 340B covered entity’s use of contract pharmacies in the Section 340B Program, to be included in an annual report detailing aggregate information from all 340B covered entities in the State. *See* HRS § 481N-6(a), (c).

The statute defines “340B covered entity” as “an entity that participates in the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act).” HRS § 481N-1. A “340B drug” is defined as “a prescription drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act) and is dispensed by a pharmacy.” *Id.* A “contract pharmacy” is defined as “a pharmacy with which a 340B covered entity has contracted to dispense 340B drugs on behalf of the 340B covered entity to patients of the 340B covered entity, whether distributed in person, via mail, or by other means.” *Id.*

With respect to enforcement and remedies, Act 143 authorizes the Attorney General to bring civil actions to enjoin violations of the statute, and to assess fines for the same.

See HRS § 481N-4(a)–(b). Moreover, “[a]ny 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.” HRS § 481N-3.

**E. Plaintiffs’ Complaints**

Following the enactment of Act 143, on June 2, 2025, and July 11, 2025, AbbVie and Pharma each commenced separate civil actions against the State challenging the constitutionality of the statute. [See AbbVie Compl.; Pharma Compl.] Plaintiffs’ Complaints each seek a declaratory judgment that Act 143 is unconstitutional, and an injunction to restrain the State from enforcing the law. [See AbbVie Compl. ¶ 22; Pharma Compl. ¶ 22.]

AbbVie’s Complaint alleges four counts. In Count 1, AbbVie alleges that Act 143 is preempted by the Section 340B Program pursuant to the Supremacy Clause of the United States Constitution. In Count 2, AbbVie alleges that Act 143 violates the Takings Clause of the United States Constitution. In Count 3, AbbVie alleges that Act 143 violates the dormant Commerce Clause of the United States Constitution. And in Count 4, AbbVie alleges that Act 143 is void for vagueness, pursuant to the Fourteenth Amendment of the United States Constitution.

Pharma’s Complaint alleges a singular count. Namely, that Act 143 is preempted by the Section 340B Program pursuant to the Supremacy Clause of the United States Constitution.

**F. The State’s Motions to Dismiss**

On August 4, 2025, the State filed its Motion to Dismiss AbbVie’s Complaint for failure to state a claim upon which relief can be granted, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure (“Fed. R. Civ. P.”). [MTD AbbVie Compl., ECF No. 25.] Then, on

August 27, 2025, this Court issued a Minute Order, among other things, finding that Plaintiffs' Complaints involve common questions of law and fact regarding the constitutionality of Act 143; and consolidating both lawsuits for purposes of determining the pending motion(s).<sup>5</sup> [ECF No. 40.] Thereafter, on September 8, 2025, the State filed its Motion to Dismiss Pharma's Complaint, also pursuant to Fed. R. Civ. P. 12(b)(6). [MTD Pharma Compl., ECF No. 48.] On September 29, 2025, Plaintiffs filed their respective oppositions to the State's Motions [AbbVie Opp., ECF No. 53; Pharma Opp., ECF No. 54.], and on October 13, 2025, the State filed its consolidated reply. [D. Reply, ECF No. 58.]

In August and September 2025, amici curiae the American Hospital Association, 340B Health, Healthcare Association of Hawaii, and American Society of Health-System Pharmacists, filed briefs, among other things, in support of the State's Motions to Dismiss. [See ECF No. 29; ECF No. 51; 1:25-cv-00292-SASP-WRP, ECF No. 34]

On November 13, 2025, the Court held a hearing on the State's Motions to Dismiss ("November 13, 2025 Hearing") and took the matters under advisement. [See ECF No. 69.]

## **II. STANDARD OF REVIEW**

Fed. R. Civ. P. 12(b)(6) permits a motion to dismiss for "failure to state a claim upon which relief can be granted." A Rule 12(b)(6) dismissal is proper when there is either a "lack of a cognizable legal theory or the absence of sufficient facts alleged." *UMG Recordings, Inc. v. Shelter Cap. Partners LLC*, 718 F.3d 1006, 1014 (9th Cir. 2013) (quoting *Balistreri v.*

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<sup>5</sup> In addition to the State's Motions to Dismiss, Plaintiffs have each filed motions for preliminary injunction, which remain pending before this Court. [See AbbVie's Motion for Preliminary Injunction, ECF No. 16; Pharma's Motion for Preliminary Injunction, 1:25-cv-00292-SASP-WRP, ECF No. 11.] The parties have agreed to await this Court's ruling on the State's Motions to Dismiss, before addressing Plaintiffs' motions for preliminary injunction. [See ECF No. 75.]

*Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1988)). And in a 12(b)(6) analysis, the court accepts as true the material facts alleged in the complaint and construes them in the light most favorable to the nonmovant. *Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir. 1996) (citation omitted). A plaintiff must make sufficient factual allegations to establish a plausible entitlement to relief. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Such allegations must amount to “more than labels and conclusions, [or] a formulaic recitation of the elements of a cause of action.” *Id.* at 555.

“Leave to amend should be granted unless the pleading could not possibly be cured by the allegation of other facts[.]” *Ramirez v. Galaza*, 334 F.3d 850, 861 (9th Cir. 2003) (citation and internal quotation marks omitted). “A district court, however, does not abuse its discretion in denying leave to amend where amendment would be futile.” *Flowers v. First Hawaiian Bank*, 295 F.3d 966, 976 (9th Cir. 2002) (citation omitted).

Accordingly, the Court will consider whether the claims dismissed in this Order should be dismissed with or without prejudice or with leave to amend.

### **III. DISCUSSION**

The State moves to dismiss Plaintiffs’ respective Complaints pursuant to Fed. R. Civ. P. 12(b)(6), alleging that Plaintiffs have failed to state claims upon which relief can be granted. [See ECF Nos. 25 and 48.] For the reasons discussed below, the State’s Motions to Dismiss are granted in part and denied in part.

#### **A. Count 1: Preemption Claim(s) (AbbVie and Pharma)**

In their respective Count 1 claims, Plaintiffs allege that Act 143 is impliedly preempted by the Section 340B Program, pursuant to the Supremacy Clause of the United States Constitution.

The Supremacy Clause provides that federal law “shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” U.S. Const. art. VI, cl. 2. Accordingly, “state law that conflicts with federal law is ‘without effect.’” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). Congress may expressly preempt a state law through federal legislation, or may implicitly preempt a state law through either field preemption or conflict preemption. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376–77 (2015).

Because Plaintiffs’ respective Count 1 claims raise implied preemption arguments under theories of field preemption and conflict preemption, the Court addresses the State’s challenge to each, in turn, below.

*I. Field Preemption*

First, Plaintiffs allege that Act 143 is field preempted. Under established principles of field preemption, “[s]tates are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.” *Arizona v. United States*, 567 U.S. 387, 399 (2012) (citation omitted). Field preemption “can be inferred from 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.’” *Id.* (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); and then citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). “Where Congress occupies an entire field, . . . even complementary state regulation is impermissible. Field preemption reflects a congressional decision to foreclose any state regulation in the area, even if it is parallel to federal standards.”

*Id.* at 401 (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 249 (1984)). Accordingly, the Ninth Circuit Court of Appeals (“Ninth Circuit”) has adopted a two-step framework for evaluating field preemption. *See Nat’l Fed’n of the Blind v. United Airlines Inc.*, 813 F.3d 718, 734 (9th Cir. 2016). “The first step in determining whether [field preemption] exists is to delineate the pertinent regulatory field; the second is to survey the scope of the federal regulation within that field.” *Id.* With respect to the first step, the Ninth Circuit has emphasized the need to define the relevant field “with specificity.” *Id.* (citation omitted).

In Plaintiffs’ respective Count 1 claims, they allege that Act 143 is field preempted because it intrudes upon the exclusive regulatory field created by the federal Section 340B Program. [*See* Pharma Compl. ¶¶ 116, 119–22; AbbVie Compl. ¶¶ 131–36.] With respect to the scope of federal regulation within the Section 340B Program, Plaintiffs allege that “[e]very element of the [Section 340B] [P]rogram—from eligibility and pricing to compliance and enforcement—is governed by federal law,” thereby leaving no express nor implied roles to the States. [AbbVie Compl. ¶ 131; *see* Pharma Compl. ¶¶ 119–20.] Plaintiffs maintain that Act 143—in, among other things, prohibiting manufacturers from denying the delivery of 340B-priced drugs to contract pharmacies—“seeks to directly intrude on this carefully balanced federal program by expanding and materially altering the scope of manufacturers’ obligations and rights, and by implementing a competing enforcement regime” beyond what is proscribed in the Section 340B Program. [Pharma Compl. ¶ 121; *see* AbbVie Compl. ¶¶ 132–33.]

The State argues, among other things, that Plaintiffs’ respective field preemption claims should be dismissed because the Section 340B Program is explicitly silent on the issues that Act 143 regulates, namely, delivery and contract pharmacies. [*See* MTD AbbVie Compl., ECF No. 25 at PageID.860–65.; MTD Pharma Compl., ECF No. 48 at PageID.1480–83.]

Here, Plaintiffs allege that every aspect of the Section 340B Program is federally regulated, such that Congress left no room for State supplementation. Plaintiffs contend that Act 143 effectively regulates pricing by purportedly forcing the transfer of discounted drugs to covered entities; and implements “a competing enforcement regime”—both areas purportedly governed by the Section 340B Program. Outside of their respective Count 1 claims, Plaintiffs’ pleadings, on the whole, extensively allege facts and legal authority supportive of their respective field preemption claims. [*See, e.g.*, AbbVie Compl. ¶¶ 1, 4–6, 13, 16, 38, 42, 48–51, 109–12, 114; Pharma Compl. ¶¶ 16–19, 21, 49, 104, 105–13.] Plaintiffs’ allegations of field preemption, taken as true, are plausible enough to survive a motion to dismiss. Based on the foregoing, the State’s Motions to Dismiss are DENIED as to Plaintiffs’ respective Count 1 field preemption claims.

2. *Conflict Preemption*

Alternatively, Plaintiffs allege that Act 143 is conflict preempted. Under established principles of conflict preemption, “state laws are preempted when they conflict with federal law.” *Arizona*, 567 U.S. at 399 (citation omitted). Conflict preemption applies “where ‘compliance with both federal and state regulation is a physical impossibility,’ . . . and those instances where the challenged state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Id.* (citations omitted). The United States Supreme Court (“Supreme Court”) has repeatedly emphasized that “[i]n preemption analysis, courts should assume that ‘the historic police powers of the States’ are not superseded ‘unless that was the clear and manifest purpose of Congress.’” *Id.* at 400 (first quoting *Rice*, 331 U.S. at 230; and then citing *Wyeth v. Levine*, 555 U.S. 555, 556 (2009)).

In Plaintiffs’ respective Count 1 claims, they assert that Act 143 is conflict preempted because Act 143 “disregards and conflicts with careful limitations in the” Section 340B Program. [See Pharma Compl. ¶ 124.] AbbVie alleges that Act 143 directly conflicts with the Section 340B Program by “expand[ing] the number of entities entitled to receive 340B-discounted prices”; “forc[ing] manufacturers to transfer their drugs to third parties . . . who are not covered entities”; “install[ing] a parallel enforcement regime” which “grant[s] enforcement authority to a state official”; granting covered entities the right to bring a civil action to enjoin violations of Act 143; and installing “an alternative compliance and enforcement regime, with different regulators and distinct penalties.” [See AbbVie Compl. ¶¶ 139, 143–45.] In so arguing, AbbVie alleges that “Act 143 does not merely interact with the 340B statute—it imposes new obligations that conflict with the structure Congress created,” and in doing so, “tears through the fabric of the federal scheme Congress designed to be uniform, voluntary, and within the exclusive federal enforcement authority of HHS.” [Id. at ¶ 148.] Pharma raises largely the same arguments in support of its conflict preemption claim. [See Pharma Compl. ¶¶ 123–39.]

The State argues, among other things, that Plaintiffs’ respective conflict preemption claims should be dismissed because Act 143 does not stand as an obstacle to compliance with the Section 340B Program. [See MTD AbbVie Compl., ECF No. 25 at PageID.865–68; MTD Pharma Compl., ECF No. 48 at PageID.1490–96.] Specifically, the State contends that Act 143 does not pose a risk of competing enforcement regimes because compliance with Act 143 concerns compliance with delivery alone, an area not governed by the Section 340B Program. [See MTD Pharma Compl., ECF No. 48 at PageID.1490.] The State maintains that the only impediment to Plaintiffs’ compliance with both the Section 340B Program and Act 143 is Plaintiffs’ own financial interests, which is not a legally cognizable basis

for relief under the Supremacy Clause. [See MTD AbbVie Compl., ECF No. 25 at PageID.865–66.]

Here, Plaintiffs allege that Act 143 directly conflicts with the Section 340B Program in several respects. Once again, outside of their respective Count 1 claims, Plaintiffs’ pleadings allege sufficiently detailed facts and legal authority to support their conflict preemption claims. [See, e.g., AbbVie Compl. ¶¶ 1, 4–6, 13–16, 38, 42, 48–51, 109–12, 114; Pharma Compl. ¶¶ 4, 10–11, 15–17, 40, 88–97, 105–13.] Plaintiffs’ allegations of conflict preemption, taken as true, are plausible enough to survive a motion to dismiss. Based on the foregoing, the State’s Motions to Dismiss are DENIED as to Plaintiffs’ respective Count 1 conflict preemption claims.

**B. Count 2: Violation of the Takings Clause Claim (AbbVie Only)**

In Count 2 of its Complaint, AbbVie alleges that Act 143 violates the Takings Clause of the United States Constitution.

The Takings Clause provides that “‘private property’ shall not ‘be taken for public use, without just compensation.’” [*Phillips v. Wash. Legal Found.*, 524 U.S. 156, 164 (1998)] (quoting U.S. Const. amend. V); see also [*Chi., Burlington & Quincy R.R. Co. v. City of Chicago*, 166 U.S. 226, 238–39 (1897)] (incorporating the Takings Clause to the States through the Fourteenth Amendment). To state a claim under the Takings Clause, a plaintiff must establish the following: (1) the plaintiff must own “private property” as contemplated under the Takings Clause; (2) that private property must be taken for “public use”; and (3) the taking entity must not have paid “just compensation” for it.

*Zeyen v. Bonneville Joint Dist.*, # 93, 114 F.4th 1129, 1139 (9th Cir. 2024). The phrase “public use” has been interpreted broadly, and requires only that the taking “serve[] a ‘public purpose,’” thereby “reflecting [the Supreme Court’s] longstanding policy of deference to legislative judgments in this field.” *Kelo v. City of New London*, 545 U.S. 469, 480 (2005). Further, the Supreme Court has expressly recognized that the Takings Clause applies equally to both personal

property and real property. *Horne v. Dep't of Agric.*, 576 U.S. 350, 357–58 (2015). Further, a taking can be either per se or regulatory, both of which entitle the property owner to just compensation. *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–49 (2021).

Because AbbVie's Count 2 claim asserts taking arguments under theories of per se taking and partial regulatory taking, the Court addresses the State's challenge to each, in turn, below.

*I. Per Se Taking*

First, AbbVie alleges that Act 143 effectuates a per se taking. “Whenever a regulation results in a physical appropriation of property, a *per se* taking has occurred[.]” *Cedar Point Nursery*, 594 U.S. at 149. “[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation. On the other hand, it is equally clear that a State may transfer property from one private party to another if future ‘use by the public’ is the purpose of the taking.” *Kelo*, 545 U.S. at 477.

AbbVie alleges that Act 143 effectuates a per se taking by, among other things, “appropriat[ing] AbbVie's property rights in its drugs for the private benefit of for-profit, commercial pharmacies” via “mandat[ing] that pharmaceutical manufacturers provide 340B-priced drugs at below-market prices, depriving them of control over their own pricing structures and revenue.” [AbbVie Compl. ¶¶ 154–55.] In doing so, Act 143 allegedly “compels sales or transfers” of its drugs at 340B-discounted prices, that would otherwise not occur. [*Id.* ¶ 155.] AbbVie maintains that in the absence of Act 143, AbbVie would condition its 340B offers on “a covered entity's acceptance of AbbVie's [limited] contract pharmacy policy,” and “if a covered entity counter-offered with a term requiring unlimited contract pharmacy access, AbbVie would

simply refuse that covered entity’s counteroffer and no sale at the 340B-discounted price would take place.” [*Id.* at ¶ 155.] According to AbbVie, “Act 143 expands the federal 340B Program requirements in a way that shifts financial burdens onto manufacturers, reducing revenue and eliminating rebate offsets, without just compensation and with no justified public use.” [*Id.* ¶ 156.]

In response, the State asserts that AbbVie’s Count 2 claim should be dismissed because (1) AbbVie’s participation in the 340B program is purely voluntary;<sup>6</sup> and (2) even if Act 143 effectuates a taking, it would not constitute a private taking because it serves a public purpose. [MTD AbbVie Compl., ECF No. 25 at PageID.869–72.]

Here, AbbVie alleges that Act 143 unconstitutionally compels sales or transfers of its 340B-discounted drugs from one private entity to another, that would otherwise not occur. [See AbbVie Compl. ¶¶ 13–15, 17–18, 47, 106–07, 116.] AbbVie further alleges that the benefits of these sales or transfers directly accrue to private, for-profit pharmacies, rather than to the public, thereby negating any purported “public purpose.” [See *id.* ¶¶ 75–84, 106–08.] Taking AbbVie’s allegations as true, the Court finds that AbbVie has sufficiently pled facts and legal authority to assert a plausible per se taking claim that survives dismissal. Based on the foregoing, the State’s Motion to Dismiss is DENIED as to AbbVie’s Count 2 per se taking claim.

## 2. *Regulatory Taking*

Second, AbbVie alleges, alternatively, that “Act 143 effectuates a partial regulatory taking.” [AbbVie Compl. ¶ 157.] The government effectuates a regulatory taking when it “goes too far” and “imposes regulations that restrict an owner’s ability to use his own

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<sup>6</sup> In support of its voluntariness argument, the State cites exclusively to the decisions of other circuit and district courts, the majority of which apply different standards of review, and none of which are binding on this Court. [See MTD AbbVie Compl., ECF No. 25 at PageID.869–72.]

property.” *Cedar Point Nursery*, 594 U.S. at 148 (citations and internal quotation marks omitted). To determine whether a law effectuates a regulatory taking, courts “appl[y] the flexible test developed in [*Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978)], balancing factors such as [(1)] the economic impact of the regulation, [(2)] its interference with reasonable investment-backed expectations, and [(3)] the character of the government action.” *Cedar Point Nursery*, 594 U.S. at 148 (citing *Penn Central*, 438 U.S. at 124)). The *Penn Central* test “necessarily entails complex factual assessments of the purposes and economic effects of government actions.” *Yee v. City of Escondido*, 503 U.S. 519, 523 (1992).

In the alternative to its per se taking claim, AbbVie alleges that Act 143 effectuates a partial regulatory taking “because it requires the physical acquisition of AbbVie’s drugs by another private party for no public purpose or use; imposes significant financial losses on AbbVie and other manufacturers; interferes with drug manufacturers’ reasonable investment backed expectations; and serves no valid government purpose because it deprives manufacturers of the full use and control of their property on a continual basis for the commercial benefit of private parties.” [AbbVie Compl. ¶ 159.] In response, the State asserts the same arguments and supporting case law as raised in its challenge to AbbVie’s per se taking claim. [See MTD AbbVie Compl., ECF No. 25 at PageID.869–72.]

Here, while AbbVie has not specified in its Count 2 claim the specific facts to illustrate the elements of a regulatory taking under the *Penn Central* test, the pleadings nonetheless contain sufficient alleged facts to support AbbVie’s regulatory taking claim at this stage. [See AbbVie Compl. ¶¶ 13–15, 17–18, 47, 71–84, 106–08, 116.] Taking AbbVie’s allegations as true, the Court finds that AbbVie has sufficiently pled a plausible regulatory taking

claim to survive dismissal at this stage in the litigation. Based on the foregoing, the State’s Motion to Dismiss is DENIED as to AbbVie’s Count 2 regulatory taking claim.

**C. Count 3: Dormant Commerce Clause Claim (AbbVie Only)**

In Count 3 of its Complaint, AbbVie alleges that Act 143 violates the dormant Commerce Clause. The Commerce Clause empowers Congress “[t]o regulate Commerce . . . among the several States.” U.S. Const. art. I, § 8, cl. 3. “From this affirmative grant of authority to Congress, the Supreme Court has inferred a limitation on the states,” which “has come to be known as the dormant Commerce Clause.” *Flynt v. Bonta*, 131 F.4th 918, 923 (9th Cir. 2025) (citation omitted). The dormant Commerce Clause “denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.” *Or. Waste Sys., Inc. v. Dep’t of Env’t Quality of the State of Or.*, 511 U.S. 93, 98 (1994) (citations omitted). “In recent years, three key strands of dormant Commerce Clause jurisprudence have emerged that are relevant to this case.” *Flynt*, 131 F.4th at 923. Under this modern jurisprudence, 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. *See id.* at 923–25 (citations omitted).

AbbVie’s Count 3 claim alleges that Act 143 violates the dormant Commerce Clause under each of the three theories identified above. Thus, for clarity purposes, this Court addresses the State’s challenge to each theory, in turn, below.

*1. Discrimination against interstate commerce*

First, AbbVie alleges that Act 143 discriminates against interstate commerce. This line of dormant commerce clause jurisprudence “prohibits the enforcement of state laws ‘driven by . . . ‘economic protectionism—that is, regulatory measures designed to benefit in-state

economic interests by burdening out-of-state competitors.’” *Nat’l Pork Producers Council v. Ross*, 598 U.S. 356, 369 (2023) (quoting *Dep’t of Revenue of Ky. v. Davis*, 553 U.S. 328, 337–38 (2008)). “State laws that discriminate against interstate commerce face ‘a virtually *per se* rule of invalidity.’” *South Dakota v. Wayfair, Inc.*, 585 U.S. 162, 173 (2018) (quoting *Granholm v. Heald*, 544 U.S. 460, 476 (2005)). Accordingly, “if a state law discriminates against out-of-state goods or nonresident economic actors, the law can be sustained only on a showing that it is narrowly tailored to advance a legitimate local purpose.” *Tenn. Wine & Spirits Retailers Ass’n v. Thomas*, 588 U.S. 504, 518 (1995) (citations and internal quotation marks omitted).

AbbVie alleges that “Act 143 discriminates against interstate commerce in favor of in-state commerce” by forcing out-of-state drug manufacturers to provide 340B-discounted drugs to in-state covered entities and pharmacies, that they would not otherwise be entitled to receive. [AbbVie Compl. ¶ 165.] AbbVie alleges that, in doing so, Hawai‘i engages in economic protectionism, by enacting Act 143 and leveraging the Section 340B Program to “protect[] local economic interests at the expense of interstate commerce.” [*Id.* ¶ 167.]

In response, the State argues that AbbVie “cannot plausibly argue that Act 143 discriminates against interstate commerce” because “[w]hile Act 143 may impose burdens on manufacturers such as Plaintiffs, it does so without regard to geographic location.” [MTD AbbVie Compl., ECF No. 25 at PageID.873.] While the State concedes “that there are no pharmaceutical manufacturers based in Hawaii,” it maintains that “Act 143’s restrictions are not limited to out-of-state entities.” [*Id.* at 873 n.15.] The State argues further that AbbVie “cannot attribute discriminatory intent” to Act 143 where none exists in the plain language of the statutory text, its preamble, associated legislative findings, nor testimony received. [*See id.* at 873–74.]

Here, AbbVie alleges that the enactment of Act 143 is driven by economic protectionism, via the statute's discriminatory effect against out-of-state drug manufacturers, for the financial benefit of in-state covered entities and pharmacies. [See AbbVie Compl. ¶¶ 19, 165–67.] Taking AbbVie's allegations as true, the Court finds that AbbVie's pleadings are plausible enough to survive dismissal at this stage. Accordingly, the State's Motion to Dismiss is DENIED as to AbbVie's Count 3 discrimination against interstate commerce claim.

2. *Extraterritorial control on interstate commerce*

Second, AbbVie alleges that Act 143 effects extraterritorial control on interstate commerce. This line of dormant Commerce Clause jurisprudence “concerns state laws that operate extraterritorially beyond the state's borders.” *Flynt*, 131 F.4th at 924. The Supreme Court has recently rejected an “almost *per se* rule forbidding enforcement of state laws that have the practical effect of controlling commerce outside the State, even when those laws do not purposely discriminate against out-of-state economic interests.” *Nat'l Pork Producers Council*, 598 U.S. at 371 (internal quotation marks omitted). Instead, the Supreme Court has clarified that while “many (maybe most) state laws have the ‘practical effect of controlling’ extraterritorial behavior,” without the existence of economic protectionism (*i.e.*, an impermissible discriminatory purpose), the nearly inevitable extraterritorial effects that state laws produce do not deem them automatically violative of the dormant Commerce Clause. *Id.* at 374; *see Flynt*, 131 F.4th at 929. As the Ninth Circuit has observed, the Supreme Court nevertheless “left open the possibility that ‘a law that *directly* regulated out-of-state transactions by those with no connection to the State’ could violate the dormant Commerce Clause or some other constitutional limitation.” *Flynt*, 131 F.4th at 924 (quoting *Nat'l Pork Producers Council*, 598 U.S. at 375–76 & n.1)).

AbbVie alleges that Act 143 “has the practical effect of extraterritorial control on interstate commerce.” [AbbVie Compl. ¶ 168.] AbbVie primarily alleges that, as written, Act 143’s broad statutory definitions of the terms “manufacturer”<sup>7</sup> and “pharmacy”<sup>8</sup>; and lack of any geographic limitations in its statutory text, indicate that Act 143’s prohibition extends to *any* manufacturer or contract pharmacy across the country, irrespective of geographical location or direct link to Hawai‘i. [*Id.* ¶¶ 169–70.] In further support of its extraterritoriality argument, AbbVie alleges that “[c]overed entities often enter contract pharmacy arrangements with pharmacies located outside the state,” “with some covered entities contracting with pharmacies as far as *4,540 miles away* in Florida.” [*Id.* ¶¶ 168, 80.] According to AbbVie, in light of the statute’s lack of geographic limitations, Act 143 authorizes the Attorney General “to regulate out-of-state manufacturers that conduct minimal to no business within the state” and “also empowers out-of-state covered entities to file civil actions against out-of-state pharmaceutical manufacturers for alleged violations of Act 143.” [*Id.* at ¶ 169.] Based on the foregoing, AbbVie maintains that “under Act 143, Hawai‘i is still attempting to regulate manufacturers’ nationwide practices and impose restrictions on their national supply chains.” [*Id.* at ¶ 171.]

In response, the State argues that AbbVie’s claim should be dismissed because there is a presumption against extraterritoriality when interpreting state statutes. [MTD AbbVie Compl., ECF No. 25 at PageID.874.] In so arguing, the State implores this Court to apply this presumption—purportedly recognized by the Hawai‘i Supreme Court in *Chun v. Bd. of Land &*

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<sup>7</sup> Act 143 defines “manufacturer” as “anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug.” HRS § 328-112; *see* HRS § 481N-1.

<sup>8</sup> Act 143 defines “pharmacy,” in relevant part, as “every store, shop, or place . . . [w]here prescription drugs are dispensed or sold at retail, or displayed for sale at retail.” HRS § 461-1; *see* HRS § 481N-1.]

*Nat. Res.*, No. SCAP-19-0000501, 2022 WL 3274268, at \*8, n.13 (Haw. Aug. 11, 2022) (mem. op.)—in interpreting Act 143, in order to (1) avoid absurdity, and (2) give effect to the Legislature’s purpose, as evidenced in Act 143’s preamble. [See *id.* at PageID.874–75.] The State maintains that AbbVie “cannot overcome this presumption against extraterritoriality under Hawaii law,” such that, their claim necessarily fails as a matter of law.

Here, AbbVie alleges that in addition to Act 143 being driven by economic protectionism, the statute also has the practical effect of extraterritorial control on interstate commerce due to its broad statutory language, lack of geographic limitations, and the existence of contract pharmacy arrangements that extend between Hawai‘i and the continental United States. [See AbbVie Compl. ¶¶ 168–71, 80.] Again, taking AbbVie’s allegations as true, the Court finds that AbbVie has sufficiently pled a plausible extraterritoriality claim to survive dismissal at this stage. Based on the foregoing, the State’s Motion to Dismiss is DENIED as to AbbVie’s Count 3 extraterritoriality claim.

### 3. *Burdens on interstate commerce*

Third, AbbVie alleges that Act 143 unduly burdens interstate commerce. This line of dormant Commerce Clause jurisprudence involves what has been dubbed “*Pike* balancing.” *Flynt*, 131 F.4th at 925 (citation omitted); see *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970). “Under *Pike*, plaintiffs must first show that the challenged laws impose a ‘substantial burden on interstate commerce’; if so, we determine whether that burden is ‘clearly excessive’ in relation to the law’s putative local benefits.” *Flynt*, 131 F.4th at 931 (citation omitted). The Supreme Court “recently reemphasized that the *Pike* line of cases can largely be justified under the dormant Commerce Clause’s core anti-discrimination principle.” *Id.* at 931–32 (citing *Nat’l Pork Producers Council*, 598 U.S. at 377–78). However, even in cases “[a]bsent discrimination that

favors in-state economic interests, state laws can create a substantial burden against interstate commerce based on ‘inconsistent regulation of activities that are inherently national or require a uniform system of regulation.’” *Id.* at 932 (quoting *Ass’n des Eleveurs de Canards et d’Oies du Quebec v. Harris (Eleveurs)*, 729 F.3d 937, 952 (9th Cir. 2013)). Such cases are, however, less typical. *See Eleveurs*, 729 F.3d at 952 (citation omitted).

AbbVie appears to allege a combination of discrimination and inconsistent regulation arguments in support of its *Pike* claim. First, AbbVie alleges that Act 143 “imposes a burden on interstate commerce that outweighs any conceivable benefit to in-state commerce” by “plac[ing] an improper thumb on the scale [that] tilts the bargaining power in favor of in-state pharmacies and covered entities at the expense of out-of-state manufacturers.” [AbbVie Compl. ¶¶ 172–73.] According to AbbVie, Act 143 places a “very high burden on the 340B Program and the national prescription drug industry” by “effectively compel[ling] manufacturers to sell discounted drugs nationwide based on Hawaii’s mandates, imposing an extraterritorial burden.” [*Id.* ¶ 175.] Second, AbbVie alleges that Act 143’s “regulation of interstate commerce subjects AbbVie to inconsistent legislation across the county.” [*Id.* ¶ 176.] AbbVie maintains that even if Act 143 was enacted for the non-discriminatory purpose of helping “ensure 340B-eligible patients receive discounts on their prescription medications, [it] will actually have the opposite effect” because it will result in abuses of the Section 340B Program. [*Id.* ¶ 177.]

In response, the State recants largely the same arguments raised in the preceding section—again, urging this Court to apply the purported presumption against extraterritoriality to construe Act 143. [*See* MTD AbbVie Compl., ECF No. 25 at PageID.876–77.]

Based on the foregoing, while the Court acknowledges that AbbVie faces a heavy burden in succeeding on its *Pike* balancing claim, the Court nonetheless finds that AbbVie has

alleged sufficient facts and legal authority in its pleadings to support a plausible claim, capable of surviving dismissal at this stage in the litigation. Accordingly, the State's Motion to Dismiss is DENIED as to AbbVie's Count 3 *Pike* claim.

**D. Count 4: Due Process/Unconstitutional Vagueness Claim (AbbVie Only)**

In Count 4 of its Complaint, AbbVie alleges that Act 143 is unconstitutionally vague. The Due Process Clause of the Fourteenth Amendment provides that “[n]o State shall . . . deprive any person of life, liberty, or property, without due process of law.” U.S. Const. amend. XIV, § 1. A law is unconstitutionally vague when it “fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement.” *United States v. Williams*, 553 U.S. 285, 304 (2008). “[T]he void-for-vagueness doctrine addresses at least two connected but discrete due process concerns: first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way.” *Fed. Comm’n Comm’n v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (citation omitted).

Further, “[t]he degree of vagueness that the Constitution tolerates—as well as the relative importance of fair notice and fair enforcement—depends in part on the nature of the enactment.” *Vill. of Hoffman Ests. v. Flipside, Hoffman Ests., Inc.*, 455 U.S. 489, 498 (1982). Accordingly, “economic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action.” *Id.* (citations and footnote omitted). The Supreme Court “has also expressed greater tolerance of enactments with civil rather than criminal penalties because the consequences of imprecision are

qualitatively less severe,” though “has recognized that a scienter requirement may mitigate a law’s vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed.” *Id.* at 498–99 (citations omitted).

In Count 4 of its Complaint, AbbVie alleges that Act 143 is unconstitutionally vague, in part, because its definition of “340B drug” conflicts with the statute’s prohibition on a manufacturer’s ability to “deny, restrict, or prohibit, either indirectly 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.” HRS § 481N-2. [See AbbVie Compl. ¶ 183.] Act 143 defines “340B drug” as “a prescription drug that is purchased by a 340B covered entity through the federal 340B drug pricing program authorized by title 42 United States Code section 256b (section 340B of the Public Health Service Act) and is dispensed by a pharmacy.” HRS § 481N-1. AbbVie argues that “Act 143 provides no notice . . . as to what conduct the law proscribes, because the definition of ‘340B drug’ requires that it ‘is dispensed by a pharmacy,’ which would necessarily take place *after* acquisition, shipping, or delivery.” [AbbVie Compl. ¶ 183.] AbbVie further alleges that because “[c]ontract pharmacies maintain a single, commingled inventory, and use post-dispensing algorithms” that are unknown to manufacturers, “manufacturers have no way to know whether a dispensed drug qualifies as a ‘340B drug’ under the statute, creating unacceptable ambiguity when compliance is required.” [*Id.* ¶ 184.] AbbVie also alleges that Act 143 does not require a scienter requirement, “rais[ing] the possibility of liability for accidental or unintended conduct.” [*Id.* ¶ 185.] AbbVie alleges that, based on the foregoing, Act 143 “does not provide fair notice of the prohibited conduct, and it invites arbitrary and discriminatory enforcement by hinging compliance on unknowable facts.” [*Id.* ¶ 186.]

The State argues, among other things, that AbbVie’s Count 4 claim must be dismissed because under the less stringent vagueness standard applicable to economic regulations, “Plaintiffs have a reasonable opportunity to understand how to comply with the law,” and regardless, “fail to demonstrate how Act 143 would be arbitrarily or discriminatorily enforced” against them. [See MTD AbbVie Compl., ECF No. 25 at PageID.879.] According to the State, “Act 143 was enacted to prevent Plaintiffs from limiting the number of eligible contract pharmacies, so Plaintiffs only need to accept orders from covered entities to comply. The after-the-fact reconciliation of the number of drugs does not alter Plaintiffs’ ability to comply.” [*Id.* at PageID.878.]

The Court finds that, as pled, AbbVie has failed to plausibly allege that Act 143 is unconstitutionally vague. AbbVie does not appear to contest that Act 143 constitutes an economic regulation that imposes civil penalties, remedies, and enforcement, such that, the less strict vagueness test applies to its review. *See Vill. of Hoffman Ests.*, 455 U.S. at 498–99. [See AbbVie Opp., ECF No. 53 at PageID.1689–90.] Based on the pleadings, AbbVie is cognizant of the simplicity of Act 143’s general prohibition: drug manufacturers are prohibited from limiting the number of pharmacies that covered entities may contract with to dispense 340B-discounted drugs. It follows that compliance with Act 143’s general prohibition is just as simple. AbbVie fails to demonstrate how the inclusion of “is dispensed by a pharmacy” language in the statutory definition of “340B drug” either unconstitutionally clouds the statute’s otherwise clear prohibition, or would result in discriminatory enforcement. HRS § 481N-1.

Further, as AbbVie is all too aware, mechanisms exist in the Section 340B Program for drug manufacturers to protect against abuse (*e.g.*, diversion and/or double-discounting) [see AbbVie Compl. ¶ 49], for example, “[i]f Plaintiffs believe that excess 340B

drugs were ordered and wish to dispute the number of eligible 340B drugs, they can exercise their audit and dispute resolution rights under the 340B program.” [MTD AbbVie Compl., ECF No. 25 at PageID.878.] These existing transparency and dispute resolution mechanisms make the allegedly “unknown facts” that AbbVie expresses concern about, knowable.

Based on the foregoing, the State’s Motion to Dismiss is GRANTED as to AbbVie’s Count 4 due process/unconstitutional vagueness claim. Further, based on the nature of AbbVie’s allegations, the Court finds that AbbVie cannot cure the stated deficiencies by alleging additional facts, such that leave to amend would be futile. Accordingly, this Court denies leave to amend AbbVie’s Count 4 claim.

#### **IV. CONCLUSION**

While the Court has found that Plaintiffs have stated sufficient allegations for a majority of their claims to survive the pleading stage, the State may ultimately prove that Plaintiffs’ allegations are false. Nonetheless, at this threshold stage, this Court must accept all well-pleaded factual allegations as true and construe them in the light most favorable to Plaintiffs. *See Cahill v. Liberty Mut. Ins. Co.*, 80 F.3d 336, 337–38 (9th Cir. 1996) (citation omitted) (“All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party.”); *see also Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974) (a well-pleaded complaint may proceed even if it appears “that a recovery is very remote and unlikely”).

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For the reasons stated herein, the State's Motions to Dismiss are GRANTED IN PART and DENIED IN PART.

IT IS SO ORDERED.

DATED: Honolulu, Hawai'i, February 18, 2026.



*Shanlyn A.S. Park*

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Shanlyn A.S. Park  
United States District Judge

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*AbbVie Inc., et al vs. Anne E. Lopez in her Official Capacity as Attorney General of the State of Hawai'i, and Pharmaceutical Research and Manufacturers of America vs. Anne E. Lopez in her Official Capacity as Attorney General of Hawai'i; CIV. NOS. 25-00230-SASP-WRP and 25-00292 SASP-WRP (Consolidated); ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTIONS TO DISMISS*