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United States District Court, D. Utah.

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.
Derek BROWN, in his official capacity as Attorney General of the State of Utah; and Jon Pike, in his official capacity as Insurance Commissioner of the State of Utah, Defendants.
Novartis Pharmaceuticals Corporation, Plaintiff,
v.
Derek Brown, in his official capacity as Attorney General of Utah; and Jon Pike, in his official capacity as Utah Insurance Commissioner, Defendants.
Pharmaceutical Research and Manufacturers of America, Plaintiff,
v.
Derek Brown, in his official capacity; and Jon Pike, in his official capacity, Defendants.

Case No. 2:25-cv-00271-RJS-DAO, Case No. 2:25-cv-00284-RJS-DAO, Case No. 2:25-cv-00308-RJS-DAO
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Signed November 19, 2025

Attorneys and Law Firms

Devin Anderson, Michael S. Lehr, Kirkland & Ellis LLP, Salt Lake City, UT, Matthew S. Owen, Pro Hac Vice, Meredith M. Pohl, Pro Hac Vice, Neil A. Joseph, Pro Hac Vice, Riley Satterwhite, Pro Hac Vice, Kirkland & Ellis LLP, Washington, DC, Tess Hand-Bender, Pro Hac Vice, Theresa Wardon Benz, Pro Hac Vice, Lamont Larsen, Davis Graham & Stubbs LLP, Denver, CO, for Plaintiff AbbVie, Allergan, Durata Therapeutics, AbbVie Products, Pharmacyclics, Allergan Sales in No. 2:25-cv-00271.

Carissa A. Uresk, David C. Reymann, Robert S. Clark, Kade N. Olsen, Parr Brown Gee & Loveless, Salt Lake City, UT, Tammy Frisby, Quinn Emanuel Urquhart & Sullivan LLP, Salt Lake City, UT, Alexander V. Sverdlov, Pro Hac Vice, Jacob T. Young, Pro Hac Vice, Jessica L. Ellsworth, Pro Hac Vice, Marlan J. Golden, Pro Hac Vice, Susan Cook, Pro Hac Vice, Hogan Lovells U.S. LLP, Washington, DC, for Plaintiff Novartis Pharmaceuticals Corporation in No. 2:25-cv-00284.

Peter C. Schofield, Allen Gardner, Kirton McConkie, Thanksgiving Park Four, Lehi, UT, Abid R. Qureshi, Pro Hac Vice, Andrew D. Prins, Pro Hac Vice, Philip J. Perry, Pro Hac Vice, Latham & Watkins LLP, Washington, DC, Christopher M. Sanders, Kirton McConkie, Salt Lake City, UT, for Plaintiff Pharmaceutical Research and Manufacturers of America in No. 2:25-cv-00308.

David N. Wolf, Lance F. Sorenson, Jason N. DuPree, Office of the Attorney General, Salt Lake City, UT, for Defendants.

Austin B. Egan, Stavros Law PC, Sandy, UT, Margaet M. Dotzel, Pro Hac Vice, Courtney Christensen, Pro Hac Vice, William B. Schultz, Pro Hac Vice, Alyssa Howard, Pro Hac Vice, Zucerkman Spaeder LLP, Washington, DC, for Amici American Hospital Association, 340B Health, Utah Hospital Association, American Society of Health System Pharmacists.

Austin B. Egan, Stavros Law PC, Sandy, UT, Christopher A. Langston, Colby Tinney, J. Ryan Mitchell, Mitchell Barlow & Mansfield PC, Salt Lake City, UT, Madelaine M. Cleghorn, Pro Hac Vice, Stephen M. Kuperberg, Pro Hac Vice, Feldesman Leifer LLP, Washington, DC, for Amicus Association for Utah Community Health.

MEMORANDUM DECISION AND ORDER

ROBERT J. SHELBY, United States District Judge

***1** In 1992, Congress enacted the 340B Program, a drug-pricing scheme designed to better serve vulnerable populations and enable certain providers to maximize their resources.[1] In recent years, states across the country have enacted legislation to augment the 340B Program.[2] In 2025, Utah followed suit in enacting S.B. 69,[3] and four pharmaceutical companies have initiated litigation in this court asserting the law is unconstitutional.[4]

Now before the court are Defendants Derek Brown and John Pike's Motions to Dismiss three of those four cases.[5] Plaintiffs in the three cases addressed by this Memorandum Decision and Order advance substantially the same or

overlapping claims. Additionally, the parties argued the Motions together before the court.[6] For judicial efficiency, the court considers the Motions together. Except where specified, the court refers to all Plaintiffs collectively as "AbbVie." For the reasons stated below, the court GRANTS IN PART Defendants' Motions to Dismiss in the AbbVie and Pharmaceutical Research and Manufacturers of America (PhRMa) cases and DENIES Defendants' Motion to Dismiss the Novartis case.

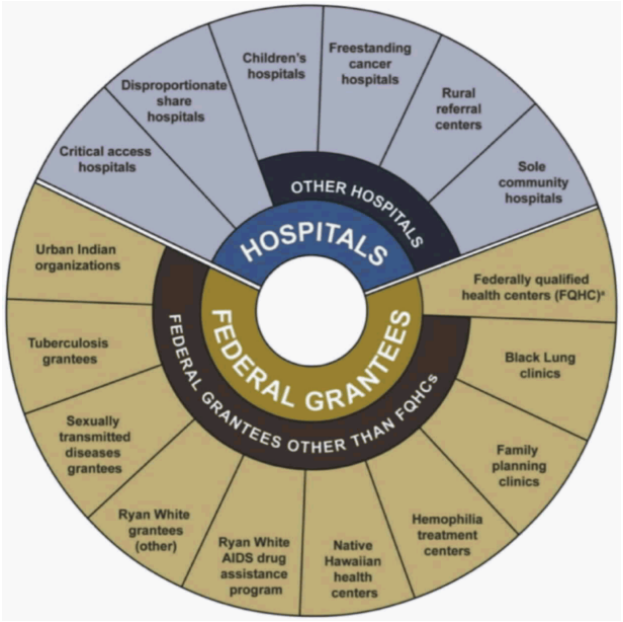
FACTUAL BACKGROUND[7]

A. The 340B Program

***2** Prior to congressional regulation, individual pharmaceutical manufacturers provided their drugs at reduced prices to health service providers.[8] In 1990, Congress passed the Medicaid Rebate Act.[9] The Medicaid Drug Rebate Program created by the Act "achieved its objective of generating savings for the Medicaid program, the VA, Federally-funded clinics, and public hospitals," but had the unintended consequence of creating disincentives for drug manufacturers to provide discounts to health providers and thereby increasing the price of outpatient prescription drugs.[10]

In response, Congress enacted the 340B Program[11] as part of the Public Health Services Act (PHSA) to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve" by providing pharmaceutical medications at a discounted cost.[12] The 340B Program is administered by the Secretary of Health and Human Services (HHS)[13] and requires any manufacturer that participates in the Medicaid Drug Rebate Program to "offer" discounted prices on its covered outpatient drugs to eligible health centers (covered entities), "if such a drug is made available to any other purchaser at any price."[14]

***3** Covered entities are the only institutions permitted to purchase the discounted drugs through the 340B Program,[15] and the 340B statute outlines which organizations qualify as covered entities.[16] Significantly, covered entities are limited to federally-funded health centers serving native and tribal populations, community hospitals serving low-income or rural areas, and specialized clinics.[17] The Government Accountability Office has diagramed covered entities thus[18]:



The 340B Program "enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[19] For example, "[h]ospitals use 340B savings to provide ... free care for uninsured patients, offer free vaccines, provide services in mental health clinics, and implement medication management and community health programs."[20]

The 340B Program imposes three requirements on covered entities. First, covered entities are prohibited from obtaining duplicate discounts or rebates by obtaining the drugs at a reduced cost under the 340B Program and then submitting a rebate request for the same drug under the Social Security Act (double dipping).[21] Second, covered entities may not "resell or otherwise transfer" any drugs they purchased through the 340B Program to anyone who is not a patient of the entity (diversion).[22] Third, covered entities must permit HHS and manufacturers of the discounted drugs to audit the covered entities' records pertaining to 340B Program compliance upon request.[23]

The 340B Program also provides an administrative dispute resolution process (ADR) which permits covered entities to submit claims for being overcharged, and manufacturers to submit claims for violations by covered entities.[24] Manufacturers may only submit claims after conducting an audit of the relevant entity.[25] Under the ADR Audit Guidelines, any covered entity or "organization purchasing or dispensing covered drugs ... on behalf of a covered entity"

must provide auditors "access to all records necessary for identifying and determining" whether any double dipping or diversion has occurred.[26] A manufacturer may request an audit if it demonstrates "reasonable cause to believe that a violation of [the 340B Program] has occurred."[27] "Significant changes in quantities of specific drugs ordered by a covered entity and complaints from patients/other manufacturers about activities of a covered entity may be a basis for establishing reasonable cause."[28]

The 340B statute includes no references to pharmacies, nor does it include any provision authorizing commercial pharmacies to purchase 340B drugs.[29] However, because building or maintaining pharmacies is cost-prohibitive for many covered entities, some covered entities have contracted with outside pharmacies (contract pharmacies) for the distribution and dispensation of 340B drugs "since the beginning."[30] Utilizing contract pharmacies has facilitated "drug dispensation closer to where low-income patients reside."[31]

***4** In 1996, HHS issued 340B Program guidance in which it "acknowledged that section 340B 'is silent as to permissible drug distribution systems' " and stated a covered entity without an in-house pharmacy could contract with a single outside pharmacy.[32] In 2010, HHS removed the one-contract-pharmacy restriction and stated covered entities, including those with in-house pharmacies, could contract with multiple outside pharmacies.[33] HHS did not limit the number of pharmacies, but advised that "[e]ach covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services."[34]

Distribution and dispensation of 340B drugs has evolved significantly over the years. Since HHS issued the 2010 Guidelines, the use of contract pharmacies has "dramatically increased."[35] Some contract pharmacies maintain an inventory of 340B drugs and fill prescriptions using their 340B inventory.[36] Many contract pharmacies fill prescriptions using a general inventory in which the discounted and non-discounted drugs are intermingled, and then retroactively determine which prescription sales qualify for 340B discounts.[37] Once a sufficient number of eligible 340B sales have accumulated, the covered entity orders additional quantities of the relevant drugs at 340B prices to replenish the contract pharmacy's inventory.[38] This process is known as "the replenishment model."[39] "The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a dispensed drug is subject to both the 340B discount and a Medicaid Rebate claim."[40]

In response to the increased use of contract pharmacies, AbbVie and other manufacturers have themselves implemented policies restricting the number of contract pharmacies a covered entity may use.[41] For example, AbbVie does not permit the use of contract pharmacies for covered entities that maintain an in-house pharmacy and, for covered entities that do not have an in-house pharmacy, AbbVie will only "take orders for one designated contract pharmacy" located within 40 miles of the "covered entity parent site," provided the contract pharmacy submits 340B claims data.[42] Similarly, Novartis updated its contract-pharmacy policy in January 2025 adding additional restrictions.[43] Its current policy (1) will recognize contracts between contract pharmacies and 340B covered entities that do not have an in-house pharmacy only, (2) requires contract pharmacies to provide claims data as a condition for receiving 340B drugs, and (3) requires the contract pharmacy to dispense drugs to patients.[44]

B. S.B. 69

***5** In response to manufacturer limitations on the use of contract pharmacies, the Utah Legislature passed S.B. 69, which went into effect on May 7, 2025.[45] S.B. 69—codified as § 31A-46-311—provides that a manufacturer may not: (1) prohibit contracts between 340B entities and pharmacies; (2) prohibit "the acquisition, dispensing, or delivery of a 340B drug to any location authorized by a 340B entity to receive the drug"; (3) prohibit a 340B entity from receiving 340B discount pricing for a 340B drug, "including by imposing a time limitation on" replenishment or submitting 340B claims; (4) require 340B entities "to submit any claim data, utilization data, or information about a [340B] entity's contracts with a [contract pharmacy] as a condition" for the purchase or delivery of a 340B drug to a 340B entity unless required by federal law; or (5) interfere with a 340B entity and a contract pharmacy's contract or their ability to contract.[46] S.B. 69 also provides that "[nothing] in this section is to

be construed to conflict with federal law." S.B. 69, as part of Utah's Insurance Code, also subjects manufacturers to penalties for any violations, including a civil fine of $5,000 per violation and a class B misdemeanor for any intentional violation. [47]

The Utah Code specifies that the " '340B drug discount program' means the 340B drug discount program described in 42 U.S.C. Sec. 256b," the federal 340B statute. [48] However, "340B entities" are not defined as the "covered entities" under the 340B Program. As used in S.B. 69, a "340B entity" means:

(a) an entity participating in the 340B drug discount program;

(b) a pharmacy of an entity participating in the 340B drug discount program; or

(c) a pharmacy contracting with an entity participating in the 340B drug discount program to dispense drugs purchased through the 340B drug discount program. [49]

The Utah Code defines "pharmacy" as any place where:

(a) drugs are dispensed;

(b) pharmaceutical care is provided;

(c) drugs are processed or handled for eventual use by a patient; or

(d) drugs are used for the purpose of analysis or research. [50]

After Governor Cox permitted S.B. 69 to take effect, AbbVie, Novartis, PhRMa, and Astrazeneca filed suit seeking to enjoin enforcement of the law. As is relevant to this Order, AbbVie asserts four claims: (1) federal preemption under the Supremacy Clause; (2) violation of the Takings Clause; (3) violation of the Due Process Clause; and (4) violation of the Commerce Clause. [51] Novartis asserts a Supremacy Clause claim, [52] and PhRMa asserts Supremacy Clause, Commerce Clause, and Due Process Clause claims. [53] Because AbbVie's claims encompass PhRMa's and Novartis' claims, the court addresses the claims as asserted by AbbVie. However, as stated above, the court's analysis and conclusions apply to all three cases. The Motions are fully briefed and ripe for review. [54]

LEGAL STANDARD

***6** Under Rule 8 of the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." [55] A defendant may move to dismiss a complaint for failure to meet this standard. [56] To survive a motion to dismiss for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' " [57] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." [58] "Determining whether a complaint states a plausible claim for relief ... [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." [59] Additionally, "[t]he court's function on a Rule 12(b)(6) motion is not to weigh potential evidence that the parties might present at trial, but to assess whether the plaintiff's complaint alone is legally sufficient to state a claim for which relief may be granted." [60]

ANALYSIS

AbbVie's Complaint alleges S.B. 69 violates the Supremacy Clause, Takings Clause, Due Process Clause, and the Commerce Clause of the United States Constitution. [61] Specifically, AbbVie alleges S.B. 69 is preempted by a "comprehensive federal healthcare program," [62] appropriates AbbVie's property rights, [63] is unconstitutionally vague, [64] and impermissibly regulates out-of-state transactions. [65]

Defendants argue the court should dismiss AbbVie's claims on four grounds. First, Defendants contend S.B. 69 is not preempted because it regulates drug distribution, not drug pricing. [66] Second, Defendants maintain S.B. 69 does not violate the Takings Clause because AbbVie voluntarily participates in the 340B Program. [67] Third, Defendants argue the language of S.B. 69 is not unconstitutionally vague. [68] And fourth, Defendants contend S.B. 69 does not violate the Commerce Clause because the statute does not advantage Utah commercial entities at the expense of out-of-state competitors. [69] The court addresses each claim in turn and concludes AbbVie has asserted viable claims for preemption under the Supremacy Clause and violation of the Takings

Clause. The court further concludes AbbVie fails to state claims for violations of the Due Process and Commerce Clauses.

I. Plaintiffs Have Adequately Alleged S.B. 69 Violates the Supremacy Clause

The Supremacy Clause provides that the Constitution and any federal law enacted pursuant thereof "shall be the supreme Law of the Land."[70] State statutes are presumed to be constitutional,[71] but federal law may preempt them.[72] Courts assume " 'the historic police powers of the States' are not superseded 'unless that was the clear and manifest purpose of Congress.' "[73] This is especially true in "area[s] traditionally occupied by the States."[74] And "matters left unaddressed in [a federal statutory] scheme are presumably left subject to the disposition provided by state law."[75] Congress's purpose "is the ultimate touchstone" in determining preemption.[76]

***7** Preemption may be express or implied.[77] Implied preemption takes two forms: (1) field preemption, and (2) conflict preemption.[78] Plaintiffs do not allege express preemption, but they do contend S.B. 69 is both field and conflict preempted.[79] As explained below, the court concludes S.B. 69 is conflict-preempted.

A. Field Preemption

Field preemption occurs when Congress determines a field "must be regulated by its exclusive governance."[80] "The intent to displace state law altogether can be inferred from the framework of regulation so pervasive that Congress left no room for the States to supplement it."[81] AbbVie alleges S.B. 69 is field preempted because "[t]he 340B program is a comprehensive federal healthcare program," every detail of which "is determined by federal law" and "the federal statute does not authorize state regulation" regarding pricing or access to "discounted 340B prices."[82] Defendants argue the 340B Program is not so comprehensive as to be preempted. Specifically, Defendants argue 340B only regulates drug pricing and S.B. 69 regulates drug distribution—an area on which 340B is silent.[83] The court agrees with Defendants.

"Undoubtedly, every subject that merits congressional legislation is, by definition, a subject of national concern. That cannot mean, however, that every federal statute ousts all related state law."[84] Further, fields related to "state police power regulations" are construed narrowly,[85] and "[g]iven the presumption that state and local regulation related to matters of health and safety can normally coexist with federal regulations, [federal courts] will seldom infer, solely from the comprehensiveness of federal regulations, an intent to pre-empt in its entirety a field related to health and safety."[86]

***8** *Hillsborough County v. Automated Medical Laboratories, Inc.* is instructive. Automated Medical Laboratories (AML), a medical laboratory corporation, operated a blood plasma center that collected and sold plasma to pharmaceutical manufacturers.[87] As vendors of blood products, the corporation was subject to federal regulations under the PHSA.[88] The Act required vendors to "meet certain safety, purity, and potency standards," be licensed by HHS, and be subject to inspection for compliance.[89]

At HHS's designation, the Food and Drug Administration established standards for plasma collection, including donor eligibility, information licensed physicians must provide donors, and collection procedures.[90] Hillsborough County adopted two ordinances subjecting plasma centers to additional obligations, including payment of a licensing fee, disclosure of any information "deemed relevant" by the county health department, and "recordkeeping requirements beyond those contained in the federal regulations."[91] One of the ordinances restricted donors to donating at only one center.[92]

AML challenged the county ordinances under the Supremacy Clause, arguing both field and conflict preemption.[93] The Supreme Court held the ordinances were not preempted, explaining that "merely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field."[94]

Like *Hillsborough*, S.B. 69 imposes restrictions on AbbVie, but those restrictions "impos[e] further requirements in [a] field" related to health and safety—a field traditionally occupied by states.[95] S.B. 69 attempts to supplement the

340B Program by addressing an additional need identified by the Utah legislature: distribution regulations. The 340B Program regulates drug prices in three ways: (1) it requires pharmaceutical manufacturers who wish to participate in State Medicaid plans to offer covered outpatient drugs "for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price"; [96] (2) it restricts covered entities from double dipping by obtaining the drugs at a reduced price and also submitting a request for payment under Medicaid; [97] and (3) it restricts covered entities from reselling or transferring the drug to a non-patient. [98] The 340B statute is silent on any distribution requirements. [99]

***9** In contrast, S.B. 69 restricts pharmaceutical companies from imposing distribution conditions on 340B entities in exchange for obtaining drugs at the discounted 340B prices. [100] Specifically, a drug manufacturer may not: (1) restrict the number of pharmacies a 340B entity may contract with to dispense 340B drugs; [101] (2) restrict the location to which 340B drugs are dispensed or delivered; [102] (3) impose time limitations for 340B entities to replenish or submit a claim for a 340B drug; [103] or (4) restrict 340B entities' 340B drug suppliers. [104] S.B. 69 does not change or add to the pricing requirements for manufacturers under the 340B Program. For example, S.B. 69 does not address how a 340B drug price is determined, [105] change what drugs are subject to 340B pricing, [106] or impose additional requirements on manufacturers for price verification [107] or refund/rebate procedures. [108] S.B. 69 regulates matters on which the 340B Program is silent, and matters left unaddressed in a federal statutory scheme are "presumably left subject to the disposition provided by state law." [109] Accordingly, the court declines to "infer, solely from the comprehensiveness of federal regulations," [110] congressional intent to entirely preempt state regulations related to the 340B program. [111]

B. Conflict Preemption

AbbVie also argues S.B. 69 is conflict preempted. Conflict preemption occurs when "compliance with both federal and state regulations is a physical impossibility," or when "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." [112] What constitutes "a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects[.]" [113] AbbVie does not argue it is impossible to comply with both federal law and S.B. 69, but AbbVie maintains S.B. 69 obstructs Congress's intent of the 340B Program because it "expands the transactions required under the federal 340B program," "conflicts with the 340B Program's audit process," and "sets up a conflicting enforcement scheme." [114]

***10** AbbVie argues S.B. 69 "obstructs the full purpose of Congress in the 340B Program ... [by] compel[ling] manufacturers to provide discounts to certain, government-approved providers while not making the Program so onerous that it forces manufactures to withdraw." [115] Specifically, AbbVie complains that S.B. 69's allowance for unlimited contract pharmacies "impos[es] requirements on drug manufacturers that conflict with requirements of the 340B statute" and "drastically expand[s]" Plaintiffs' obligations to "provide access to 340B pricing to entities other than those explicitly enumerated by Congress." [116] The court agrees. [117]

Congress enacted the 340B Program in response to "rising drug costs on state funded Medicaid programs." [118] The Program is meant "to guarantee prescription drug discounts for medically vulnerable populations" [119] and assist covered entities in "stretch[ing] scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." [120] To that end, the 340B Program restricts covered entities to only "federally funded health centers serving native and tribal populations, community hospitals serving low-income or rural areas, and specialized clinics." [121] And only these entities may purchase covered outpatient drugs at the discounted price. [122] Further, covered entities may only sell or transfer 340B drugs to their patients. [123]

However, under S.B. 69, a "340B entity" is not equivalent to "covered entities" as defined in the 340B statute. Rather than restricting eligible entities to health centers receiving federal funds or serving vulnerable populations, S.B. 69 meaningfully expands the scope of entities entitled to 340B discounts to include "pharmac[ies] of an entity participating in the 340B drug discount program," and "pharmac[ies]

contracting with an entity participating in the 340B drug discount program to dispense drugs purchased through the 340B drug discount program." [124] This is legally significant because, under Utah law, pharmacies are not restricted to entities that distribute medications. "Pharmacies" also include any place where "pharmaceutical care is provided, drugs are processed or handled for eventual use by a patient, or drugs are used for the purpose of analysis or research." [125] Accordingly, S.B. 69 permits the sale and transfer of 340B drugs at 340B prices to entities that do not receive federal funds or serve vulnerable populations. Indeed, under S.B. 69, entities that potentially do not dispense drugs to patients *at all* may acquire 340B drugs at 340B prices. [126] This is directly contrary to the 340B Program's purpose. [127] Accordingly, AbbVie has adequately alleged that S.B. 69 violates the Supremacy Clause.

II. AbbVie Has Adequately Alleged S.B. 69 Violates the Takings Clause

***11** AbbVie also alleges S.B. 69 violates the Takings Clause. [128] "The Takings Clause of the Fifth Amendment states that private property shall not be taken for public use, without just compensation." [129] The Fourteenth Amendment extends this prohibition to the States. [130] A taking may be either per se or regulatory. [131] Whether a taking is per se or regulatory depends on if "the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner's ability to use his own property." [132] A taking may "come[ ] garbed as a regulation" by statute, but when a statute mandates the transfer of physical property "to itself or someone else," it is a per se taking. [133] If a sovereign justly compensates a party in exchange for property appropriated for public use—either by cash or some other benefit—it has not effectuated a taking. [134] Additionally, these constitutional protections "presuppose[ ] that [the property] is wanted for public use." [135] AbbVie alleges S.B. 69 effects a per se taking by mandating the physical transfer of personal property—the 340B drugs—to another private party without just compensation. [136] The court concludes AbbVie has adequately alleged a per se taking claim.

AbbVie alleges S.B. 69 effectuates a taking because it forces AbbVie to transfer its property for the benefit of private parties "without serving any valid public purpose." [137] AbbVie further alleges S.B. 69 provides for potential diversion of 340B drugs to entities that do not serve the public purpose for which the 340B Program was designed—"reduc[ing] pharmaceutical costs for safety-net medical providers and the indigent populations they serve." [138] Taken as true, these allegations are sufficient at this stage to support a takings claim under Utah law. [139] Defendants' primary argument in opposition is that AbbVie's takings claim is foreclosed because AbbVie chooses to "voluntarily participate in the 340B Program." [140]

***12** The court is not persuaded that AbbVie's voluntary participation in the 340B Program precludes such a claim. AbbVie voluntarily participates in the 340B Program in exchange for a federal benefit—its drugs are covered under the Medicaid and Medicare program. [141] However, AbbVie does not voluntarily accede to the wider parameters of S.B. 69 in exchange for some benefit. As explained above, S.B. 69 expands the entities potentially eligible for 340B prices beyond the 340B Program's covered entities, including entities that may not necessarily dispense 340B drugs. [142] Thus, S.B. 69 potentially expands the 340B Program benefits for Utah without providing any additional benefit or compensation to AbbVie. Defendants may not broaden the bargain by riding the coattails of a federal benefit.

III. AbbVie Has Failed to Allege S.B. 69 Violates the Due Process Clause

AbbVie also alleges S.B. 69 violates the Due Process Clause. Specifically, AbbVie argues the term "interfere" is unconstitutionally vague on its face and the scope of "pharmacy" is "vast and unbounded." [143] The Due Process Clause of the Fourteenth Amendment provides that no State shall "deprive any person of life, liberty, or property, without due process of law." [144] The 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. [145]

Thus, a court may find a statute unconstitutionally vague if it either "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits," or "authorizes or even encourages arbitrary and discriminatory enforcement." [146] The Due Process Clause "does not require precision," [147] and is not applied mechanically. [148] "[M]ost statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions." [149] "The degree of vagueness that the Constitution tolerates ... depends in part on the nature of the enactment" [150] and the timing of the constitutional challenge. Wider latitude for vagueness is permitted in economic regulation because "its subject matter is often more narrow" and businesses facing economic demands "can be expected to consult relevant legislation in advance of action." [151] Further, "a plaintiff can only succeed in a facial challenge by establishing ... that the law is unconstitutional in all of its applications," [152] and "federal courts are less likely to find a state statute to be unconstitutionally vague in the pre-enforcement context." [153]

***13** AbbVie alleges S.B. 69's provision stating manufacturers may not "interfere" with a contract between a pharmacy and a covered entity or the ability of pharmacies and covered entities to enter into contracts: (1) does not "provide drug manufacturers with fair notice as to what conduct is actually prohibited;" (2) does not "contain a scienter requirement;" and (3) is geographically vague. [154] Defendants maintain the term "interfere" is commonly understood in ordinary language, the scienter requirement is defined in the penalties statute, and S.B. 69 is limited to pharmacies associated with a 340B entity in Utah. [155] The court agrees with Defendants.

S.B. 69 does not define "interfere." [156] However, both Black's Law Dictionary [157] and general dictionaries [158] define the term. Further, the statute as a whole provides context. The statute is titled "Prohibited actions with respect to the 340B drug discount program," and one of its other provisions includes examples of interference. [159] Specifically, S.B. 69 prohibits a manufacturer from restricting or prohibiting contracts between pharmacies and covered entities, including by denying the pharmacy or the covered entity "access to a drug that is manufactured by the manufacturer," or by placing conditions on those contracts. [160] The court is not persuaded the term "interfere" in S.B. 69 is so vague as to require persons or entities "of common intelligence [to] guess at its meaning and differ as to its application." [161]

AbbVie also alleges the interference provision is vague because it does not "contain a scienter requirement" with respect to civil, and potentially criminal, enforcement. [162] The Supreme Court has recognized that "scienter requirements alleviate vagueness concerns." [163] This is because "the constitutionality of a vague statutory standard is closely related to whether that standard incorporates a requirement of *mens rea*." [164] It is true S.B. 69 does not include a specific scienter requirement. [165] But S.B. 69 provides for penalties through the Utah Pharmacy Benefits Act's penalties statute, [166] which *does* include a scienter requirement. Section 31A-2-308 states that only those who "intentionally" violate a Utah insurance statute are subject to a class B misdemeanor. [167] And "intentionally" is further defined by cross reference as acting "with intent or willfully with respect to the nature of his conduct or to a result of his conduct, when it is his conscious objective or desire to engage in the conduct or cause the result." [168] Thus, manufacturers would not be potentially liable for interfering "by accident" as AbbVie maintains. [169] Contrary to compounding any vagueness, S.B. 69's reference to specific scienter requirements cuts against any vagueness concerns. [170]

***14** AbbVie further contends that S.B. 69's definition of "pharmacy" is so "vast and unbounded" that it leaves manufacturers with "no way of predicting or understanding the scope of S.B. 69's prohibition on 'interference.' " [171] The court again disagrees. S.B. 69 is part of Utah's Insurance Code. The purpose of Utah's Insurance Code is, among other things, to "ensure that Utah has an adequate and healthy insurance market, characterized by competitive conditions." [172] This context "provides some boundaries" to the scope of the statute—it is limited to pharmacies that have a contractual relationship with a Utah 340B entity. [173]

Accordingly, the court concludes S.B. 69 does not violate the Due Process Clause of the Fourteenth Amendment.

IV. AbbVie Has Failed to Allege S.B. 69 Violates the Commerce Clause

AbbVie's final claim alleges S.B. 69 violates the Commerce Clause.[174] Specifically, AbbVie alleges S.B. 69 "permit[s] the Insurance Commissioner and Attorney General ... to regulate out-of-state pharmacies that conduct minimal business within [Utah]" and imposes an "excessive" burden on the drug industry while "provid[ing] no legitimate benefit to the State of Utah."[175]

The Commerce Clause confers on Congress the power "[t]o regulate Commerce with foreign Nations, and among the several states"[176] and limits "the power of the States to enact laws imposing substantial burdens on ... commerce."[177] However, the limitation on state power "is by no means absolute."[178] "States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected."[179] There is no per se rule against extraterritorial effects; the Commerce Clause prohibits discriminatory "regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors."[180]

AbbVie does not allege S.B. 69 "seeks to advantage [Utah] or disadvantage" other states. Rather, AbbVie implies S.B. 69 "directly regulate[s] out-of-state transactions by those with no connection to the State" because "S.B. 69 prohibits *any* manufacturer across the country from imposing conditions to the transactions between itself and *any* covered entity or pharmacy contracting with a covered entity across the country, regardless of whether such manufacturer or entity has any nexus to Utah."[181] The court is unpersuaded.

As explained above, S.B. 69 is limited in application to pharmacies and 340B entities in Utah. Further, Plaintiffs have not alleged any facts from which the court can infer S.B. 69 discriminates against other states.[182] For the same reasons, S.B. 69 does not subject manufacturers "across the country" doing business with any 340B entity or contract pharmacy "to enforcement actions in Utah."[183] Additionally, "the dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach, absent protectionist intent or effect."[184] In any case, S.B. 69 does not contain language indicating "it is intended to be applied extraterritorially,"[185] and the court declines to so construe it. Utah has a "well-settled presumption against extraterritorial application of statutory provisions,"[186] and "statutes should be construed to avoid constitutional questions if such a construction is fairly possible."[187] Accordingly, the court concludes Plaintiffs have failed to plausibly allege S.B. 69 runs afoul of the Commerce Clause.

CONCLUSION

***15** For the reasons stated above, Defendants' Motions to Dismiss the AbbVie[188] and PhRMa[189] cases are GRANTED IN PART and DENIED IN PART. Specifically, the court grants Defendants' Motion to Dismiss AbbVie's Due Process and Commerce Clause claims and denies the Motion with respect to AbbVie's Supremacy Clause and Takings claims. The court grants Defendants' Motion to Dismiss PhRMa's Due Process and Commerce Clause claims and denies the Motion with respect to PhRMa's Supremacy Clause claim. Defendants' Motion to Dismiss the Novartis case is DENIED.[190]

All Citations

--- F.Supp.3d ----, 2025 WL 3228898

Footnotes

1 *See* *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 146 (D.N.J. 2021), *aff'd in part, rev'd in part sub nom.*, *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Human Servs.*, 58 F.4th 696 (3d Cir. 2023).

2 *See, e.g.*, *Pharm. Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024); *AbbVie Inc. v. Skrmetti*, No. 3:25-cv-00519, 2025 WL 1805271 (M.D. Tenn. June 30, 2025); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024); *Pharm. Rsch. & Mfrs. of Am. v. Murrill*, No. 6:23-CV-00997, 2024 WL 4361597 (W.D. La. Sept. 30, 2024); *Astrazeneca Pharms. LP v. Bailey*, No. 2:24-cv-04143-MDH, 2025 WL 644285 (W.D. Mo. Feb. 27, 2025); *Pharm. Research & Mfrs. of Am. v. Morrisey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024).

3 S.B. 69 was enacted as Utah Code § 31A-46-311, *Prohibited actions with respect to the 340B drug discount program.* Because the parties discuss the law as S.B. 69, the court also refers to the law as S.B. 69 and cites to the Utah Code as enacted.

4 The fourth case, not addressed in this Order, is *Astrazeneca Pharmaceuticals LP v. Brown*, No. 2:25-cv-00411-RJS-DAO.

5 *AbbVie v. Brown*, No. 2:25-cv-00271-RJS-DAO (*AbbVie*), Dkt. 28, *Motion to Dismiss and Memorandum in Support* (*AbbVie Motion to Dismiss*); *Novartis v. Brown*, No. 2:25-cv-00284-RJS-DAO (*Novartis*), Dkt. 30, *Motion to Dismiss and Memorandum in Support* (*Novartis Motion to Dismiss*); *Pharm. Research & Mfrs. of Am. v. Pike*, No. 2:25-cv-00308-RJS-DAO (*PhRMa*), Dkt. 28, *Motion to Dismiss and Memorandum in Support* (*PhRMa Motion to Dismiss*). There is also a pending motion to dismiss in the *Astrazeneca* case, but this Order does not address that motion because the case is stayed. *See Astrazeneca*, No. 2:25-cv-411, Dkt. 24 (*Motion to Dismiss and Memorandum in Support*); Dkt. 25, *Docket Order.*

6 *See AbbVie*, No. 2:25-cv-271, Dkt. 73, *Minute Entry*; *Novartis*, No. 2:25-cv-284, Dkt. 76, *Minute Entry*; *PhRMa*, No. 2:25-cv-311, Dkt. 66, *Minute Entry.*

7 The following facts are set forth as alleged in the AbbVie, PhRMa, and Novartis Complaints and the parties' briefing, including the attached exhibits, with any factual disputes resolved in Plaintiffs' favor. *See Beedle v. Wilson*, 422 F.3d 1059, 1063 (10th Cir. 2005) ("We accept as true all well-pleaded facts, as distinguished from conclusory allegations, and view those facts in the light most favorable to the nonmoving party.") (citation modified).

8 *AbbVie*, Dkt. 2, *AbbVie Complaint* ¶ 33.

9 *Id.*

10 *See id.*; *see also Genesis Health Care, Inc. v. Becerra*, 701 F. Supp. 3d 312, 315–16 (D.S.C. 2023).

11 The 340B Program is codified at 42 U.S.C. § 256b, *Limitation on prices of drugs purchased by covered entities.*

12 *AbbVie Complaint* ¶¶ 31–32; *see also* 42 C.F.R. § 10.2 ("Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily-defined covered entities does not exceed the 340B ceiling price."); *Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,277 (Mar. 5, 2010) (*2010 Guidelines*) (explaining that "the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities"); *McClain*, 95 F.4th at 1139 ("Section 340B incentivizes pharmaceutical manufacturers to provide qualified health care providers ... with pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty level."); *Fact Sheet: The 340B Drug Pricing Program*, American Hospital Association (January 2025), https://perma.cc/5SXC-TD8Z (*AHA Fact Sheet*) ("The program allows 340B hospitals to stretch limited federal resources to reduce the

price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve.").

13 *AbbVie Motion to Dismiss* at 2; *see also* *Sanofi Aventis U.S. LLC*, 58 F.4th at 699–700.

14 *AbbVie Complaint* ¶ 34; 42 U.S.C. § 256b(a)(1).

15 *AbbVie Complaint* ¶ 34; *see also* 42 U.S.C. § 256b(1).

16 42 U.S.C. § 256b(a)(4).

17 *Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 147; *see also* 42 U.S.C. § 256b(4) (limiting "covered entity" to "one of the following").

18 GAO, Report No. 18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 8 (June 21, 2018), https://perma.cc/GV4W-X9ZH.

19 *Morrisey*, 760 F. Supp. 3d at 446 (citation modified).

20 *AHA Fact Sheet.*

21 42 U.S.C. § 256b(a)(5)(A).

22 *Id.* § 256b(a)(5)(B).

23 *Id.* § 256b(a)(5)(C); 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996).

24 42 U.S.C. § 256b(d)(3)(A).

25 *Id.* § 256b(3)(B)(iv); *see also* 42 C.F.R. § 10.21.

26 *Mfr. Audit Guidelines and Dispute Resolution Process*, 0905-ZA-19, 61 Fed. Reg. 65,406-01, 65,407 (Dec. 12, 1996).

27 *Id.* at 65,410.

28 *Id.* at 65,406.

29 *See generally*, 42 U.S.C. § 256b.

30 *McClain*, 95 F.4th at 1139 (citation modified).

31 *Id.*

32 *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 456–57 (D.C.Cir. 2024) (quoting *Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,549–50, 43,555 (Aug. 23, 1996)).

33 *Id.*; *Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services*, 75 Fed. Reg. 10,272, 10,273 (Mar. 5, 2010) (*2010 Guidelines*) ("Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts .... [The] use of a contract pharmacy is voluntary. Covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all.").

34 *2010 Guidelines*, 75 Fed. Reg. at 10,273.

35 *AbbVie Complaint* ¶ 53.

36 *Id.* ¶ 58.

37 *Id.* ¶ 60; *see also Johnson*, 102 F.4th at 457 (explaining that contract pharmacies determine which prescriptions were eligible for the 340B discount by discerning which individual customers were patients of covered entities).

38 *AbbVie Complaint* ¶ 60.

39 *Id.* ¶¶ 59–62.

40 *2010 Guidelines* at 10,273.

41 *AbbVie Complaint* ¶ 75.

42 *Id.* ¶ 77. "Claims data, as used in the administration of the 340B program, refers to prescription-level information necessary to determine whether a drug is subject to a 340B discount, a Medicaid rebate, or both, and whether the recipient is a patient of a covered entity." *Id.* n.2.

43 *Novartis*, 2:25-cv-00284-RJS-DAO, Dkt. 1, *Complaint* (*Novartis Complaint*) at 23.

44 *Id.* at 23-24.

45 *AbbVie Complaint* ¶ 94. AbbVie points out that Utah Governor Spencer Cox expressed some concern that the bill did not "exactly serve [the] intended purpose" of the 340B Program and did not pass on cost savings on to patients. *Id.* ¶ 95. However, Governor Cox allowed S.B. 69 to take effect without signing the bill. *Id.* ¶ 94.

46 Utah Code § 31A-46-311. Many other states have enacted similar laws that were subsequently challenged by drug manufacturers. *AbbVie Complaint* ¶ 133 (identifying "12 states that have passed contract pharmacy laws akin to S.B. 69"—Maryland, West Virginia, Mississippi, Minnesota, Missouri, Arkansas, Kansas, Louisiana, New Mexico, Nebraska, South Dakota, and North Dakota). Those challenges have been largely unsuccessful. *See, e.g.*, *McClain*, 95 F.4th at 1139; *Skrmetti*, 2025 WL 1805271, at *25; *Fitch*, 2024 WL 3503965, at *21; *Murrill*, 2024 WL 4361597, at *15; *Bailey*, 2025 WL 644285, at *6; *Morrisey*, 760 F. Supp. 3d at 464.

47 *See* Utah Code § 31A-46-401 ("A person that violates a provision of this chapter is subject to the penalties described in Section 31A-2-308."); *id.* § 31A-2-308(1), (9).

48 *Id.* § 31A-46-102(2).

49 *Id.* § 31A-46-102(3).

50 *Id.* § 58-17b-102(51); *id.* § 31A-46-102(19) (" 'Pharmacy' means the same as that term is defined in Section 58-17b-102.").

51 *AbbVie Complaint* ¶¶ 120–64.

52 *Novartis Complaint* ¶¶ 133–44.

53 *PhRMa*, Dkt. 2, *Complaint* (*PhRMa Complaint*) ¶¶ 119–54.

54 *AbbVie Motion to Dismiss*; *AbbVie*, Dkt. 60, *Plaintiffs' Brief in Opposition to Defendants' Motion to Dismiss* (*AbbVie Opposition*); *AbbVie*, Dkt. 53, *Defendants' Reply Memorandum in Support of Their Motion to Dismiss the Complaint Pursuant to Rule 12(b)(6)* (*AbbVie Reply*); *AbbVie*, Dkt. 59, *Brief of Amicus Curiae*

Association for Utah Community Health in Support of Defendants' Motion to Dismiss (*AbbVie Amici Curiae*); *PhRMa Motion to Dismiss*; *PhRMa*, Dkt. 60, *Plaintiff's Opposition to Defendants' Motion to Dismiss* (*PhRMa Opposition*); *PhRMa*, Dkt. 61, *Defendants' Reply Memorandum in Support of Their Motion to Dismiss the Complaint Pursuant to Rule 12(b)(6)* (*PhRMa Reply*); *Novartis Motion to Dismiss*; *Novartis*, Dkt. 66, *Plaintiff's Consolidated Reply in Support of its Motion for a Preliminary Injunction and Opposition to Defendants' Motion to Dismiss* (*Novartis Opposition*); *Novartis*, Dkt. 69, *Defendants' Overlength Reply Memorandum in Support of Their Motion to Dismiss the Complaint Pursuant to Rule 12(b)(6)* (*Novartis Reply*).

55 Fed. R. Civ. P. 8(a)(2).

56 *Id.* 12(b)(6).

57 *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).

58 *Id.* (citing *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955).

59 *Id.* at 679, 129 S.Ct. 1937.

60 *Dubbs v. Head Start, Inc.*, 336 F.3d 1194, 1201 (10th Cir. 2003) (citation omitted).

61 *AbbVie Complaint* ¶¶ 120–64.

62 *Id.* ¶¶ 120–33.

63 *Id.* ¶¶ 134–44.

64 *Id.* ¶¶ 145–53.

65 *Id.* ¶¶ 154–64.

66 *AbbVie Motion to Dismiss* at 1, 9–18.

67 *Id.* at 19–22.

68 *Id.* at 22–24.

69 *Id.* at 24–25.

70 U.S. CONST. art. VI, cl. 2; *Arizona v. United States*, 567 U.S. 387, 399, 132 S.Ct. 2492, 183 L.Ed.2d 351 (2012) ("The Supremacy Clause provides a clear rule 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.") (citation modified).

71 *Gillmor v. Thomas*, 490 F.3d 791, 798 (10th Cir. 2007) ("As a general matter, we give all statutes a presumption of constitutionality ....").

72 *See Kidneigh v. UNUM Life Ins. Co. of Am.*, 345 F.3d 1182, 1185 (10th Cir. 2003).

73 *Arizona*, 567 U.S. at 400, 132 S.Ct. 2492 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).

74 *Ramsey Winch Inc. v. Henry*, 555 F.3d 1199, 1204 (10th Cir. 2009).

75 *O'Melveny & Myers v. F.D.I.C.*, 512 U.S. 79, 85, 114 S.Ct. 2048, 129 L.Ed.2d 67 (1994).

76 *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (citation omitted). AbbVie contends the presumption against preemption does not apply because the "state law explicitly depends on a federal statute" in referencing the 340B Program. *AbbVie Opposition* at 8 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347–48, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) and *Boyle v. United Techs. Corp.*, 487 U.S. 500, 507–08, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988)). But AbbVie misapprehends the principle discussed in *Buckman* and *Boyle*. *Buckman* concluded there was no presumption against federal preemption because the state-law cause of action at issue did not concern "a field which the States ha[d] traditionally occupied." *Buckman*, 531 U.S. at 347, 121 S.Ct. 1012. Similarly, *Boyle* stands for the proposition that there is no presumption for areas "involving uniquely federal interests." *Boyle*, 487 U.S. at 504, 108 S.Ct. 2510 (citation modified). The Supreme Court has stated federal interests are those in which the Constitution clearly indicates "the supremacy of the national power" and those fields that are "intimately blended and intertwined with responsibilities of the national government." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985) (citations omitted). The cases *Boyle* cites for "uniquely federal" areas of law underscore those characteristics. *See Boyle*, 487 U.S. at 504, 108 S.Ct. 2510 (concerning the "obligations to and rights of the United States under its contracts"); *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726, 99 S.Ct. 1448, 59 L.Ed.2d 711 (1979) (concerning "the rights of the United States arising under nationwide federal programs"); *Banco Nacional de Cuba v. Sabbatino*, 376 U.S. 398, 426–27, 84 S.Ct. 923, 11 L.Ed.2d 804 (1964) (regarding international relations); *Howard v. Lyons*, 360 U.S. 593, 597, 79 S.Ct. 1331, 3 L.Ed.2d 1454 (1959) (concerning military reports to Congress); *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366–67, 63 S.Ct. 573, 87 L.Ed. 838 (1943) (concerning national currency); *D'Oench, Duhme & Co. v. FDIC*, 315 U.S. 447, 457–58, 62 S.Ct. 676, 86 L.Ed. 956 (concerning policies governing banking transactions). Because S.B. 69 does not implicate a field that involves "uniquely federal interests," the court is not persuaded that the presumption against federal preemption does not apply. *See Boyle*, 487 U.S. at 504, 108 S.Ct. 2510.

77 *US Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1324 (10th Cir. 2010) ("Congress may indicate pre-emptive intent through a statute's express language or through its structure and purpose." (quoting *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008))).

78 *Id.*

79 *AbbVie Complaint* ¶¶ 121–33.

80 *Arizona*, 567 U.S. at 399, 132 S.Ct. 2492 (citation omitted).

81 *Id.*

82 *AbbVie Complaint* ¶ 124.

83 *AbbVie Motion to Dismiss* at 1.

84 *Hillsborough*, 471 U.S. at 719, 105 S.Ct. 2371; *see also id.* at 715, 105 S.Ct. 2371 (stating there is a "presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause").

85 *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 518, 523, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992) (narrowly construing a section of the Federal Cigarette Labeling and Advertising Act and the Public Health Cigarette Smoking Act of 1969 "in light of the strong presumption against pre-emption"). *See also United States v. Texas*, 97 F.4th 268, 278 (5th Cir. 2024) ("When analyzing field preemption, the relevant field should be defined narrowly." (citation modified)); *Farina v. Nokia Inc.*, 625 F.3d 97, 121 n.25 (3d Cir. 2010) (stating "the

scope of a field deemed preempted by federal law may be narrowly defined" and "cases have used narrow conceptions of the relevant field"); *Nat'l Fed'n of the Blind v. United Airlines, Inc.*, 813 F.3d 718, 734 (9th Cir. 2016) (emphasizing "the importance of delineating the pertinent area of regulation with specificity before proceeding with the field preemption inquiry").

86 *Hillsborough*, 471 U.S. at 718, 105 S.Ct. 2371.

87 *Id.* at 709, 105 S.Ct. 2371.

88 *Id.*

89 *Id.*

90 *Id.* at 710, 105 S.Ct. 2371.

91 *Id.*

92 *Id.*

93 *Id.* at 711, 714, 105 S.Ct. 2371.

94 *Id.* at 717, 105 S.Ct. 2371; *see also* *New York State Dep't of Social Servs. v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 37 L.Ed.2d 688 (1973) ("The subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem[.]" (citation omitted)); *Decanas v. Bica*, 424 U.S. 351, 360–61, 96 S.Ct. 933, 47 L.Ed.2d 43 (1976) ("Due regard for the presuppositions of our embracing federal system, including the principle of diffusion of power not as a matter of doctrinaire localism but as a promoter of democracy, has required us not to find withdrawal from the States of power to regulate where the activity regulated was a merely peripheral concern of the federal regulation." (citation modified)).

95 *See* *Hillsborough*, 471 U.S. at 717, 105 S.Ct. 2371; *see also* *id.* at 719, 105 S.Ct. 2371 ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern." (citation omitted)).

96 42 U.S.C. § 256b(a)(1).

97 *Id.* § 256b(a)(5)(A)(i) ("A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act."); *Hern v. Beye*, 57 F.3d 906, 909 (10th Cir. 1995) ("Title XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396–1396v, establishes Medicaid ....").

98 42 U.S.C. § 256b(a)(5)(B).

99 *See generally, id.* § 256b.

100 *See generally*, Utah Code § 31A-46-311.

101 *Id.* § 31A-46-311(2)(a)(i)–(ii).

102 *Id.* § 31A-46-311(2)(a)(iii).

103 *Id.* § 31A-46-311(2)(a)(iv).

104 *Id.* § 31A-46-311(2)(b)(i).

105 *Compare* Utah Code § 31A-46-311, *with* 42 U.S.C. § 256b(a)(1), (d)(1)(B)(i).

106 *Compare* Utah Code § 31A-46-311, *with* 42 U.S.C. § 256b(a)(3).

107 *Compare* Utah Code § 31A-46-311, *with* 42 U.S.C. § 256b(d)(1)(B)(ii).

108 *Compare* Utah Code § 31A-46-311, *with* 42 U.S.C. § 256b(d)(1)(B)(ii), (iv).

109 *O'Melveny & Myers*, 512 U.S. at 85, 114 S.Ct. 2048 (citations omitted).

110 *Hillsborough*, 471 U.S. at 718, 105 S.Ct. 2371.

111 *See also Skrmetti*, 2025 WL 1805271, at *12 (concluding a similar Tennessee law regulated delivery and not pricing because "AbbVie seeks to limit the locations to which it is required to deliver 340B drugs and to impose additional requirements whenever its drugs are delivered to an outside pharmacy rather than to a covered entity. Tennessee seeks to restrict drug manufacturers' ability to impose such restrictions on delivery."); *Astrazeneca Pharms. LP*, 2025 WL 644285, at *3 ("Both the plain language of the [Missouri] statute as well as precedent within the Eighth Circuit has established that statutes akin to S.B. 751 do not directly regulate the pricing of 340B drugs as regulation of pricing is determined by the federal 340B statute. Further, S.B. 751 does not require manufacturers to give the 340B discount to contract pharmacies. As such S.B. 751 does not ... preempt federal ... laws under the Supremacy Clause."); *Murrill*, 2024 WL 4361597, at *8 ("[T]he Louisiana statute ... pertains solely to pharmaceutical companies' actions toward pharmacies who enter into contracts with covered entities under the Section 340B program. The Louisiana statute does not address the pharmaceutical companies' agreements with HHS or the pricing, diversion, or 'double dipping' restrictions addressed in the HHS' enforcement scheme. Accordingly, even if the federal statute 'occupies the field' with respect to the enforcement of the Section 340B program, Louisiana's Act 358 does not encroach on that enforcement scheme."); and *McClain*, 95 F.4th at 1142–46 (concluding a similar Arkansas law is not preempted by 340B because "[p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts," rather "[c]overed entities purchase and maintain title to the 340B-discounted drugs, while contract pharmacies dispense these drugs to covered entities' patients").

112 *AbbVie, Inc. v. Fitch*, 152 F.4th 635, 647 (5th Cir. 2025) (cleaned up).

113 *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373, 120 S.Ct. 2288, 147 L.Ed.2d 352 (2000).

114 *AbbVie Opposition* at 11.

115 *Id.* at 11–12.

116 *Id.* at 13.

117 AbbVie also argues S.B. 69 interferes with the 340B audit process and enforcement scheme. *AbbVie Opposition* at 11. Because the court concludes S.B. 69 conflicts with the objectives of the 340B Program and interferes with the execution of its full purposes, the court does not address AbbVie's audit and enforcement arguments.

118 *Morrisey*, 760 F. Supp. 3d at 446.

119 *Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 146.

120 H.R. Rep. No. 102-384, pt. 2, at 12, https://perma.cc/TR4F-S977.

121 *Sanofi-Aventis U.S., LLC*, 570 F. Supp. 3d at 147.

122 *See* 42 U.S.C. § 256b(a)(1).

123 *Id.* § 256b(a)(5)(B).

124 Utah Code § 31A-46-102(3).

125 *Id.* § 58-17b-102(51); *id.* § 31A-46-102(19) (stating " 'pharmacy' means the same as that term is defined in Section 58-17b-102").

126 *See id.* § 58-17b-102(51) (including entities that "process[ ] or handle[ ]" drugs for "eventual use" and entities where "drugs are used for the purpose of analysis or research").

127 *See 2010 Guidelines* (explaining "the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities"); *McClain*, 95 F.4th at 1139 ("Section 340B incentivizes pharmaceutical manufacturers to provide qualified health care providers ... with pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty level."); *AHA Fact Sheet* ("The program allows 340B hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve.").

128 *AbbVie Complaint* ¶¶ 134–44.

129 *Knick v. Township of Scott*, 588 U.S. 180, 184, 139 S.Ct. 2162, 204 L.Ed.2d 558 (2019) (citation modified).

130 U.S. CONST. amend. XIV, § 1 ("No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States[.]").

131 *Cedar Point Nursery v. Hassid*, 594 U.S. 139, 147–49, 141 S.Ct. 2063, 210 L.Ed.2d 369 (2021).

132 *Id.* at 149, 141 S.Ct. 2063.

133 *Id.*; *see also Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435, 102 S.Ct. 3164, 73 L.Ed.2d 868 (1982) ("Property rights in a physical thing have been described as the rights to 'possess, use and dispose of it.' " (quoting *United States v. Gen. Motors Corp.*, 323 U.S. 373, 378, 65 S.Ct. 357, 89 L.Ed. 311 (1945))); *see also Horne v. Dep't of Agric.*, 576 U.S. 350, 360, 135 S.Ct. 2419, 192 L.Ed.2d 388 (2015) ("[A] physical appropriation of property [gives] rise to a per se taking ...." (emphasis omitted)).

134 *See Blanchette v. Conn. Gen. Ins. Corps.*, 419 U.S. 102, 151, 95 S.Ct. 335, 42 L.Ed.2d 320 (1974) ("[C]onsideration other than cash—for example, any special benefits to a property owner's remaining properties—may be counted in the determination of just compensation." (citing *Bauman v. Ross*, 167 U.S. 548, 584, 17 S.Ct. 966, 42 L.Ed. 270 (1897))).

135 *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415, 43 S.Ct. 158, 67 L.Ed. 322 (1922); *see also* U.S. CONST. amend. V (stating no "private property [may] be taken *for public use*, without just compensation" (emphasis added)); *id.* amend. XIV, § 1 ("No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States[.]").

136 *AbbVie Complaint* ¶ 138–40.

137 *Id.* ¶ 15.

138 Dkt. 2, *AbbVie Complaint* ¶¶ 31–32; *see also* 42 C.F.R. § 10.2 ("Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily-defined covered entities

does not exceed the 340B ceiling price."); *2010 Guidelines* (explaining that "the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities"); *McClain*, 95 F.4th at 1139 ("Section 340B incentivizes pharmaceutical manufacturers to provide qualified health care providers ... with pricing discounts on certain drugs prescribed to individuals and families whose incomes fall below the federal poverty level."); *AHA Fact Sheet* ("The program allows 340B hospitals to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve.").

139 *Twombly*, 550 U.S. at 556, 127 S.Ct. 1955 (stating the court must accept as true all well-pleaded allegations); *see also Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974) ("When a federal court reviews the sufficiency of a complaint, before the reception of any evidence either by affidavit or admissions, its task is necessarily a limited one. The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims. Indeed it may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test.").

140 *AbbVie Motion to Dismiss*, at 1.

141 *Amgen, Inc. v. Kennedy*, No. CV 24-3571 (JEB), 2025 WL 2206948, at *1 (D.D.C. Aug. 4, 2025) ("Section 340B offers drug manufacturers a deal: in exchange for Medicaid and Medicare Part B's covering a drug, its manufacturer must sell it at a discount to 'covered entit[ies]' ....").

142 *See* Utah Code § 31A-46-311(2) (stating a drug manufacturer may not restrict or prohibit "a 340B entity from receiving 340B drug discount program pricing for a 340B drug); *id.* § 31A-46-102(3) (defining "340B entity" to include "a pharmacy of an entity participating in the 340B drug discount program" or "a pharmacy contracting with an entity participating in the 340B drug discount program"); *id.* § 58-17b-102(51) (defining "pharmacy" as including, among others places, any place where "drugs are processed or handled for eventual use by a patient" or "drugs are used for the purpose of analysis or research").

143 *AbbVie Complaint* ¶¶ 146–153.

144 U.S. CONST. amend. XIV, § 1.

145 *Wyo. Gun Owners v. Gray*, 83 F.4th 1224, 1233 (10th Cir. 2023) (citation omitted).

146 *Id.* (citation omitted). AbbVie implies that a heightened level of scrutiny apples to S.B. 69 because it imposes criminal sanctions. *AbbVie Complaint* ¶¶ 147–48. However, the requirement for greater precision applies to criminal statutes, not civil statutes. *See United States v. Lesh*, 107 F.4th 1239, 1247 (10th Cir. 2024) ("Criminal statutes must be more precise than civil statutes because the consequences of vagueness are more severe." (citation omitted)). *Lesh* does not distinguish criminal statutes and civil statutes that carry potential criminal penalties. *See id.* In any case, the void-for-vagueness doctrine for criminal statutes requires that "a person of ordinary intelligence could reasonably understand [what] conduct is prohibited." *Id.* Accordingly, the court concludes that S.B. 69 does not require "a higher level of scrutiny." *AbbVie Complaint* ¶ 147.

147 *Skrmetti*, 2025 WL 1805271, at *22 (citation omitted).

148 *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498, 102 S.Ct. 1186, 71 L.Ed.2d 362 (1982).

149 *Boyce Motor Lines v. United States*, 342 U.S. 337, 340, 72 S.Ct. 329, 96 L.Ed. 367 (1952).

150 *Village of Hoffman Estates*, 455 U.S. at 498, 102 S.Ct. 1186.

151 *Id.*

152 *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 449, 128 S.Ct. 1184, 170 L.Ed.2d 151 (2008).

153 *AbbVie v. Frey*, No. 1:25-cv-00416-JCN, 2025 WL 2813787, at *15 (D. Me. Sept. 23, 2025) (citing *Donovan v. City of Haverhill*, 311 F.3d 74, 78 (1st Cir. 2002), *and Wash. State Grange*, 552 U.S. at 450, 128 S.Ct. 1184).

154 *AbbVie Complaint* ¶¶ 149, 151–52.

155 *AbbVie Motion to Dismiss* at 22–24.

156 *See* Utah Code § 31A-46-311.

157 *Interference*, BLACK'S LAW DICTIONARY (12th ed. 2024) ("The act or process of obstructing normal operations or intervening or meddling in the affairs of others.").

158 *See interfere*, OED, Oxford University Press (2025), https://perma.cc/UCA9-7A7E; *Interfere*, Merriam-Webster Dictionary (2025), https://perma.cc/8HEG-BPX7.

159 *See, e.g.*, Utah Code § 31A-46-311(2)(a) (listing restrictions manufacturers may not impose on agreements between 340B entities and pharmacies).

160 *See, e.g.*, *id.* § 31A-46-311(2)(a)(iii)(prohibiting manufacturers from imposing delivery requirements).

161 *Kleinsmith v. Shurtleff*, 571 F.3d 1033, 1038 (10th Cir. 2009) (citation omitted); *see also Murrill*, 2024 WL 4361597, at *10 (rejecting AbbVie's argument that the word "interfere" in a Louisiana delivery statute was vague because, in context of the statute's title and text, "the term is sufficiently definite to provide notice of the conduct proscribed and to prevent arbitrary or discriminatory enforcement").

162 *AbbVie Complaint* ¶ 151.

163 *Gonzales v. Carhart*, 550 U.S. 124, 149, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007) (citations omitted).

164 *Colautti v. Franklin*, 439 U.S. 379, 395, 99 S.Ct. 675, 58 L.Ed.2d 596 (1979) (citations omitted).

165 *See generally*, Utah Code § 31A-46-311.

166 *See id.* § 31A-46-401 ("A person that violates a provision of this chapter is subject to the penalties described in Section 31A-2-308.").

167 *Id.* § 31A-2-308(9)(a).

168 *Id.* § 76-2-103.

169 *AbbVie Complaint* ¶ 151.

170 *See Gonzales*, 550 U.S. at 149, 127 S.Ct. 1610.

171 *AbbVie Complaint* ¶ 152.

172 Utah Code §§ 31A-1-102; *see also id.* 31A-1-105 (providing for a presumption of jurisdiction for "[a]ny insurer that provides coverage of a resident of this state, property located in this state, or a business activity conducted in this state").

173 *Id.*

174 *AbbVie Complaint* ¶¶ 154–64.

175 *Id.* ¶¶ 158, 164.

176 U.S. CONST. art. I, § 8, cl. 3.

177 *S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 87, 104 S.Ct. 2237, 81 L.Ed.2d 71 (1984); *see also Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27, 35, 100 S.Ct. 2009, 64 L.Ed.2d 702 (1980) ("Although the [Commerce] Clause ... speaks in terms of powers bestowed upon Congress, the Court long has recognized that it also limits the power of the States to erect barriers against interstate trade.") (citations omitted).

178 *Lewis*, 447 U.S. at 36, 100 S.Ct. 2009.

179 *Id.* (citation modified); *see also Healy v. Beer Inst., Inc.*, 491 U.S. 324, 332, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989) ("[R]egulating commerce occurring *wholly outside* [a] State's borders is invalid under the Commerce Clause.") (emphasis added).

180 *Nat'l Pork Producers Council v. Ross*, 598 U.S. 356, 369, 373–74, 143 S.Ct. 1142, 215 L.Ed.2d 336 (2023) (citation modified).

181 *AbbVie Complaint* ¶¶ 157, 159.

182 *See Iqbal*, 556 U.S. at 678, 129 S.Ct. 1937 ("To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.").

183 *AbbVie Complaint* ¶ 162.

184 *Skrmetti*, 2025 WL 1805271, at *23 (citing *Nat'l Pork Producers Council*, 598 U.S. at 373, 143 S.Ct. 1142).

185 *Id.* at *24.

186 *Nevares v. M.L.S.*, 345 P.3d 719, 725 (Utah 2015).

187 *Boos v. Barry*, 485 U.S. 312, 333, 108 S.Ct. 1157, 99 L.Ed.2d 333 (1988) (citations omitted).

188 *AbbVie v. Brown*, No. 2:25-cv-0027, Dkt. 28.

189 *Pharm. Research & Mfrs. of Am. v. Pike*, No. 2:25-cv-00308, Dkt. 28.

190 *Novartis v. Brown*, No. 2:25-cv-00284, Dkt. 30.