Association for Accessible Medicines v. Frosh et al Doc. 43

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION FOR ACCESSIBLE MEDICINES	*	
	*	
Plaintiff	*	
vs.		CIVIL ACTION NO. MJG-17-1860
	*	
FROSH, et al.	*	
Defendants		

* * * * * * * * *

MEMORANDUM AND ORDER RE: MOTION TO DISMISS AND PRELIMINARY INJUNCTION

The Court has before it Defendants' Motion to Dismiss [ECF No. 29], Plaintiff's Motion for Preliminary Injunction [ECF No. 9] and the materials submitted relating thereto. The Court has held a hearing and has had the benefit of the arguments of counsel.

I. BACKGROUND

Plaintiff Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing a number of manufacturers and distributors of generic and biosimilar medicines. AAM brings an action for declaratory and injunctive relief under the Commerce Clause and the Fourteenth Amendment Due Process Clause, pursuant to 42 U.S.C. § 1983 and § 1988,

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against Brian E. Frosh and Dennis R. Schrader in their respective capacities as Attorney General for the State of Maryland and Secretary of the Maryland Department of Health (collectively, "Defendants").

AAM challenges the constitutionality of Maryland's House Bill 631 ("HB 631"), which prohibits manufacturers and wholesale distributors from engaging in price-gouging in the sale of essential off–patent or generic drugs that are made available for sale in Maryland. § 2-802(a). AAM alleges that HB 631 violates the dormant Commerce Clause as applied to the sales of drugs between out-of-state manufacturers and out-of-state wholesale distributors. Additionally, AAM brings a facial challenge to HB 631 as impermissibly vague under the Due Process Clause of the Fourteenth Amendment.

A. History of HB 631

Defendants state that HB 631 "seeks to protect Marylanders from the imposition of unconscionable price increases for certain off-patent or generic drugs in circumstances of market failure or dysfunction." Defs.' Mot. Dismiss at 1, ECF No. 29-1. It was enacted in response to two government reports detailing price-gouging of off-patent drugs under specific market conditions. Id. at 4.

One of the reports, issued by the U.S. Senate's bipartisan

Special Committee on Aging, is entitled "Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System." Defs.' Mot. Dismiss Ex. A ("U.S. Senate Report"). This Report describes a "business model" in which some generic drug companies would choose to produce a drug serving a small market for which there was only one manufacturer, ensure the drug was the "gold standard" for the condition it treats, control access to the drug through a closed distribution system or specialty pharmacy, and engage in "price gouging," or "maximizing profits by jacking up prices as high as possible." U.S. Senate Report at 4. Illustrations provided of this "business model" included:

- Turing's increase of Daraprim (which treats the life-threatening toxoplasmosis) from $13.50 to $750.00 per pill, a more than 5000% increase,
- Retrophin's increase of Thiola (which treats a genetic kidney disease) from $1.50 to $30.00 per pill, a nearly 2000% increase,
- Valeant's increase of Cuprimine and Syphine supplies (which treat Wilson's disease) from a few hundred dollars per supply to $26,189.00 or $21,267.00 per supply, respectively, corresponding to 5,785% and 3,162% increases; and

- Rodelis's increase of 30 capsules of Seromycin (which treats a life-threatening form of multi-drug resistant tuberculosis) from $500.00 to $10,800.00, an increase of 2060%.

Id. at 4-6.

The second report, issued by the Government Accountability Office in August 2016, studied a basket of 1,441 established generic drugs and found that, during the period from 2010 to 2015, manufacturers had imposed at least one "extraordinary price increase" for 315 of those drugs.[1] Defs.' Mot. Dismiss Ex. B at 12 ("GAO Report"). Moreover, "out of the 351 extraordinary price increases, 48 were 500 percent or higher and 15 were 1,000 percent or higher." GAO Report at 14.

HB 631 was introduced in early 2017 and passed both houses of the Maryland General Assembly by large bipartisan majorities. Although it was not signed by Governor Larry Hogan, it is scheduled to go into effect on October 1, 2017.

B. Text of HB 631

Under HB 631, "[a] manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-

[1] An "extraordinary price increase" is defined as an increase of more than 100% within a one-year period. GAO Report at 45.

patent or generic drug." § 2-802(a).[2] "Price gouging" is defined as "an unconscionable increase in the price of a prescription drug." § 2-801(c). The term "[u]nconscionable increase" is defined as

> an increase in the price of a prescription drug that:
>
> (1) Is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and
>
> (2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> (i) The importance of the drug to their health; and
>
> (ii)Insufficient competition in the market for the drug.

§ 2-801(f). HB 631 contains a reporting provision that authorizes the Maryland Medical Assistance Program ("MMAP") to notify the Attorney General when there is an increase in a drug price that amounts to an increase of "50% or more in the wholesale acquisition cost of the drug" within the preceding one year, or if a 30-day supply or full course of treatment would

[2] "Essential off–patent or generic drug" is defined as any prescription drug that is (1) off-patent, (2) appears on the Model List of Essential Medicines adopted by the World Health Organization or designated by the Secretary as essential, (3) is "actively manufactured and marketed for sale in the United States by three or fewer manufacturers," and (4) is "made available for sale in the State." § 2-801(b)(1).

"cost more than $80 at the drug's wholesale acquisition cost."[3] § 2-803(a). If there is such a notification by MMAP, the Attorney General may request the manufacturer to submit a statement to the Attorney General justifying the price increase. § 2-803(b). The Attorney General also has the power to require a manufacturer or distributor to produce records relevant to determining whether a violation has occurred. § 2-803(c).

Finally, HB 631 authorizes Maryland Circuit Courts,[4] on petition of the Attorney General, to issue orders to compel the violating party to produce certain records, to restrain or enjoin a violation, to restore to any consumer money lost as a result of the violation, to require a violating party engaging in price-gouging to make the drug available at the pre-violation price for one year, and to impose a civil penalty of up to $10,000 for each violation. § 2-803(d). Except for compelling parties to produce records, the Attorney General may not bring an action without first giving the violating party an opportunity to justify the price increase. § 2-803(e). It is not a defense that the manufacturer or distributor did not deal directly with a consumer residing in Maryland. § 2-803(g).

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[3] The term "wholesale acquisition cost" is given the same meaning in HB 631 as in 42 U.S.C. § 1395w-3A. § 2-801(g).

[4] At the hearing, counsel for Defendant Frosh confirmed that Frosh's interpretation of HB 631's reference to "circuit court" is that it means "Maryland Circuit Court" only, not the courts of any other jurisdiction.

II. MOTION TO DISMISS

A. LEGAL STANDARD

A motion to dismiss filed pursuant to Rule 12(b)(6) tests the legal sufficiency of a complaint. A complaint need only contain "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the ... claim is and the grounds upon which it rests.'" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (citations omitted). When evaluating a 12(b)(6) motion to dismiss, a plaintiff's well-pleaded allegations are accepted as true and the complaint is viewed in the light most favorable to the plaintiff. However, conclusory statements or "a formulaic recitation of the elements of a cause of action will not [suffice]." Id. A complaint must allege sufficient facts "to cross 'the line between possibility and plausibility of entitlement to relief.'" Francis v. Giacomelli, 588 F.3d 186, 193 (4th Cir. 2009) (quoting Twombly, 550 U.S. at 557). Inquiry into whether a complaint states a plausible claim is "'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" Id. Thus, if "the well-pleaded facts [contained within a complaint] do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]'

– 'that the pleader is entitled to relief.'" Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).

B. DORMANT COMMERCE CLAUSE CHALLENGE

i. Legal Standard

To determine whether a state statute violates the dormant Commerce Clause, the court must conduct a two-tiered analysis. Brown–Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986); Star Scientific Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002).

Under the first tier, "[w]hen a state statute directly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out-of-state interests," the statute is generally struck down "without further inquiry." Brown–Forman, 476 U.S. at 579. Thus, for state statutes that discriminate against interstate commerce, the court applies "a virtually per se rule of invalidity." Philadelphia v. New Jersey, 437 U.S. 617, 624 (1978), see also Wyoming v. Oklahoma, 502 U.S. 437, 454–55 (1992).

When a statute does not discriminate against interstate commerce but "regulates even-handedly" and only incidentally affects interstate commerce, the court conducts a second tier analysis, involving a balancing test first articulated under Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970). Under

this balancing test, courts look to "whether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits." Brown–Forman, 476 U.S. at 579. "A 'less strict scrutiny' applies under [this] undue burden tier." Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc., 401 F.3d 560, 567 (4th Cir. 2005) (internal citations omitted).

Based on recent Supreme Court precedent, there may be an emerging "third strand" of analysis that applies to "certain price control and price affirmation laws that control 'extraterritorial' conduct – that is, conduct outside the state's borders." Energy & Env't Legal Inst. v. Epel, 793 F.3d 1169, 1172 (10th Cir. 2015), cert. denied, 136 S. Ct. 595 (2015). Three Supreme Court decisions illustrate the reasoning under this "third strand," or extraterritoriality principle: Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935), Brown-Forman, 476 U.S. 573 (1986), and Healy v. Beer Inst., Inc., 491 U.S. 324 (1989).

In Baldwin, the Supreme Court struck down a New York law that prohibited out-of-state companies from selling milk in the state unless they purchased their milk from dairy farmers at the same price paid to New York dairy farmers. The Court explained that it impermissibly established "a wage scale or a scale of prices for use in other states," and would "bar the sale of the

products, whether in the original packages or in others, unless the scale has been observed." Baldwin, 294 U.S. at 528.

In Brown–Forman, the Supreme Court struck down a provision of the New York Alcoholic Beverage Control Law that required liquor distillers or producers selling to wholesalers within the state to affirm that their prices for products sold to in-state wholesalers were no higher than the lowest price at which the same product was sold in any other state during that month. The Court found that, although the statute was addressed only to the sale of liquor in New York, it had the impermissible "practical effect" of controlling liquor prices in other states. Brown-Forman, 476 U.S. at 583.

Similarly, in Healy, the Supreme Court struck down the Connecticut Liquor Control Act, which required out-of-state beer shippers to affirm that the prices of their products sold to Connecticut wholesalers were no higher than the prices of those same products sold in bordering states. The Court reasoned that the statute tied pricing decisions to the regulatory schemes of these bordering states, thus preventing brewers from undertaking competitive pricing in other states. Healy, 491 U.S. at 338–39.

The Supreme Court and other courts have stated that this extraterritoriality principle is limited to price-control statutes or price-affirmation statutes which link prices paid in-state with those paid out-of-state. See Pharm. Research &

Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003); Energy & Env't Legal Inst., 793 F.3d at 1175 (explaining that extending the Baldwin doctrine to become a "weapon far more powerful than" the two established tiers would be a "novel lawmaking project [the court] decline[s] to take up on [its] own"); Ass'n des Eleveurs de Canards et d'Oies du Quebec v. Harris, 729 F.3d 937, 951 (9th Cir. 2013) ("[t]he Supreme Court has explained that Healy and Baldwin involved 'price control or price affirmation statutes'" and are inapplicable to a statute "that does not dictate the price of a product and does not 't[ie] the price of its in-state products to out-of-state prices.'").

In Walsh, nonresident drug manufacturers challenged a Maine statute that required certain manufacturers selling drugs in Maine to enter into a rebate agreement with the Maine State Commissioner, or else meet a set of prior authorization requirements to dispense drugs in the state. Walsh, 538 U.S. at 653-54. The Walsh plaintiff argued that "with the exception of sales to two resident distributors, all of their prescription drug sales occur outside of Maine," so the act must be impermissible extraterritorial regulation. Id. at 656. The Supreme Court disagreed, explaining that the rule articulated in Baldwin and Healy "is not applicable to this case" because the Maine Act is not a price-control or price-affirmation statute,

does not regulate prices of any out-of-state transaction, and does not tie in-state prices to out-of-state ones. Id. at 669.

The Fourth Circuit has also declined to apply the Baldwin, Brown-Forman, and Healy price-parity principle in a situation similar to the context of the instant case involving HB 631. In Star Scientific, a cigarette manufacturer challenged the constitutionality of the Master Settlement Agreement ("MSA") between the Commonwealth of Virginia and the major tobacco manufacturers, which assesses an escrow payment amount on each cigarette sold by nonparticipating tobacco manufacturers "within the Commonwealth, whether directly or through a distributor, retailer, or similar intermediary or intermediaries." Star Scientific, 278 F.3d at 354. Presenting a "third-strand" extraterritoriality argument, the Star Scientific plaintiff contended that the statute required it to "make payments on cigarettes sold by it to independent distributors in other states if the cigarettes are later sold into Virginia," and thus "regulates transactions beyond the Commonwealth's borders." Id.

The Fourth Circuit distinguished the Star Scientific statute from the laws at issue in Healy and Brown-Forman, because Virginia's Star Scientific statute expressly limited its applicability to the sale of cigarettes "within the Commonwealth." Star Scientific, 278 F.3d at 356. Moreover, the court noted that to the extent that the statute may affect the

prices charged by out-of-state distributors, the effect would be "applicable only to prices charged on cigarettes sold within Virginia." Id. Because the statute did not insist on "price parity" with the prices of cigarettes sold outside of the state, it did not have the "'practical effect' of controlling prices or transactions occurring wholly outside of the boundaries of Virginia, as was the case in Brown–Forman and Healy." Id.

ii. Application to HB 631: First Tier and Extraterritoriality

Regardless of whether these extraterritoriality cases are construed as a separate line of cases or as applications of the first tier analysis, Energy & Env't Legal Inst., 793 F.3d at 1174-75, this Court must follow Star Scientific's reasoning. Like the plaintiff in Star Scientific, AAM argues that HB 631 impermissibly regulates conduct occurring wholly outside the state, because its members are manufacturers and wholesalers of generic drugs who almost all reside outside of Maryland, operate under national contracts, and do not sell directly to actors in Maryland.[5] Pl.'s Opp. Mot. Dismiss at 21, ECF No. 36. Even if

[5] AAM's pre-implementation challenge to HB 631 under the dormant Commerce Clause only applies to sales between out-of-state manufacturers and out-of-state distributors. AAM concedes that the statute would not violate the dormant Commerce Clause as applied to manufacturers or wholesalers who sell drugs directly to a person or entity within Maryland's borders.

that characterization is correct,[6] that argument was rejected by the Fourth Circuit in Star Scientific and must be rejected here.

The structure of HB 631 is similar to the challenged statute in Star Scientific. HB 631 only regulates drug manufacturers or wholesale distributors engaging in the sale of an essential off-patent or generic drug "made available for sale in the State." § 2-801(b)(1). The Virginia statute in Star Scientific regulates tobacco product manufacturers selling cigarettes to consumers within the Commonwealth, "whether directly or through a distributor, retailer or similar intermediary or intermediaries." Va. Code Ann. § 3.2-4200. Therefore, both HB 631 and the Star Scientific statute apply only to products being made available for sale within the boundaries of the state, and both laws place liability on the out-of-state manufacturer whether or not the Maryland sale was direct or through an intermediary.

To the extent that HB 631 may affect the prices charged by out-of-state distributors or producers, the effect would be applicable only to prices charged on drugs to be sold within Maryland. As with the challenged law in Star Scientific, HB 631 does not tie the price charged on the sales of in-state drugs with the price charged on the sales of out-of-state drugs.

[6] Defendants note that almost all of AAM's members hold a Maryland wholesale distributor permit. Defs.' Suppl. Statement at 2, ECF No. 34.

Because HB 631 does not "insist on price parity" with drugs sold outside of the state, it does not have the "practical effect" of regulating commerce occurring wholly outside of the state, as was the case in Baldwin, Brown–Forman, and Healy. Star Scientific, 278 F.3d at 356.

AAM tries to distinguish Star Scientific by arguing that the punishable act in Star Scientific was refusing to pay the required escrow amount on each cigarette sold by nonparticipating tobacco manufacturers within Virginia (which is "in-state"), whereas the punishable act under HB 631 is the sale of drugs at unconscionable prices between an out-of-state manufacturer and an out-of-state distributor. Hearing Rough Tr. at 9:14-24 (Sept. 14, 2017).

AAM's comparison is inaccurate. HB 631 and the Star Scientific statute are triggered only when there is a drug or a cigarette made available for sale within the state. Whether any subsequent fine or escrow payment is made within Maryland is not relevant to the analysis. Under HB 631, a sale of drugs between an out-of-state manufacturer and an out-of-state distributor – regardless of the price - does not give rise to liability. Only if those drugs are then made available for sale in Maryland would the provisions of HB 631 apply to the transaction. Indeed, HB 631 is more limited in scope than the law in Star Scientific: whereas the Star Scientific law applied to each and

every sale of tobacco, HB 631 only applies to specific essential drugs made available in the state at an unconscionable price and under certain market conditions.

AAM also points to the language in Healy and Brown-Forman cautioning against laws that apply to commerce taking place "wholly outside" of the state's borders, or having the "practical effect" of regulating commerce occurring wholly outside that state's borders. Brown-Forman, 476 U.S. at 582; Healy at 491 U.S. at 336. However, when read within the decision as a whole, these statements were clearly made in the context of one state attempting to tie the price of a good inside the state with the price charged for the good in another state. See Brown-Forman, 476 U.S. 573 at 583 (explaining the practical effect under the New York price-affirmation statute that once a distiller's posted price "is in effect in New York, it must seek the approval of the New York State Liquor Authority" before lowering prices for the same item in other states); Healy, 491 U.S. at 332-33 ([T]he Commerce Clause does not permit a state "to establish a wage scale or a scale of prices for use in other states . . . ."), quoting Baldwin, 294 U.S. at 528.

AAM repeatedly cites these statements without adequately engaging with the fact that HB 631 could only give rise to liability when the drug is made available for sale in Maryland.

These statements from Brown-Forman, Healy, and Baldwin do not stand for the much broader proposition that a regulation that has effects outside the state is per se invalid. C.f. Energy & Env't Legal Inst., 793 F.3d at 1175 ("if any state regulation that 'control[s] . . . conduct' out of state is per se unconstitutional, wouldn't we have to strike down state health and safety regulations that require out-of-state manufacturers to alter their designs or labels?").

Moreover, the policy concerns first raised in Baldwin and reiterated in Healy and Brown-Forman clarify that price-parity or price-affirmation statutes must be treated differently because they are barriers to free trade between states. See Baldwin, 294 U.S. at 521 (these statutes "will set a barrier to traffic between one state and another as effective as if customs duties . . . had been laid upon the thing transported"); Brown-Forman, 476 U.S. at 580 ("Economic protectionism . . . may include attempts to give local consumers an advantage over consumers in other States"); Healy, 491 U.S. at 335-36 (noting the Constitution's "special concern . . . with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce"). The concerns about local price gridlock or restricted trade between states are not similarly raised with regard to HB 631, because AAM's members may still sell drugs to other states at different prices.

The activity regulated under HB 631 is not the ability of AAM members to make profits (which was the concern of the plaintiffs in Baldwin, Brown-Forman, and Healy), but the ability of AAM members to extract excessive profits by price-gouging Maryland consumers on essential drugs for which there is limited competition.[7] Under HB 631, AAM members may raise prices to make profits in other states – even to uncontrolled levels – but not for the drugs made available for sale in Maryland. AAM's concern that it faces a "Hobson's choice" in complying with this anti-price-gouging law fails to engage with this reality. Pl.'s Mot. Prelim. Inj. at 32, ECF No. 9-1.

Ultimately, AAM's concern with the law appears to rest in part on a practical problem. It argues that its members do not currently track where the drugs first sold to distributors or intermediaries are ultimately offered for sale to patients, so they do not know which of their drugs end up in Maryland. The practical effect of complying with this regulation, AAM claims, is that their members will have to "rejigger" their business practices. Pl.'s Mot. Prelim. Inj. at 35, ECF No. 9-1. Thus, AAM argues, HB 631 necessarily regulates conduct wholly outside of the state.

[7] Indeed, AAM agrees that "generic drug manufacturers are able to charge low prices for their products because of robust competition in the market." Pl.'s Mot. Prelim. Inj. at 9, ECF No. 9-1. Drugs priced in a competitive marketplace would not be subject to HB 631. § 2-801(b)(1), § 2-801(f)(2).

Because many physical consumer products must conform to differing state requirements, this argument is unpersuasive. AAM has not offered a reason for why its members – who are leading manufacturers and distributors of generic drugs in this country – could not apply a tracking system to determine which of their drugs are eventually made available for sale in Maryland. Certainly, the plaintiff in Star Scientific – a manufacturer of tobacco products - overcame this practical challenge. Star Scientific, 278 F.3d 339 at 357 (explaining that Star Scientific "overstat[ed] its burden" when arguing that because the escrow payments are imposed "on cigarettes sold not only by it, but also by its distributors, even when the distributors purchased the cigarettes outside the state," so it has to "police interstate sales or channel those sales into contractual forms that may be more burdensome to commerce").

Although AAM appears to rest its argument on the extraterritoriality principle, it also alleges that because in-state retailers are not subject to HB 631, the law discriminates against out-of-state actors in favor of in-state actors. Pl.'s Opp. Mot. Dismiss at 10, ECF No. 36. However, this comparison inappropriately compares retailers with wholesalers and distributors. That the legislature chose to regulate some actors in the drug distribution chain instead of all of them is not indicative of discriminatory activity or economic

protectionism against upstream out-of-state actors in favor of in-state retailers. Manufacturers and distributors residing within Maryland (of which there is at least one) would have to comply with the same rules as manufacturers and distributors residing outside of Maryland.[8]

AAM has not alleged a plausible dormant Commerce Clause violation under the first tier or the extraterritoriality principle, because of the Fourth Circuit's Star Scientific precedent. Hence, the dormant Commerce Clause analysis must proceed to the second tier.

iii. Application to HB 631: Second Tier Balancing

"Under the undue burden (or Pike balancing) tier, '[w]here the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.'" Yamaha Motor Corp, 401 F.3d at 567.

Defendants have explained that their legitimate interest is enforcing HB 631 to prevent price-gouging in Maryland for

[8] The parties have not argued, and the Court declines to address, the question of whether – in case discrimination was found - Defendant has met the burden to justify HB 631 "in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake." Wyoming, 502 U.S. at 456.

essential medicines and to protect the safety and health of Maryland residents. Defs.' Opp. Prelim. Inj. at 10, ECF No. 30. This interest has been reasonably illustrated in Exhibits A and B to its Motion to Dismiss and discussed herein at Section I.A. AAM, on the other hand, does not present an argument that HB 631 should be held unconstitutional under this balancing test.

Given the strength of the state's interest and the requirement that AAM must show that "the burden on interstate commerce would clearly exceed the local benefits" (emphasis added), AAM's challenge cannot succeed under this second tier test. Yamaha Motor Corp., 401 F.3d at 567.

Accordingly, because HB 631 is valid under the Star Scientific Fourth Circuit precedent, and AAM has not shown that any burden imposed by the law does not clearly exceed the local benefits to Maryland consumers, it has failed to adequately allege a plausible claim that HB 631 violates the dormant Commerce Clause.

B. DUE PROCESS VAGUENESS CHALLENGE

i. Legal Standard

A law is not void for vagueness so long as it "(1) establishes 'minimal guidelines to govern law enforcement,' and (2) gives reasonable notice of the proscribed conduct." Schleifer by Schleifer v. City of Charlottesville, 159 F.3d 843,

853 (4th Cir. 1998). See also Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Envtl. Control, 317 F.3d 357, 367 (4th Cir. 2002) ("[A] regulation is not void for vagueness unless it is so unclear with regard to what conduct is prohibited that it 'may trap the innocent by not providing fair warning,' or it is so standardless that it enables 'arbitrary and discriminatory enforcement.'").

Judges are cautioned to exercise restraint in facial vagueness challenges. Schleifer by Schleifer, 159 F.3d at 853. ("Striking down ordinances . . . as facially void for vagueness is a disfavored judicial exercise."). See also Washington State Grange v. Washington State Republican Party, 552 U.S. 442, 450 (2008) (facial challenges are disfavored because they "rest on speculation," "run contrary to the fundamental principle of judicial restraint," and "threaten to short circuit the democratic process").

The precedents do not provide a clear statement of the proper standard to apply in facial vagueness challenges. Under one formulation of the test, "the complainant must demonstrate that the law is impermissibly vague in all of its applications." Village of Hoffman Estates v. Flipside, 455 U.S. 489, 497 (1982). In other words, "the challenger must establish that no set of circumstances exists under which the Act would be valid." United States v. Salerno, 481 U.S. 739, 745 (1987).

However, in a recent decision involving a criminal statute, the Supreme Court rejected the view that "a statute is void for vagueness only if it is vague in all its applications." Johnson v. United States, 135 S. Ct. 2551, 2561 (2015). Instead, the Court explained that "our holdings squarely contradict the theory that a vague provision is constitutional merely because there is some conduct that clearly falls within the provision's grasp" (emphasis in original).[9] Id. See also United States v. Comstock, 627 F.3d 513, 518 (4th Cir. 2010) (acknowledging reservations within the Supreme Court in the years since Salerno about the stringent "no set of circumstances" test).

At the very least, it appears that a facial challenge cannot succeed if a "statute has a 'plainly legitimate sweep.'" Comstock, 627 F.3d at 518; Washington State Grange, 552 U.S. at 449 ("While some Members of the Court have criticized the Salerno formulation, all agree that a facial challenge must fail where the statute has a 'plainly legitimate sweep.'").

A statute that has a "plainly legitimate sweep" has also been described as having "more than a conceivable application." Martin v. Lloyd, 700 F.3d 132, 136-37 (4th Cir. 2012). However, concrete illustrations of what constitutes a "plainly legitimate

[9] There is good reason to question the direct applicability of this sentence in Johnson to the instant case. Due to the gravity of criminal penalties, "the [required] standard of certainty is higher" for criminal statutes than it is for civil statutes. Schleifer by Schleifer, 159 F.3d at 853.

sweep" for a non-criminal, non-First Amendment statute – such as HB 631 - are limited. In Hightower v. City of Boston, the plaintiff's facial challenge to Massachusetts's gun licensing statute failed because she did not establish that the statute lacked a "plainly legitimate sweep" of circumstances where an applicant may properly be denied a license on the grounds of unsuitability. 693 F.3d at 77-78. In its reasoning, the court pointed to at least one set of circumstances in which the suitability requirement is clearly constitutional - where false information is provided on an application form. Id. at 78.

Moreover, when considering phrases or words within a statute, those phrases or words should be considered in the context of the statute as a whole. The Real Truth About Abortion, Inc. v. Fed. Election Comm'n, 681 F.3d 544, 554 (4th Cir. 2012); Martin, 700 F.3d at 136. In doing so, a court is "not confined to the plain language of the contested statute." Martin, 700 F.3d at 136.

Finally, these standards "should not . . . be mechanically applied." Village of Hoffman Estates, 455 U.S. at 498. Rather, "[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." Id. Indeed, "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. 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." Id. at 498-99.

ii. Application to HB 631

HB 631 prohibits price gouging, which is defined as "an unconscionable increase in the price of a prescription drug." § 2-801(c). The term "[u]nconscionable increase" is defined as

> an increase in the price of a prescription drug that:
>
> (1) Is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health; and
>
> (2) Results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of:
>
> (i) The importance of the drug to their health; and
>
> (ii)Insufficient competition in the market for the drug.

§ 2-801(f). AAM argues that "HB 631 falls well short of any reasonable standard of clarity," and contends that several terms

within the statute are vague.[10] Pl.'s Mot. Prelim. Inj. at 26, ECF No. 9-1. The Court will address each in turn.

- "Unconscionable increase"

AAM argues that the definition of "unconscionable increase" is keyed on a number of "expansive adjectives," including "excessive," "justified," "appropriate," and "meaningful." Pl.'s Mot. Prelim. Inj. at 2, ECF No. 9-1. Defendants argue that "HB 631 closely tracks both the 'procedural' and 'substantive' components of the common law doctrine of unconscionability" which is "centuries-old." Defs.' Opp. Prelim. Inj. at 4, ECF No. 30.

Although the term "unconscionability" itself has been defined by judges in the contracts context, those judicial interpretations may not be directly applicable to non-contracts cases. See, e.g., Williams v. Walker-Thomas Furniture Co., 350 F.2d 445 (D.C. Cir. 1965). Ultimately, the question of whether the body of common law unconscionability doctrine is incorporated into the statute is not determinative because the term "unconscionable increase" is defined in the statute. The Court will address the sub-components of the definition.

[10] Although AAC brought an as-applied challenge to HB 631 under the dormant Commerce Clause, its challenge under the Fourteenth Amendment Due Process Clause is facial.

- "Excessive," "not justified," and "appropriate"

AAM relies on Governor Hogan's statements that the term "excessive" is at "the heart of" the law and renders it unconstitutionally vague. Pl.'s Mot. Prelim. Inj. at 3, ECF No. 9-1. AAM argues that because the statute does not define "excessive," it is not "sufficiently concrete to be cognizable absent further elaboration." Pl.'s Opp. Mot. Dismiss at 12, ECF No. 36. Defendants argue that courts have rejected vagueness challenges to civil statutes based on the imprecision of words such as "excessive," and based on "qualitative standards rooted in common law." Def. Mot. Dismiss at 32-33, ECF No. 29-1.

It is true that statutes often use broad terms, and that courts have upheld some of these statutes under a vagueness challenge. See, e.g., Grayned v. City of Rockford, 408 U.S. 104, 110 (1972) (upholding an antinoise regulation that used the phrase "tends to disturb"); United Companies Lending Corp. v. Sargeant, 20 F. Supp. 2d 192, 205 (D. Mass. 1998) (rejecting vagueness challenge where the phrase "otherwise unconscionable" was used but undefined). However, each phrase is context specific and must be examined within its own statutory framework.

Here, "excessive" is a comparative term – a price must be "excessive" in relation to a benchmark. Although HB 631's reporting provision could serve as a benchmark, it does not

appear to be binding on the Attorney General. See § 2-803(a) (allowing the MMAP to notify the Attorney General when there is, inter alia, an increase in drug price that amounts to an increase of "50% or more in the wholesale acquisition cost of the drug" within the preceding one year). Even though "excessive" is joined with another provision (i.e., "excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health . . ."") (emphasis added), AAM argues that "justified" and "appropriate" are also modifiers that cannot be readily defined absent meaningful contextual distillation. Pl.'s Mot. Prelim. Inj. at 27, ECF No. 9-1.

The Court finds that it is at the very least plausible that the combination of these broader words renders the statute unconstitutionally vague. A complaint must allege sufficient facts "to cross 'the line between possibility and plausibility of entitlement to relief.'" Francis v. Giacomelli, 588 F.3d 186, 193 (4th Cir. 2009).

- "No meaningful choice"

AAM also argues that the term "meaningful" is unconstitutionally vague. Pl.'s Mot. Prelim. Inj. at 27, ECF No. 9-1. However, in the context of the whole statute, it becomes apparent that this standard is more than sufficient.

The phrase is qualified by two sub-provisions: "(i) The importance of the drug to their health; and (ii) insufficient competition in the market for the drug" (emphasis added). AAM does not allege that either of these sub-provisions is vague.

On the current state of the record, AAM has alleged at least a plausible basis to challenge some of the HB 631 provisions discussed above as unconstitutionally vague. However, the Court finds that the parties have not presented a record adequate to enable a final decision as to the alleged vagueness of HB 631, and cannot now determine whether the statute would pass constitutional muster on a more complete record which includes evidence regarding pricing decisions made by drug manufacturers and/or distributors.[11]

It is also possible that the relevant state agencies may issue additional guidance or regulations, which this Court must then consider. Village of Hoffman Estates, 455 U.S. at 495 n.5 ("In evaluating a facial challenge to a state law, a federal court must, of course, consider any limiting construction that a state court or enforcement agency has proffered.").

The Court recognizes that there are reasonable - though not necessarily prevailing - contentions asserted by the Plaintiff. Accordingly, AAM has presented a plausible claim that HB 631 may

[11] For example, AAM contends that "[b]asic macroeconomic forces" as well as "other interconnected factors," including regulatory requirements, affect pricing decisions. Compl. ¶ 23, ECF No. 1.

be void for vagueness and shall not grant Defendants' motion seeking dismissal of the vagueness claims.

III. PRELIMINARY INJUNCTION

A. LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy, to be granted only if the moving party clearly establishes entitlement to the relief sought." Manning v. Hunt, 119 F.3d 254, 263 (4th Cir. 1997). See also MicroStrategy Inc. v. Motorola, Inc., 245 F.3d 335, 339 (4th Cir. 2001) ("preliminary injunctions are extraordinary remedies involving the exercise of very far-reaching power to be granted only sparingly and in limited circumstances.").

To obtain a preliminary injunction, the Plaintiff must make a clear showing:

1. That it will likely succeed on the merits;
2. That it is likely to suffer irreparable harm absent preliminary relief;
3. That the balance of equities tips in its favor; and
4. That an injunction is in the public interest.

Winter v. Natural Resources Defense Council, Inc., 555 U.S. 7, 20 (2008); Centro Tepeye v. Montgomery County, 722 F.3d 184, 188 (4th Cir. 2013). The plaintiff has the burden of establishing that it meets the Winter factors. Dewhurst v. Century Aluminum

Co., 649 F.3d 287, 293 (4th Cir. 2011) ("[Plaintiffs], who 'must establish' that they meet the Winter standard in order to be awarded a preliminary injunction, fail to do so.").

B. DISCUSSION

i. Likelihood of Success on the Merits

First, AAM must make a clear showing that it will likely succeed on the merits at trial. Winter, 555 U.S. at 20.

As discussed in the preceding sections, the Court does not find that AAM has shown that it is likely to prevail on the as-applied dormant Commerce Clause challenge. Moreover, the factual record at the moment does not support its likelihood of prevailing on the facial Due Process Clause challenge. Accordingly, this factor weighs in favor of denying a preliminary injunction.

ii. Likelihood of Irreparable Harm

Second, AAM must make a clear showing that it is likely to be irreparably harmed absent preliminary relief. Id.

This showing must not be speculative. The Court in Winter rejected a standard where issuing a preliminary injunction is "based only on a possibility of irreparable harm," because such standard is "inconsistent with our characterization of injunctive relief as an extraordinary remedy that may only be

awarded upon a clear showing that the plaintiff is entitled to such relief." Winter, 555 U.S. at 22.

AAM claims that its members would suffer irreparable harm for three reasons: (1) they will need to conform their conduct to the law's "sweeping terms" and face a barrage of investigations, (2) they would suffer "irreparable reputational and economic harm," and (3) the mere fact that the law violates the Constitution will subject AAM members to irreparable injury. Pl.'s Mot. Prelim. Inj. at 32-37, ECF No. 9-1.

Generally, economic harms do not by themselves constitute irreparable injury. Sampson v. Murray, 415 U.S. 61, 90 (1974) ("the temporary loss of income, ultimately to be recovered, does not usually constitute irreparable injury."). However, several circuit courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable for preliminary injunction purposes. See, e.g., Odebrecht Const., Inc. v. Sec'y, Florida Dep't of Transp., 715 F.3d 1268, 1289 (11th Cir. 2013) (noting that "numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable"); Chamber of Commerce of U.S. v. Edmondson, 594 F.3d 742, 770–71 (10th Cir. 2010) (holding that "monetary damages that cannot later be recovered for reasons such as sovereign immunity constitute irreparable injury"). But see Otsuka Pharm. Co. v.

Burwell, No. GJH-15-852, 2015 WL 1962240, at *11 (D. Md. Apr. 29, 2015) ("That Otsuka is unable to recover monetary damages from FDA or Defendant–Intervenors does not, however, automatically make its harm irreparable.").

It is possible that AAM cannot recover potential losses it would suffer from the Maryland government if HB 631 were applied and later found to be unconstitutional. However, AAM's actual claims of irreparable harm are unconvincing.

AAM's concern that it will "face a barrage of investigations and lawsuits" is entirely speculative and supported by no evidence in the record. Pl.'s Mot. Prelim. Inj. at 32, ECF No. 9-1. It also provides little to no support for how its members "will need to conform their conduct" to the law's terms or how much those individual actions would cost. Id. Although AAM refers generally to "multiple, costly steps to restructure their pricing, distribution, and other business practices," it does not specify what those "multiple, costly" steps would involve. Id. It is insufficient to state in a conclusory manner that AAM members would have to "rejigger" their own business models, which would cost "time and money." Id. at 35.

Moreover, AAM claims that the implementation of the law would force its members to discontinue marking certain medicines in Maryland or in the United States as a whole. Compl. ¶ 7, ECF

No. 1. They imply that patients and customers would be left with no generic medication choices and would "simply perceive manufacturers as making life tougher on them," causing alleged reputational harm. Pl.'s Mot. Prelim. Inj. at 35, ECF No. 9-1. See also Hearing Rough Tr. at 64:1-3 (Sept. 14, 2017) (Counsel for Plaintiff: "So we actually, I don't think, have the ability in any way at all, to control whether our drugs end up in Maryland, except by not selling them."). No support is provided for the dramatic statement that AAM members would shut down parts of their businesses in order to comply with HB 631.

AAM's submitted declarations are conclusory:

- Chester Davis, President and CEO of AAM, states that AAM members would need to take "nontrivial steps to modify [their] pricing, distribution, or other business practices." ECF No. 9-2 ¶ 9. However, he does not explain what those nontrivial steps are and how much money those modifications would cost.

- Sean Moriarty, Secretary of Lupin Pharmaceuticals, states that "Lupin will be forced to expend unnecessary resources attempting to achieve compliance with an uncertain target." ECF No. 9-3 ¶ 10. However, he does not explain what resources would be expended in this process. The same or similar conclusory sentence appears in the Declarations of Don Bullock of Sagent Pharmaceuticals (ECF No. 9-4 ¶ 9), Lisa Graver of Alvogen Group (ECF No. 9-5 ¶ 11), Michael Keenley of Zydus USA (ECF No. 9-6 ¶ 11), Andrew Bower of Teva Pharmaceutical (ECF No. 9-7 ¶ 11), Jeffrey Hampton of Apotex Corp. (ECF No. 9-9 ¶ 7), Jim Luce of Amneal Pharmaceuticals(ECF No. 9-10 ¶ 8),

and Michael Raya of West-Ward Pharmaceuticals Corp. (ECF No. 9-11 ¶ 9).

- Don Bullock, Executive VP of Sales for Sageant Pharmaceuticals, states that Sagent will be "injured" both "directly and reputationally" if it changes its pricing or distribution practices, but provides no rationale for how those injuries might occur. ECF No. 9-4 ¶ 10. He also states that "HB 631 exposes Sagent to a level of risk that will require it to evaluate whether to continue to market certain medicines within Maryland, or in the U.S. market as a whole," but does not provide support for this dramatic statement. The same or similar conclusory statements appear in the Declarations of Lisa Graver of Alvogen Group (ECF No. 9-5 at ¶ 12), Michael Keenley of Zydus USA (ECF No. 9-6 ¶ 12), Andrew Bower of Teva Pharmaceuticals (ECF No. 9-7 ¶ 12), Jeffrey Hampton of Apotex Corp. (ECF No. 9-9 ¶ 8), Jim Luce of Amneal Pharmaceuticals(ECF No. 9-10 ¶ 9), and Michael Raya of West-Ward Pharmaceuticals Corp. (ECF No. 9-11 ¶ 10).

These statements are insufficient to meet the "clear showing" standard in Winter, 555 U.S. at 22.

AAM also argues that simply being held to unconstitutional state action "constitutes irreparable injury for purposes of obtaining a preliminary injunction." Id. at 37. However, the controlling cases that contain this reasoning may be limited to deprivations of individual rights (e.g., First Amendment rights, Fourth Amendment rights, voting rights). See, e.g., Elrod v. Burns, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably

constitutes irreparable injury."); League of Women Voters of N. Carolina v. North Carolina, 769 F.3d 224, 247 (4th Cir. 2014) ("Courts routinely deem restrictions on fundamental voting rights irreparable injury," noting that this makes sense because "once the election occurs, there can be no do-over and no redress."); Ross v. Meese, 818 F.2d 1132, 1135 (4th Cir. 1987) (Courts may "order injunctive relief to remedy constitutional violations which are based on the plaintiff's right to privacy in her home and her person which the Fourth Amendment protects against unreasonable government search and seizure"). Regardless, with the current record the Court does not find that HB 631 would cause a deprivation of rights under the dormant Commerce Clause. There is an insufficient record to make a determination as to the Due Process Clause of the Fourteenth Amendment.

AAM has not provided support for its speculative claims of irreparable economic and reputational harm. Accordingly, this factor weighs in favor of denying a preliminary injunction.

iii. Balance of the Equities

Third, AAM must make a clear showing that the balance of equities tips in its favor. Winter, 555 U.S. at 20. In examining this third factor, courts "must balance the competing claims of injury and must consider the effect on each party of

the granting or withholding of the requested relief." Id. at 24.

AAM simply argues that there is no substantial harm in not enforcing a likely unconstitutional statute, and that the Defendants will "suffer little, if any, injury from the relief sought." Pl.'s Mot. Prelim. Inj. at 38, ECF No. 9-1. However, as discussed above, the Court does not find AAM to have shown that HB 631 is substantially likely to be held unconstitutional. Moreover, the Court finds that an erroneous grant of a preliminary injunction would cause substantial harm by permitting the sale of essential drugs to Maryland residents at unconscionable prices. Defs.' Opp. Prelim. Inj. at 10, ECF No. 30.

Accordingly, this factor weighs in favor of denying a preliminary injunction.

iv. Public Interest

Finally, AAM must make a clear showing that the requested injunction is in the public interest. Winter, 555 U.S. at 20. See also id. at 24 ("[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.").

AAM makes two main public interest arguments: (1) that upholding AAM's constitutional rights is in the public interest

and (2) that HB 631 will introduce enough uncertainty and business risk for generic drug manufacturers that some will discontinue marketing their medicines in Maryland or in the United States as a whole and "decline altogether to enter the market of developing new, low cost generic alternatives to expensive brand products." Pl.'s Mot. Prelim. Inj. at 38-39, ECF No. 9-1. They claim that this "retrenchment" will result in decreased competition, fewer treatment options, and higher costs for patients and taxpayers. Id.

Defendants argue that this law is meant to prohibit unconscionable price increases for essential medicines, and that there is ample evidence that this type of conduct is presently causing public harm, and will continue to do so in the future absent legislative change. Defs.' Opp. Prelim. Inj. at 11-14, ECF No. 30. They explain that disempowering Maryland from implementing this bill would "signal to the pharmaceutical industry that state governments lack the authority to protect their citizens from even unconscionable increases in the prices of essential medicines" and encourage future abuses. Id. at 16.

As discussed above, AAM's claim that its members may stop marketing their drugs completely in response to HB 631 (essentially, shutting down parts of their businesses), which would result in decreased competition, fewer treatment options, and higher costs for patients and taxpayers, is entirely

speculative. Litigants may not, without adequate factual support, hold courts hostage by resorting to these kinds of hypothetical scenarios. C.f. Martin v. Lloyd, 700 F.3d at 137 (in the context of a vagueness challenge, "[a]ppellants made a tactical decision to bring a facial challenge to this law—that decision does not allow them to lean on extravagant hypothetical scenarios that bear no resemblance to their own conduct . . .").

In contrast, the Defendants have provided ample support for their position that HB 631 targets a narrow set of conduct that is intended to protect Maryland consumers from unconscionable price increases in the drugs that are essential to their health. See supra, Section I.A.

* * *

In summary, Winter factors 1, 2, 3, and 4 all weigh in favor of denying a preliminary injunction. The Court shall deny Plaintiff the preliminary injunction it seeks.

IV. 42 U.S.C. § 1983 and § 1988

AAM's claims presented under 42 U.S.C. § 1983 and § 1988 are dependent on its dormant Commerce Clause and Due Process Clause challenges. As held, the Court is allowing Plaintiff's vagueness contentions to proceed further but dismissing their other claims and denying the requested preliminary injunction.

V. CONCLUSION

For the foregoing reasons:

1. Plaintiff's Motion for Preliminary Injunction [ECF No. 9] is DENIED.

2. Defendants' Motion to Dismiss [ECF No. 29] is GRANTED IN PART and DENIED IN PART.

   a. The Motion is GRANTED as to the First Cause of Action under the dormant Commerce Clause.

   b. The Motion is DENIED as to the Second Cause of Action under the Fourteenth Amendment Due Process Clause.

   c. The Motion is GRANTED as to the Third Cause of Action under 42 U.S.C. § 1983 and § 1988 to the extent it is dependent on the dormant Commerce Clause challenge.

3. Plaintiff shall arrange a telephone conference to be held by October 6, 2017 to discuss the scheduling of further proceedings herein.

SO ORDERED, on Friday, September 29, 2017.

/s/
Marvin J. Garbis
United States District Judge