IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION FOR ACCESSIBLE MEDICINES,	*	
	*	
Plaintiff,		
	*	Civil Action No. 17-1860-MJG
v.		
	*	
BRIAN E. FROSH *et al.*,		
	*	
Defendants.		
	*	

* * * * * * * * * * * * *

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

Dated: August 14, 2017

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INTRODUCTION

The legislation at issue in this case, Chapter 818 of the 2017 Laws of Maryland or House Bill 631 ("HB 631" or "the Act"), 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. The conduct proscribed by HB 631 was previously described in a December 2016 report of the U.S. Senate's bipartisan Special Committee on Aging, which referred to the conduct as "price gouging." Titled *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers and the U.S. Health Care System*, the Special Committee's report, issued after a year-long investigation, describes a "monopoly business model" through which certain pharmaceutical manufacturers used brute market power to impose extraordinary price increases for life-sustaining drugs that had long been off patent. The report further describes the profound harm inflicted by those manufacturers on patients, their families, and the health system as a whole. The Special Committee found this conduct to be "indefensible." *See generally* Ex. A.[1]

HB 631, by its own terms, targets the particular form of conduct described in the Special Committee's report. HB 631 applies *only* to drugs that are (a) essential to the

[1] Defendants respectfully request that this Court take judicial notice of the documents attached as exhibits to this memorandum, all of which are public records. *See Wicomico Nursing Home v. Padilla*, No. CV RDB-16-1078, 2017 WL 3383105, at *4 (D. Md. Aug. 7, 2017) (noting that a court does not "convert a motion to dismiss to a motion for summary judgment when it takes judicial notice of public records or of adjudicative facts under Federal Rule of Evidence 201." (alterations omitted) (quoting *Goldfarb v. Mayor & City Council of Baltimore*, 791 F.3d 500, 506 (4th Cir. 2015)).

health and well-being of patients, (b) off-patent, and (c) actively manufactured by three or fewer manufacturers. It applies *only* when a manufacturer or distributor exploits market dysfunction and increases the price of such a drug so sharply that the price offends deeply established common law principles of unconscionability—*i.e.*, only when a price increase shocks the conscience. It applies only when such a conscience-shocking price increase cannot be justified by production costs or by costs associated with expansion of access to the drug. And, contrary to what Plaintiff Association of Accessible Medicines ("AAM") says, the Act applies *only* when a drug product is made available for sale in Maryland.

HB 631, which does not discriminate in any fashion against interstate commerce or engage in economic protectionism in any form, does not violate the dormant Commerce Clause. The sole purpose of HB 631 is to protect Maryland patients against unconscionable price increases for certain drugs in situations when patients—by virtue of both dysfunction in the market for the drug and the importance of the drug to their health—have no meaningful choice other than to purchase the drug. And, critically, HB 631's sole extraterritorial impact is *upstream* impact: it requires manufacturers that want particular drug products to be sold downstream in Maryland to avoid increasing the price of those particular drug products to an extent that shocks the conscience. Conversely, it imposes no limit on the ability of manufacturers to impose such price increases for the same drug in streams of commerce that do not reach Maryland. The Fourth Circuit's decision in *Star Scientific Inc. v. Beales*, 278 F.3d 339, 356 (4th Cir. 2002), stands squarely for the proposition that states may enact laws that have an impact on upstream transactions between out-of-state manufacturers and out-of-state distributors so long as those laws, like

HB 631, "ha[ve] no effect on transactions undertaken by out-of-state distributors in other States." *Star Scientific* compels the dismissal of AAM's dormant Commerce Clause claim, because HB 631, properly understood, has precisely the same type of "upstream" extraterritorial impact as the statute at issue in that case, albeit of substantially lesser magnitude. Indeed, AAM seeks to advance what Justice (then-Judge) Gorsuch recently described as a "novel lawmaking project": that of unmooring dormant Commerce Clause jurisprudence from its origin and core function as a check on state laws that discriminate against interstate commerce or otherwise advance economic protectionism. The Tenth Circuit declined to participate in that "novel" project, *see Energy & Environment Legal Institute v. Epel*, 793 F.3d 1169, 1174 (10th Cir. 2015), and this Court should likewise decline to do so.

Properly understood, too, HB 631 does not transgress constitutional vagueness standards. On the contrary, although the standards set forth in the law are not quantitative in nature, HB 631 closely tracks the common law doctrine of unconscionability, which predates the Constitution itself. The Constitution has never been understood to uproot such non-quantitative legal standards or to prohibit their use in statutes, and vagueness challenges like those brought by AAM have been overwhelmingly rejected by the courts.

HB 631 is targeted; it imposes a non-quantitative but well-accepted (and wholly unintrusive) standard of conduct on the actors who are subject to it; and it has no cognizable impact on streams of commerce other than those that end in Maryland. This Court should analyze HB 631 as it is written, apply a narrowing construction if necessary, and ignore the bogeyman version of the statute repeatedly conjured by AAM. Upon doing so, it

becomes clear that AAM's Complaint fails to state a claim upon which relief can be granted under either the Commerce Clause or the Due Process Clause of the Fourteenth Amendment and must therefore be dismissed.

FACTUAL BACKGROUND

Although the introduction of a generic version of a prescription drug typically causes a reduction in the price of that drug, certain manufacturers in recent years have exploited conditions of market dysfunction to impose drastic price increases for off-patent and generic drugs that had long been on the market at a reasonable price. HB 631, passed by large, bipartisan majorities of both houses of the Maryland General Assembly, attempts to address the most egregious instances of such price increases. Two federal government reports, both issued in the months prior to the 2017 legislative session, were discussed at length in the legislative committees to which HB 631 was assigned and represent an essential part of the legislative history of the statute.

Report of the Special Committee on Aging. In December 2016, the U.S. Senate's Special Committee on Aging, led by Senators Susan Collins (R-ME) and Claire McCaskill (D-MO), published a report detailing the results of a year-long, bipartisan investigation of "abrupt and dramatic price increases in prescription drugs whose patents had expired long ago." Ex. A at 3. The Special Committee focused on price increases imposed by four companies on seven drugs:

- In August 2015, Turing Pharmaceuticals (famously led by Martin Shkreli) raised the price of Daraprim from $13.50 per pill to $750 per pill, an overnight increase of more than 5000 percent. Turing is the sole producer of Daraprim, an off-patent drug for the treatment of

toxoplasmosis, which is a life-threatening infection to which infants and people with HIV are particularly vulnerable.

- In September 2014, Retrophin, Inc. (another company linked to Mr. Shkreli) raised the price of Thiola from $1.50 per tablet to $30 per tablet, an increase of 1900 percent. At the time, Retrophin was the only active manufacturer of Thiola, an off-patent drug that prevents the development of kidney stones and that is the only viable treatment for certain patients.

- From June 2010 to July 2015, Valeant Pharmaceuticals International imposed a series of price increases for the drug Cuprimine, ranging from 7% to 60%, that cumulatively caused the price of a typical supply of the drug to rise from $444.89 to $26,188.65. During roughly the same period, Valeant also imposed a series of price increases for the drug Syphine, ranging from 5% to 97%, that caused the price of a supply of the drug to increase from $652.05 to $21,266.80. Cuprimine and Syphine, both off-patent drugs, are "gold standard" treatments for Wilson disease, a rare genetic condition that inhibits the processing of copper. In February 2015, Valeant also imposed overnight price increases for the drugs Isuprel and Nitropress of 500% and 200%, respectively. Valeant was the sole producer of Isuprel and Nitropress, both off-patent drugs typically used in hospital emergency rooms to address cardiac emergencies.

- In April 2015, Rodelis Therapeutics raised the price overnight for 30 capsules of Seromycin from $500 to $10,800. Rodelis was the sole producer of Seromycin, which treats a life-threatening form of multi-drug resistant tuberculosis.

As the Special Committee explained, its "investigation uncovered a business model that these four companies used (with some variation) to exploit market failures at the expense of patients." *Id.* at 4. This business model has a number of common features, according to the Special Committee. First, despite the fact that all seven of the drugs at issue had gone off patent, there was little or no marketplace competition in manufacturing them; the drugs were all actually or effectively sole-source drugs. Second, each of these drugs was a preferred or "gold standard" treatment for certain conditions under certain circumstances. Third, the drugs served a relatively small number of patients. Fourth, each

company relied on structural barriers against competitors entering the market, and some employed strategies—such as limiting the drug to closed distribution networks—intended to impede market entry. Finally, each engaged in what the Special Committee called "price gouging," imposing extraordinary price increases that were not rooted in the cost of producing the drugs, each of which had long been on the market. *Id*. at 4-6, 30-31. The report describes the tactics used by these companies as both "disturbing" and "indefensible." *Id.* at 11, 73. The Special Committee declined to accept that the four companies whose practices it reviewed were isolated examples, noting that, "during the course of the Committee's investigation, other companies raised their prices sharply." *Id.* at 11.

The Special Committee also described the harm that the four companies inflicted on patients and families, as well as the health system as a whole. The report states that "[s]taggering increases in the price of some prescription drugs threaten not only the economic stability of American households, but also the health of individuals who discover that drugs they need are unaffordable and difficult to access." *Id.* at 3. The report describes in particular how three patients lost access to essential medicines as a result of the price increases, including a 35-year-old father suffering from Wilson disease, whose treatment with Cuprimine was interrupted for several weeks when faced with a $20,000 per month copay as a result of the price imposed by Valeant, and who soon thereafter had a stroke and died. *See generally id.* at 98-110 (cataloging the impacts of sudden drug price increases on patients, their families, physicians, hospitals, government budgets, and private insurers).

The Special Committee lamented in its report that antitrust law and other existing law may not adequately prevent pharmaceutical companies from adopting the "business model" that it described. *Id*. at 116-17. The Special Committee suggested, however, that a "targeted statutory approach to prevent abuses could be pursued." *Id.* at 117.

Report of the Government Accountability Office. The General Assembly's legislative committees also considered an August 2016 report of the federal Government Accountability Office ("GAO"), which 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" (defined as an increase of more than 100% within a one-year period) for 315 of those drugs. *See* U.S. Government Accountability Office, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases* (Aug. 2016), attached as Ex. B. Forty-eight of these one-year price increases exceeded 500 percent and 15 of them exceeded *1000 percent*. *Id.* at 14. According to the GAO, the federal Medicare program alone spent approximately $4.5 billion in 2014 on the 315 drugs that had experienced an "extraordinary price increase" during the period of study. *Id.* at 21 n.28. Although the GAO did not study the cause of specific price increases, and while many of the price increases identified by the GAO could conceivably have been driven in whole or in part by a legitimate cause, the GAO identified "supplier consolidation" as a major cause of increased prices and found that "competition is the primary driver of generic drug prices." *Id.* at 23, 24. The GAO report thus complements the Special Committee on Aging report in suggesting that the nine drugs

studied by the Special Committee may not be isolated examples and in providing some sense of the potential scale of the problem.

The Act. In HB 631 (An Act concerning Public Health – Essential Off-Patent or Generic Drugs – Price Gouging – Prohibition), to be codified at §§ 2-801 to 2-803 of the Health-General Article of the Maryland Code, the General Assembly has attempted to address, in the targeted fashion that the Special Committee on Aging anticipated, precisely the type of harmful and unethical conduct described in the Committee's December 2016 report. A review of the key provisions of the Act demonstrate that it is carefully designed to do just that.

The core provision of the Act is its prohibition on price gouging, which states that "[a] manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug." Md. Code Ann., Health-Gen. § 2-802(a). The Act defines an "essential off-patent or generic drug" as "any prescription drug"

> (i) "for which all exclusive marketing rights, if any, granted under the Federal Food, Drug, and Cosmetic Act, § 351 of the Federal Public Health Service Act, and federal patent law have expired";
>
> (ii) that either appears on the World Health Organization's most recently adopted Model List of Essential Medicines or "has been designated by the Secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living";
>
> (iii) "that is actively manufactured and marketed for sale in the United States by three or fewer manufacturers"; and
>
> (iv) that is "made available for sale in the State."

Id. § 2-801(b)(1)(i)-(iv). In other words, the Act applies *only* to drugs that are off-patent, that are expressly designated as being essential to the health and well-being of patients, and that are manufactured by monopolists or others who may have significant market power. It also applies only when drugs are sold in Maryland.

The Act defines "price gouging" as an "unconscionable increase in the price of a prescription drug," *id.* § 2-801(c), and further defines an "unconscionable increase" as a price increase with two components. First, the increase must be "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." *Id.* § 2-801(f)(1). As discussed below, this provision references the "substantive" component of the common low doctrine of unconscionability. In addition, the price increase must "result[] 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" *both* the "importance of the drug to their health" and "insufficient competition in the market for the drug." *Id.* § 2-801(f)(2)(i)-(ii). This provision describes a particular instance of "procedural" unconscionability, as that concept has been defined at common law.

The Act places primary enforcement authority in the hands of the Attorney General, who is empowered to "require a manufacturer or wholesale distributor to produce any records or other documents that may be relevant to a determination of whether a violation of [the Act] has occurred." Health-Gen. § 2-803(c). The Attorney General may also petition a circuit court to issue an order compelling the manufacturer or wholesale distributor of an essential off-patent or generic drug to produce records or information as

required under the Act; providing injunctive relief; requiring disgorgement of any money acquired as a result of an unconscionable price increase; requiring the manufacturer to make the drug available to participants in a State health plan for up to one year at the price that preceded the unconscionable increase; and imposing a civil penalty of up to $10,000 for each violation of the Act. *Id.* § 2-803(d)(1)-(5). Before seeking redress in court, however, the Attorney General must provide the manufacturer or wholesale distributor with an opportunity to "meet with the Attorney General to offer a justification" for the price increase. *Id.* § 2-803(e).

Thus, as written, the Act targets only extraordinary price increases by monopolists or other actors that may have market power, and it is specifically designed to protect vulnerable patients who have no choice but to buy the drug at whatever price is charged. The Act was approved both houses of the General Assembly in April 2017. It is set to go into effect on October 1, 2017.

ARGUMENT

I. AAM'S COMPLAINT IS PREMISED ON INACCURATE AND EXAGGERATED CLAIMS ABOUT THE REACH OF THE ACT.

A foundational premise of AAM's Complaint is that "HB 631's sweeping price control reaches into every corner of the United States, if not beyond." Compl. ¶ 2. The plain text of the Act, however, spells out the General Assembly's intention to address only the most egregious instances of misconduct in the pricing of certain types of prescription drugs, such as those instances identified in the report of the Senate's Special Committee on Aging, and to have an impact on unconscionable conduct outside of Maryland only to

the extent that such conduct occurs upstream from a consumer transaction in Maryland. As discussed above, the Act applies only to drugs that are essential, off-patent, manufactured by three or fewer manufacturers, and only when patients lack any meaningful choice about whether to purchase the drug. Health-Gen. § 2-801(b)(1), (f)(2). It applies only when a manufacturer or distributor increases the price of such a drug to an unconscionable extent, *id*. § 2-801(c) & (f), and only when the drug is "made available for sale in Maryland," *id*. § 2-801(b)(1)(iv). In addressing AAM's inaccurate claims about the nature and reach of the bill, the latter two features of the law bear special, additional emphasis.

First, it is, at best, sheer hyperbole to describe the Act as a "sweeping price control." Compl. ¶ 2. The Act does not control all prices; rather, it targets only *unconscionable* price increases, and in doing so it relies upon, and goes no further than, the common law doctrine of unconscionability. Indeed, the Act's definition of an "unconscionable increase" incorporates both the "substantive" and "procedural" components of the unconscionability doctrine, mirroring J. Skelly Wright's classic formulation of the doctrine in *Williams v. Walker-Thomas Furniture Co*., 350 F.2d 445 (D.C. Cir. 1965). *Compare* Health-Gen. § 2-801(f) (price increase that "is excessive and not justified" and "results in consumers . . . having no meaningful choice about whether to purchase the drug"), *with* 350 F.2d at 449 (describing "an absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party"); *see also Shih Ping Li v. Tzu Lee*, 210 Md. App. 73, 112 (2013) ("[U]nconscionability can be classified as

'procedural' when there is a lack of meaningful choice in the formation of the contract, or 'substantive' when the terms are so one-sided as to 'shock the conscience' of the court.").

For present purposes, it is sufficient to observe that courts applying the doctrine of unconscionability have stated that it requires results "so harsh as to shock the conscience"; transaction terms "so outrageously unfair as to shock the judicial conscience"; an agreement that "no sane man not acting under a delusion would make, and that no honest man would take advantage of"; and "inequity so strong, gross, and manifest that it must be impossible to state it to one with common sense without producing an exclamation at the inequality of it." *Oddo v. Arcoaire Air Condition & Heating*, No. 8:15-cv-01985-CAS(Ex), 2017 WL 372975, at *9 (C.D. Cal. Jan. 24, 2017) (quoting cases from various states). To say the least, and as dozens of courts have recognized, unconscionability establishes a "high bar." *See, e.g.*, *Crawford Prof'l Drugs, Inc. v. CVS Caremark Corp.*, 748 F.3d 249, 263 (5th Cir. 2014); *Longnecker v. American Express Co.*, 23 F. Supp. 3d 1099 (D. Ariz. 2014). Here, to fall within the Act's prohibition, a price increase for a covered pharmaceutical must be so extreme as to "shock the conscience," and the drug at issue must be of such importance to a patient's health that he or she has no "meaningful choice" whether to purchase it. If the Act can fairly be described as a "price control" regulation at all, it is price regulation in its minimalist—and least "sweeping"—form.

Second, the Act applies only when a covered drug is "made available for sale in Maryland," Health-Gen. § 2-801(b)(1)(iv), and it therefore does not "reach[] into every corner of the United States, if not beyond." Compl. ¶ 2. On this point at least, AAM's exaggerated claim does begin with a kernel of truth. The Act seeks to protect Maryland

consumers from harms that result from "upstream" pricing decisions—from a decision, for example, made by an out-of-state monopolist or near-monopolist to impose a conscience-shocking price increase on pharmaceutical items that are intended for sale in Maryland. But the Act applies only when such items are later sold "downstream" in Maryland, and only to the extent necessary to remedy the harms caused in Maryland by the actor's unconscionable "upstream" conduct. In limiting its reach to drugs "made available for sale in Maryland," HB 631 avoids regulating, or purporting to regulate, streams of commerce that do not flow through Maryland. Thus, for example, the Act does not limit the ability of an out-of-state drug manufacturer to impose a conscience-shocking price increase on items that are not intended to be made available for sale in Maryland, even if the manufacturer makes other items of the same type available for sale in Maryland.

If the Court does not find the Act to be sufficiently clear on this point, the Court can and should construe the law to apply only to drugs that are ultimately sold to consumers in Maryland. For example, in *K-S Pharmacies, Inc. v. Am. Home Products Corp.*, 962 F.2d 728, 730 (7th Cir. 1992), a case analogous to this one in various respects, a national drug reseller brought a dormant commerce clause challenge to a Wisconsin law that prohibited price discrimination in certain drug sales. The reseller asserted that although the law guaranteed to "every purchaser *in this state*" the same price as "the most favored purchaser," it did not expressly make clear that "the most favored purchaser" also referred to an *in-state* purchaser. *Id.* at 730-31 (emphases added). If the Wisconsin statute had been construed as the drug reseller insisted, it would have been a price-tying statute—requiring sellers to charge the same prices within the state that they charge in other states—of the

type that the Supreme Court has found to violate the dormant commerce clause. *See id*. at 730 (citing cases). The Seventh Circuit nonetheless readily construed the statute to prohibit price discrimination only among in-state purchasers, asking rhetorically "[w]hat sense would it make" to construe the statute otherwise. *Id*.

Here, too, if the Act were construed as AAM insists, it would prohibit unconscionable price increases in all transactions everywhere ("in[] every corner of the United States, if not beyond"), so long as those transactions involved drugs of the regulated type. But it makes no sense to adopt AAM's far-fetched interpretation, especially because the Maryland Court of Appeals has expressly adopted a presumption against extraterritoriality in the interpretation of Maryland statutes. *See, e.g.*, *Chairman of Board of Trustees of Employees' Retirement Sys. v. Waldron*, 285 Md. 175, 184 (1979) ("Unless an intent to the contrary is expressly stated, acts of the legislature will be presumed not to have any extraterritorial effect."); *cf. United States v. Bollinger*, 798 F.3d 201, 207 (4th Cir. 2015) (statutes carry a presumption of constitutionality); *Koshko v. Haining*, 398 Md. 404, 426 (2007) (same).

II. THE ACT IS NOT SUBJECT TO FACIAL CHALLENGE, BECAUSE, AS AAM ITSELF IMPLICITLY CONCEDES, THE ACT HAS A PLAINLY LEGITIMATE SWEEP.

AAM has brought a facial, pre-enforcement challenge seeking to prevent the Act from ever taking effect. Such challenges "are generally disfavored." *MacDonald v. Moose*, 710 F.3d 154, 166 (4th Cir. 2013). Indeed, courts approach such challenges with skepticism "because they 'often rest on speculation,' 'run contrary to the fundamental principle of judicial restraint,' and 'threaten to short circuit the democratic process by

preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution.'" *H.B. Rowe Co. v. Tippett*, 615 F.3d 233, 243 (4th Cir. 2010) (quoting *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450-51 (2008)); *see also Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 163-64 (4th Cir. 2000) ("Because of the nature of facial challenges, . . . [the plaintiffs] must argue about the Regulation's impact generally and prospectively, the type of action typically undertaken by legislatures, not courts.").

Because facial challenges are disfavored, the Supreme Court has long declared that such a challenge cannot succeed unless the plaintiff can establish "'that no set of circumstances exists under which the Act would be valid,' *i.e.*, that the law is unconstitutional in all of its applications." *Wash. State Grange*, 552 U.S. at 449 (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)). And even where the "no set of circumstances" test does not apply, a facial challenge must nevertheless fail where "the statute has a plainly legitimate sweep." *Id.* (internal quotation marks omitted). AAM fails to meet either of these standards with respect to either of its legal theories.

With respect to AAM's dormant Commerce Clause claim, the Complaint alleges that "in the *overwhelming majority* of off-patent and generic drug sales to patients in Maryland, the only involvement a drug manufacturer has to the end transaction is via an upstream sale that occurred wholly outside of the state." Compl. ¶ 26 (emphasis added). Importantly, the Complaint does *not* allege that drug manufacturers and wholesale distributors never engage in transactions within the state of Maryland. As explained further below, nothing in dormant Commerce Clause jurisprudence suggests that the Act cannot

be constitutionally applied to in-state transactions that have an upstream impact. But even accepting the novel theory of the dormant Commerce Clause advanced in the Complaint (under which state laws may have no upstream extraterritorial impact), AAM appears to concede that the Act could be constitutionally applied to transactions between manufacturers, wholesale distributors, retailers, and healthcare institutions that take place wholly inside Maryland's borders. Because the Complaint implicitly acknowledges that there likely are some such transactions, *see* Compl. ¶¶ 25, 49, AAM effectively concedes that the Act has constitutional applications, thus foreclosing its facial challenge.[2]

AAM also fails to meet the standard for a facial void-for-vagueness claim. There are clearly circumstances in which HB 631 would be constitutional if applied—such as a 5000% increase in a life-saving treatment for a potentially deadly parasitic infection, to take just one example. And the Act explicitly invokes the common law doctrine of unconscionability, a doctrine with droves of precedents to which manufacturers and wholesale distributors can look to find guideposts for what types of price increases may be considered unconscionable under the Act. Even if there may be some gray areas in determining whether some price increases are unconscionable, HB 631 is sufficiently clear to give regulated parties fair notice of what conduct is likely proscribed. *Kolbe v. Hogan*, 849 F.3d 114, 149 (4th Cir. 2017) (in rejecting vagueness challenge to assault weapon ban,

[2] The same is true even if the lower "plainly legitimate sweep" test were applied to this claim. *See Washington State Grange*, 552 U.S. at 449 (acknowledging that some members of the Court have objected to the *Salerno* "no set of circumstances" formulation but that "all agree" on the "plainly legitimate sweep" standard); *accord United States v. Comstock*, 627 F.3d 513, 518-19 (4th Cir. 2010).

explaining that "the vagueness inquiry . . . focuses on the intractability of identifying the applicable legal standard, not on the difficulty of ascertaining the relevant facts in close cases."). That holds true regardless of which standard this Court applies in evaluating AAM's facial challenge.[3]

III. THE ACT DOES NOT DISCRIMINATE AGAINST INTERSTATE COMMERCE, AND ITS SOLE EXTRATERRITORIAL IMPACT IS TO PROTECT MARYLAND PATIENTS AGAINST UPSTREAM PRICING DECISIONS THAT IMPEDE ACCESS TO ESSENTIAL MEDICINES.

A. The Dormant Commerce Clause Does Not Limit the Authority of States to Adopt Laws That May Have Out-Of-State Effects As Long As Such Laws Do Not Discriminate Against or Impermissibly Burden Interstate Commerce.

The Supreme Court has long recognized a restriction on the regulatory power of the States arising from the Commerce Clause of the U.S. Constitution. U.S. Const., art. I, § 8. Commonly referred to as the dormant Commerce Clause, this negative restraint "denies the

[3] The Supreme Court has long held that a plaintiff bringing a facial challenge to a law that neither impinges on First Amendment interests nor carries criminal penalties "must demonstrate that the law is impermissibly vague in all of its applications." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982). *Johnson v. United States*, 135 S. Ct. 2551, 2560-61 (2015), where the Supreme Court refused to apply the "no set of circumstances" standard in the context of a vagueness challenge to a criminal law, did nothing to disturb that standard. *See, e.g., Crooks v. Mabus*, 845 F.3d 412, 417 (D.C. Cir. 2016) (citing *Johnson* but applying *Village of Hoffman Estates* standard in upholding non-criminal Navy regulation against facial challenge); *Expressions Hair Design v. Schneiderman*, 808 F.3d 118, 143 (2d Cir. 2015), *vacated and remanded on other grounds*, 137 S. Ct. 1144 (2017); *United States v. Petras*, No. CR 2:15-CR-087-D, 2016 WL 1054597, at *9 (N.D. Tex. Mar. 17, 2016) (declining to "assume that *Johnson* overruled *Village of Hoffman Estates* and citing cases since *Johnson* was decided in which "courts have continued to follow *Village of Hoffman Estates*' test for vagueness"); *see generally Village of Hoffman*, 455 U.S. at 497 ("The 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.").

States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce." *Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality*, 511 U.S. 93, 99 (1994). It is equally well-established, however, that "[t]he limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138 (1986); *see also Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 306 (1997); *Colon Health Centers of Am., LLC v. Hazel*, 813 F.3d 145, 158 (4th Cir. 2016).

Generally speaking, courts "apply a two-tiered analysis to state actions allegedly violating the dormant Commerce Clause." *Envtl. Tech. Council v. Sierra Club*, 98 F.3d 774, 785 (4th Cir. 1996). The first tier "applies where a state law discriminates facially, in its practical effect, or in its purpose." *Id.* (citations and internal quotation marks omitted)). Because the Supreme Court has upheld facially discriminatory laws in very narrow circumstances, this first tier of analysis has been described as "a virtually *per se* rule of invalidity." *Wyoming v. Oklahoma*, 502 U.S. 437, 454-55 (1992) (quoting *Philadelphia v. New Jersey*, 437 U.S. 617, 624 (1978)).

The second tier of analysis "applies if a statute regulates evenhandedly and only indirectly affects interstate commerce.'" *Envtl. Tech. Council*, 98 F.3d at 785. Regulations that do not discriminate and that have only incidental effects on interstate commerce are valid unless "the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Courts rarely invalidate state statutes under the *Pike* balancing test, and many—

including the Fourth Circuit—have expressed concerns about the potential for application of the test to result in judicial overreach. *See Colon Health Centers of Am.*, 813 F.3d at 155 ("[T]he *Pike* approach is often too soggy to properly cabin the judicial inquiry or effectively prevent the district court from assuming a super-legislative role." (internal quotation marks omitted)). Thus, "reasonable debates" about the benefits or burdens associated with a state law "are resolved in favor of upholding" the challenged law. *Id.* at 158.

As the then-Judge Gorsuch recently explained for the Tenth Circuit, "[t]he usual telling of the law in this area suggests" that there is a third separate strand of authority. *EELI*, 793 F.3d at 1173. This purported third strand, the so-called extraterritoriality doctrine of the dormant Commerce Clause, has on occasion been invoked to invalidate certain state laws that purport to "directly control[] commerce occurring wholly outside the boundaries of a State." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989). The Tenth Circuit described the extraterritoriality doctrine as perhaps "the least understood of the Court's three strands of dormant commerce clause jurisprudence" and, indeed, cast serious doubt on its existence as an independent basis for invalidating state laws under the dormant Commerce Clause. *See EELI*, 793 F.3d at 1172. As the *EELI* court pointed out, the Supreme Court has "used its extraterritoriality principle to strike down state laws only three times," and, in each of those cases, the statute at issue (unlike the statute at issue in this case) tied in-state prices for a class of goods to prices charged out-of-state for the same class of goods and thereby "had the effect of inhibiting out-of-state price competition." *Id.* (citing *Healy*, 491 U.S. 324; *Brown-Forman Distillers Corp. v. New York State Liquor*

Auth., 476 U.S. 573 (1986); and *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511 (1935)). Thus, the Tenth Circuit further explained, the Supreme Court cases purportedly illustrating the third strand of dormant commerce clause jurisprudence—the strand on which AAM relies here—may not describe a third strand at all. Rather, they are best understood as "no more than instantiations of the . . . anti-discrimination rule." *Id*. at 1173.

B. HB 631 Does Not Discriminate in Any Fashion Against Interstate Commerce, Nor Does It Impermissibly Burden Interstate Commerce in Any Cognizable Fashion.

AAM largely ignores the traditional two-tier framework, relying almost exclusively on the questionable theory that the dormant Commerce Clause reaches non-discriminatory state laws based solely on their purported extraterritorial impact. In at least one place, however, the Complaint does claim that HB 631 "clearly discriminate[s] against out-of-state commerce." Compl. ¶ 25. In doing so, AAM misapprehends what constitutes "discrimination" for purposes of dormant Commerce Clause analysis. "In this context, discrimination simply means differential treatment of in-state and out-of-state economic interests that *benefits the former and burdens the latter*." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007) (citations and internal quotation marks omitted) (emphasis added). AAM concedes as much when it acknowledges that what underpins the dormant Commerce Clause doctrine are concerns about "'economic protectionism, that is, regulatory measures designed to benefit *in-state economic interests* by burdening out-of-state *competitors*.'" Pl.'s Br. In Support of Motion

for Prelim. Injunction at 18 (ECF No. 9-1) (quoting *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008)) (emphasis added).

AAM, moreover, makes no attempt to explain either how HB 631 treats in-state and out-of-state economic interests differently or how any provision of the Act would "benefit[] the former and burden[] the latter." *See United Haulers Ass'n*, 550 U.S. at 338. Nor could it plausibly advance such an argument. In fact, the very case that AAM quotes to support its assertion that the provisions here are "not close calls" underscores that the Act does not discriminate against out-of-state interests. Compl. ¶ 54 (quoting *Envtl. Tech. Council*, 98 F.3d at 785). There, the Fourth Circuit affirmed the district court's grant of preliminary injunctive relief against a series of South Carolina laws, executive orders, and ordinances that imposed limits on the burial of out-of-state hazardous waste within its borders. 98 F.3d at 777. Those provisions included, *inter alia*, ceilings on out-of-state wastes and blacklisting provisions that gave preference to in-state hazardous waste generators. *Id.* at 785-86. As the court explained, those provisions "facially discriminate[d] against out-of-state wastes by refusing admittance into South Carolina and giving express preference over South Carolina capacity to in-state wastes." *Id.* at 785.

In contrast, both on its face and in its purpose and practical effect, the Act imposes the same requirements on all manufacturers and wholesale distributors of essential off-patent or generic drugs intended for sale in Maryland, regardless of where they are located. *See* HB 631. Even if, as AAM alleges, the majority of manufacturers and wholesale distributors are located outside of Maryland, *see* Compl. ¶ 51, that fact would be insufficient to demonstrate that the Act discriminates against out-of-state commerce. *See*,

e.g., *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 123 (1978) (rejecting dormant Commerce Clause challenge to law prohibiting petroleum producers or refiners from also operating retail service stations within the state, despite evidence at trial that "no petroleum products [were] produced in Maryland"). Indeed, such a fact would be entirely irrelevant as long as Maryland is not seeking to prop up in-state industry.

In *Exxon*, the Supreme Court emphasized that "[t]he fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." *Id.* at 126. So too here. Like the statute at issue in *Exxon*, HB 631 "creates no barriers whatsoever against interstate [manufacturers and wholesale distributors]; it does not prohibit the flow of interstate goods, place added costs upon them, or distinguish between in-state and out-of-state companies in the . . . market." *Id.* "The absence of any of these factors fully distinguishes this case from those in which a State has been found to have discriminated against interstate commerce." *Id*.

Finally, AAM makes no attempt to claim that the Act imposes incidental effects on interstate commerce or that any in-state benefits are outweighed by the burdens it imposes on interstate commerce. Any such claim, moreover, would be implausible on its face. Maryland has a strong interest in ensuring that its citizens have access to life-saving essential drugs and in protecting them from the harms associated with unconscionable price increases. *See, e.g.*, *Taylor*, 477 U.S. at 148 (protecting health is a legitimate local interest for purposes of dormant Commerce Clause analysis).

C. The Case Law Has Long Established That State Laws, Like HB 631, May Reach Out-of-State, "Upstream" Commercial Conduct to Protect

Citizens from In-State, "Downstream" Harms, Without Infringing on Dormant Commerce Clause Principles.

As explained in Section I above, a proper application of dormant Commerce Clause principles to HB 631 requires first disregarding AAM's inaccurate claims about the scope of the Act. Simply put, the Act does not reach, or purport to reach, any stream of commerce that does not end in Maryland. HB 631 applies only when a drug product is "made available for sale in Maryland," Health-Gen. § 2-801(b)(1)(iv), and, in particular, it leaves pharmaceutical manufacturers and distributors free to impose conscience-shocking price increases for any items that are not sold in Maryland.

Shorn of conclusory and wholly inapt references to "discrimination" discussed above, AAM's dormant Commerce Clause theory relies exclusively on extraterritorial impact as the basis for its theory of HB 631's invalidity. AAM's extraterritoriality-only theory, precisely stated, is that HB 631 is invalid because its "practical effect" is to "control" anticipated transactions between out-of-state manufacturers and out-of-state distributors involving pharmaceutical items intended for resale in Maryland. *See* Compl. ¶ 48 (quoting *Healy*, 491 U.S. at 336). As further discussed below, this theory has been conclusively rejected by the Fourth Circuit in *Star Scientific*. There, the court held that states, without implicating dormant Commerce Clause principles, may enact laws that have an impact on upstream transactions between out-of-state manufacturers and out-of-state distributors involving goods intended for sale in the state, so long as those laws, like HB

631, "ha[ve] no effect on transactions by out-of-state distributors in other states." 278 F.3d at 356.

In addition to being squarely foreclosed by controlling authority, AAM's extraterritoriality-only theory would unmoor the dormant Commerce Clause from its core function as an *anti-discrimination* principle and as a check on *economic protectionism*, neither of which is present here even in any scant form. Indeed, AAM has extended to this Court the very same "audacious invitation" to engage in "a novel lawmaking project" declined by the Tenth Circuit in *EELI*, per then-Judge Gorsuch. *See EELI*, 793 F.3d at 1174. As the court in *EELI* explained, in the three cases where the Supreme Court has applied the dormant Commerce Clause doctrine based on extraterritorial effects, the challenged regulations shared "three essential characteristics": they controlled prices, they linked prices paid in a state with those paid out of state, *and* they discriminated against out-of-staters. *See id.* at 1173. As discussed above, the Tenth Circuit's observation that each of these cases involved both price-tying and outright economic protectionism led the court to question whether the extraterritoriality doctrine should even be considered a "distinct line of dormant commerce clause jurisprudence at all," as opposed to simply an application of the anti-discrimination rule. *Id.*; *see also Alliant Energy Corp. v. Bie*, 336 F.3d 545, 547 (7th Cir. 2003) (describing "the unsurprising principle that a *direct* or *facial* regulation of wholly extraterritorial transactions is *per se* invalid" as "an unremarkable application of the traditional two-tiered analysis").

The contours of AAM's extraterritoriality-only theory become most clear when one isolates the two factual allegations on which AAM principally relies—namely, that

most (but not all) of the manufacturers and distributors of off-patent drugs are located outside of Maryland, and that the relevant markets are organized on a national basis. The case law squarely holds that both of these types of "extraterritorial impact" are not cognizable under the dormant Commerce Clause.

First, AAM alleges that, because "next to none of the relevant participants" in the generic drug distribution chain "resides in Maryland," the Act necessarily "targets pricing and conduct . . . [that] occurs largely, if not exclusively, outside of the state." *Id.* ¶¶ 25, 49. This claim, again, establishes nothing more than that the Act may have an extraterritorial impact on upstream transactions between out-of-state manufacturers and out-of-state distributors involving products intended for sale in Maryland. As explained above, numerous courts, including the Fourth Circuit, have held that such an impact does not violate the dormant Commerce Clause, "even if the impact is felt out-of-state where the stream originates." *Freedom Holdings Inc. v. Cuomo (Freedom Holdings II)*, 624 F.3d 38, 67 (2d Cir. 2010); *see also K-S Pharmacies*, 962 F.2d at 731 ("States may regulate transactions that wind up within their borders.").

This principle is best illustrated by two cases that addressed challenges to statutes enacted in the wake of the tobacco Master Settlement Agreement ("MSA") between cigarette manufacturers and States. In *Star Scientific*, 278 F.3d at 354, manufacturers that had not participated in the MSA brought a dormant Commerce Clause challenge to Virginia's escrow statute, which required such manufacturers to make escrow payments on cigarettes that they sold to distributors if the cigarettes were later sold into Virginia, even if both the manufacturer and the distributor were located outside of Virginia. The plaintiff

argued that the statute had the practical effect of regulating upstream transactions occurring wholly outside of Virginia, in violation of the principles announced in *Healy*. *Id.* at 356. The Fourth Circuit rejected the plaintiff's claim, explaining that even if the statute "affect[ed] the prices charged by out-of-state distributors," the law did not violate the extraterritoriality principle, because it imposed a fee only on cigarettes actually sold within the state and did not "insist on price parity with cigarettes sold outside of the State." *Id.* In this respect, and critically, *Star Scientific* is wholly consistent with then-Judge Gorsuch's observation in *EELI* that the so-called "extraterritoriality" cases under the dormant Commerce Clause in fact evidence a much more particular concern with statutes that regulate the terms of transactions in-state based on the terms of transactions that occur out-of-state, a concern that was absent in *Star Scientific* and is likewise absent here.

HB 631's extraterritorial impact is of precisely the same character as, but substantially more limited than, the upstream impact at issue *Star Scientific*. Whereas *Star Scientific* involved a statute that imposed an escrow payment on each and every transaction between out-of-state manufacturers and out-of-state distributors involving cigarettes intended for sale in Virginia, HB 631 has no impact on such transactions unless an out-of-state manufacturer imposes a conscience-shocking price increase for a drug product intended for sale in Maryland. *Star Scientific* compels rejection of AAM's theory.

Similarly, in *Freedom Holdings Inc. v. Spitzer (Freedom Holdings I)*, 357 F.3d 205, 215 (2d Cir. 2004), importers of tobacco products alleged New York could not, consistent with the dormant Commerce Clause, require out-of-state manufacturers that did not participate in the MSA to certify their compliance with the state's escrow-payment scheme

as a condition of their cigarettes ultimate lawful sale in the state. Just as AAM claims that HB 631 would affect transactions between out-of-state manufacturers and out-of-state wholesale distributors or retailers, the importers in *Freedom Holdings I* argued that the law was invalid because it inflated the prices that out-of-state actors charged to out-of-state resellers "in sales transactions that occur wholly outside the State of New York." *Id.* at 220. The Second Circuit rejected that argument, noting that the practical effect described by appellants "amount[ed] to no more than the *upstream pricing impact* of a state regulation," and that having such an effect "on extraterritorial commerce does not rise to the level of a constitutionally impermissible act." *Id.* (emphasis added).

AAM's dormant Commerce Clause theory would also be fundamentally inconsistent with the longstanding application of state antitrust law, under which states have consistently addressed, for example, price fixing between or among out-of-state manufacturers and out-of-state wholesalers. Indeed, the courts have previously rejected claims by pharmaceutical manufacturers that the dormant Commerce Clause prevents state antitrust law from reaching such conduct. *See In re Brand Name Prescription Drugs Antitrust Litigation*, 123 F.3d 599, 612-14 (7th Cir. 1997) (holding that Alabama antitrust law could reach alleged price-fixing conspiracy between out-of-state manufacturers and out-of-state wholesalers, to the extent that the conspiracy affected sales to pharmacies in Alabama, and recognizing that expansive theory of the dormant Commerce Clause would render state antitrust law "a dead letter"); *In re Lorazepam & Clorazepate Antitrust Litigation*, 295 F. Supp. 2d 30, 48-50 (D.D.C. 2003) (holding that Illinois insurer could bring suit under Illinois antitrust law for alleged violations affecting out-of-state

transactions, based on its allegation that it was "ultimately financially responsible for overpayments" resulting from those violations); *Johnson & Johnson Vision Care, Inc. v. Reyes*, 665 F. App'x 736, 744 (10th Cir. 2016) (rejecting Commerce Clause challenge to Utah antitrust statute preventing manufacturers from fixing retail contact lens prices even though all contact-lens manufacturers were located outside of the state).

The second type of extraterritorial impact cited by AAM is its allegation that "decisions relating to pricing and distribution of off-patent and generic prescription drugs are made at a national, not a state-by-state, level," and that HB 631 will therefore "inevitably affect commercial transactions, pricing, and commerce in other states." Compl. ¶ 24. The Supreme Court has held that allegations of this kind have no relevance under the dormant Commerce Clause. In *Exxon Corporation v. Governor of Maryland*, the Court conclusively rejected "the notion that the Commerce Clause protects the particular structure or methods of operation in a retail market." 437 U.S. at 123. The Court declined to accept Exxon's "novel suggestion" in that case "that because the economic market for petroleum products is nationwide, no State has the power to regulate the retail marketing of gas." *Id*. at 128. Indeed, the courts have long recognized that "any state regulation of a product" that flows in interstate commerce will likely have some extraterritorial impact, but "[t]he mere fact that state action may have repercussions beyond state lines is of no judicial significance so long as the action is not within that domain which the Constitution forbids." *Freedom Holdings I*, 357 F.3d at 220-21 (quoting *Osborn v. Ozlin*, 310 U.S. 53, 62 (1940)). At best, AAM's allegations demonstrate that it may be inconvenient for a manufacturer of an off-patent or generic drug to comply with the Act if the manufacturer

also wishes to exploit market dysfunction to impose unconscionable price increases for the drug.[4]

IV. THE ACT EXPRESSLY RELIES UPON THE COMMON LAW DOCTRINE OF UNCONSCIONABILITY TO TARGET A PARTICULAR FORM OF CONDUCT, AND IT IS NOT UNCONSTITUTIONALLY VAGUE MERELY BECAUSE IT DOES NOT SUPPLY A QUANTITATIVE STANDARD TO EVALUATE PRICE INCREASES.

AAM also claims that the Act is unconstitutionally vague on its face and that it therefore violates the Due Process Clause of the Fourteenth Amendment. The "void for vagueness doctrine addresses at least two connected but discrete due process concerns: first, that regulated parties should know what is required of them so they may act accordingly; second, precision and guidance are necessary so that those enforcing the law do not act in an arbitrary or discriminatory way." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). A law, however, is not unconstitutionally vague so long as it

[4] To support its novel dormant Commerce Clause theory, AAM relies exclusively on a case from a district court in another circuit, *Pharmaceutical Research & Manufacturers of Am. v. District of Columbia*, 406 F. Supp. 2d 56 (D.D.C. 2005), in which the court invalidated a District of Columbia law addressing the prices of both on-patent and off-patent drugs. For several reasons, that case should not be regarded as persuasive authority here. First, the D.C. statute at issue had two *Healy*-esque features—price tying and facial discrimination—that HB 631 does not. With respect to price tying, the D.C. statute permitted a plaintiff to establish a *prima facie* case of excessive pricing by showing that the price was 30% higher than the price in a few foreign jurisdictions. *Id.* at 60-61. And, with respect to discrimination, the statute treated in-state and out-of-state retailers differently by exempting the former but not the latter. *See id.* at 68. Second, the court failed to grapple with any of the cases interpreting *Healy* and the Supreme Court's other extraterritoriality cases, including *Star Scientific*, which is binding on this Court. Finally, the court in *PhRMA* itself acknowledged that, having already found the challenged statute unconstitutional under the Supremacy Clause based on its impact on the price of on-patent drugs, its dormant Commerce Clause analysis was superfluous. *Id.* at 67; *see also Biotech. Industry Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007) (affirming the district court's decision on the alternative ground that the statute violated the Supremacy Clause).

"(1) establishes minimal guidelines to govern law enforcement, and (2) gives reasonable notice of the proscribed conduct." *Schliefer v. City of Charlottesville*, 159 F.3d 843, 853 (4th Cir. 1998) (citations and internal quotation marks omitted). Likewise, "the degree of vagueness that the Constitution tolerates . . . depends in part on the nature of the enactment." *Village of Hoffman Estates*, 455 U.S. at 497. Where, as here, a statute regulates economic activity and does not impose criminal penalties, "[c]ourts will tolerate greater degrees of ambiguity." *Minter v. Wells Fargo Bank, N.A.*, 274 F.R.D. 525, 544 (D. Md. 2011). Because the Act provides reasonable notice of the conduct that it proscribes, AAM's vagueness claim must be dismissed.

A. Courts Have Consistently Upheld Statutes That Establish Standards of Conduct Based on the Common Law Doctrine of Unconscionability and Other, Similar Standards.

AAM claims that drug manufacturers and wholesale distributors "have no way to determine whether a given price is 'excessive,' whether a given market expansion is 'appropriate,' or whether a given consumer's option set is 'meaningful,'" and that they therefore "lack the necessary clarity to determine whether certain price increases they may consider in the future would be considered 'unconscionable.'" Compl. ¶ 60. In other words, AAM claims that the very provisions that help to define what makes a price increase "unconscionable" are themselves unconstitutionally vague.

Despite what AAM suggests, and as discussed above, HB 631 simply cannot be characterized as a broad prohibition on big price increases. The Act targets with some linguistic precision the "business model" described in the report of the Senate's Special Committee on Aging—with provisions limiting its application, among other things, to

medicines that are essential; to situations involving market dysfunction or failure; and to circumstances in which patients, because of the importance of the medicine at issue, have no meaningful choice about whether to purchase it. In so doing, the Act draws directly from the well-established common law doctrine of unconscionability, expressly invoking both the "procedural" and "substantive" components of that doctrine. The doctrine has been applied by courts in literally hundreds of cases over the course of centuries, without threat to anyone's constitutional rights. Indeed, this jurisprudence, including its longstanding, consistent emphasis on transactions devoid of "meaningful choice" for one party and substantive terms that "shock the conscience," *see, e.g.*, *Shih Ping Li*, 210 Md. App. at 235, provides sufficient guidance to regulated parties. *See United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 205 (D. Mass. 1998) (rejecting vagueness challenge where term "unconscionable" was used but undefined; emphasizing that the common law doctrine of unconscionability gave the plaintiff a sufficient "reference point[] by which to gauge its conduct"). Moreover, case law decided under the Act will refine this guidance. *See, e.g.*, *FTC v. R.F. Keppel & Bro., Inc.*, 291 U.S. 304, 310-11, 314 (1934) (recognizing that precise application of phrase "unfair methods of competition" as used in Federal Trade Commission Act would be refined through "the gradual process of judicial inclusion and exclusion" and that it was therefore "unnecessary to attempt a comprehensive definition of the unfair methods which are banned, even if it were possible to do so").

Similarly, that the Act contains a qualitative standard and uses terms marked by "flexibility and reasonable breadth" does not render it unconstitutional on its face. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (rejecting vagueness challenge to

an ordinance that prohibited the making of "noise or diversion which disturbs or tends to disturb the peace or good order"); *see also Johnson*, 135 S. Ct. at 2561 ("[W]e do not doubt the constitutionality of laws that call for the application of a qualitative standard . . . to real-world conduct; the law is full of instances where a man's fate depends on his estimating rightly some matter of degree." (citation, alteration, and internal quotation marks omitted)). Here, seeking to avoid legislation that might be significantly under-inclusive or that might seem to validate an otherwise-unjustified price increase based solely on the fact that it remained below a particular quantitative threshold, the General Assembly selected a qualitative standard, rather than a qualitative one. Numerous other legislative bodies, acting in analogous consumer protection contexts, have made the same choice. *See, e.g.*, *Sargeant*, 20 F. Supp. 2d at 205 ("In speaking of unfair or deceptive practices, Congress and the Federal Trade Commission have taken the position that a specific definition of such practices is not appropriate as it would necessarily be underinclusive, creating a shield for subsequent unfair or deceptive practices as the markets for goods and services evolve.").

Accordingly, courts have overwhelmingly rejected vagueness challenges to civil enforcement and regulatory statutes, like the one at issue here, based on the supposed imprecision of words like "unconscionable," "excessive," and "unreasonable." Several of these cases involve price gouging and other consumer protection laws prohibiting various forms of "unconscionable" commercial conduct and are therefore closely analogous to this case. *See, e.g.*, *Sargeant*, 20 F. Supp. 2d at 204-05 (rejecting vagueness challenge to consumer protection statute prohibiting mortgage loans with "unconscionable" rates or terms); *Massachusetts v. Gustafson*, 346 N.E.2d 706, 711 (Mass. 1976) (rejecting

vagueness challenge to consumer protection statute and stating that, "[a]lthough the words 'unfair,' 'unreasonable,' 'unconscionable,' and 'deceptive' may appear to lack specificity, if considered in the abstract, we believe that their meaning may be determined from the circumstances of each case," and that "we may rely . . . on the well settled common law meanings of [such] words"); *People v. Two Wheel Corp.*, 512 N.Y.S.2d 439, 441 (N.Y. App. Div. 1987) (rejecting vagueness challenge to price gouging statute prohibiting "unconscionably excessive" prices for "essential consumer goods" during an emergency); *Pennington v. Singleton*, 606 S.W.2d 682, 688-90 (Tex. 1980) (holding that prohibition under consumer protection law against "any unconscionable action or course of action" was not unconstitutionally vague, even though it gave rise to treble damages). As one court explained in upholding the application of a price gouging statute to a particular price increase, "[t]he mere fact that no fixed rate or percentage of permissible price is supplied by the statute does not render it unconstitutional, for the standards set forth in the [price gouging statute] are sufficient to apprise appellants that their gross price increases of as much as 67% during the power outage were prohibited unless they were attributable to additional costs imposed by the suppliers of the generators." *Two Wheel Corp.*, 512 N.Y.S.2d at 441.

The courts have reached essentially the same conclusion in rejecting vagueness challenges to other statutes in a wide range of contexts that rely on qualitative standards rooted in the common law. *See, e.g.*, *City of Wichita v. Smith*, 75 P.3d 1228, 1233 (Kan. Ct. App. 2003) (rejecting vagueness challenge to local noise ordinance prohibiting "unnecessarily loud or excessive noise"); *Gust v. Pomeroy*, 466 N.W.2d 137, 140 (N.D.

1991) (holding that, just as "the general public is held to understand the meaning of the phrase 'excessive or unusual noise' in a criminal statute . . . , certainly insurance professionals can be held to understand the phrase 'unnecessary or excessive insurance coverage' in a regulatory statute."); *North Carolina v. Taylor*, 495 S.E.2d 413, 416 (N.C. Ct. App. 1998) ("The terms in the Marin County Animal Control Ordinance—'habitually,' 'repeatedly,' 'excessive,' 'annoy,' 'disturb,' or 'frighten'—have common ordinary meanings by which to understand and measure the noise of a particular animal."); *In re Application of Columbus Southern Power Co.*, 983 N.E.2d 276, 281-84 (Ohio 2012) (rejecting vagueness challenge to statute requiring public utilities to return "significantly excessive earnings" to ratepayers and upholding order requiring return of $42 million). As the Supreme Court of Mississippi has stated, in reasoning that could apply to any of the above cases and to the present case, "[a] rule or standard is not objectionable merely because it is stated in general terms and is not susceptible of precise application. Familiar examples of such general standards abound in our law, *e.g.*, negligence, unconscionability, fraud. We doubt anyone would seriously argue today that these standards are unconstitutionally vague." *Transcontinental Gas Pipeline Corp. v. State Oil & Gas Bd.*, 457 So.2d 1298, 1323 (Miss. 1984) (rejecting vagueness challenge to standard imposed by state regulator on public utilities).

B. The Act Provides Sufficiently Clear Enforcement Standards.

AAM further alleges that the Act is unconstitutionally vague because it leaves "the decision to launch an investigation or lawsuit entirely up to the interpretation of the Attorney General." Compl. ¶ 61 (citation and internal quotation marks omitted). AAM

has not identified a single case in which a facial challenge to a statute has succeeded on the grounds that the Constitution requires statutes to articulate standards—*separate from their substantive standards*—to guide enforcement authorities in deciding whether to initiate enforcement activity concerning a potential violation of those standards.[5] It is unclear what purpose such a constitutional requirement would serve, but it *is* clear that no such requirement exists. *See Schleifer*, 159 F.3d at 854 ("Every . . . law, of course, reposes some discretion in those who must enforce it. The mere possibility that such discretion might be abused hardly entitles courts to strike a law down.").

In support of its theory, AAM suggests that the Attorney General cannot evenhandedly enforce the Act because he "was one of [its] major proponents." Compl. ¶ 62. Again, though, no court has held that a state official should be presumed incapable of evenhandedly enforcing a law for which he or she was an advocate. Indeed, such a rule would have absurd consequences, preventing administrative agencies, for example, from enforcing regulations that they had promulgated. Because, as demonstrated above, the Act is not "so standardless that it authorizes or encourages seriously discriminatory enforcement," *United States v. Williams*, 553 U.S. 285, 304 (2008), AAM's vagueness claim must be dismissed.

[5] Indeed, Plaintiff cites only three sources in the context of discussing the potential for arbitrary enforcement in the vagueness context: *Grayned v. City of Rockford*, 408 U.S. 104 (1972), and *United States v. Williams*, 553 U.S. 285 (2008), both of which rejected vagueness challenges to criminal statutes; and a law review article from 1960. *See* Compl. ¶¶ 33, 61-62.

CONCLUSION

Defendants' Motion to Dismiss should be granted, and Plaintiff's Complaint should be dismissed with prejudice.

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