

## Legal Strategies for Reining in “Unconscionable” Prices for Prescription Drugs

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## Abstract

Policy discussions about the affordability of prescription drugs in the United States are infused with the theme that drug prices are unconscionably high. Many of the policy interventions proposed in Congress, the White House, and the states adopt this frame, authorizing regulatory action when prices exceed particular thresholds or otherwise constitute “price gouging” on the part of drug companies. Unsurprisingly, such initiatives have prompted legal challenges by the biopharmaceutical industry. State laws in particular are vulnerable on a number of grounds. In this Article, we focus on one avenue of challenge that has received little scholarly attention in the context of drug pricing: void-for-vagueness claims under the Due Process Clause. These challenges allege that the laws’ definition of “excessive” or “unconscionable” drug prices is so ambiguous as to fail basic requirements of procedural due process.

To better understand how federal and state legislation can be designed to survive vagueness challenges, we review and extract lessons from four adjacent areas of law in which a standard of “unconscionable” or “excessive” price has been operationalized: (1) price-gouging laws relating to times of emergency, (2) contract law, (3) consumer lending law, and (4) public utilities rate regulation. We analyze the approaches taken in each field and their potential applicability to the prescription-drug context. We conclude that consumer lending law offers the most promising model, particularly if advanced via federal legislation, and offer a series of recommendations for drafting legislation aimed at identifying and curbing excessive drug prices.

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## Introduction

In February 2019, the United States Senate Committee on Finance summoned executives from seven large biopharmaceutical companies to defend their pricing practices before the Congress. Senator Ron Wyden’s introductory statement was laced with morally freighted language: medicines are “outrageously expensive;” “astronomically high” prices are the product of “profiteering and two-faced scheming;” and American families are driven to “morally repugnant” economic choices.<sup>1</sup> Senator Grassley’s opening statement similarly spoke of Americans’ “sticker shock” and the importance of “holding the private sector ... accountable through oversight.”<sup>2</sup> On the presidential campaign trail, Senator Cory Booker, reflecting on drug price increases, asserted that “It’s unconscionable how people are profiteering off the pain of others.”<sup>3</sup> In short, a pervasive theme in policy discussions about the affordability of medicines is that drug prices are unconscionably high, and policy intervention is required.

Public opinion reflects this view. In a February 2019 national poll, 79 percent of Americans said the cost of prescription drugs was “unreasonable.”<sup>4</sup> Eighty percent perceived that profits made by biopharmaceutical companies were a major factor contributing to high drug prices, and 52 percent believed drug companies’ marketing and advertising expenses were a major contributor.<sup>5</sup> Only 25 percent trusted drug companies even “somewhat” to price their products fairly.<sup>6</sup> A majority or supermajority of respondents supported each of ten proposed regulatory interventions, with the lone exception of allowing Medicare drug plans to exclude more drugs.<sup>7</sup>

Allegations of unconscionably high drug prices focus on two dimensions of the problem: high prices at a drug’s initial launch and large periodic price increases. A recent study of drug pricing and insurance claims data from 2005 to 2016 concluded that rising national costs for generic and specialty drugs are primarily attributable to new drugs, while costs for other, brand-name drugs are rising primarily due to increases in the price of existing drugs.<sup>8</sup> Average annual price increases for orally administered, brand-name drugs exceeded nine percent, and injectables 15 percent—both of which are several times the rate of general inflation.<sup>9</sup> Among the 16 new cancer treatments approved by the Food and Drug Administration in 2018, ten were launched at a monthly wholesale acquisition cost (WAC) exceeding \$9,000, or over \$100,000 for a year’s worth of medicine.<sup>10</sup>

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<sup>1</sup> Ron Wyden, Wyden Statement at Finance Committee Hearing on Drug Prices with Pharma CEOs 1-2 (Feb. 26, 2019), <https://www.finance.senate.gov/imo/media/doc/022619%20Wyden%20Statement%20at%20Finance%20Committee%20Hearing.pdf>.

<sup>2</sup> Chuck Grassley, Opening Remarks by Senator Chuck Grassley of Iowa: Hearing on Drug Pricing in America: A Prescription for Change, Part II 1 (Feb. 26, 2019), <https://www.finance.senate.gov/imo/media/doc/Opening%20Remarks%20by%20Senator%20Chuck%20Grassley%20of%20Iowa.pdf>.

<sup>3</sup> Lev Facher, *The ‘Big Pharma’ Candidate? As He Runs for President, Cory Booker Looks to Shake His Reputation for Drug Industry Coziness*, STAT (Feb. 12, 2019), <https://www.statnews.com/2019/02/12/cory-booker-presidential-run-pharmaceutical-industry-ties/>.

<sup>4</sup> Ashley Kirzinger et al., *KFF Health Tracking Poll – February 2019: Prescription Drugs*, KFF (Mar. 1, 2019), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* Three percent trusted companies to price products fairly “a lot” and 22 percent “somewhat.”

<sup>7</sup> *Id.*

<sup>8</sup> Immaculada Hernandez et al., *The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Costs of Drugs*, 38 HEALTH AFF. 76 (2019).

<sup>9</sup> *Id.*

<sup>10</sup> Lisa M. Jarvis, *The New Drugs of 2018*, CHEMICAL & ENGINEERING NEWS, Jan. 21, 2019, at 33, 37. The highest-cost drug, Loxo’s Vitrakvi, is priced at \$32,800 per month, or \$393,600 per year, for the oral formulation. *Id.*

Congress, the Trump Administration, and the states have responded with a bevy of policy proposals, many of which focus on taking action against instances of “price gouging”.<sup>11</sup> Several states have successfully enacted legislation. Unsurprisingly, these efforts have drawn the ire of industry actors and prompted litigation. The industry’s major trade associations—Biotechnology Innovation Organization (BIO), Pharmaceutical Researchers and Manufacturers of America (PhRMA) and the Association for Accessible Medications (AAM)—have each been plaintiffs in recent drug-pricing related litigation.<sup>12</sup> One such challenge resulted in a high-profile legislative victory in Maryland being unraveled by the courts in 2018.<sup>13</sup>

State laws in particular are vulnerable to challenge on a number of bases. They have faced challenges under the dormant Commerce Clause (responsible for the demise of Maryland’s price-gouging law for generic drugs), patent law, trade secret law, the Takings Clause, the First Amendment, and the Due Process Clause.<sup>14</sup> Many of these claims have previously been summarized in the academic literature.<sup>15</sup> In this Article, we focus on one avenue of challenge that has received comparatively little scholarly attention in the drug-pricing context: void-for-vagueness challenges under the Due Process Clause. These challenges allege that the laws’ definition of excessive or unconscionable drug prices is so ambiguous as to fail basic requirements of constitutionally-protected due process.

Void-for-vagueness challenges are worthy of greater attention for several reasons. First, efforts to regulate “excessive” drug prices are particularly vulnerable given the subjectivity and controversy involved in what constitutes an excessive or unfairly high price. Legal disputes tap into deeper normative questions about what fair pricing consists of and how it should be evaluated. Second, vagueness claims have already arisen in lawsuits against drug-pricing laws passed in Maryland and California. They therefore have practical salience to policymakers deliberating about which legislative approaches to pursue and how to craft bills going forward. Finally, as both federal and state laws are potentially vulnerable to vagueness challenges, the potential implications of such challenges are broad.

Our purpose is to identify a workable approach to the design of prescription drug price-gouging legislation—one that will survive constitutional challenges, in particular on the basis of vagueness, and facilitate substantial progress in improving drug affordability. To generate recommendations about surmounting vagueness challenges, we extract lessons from other areas of law in which a standard of “unconscionable” or “excessive” price has been operationalized.

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<sup>11</sup> See generally William V. Padula, *State and Federal Policy Solutions to Rising Prescription Drug Prices in the U.S.*, 22 J. HEALTH CARE L. & POL’Y 15 (2019) (summarizing legislative activity).

<sup>12</sup> See *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007); *Pharm. Research & Mfrs. of Am. v. David*, No. 2:17-cv-02573 (filed Sept. 28, 2018) (still ongoing); *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315 (D. Nev. dismissed June 28, 2018); *Ass’n for Accessible Meds. v. Frosh*, 2017 WL 4347818 (D. Md. Sept. 29, 2017), *rev’d*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

<sup>13</sup> See *infra* Part II.B.

<sup>14</sup> See *supra* note 12 (collecting cases); Robin Feldman et al., *The Patent Act and the Constitutionality of State Pharmaceutical Regulation*, 45 RUTGERS COMPUTER & TECH. L.J. 40 (2019) (summarizing Takings and patent-preemption challenges).

<sup>15</sup> See generally Isaac D. Buck, *States As Activists*, 39 J. LEGAL MED. (forthcoming 2019); Katherine L. Gudiksen & Jaime S. King, *The Burden of Federalism: Challenges to State Attempts at Controlling Prescription Drug Costs*, 39 J. LEGAL MED. (forthcoming 2019); Katherine L. Gudiksen et al., *California’s Drug Transparency Law: Navigating the Boundaries of State Authority on Drug Pricing*, 37 HEALTH AFFAIRS 1503 (2018) (discussing legal challenges to California’s drug price transparency law SB 17); Theodore T. Lee et al., *Legal Challenges to State Drug Pricing Laws*, 319 JAMA 865 (2018) (discussing the legal claims brought against Maryland and Nevada laws); Christopher Robertson, *Will Courts Allow States to Regulate Drug Prices?*, 379 NEW ENGL. J. MED. 1000 (2018) (describing dormant commerce clause challenge to Maryland’s HB 631).

This Article proceeds in four Parts. In Part I, we survey recent state and federal legislative activity in the price-gouging, unconscionability, and rate-setting spaces. For simplicity, we refer to this legislation collectively as “excessive-price legislation.” Given space constraints, our review of federal and state bills is illustrative rather than exhaustive. In Part II, we describe vagueness challenges as part of the biopharmaceutical industry’s litigation strategy to resist these laws. In Part III, we canvass four adjacent areas of law in which legislatures, regulatory agencies, and the courts have been involved in regulating excessive prices: (1) price-gouging laws relating to times of emergency; (2) consumer lending laws; (3) contract law; and (4) public utilities rate regulation. We analyze the regulatory approaches taken and their potential applicability to the prescription drug context. Our analysis is based on a review of legal cases, treatises, and scholarship in these areas. We focus on U.S. law, although it is noteworthy that drug regulators in Europe and elsewhere have also stepped up scrutiny of excessive drug prices and applied their own operational definitions of what is “excessive”.<sup>16</sup> Finally, in Part IV, we provide recommendations concerning key decisions in the design of excessive-price statutes.

Our analysis and recommendations reflect several commonsense assumptions about what a workable definition of unconscionable or excessive prices must be able to do. First, the standard must advance the government’s purpose in adopting the law. As these laws are motivated by a desire to advance patients’ interests by making medicines more accessible, their application must reach the products posing the greatest financial challenges.<sup>17</sup> Second, the standard must have a strong prospect of surviving legal challenges. Third, it must be feasible to operationalize. It must be measurable using available information and provide useful information about which products regulators should target for enforcement. Fourth, it must be fair to biopharmaceutical companies. As we discuss, fairness considerations are both procedural—the law must put companies on reasonable notice of what will and will not be considered an acceptable pricing decision—and substantive—it must permit companies a reasonable return on their overall investment in research, development, and manufacturing.<sup>18</sup> Finally, it must not be unduly susceptible to gaming by the regulated entities. For example, approaches that focus solely on whether a drug’s launch price is excessive will encourage companies to price the product low on market entry and raise the price steadily over time, and approaches that focus solely on annual price increases can be gamed for new drugs by setting the launch price high.

## I. Excessive-Price Legislation in the Congress and the States

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<sup>16</sup> Fiona Carlin et al., *Recent Pharmaceutical Excessive Pricing Cases in Context*, GCR (Sept. 7, 2017), <https://globalcompetitionreview.com/article/1147163/recent-pharmaceutical-excessive-pricing-cases-in-context>.

<sup>17</sup> In practice “excessive” drug prices may overlap with “unaffordable” drug prices, but it is important to mark these two terms as conceptually distinct. Although affordability may be a good metric for controlling prices, an affordable price may not be a fair price. This is a significant normative vulnerability that also has potentially serious practical implications for innovation incentives. Furthermore, focusing on affordable pricing as opposed to excessive price could conflict with our fourth criterion, fairness to drug manufacturers.

<sup>18</sup> A related concern, voiced by pharmaceutical manufacturers in response to nearly all proposals to curb high drug prices, is that price regulation may dampen incentives for investment in drug innovation, to the long-term detriment of the public. At some level of price constraint, this tradeoff surely must be real; the difficulty is knowing at which level. See Rena M. Conti & Frank S. David, *Rebalancing High Prescription Drug Prices With Innovation Incentives*, Health Affairs Blog (Jul. 1, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190626.569971/full/>; Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273, 2280-82 (2018); NAT’L ACADS. OF SCIS., ENG’G, AND MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 18, 24 (2018). In evaluating potential policy models, this conundrum leads us to shy away from stringent approaches such as hard caps on prices. But given the healthy financial margins enjoyed by many drug companies, we suspect there is some room for price reductions on the most expensive drugs before innovation incentives are seriously jeopardized.

Legislators at both the federal and state levels have been active in proposing a broad range of approaches to address expensive prescription medications.<sup>19</sup> Proposals run the gamut, for instance, from requiring provision of drug samples to facilitate development of generics<sup>20</sup> to prohibiting gag clause provisions that prevent pharmacists from informing patients that a prescription would be cheaper without insurance.<sup>21</sup> A number of measures, however, specifically target instances of apparent “price-gouging,” or “unconscionable” or “excessive” pricing. In this Part, we survey an illustrative sample of recent legislative efforts in this space.<sup>22</sup>

## A. Federal Bills

### 1. Combatting Unreasonable Rises and Excessively (CURE) High Drug Prices Act

The Combatting Unreasonable Rises and Excessively (CURE) High Drug Prices Act was introduced on December 13, 2018 by Richard Blumenthal<sup>23</sup> and reintroduced on February 28, 2019.<sup>24</sup> Although the title of this Act references “unreasonable” and “excessive” prices (and a press release calls such high prices “predatory” and “unconscionable”),<sup>25</sup> the statutory term of choice in S.637 is “price gouging.”<sup>26</sup> The bill provides a general definition of “price gouging” and identifies three situations in which there will be a default presumption that price gouging has occurred.<sup>27</sup> The general definition provides that price gouging is

an increase in the average manufacturer price (AMP) of a qualifying drug that—

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<sup>19</sup> Efforts to address prescription drug affordability are also being made within the executive branch under the White House “Blueprint” for drug costs. *See, e.g.*, DEP’T HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>. However, the White House proposals, unlike the legislative proposals, do not directly target “excessive” drug prices for regulatory action. They are therefore beyond the ambit of our analysis.

<sup>20</sup> Creating and Restoring Equal Access to Equivalent Samples Act of 2017, S. 974, 115th Cong. (2017).

<sup>21</sup> *See* Gudiksen & King, *supra* note 15; Susan Jaffe, *No More Secrets: Congress Bans Pharmacist ‘Gag Orders’ on Drug Prices*, KHN (Oct. 10, 2018), <https://khn.org/news/no-more-secrets-congress-bans-pharmacist-gag-orders-on-drug-prices/>.

<sup>22</sup> Given space constraints and the plethora of bills introduced, we confine our review to legislation defining substantive actions to be taken in response to identified instances of excessive pricing. Though we will not discuss them at length, we acknowledge that an adjacent set of bills—disclosure and transparency laws—are germane to making such laws effective. Transparency laws require biopharmaceutical companies to publicly disclose when their products’ prices exceed a specified threshold. By making available the pertinent data, they serve as handmaidens to laws seeking to take direct action on excessive prices. *See, e.g.*, Zachary Brennan, *Vermont Drug Price Transparency: New Law Calls Out Egregious Price Spikes*, REGULATORY FOCUS (Dec. 6, 2016), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2016/12/vermont-drug-price-transparency-new-law-calls-out-egregious-price-spikes>. Transparency laws have been a popular approach in the states, and in spring 2019 found expression in several federal bills. For example, H.R. 2113, introduced in April 2019, would require the Secretary of Health and Human Services to annually determine whether an applicable drug has experienced a price increase at or above a specified level. Prescription Drug Sunshine, Transparency, Accountability and Reporting Act, H.R. 2113, 116th Cong. (2019).

<sup>23</sup> CURE High Drug Prices Act, S. 3754, 115th Cong. (2018).

<sup>24</sup> CURE High Drug Prices Act, S. 637, 116th Cong. (2019).

<sup>25</sup> *Blumenthal, Harris, Merkley & Klobuchar Introduce Bill to End Predatory Price Gouging On Lifesaving Drugs*, RICHARD BLUMENTHAL (Dec. 13, 2018), <https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-harris-merkley-and-klobuchar-introduce-bill-to-end-predatory-price-gouging-on-lifesaving-drugs>.

<sup>26</sup> S. 637, *supra* note 30.

<sup>27</sup> *Id.* §§ 2(5), 3(b). The Blumenthal bill’s definition of price gouging bears resemblance to the language passed by Maryland’s anti-price gouging law, discussed *infra*.

- (A) is in substantial excess of an amount that could be reasonably justified by an increase in cost of producing the drug or by an increase in cost due to appropriate expansion of access to the drug to promote public health; and
- (B) that because of insufficient competition in the marketplace, consumers cannot reasonably avoid.<sup>28</sup>

The presumption of price gouging is triggered if a drug's AMP has increased 10% or more in the previous 12 months, 20% or more in the previous 36 months, or 30% or more in the previous 60 months.<sup>29</sup> Although standards triggering the presumption of price gouging are clear, the general definition is open to considerable interpretation.

If the Secretary of Health and Human Services (HHS) believes that a manufacturer has engaged in price gouging, she will notify the manufacturer and request a "statement of justification" for the price increase.<sup>30</sup> This statement may include information about the drug's production costs, efforts to expand access to the drug, marketplace competition, and "any other information "that the manufacturer believes to be relevant."<sup>31</sup> Manufacturers have 45 days to respond.<sup>32</sup> If the Secretary determines that there has been a prohibited price increase, she may choose to pursue any of three options—or no action at all.<sup>33</sup> First, the Secretary may disgorge excessive payments and restore them to those who have overpaid.<sup>34</sup> Second, she may order the manufacturer to make the drug available to certain health plans at the pre-gouging price for up to a year.<sup>35</sup> Third, in situations of repeat offenders or where price gouging occurs knowingly, the manufacturer may be compelled to "pay a civil penalty of up to 3 times the excessive amount the manufacturer received as a result of a violation of this Act."<sup>36</sup>

## 2. Stop Price Gouging Act

On February 7, 2019, Senator Brown and two other Democratic Senators introduced the Stop Price Gouging Act, which imposes an excise tax<sup>37</sup> on biopharmaceutical companies for sales of prescription medications experiencing a "price spike."<sup>38</sup> Entities covered by the Act must submit quarterly cost, volume, pricing, revenue, and other information on their prescription drugs to the HHS Inspector General,<sup>39</sup> who reviews this information annually to determine whether a "price-spike" has occurred.<sup>40</sup> A price spike is defined as "an increase in the average manufacturer price in commerce of a prescription drug for which the price spike percentage is equal to or greater than

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<sup>28</sup> *Id.* § 2(5).

<sup>29</sup> *Id.* § 3(b).

<sup>30</sup> *Id.* § 3(c).

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* § 3(d).

<sup>33</sup> *Id.* § 3(f).

<sup>34</sup> *Id.* § 3(f)(1)(A).

<sup>35</sup> *Id.* § 3(f)(1)(B).

<sup>36</sup> *Id.* § 3(f)(1)(C).

<sup>37</sup> Excise taxes are taxes paid on the purchase of a specific good or the conduct of a certain activity (e.g., highway trucking). *Excise Tax*, IRS (May 29, 2019), <https://www.irs.gov/businesses/small-businesses-self-employed/excise-tax>.

<sup>38</sup> Stop Price Gouging Act, S. 378, 116th Cong. (2019). Representative Pocan introduced an identical bill in the House. Stop Price Gouging Act, H.R. 1093, 116th Cong. (2019).

<sup>39</sup> *Id.* § 2(b).

<sup>40</sup> *Id.* § 2(c).



applicable price increase allowance.”<sup>41</sup> In other words, if a drug’s price increases more than an allowable amount—in this case the Chained Consumer Price Index—a price spike has occurred.<sup>42</sup>

Unless one of a series of specific exemptions applies, the Inspector General reports findings to the Internal Revenue Service (IRS),<sup>43</sup> which then imposes a calibrated tax on the offending company. Price spikes of less than 15% above the allotted allowance are subject to a 50% tax on price-spike revenue,<sup>44</sup> those 15-20% above the allowance are taxed at 75%, and those 20% above are taxed at 100%.<sup>45</sup> Different calculations are performed for cumulative price-spike taxes.<sup>46</sup> In summary, the Act is quite clear in its specification of which pricing practices will give rise to which consequences.

### 3. Prescription Drug Price Relief Act of 2019

On January 10, 2019, Senator Sanders and Representative Khanna introduced to the Senate and House, respectively, the Prescription Drug Price Relief Act of 2019.<sup>47</sup> This Act provides that “excessively priced drugs” will lose their government-granted market exclusivities.

To determine whether a brand-name drug’s domestic price is excessive, the HHS Secretary must review all brand-name drugs at least annually.<sup>48</sup> The Act sets forth two ways in which a drug may be excessively priced: (1) if the “domestic average manufacturing price exceeds the median price charged for such drug in Canada, the United Kingdom, Germany, France, and Japan”<sup>49</sup> or (2) if, based on consideration of a number of factors, the Secretary judges the drug’s price to be “higher than reasonable.”<sup>50</sup> The Act’s enumerated factors run the gamut from the specific (e.g., patient population size, government investment in R&D) to the very open-ended (“[o]ther factors the Secretary determines appropriate”).<sup>51</sup> Any person may petition the Secretary “to make an excessive drug price determination for an applicable drug” under this second category, and the Secretary must respond within 90 days.<sup>52</sup>

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<sup>41</sup> *Id.* § 2(a)(6).

<sup>42</sup> *Id.* § 2(a)(6)(C).

<sup>43</sup> *Id.* § 2(e).

<sup>44</sup> *Id.* § 4192 (b)(2)(A).

<sup>45</sup> *Id.* § 4192 (b)(2)(B)(C).

<sup>46</sup> *Id.* § 4192 (c).

<sup>47</sup> Prescription Drug Relief Act, S. 102, 116th Cong. (2019); Prescription Drug Relief Act, H.R. 465, 116th Cong. (2019).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* § 2(b)(1). Another bill proposed by Sen. Rick Scott, the “Transparent Drug Pricing Act of 2019,” would create an “International Retail List Price Index” which would prohibit a U.S. retail list price from exceeding the “lowest retail list price for the drug among Canada, France, the United Kingdom, Japan, or Germany.” S. 977, 116th Cong. (2019).

<sup>50</sup> S. 102, *supra* note 47, at § 2(b)(2).

<sup>51</sup> The full list of factors to be considered is as follows: “(A) The size of the affected patient population. (B) The value of the drug to patients, including the impact of the price on access to the drug and the relationship of the price of the drug to its therapeutic health benefits. (C) The risk adjusted value of Federal Government subsidies and investments related to the drug. (D) The costs associated with development of the drug. (E) Whether the drug provided a significant improvement in health outcomes, compared to other therapies available at the time of its approval. (F) The cumulative global revenues generated by the drug. (G) Whether the domestic average manufacturer price of the drug increased during any annual quarter by a percentage that is more than the percentage increase in the consumer price index for all urban consumers for the respective annual quarter. (H) Other factors the Secretary determines appropriate.” *Id.*

<sup>52</sup> *Id.* § 2(c).

For those drugs identified as excessively priced, the Secretary “shall waive or void any government-granted exclusivities,” and “shall grant open, non-exclusive licenses” to others.<sup>53</sup> The impacted exclusivities fall under various sections of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, but also include “[a]ny other provision of law that provides for exclusivity (or extension of exclusivity) with respect to a drug.”<sup>54</sup> The bill has additional provisions governing reasonable royalties to be paid from licensees to those who have lost their exclusivities,<sup>55</sup> the establishment of a database of brand-name drugs and excessive price determinations,<sup>56</sup> and reporting requirements for both the Secretary and drug manufacturers.<sup>57</sup>

The bill’s definition of excessive price is an unusual hybrid of clear and opaque measures. The international reference pricing standard is relatively straightforward (although disputes may arise about how to calculate the price in foreign countries), but the “higher than reasonable” standard is not. Although the legislation provides specific considerations to be weighed in determining whether a price is “higher than reasonable,” the breadth of these factors and lack of direction as to how to weigh them against one another (in the absence of clarifying regulations) leaves considerable room for discretion.

#### 4. Affordable Drug Manufacturing Act of 2018

On December 18, 2018, Senator Warren introduced S. 3775, the Affordable Drug Manufacturing Act of 2018.<sup>58</sup> This bill would create an Office of Drug Manufacturing within HHS that would either manufacture generic medications itself or contract with others when it determines (1) a drug is “not readily available from existing suppliers,” (2) it would facilitate market entry of other generics, or (3) it is “necessary for the Office to carry out its duties.”<sup>59</sup> The Act aims to increase competition, reduce prices, address shortages, and “increase patient access to affordable drugs.”<sup>60</sup> Rather than identify and penalize offending conduct, this bill seeks to ameliorate the conditions which make excessive pricing possible—namely, limited competition.<sup>61</sup>

The provisions pertaining to insulin are of particular interest. The Act requires that within a year of enactment, the Secretary must manufacture certain insulins.<sup>62</sup> These include insulins with no current market exclusivities and less than three manufacturers for the U.S. market that in the

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<sup>53</sup> *Id.* § 3. Other federal bills have taken similar approaches. For example, the “FLAT Prices Act,” introduced in February 2019 in both the Senate and the House, identifies three threshold price increases for which a drug manufacturer loses 180 days of market exclusivities. FLAT Prices Act § 2 (a)(1), (b), S. 366, 116th Cong. (2019). It further provides that for each five percent price increase in WAC over those three identified thresholds, certain market exclusivities “shall be reduced for an additional 30 days.” *Id.* § 2(a)(2).

<sup>54</sup> *Id.* § 8(5).

<sup>55</sup> *Id.* § 4.

<sup>56</sup> *Id.* § 5.

<sup>57</sup> *Id.* §§ 5(b), 6.

<sup>58</sup> Affordable Drug Manufacturing Act of 2018, S. 3775, 115th Cong. (2d Sess. 2018); Affordable Drug Manufacturing Act of 2018, H.R. 7348, 115th Cong. (2d Sess. 2018).

<sup>59</sup> *Id.* § 310B.

<sup>60</sup> *Id.* § 310B(a)(2).

<sup>61</sup> See Warren, Schakowsky Introduce Bicameral Legislation to Radically Reduce Drug Prices Through Public Manufacturing of Prescription Drugs, ELIZABETH WARREN (Dec. 18, 2018), <https://www.warren.senate.gov/newsroom/press-releases/warren-schakowsky-introduce-bicameral-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs> (calling the bill “an ambitious proposal to address the skyrocketing price of prescription drugs”); Elizabeth Warren, *It’s Time to Let the Government Manufacture Generic Drugs*, WASH. POST (Dec. 18, 2018), [https://www.washingtonpost.com/opinions/elizabeth-warren-its-time-to-let-the-government-manufacture-generic-drugs/2018/12/17/66bc0fb0-023f-11e9-b5df-5d3874f1ac36\\_story.html?utm\\_term=.d66ed26300b4](https://www.washingtonpost.com/opinions/elizabeth-warren-its-time-to-let-the-government-manufacture-generic-drugs/2018/12/17/66bc0fb0-023f-11e9-b5df-5d3874f1ac36_story.html?utm_term=.d66ed26300b4).

<sup>62</sup> S. 3775, *supra* note 58, § 310B(d).

previous twelve months have had a price hike above the Consumer Price Index for Medical Care.<sup>63</sup> This definition of a trigger price for regulatory action is quite clear.

## 5. Low Drug Prices Act

Senator Merkley introduced the Low Drug Prices Act on November 29, 2018.<sup>64</sup> This bill implicitly addresses the problem of excessive pricing through reference pricing. S.3680 requires HHS to “establish annual reference prices,”<sup>65</sup> and mandates that the total acquisition costs of prescription drugs for federal health programs cannot exceed those reference prices.<sup>66</sup> The total acquisition cost is the amount paid by the federal program plus the amount paid by the patient, after discounts and rebates.<sup>67</sup> Reference prices are set using the median price of the drug sold in specified foreign countries (Japan, Germany, the United Kingdom, France, Italy, Canada, Australia, Spain, the Netherlands, Switzerland, and Sweden).<sup>68</sup> Further, the bill conditions reimbursement of a drug in federal health programs on drug manufacturers offering the reference price to all buyers, including the uninsured and patients with commercial and individual health plans.<sup>69</sup>

### B. State Bills and Enacted Legislation

Although the Congress has only recently become a locus of bills addressing excessively-priced prescription drugs, states (and the District of Columbia) have been active in this space for several years.<sup>70</sup> In the first half of 2019, 268 bills were filed at the state level to address prescription drug costs.<sup>71</sup> In 2018, “forty-four states considered 227 bills to address rising drug costs, of which 55 became laws in thirty-two states.”<sup>72</sup> In what follows, we survey two key strategies states have pursued to directly target excessive pricing: anti-price-gouging laws and rate-setting laws.

#### 1. Price-gouging Laws

As we describe further below, state price-gouging statutes are a common legislative fixture for addressing steep price increases on necessary goods during emergency situations.<sup>73</sup> Recently, this approach has been applied to prescription drugs. During the 2018 legislative session, fifteen states considered anti-gouging legislation specific to medicines.<sup>74</sup> Thus far, 2019 has seen four prescription

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<sup>63</sup> *Id.* § 310B(e)(ii)(I).

<sup>64</sup> Low Drug Prices Act, S. 3680, 115th Cong. (2d Sess. 2018).

<sup>65</sup> *Id.* § 2(a).

<sup>66</sup> *Id.* § 2(a).

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* § 2(b)(2).

<sup>69</sup> *Id.* § 2(d) (stating that manufacturers “as a condition for receiving reimbursements under any of the Federal programs . . . shall offer prescription drugs at the reference price to all individuals, including individuals who are not insured and individuals who are covered under a group health plan or group or individual health insurance coverage.”).

<sup>70</sup> See, e.g., Gudiksen & King, *supra* note 15; NASHP, *State Legislative Action to Lower Pharmaceutical Costs*, (July 8, 2019), <https://nashp.org/rx-legislative-tracker-2019/>.

<sup>71</sup> Data are current as of June 27, 2019. See *id.*

<sup>72</sup> Katie Gudiksen, *Spotlight on 2018 State Drug Legislation Summary: The Year in Review*, THE SOURCE (Feb. 4, 2019), <http://sourceonhealthcare.org/spotlight-on-2018-state-drug-legislation-summary-the-year-in-review/>.

<sup>73</sup> See *infra* Part III.A.

<sup>74</sup> Gudiksen & King, *supra* note 15, at 11; Gudiksen, *Spotlight on 2018 State Drug Legislation Summary*, *supra* note 72; Nat’l Acad. for State Health Policy, *State Prescription Drug Tracker 2018* (2018), <https://nashp.org/wp-content/uploads/2018/01/Rx-Legislative-Tracker-Update-9.5.2018.pdf>.

drug price-gouging bills introduced in three states.<sup>75</sup> These bills all prohibit unconscionable or excessive prices for prescription drugs, with varying definitions of the excessive price and varying scope of covered drugs.

These laws have faced formidable constitutional challenges.<sup>76</sup> The District of Columbia's excessive-price prohibition for patented medications was struck down by the Federal Circuit on patent preemption grounds.<sup>77</sup> Likewise, a decade later, Maryland's price-gouging law for generic drugs, HB 631, hailed as a "first-in-the-nation state law,"<sup>78</sup> was invalidated on dormant Commerce Clause grounds by the Fourth Circuit.<sup>79</sup> Even before HB 631's defeat, the legal challenge to it appears to have had a "chilling effect on pharmaceutical price gouging laws"<sup>80</sup>: of the fifteen price-gouging bills considered in 2018, none were enacted.<sup>81</sup> Ten of these bills used similar language to HB 631, including their definitions of "unconscionable increase."<sup>82</sup>

These setbacks are palpable, but they are not necessarily definitive. Though the Supreme Court declined to grant certiorari in the Maryland case, no prescription price-gouging legislation has yet been reviewed beyond the Courts of Appeals. As others point out, if legislation similar to Maryland's were enacted by a different state and challenged in another circuit reaching a different result, a circuit split might encourage Supreme Court review.<sup>83</sup> Even if these statutes pass muster under the dormant Commerce Clause, however, a lingering sticking point for price-gouging prohibitions will be defining key terms such as "excessive" or "unconscionable" in a manner that avoids a void-for-vagueness challenge.<sup>84</sup> That issue has not yet been fully litigated.

This Section details the rise and fall of the two most notable state prescription drug price-gouging statutes—the District of Columbia's Prescription Drug Excessive Pricing Act of 2005 and Maryland's Prohibition Against Price Gouging for Essential off-Patent or Generic Drugs—and then briefly reviews price-gouging bills introduced in other states, many of which follow Maryland's template. The efforts of the District of Columbia and Maryland are interesting foils to one another. Each tackled a different segment of excessive pricing problems—patented medications versus generics—and each had a distinct approach for identifying problematic pricing as well as enforcement. These differences had implications for the kind of legal challenges that would ultimately be their downfall.

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<sup>75</sup> *State Legislative Action to Lower Pharmaceutical Costs*, *supra* note 71.

<sup>76</sup> See, e.g., Dana A. Elfin, *Spiked Maryland Rx Pricing Law Could Kill Similar Efforts*, BLOOMBERG LAW (Apr. 16, 2018), <https://news.bloomberglaw.com/pharma-and-life-sciences/spiked-maryland-rx-pricing-law-could-kill-similar-efforts?context=article-related>.

<sup>77</sup> *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362 (Fed. Cir. 2007). Although the District of Columbia is not a state, it is treated as such by the Federal Circuit opinion. *Id.* at 1371-72.

<sup>78</sup> Darien Shanske & Jane Horvath, *Maryland's Generic Drug Pricing Law Is Constitutional: A Recent Decision Misunderstands the Structure of the Industry*, HEALTH AFFAIRS (June 22, 2018),

<https://www.healthaffairs.org/doi/10.1377/hblog20180621.752771/full/>; Lucas Allen, *Demanding Affordable Medicines: Lessons From Maryland's Law Against Price Gouging*, TRUTHOUT (Sept. 18, 2017), <https://truthout.org/articles/demanding-affordable-medicines-lessons-from-maryland-s-law-against-price-gouging/> ("Maryland's passage of HB 631 is one of a few victories in state drug-pricing legislation over the past year.").

<sup>79</sup> *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

<sup>80</sup> Gudiksen, *Spotlight on 2018 State Drug Legislation Summary*, *supra* note 72.

<sup>81</sup> *Id.*

<sup>82</sup> Katie Gudiksen, *Spotlight on 2018 State Drug Legislation Summary: Part 4 – Price Gouging Prohibitions*, THE SOURCE (Sept. 11, 2018), <http://sourceonhealthcare.org/spotlight-on-2018-state-drug-legislation-part-4-price-gouging-prohibitions>.

<sup>83</sup> *Id.*

<sup>84</sup> See Robertson, *supra* note 15, at 1001 ("Under any such policy, it will remain difficult and contentious to determine what is and is not an 'unconscionable' price and to set the amount of any required rebate.").

a. *D.C.’s Prescription Drug Excessive Pricing Act of 2005*

More than a decade before the recent spate of state legislative efforts to control prescription drug costs, the District of Columbia led the field with the Prescription Drug Excessive Pricing Act of 2005.<sup>85</sup> This Act was passed based on findings that “the excessive prices of prescription drugs” was “threatening the health and welfare of the residents of the District”.<sup>86</sup> The legislation focused specifically on patented medications, and the tool it utilized was a price cap. The Act prohibited drug manufacturers and licensees from selling patented medications in the District of Columbia for an excessive price, stating, “It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.”<sup>87</sup>

As with several of the federal proposals already discussed, the law defined an “excessive price” by reference to prices paid in high-income foreign countries.<sup>88</sup> It established a *prima facie* case of excessive pricing if the wholesale price of a patented medication was more than 30% higher than that medicine’s price “in any high income country in which the product is protected by patents or other exclusive marketing rights.”<sup>89</sup> The United Kingdom, Germany, Canada, and Australia served as reference countries.<sup>90</sup>

Once a *prima facie* case was established, a defending manufacturer or rights-holder would have the opportunity to rebut the presumption of price gouging by providing evidence of the

demonstrated costs of invention, development and production of the prescription drug, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia.<sup>91</sup>

The Act provided that “any affected party” had standing to file a civil enforcement suit, and a finding of excessive pricing could yield injunctive relief, fines, damages (including treble damages), attorneys fees, litigation costs, or “[a]ny other relief the court deems proper.”<sup>92</sup>

BIO and PhRMA challenged the Act, claiming that it was invalid under the Commerce Clause and preempted by federal patent law.<sup>93</sup> The District Court for the District of Columbia found that the Act violated the dormant Commerce Clause as applied to transactions not within the District’s borders,<sup>94</sup> and further ruled it preempted by patent law.<sup>95</sup> The patent issue was appealed, eventually landing before the Federal Circuit Court of Appeals. The Federal Circuit affirmed and enjoined the Act’s enforcement, deeming it to be conflict preempted.<sup>96</sup> It explained that “by penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives

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<sup>85</sup> D.C. CODE § 28-4551 (2019).

<sup>86</sup> *Id.* § 28-4551(1).

<sup>87</sup> *Id.* § 28-4553.

<sup>88</sup> *Id.* § 28-4552(2).

<sup>89</sup> *Id.* § 28-4554(a).

<sup>90</sup> *Id.* § 28-4552(2).

<sup>91</sup> *Id.* § 28-4554(b).

<sup>92</sup> *Id.* § 28-4555.

<sup>93</sup> *Biotechnology Indus. Org.*, 496 F.3d at 1366.

<sup>94</sup> *Id.* For a discussion of dormant Commerce Clause doctrine, see *infra* section II.B.1.b.

<sup>95</sup> *Biotechnology Indus. Org.*, 496 F.3d at 1366.

<sup>96</sup> *Id.* Conflict preemption occurs when state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Id.* at 1372, citing *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

from a patent,” the Act impermissibly tinkered with the balance set by Congress in the patent system between incentives for invention and public access to patented products.<sup>97</sup>

Although much about this ruling invites further inquiry, if not skepticism,<sup>98</sup> the issue was not appealed to the U.S. Supreme Court. The ruling appears to have had a chilling effect on states’ interest in attempting to regulate high-priced, on-patent medications through price caps. Importantly, however, although the decision appears to foreclose state efforts to regulate the prices at which patented medications may be sold, it does not appear to reach initiatives that regulate what payers will pay for patented medications. Thus, rate-setting proposals, discussed below, appear unaffected by the ruling, as long as they do not raise dormant Commerce Clause or other constitutional concerns.<sup>99</sup> Moreover, the decision does not reach regulation of off-patent or generic medications.

*b. Maryland’s Prohibition Against Price Gouging for Essential off-Patent or Generic Drugs*

Given the invalidation of the District of Columbia’s earlier effort to regulate the prices of patented medications, it is unsurprising that subsequent state-level price-gouging bills went in a different direction: generics. Of notable importance is Maryland’s HB 631, which was struck down in 2018.

On May 25, 2017, Maryland enacted HB 631, entitled “Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs.”<sup>100</sup> Leaving patented medications aside, Maryland’s legislation focused on off-patent or generic medications for which all federal exclusivities—patent or otherwise—had expired.<sup>101</sup> Further, it only covered medications deemed “essential” and produced by “three or fewer manufacturers.”<sup>102</sup> HB 631’s anti-gouging prohibition stated that “A manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug.”<sup>103</sup>

A further distinction between the District of Columbia’s law and Maryland’s is the metrics for determining an excessive price. While the District of Columbia used foreign reference pricing plus a 30% markup as a benchmark, Maryland’s key terms were not defined quantitatively.<sup>104</sup> Instead, borrowing terminology from the common-law doctrine of unconscionability,<sup>105</sup> HB 631 defined

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<sup>97</sup> *Id.* at 1374.

<sup>98</sup> See, e.g., Joshua D. Sarnoff, *BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation*, PATENTLYO (Aug. 2, 2007), <https://patentlyo.com/lawjournal/2007/08/bio-v-dc-and-th.html>.

<sup>99</sup> See Feldman et al., *supra* note 14, at 49-50.

<sup>100</sup> *Legislation by Session: 2017*, GENERAL ASSEMBLY OF MARYLAND (Nov. 28, 2017), <http://mgaleg.maryland.gov/webmga/frnMain.aspx?pid=billpage&stab=03&id=HB0631&tab=subject3&ys=2017rs>.

<sup>101</sup> MD. CODE ANN., HEALTH-GEN. § 2-801(b)(1) (West 2019).

<sup>102</sup> *Id.* Three seems to be minimum number of manufacturers required for a reasonably well-functioning generic market. See NAT’L ACADS. OF SCIS., ENG’G, AND MED., *supra* note 18, at 77 (“If only a single generic producer enters the market, it does not necessarily reduce prices . . . . It may take several competing generic companies to enter the market [for prices to reach their lowest level].”).

<sup>103</sup> HEALTH-GEN. § 2-802(a).

<sup>104</sup> This was done “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.” Memorandum in Support of Defendants’ Motion to Dismiss at 32, *Ass’n for Accessible Meds. v. Frosh*, No. 17-cv-1860, 2017 WL 4347818 (D. Md. Sept. 29, 2017), 2017 WL 9438490 [hereinafter *Frosh* Motion to Dismiss].

<sup>105</sup> See, e.g., *id.* at 31 (“[T]he 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.”); *id.* at 3 (“HB 631 closely tracks the common law doctrine of unconscionability, which predates the Constitution itself.”).

“price-gouging” in terms of an “unconscionable increase.”<sup>106</sup> “Unconscionable increase” was in turn 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.<sup>107</sup>

Although this definition, on its face, leaves considerable room for interpretation as to what counts as an “unconscionable increase,” it is rendered more concrete when read in conjunction with HB 631’s notification provisions. HB 631 endows the Attorney General with enforcement powers (another departure from the District of Columbia’s statute),<sup>108</sup> and enforcement can begin<sup>109</sup> with notification of a price increase to Maryland’s Attorney General by the Maryland Medical Assistance Program.<sup>110</sup> The Maryland Medical Assistance Program can only notify the Attorney General, however, of certain price increases.<sup>111</sup> Among these increases are those where the increase “by itself or in combination” results in a 50% or greater increase in the WAC within the past year, or relates to drugs with a WAC over \$80 for defined periods of time, dosing, or treatment course.<sup>112</sup> Although the notification provisions specify which price is to be examined (the WAC, which approximates the list price of the drug), the more general definition of excessive price gives no such specification.

Once notification of a price increase is received, the Attorney General has discretion to choose a path forward, if at all.<sup>113</sup> One option is turning to Maryland’s courts for relief.<sup>114</sup> Available remedies include an injunction, restoration of money acquired through prohibited pricing to consumers and payers, restrictions on future pricing available to state health programs, and civil penalties of up to \$10,000 per violation.<sup>115</sup>

Dismayed with the passage of this legislation, the trade association representing generic manufacturers, the AAM, sued. It advanced two main claims: that HB 631 violated the dormant Commerce Clause, and that it was unconstitutionally vague, in violation of the Due Process Clause of the Fourteenth Amendment.<sup>116</sup> AAM argued that HB 631 violated the dormant Commerce

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<sup>106</sup> HEALTH-GEN. § 2-801(c).

<sup>107</sup> *Id.* § 2-801(f); *see also* *Frosh*, 2017 WL 4347818, at \*9, *rev’d*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

<sup>108</sup> HEALTH-GEN. § 2-803.

<sup>109</sup> We say “can begin” because it is unclear if enforcement *must* begin with notification. Furthermore, the District Court observed: “Although HB 631’s reporting provision could serve as a benchmark, it does not appear to be binding on the Attorney General.” *Frosh*, 2017 WL 4347818, at \*10 (citing HEALTH-GEN. § 2-803(a)).

<sup>110</sup> HEALTH-GEN. § 2-803.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

<sup>115</sup> *Id.*

<sup>116</sup> Complaint for Declaratory and Injunctive Relief at 23-27, *Ass’n for Accessible Meds. v. Frosh*, No. 17-cv-1860, 2017 WL 4347818 (D. Md. Sept. 29, 2017), 2017 WL 2884401 [hereinafter *Ass’n for Accessible Meds. Complaint*].

Clause because it reached transactions occurring wholly outside the State of Maryland, and with respect to vagueness, it argued that several of the legislation’s key terms including “unconscionable increase” and “excessive” were impermissibly unclear as to proscribed conduct.<sup>117</sup> Maryland filed a motion to dismiss.<sup>118</sup>

On September 29, 2017, the District Court granted Maryland’s motion in part and denied it in part.<sup>119</sup> (It further denied AAM’s motion for a preliminary injunction.<sup>120</sup>) The Court dismissed the dormant Commerce Clause claim but preserved the vagueness claim.<sup>121</sup> AAM appealed,<sup>122</sup> and the Fourth Circuit reversed the dismissal of the dormant Commerce Clause claim and invalidated the statute on that basis.<sup>123</sup>

The dormant Commerce Clause doctrine, a corollary of the Commerce Clause,<sup>124</sup> holds that states cannot interfere with or burden interstate commerce.<sup>125</sup> Its purpose is to guard against economic protectionism and state legislation that privileges in-state parties at the expense of similarly situated out-of-state competitors.<sup>126</sup>

Dormant Commerce Clause jurisprudence provides several different routes for evaluating whether state legislation runs afoul of its prohibitions.<sup>127</sup> A historically small corner of this analysis,<sup>128</sup> the extraterritoriality principle played a central role in the Fourth Circuit’s decision. The Fourth Circuit articulated two ways state legislation could violate this principle: “if it either expressly applies to out-of-state commerce, or has that ‘practical effect,’ regardless of the legislature’s intent.”<sup>129</sup> Whereas the District Court had rejected an interpretation of the extraterritoriality principle as “stand[ing] for the much broader proposition that a regulation that has effects outside the state is per se invalid,”<sup>130</sup> that appears to be precisely the interpretation embraced by the Fourth Circuit. Given that HB 631’s prohibition against unconscionable increases applied to sales by manufacturers and wholesalers, the statute would reach transactions occurring outside of Maryland.<sup>131</sup> The Fourth Circuit concluded:

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<sup>117</sup> *Id.*

<sup>118</sup> Frosh Motion to Dismiss, *supra* note 104.

<sup>119</sup> *Frosh*, 2017 WL 4347818, at \*15.

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Association for Accessible Medicines v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

<sup>127</sup> *Ass’n for Accessible Meds. v. Frosh*, No. 17-cv-1860, 2017 WL 4347818, at \*3-4 (D. Md. Sept. 29, 2017), *rev’d*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019) (laying out a “two-tiered” analysis of per se violations and a balancing test under *Pike v. Bruce Church*, plus a third “emerging” strand of cases formulating an extraterritoriality principle). The *Pike* balancing test, however, has become disfavored, though not yet invalidated by the Supreme Court. *See Dep’t of Revenue of Kentucky v. Davis*, 553 U.S. 328 (2008); *United Haulers Ass’n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330 (2007).

<sup>128</sup> *Frosh*, 887 F.3d at 681 (Wynn, J., dissenting) (stating that the extraterritoriality principle “has been characterized by our sister circuits as the ‘the most dormant’ of the Supreme Court’s dormant Commerce Clause”).

<sup>129</sup> *Id.* at 668 (citations omitted).

<sup>130</sup> *Frosh*, 2017 WL 4347818, at \*6 (“[I]f 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?” (quoting *Energy & Env’t Legal Inst. v. Epel*, 793 F.3d 1169, 1175 (2015))).

<sup>131</sup> *Frosh*, 887 F.3d at 672-73.



The Act instructs prescription drug manufacturers that they are prohibited from charging an “unconscionable” price in the initial sale of a drug, which occurs outside Maryland’s borders. Maryland cannot, even in an effort to protect its consumers from skyrocketing prescription drug costs, impose its preferences in this manner. The “practical effect” of the Act...is to specify the price at which goods may be sold beyond Maryland’s borders.<sup>132</sup>

The Court found the argument that the statute *only* reached upstream transactions for drugs made for sale in Maryland unavailing.<sup>133</sup> Despite the states’ and even AAM’s understanding of the statute as only implicating drugs made for eventual sale in Maryland, the Court found that HB 631 could reach transactions that had no nexus to drug sales in the state.<sup>134</sup> Maryland’s petition for a rehearing en banc was denied,<sup>135</sup> as was its petition for certiorari to the Supreme Court.<sup>136</sup> Thus, its price-gouging law remains void until such time that it is reworked to be consistent with the Fourth Circuit’s ruling. Because the vagueness argument was not fully litigated, it remains a viable basis for legal challenges to future statutes like HB 631.

### *c. Other State Price-Gouging Laws*

The efforts of District of Columbia and Maryland are the most notable state level experiments with utilizing excessive price and price-gouging legislation. Maryland’s legislation, in particular, has been remarkably influential. As noted above, of the fifteen prescription drug price-gouging proposals introduced during the 2018 legislative session, ten included language drawn from or identical to HB 631.<sup>137</sup> Further, all of the 2019 price-gouging bills under consideration—Indiana’s SB 415,<sup>138</sup> New Jersey’s S2630<sup>139</sup> and S1590,<sup>140</sup> and Virginia’s SB 1308<sup>141</sup>—are identical or nearly identical to HB 631’s key language and requirements.

Although most state price-gouging legislation is modeled after Maryland’s, there are some departures. Rhode Island’s H 7022, for instance, hewed closely to traditional price-gouging statutes for times of emergency.<sup>142</sup> Contemplating situations of drug shortage, it only applied during a “market emergency” declared by the governor or President, and then only for six months.<sup>143</sup> Price gouging is measured by comparing average prices (prior to rebates and discounts being applied) of drugs sold before and during the emergency to determine whether a “gross disparity” exists.<sup>144</sup> Another example is New York’s S5262,<sup>145</sup> which would have amended New York’s business law to prohibit price gouging of prescription medications subject to shortages. Specifically, S 5262 provided that “No party within the chain of distribution of any drug subject to a shortage shall sell or offer to sell any such drug subject to a shortage for an amount which represents an unconscionably excessive

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<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 672.

<sup>134</sup> *Id.* at 678-79 (Wynn, J., dissenting).

<sup>135</sup> *Ass’n for Accessible Meds. v. Frosh*, 742 F. App’x 720 (4th Cir. 2018).

<sup>136</sup> *Frosh v. Ass’n for Accessible Meds.*, 139 S. Ct. 1168 (2019).

<sup>137</sup> For a state-by-state summary of laws introduced in 2018, see Gudiksen, *supra* note 82.

<sup>138</sup> S.B. 415, 121st Gen. Assemb., 1st Reg. Sess. (Ind. 2019).

<sup>139</sup> S.B. 2630, 218th Leg. (N.J. 2018).

<sup>140</sup> S.B. 1590, 218th Leg. (N.J. 2018).

<sup>141</sup> S.B. 1306, 2019 Gen. Assemb. (Va. 2019).

<sup>142</sup> H. 7022, 2018 Gen. Assemb. (R.I. 2018).

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> S. 5262, 2017 Leg., Reg. Sess. (N.Y. 2017).

price.”<sup>146</sup> The bill provided that a determination of “unconscionably excessive is a question of law for the court,”<sup>147</sup> but provided some guideposts: courts should consider disparities between the price after and before the shortage began, or between prices charged by the same seller to different purchasers. The legislation did not specify which price should be assessed.

In summary, price-gouging laws have been a fairly popular approach for states, with Maryland in particular inspiring a number of imitators. Given the discouraging litigation outcomes concerning these early laws, however, continued policymaking momentum in this area requires finding ways around patent preemption and dormant Commerce Clause challenges—for example, imposing price-gouging prohibitions on patented drugs via federal rather than state legislation, and focusing on within-state transactions for state laws that prohibit excessive prices for off-patent drugs. And such laws may continue to be confronted with vagueness challenges, as we describe further in Part II, necessitating careful drafting of statutory definitions of excessive price.

## 2. Rate-Setting Laws

There is growing interest among states in using rate setting by “drug affordability boards” to address unconscionable pricing.<sup>148</sup> This approach does not restrict drug prices per se, but rather sets an upper limit on the amount that specified drug purchasers in the state will pay.<sup>149</sup> In 2018, seven states considered bills along these lines;<sup>150</sup> as of the first quarter of 2019, thirteen bills were pending in seven states.<sup>151</sup> In the highest-profile legislative victories to date, rate-setting legislation known as HB 768 was passed by the Maryland legislature in April 2019,<sup>152</sup> and similar legislation, LD 1499, was passed in Maine two months later.<sup>153</sup>

Early permutations of rate setting in the prescription drug space, proposed by ballot initiatives in California and Ohio, would have imposed a price ceiling for state government payers, such as state employee health insurance plans.<sup>154</sup> That price ceiling was keyed to the prices paid by the United States Department of Veteran’s Affairs, which receives a statutory discount of 24% “off

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<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> Ed Silverman, *If the States Don’t Treat Pharma as a Utility, It May Be ‘Lights Out’ For Too Many Patients*, STAT (Apr. 25, 2019), <https://www.statnews.com/2019/04/25/states-pharma-utility-price-caps-patients/>; see also Jane C. Horvath & Gerard F. Anderson, *The States as Important Laboratories for Federal Prescription Drug Cost-Containment Efforts*, 321 JAMA 1561 (2019) (describing initiatives in Maryland and other states to establish “all-payor upper payment limits” for select high-cost drugs).

<sup>149</sup> Horvath & Anderson, *supra* note 148, at 1561.

<sup>150</sup> Gudiksen, *Spotlight on 2018 State Drug Legislation Summary*, *supra* note 72.

<sup>151</sup> *Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, NASHP (Mar. 19, 2019), <https://nashp.org/comparison-of-bills-creating-state-prescription-drug-affordability-review-boards/> (noting that New Jersey’s proposal caps prices rather than sets payment or reimbursement rates).

<sup>152</sup> Prescription Drug Affordability Board Act, ch. 692, 2019 Md. Laws 692; Lev Facher, *Pharma Lobbyists Flooded Maryland to Block a Drug-Pricing Bill. Opponents Pushed Back—and Won.*, STAT (Apr. 11, 2019), <https://www.statnews.com/2019/04/11/pharma-lobbyists-flooded-maryland-to-block-a-drug-pricing-bill-opponents-pushed-back-and-won/>.

<sup>153</sup> An Act to Establish the Maine Prescription Drug Affordability Board, ch. 471, 2019 Me. Laws 471.

<sup>154</sup> *California Proposition 61, Drug Price Standards (2016)*, BALLOTEDIA, [https://ballotpedia.org/California\\_Proposition\\_61\\_Drug\\_Price\\_Standards\\_\(2016\)](https://ballotpedia.org/California_Proposition_61_Drug_Price_Standards_(2016)) (last visited June 30, 2019); *Ohio Issue 2, Drug Price Standards Initiative (2017)*, BALLOTEDIA, [https://ballotpedia.org/Ohio\\_Issue\\_2\\_Drug\\_Price\\_Standards\\_Initiative\\_\(2017\)](https://ballotpedia.org/Ohio_Issue_2_Drug_Price_Standards_Initiative_(2017)) (last visited June 30, 2019).

of the non-federal AMP<sup>155</sup> plus additional, negotiated rebates.<sup>156</sup> The Ohio Drug Price Relief Act and its California cousin both failed at the polls.<sup>157</sup>

The general mechanism in rate-setting proposals is the creation of a board that is empowered to review drug prices and set upper payment limits. These bills also often incorporate transparency provisions requiring drug manufacturers to submit information pertaining to price increases and launch prices.<sup>158</sup> Some proposals frame rate setting as triggered by drugs that present an “affordability challenge,”<sup>159</sup> but many are explicitly concerned with regulating “excessive” prices—including the influential model legislation proposed by the National Academy for State Health Policy (NASHP).<sup>160</sup> The model legislation seeks to “protect State residents, state and local governments (including their contractors and vendors), commercial health plans, providers, state-licensed pharmacies, and other health care system stakeholders from excessive costs of certain prescription drugs.”<sup>161</sup>

Many states have proposed legislation following this approach.<sup>162</sup> Their provisions commonly include setting out criteria for a board or commission’s makeup, identifying triggering requirements for which drugs will be subject to potential cost review, identifying information required from manufacturers, establishing policies for public disclosure, determining which drugs based on submitted information will be subject to a maximum payment allowance, establishing criteria for setting payments, and specifying enforcement provisions.<sup>163</sup> Oregon’s rate-setting bill, HB 2696, for instance, is specifically structured to set rates for drugs imposing excess costs. It provides: “If the Drug Cost Review Commission finds, based on a drug cost review, that the cost of a prescription drug will result in excess costs for payers in this state, the commission shall establish the maximum payment rate that may be claimed for the drug...”<sup>164</sup> HB 2696 further defines “excess costs” as either exceeding “the cost of alternative treatment options with equivalent therapeutic benefits” or imposing costs that are “not financially sustainable for public and private health care systems over a period of 10 years.”<sup>165</sup>

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<sup>155</sup> Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2338 (2018) (citing 38 U.S.C. § 8126(a)(2) (2012)).

<sup>156</sup> Catherine Candisky & Megan Henry, *Ohioans Nix Controversial Drug-Price Issue*, COLUMBUS DISPATCH (Nov. 8, 2017 5:54 AM), <https://www.dispatch.com/news/20171107/ohioans-nix-controversial-drug-price-issue>.

<sup>157</sup> *Id.* For further thoughts about why such initiatives may not work well, see Sachs, *supra* note 155.

<sup>158</sup> See, e.g., *Drug Rate Setting Model Act Overview*, NASHP, <https://nashp.org/wp-content/uploads/2018/08/Rate-Setting-Model-Act-Explanation-final.pdf> (last visited June 26, 2019) (discussing NAHSP’s Model Act and stating “[t]he reporting requirements in this section parallel the NASHP Transparency Model Act, which requires reporting for drugs priced at or above specific thresholds.”).

<sup>159</sup> See, e.g., H.B. 768, 2019 Gen. Assemb. (Md. 2019).

<sup>160</sup> *An Act to Establish Rate Setting of Prescription Drugs in [State]*, NASHP, <https://nashp.org/wp-content/uploads/2018/08/NASHP-RX-Rate-Setting-Model-Act.pdf> (last visited June 28, 2019) [hereinafter NASHP Model Rate Setting Law]. Some discuss both affordability and excessive costs. See, e.g., H. 1133, 191st Gen. Court (Mass. 2019). Regarding influence, compare NASHP Model Rate Setting Law, *supra*, with *Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, *supra* note 151.

<sup>161</sup> NASHP Model Rate Setting Law, *supra* note 160 (defining “excess costs” in section 4).

<sup>162</sup> See, e.g., H. 1193, *supra* note 160 (pulling NASHP quoted language nearly verbatim in section 2(a)); H.B. 2696, 80th Leg. Assemb., Reg. Sess. (Ore. 2019).

<sup>163</sup> *Id.*

<sup>164</sup> H.B. 2696, *supra* note 162, at § 13.

<sup>165</sup> *Id.* § 7. Note this two part definition is a slight variation on NAHSP’s model legislation. Although the second prong is the same, the first prong is different. NAHSP’s first prong is more of a cost-effectiveness test. NASHP Model Rate Setting Law, *supra* note 160 (“Costs of appropriate utilization of a prescription drug product that exceed the therapeutic benefit relative to other therapeutic options/alternative treatments.”).

With the exception of New Jersey’s 583 and Minnesota’s insulin-specific HF 284, every bill proposed thus far in 2019 covers patented as well as generic medications, and price increases and as well as launch prices for new products.<sup>166</sup> Illinois’s HB 3493, Massachusetts’s H 1133, and Maryland’s new law, HB 768, moreover, have largely identical triggering criteria for their reporting requirements.<sup>167</sup> They authorize boards to consider cost reviews for drugs and biologics with a WAC at launch of \$30,000 or more, or a WAC increase of \$3,000 or more over 12 months; biosimilars with a launch WAC that is not at least 15% lower than its branded counterpart; generic drugs with a WAC of \$100 or more per month, and generic drugs with a WAC increase of 200% or more over 12 months.<sup>168</sup> Maryland’s law and Illinois’s bill also include a catchall provision for drugs creating affordability challenges for the state health care system and patients.<sup>169</sup> Maine’s new law, by contrast, does not identify triggering criteria. Rather, Maine’s Board “will determine annual spending targets for prescription drugs purchased by public payers based on a 10-year rolling average of the medical care services component of the Consumer Price Index” taking into account inflation and pharmacy savings.<sup>170</sup> Maine’s board will further have the ability to identify spending targets for specific drugs creating affordability issues for those enrolled in public plans.<sup>171</sup>

An important feature of the NASHP model legislation is that whether a drug’s cost is excessive is *not* determined primarily by reference to the manufacturer—for instance, its R&D and marketing costs or its gross and net revenues.<sup>172</sup> That information is considered secondarily if primary considerations for determining excess cost fail to yield a determination.<sup>173</sup> The information of primary interest in determining whether a drug imposes excess costs or an affordability challenge instead pertains to “commercial payor, provider, and consumer costs.”<sup>174</sup> Maryland’s law, for instance, requires its Board to consider factors including the drug’s WAC in the state and other relevant drug cost indexes; average discounts and rebates to state health plans and pharmacy benefit managers (PBMs); discounts given to patients through patient assistance programs; the WAC, discounts, and rebates for competitor therapies; total costs to health plans; the impact on patient access that results from the drug’s price in conjunction with the amount of patient cost-sharing that insurance plans require; how paying for the drug will financially impact overall health and social-services costs compared to therapeutic alternatives; and “any other factors as determined by the Board in regulations adopted by the Board.”<sup>175</sup>

Legislative proposals for drug affordability review boards and rate setting are relatively new, but may have promise for addressing excessively priced medications. As NASHP details, its model legislation has taken some cues from the Canadian Patented Medicines Review Board.<sup>176</sup> Although there are fundamental differences—Canada’s Board reviews drugs for excessive price while the

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<sup>166</sup> *Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, *supra* note 151.

<sup>167</sup> See *id.*; 2019 Prescription Drug Affordability Initiative, HEALTH CARE FOR ALL, <http://healthcareforall.com/2019/01/2019-prescription-drug-affordability-initiative/> (last visited June 28, 2019) (confirming that triggering criteria remained the same in the final version of the bill).

<sup>168</sup> H. 1133, 191st Gen. Court (Mass. 2019); H.B. 768, 2019 Gen. Assemb. (Md. 2019); H.B. 3493, 101st Gen. Assemb. (Ill. 2019).

<sup>169</sup> H.B. 768, *supra* note 168; H.B. 2696, 80th Leg. Assemb., Reg. Sess. (Ore. 2019).

<sup>170</sup> An Act to Establish the Maine Prescription Drug Affordability Board, ch. 471, 2019 Me. Laws 471; *Newly-Enacted Laws*, NASHP, <https://nashp.org/new-laws/> (last visited July 10, 2019).

<sup>171</sup> 2019 Me. Laws 471.

<sup>172</sup> *Drug Rate Setting Model Act Overview*, *supra* note 158; see also H.B. 2696, *supra* note 169, at § 8;

<sup>173</sup> *Drug Rate Setting Model Act Overview*, *supra* note 158.

<sup>174</sup> *Id.*

<sup>175</sup> H.B. 768, *supra* note 168.

<sup>176</sup> *Drug Rate Setting Model Act Overview*, *supra* note 158.

NASHP state Commission would consider whether drugs generate excessive costs for the state<sup>177</sup>—drug costs in the Canadian system are lower than in the United States.<sup>178</sup>

As with all state efforts to address excessive pricing, rate-setting proposals raise concerns, among others, about whether industry opposition will lead to legal challenges.<sup>179</sup> One legal claim the industry may raise is that rate setting, insofar as it applies to patented medications, is preempted—though some experts find this claim to be unavailing.<sup>180</sup> Vagueness claims are also a possibility.

## II. Void-for-Vagueness Challenges to Excessive-Price Laws

As discussed above, courts have already grappled with a number of different constitutional challenges to state laws regulating excessive drug prices. Although we and others have reviewed the contours of some types of challenges,<sup>181</sup> void-for-vagueness claims remain largely unexplored in the scholarly literature on drug pricing and have not yet been fully adjudicated by the courts. As parsing “excessive” pricing can be a fraught task and vagueness challenges have the potential to undermine legislative efforts, we provide an overview of the void-for-vagueness doctrine and then turn to the specific application of this claim to the drug-pricing context.

### A. Void-for-Vagueness under the Due Process Clause

The Due Process Clauses of the Fifth and Fourteenth Amendments of the United States Constitution provide that no person may be deprived of “life, liberty, or property, without due process of law.”<sup>182</sup> The void-for-vagueness doctrine is an integral part of these due-process protections.<sup>183</sup> It invalidates “laws that are impermissibly vague”<sup>184</sup> and requires that enactments be “clearly defined.”<sup>185</sup>

The void-for-vagueness doctrine serves two important purposes.<sup>186</sup> First, it “guarantees that ordinary people have ‘fair notice’ of the conduct a statute proscribes.”<sup>187</sup> Second, “the doctrine guards against arbitrary or discriminatory law enforcement by insisting that a statute provide

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<sup>177</sup> *Id.*

<sup>178</sup> See e.g., So-Yeon Kang et al, *Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries*, 38 HEALTH AFF. 804 (2019) (concluding that the U.S. pays “substantially higher prices for single-sourced brand-name drugs that have been on the market for longer than three years”).

<sup>179</sup> Jane Horvath, *Maryland Rate-Setting Legislation Question and Answer*, NASHP (Oct. 17, 2017), <https://nashp.org/maryland-rate-setting-legislation-question-and-answer/#q8>; see also Silverman, *supra* note 148 (quoting PhRMA as having “serious concerns” about the constitutionality of Maryland’s rate-setting legislation).

<sup>180</sup> See e.g., Feldman et al., *supra* note 14, at 49-50.

<sup>181</sup> See generally Buck, *supra* note 15; Gudiksen & King, *supra* note 15; Gudiksen et al., *California’s Drug Transparency Law*, *supra* note 15; Lee et al., *supra* note 15 (discussing the legal claims brought against Maryland and Nevada laws); Robertson, *supra* note 15 (describing dormant Commerce Clause challenge to Maryland’s HB 631).

<sup>182</sup> U.S. Const., amends. V, XIV, § 1.

<sup>183</sup> *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (“This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment.”).

<sup>184</sup> *Fox Television Stations*, 567 U.S. at 253.

<sup>185</sup> *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972).

<sup>186</sup> See, e.g., *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212, (2018) (noting two protections of ensuring fair notice and non-arbitrary enforcement); *Fox Television Stations*, 567 U.S. at 253-54 (“the void for vagueness doctrine addresses at least two connected but discrete due process concerns”).

<sup>187</sup> *Dimaya*, 138 S. Ct. at 1212; *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939) (“No one may be required at peril of life, liberty or property to speculate as to the meaning of penal statutes. All are entitled to be informed as to what the State commands or forbids.” (citations omitted)); *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926).

standards to govern the actions of police officers, prosecutors, juries, and judges.”<sup>188</sup> Thus, a statute can be invalidated as vague if it either (1) “fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits” or (2) “authorizes or even encourages arbitrary and discriminatory enforcement.”<sup>189</sup> In interpreting the notice aspect of the doctrine, courts look for “reasonably clear lines between the kinds of” conduct that are permitted and those that are not.<sup>190</sup> This standard will be met where the statute’s meaning can be ascertained from review of judicial interpretations, dictionaries, treatises, or commonly understood meanings of words.<sup>191</sup> With respect to the enforcement aspect, the doctrine requires “that a legislature establish minimal guidelines to govern law enforcement.”<sup>192</sup>

The standard applied to determine whether a law is impermissibly vague varies depending on the nature of the law.<sup>193</sup> Because less is presumed to be at stake, provisions involving civil penalties are afforded more flexibility than those imposing criminal penalties.<sup>194</sup> Further, the Court has applied relatively lax review to economic regulation “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.”<sup>195</sup> Compared to individuals, businesses are thought to have greater “access to the law and political capital”<sup>196</sup> and greater capability to stay abreast of regulatory developments.<sup>197</sup> The Court has suggested that in the commercial context, “the most meaningful” aspect of the vagueness doctrine may be the notice aspect.<sup>198</sup> The less-strict standard of review for economic regulation will not, however, be applied if the regulation potentially infringes an individual’s or entity’s constitutionally-protected rights. Under such circumstances, the Court has stated that “a more stringent vagueness test should apply.”<sup>199</sup> In particular, greater precision and clarity are required of a law that threatened rights to freedom of speech.<sup>200</sup>

The Court’s comments on economic regulation and civil penalties have particular salience for our analysis of potential vagueness challenges to laws regulating prescription drug prices. Although the fact patterns in many of the Supreme Court’s modern vagueness doctrine cases are

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<sup>188</sup> *Dimaya*, 138 S. Ct. at 1212; *Fox Television Stations*, 567 U.S. at 253; *Grayned*, 408 U.S. at 108-09.

<sup>189</sup> *Hill v. Colorado*, 530 U.S. 703, 732 (2000).

<sup>190</sup> *Smith v. Goguen*, 415 U.S. 566, 574 (1974).

<sup>191</sup> 16B AM. JUR. 2D *Constitutional Law* § 972 (2019).

<sup>192</sup> *Id.*

<sup>193</sup> *Sessions v. Dimaya*, 138 S. Ct. 1204, 1212-13 (2018); Blum et al., *supra* note 191.

<sup>194</sup> *Id.*

<sup>195</sup> *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982).

<sup>196</sup> Jennifer Lee Koh, *Crimmigration and the Void for Vagueness Doctrine*, 2016 WIS. L. REV. 1127, 1138 (2016).

<sup>197</sup> *Village of Hoffman Estates*, 455 U.S. at 498-99; *Smith v. Goguen*, 415 U.S. 566, 574 (1974) (“We recognize that in a noncommercial context behavior as a general rule is not mapped out in advance on the basis of statutory language.”).

<sup>198</sup> *Goguen*, 415 U.S. at 574.

<sup>199</sup> *Village of Hoffman Estates*, 455 U.S. at 499; *see also* *Holder v. Humanitarian Law Project*, 561 U.S. 1, 18-19 (2010).

<sup>200</sup> *Village of Hoffman Estates*, 455 U.S. at 499. Vague statutes “abutting upon sensitive areas of basic First Amendment Freedoms” are especially concerning because they can “inhibit the exercise of (those) freedoms” and “lead citizens to ‘steer far wider of the unlawful zone.’” *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972); *see also* *F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253-54 (2012) (“When speech is involved, rigorous adherence to those requirements is necessary to ensure that ambiguity does not chill protected speech.”). However, “perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity.” *Humanitarian Law Project*, 561 U.S. at 18-19 (quoting *United States v. Williams*, 553 U.S. 285, 304 (2008)).

somewhat removed from the drug-pricing context,<sup>201</sup> several older cases dealing directly with the regulation of “excessive” and “unreasonable” prices bear striking similarities.<sup>202</sup>

On February 28, 1921, the Supreme Court issued rulings in five related cases pertaining to the Lever Act,<sup>203</sup> which among other things criminalized exacting “any unjust or unreasonable rate or charge in handling or dealing in or with any necessities” and “excessive prices for any necessities.”<sup>204</sup> In the main case outlining the Court’s reasoning, the Cohen Grocery Company was charged with “willfully and feloniously making an unjust and unreasonable rate and charge in handling and dealing in a certain necessity,” which was sugar.<sup>205</sup> Other cases dealt with unreasonable prices for milk and clothing.<sup>206</sup> These cases challenged the pertinent provisions of the Lever Act as unconstitutionally vague, and the Court agreed.<sup>207</sup> The Court found that “the section forbids no specific or definite act. ... It leaves open, therefore, the widest conceivable inquiry, the scope of which no one can foresee and the result of which no one can foreshadow or adequately guard against.”<sup>208</sup> Remarking that the arbitrariness of a standard used for enforcement of the section was “not a mere abstraction,” the Court included a lengthy footnote detailing differences in interpretation of the term “unreasonable prices” among lower courts.<sup>209</sup>

A more recent case, *United States v. National Dairy Products Corporation*, considered a provision of the Robinson-Patman Act that criminalized the sale of goods at “unreasonably low prices for the purpose of destroying competition or eliminating a competitor.”<sup>210</sup> Charged with selling products for below cost with the intent to drive competitors out of business, National Dairy alleged that the phrase “unreasonably low prices” was unconstitutionally vague. Focusing on the notice issue, the Court upheld the statute. It distinguished the facts of this case from those of *L. Cohen Grocery Co.*, because here the statute made clear which kinds of business practices it targeted.<sup>211</sup> A seemingly important factor was the statute’s intent element.<sup>212</sup> National Dairy was not just selling its products below cost, but doing so with the intent to undermine competition.<sup>213</sup> The Court further reiterated that a vagueness analysis varies depending on whether constitutional rights (particularly under the First Amendment) are implicated, and here, they were not.<sup>214</sup>

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<sup>201</sup> See, e.g., *Goguen*, 415 U.S. at 574 (small flag placed on seat of pants), *Grayned*, 408 U.S. at 112 (picketing outside of a school).

<sup>202</sup> See *United States v. Nat’l Dairy Prods. Corp.*, 372 U.S. 29 (1963); *United States v. L. Cohen Grocery Co.*, 255 U.S. 81, 86 (1921); *C.A. Weed & Co. v. Lockwood*, 255 U.S. 104, 105 (1921); *Tedrow v. A.T. Lewis & Son Dry Goods Co.*, 255 U.S. 98, 99 (1921); *Weeds, Inc. v. United States*, 255 U.S. 109, 110 (1921); *Kinnane v. Detroit Creamery Co.*, 255 U.S. 102, 103 (1921); see also *Johnson v. United States*, 135 S. Ct. 2551, 2570 (2015) (Thomas, J., concurring) (describing a 1914 case finding the phrase “real value” unconstitutionally vague).

<sup>203</sup> See *supra* cases accompanying note 202.

<sup>204</sup> *L. Cohen Grocery Co.*, 255 U.S. at 86.

<sup>205</sup> *Id.*

<sup>206</sup> *Lockwood*, 255 U.S. at 105.

<sup>207</sup> See, e.g., *id.*; *L. Cohen Grocery Co.*, 255 U.S. at 86.

<sup>208</sup> *L. Cohen Grocery Co.*, 255 U.S. at 89.

<sup>209</sup> *Id.* at 89 n.2.

<sup>210</sup> 372 U.S. 29 (1963).

<sup>211</sup> *Id.* at 35-36.

<sup>212</sup> *Id.* at 37; see also Andrew E. Goldsmith, *The Void-for-Vagueness Doctrine in the Supreme Court, Revisited*, 30 AM. J. CRIM. L. 279, 301 *et seq.* (2003) (discussing scienter element as a controversial mechanism courts sometimes use to mitigate vagueness).

<sup>213</sup> *Nat’l Dairy Prod. Corp.*, 372 U.S. at 37 (“[S]ales made below cost without legitimate commercial objective and with specific intent to destroy competition would clearly fall within the prohibitions.”).

<sup>214</sup> *Id.* at 36 (“No such factor is present here where the statute is directed only at conduct designed to destroy competition, activity which is neither constitutionally protected nor socially desirable.”).

Lower federal courts and state courts considering claims that the term “unconscionable” is unconstitutionally vague have issued decisions in both directions. A Massachusetts federal district court, for instance, upheld a mortgage lending statute providing that a mortgage lender could not offer rates or other terms which ‘significantly deviate from industry-wide standards or which are otherwise unconscionable.’”<sup>215</sup> Noting the relatively weak standard of review applied to economic regulations, the court found that the law gave the defendant sufficient guidance as to what constituted proscribed behavior. That guidance included the industry-wide standard for subprime mortgage origination fees (where charging twice as much would be viewed as a likely deviation) and Massachusetts’s unconscionability doctrine.”<sup>216</sup>

On the other hand, the Colorado Supreme Court deemed the term “unconscionable” unconstitutionally vague in a statute providing that a used car dealer’s license could be revoked if the dealer “indulged in an unconscionable practice relating to said business.”<sup>217</sup> At issue in the case was a dealership accused of resetting odometers to understate a car’s true mileage.<sup>218</sup> The Court invalidated the statute’s “catchall” phrase, reasoning that “Where criminal or quasi-criminal sanctions are to be imposed, we think the threat of arbitrary enforcement of the law requires more specificity than is contained in subsection (3)(k).”<sup>219</sup> The Court rejected the state’s argument that it was impossible to catalog all of the unsavory practices against which the public required protection, quipping that cars are “not a new mercantile invention” and regulators “have years of experience to guide them in formulating their regulations.”<sup>220</sup> As evidence, the Court pointed to other parts of the statute where specific acts were enumerated.<sup>221</sup>

To sum up, the Supreme Court’s void-for-vagueness doctrine has several clear themes. The concept of fair warning and the avoidance of arbitrary and standardless enforcement are pillars of the doctrine. Regulations impacting constitutional rights or involving criminal penalties demand a higher level of scrutiny than economic regulation and statutes involving civil penalties.

Although these guideposts are clearly laid out, many commentators have argued that the void-for-vagueness doctrine is itself vague and the Court’s application of it lacks predictability.<sup>222</sup> For instance, it is not clear how the Court balances the two key factors—notice and nonarbitrary enforcement—against one another; it has at times seemed to weigh notice without giving much attention to fair-enforcement concerns, and vice versa.”<sup>223</sup> Another aspect of the doctrine that appears to lack clarity is what needs to be shown in bringing a facial challenge. As we describe next, the District Court in case against Maryland’s HB 631 noted that the Supreme Court has put forward

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<sup>215</sup> *United Cos. Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 204, 205 (D. Mass. 1998).

<sup>216</sup> *Id.* at 205.

<sup>217</sup> *Trail Ridge Ford, Inc. v. Colo. Dealer Licensing Bd.*, 543 P.2d 1245, 1246 (1975).

<sup>218</sup> *Id.*

<sup>219</sup> *Id.*; *cf. State ex rel. Bryant v. R & A Inv. Co.*, 985 S.W.2d 299, 302 (1999) (permitting the inclusion of unconscionable practice in a catchall provision “because the General Assembly could not be expected to envision every conceivable violation . . .”).

<sup>220</sup> *Trail Ridge Ford, Inc.*, 543 P.2d at 1247.

<sup>221</sup> *Id.* Although the Court found this particular instance of the term “unconscionable” to be impermissibly vague, it cautioned that “We should not be understood to say that a reference to ‘unconscionable practices’ will always be unconstitutionally vague. There may be numerous areas of the law where a stronger argument for the validity of such a reference can be made, particularly in the civil field. *Id.*”

<sup>222</sup> Bradley E. Abruzzi, *Copyright and the Vagueness Doctrine*, 45 U. MICH. J.L. REFORM 351, 359-60 (2012) (“Given the state of the Court’s jurisprudence, one could even argue that the void-for-vagueness doctrine is itself standardless, vague, and susceptible to arbitrary or selective application by the courts.”). *See also* Koh, *supra* note 196, at 1137.

<sup>223</sup> Koh, *supra* note 196, at 1137.



different standards.<sup>224</sup> The complainant's burden of proof has obvious ramifications for how challenging it will be to invalidate a statute as unconstitutionally vague.

## B. Vagueness Challenges to Drug Price Legislation in California and Maryland

Industry trade associations have brought void-for-vagueness challenges against a California drug price transparency law, SB 17, and Maryland's anti-price gouging law, HB 631. In the ongoing California litigation, *PhRMA v. David*, PhRMA's vagueness claim focuses on the notice aspect of the doctrine<sup>225</sup> and challenges a purported ambiguity that allegedly impinges upon drug manufacturers' freedom of speech. By contrast, in the Maryland case, *Association of Accessible Medications v. Frosh*, the void-for-vagueness claim challenged the core definitions and aims of the statute. It raised key questions about just what kinds of pricing activities constitute a prohibited "unconscionable increase."

Because California's transparency law is outside the ambit of our focus on price-gouging laws we do not delve into its intricacies here, but its key component is a requirement that drug manufacturers provide sixty-day advance notice of price increases that amount to 16% or greater over two years.<sup>226</sup> In *David*, PhRMA argues that this notification requirement "offends due process because the Act is silent on which WAC increases determine whether a manufacturer has breached the statutory threshold."<sup>227</sup> The statute became effective on January 1, 2018, but PhRMA claims it is unclear whether the notice provision calculation includes retroactive price increases occurring between January 1, 2016 and January 1, 2018.<sup>228</sup> PhRMA alleges that "multiple direct requests to clarify this ambiguity" with the administering agency have been unsuccessful.<sup>229</sup>

This timing issue affects whether and to what extent a drug manufacturer may impose current or future increases if it wishes to avoid triggering notification.<sup>230</sup> According to PhRMA, the vagueness is not just a matter of not knowing how statutory price increases are calculated. PhRMA argues that the notification requirement violates its members' First Amendment free-speech rights by compelling a disclosure: "It is inappropriate to implement a de facto nationwide ban on WAC increases and to compel self-accusatory statements by manufacturers based on price increases before

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<sup>224</sup> *Ass'n for Accessible Meds. v. Frosh*, No. 17-cv-1860, 2017 WL 4347818, at \*8 (D. Md. Sept. 29, 2017), *rev'd*, 887 F.3d 664 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019) ("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. 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."). This Court also noted the apparent lack of clarity about how to interpret "plainly legitimate sweep" of a statute in a civil case that does not involve First Amendment rights. *Id.*

<sup>225</sup> See Plaintiff's Opposition to Defendant's Motion to Dismiss at 30, *Pharm. Research & Mfrs. of Am. v. David*, No. 2:17-cv-02573 (filed Sept. 28, 2018).

<sup>226</sup> S.B. 17 § 127677(a).

<sup>227</sup> See Amended Complaint for Declaratory and Injunctive Relief at 32, *Pharm. Research & Mfrs. of Am. v. David*, No. 2:17-cv-02573 (filed Sept. 28, 2018) [hereinafter PhRMA Amended Complaint].

<sup>228</sup> *Id.*

<sup>229</sup> *Id.* But note, that "California law prohibits an administrative agency from providing any pre-regulatory guidance regarding the application of a law, and OSHPD's regulations when published may not provide that guidance. Final responsibility for construing SB 17's retroactive application rests with courts...." Defendant's Motion to Dismiss First Amended Complaint for Declaratory and Injunctive Relief Pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) at 27 n.8, *Pharm. Research & Mfrs. of Am. v. David*, No. 2:17-cv-02573 (filed Sept. 28, 2018) (citing CAL. GOV'T CODE § 11340.5(a) (West 2019)).

<sup>230</sup> PhRMA alleges that, "[m]any of these manufacturers will not increase the WAC of products at the same time and in the same manner that they otherwise would without the risk of past increases triggering SB 17's 60-day notice provision." PhRMA Amended Complaint, *supra* note 227, at 33.

adoption of SB 17....Each day, affected members must refrain from legitimate price increases to preserve their constitutionally protected silence.”<sup>231</sup>

Although much is unclear about the application of the void-for-vagueness doctrine, the Supreme Court has consistently stated that a higher standard applies when First Amendment rights are implicated.<sup>232</sup> The success of PhRMA’s vagueness claim thus may hinge on the resolution of its underlying First Amendment claim. As of this writing, the Court has yet to rule on California’s Motion to Dismiss in *David*.<sup>233</sup>

In AAM’s lawsuit challenging Maryland’s HB 631, the Fourth Circuit ruled the statute unconstitutional under the dormant Commerce Clause and declined to reach the vagueness claim.<sup>234</sup> Although the void-for-vagueness challenge was never fully litigated, the District Court’s discussion of this claim offers some insights.

As detailed above, HB 631 prohibited price gouging for generics, which it defined as an “unconscionable increase in the price of a prescription drug.”<sup>235</sup> “Unconscionable increase” was defined using general criteria relating to whether price increases were “excessive and not justified” by increases in production costs or “appropriate expansion of access to the drug,” and whether the increases relate to drugs that consumers have “no meaningful choice” but to purchase.<sup>236</sup> Further, other provisions of the statute stipulated what sort of price increases could trigger Maryland’s Medicaid program to notify the Attorney General that action may be appropriate under the statute.

AAM alleged that the terms “excessive,” “justified,” “appropriate” and “no meaningful choice” were unconstitutionally vague.<sup>237</sup> It argued that the bill “provides no guidance ... on how to interpret or apply *any* of these provisions,” leaving plaintiffs unable to determine whether contemplated price increases “would be considered “unconscionable.”<sup>238</sup> In response, Maryland argued that HB 631 explicitly drew upon the “centuries-old” common-law doctrine of unconscionability,<sup>239</sup> which provides “droves of precedents to which manufacturers and wholesale distributors can look to find guideposts . . . .”<sup>240</sup>

In denying Maryland’s Motion to Dismiss on the claim for vagueness, the district court rejected Maryland’s assertions about the common-law doctrine of unconscionability.<sup>241</sup> Because the statute provided its own definition of “unconscionable,” the court found, it was unclear whether common-law understandings were “directly applicable.”<sup>242</sup> The Court went on to find that the terms “excessive” “justified” and “appropriate” raised at least the possibility of vagueness.<sup>243</sup> The phrase “no meaningful choice,” by contrast, was sufficiently defined, as neither of its two qualifying sub-

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<sup>231</sup> Plaintiff’s Opposition to Defendant’s Motion to Dismiss at 29, *Pharm. Research & Mfrs. of Am. v. David*, No. 2:17-cv-02573 (filed Sept. 28, 2018).

<sup>232</sup> See, e.g., *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982); *Grayned v. City of Rockford*, 408 U.S. 104, 109 (1972).

<sup>233</sup> The docket was last checked on June 28, 2019.

<sup>234</sup> *Ass’n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 n.1 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019) (“Because we hold that the statute is unconstitutional pursuant to the dormant commerce clause, we need not address whether it is also void for vagueness.”).

<sup>235</sup> *Id.* § 2-801(c). See also *Ass’n for Accessible Meds.*, 2017 WL 4347818, at \*9.

<sup>236</sup> For specifics, see *supra* Part I.B.1.b.

<sup>237</sup> See also *Ass’n for Accessible Meds.*, 2017 WL 4347818, at \*10.

<sup>238</sup> *Ass’n for Accessible Meds. Complaint*, *supra* note 116, at 28 60.

<sup>239</sup> Defendant’s Opposition to Plaintiff’s Motion for Preliminary Injunction at 8, *Ass’n for Accessible Meds.*, 2017 WL 4347818 (No. 17-cv-01860); see also *Frosh Motion to Dismiss*, *supra* note 104, at 16.

<sup>240</sup> *Frosh Motion to Dismiss*, *supra* note 104, at 16.

<sup>241</sup> *Ass’n for Accessible Meds. v. Frosh*, 2017 WL 4347818, at \*10.

<sup>242</sup> *Id.*

<sup>243</sup> *Id.* at \*10-11.

divisions were vague.<sup>244</sup> Thus, the court “recognize[d] that there are reasonable—though not necessarily prevailing—contentions [of unconstitutional vagueness] asserted by the Plaintiff.”<sup>245</sup>

The Maryland case illustrates that vagueness challenges are a cognizable challenge to price-gouging laws—one that seems likely to crop up again as other states and the Congress take a bite at the apple. To better understand how future laws could be designed to withstand allegations of constitutional invalidity for vagueness, we turn now to lessons from legal prohibitions on excessive prices in other domains.

### III. Defining Excessive Price: Lessons From Other Areas of Law

#### A. Price-Gouging Laws For Times of Emergency

The clearest analogue to excessive-price laws for prescription drugs are price-gouging laws adopted by states in an effort to keep essential products affordable during times of emergency. These laws address the practice of escalating the price of a good or service above the regular selling price when a market disruption<sup>246</sup> caused by an acute event, typically a natural disaster or manmade emergency,<sup>247</sup> interrupts supply or causes demand to spike. They are typically adopted after states have experienced a natural disaster that led to price spikes for necessities such as gasoline or portable generators.<sup>248</sup> The broadest of the laws permits the invocations of its price-gouging provisions before a market disruption occurs, if “there is a substantial likelihood that an abnormal market disruption is imminent.”<sup>249</sup> The statutes’ prohibitions on price hikes are always time limited—for example, they may last thirty days after a formal declaration of emergency, or for the duration of the emergency.<sup>250</sup>

Emergency price-gouging laws impose civil penalties for violations, which may be substantial because they are pegged to each violation (i.e., each sale), and some allow for injunctive relief, criminal charges, or a private right of action for consumers.<sup>251</sup> In some states, the statutes operate by defining excessive price hikes as a violation of the state’s general consumer protection statute prohibiting unfair and deceptive business practices; in others, price-gouging laws are freestanding.

Most states—34, at last count, plus the District of Columbia—have adopted some type of emergency price-gouging law.<sup>252</sup> They vary in the scope of products and services covered. Some are

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<sup>244</sup> *Id.* at \*11.

<sup>245</sup> *Id.*

<sup>246</sup> An exception is a Michigan statute, which prohibits “charging the consumer a price that is grossly in excess of the price at which similar property or services are sold” without any requirement of an emergency or market disruption. MICH. COMP. LAWS § 445.903(1)(z) (2019).

<sup>247</sup> Acts of terrorism and civil unrest are illustrative of the situations commonly contemplated as manmade emergencies. *See, e.g.*, N.Y. GEN. BUS. LAW § 396-r(3)(a) (Consol. 2019) (listing as potential causes of market disruption “failure or shortage of electric power or other source of energy, strike, civil disorder, war, military action”).

<sup>248</sup> Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 KY. L.J. 535, 542-43 (2005).

<sup>249</sup> ME. REV. STAT. ANN. tit.10, §1105 (2014); *see also* Justin Schuster, *America’s Drug Problem*, POLITIC (Feb. 11, 2013), <http://thepolitic.org/price-gouging-and-the-prescription-drug-gray-market/> (indicating that Maine has the most expansive anti-price-gouging statute in the nation).

<sup>250</sup> Rapp, *supra* note 248, at 543-45.

<sup>251</sup> *Price Gouging Laws by State*, FINDLAW, <https://consumer.findlaw.com/consumer-transactions/price-gouging-laws-by-state.html> (last visited June 29, 2019) (listing enforcement mechanisms of each law).

<sup>252</sup> *Id.* (summarizing 34 states’ laws); Michael Giberson, *Thirty-four States and the District of Columbia Have Anti-Price Gouging Laws*, KNOWLEDGEPROBLEM (Nov. 3, 2012), <https://knowledgeproblem.com/2012/11/03/list-of-price-gouging->

narrowly crafted, with specific products listed,<sup>253</sup> while others are broader, giving discretion to officials to determine what constitute necessities in the wake of an emergency. Broader statutes typically specify that the goods and services be essential to the public's health, safety, or welfare. Prior to the recent wave of adoption of statutes specifically aimed at prescription drugs, very few state price-gouging laws specifically mentioned pharmaceuticals.<sup>254</sup>

## 1. Approaches to Defining Excessive Price

In describing the prohibited conduct, emergency price-gouging laws take three approaches.<sup>255</sup> What we will call “type 1” laws specify a maximum percentage price increase that may occur after the market disruption occurs. “Type 2” laws prohibit any price increase beyond the amount necessitated by increased operational costs on the part of the seller. “Type 3” laws impose a general prohibition on the sale of covered goods during emergencies at an excessive or unconscionable price.<sup>256</sup> For example, Idaho’s statute prohibits selling covered goods or offering them for sale at an “exorbitant or excessive price”.<sup>257</sup>

Type 1 laws commonly limit price increases to 10 to 25 percent above pre-emergency levels.<sup>258</sup> Some laws allow sellers to argue, in defense to a price-gouging allegation, that increased operational costs arising due to the market disruption (for example, because supply chains were interrupted) justify price the increase in the product’s price. Others do not, presuming that the allowable price increase specified in the statute adequately accounts for the fact that sellers’ costs may increase during emergencies.<sup>259</sup>

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laws/(listing state laws as of November 2012). *See also* Gudiksen, *supra* note 82 (identifying Giberson’s as the most recent available list of laws as of September 2018).

<sup>253</sup> Fuel is the most common product mentioned, but statutes also mention water, food, rental facilities, medical supplies, building materials, transportation services, storage services, housing, and emergency supplies such as batteries and flashlights. For further details, see the statutes compiled at *Price Gouging Laws by State*, *supra* note 251. *See also* Joshua Gregg, *The Implications, Negative Health Effects, Legal Issues, and Potential Solutions Associated with the Shortage of Essential Drugs in the U.S. Medical Care Market*, 25 ALB. L.J. SCI. & TECH. 381, 431-32 (2015) (summarizing states’ approaches to price-gouging legislation).

<sup>254</sup> *But see* IDAHO CODE ANN. § 48-603 (West 2014) (listing “pharmaceuticals”); IOWA ADMIN. CODE r. 61-31.1(714) (2019) (“medicines”); KY. REV. STAT. ANN. § 367.372 (West 2019) (defining “medical supplies” to include “prescription and nonprescription medications”); ME. REV. STAT. ANN. tit.10, §1105 (2014) (listing “pharmaceutical products, including prescription medications” among the “necessities” covered); TENN. CODE ANN. § 47-18-5012 (2019) (“prescription and nonprescription medications”); TEX. BUS. & COM. CODE ANN. § 17.46(b)(27) (West 2019) (“medicine”); VA. CODE ANN. § 59.1-526 (2019) (“medical supplies and services”; W. VA. CODE § 46A-6J-2 (2019) (“prescription and nonprescription medications”). A few other states’ laws refer to “chemicals,” but that term is placed among a list of building supplies and may be intended to mean non-pharmaceutical chemicals. *See, e.g.*, 30 R.I. GEN. LAWS ANN. § 30-15-9 (West 2019).

<sup>255</sup> This typology was offered by Rapp, *supra* note 248, at 543-50, and cited in Caitlin E. Ball, Note, *Sticker Shock at the Pump: An Evaluation of the Massachusetts Petroleum Price-Gouging Regulation*, 44 SUFFOLK U. L. REV. 907, 913 (2011) and Emily Bae, Note, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters?*, 4 ENTREPRENEURIAL BUS. L.J. 79, 83 (2009) (listing state laws falling into each of these 3 groups). Close review of the statutes reveals that some are a hybrid of the three approaches. For instance, Kentucky’s law sets forth a general standard, “grossly in excess of the price prior to the declaration and unrelated to any increased cost to the seller,” but creates safe harbors for price increases below a specified numeric threshold (10 percent). KY. REV. STAT. ANN. § 367.372.

<sup>256</sup> Depending on how courts interpret the unconscionability standard, type 2 and 3 laws may be functionally similar. For example, a New York court, interpreting the state’s type 3 statute, held that no price increase above that necessary to account for increased operational costs would survive review. *See People ex rel. Abrams v. Two Wheel Corp.*, 525 N.E.2d 692, 696 (N.Y. 1988).

<sup>257</sup> IDAHO CODE ANN. § 48-603.

<sup>258</sup> Ball, *supra* note 255, at 914 (citing Bae, *supra* note 255, at 87).

<sup>259</sup> Bae, *supra* note 255, at 84.

In defining what constitutes an excessive or unconscionable price, type 3 laws (like type 1 laws) typically refer to the difference between the pre- and post-emergency price of the product. A common approach is to call for an assessment of whether there is a “gross disparity” between the prices charged before and after the market disruption in the affected market area.<sup>260</sup> Some type 3 laws also permit benchmarking to the current price of similar goods outside the emergency zone or by other sellers within the zone.<sup>261</sup> Further, some require a showing that the disparity is not attributable to increased operational costs.<sup>262</sup> In addition to examining the magnitude of price increases, New York’s law has a procedural element: it permits courts to find that a price is “unconscionably excessive” if there is a gross price disparity, “an exercise of unfair leverage or unconscionable means” in the transaction with the consumer, or both.<sup>263</sup>

## 2. Legal Challenges

Legal challenges to the validity of states’ emergency price-gouging laws are rare. Our review of the 35 laws identified no challenges to type 1 laws, one challenge to a type 2 law, and three challenges to type 3 laws.

The type-2 challenge was to Mississippi’s statute, which imposes penalties for raising prices above their level in the “same market area” “at or immediately before” the market disruption, unless necessitated by increased costs.<sup>264</sup> The state attorney general brought an enforcement action against a chain of gas stations that hiked the price of gasoline after Hurricane Katrina. In its facial challenge to the statute, the company claimed that the phrases “in the same market area” and “at or immediately before” were impermissibly vague. The Mississippi Supreme Court disagreed. Applying the U.S. Supreme Court’s standard of review for vagueness challenges,<sup>265</sup> it found that the statute’s terms “would be clear to any businessman who wants to charge competitive prices and attract customers.”<sup>266</sup>

Type-3 laws in Kentucky, Massachusetts, and New York have been challenged on vagueness grounds, but not successfully. In *Marathon Petroleum Co. LLC v. Stumbo*, a Kentucky trial court found a gasoline company’s vagueness argument regarding that state’s price-gouging law too poorly and cursorily argued to be sustained.<sup>267</sup> New York’s law, which uses an “unconscionably excessive” price

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<sup>260</sup> See, e.g., FLA. STAT. § 501.160 (2019) (stating that it is prima facie evidence that a price is unconscionable if it is either (1) “a gross disparity” between the price and the price at which that good was sold during the 30 days before the emergency declaration, unless the increase is due to increased costs on the part of the seller, or regional, national or international market trends; or (2) the price “grossly exceeds” the average price at which the same or similar commodity was readily obtainable in the trade area in the 30 days prior (unless due to increased costs or market trends)). Some courts have characterized the gross disparity showing as procedural rather than substantive in nature because its legal effect is to establish a presumption of price gouging. See, e.g., *People by Abrams*, 525 N.E.2d at 698 (“gross disparity” provision in New York’s price-gouging statute “is procedural rather than definitional; it simply establishes a means of providing presumptive evidence” of price gouging).

<sup>261</sup> *People ex rel. Vacco v. Beach Boys Equipment Co., Inc.*, 709 N.Y.S.2d 729 (N.Y. App. Div. 2000) (examining prices charged for generators by other retailers in the trade area, in applying New York’s law); Bae, *supra* note 255, at 85-86.

<sup>262</sup> See, e.g., 940 MASS. CODE REGS. 3.18 (2019) (defining an “unconscionably high” price for gasoline” as one with a “gross disparity” that “is not substantially attributable” to increased prices charged by the petroleum-related business suppliers or increased costs due to abnormal market disruption”).

<sup>263</sup> N.Y. GEN. BUS. LAW § 396-r(3)(a) (Consol. 2019).

<sup>264</sup> *State ex rel. Hood v. Louisville Tire Ctr., Inc.*, 55 So. 3d 1068 (Miss. 2011).

<sup>265</sup> See *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1925) (“A statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application”).

<sup>266</sup> *Louisville Tire Ctr.*, 55 So. 3d at 1073.

<sup>267</sup> *Marathon Petroleum Co. LLC v. Stumbo*, 528 F. Supp. 2d 639, 651 (E.D. Ky. 2007).

standard, has been challenged by sellers of portable generators and home heating oil. In *People ex rel. Abrams v. Two Wheel Corp.*, the state Court of Appeals rejected the vagueness argument because it found that sufficient guidance as to the meaning of “unconscionably excessive” was provided by (1) the statute’s enumeration of factors to be considered in arriving at a determination of unconscionability, in conjunction with (2) common-law decisions on the unconscionability defense in contract disputes, and (3) the definition of unconscionable contracts provided in section 2-302 of the Uniform Commercial Code.<sup>268</sup> Applying those guideposts, the court held that a price may be unconscionable under New York’s statute either because there is an extreme price disparity or because “procedurally, the excess was obtained through unconscionable means,” such as the bargaining advantage gained by a natural disaster,<sup>269</sup> and that merchants had been given sufficient notice of this. Similarly, in *People ex rel. Vacco v. Chazy Hardware, Inc.*,<sup>270</sup> a New York trial court concluded, without elaboration, that the statute did not impose “such an amorphous standard that a merchant would be unable to conduct itself in accordance with the terms.”<sup>271</sup> And in *State v. Strong Oil*, the home heating oil case, the court had no difficulty concluding that the statute set forth sufficiently clear criteria in directing the factfinder to compare the seller’s price after the market disruption to its pre-disruption price or to prices charged to other consumers in the same trade area.<sup>272</sup>

The final challenge, to Massachusetts’s law, was narrower. In *White v. R.M. Packer Co.*, the First Circuit Court of Appeals was asked to determine whether gasoline retailers had engaged in price gouging after Hurricane Katrina.<sup>273</sup> That involved determining whether the state had shown a “gross disparity” between the pre- and post-disaster prices. The district court, looking at the plain language of the applicable regulations, rejected the notion that the state could make out a claim merely by showing high profit margins or large price increases. To the contrary, the regulation also evinced concern about increases in sellers’ operational costs, so it was necessary to examine changes in price relative to changes in costs over the same period.<sup>274</sup> The court concluded no price gouging was shown under the facts of the case.

The takeaways from this review of litigation are that the validity of emergency price-gouging statutes is rarely challenged; and when challenges are brought, courts have little difficulty interpreting and applying even the relatively nonspecific, type-3 statutes. A possible reason for the paucity of litigation may be that the laws are infrequently invoked—fortunately, the disasters that would trigger them are rare, and consumers and attorneys general may deem some price hikes as involving consumer harms too trivial to justify the time and expense involved in bringing an enforcement action.<sup>275</sup> A second reason is that type-1 statutes, which account for nine of the 34 laws, by our

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<sup>268</sup> 525 N.E.2d 692, 698-99 (N.Y. 1988).

<sup>269</sup> *Id.* at 699.

<sup>270</sup> 675 N.Y.S.2d 770 (N.Y. Sup. Ct. 1998).

<sup>271</sup> The conduct at issue in *Chazy Hardware* presented a fairly easy case for the court: the defendant had purchased 54 portable generators during an ice storm and sold them two days later at double the price. *Id.* at 772.

<sup>272</sup> *State v. Strong Oil Co., Inc.*, 105 Misc. 2d 803, 818-19, 824-25 (N.Y. Sup. Ct. 1980).

<sup>273</sup> 635 F.3d 571 (1st Cir. 2011). The case involved increases in the price of gasoline on the Massachusetts island of Martha’s Vineyard following two hurricanes. The price-gouging claims were brought under Massachusetts’s gasoline price-gouging statute. *See* MASS. GEN. LAWS ch. 93A, § 2(a), (c) (2019); 940 MASS. CODE REGS. 3.18 (2019). The gas retailers did not challenge the law on vagueness grounds, but merely disputed whether their prices violated it.

<sup>274</sup> *White*, 636 F.3d at 588 (“Dramatic changes in gross margin might illustrate that a price increase is a ‘gross disparity’ in price because it reflects price increases unexplained by cost increases. But nothing in the regulation suggests that increases in gross margin alone, in the absence of any price increase and simultaneous with *declining* retail prices, can support a price-gouging claim.”).

<sup>275</sup> Gary E. Lehman, *Price Gouging: Application of Florida’s Deceptive and Unfair Trade Practices Act in the Aftermath of Hurricane Andrew*, 17 NOVA L. REV., 1029, 1049-50 (1993).

count,<sup>276</sup> are really quite clear. When a percentage price increase is specified, there is little to quibble about beyond the applicable time period and market area for measuring the percentage change. Type-2 statutes are somewhat more open to argument because their prohibition on price increases is typically accompanied by exceptions where the seller's increased operational costs justify an increase. Nevertheless, no challenges have been brought on the basis of increased cost. Finally, although type-3 laws may seem quite vulnerable to vagueness challenges, many specify criteria for assessing whether an excessive increase has occurred. Even where they do not, the limited case law available suggests that courts will seek and find useful standards for operationalizing the concept in the contract-law doctrine of unconscionability. For these reasons, emergency price-gouging laws appear to provide a legally unproblematic model for prohibiting excessive prices.

### 3. Applicability to Prescription Drug Prices

As noted above, most emergency price-gouging statutes as currently written do not explicitly cover medicines—hence the new bills proposing to amend or extend them. The interesting question is not whether they presently apply to drugs, but whether this type of approach is a useful one to take for drugs.

The approach is appealing because of its simplicity and its apparent durability before the courts. It asks adjudicators simply to compare prices before and after a triggering event. In the case of type-1 statutes, it supplies a concrete, mathematical calculation to perform. Type 2 and 3 statutes involve more discretion for the factfinder, but often provide one or more specific criteria by which to evaluate price hikes.

Yet several shortcomings as an approach for drug prices are notable. First and foremost, it has no application to a drug's launch price. It may be useful for addressing price increases for generics and (at the federal level) branded medications, but its focus is solely on the magnitude of price increases over time, not the reasonableness of the product's initial price. In the context of the products and services subject to price gouging during emergencies, this makes sense: for batteries, generators, building supplies, diapers, and the like, there is often no public concern about the reasonableness of their market price. That is because, in ordinary times, the market functions well as a pricing mechanism. There is robust competition, consumers have adequate knowledge of and ability to choose among competing products, and desperate need does not drive purchasing decisions. For many new prescription drugs, in contrast, such market conditions are not present, permitting launch prices to be set at very high (often monopoly) levels. These baseline prices are a substantial public concern, and the emergency price-gouging law approach is unable to address them.

A second question is how to adapt an approach based on acute, time-limited emergencies to the drug-affordability problem, which is longstanding and likely to endure indefinitely. It is not unprecedented to characterize a chronic public health problem that has recently increased in seriousness as an emergency. Several states and President Trump, for example, have declared a public health emergency in response to the opioid epidemic.<sup>277</sup> At least one state price-gouging bill proposed for prescription drugs hewed to the emergency framework, confining its protections to

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<sup>276</sup> Type-1 states include Arkansas, California, District of Columbia, Oklahoma, Oregon, Utah, West Virginia, and Wisconsin, based on our review of state statutes.

<sup>277</sup> Rebecca L. Haffajee et al., *What Is a Public Health "Emergency"?*, 371 NEW ENGL. J. MED. 986 (2014); Alexander Walsdorf, Note, *I Get by With a Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases*, 102 MINN. L. REV. 2497, 2522 (2018).

times when a market shortage triggers the governor to declare a market emergency.<sup>278</sup> But most state bills, as well as the federal drug price-gouging bills, do not make reference to an emergency or market disruption.<sup>279</sup> Instead, they require companies to regularly report the price increases and authorize enforcement action whenever those increases exceed a specified standard. That seems the most straightforward response to the question of how to adapt price-gouging laws to the drug context.

A third issue is what benchmark price could be used to gauge the excessiveness of drug price increases.<sup>280</sup> The approach of emergency price-gouging laws is nearly always to compare the prices charged by a given seller in the same market area before and after an emergency declaration. Occasionally, prices are evaluated by reference to what other sellers in the same market area charge, or by what is charged in another market area. The last two approaches are not feasible for drugs because prices do not vary geographically within the United States in the same way the prices for gasoline or generators do, and because many drugs have only one seller.<sup>281</sup> Often, there will be no set of comparable products in the market from which one could infer whether a drug's current price departs from the usual price for similar goods. Further, the usual, pre/post approach is not easily applied if there is no discrete declaration of an emergency. In that case, some dates must be chosen as setting the price against which future increases will be benchmark. Again, the difficulty is that any such price, because of the monopoly or near-monopoly position of the seller, may be considerably above what policymakers would consider reasonable or what a more competitive market would produce.

No way around this problem is apparent. Policy approaches inspired by emergency price-gouging laws must be content with arresting the trend of escalating drug prices; they will not be able to reverse it. Selecting a type 3 approach rather than type 1 at least permits the state to vary what constitutes an acceptable price increase according to the baseline cost against which the increase is being assessed. While type 1 statutes impose a one-size-fits-all standard in specifying a percentage cap on price increases, type 3 statutes permit the state to calibrate its actions to the impact of a particular price increase on consumers. For inexpensive drugs, states may prefer not to expend resources going after a company's decision to increase a drug's price substantially in percentage terms. In contrast, a drug that starts out costing several thousand dollars per year might reasonably be targeted for enforcement for any price increase in excess of general inflation. Such discretion under a type-3 statute would create greater uncertainty for biopharmaceutical companies about what will be deemed acceptable, and therefore open the statute up to vagueness challenges. Solutions, however, are available. The statute could provide specific criteria for evaluating the unreasonableness of a particular percentage price increase or specify brackets of acceptable increases for drugs with different baseline costs.

A final issue is whether and how to import from emergency price-gouging laws the practice of taking companies' increased operational costs into consideration. Many such statutes provide a defense to price-gouging actions if the company can show that its own costs greatly increased during the emergency, or provide that operational costs are to be considered when deciding whether price gouging has occurred. The rationale for this approach in the context of emergencies is obvious: the same market disruptions that increase demand for the product, making it possible to price gouge,

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<sup>278</sup> H.7022, 2018 Gen. Assemb., Reg. Sess. (R.I. 2018).

<sup>279</sup> For details, refer to Part I, *supra*.

<sup>280</sup> This issue has been raised by Zack Buck, who has noted the lack of an "organic price equilibrium" for prescription drugs. Isaac D. Buck, Presentation at Health Law Professors Conference (June 2018) (unpublished) (on file with authors).

<sup>281</sup> Furthermore, the use of foreign benchmarks would appear to be outside the approach embraced by these emergency laws as the U.S. does not have a comparable foreign market.



may also increase the costs of producing or obtaining it. The supply of product components or ingredients may have been interrupted or it may be more costly to locate and transport those components under emergency conditions. Those considerations apply to a much lesser extent in the day-to-day operation of the prescription drug market. Acute problems such as problems at manufacturing facilities do occur, and have led on many occasions to drug shortages.<sup>282</sup> Manufacturers have rarely cited such problems as justifications for drug price increases, but in some cases reasonably may do so. There is thus an argument for taking them into account.

The danger of doing so is that it may allow companies to pass on inefficiencies in their operations to consumers, creating perverse incentives. That problem is why regulators of the price of public utilities moved away from focusing on companies' rate of return (which implicitly accounts for operational costs) in favor of imposing flat price caps.<sup>283</sup> Another challenge in the drug context is that biopharmaceutical companies number among their operational costs the vast amounts they spend on marketing and promotion activities. There is broad public agreement that too much is spent on such activities, so allowing companies to use such expenses as a basis for increasing prices is undesirable. Thus, if statutes do permit companies to argue that their drug price increases are justified by higher operational costs, the allowable costs should be limited to expenses incurred because of an acute disruption in the market or their supply chain.

## B. Contract Law

Although the term “unconscionable” is used in many places in the law, it has deep doctrinal roots in contract law. The doctrine of unconscionability in contract law permits a court to refuse to enforce a contract or contractual provision because to do so would yield results that “shock the conscience.”<sup>284</sup> It permits courts to modify or reject a contractual agreement or provision on grounds of unfairness.<sup>285</sup> A motivating premise of the doctrine is that courts ought not to participate in enforcing a contract that is technically valid but works a deep injustice against one of the parties.<sup>286</sup> Furthermore, the doctrine of unconscionability allows courts to “police bargains overtly,” as opposed to covertly.<sup>287</sup>

The doctrine of unconscionability is now widely recognized as having two distinct dimensions, one procedural and one substantive.<sup>288</sup> That is, courts will examine the fairness of the process by which the contract came into existence as well as the contract's actual provisions.<sup>289</sup> It is well established that the unconscionability doctrine can be applied to a contract's price terms,<sup>290</sup> although such cases are relatively unusual. Reported cases have involved door-to-door sales, rent-to-

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<sup>282</sup> See *Frequently Asked Questions About Drug Shortages*, FDA (Jul. 5, 2018), <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q4>.

<sup>283</sup> See *infra* Part III.D.

<sup>284</sup> 156 AM. JUR. PROOF OF FACTS 3D 343 § 1 (2019).

<sup>285</sup> E. ALLAN FARNSWORTH, *CONTRACTS* 298 (4th ed. 2004); see also U.C.C. § 2-302 cmts. 1-3 (Am. Law Inst. & Unif. Law Comm'n).

<sup>286</sup> See, e.g., *Maxwell v. Fid. Fin. Servs., Inc.*, 907 P.2d 51, 60 (Ariz. 1995) (“[C]ourts will not lend their hand to the enforcement of oppressive contracts.”)

<sup>287</sup> FARNSWORTH, *supra* note 285, at 298; see also U.C.C. § 2-302 cmts. 1-3.

<sup>288</sup> Arthur Leff is generally recognized as the originator of these terms. See Arthur A. Leff, *Unconscionability and the Code—The Emperor's New Clause*, 115 U. PENN. L. REV. 485, 516 (1967).

<sup>289</sup> *Id.*; Frank P. Darr, *Unconscionability and Price Fairness*, 30 Hous. L. Rev. 1819, 1820 (1994).

<sup>290</sup> See Charles L. Knapp, *Unconscionability in American Contract Law: A Twenty-First Century Survey*, in *COMMERCIAL CONTRACT LAW: A TRANSATLANTIC PERSPECTIVE* 312 (Larry A. DiMatteo et al. eds., 2013) (“Although not seen originally as being applicable to a contract's price term, § 2-302 was in time also applied in cases where courts found the contract price for goods or services to be unconscionably high.”).

own contracts, loans and interest charges, royalties, rents, commodities, and water.<sup>291</sup> A typical fact pattern involves an unsophisticated buyer purchasing goods from an aggressive seller for far more than their fair market value.<sup>292</sup>

The doctrine of unconscionability is traditionally not a freestanding cause of action, though it is occasionally treated as such.<sup>293</sup> Rather, unconscionability is conventionally asserted as a defense by a party alleged to be in breach of contract.<sup>294</sup> Courts are not in consensus about whether judges may raise the issue of unconscionability *sua sponte*,<sup>295</sup> but it is clear that unconscionability is an issue for the judge, not the jury.<sup>296</sup> Although facts and evidence about context are very important for the analysis, they do not “convert the determination on unconscionability from one that is a matter of law as applied to those facts to one that is in whole a matter of fact.”<sup>297</sup>

## 1. Approach to Defining Excessive Price

Principles of equity underlying the doctrine of unconscionability trace back to at least the Roman era, but the doctrine got its modern start in the United States in the mid-twentieth century.<sup>298</sup> Drafters of the Uniform Commercial Code (UCC), which offers model state legislation for commercial transactions, codified the doctrine in § 2-302 pertaining to the sales of goods:<sup>299</sup>

(1) If the court as a matter of law finds the contract or any clause of the contract to have been unconscionable at the time it was made the court may refuse to enforce the contract, or it may enforce the remainder of the contract without the unconscionable clause, or it may so limit the application of any unconscionable clause as to avoid any unconscionable result.

(2) When it is claimed or appears to the court that the contract or any clause thereof may be unconscionable the parties shall be afforded a reasonable opportunity to present evidence as to its commercial setting, purpose and effect to aid the court in making the determination.<sup>300</sup>

Similar provisions can be found in the Restatement (Second) of Contracts section 208, as well as uniform laws dealing with consumer credit, consumer sales, land transactions, and residential leases.<sup>301</sup> Although UCC section 2-302 pertains to contracts involving goods, “it has wisely been applied either by analogy or as an expression of a general doctrine, to many other kinds of

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<sup>291</sup> Darr, *supra* note 289, at 1821-22.

<sup>292</sup> See, e.g., *id.* at 1820-21; Williams v. Walker-Thomas Furniture Co., 350 F.2d 445 (D.C. Cir. 1965).

<sup>293</sup> See, e.g., Knapp, *supra* note 290, at 335-37 (discussing court’s treatment of claims of procedural and substantive unconscionability as a cause of action in *In re Checking Account Overdraft Litigation*, 694 F. Supp. 2d 1302 (S.D. Fla. 2010)).

<sup>294</sup> FARNSWORTH, *supra* note 285, at 299.

<sup>295</sup> For a discussion, see Hazel Glenn Beh, *Curing the Infirmitities of the Unconscionability Doctrine*, 66 HASTINGS L.J. 1011, 1028-29 (2015).

<sup>296</sup> Maxwell v. Fid. Fin. Servs., Inc., 907 P.2d 51, 56 (Ariz. 1995) (“Maxwell contends that the determination of whether a contract is unconscionable is for the trier of fact. We find no support for this position given that Arizona law, which is consistent with the law in every other jurisdiction that has ruled on this issue, clearly provides that the determination of unconscionability is to be made by the court as a matter of law.”).

<sup>297</sup> *Id.*

<sup>298</sup> Knapp, *supra* note 290, at 310.

<sup>299</sup> *Id.*; 156 AM. JUR. PROOF OF FACTS 3D 343 § 1 (2019).

<sup>300</sup> U.C.C. § 2-302.

<sup>301</sup> FARNSWORTH, *supra* note 285, at 299.

contracts....”<sup>302</sup> In addition to wielding their authority under state statutes, many of which are based on the UCC, courts have “asserted the power to employ the notion of unconscionability as a matter of general common law.”<sup>303</sup>

*Williams v. Walker-Thomas Furniture Co.* is an important and widely cited case articulating the common-law authority of courts to use unconscionability as a justification for refusing to enforce a contract.<sup>304</sup> Ora Lee Williams had a middle-school education and supported seven children on public assistance of \$218 per month.<sup>305</sup> As was fairly common in low-income neighborhoods at the time, Walker-Thomas Furniture deployed door-to-door salesmen to sell merchandise on credit, to be paid in installments.<sup>306</sup> Williams purchased a number of household items from Walker-Thomas Furniture between 1957 and 1962<sup>307</sup> and signed more than a dozen purchase contracts, “nearly all in response to a salesman’s home visit.”<sup>308</sup> The contracts included egregious cross-collateralization provisions effectively forcing her to carry a balance on each item until all her purchases were paid in full. They further permitted Walker-Thomas Furniture to repossess *all* items purchased from its store in the event of default on *any* single item.<sup>309</sup>

In 1962, Williams defaulted after buying a stereo and the store “sought to replevy all the items purchased since December 1957.”<sup>310</sup> The lower courts reviewing Williams’s case rejected her contention that these contracts were unconscionable and therefore unenforceable. Despite language condemning the store’s conduct, the opinion issued by the District of Columbia Court of Appeals held that there was “no ground upon which this court can declare the contracts in question contrary to public policy.”<sup>311</sup> However, the Court of Appeals disagreed about the power of the courts to find contracts unconscionable and remanded the case to the trial court for rehearing.<sup>312</sup>

The existence of the unconscionability doctrine is well established in contract law, but a precise definition of “unconscionable” is elusive. One commentator has observed, the fact that “the term is incapable of precise definition is a source of both strength and weakness.”<sup>313</sup> It imparts flexibility, but also confusion. Others have been deeply critical of the doctrine, particularly UCC section 2-302, writing, “If reading this section makes anything clear it is that reading this section alone makes nothing clear about the meaning of ‘unconscionable’ except perhaps that it is pejorative.”<sup>314</sup> The comments to UCC § 2-302 shed only a dim light on the term’s meaning. They state that “[t]he basic test is whether, in the light of the general commercial background and the commercial needs of the particular trade or case, the clauses involved are so one-sided as to be unconscionable under the circumstances existing at the time of the making of the contract.”<sup>315</sup> A bit

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<sup>302</sup> *Id.* at 298; see also Knapp, *supra* note 290, at 311.

<sup>303</sup> Knapp, *supra* note 290, at 311; see also Beh, *supra* note 295, at 1016 (citing Kathleen S. Morris, *Expanding Local Enforcement of State and Federal Consumer Protection Laws*, 40 FORDHAM URB. L.J. 1903, 1928-49 (2013)) (identifying several state statutes).

<sup>304</sup> Knapp, *supra* note 290, at 311 (calling the case “probably the most important”). The “paternity of the unconscionability doctrine” can be traced back to pre-UCC equity cases. See, e.g., *Campbell Soup Co. v. Wentz*, 172 F.2d 80 (3d Cir. 1948); see also FARNSWORTH, *supra* note 285, at 300.

<sup>305</sup> Anne Fleming, *The Rise and Fall of Unconscionability As the “Law of the Poor”*, 102 GEO. L.J. 1383, 1385, 1392 (2014).

<sup>306</sup> *Id.*

<sup>307</sup> *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445, 447 (D.C. Cir. 1965).

<sup>308</sup> Fleming, *supra* note 305, at 1392-93 (2014).

<sup>309</sup> *Williams*, 198 F.2d at 447.

<sup>310</sup> *Id.*

<sup>311</sup> *Id.* at 448.

<sup>312</sup> *Id.* at 450.

<sup>313</sup> FARNSWORTH, *supra* note 285, at 300.

<sup>314</sup> Leff, *supra* note 288, at 487.

<sup>315</sup> U.C.C. § 2-302 cmt. 1.

more helpfully, they explain that the doctrine aims to prevent “oppression and unfair surprise,” and is not concerned with the “disturbance of allocation of risks because of superior bargaining power.”<sup>316</sup>

The concept of unconscionability—as with many standards used in contract and commercial law and beyond—thus involves some imprecision.<sup>317</sup> Although the unconscionability doctrine has been criticized for its vagueness,<sup>318</sup> courts have developed fairly standardized and workable doctrinal analyses for determining if a contract or contractual provision is unconscionable.<sup>319</sup> Moreover, as discussed below, this doctrine has been applied to contractual price terms relating to hospital charges.

## 2. Legal Challenges

*Williams* has been credited with providing “[t]he most durable answer” to the meaning of unconscionability.<sup>320</sup> According to the Court, “[u]nconscionability has generally been recognized to include 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.”<sup>321</sup> These two aspects are often referred to, respectively, as “procedural unconscionability” and “substantive unconscionability.”<sup>322</sup>

Procedural unconscionability pertains to the bargaining process itself.<sup>323</sup> In general, following the comment to UCC § 2-302, procedural unconscionability has been thought to consist of two principal aspects: “oppression” and “surprise.”<sup>324</sup> Oppression refers to the “inability to bargain about a particular term”—for example, because of extreme inequality of bargaining power and “lack of meaningful choice” or lack of alternative suppliers in the market.<sup>325</sup> Surprise can arise from “fine print” contracts or other circumstances that submerge a provision that disadvantages one party.<sup>326</sup>

Typical fact patterns of procedural unconscionability involve sharp or deceptive bargaining practices; fine print, boilerplate or convoluted contracts; exploitation of language barriers or uneducated, illiterate, mentally infirm, or otherwise unsophisticated parties; emergency situations; or

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<sup>316</sup> *Id.*

<sup>317</sup> See e.g., *Sonic-Calabasas A, Inc. v. Moreno*, 311 P.3d 184, 214-15 (Cal. 2013) (defending unconscionability analysis against charge of being “hopelessly vague” by noting that imprecision is “hardly anomalous” in the law).

<sup>318</sup> Darr, *supra* note 289, at 1830-32. One of the earliest and most prominent critics of the unconscionability doctrine is Arthur Leff, who characterized substantive unconscionability as grounded in little more than “the emotional state of the trier” and argued that “what may permissibly make the judges’ pulses race or their cheeks redden, so as to justify the destruction of a particular provision, is, one would suppose, what the judge ought to have been told by the statute.” Leff, *supra* note 288, at 516; see also ROBERT COOTER & THOMAS ULEN, *LAW AND ECONOMICS* 267 (1988) (calling the doctrine “troubling because there is no precise definition of when a contract is unconscionable”).

<sup>319</sup> See, e.g., *Alpha One v. NYNEX Info. Res. Co.*, No. 930129C, 1994 WL 879488, at \*3 (Mass. Super. Ct. May 23, 1994) (noting criticism of doctrine’s vagueness, but explaining standards used by the courts); *Abel Holding Co., Inc. v. Am. Dist. Tel. Co.*, 350 A.2d 292, 303-04 (N.J. Super. Ct. Law Div. 1975), *aff’d*, 371 A.2d 111 (N.J. Super. Ct. App. Div. 1977) (noting that “[u]nconscionability is not defined, and the definition most commonly used is vague and unsatisfactory” but then proceeding to explain how courts have fleshed out the doctrine).

<sup>320</sup> FARNSWORTH, *supra* note 285, at 301.

<sup>321</sup> *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445, 449 (D.C. Cir. 1965); see also FARNSWORTH, *supra* note 285, at 301.

<sup>322</sup> FARNSWORTH, *supra* note 285, at 301; see also Leff, *supra* note 288; Knapp, *supra* note 290, at 313 (discussing the influence of Leff’s article and how it closely tracked elements in the *Williams* case).

<sup>323</sup> Melissa T. Lonegrass, *Finding Room for Fairness in Formalism: The Sliding Scale Approach to Unconscionability*, 44 LOY. U. CHI. L.J. 1, 9 (2012).

<sup>324</sup> Jonathan A. Eddy, *On the Essential Purposes of Limited Remedies: The Metaphysics of UCC Section 2-719(2)*, 65 CAL. L. REV. 28, 42 (1977).

<sup>325</sup> RESTATEMENT (SECOND) OF CONTRACTS § 208 (AM. LAW INST. 1981).

<sup>326</sup> Eddy, *supra* note 324, at 43.

unequal bargaining power.<sup>327</sup> Inequality in bargaining power alone is rarely sufficient, but may clear the bar in combination with other elements of either procedural or substantive unconscionability.<sup>328</sup> Although courts commonly turn to these factors to make a determination of procedural unconscionability, they “have not clearly articulated the requisite proof of these factors or specified a recipe for their successful combination.”<sup>329</sup>

Whereas procedural unconscionability is concerned with the process of contract formation, substantive unconscionability is concerned with the fairness of a contract’s terms.<sup>330</sup> Defining standards for substantive unconscionability appears a more difficult task than defining them for procedural unconscionability. Scholars “often describe the concept by listing the types of clauses most commonly deemed substantively unconscionable.”<sup>331</sup> That said, central themes pertain to the one-sided allocation of risks and terms that are “commercially unreasonable.”<sup>332</sup> A substantively unconscionable bargain is one “such as no man in his senses and not under delusion would make on the one hand, and as no honest and fair man would accept on the other.”<sup>333</sup>

In undertaking a substantive unconscionability analysis, courts have searched for evidence of a significant disparity between the price and cost or value of the good, for penalty clauses, and for provisions denying rights and remedies to the consumer.<sup>334</sup> An example from among price term cases cited in the Reporter’s note to comment d of the *Restatement (Second) of Contracts* is a case in which the price of goods were two and a half times the “reasonable market price” and several other conditions also pointed to an unfair bargain.<sup>335</sup> Courts also examine “the basis and justification for the price,” including prices paid by other, similar consumers in similar transactions.<sup>336</sup> The California Supreme Court for example, declined to hold a high bank fee for processing checks unconscionable on its face; further inquiry into the context for the price and transaction was required.<sup>337</sup>

Courts applying the doctrine of unconscionability have “reviewed evidence of procedural and substantive unconscionability separately, requiring a minimum threshold or ‘quantum’ of each type of unconscionability to justify intervention in the contract.”<sup>338</sup> Many courts have used a “sliding-scale” approach,<sup>339</sup> in which more of one type of unconscionability can “offset” less of the

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<sup>327</sup> Johnson v. Mobil Oil Corp., 415 F. Supp. 264, 268 (E.D. Mich. 1976); Willie v. Southwestern Bell Telephone Co., 549 P.2d 903 (Kan. 1976); RESTATEMENT (SECOND), *supra* note 325, § 208 cmt. d; FARNSWORTH, *supra* note 285, at 301; M. Neil Browne & Lauren Biksacky, *Unconscionability and the Contingent Assumptions of Contract Theory*, 2013 MICH. ST. L. REV. 211, 222 (2013).

<sup>328</sup> FARNSWORTH, *supra* note 285, at 302; *see also* RESTATEMENT, *supra* note 325, at § 208 cmt. d (summarizing factors courts have said weigh in favor of a finding of unconscionability).

<sup>329</sup> Steven W. Bender, *Rate Regulation at the Crossroads of Usury and Unconscionability: The Case for Regulating Abusive Commercial and Consumer Interest Rates Under the Unconscionability Standard*, 31 HOUS. L. REV. 721, 752-53 (1997).

<sup>330</sup> Lonegrass, *supra* note 323, at 10-11.

<sup>331</sup> *Id.*

<sup>332</sup> *Id.*

<sup>333</sup> RESTATEMENT (SECOND), *supra* note 325, at § 208 cmt. b; *see also* Philpot v. Tenn. Health Mgmt., 279 S.W.3d 573, 579 (Tenn. Ct. App. 2007).

<sup>334</sup> Klas v. Van Wagoner, 829 P.2d 135, 139 (Utah Ct. App. 1992); Willie v. Sw. Bell Tel. Co., 549 P.2d 903, 906-07 (Kan. 1976); Lonegrass, *supra* note 323, at 10-11.

<sup>335</sup> RESTATEMENT (SECOND), *supra* note 325, at § 208 cmt. d (citing Kugler v. Romain, 279 A.2d 640 (N.J. 1971) (finding unconscionability where goods were of extremely little use to buyers, price was two and one-half times a “reasonable market price,” sellers made many misrepresentations and deceptions, and buyers were poor, uneducated and inexperienced)).

<sup>336</sup> Perdue v. Crocker Nat’l Bank, 702 P.2d 503, 512-14 (Cal. 1985).

<sup>337</sup> *Id.* at 513-14.

<sup>338</sup> Lonegrass, *supra* note 323, at 12.

<sup>339</sup> *Id.* at 12-19; Knapp, *supra* note 290, at 323.

other.<sup>340</sup> The Arizona Supreme Court, for instance, has observed that although some courts have questioned whether both kinds of unconscionability must be present, the majority of courts “have held that there must be some quantum of *both*...and take a balancing approach in applying them.”<sup>341</sup>

Historically, courts “have been more reluctant” to apply the doctrine of unconscionability to price terms than to other contractual provisions.<sup>342</sup> Judicial hesitance stems from the fact that price rarely comes as a surprise in a contract, can sometimes be negotiable, and, most importantly, can be extraordinarily complex to evaluate on fairness grounds.<sup>343</sup> Given the centrality of price terms in the overall contract, furthermore, it is difficult for a court to invalidate price provisions while enforcing the remainder of the contract.<sup>344</sup> Although some commentators have dismissed the doctrine of unconscionability as essentially inapplicable to price terms, analysis of recent cases suggests such a conclusion is mistaken.<sup>345</sup>

Courts’ concerns about applying the unconscionability doctrine to price may, however, help to explain why when they have chosen to do so they often cite deficiencies in both substantive and procedural aspects of the price bargain.<sup>346</sup> A 1994 study of forty-four price unconscionability cases found that among those with an outcome of unconscionable terms, all “involved a determination that the price was outrageous and in nearly three-fourths of the cases, the contracting process was procedurally flawed.”<sup>347</sup> Only two cases held that “a high price alone, without process problems, resulted in an unconscionable contract.”<sup>348</sup> A more recent analysis identified several decisions handed down in the wake of the 2008 financial crisis that signaled courts’ willingness to hold the price term of consumer credit contracts unconscionable purely because the price was high, but such cases appear exceptional.<sup>349</sup>

A 2018 California Supreme Court case represents the sliding-scale approach and demonstrates the continuing importance of finding at least some degree of both procedural and substantive unconscionability in a price-term case. At issue in *de la Torre v. CashCall Inc.* was whether courts had the authority to deem a high interest rate on consumer loans of \$2,500 or more unconscionable.<sup>350</sup> The facts involved high-risk borrowers taking out unsecured loans of \$2,600 with a 96% or 135% interest rate.<sup>351</sup> By statute, interest rates were capped only on consumer loans less than \$2,500.<sup>352</sup> The issue was not the unconscionability of these interest rates, but whether courts

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<sup>340</sup> Lonegrass, *supra* note 323, at 12; *cited in* FARNSWORTH, *supra* note 285, at 302 (citing *Armendariz v. Foundation Health Psychcare Servs.*, 6 P.3d 669 (Cal. 2000)).

<sup>341</sup> Larry A. DiMatteo & Bruce Louis Rich, *A Consent Theory of Unconscionability: An Empirical Study of Law in Action*, 33 FLA. ST. U. L. REV. 1067, 1073-74 (2006) (discussing *Maxwell v. Fid. Fin. Servs., Inc.*, 907 P.2d 51, 58 (Ariz. 1995)).

<sup>342</sup> FARNSWORTH, *supra* note 285, at 306.

<sup>343</sup> *Id.* at 306-07.

<sup>344</sup> *Id.* at 307.

<sup>345</sup> Jacob Hale Russell, *Unconscionability’s Greatly Exaggerated Death*, 53 U.C. Davis L. Rev. \_\_ (forthcoming), available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3213542](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3213542) (concluding that “in stark contrast to the conventional wisdom, the doctrine has quietly flourished in recent years,” undermining the “widely held belief...that ‘price alone is insufficient to establish unconscionability.’”).

<sup>346</sup> *Id.*

<sup>347</sup> Darr, *supra* note 289, at 842-43.

<sup>348</sup> *Id.* at 1843.

<sup>349</sup> Russell, *supra* note 345, at [p.15-21 on the SSRN version] (collecting cases, many of which also involve a deficiency of procedural unconscionability with respect to the price term of the contract).

<sup>350</sup> *De la Torre v. CashCall, Inc.*, 433 P.3d 1004, 1007 (Cal. 2018).

<sup>351</sup> *Id.* at 1008.

<sup>352</sup> *Id.*

had authority to rule on the unconscionability of interest rates for loans not capped by statute.<sup>353</sup> Nevertheless, its analysis is instructive.

The Court began by acknowledging that it was “long established under California law” that “the doctrine of unconscionability reaches contract terms related to the price of goods or services exchanged,” including interest rates.<sup>354</sup> Whether a price term is “unreasonably and unexpectedly harsh” is a holistic analysis<sup>355</sup> that “depends on more than just a single printed number,” so courts examine other provisions and circumstances affecting a transaction’s benefits and burdens along with the price itself.<sup>356</sup> The Court further observed that procedural elements are an integral part of the analysis of the unconscionability of price terms.<sup>357</sup> Although aspects of the doctrinal analysis lack clarity, the Court stated it was clear that “unconscionability requires...procedural unconscionability — along with the overly harsh or one-sided results that epitomize substantive unconscionability.”<sup>358</sup>

The Court noted that substantive unconscionability is not sufficiently established by examining whether the “price exceeds cost or fair value.”<sup>359</sup> Rather, an inquiry must also be made into “the basis and justification for the price”<sup>360</sup> and whether there are “market imperfections that make it less likely that the price was set by a ‘freely competitive market’.”<sup>361</sup> The Court summarized its approach by emphasizing the flexibility of the unconscionability doctrine (particularly as compared to a statutory price cap) and the importance of considering a host of contextual features both procedural and substantive.<sup>362</sup> Unconscionability is a finding that “under the circumstances of the case, taking into account the bargaining process and prevailing market conditions—a particular rate was ‘overly harsh,’ ‘unduly oppressive,’ or ‘so one-sided as to shock the conscience.’”<sup>363</sup>

The 1995 Arizona Supreme Court case, *Maxwell v. Fidelity Financial Services, Inc.*, offers an example of the minority approach that an unconscionability finding can be based on substantive unfairness alone.<sup>364</sup> At issue in *Maxwell* was a loan for a water heater costing \$6,512 “payable at 19.5 percent interest, for a total time-payment price of \$14,860.43.”<sup>365</sup> The contract included provisions that in the event of default, Fidelity would not only be able to repossess the water heater, but could also foreclose on Maxwell’s house, valued at approximately \$40,000.<sup>366</sup> The court held that the best reading of both the U.C.C. and Arizona statutory law was that procedural unfairness was not strictly required, “especially in cases involving either price-cost disparity or limitation of remedies.”<sup>367</sup> It further found that the interest rate and amount of total payments in Williams’s loan raised “a question of grossly-excessive price, constituting substantive unconscionability” and that the

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<sup>353</sup> The Court did not rule on whether the terms at issue were unconscionable because they were not asked to do so by the Ninth Circuit. *Id.* at 1021.

<sup>354</sup> *Id.* at 1009.

<sup>355</sup> *Id.*

<sup>356</sup> *Id.*

<sup>357</sup> *Id.* at 1009, 1014 (describing the sliding-scale approach).

<sup>358</sup> *Id.* at 1014.

<sup>359</sup> *Id.* (citations omitted).

<sup>360</sup> *Id.* at 1015 (citations omitted).

<sup>361</sup> *Id.*

<sup>362</sup> *Id.*

<sup>363</sup> *Id.*

<sup>364</sup> *Maxwell v. Fid. Fin. Servs., Inc.*, 907 P.2d 51, 58 (Ariz. 1995) (characterizing the sliding-scale approach as the approach of “many courts, perhaps a majority” and cases involving a procedural finding alone as “exceptional”).

<sup>365</sup> *Id.* at 59-60.

<sup>366</sup> *Id.*

<sup>367</sup> *Id.* at 59.

oppressive default provisions “not only may constitute substantive unconscionability but also may provide evidence of procedural unconscionability.”<sup>368</sup>

In unconscionable-price cases courts tend to intervene where market conditions appear to be such that the usual supply-and-demand mechanism does not adequately constrain prices.<sup>369</sup> Even commentators who are skeptical of the unconscionability doctrine because they believe that economic exigency should not incur a coercive fix acknowledge a role for it under conditions of market failure.<sup>370</sup>

But how to determine whether prices reveal a problem with the market? Steven Bender has identified four different metrics suggested by the case law for determining substantive price unconscionability.<sup>371</sup> These are (1) the difference between the sales price of the good and the seller’s cost for the good; (2) net profit, i.e., the sales price compared to the seller’s total cost of operation, including the cost of the good; (3) the sales price compared to that of other sellers, and (4) the sales price compared to that of other “similarly situated” sellers.<sup>372</sup> Courts applying the retail-price comparison approach (measures 3 and 4) have generally found unconscionability where the retail price exceeds the comparator by a ratio of two to one.<sup>373</sup> Notably, most state statutes (as opposed to court decisions) employing an unconscionability standard use the retail-price approach rather than examining the seller’s profits.<sup>374</sup> In terms of which approach is best, Bender criticizes option (1) for disregarding the seller’s operational costs, and (3) and (4) for being unhelpful in cases of a monopoly.<sup>375</sup> Thus, Bender argues, option (2) is best.<sup>376</sup>

Before turning to applications of these principles to prescription drugs, we note that there is precedent for applying the unconscionability doctrine to medical bills.<sup>377</sup> Medical-bill cases generally concern hospital charges, particularly for emergency department visits.<sup>378</sup> In gauging substantive unconscionability in such cases, courts have compared the hospital’s usual charge for the service with what other hospitals charge or what is typically actually paid after charges are discounted to insurers’ negotiated rates.<sup>379</sup> On the procedural front, several courts have held that hospital admission and payment agreements may be held unconscionable merely because under exigent circumstances a reasonable person may not pay much attention or have much choice but to sign.<sup>380</sup>

A recent example of a medical-bill case concerned an uninsured California patient’s challenge to charges of more than \$10,000 for three emergency department visits. The plaintiff claimed that the charges were unconscionable because they were “not tethered to [the providers’]

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<sup>368</sup> *Id.*

<sup>369</sup> Darr, *supra* note 289, at 1823 (stating that where there is a “lack of market mechanisms to assure that the gouger is policed” the courts “may serve as a market surrogate and police prices in conformity with existing notions of price fairness”).

<sup>370</sup> Mark Klock, *Unconscionability and Price Discrimination*, 69 TENN. L. REV. 317, 354-55, 373 (2002).

<sup>371</sup> Bender, *supra* note 329, at 754.

<sup>372</sup> *Id.* It is also worth noting that others have observed a different kind of reference pricing that benchmarks prices against other recent transactions between the same parties. *See, e.g.*, Darr, *supra* note 289, at 1837-8 (quoting Daniel Kahneman et al., *Fairness As a Constraint on Profit Seeking: Entitlement in the Market*, 76 AM. ECON. REV. 728, 729, 730 (1986)).

<sup>373</sup> Bender, *supra* note 329, at 756.

<sup>374</sup> *Id.* at 764.

<sup>375</sup> *Id.* at 755.

<sup>376</sup> *Id.*

<sup>377</sup> For a discussion of cases, see George A. Nation III, *Obscene Contracts: The Doctrine of Unconscionability and Hospital Billing of the Uninsured*, 94 KY. L.J. 101, 126-28 (2005).

<sup>378</sup> *Id.*

<sup>379</sup> Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 686 (2008).

<sup>380</sup> *See* Nation, *supra* note 377, at 126-28.



actual costs,” but were “four to six times” those costs “and far beyond any reasonable profit margin.”<sup>381</sup> The Court held that his claim under the state’s unlawful competition statute prohibiting “unlawful, unfair or fraudulent” business practices could proceed over defendant’s demurrer.<sup>382</sup> The fact that all emergency patients had to sign the admission contract before being treated could support a finding of procedural unconscionability,<sup>383</sup> and that although mere demonstration that the “price exceeds cost or fair value” was insufficient to prove substantive unconscionability,<sup>384</sup> the plaintiff’s allegations did adequately state a cause of action.<sup>385</sup> The Court went on to note that in assessing substantive unconscionability it looks to factors such as the justification for a price, certain costs incurred by the seller, and the price paid by “similarly situated consumers in a similar transaction.”<sup>386</sup>

In arguing for the application of unconscionability to hospital-admission agreements for uninsured patients, George Nation has argued that the usual concerns about courts being bad at deciding what a fair price is do not apply.<sup>387</sup> This is because, hospitals have, in effect, already set a reasonable price: what they charge Medicare and other payers.<sup>388</sup> (The same could be said about prescription drugs.) Nation further argues for application of the unconscionability doctrine to hospital agreements because (1) there is price discrimination among buyers, which often serves as a basis for a finding of unconscionability in other cases; (2) the buyer has no meaningful choice; (3) the buyer may not realize he will pay more than other patients; and (4) the magnitude of the markup over hospitals’ costs is grossly shocking.<sup>389</sup>

Three key takeaways emerge from the foregoing review. First, despite unconscionability’s long-held reputation as a hopelessly indeterminate doctrine, courts have identified and consistently applied a method for applying it to the price term of contracts. The doctrine has form and force as a mechanism for policing unfair prices. Second, in the majority of jurisdictions, the method requires that procedural as well as substantive unconscionability be shown. Under the sliding-scale approach, the procedural unfairness can be relatively minor if the substantive unfairness of the price term is severe, but it must still be present to some degree. Finally, courts have articulated three basic metrics for proving substantive unconscionability: the seller’s markup on the good, the seller’s profit, and (merging options (3) and (4) identified by Bender, which are similar), the seller’s price compared to prices offered by competitors.

### 3. Applicability to Prescription Drug Prices

At first glance, the unconscionability doctrine in contract law seems to provide an attractive model for tackling high pharmaceutical prices in several respects. First, it offers powerful rhetoric drawing on a sense of moral unfairness. This strongly resonates with current debates about high drug prices. The unconscionability doctrine arose in the common law out of a felt need to come to the aid of consumers who are victims of market failures (e.g., lack of choice due to a paucity of alternative sellers) or are being exploited because of their vulnerable position. Many people have similar feelings about consumers who depend on high-cost drugs, especially single-source drugs.

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<sup>381</sup> *Moran v. Prime Healthcare Mgmt., Inc.*, 208 Cal. Rptr. 3d 303, 315 (Cal. Ct. App. 2016).

<sup>382</sup> *Id.*

<sup>383</sup> *Id.* at 316.

<sup>384</sup> *Id.*

<sup>385</sup> *Id.* at 317.

<sup>386</sup> *Id.*

<sup>387</sup> *See generally* Nation, *supra* note 377, at 131-36.

<sup>388</sup> *Id.* at 135-36.

<sup>389</sup> *Id.* at 136.

Second, unlike alternative models such as emergency price-gouging laws, the unconscionability doctrine in contract law has potential utility for policing the base price of prescription drugs, not just price hikes. It therefore offers the prospect of creating a regulatory regime in which gaming (adjusting one aspect of prices to avoid regulatory constraints on another) is comparatively more difficult. A legislature could simply announce that any drug price that reaches an unconscionable level—whether through price hikes or high initial prices—is unlawful.

Third, such a standard is, obviously, very flexible. Its flexibility is what has made it so useful in policing contracts that violate public policy: because it is impossible for legislators and agencies to anticipate every possible provision that contracting actors might dream up to take advantage of an unsophisticated party, the system benefits from allowing judges latitude to apply a general standard to specific transactions. In the prescription drug space, such flexibility would be advantageous because of the very different contexts surrounding prices for different drugs. Some drugs cost more than others to bring to market; some are blockbusters while others target small markets; some are lifesaving and essential while others are merely quality-of-life-enhancing; some are sold in markets with many therapeutic alternatives and substantial consumer choice and others are alone in their class. Each of those factors arguably bears on whether the price of the drug is substantively and procedurally unfair, and the contract-law conception of unconscionability allows for a case-by-case weighing. In contrast, a legislative pronouncement that a WAC over a certain dollar amount per year is unlawful does not.

Thus, unconscionability doctrine in the common law is flexible not only as to which price terms are unconscionable, but also how that proof is made. Under the sliding-scale approach, litigants can advance arguments under a variety of indicia of procedural unfairness (unequal bargaining power, lack of opportunity to bargain, lack of choice or of meaningful choice, surprise, lack of education/sophistication, and so on) and substantive unfairness (e.g., comparison to the seller's acquisition cost, seller's total costs, or prices charged by others). Such flexibility maximizes opportunities to use the doctrine to go after a wide range of problematic situations.

Despite these positive features, the contract-law approach to defining excessive price would encounter significant problems if marshaled to combat high prescription drug prices. A threshold issue is that the model is hard to scale. Common-law contract doctrine evolved to resolve disputes between the parties to one specific contract. The model is one of private enforcement (i.e., court actions are initiated by one of the parties to the contract); state attorneys general and other public enforcers are not involved. Some of the indicia included in courts' traditional analysis of procedural and substantive unconscionability really only make sense in the context of evaluating a particular buyer and a particular seller under particular circumstances. For example, courts often examine the buyer's likely understanding of the bargain she was entering into by looking at her level of educational attainment, language proficiency, and naivete. All of these considerations make the contract-law model a poor fit if policymakers wish to impose across-the-board regulation of the ways in which particular goods can be bought and sold.

It is also unclear how a contract-law model would work in light of the complexity of the prescription-drug supply chain, with its many intermediaries. Unlike furniture or hospital services, medicines are not purchased by the consumer from the supplier. The patient sits at the distal end of a long supply chain; the actors that directly contract with drug manufacturers are wholesalers and mail-order pharmacies (many of which share corporate ownership with a PBM).<sup>390</sup> If those initial contracts produce unfair effects for the ultimate third-party beneficiaries, it is unclear how they would be redressable under the unconscionability doctrine.

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<sup>390</sup> For a discussion of the complexity of the system, see NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 19, 41-49.

The remedies available in contract law are another sticking point. Traditional remedies for unconscionable contracts—refunding the buyer’s money, eliminating the obligation to pay, or voiding the contract altogether<sup>391</sup>—are not particularly helpful for patients who still need the drug and have no alternative supplier. These remedies may also be too weak to incentivize biopharmaceutical companies to change their pricing behavior. The upshot of this discussion is that although there may be utility in borrowing something from the common-law *standard* of unconscionability, there is no allure to leaving the *process* of policing excessive drug prices as a matter of contract law (i.e., to police them through litigation relating to particular contracts).

Second, although the flexible nature of the unconscionability doctrine is alluring, the flipside of flexibility is unpredictability. Unconscionability is a judge-made, judge-administered doctrine. Adopting the common-law understanding of the doctrine as the basis for a statutory definition of unconscionability (either expressly or by omitting any explicit definition of that term in the statute, which will cause courts to default to the common-law understanding) means that it will fall to judges to decide which drug prices are unconscionable. This may be undesirable because different judges may reach different conclusions when applying the indicia of unconscionable prices. They may have different ideological perspectives on the extent to which market failures must be present before intervention in markets is justified. Some may hew more closely than others to judges’ historical view that unconscionability is an extraordinary remedy, not to be applied casually to bargains that arise in markets that basically function well. These potential variations in how judges may apply the doctrine to drug prices raise the question of whether biopharmaceutical manufacturers will have reasonable notice as to what the legal standard requires of them.

Third, although there are some exceptional cases,<sup>392</sup> most courts have made clear that a showing of at least some degree of procedural unfairness is required in order to find a contractual provision unconscionable. Yet such a showing may be quite tricky in the prescription-drug context. It shifts the focus from an analysis of the price to an analysis of the buyer, the seller, and their relationship to one another. In practice, the characteristics of the buyer weigh heavily. If used, this approach to defining excessive price would push regulators to focus on particular kinds of drugs that are most likely to raise procedural-unfairness issues (i.e., drugs that patients must take in order to avoid serious health effects, drugs for which there is no therapeutic alternative in the marketplace) and possibly on particular classes of consumers who are especially vulnerable (e.g., the uninsured, patients with conditions like diabetes and hepatitis C that predominantly affect low-income populations). Procedural unconscionability could be hard to establish for other drugs. Even for these drugs, to the extent that courts consider the relevant buyer for examining procedural unconscionability to be the wholesaler or mail-order pharmacy rather than the patient, arguing vulnerability or lack of sophistication would be difficult.

It is questionable whether courts would find the medical necessity of even essential drugs sufficient to constitute lack of choice in satisfaction of the procedural unconscionability requirement. As commentators have noted about unconscionability cases pertaining to hospital bills for emergency care, “if need alone vitiated promises to pay, few medical contracts could be

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<sup>391</sup> FARNSWORTH, *supra* note 285, at 305-06; *see also* *Vom Lehn v. Astor Art Galleries, Ltd.*, 380 N.Y.S.2d 532, 542 (N.Y. Sup. Ct. 1976) (noting that UCC § 2-302 “makes no provision for damages and none may be recovered thereunder.”). *See generally* RESTATEMENT (SECOND), *supra* note 325, at § 208 (“Perhaps the simplest application of the policy against unconscionable agreements is the denial of specific performance where the contract as a whole was unconscionable when made . . . . Where a term rather than the entire contract is unconscionable, the appropriate remedy is ordinarily to deny effect to the unconscionable term.”).

<sup>392</sup> *See supra* note 349 and accompanying text.

enforced.”<sup>393</sup> Courts have also unmoved by the fact that hospital fees are not disclosed in advance.<sup>394</sup> These precedents strongly suggest that it is undesirable to use a definition of unconscionability that requires a procedural-unfairness showing for prescription drugs.

A final concern is that metrics used at common law for measuring substantive unconscionability do not straightforwardly apply to prescription drug prices. Cases examining the difference between the sales price of a good and the seller’s cost have involved situations where a retailer is marking up a product made by someone else. Quantifying this difference is more difficult for prescription drugs, where the seller is also the manufacturer. Examining its profit requires determining its cost to produce the drug, including R&D costs. As we discuss in greater depth when we turn to public utilities regulation,<sup>395</sup> this is extremely difficult to do for drug companies in general and at the level of individual drugs in particular. For one thing, it requires allocating the manufacturer’s total costs over its portfolio of multiple drugs. Additionally, this “cost plus” or “rate-of-return” approach simply does not reflect how prescription drugs are priced even in well-functioning, competitive markets.<sup>396</sup> For the same reason, the alternative measure of the seller’s profit is fraught for prescription drugs. Instead, one might compare a seller’s price against prices offered by other sellers of similar goods. Yet, while rulings of price unconscionability often involve prices being roughly at least twice that of an item’s market value,<sup>397</sup> that rule of thumb appears too blunt an assessment for evaluating drug prices in light of innovation policy concerns. Further, although market comparisons are possible for drugs that have competition from generics or from on-patent drugs with similar efficacy and safety profiles,<sup>398</sup> many drugs do not fit that description. Thus, if the common-law notion of unconscionability has a role to play in addressing high drug prices, it is better suited to serving as a basis for interventions in drug markets that, despite competition, have seen prices remain high. Though courts are unlikely to rule a price set by a competitive market unconscionable, prices set through oligopolies are not “immune from scrutiny.”<sup>399</sup>

Because of these problems, contract-law precedent is useful primarily for establishing a default definition of unconscionability that legislators can work from and adjust when drafting statutes specific to prescription drugs. As we discuss further in Part IV, quite substantial adjustments are desirable.

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<sup>393</sup> Hall & Schneider, *supra* note 379, at 675.

<sup>394</sup> *Id.* at 675-76 (citing *Cox v. Athens Reg’l Med. Ctr., Inc.*, 631 S.E.2d 792, 796 (Ga. Ct. App. 2006)).

<sup>395</sup> See *infra* section III.D.

<sup>396</sup> See, e.g., Ezekiel J. Emanuel, *Big Pharma’s Go-to Defense of Soaring Drug Prices Doesn’t Add Up*, ATLANTIC (Mar. 23, 2019), [https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/?utm\\_source=twitter&utm\\_medium=social&utm\\_campaign=share](https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/?utm_source=twitter&utm_medium=social&utm_campaign=share).

<sup>397</sup> Bender, *supra* note 329, at 756.

<sup>398</sup> Even in such cases, the seller is likely to argue that its product offers unique advantages. For example, the Auvi-Q epinephrine auto-injector entered the market at a price seven times higher than its biggest competitor, the EpiPen. Although the auto-injectors administered the same drug at the same dose using the same method of administration, Auvi-Q was touted as superior because its dose was delivered in five seconds instead of ten and it provided audio rather than written instructions. See Mello, *supra* note 18, at 2275-76.

<sup>399</sup> *Perdue v. Crocker Nat’l Bank*, 702 P.2d 503, 512 (Cal. 1985) (“While it is unlikely that a court would find a price set by a freely competitive market to be unconscionable, the market price set by an oligopoly should not be immune from scrutiny. Thus courts consider not only the market price, but also the cost of the goods or services to the seller, the inconvenience imposed on the seller, and the true value of the product or service.”).

## C. Consumer Lending Laws

Although the common-law contracts doctrine of unconscionability provides consumers some protection against the consequences of borrowing money via high-interest loans, most states have also adopted provisions that explicitly regulate the interest rates that may be charged in consumer loans. States' efforts to regulate consumer lending practices have taken a bifurcated approach: (1) freestanding usury laws,<sup>400</sup> which establish a legally permissible ceiling on interest rates for a specified range of consumer loans; and (2) more general consumer protection laws, covering lending as well as sales of goods and services, which prohibit unfair and deceptive business practices. Statutes in the latter group, instead of specifying maximum interest rates, typically use terms such as "unfair" or "unconscionable" to describe the prohibited conduct. Thus, they are analogous to "type 3" emergency price-gouging laws, whereas usury laws look more like "type 1" laws. We discuss the history, strengths, and weaknesses of these two approaches to protecting consumers against excessively-priced loans, and then discuss their potential applications to prescription-drug prices.

### 1. Approaches to Defining Excessive Price

#### a. Usury Laws

Usury is defined as the exaction of a greater sum for the use of money than the highest interest rate allowed by law.<sup>401</sup> Borrowers can assert usury as a defense to the enforcement of a loan contract, and states may also create civil or criminal penalties for usurious practices.

Regulation of usury has ancient roots and has been part of American law since colonial times, but has changed in the last four decades. Until the 1970s, most states had usury laws of broad scope. With the advent of hyperinflation, however, lenders who were subject to these statutory caps on interest rates felt their margins tightly squeezed and pressured legislatures for relief.<sup>402</sup> Many states responded by easing, or in a few cases abandoning, interest-rate ceilings in the late 1970s and early 1980s.<sup>403</sup> Congress also responded by preempting the application of state usury laws to major categories of lenders and loans in a series of new federal statutes;<sup>404</sup> as a result, much modern consumer lending takes place outside the reach of state law. Further, in 1978 the Supreme Court held that when a consumer borrows money from a national bank in another state, the laws of the bank's state, rather than the consumer's, apply.<sup>405</sup> That holding opened the door for states to compete to attract national banks by permitting higher interest rates.<sup>406</sup> This, in turn, spurred state

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<sup>400</sup> Usury protections have been almost universally adopted in the states via statute, but some states have usury provisions in their state constitutions. Ann K. Wooster, *Construction and Application of Usury Provisions in State Constitutions*, 73 A.L.R. 6th 571, § 2 (2012).

<sup>401</sup> 44B AM. JUR. 2D *Interest and Usury* § 2 (2019).

<sup>402</sup> Adriel D. Orozco, Note, *The Judicial Expansion of an Old Tool to Combat Predatory Lending in New Mexico*, 46 N.M. L. REV. 191, 200 (2016).

<sup>403</sup> Bender, *supra* note 329, at 732-34.

<sup>404</sup> For example, The National Bank Act limits the interest rate charged by national banks to that allowed by the law of the bank's home state and preempts conflicting state usury laws. 12 U.S.C. § 85 (2018); 75 AM. JUR. PROOF OF FACTS 3D 103 § 13 (2019). The Federal Deposit Insurance Act preempts claims against state-chartered, federally-insured banks. *See* Wooster, *supra* note 400, at § 2.

<sup>405</sup> *Marquette Nat'l Bank v. First Omaha Serv. Corp.*, 439 U.S. 299 (1978).

<sup>406</sup> Nathalie Martin, *Public Opinion and the Limits of State Law: The Case for a Federal Usury Cap*, 34 N. ILL. U. L. REV. 259, 264 (2014).

banks (and then nonbank lenders) competing with national banks to demand equal footing in terms of the rates they could charge.<sup>407</sup>

Although consumer advocates retook some of the lost ground beginning in the 1990s, today a “legislative patchwork”<sup>408</sup> exists in which most states have replaced broad caps covering all consumer loans with usury laws covering a narrower range of products, and a few have abandoned their usury laws altogether. Nevertheless, as we discuss below, courts applying usury statutes have done so in a manner that robustly protects consumers, rebuffed vagueness challenges, and construed them to cover a range of situations not expressly covered in the statutes.

Usury statutes vary considerably in the permissible interest rate, types of loans covered, and remedies and penalties.<sup>409</sup> Several states adopted the 1968 Uniform Consumer Credit Code (or a subsequent 1974 version),<sup>410</sup> which sought to create greater consistency across states in prohibited practices and set a maximum interest rate of 18% for consumer loans.<sup>411</sup> In other states, maximum interest rates range from around 8% to as high as 30%; rates in the 15-18% range are common.<sup>412</sup> Rather than specifying a numerical interest rate, some usury statutes peg the maximum to a benchmark indicator, such as the U.S. prime rate. But even these statutes set forth the basis for calculating the allowable rate with great specificity.<sup>413</sup> In terms of penalties, some statutes provide that the entire contract is void, while others allow collection of the principal and the legally permitted amount of interest. Some, but not all, provide for additional civil or criminal penalties (fines).<sup>414</sup>

Despite these differences, usury laws have some broad commonalities. Most saliently, they have taken a consistent approach to defining excessive price: specifying, in clear terms, a maximum annual percentage interest rate.<sup>415</sup> Additionally, they permit consumers to bring a usury claim to get out of paying some or all of a usurious loan or to recover illegal interest already paid, as well as to raise usury as a defense in an action to collect on the debt. They generally require a showing of four elements to make out a usury claim: (1) the transaction at issue is properly characterized as a loan or forbearance; (2) what is loaned is money or something circulating as money; (3) the loan is repayable absolutely; and (4) something was exacted for the use of the money in excess of the interest allowed

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<sup>407</sup> *Id.* at 264-65.

<sup>408</sup> *Id.* at 266.

<sup>409</sup> 9 WILLISTON ON CONTRACTS § 20:2 (4th ed. 2018).

<sup>410</sup> Gary D. Spivey, *Regulation of Consumer Loans Under Uniform Consumer Credit Code*, 73 A.L.R. 6th 425, § 1 (2012).

<sup>411</sup> UNIF. CONSUMER CREDIT CODE § 3.201 (UNIF. LAW COMM’N 1968); UNIF. CONSUMER CREDIT CODE § 2.401(1) (UNIF. LAW COMM’N 1974).

<sup>412</sup> BANKING LAW—CONSUMER PROTECTION: INTEREST RATES & USURY, LEXISNEXIS 50-STATE SURVEYS: STATUTES & REGULATIONS (2018).

<sup>413</sup> For example, Rhode Island’s statute sets the maximum at 21% per annum or an “alternate rate” that is “equal to nine percentage points (9%) plus an index that is the domestic prime rate as published in the Money Rates section of The Wall Street Journal on the last business day of each month preceding the later of the date of the debtor’s agreement or the date on which the interest rate is redetermined in accordance with the terms of the debtor’s agreement.” 6 R.I. GEN. LAWS § 6-26-2 (2019). Some states set as their benchmark the federal discount rate, which was abolished by the Federal Reserve Board in 2003; however, courts have readily substituted an analogous benchmark from the obsolete one where necessary to sustain the statute against a vagueness challenge. *See, e.g.,* Pakay v. Davis, 241 S.W.3d 257, 261-62 (Ark. 2006) (substituting the primary credit rate).

<sup>414</sup> 75 AM. JUR. PROOF OF FACTS, *supra* note 404, at §§ 34-36, 45.

<sup>415</sup> Christopher Peterson, *Usury Law, Payday Loans, Statutory Sleight of Hand: Salience Distortion in American Credit Pricing Limits*, 92 MINN. L. REV. 1110, 1117 (2008). Interestingly, some states have established an administrative process for reviewing and updating the interest-rate ceiling which resembles in some respects the way rates are set for public utilities. Virginia, for instance, tasks the Commissioner of Financial Institutions with setting “fair and reasonable” rates for small consumer loans. For a discussion, see Bender, *supra* note 329, at 800 & n.384.

by law. Some jurisdictions also require a fifth element: that the lender intended the transaction to exact interest in excess of the allowable rate.<sup>416</sup>

### *b. General Consumer Protection Laws*

States have also sought to curtail abusive consumer lending practices using general consumer protection acts (CPAs), which in most states cover sales as well as lending.<sup>417</sup> CPAs blossomed during the pro-consumer movement of the 1960s, when consensus emerged that the efforts of the Federal Trade Commission to combat unfair and deceptive practices pursuant to the Federal Trade Commission Act, even when combined with remedies available in the common law of torts and contracts, were insufficient to protect consumers.<sup>418</sup> Several rounds of drafting of uniform laws gave states the template they needed to adopt additional protections, and by the mid-1970s nearly every state had adopted a CPA providing consumers with a private right of action.<sup>419</sup> Today, all fifty states have such laws, and consumer advocates describe them as “the main lines of defense protecting consumers from predatory, deceptive, and unscrupulous business practices.”<sup>420</sup> The laws allow both individual consumers and state attorneys general to bring civil actions in response to violations of the statute. In addition to civil penalties, some states permit criminal sanctions for extreme violations.

Some CPAs are tied to a companion usury statute, serving to expand the range of remedies available for violating the usury law. For example, “a violation of the Massachusetts usury statute constitutes a per se violation” of Massachusetts’s CPA.<sup>421</sup> More commonly, CPAs are freestanding and prohibit acts that violate a general standard of “unfair” or “unconscionable” business practices. (They also prohibit deceptive practices, but we confine our discussion to their unfair or unconscionable practices component.) Florida’s CPA, for instance, prohibits “unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce;”<sup>422</sup> Arkansas’s prohibits “any other unconscionable ... practice in business, commerce, or trade.”<sup>423</sup>

CPAs using the term “unfair” often incorporate by reference the Federal Trade Commission’s understanding of that term.<sup>424</sup> “Unconscionable” acts are not synonymous with “unfair” ones, however, and in defining “unconscionable” legislatures and courts have incorporated common-law understandings of that term from contracts cases and U.C.C. § 2-302.<sup>425</sup> As discussed

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<sup>416</sup> Williston, *supra* note 409, at § 20:4.

<sup>417</sup> Five states carve lenders out of their general CPAs altogether and another 15 have CPAs that cover some but not all lenders or loans. CAROLYN L. CARTER, NAT’L CONSUMER LAW CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE REPORT ON UNFAIR AND DECEPTIVE ACTS AND PRACTICES STATUTES (2009), [http://www.nclc.org/images/pdf/udap/report\\_50\\_states.pdf](http://www.nclc.org/images/pdf/udap/report_50_states.pdf).

<sup>418</sup> D. Matthew Allen et al., *The Federal Character of Florida’s Deceptive and Unfair Trade Practices Act*, 65 U. MIAMI L. REV. 1083, 1085-86 (2011).

<sup>419</sup> *Id.* at 1086.

<sup>420</sup> Carter, *supra* note 417, at 3.

<sup>421</sup> *Pena v. Gonzalez*, 397 B.R. 566, 577 (B.A.P. 1st Cir. 2008).

<sup>422</sup> FLA. STAT. § 501.204(1) (2019).

<sup>423</sup> ARK. CODE ANN. § 4-88-107(a)(10) (2019).

<sup>424</sup> For a summary of the Federal Trade Commission’s evolving definition of unfair practices, see *United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 200-01 (D. Mass. 1998).

<sup>425</sup> See Russell, *supra* note 345, at [p.26 on SSRN version]. These understandings were enshrined in the 1971 Uniform Consumer Sales Practices Act, which does not apply to lending. See UNIF. CONSUMER SALES PRACTICES ACT § 4(c) (UNIF. LAW COMM’N 1971) (listing six factors that should be considered in determining whether an act is unconscionable: (1) the seller’s having taken advantage of the consumer’s inability to protect his interests because of disadvantages such as infirmity, illiteracy, or language barriers; (2) a price “grossly exceeding” the price at which similar

above,<sup>426</sup> such understandings pin unconscionability to findings of procedural and substantive unfairness. New Mexico’s CPA, for example, defines “unconscionable trade practices” to include procedural and substantive standards lifted directly from the U.C.C.<sup>427</sup> Thus, our earlier analysis of the requirements for a finding of unconscionability in contract law also describes the typical analysis in a CPA case applying an unconscionability standard. When fleshing out procedural unconscionability, for instance, CPAs commonly name as key indicia lack of sophistication on the part of the borrower, financial necessity, sharp practices by the lender, and lack of choice.<sup>428</sup>

The two approaches states have taken to defining excessive price in the consumer-lending context—maximum interest rates and prohibitions on unconscionable lending practices—can and do peacefully coexist as complementary efforts to protect consumers against predatory lending.<sup>429</sup> Where usury statutes’ protections do not apply, or offer inadequate remedies, CPAs can fill gaps. The *CashCall* case discussed earlier illustrates the point: the court held that the fact that California’s usury law applies only to loans under \$2,500 had no bearing on the plaintiffs’ ability to bring an action under the state’s general CPA alleging an unconscionably high interest rate on a loan greater than \$2,500, because the legislature had adopted a separate provision applying the unconscionability doctrine to all consumer loans.<sup>430</sup> Usury statutes, the court went on, simply provide a “bright-line rule” about excessive price that supplements the more flexible, context-dependent unconscionability standard.<sup>431</sup>

The two approaches have complementary strengths and weaknesses. One advantage that usury laws offer over CPAs’ unconscionability standard is that the characteristics of the borrower do not matter. If the loan’s interest rate is over the limit, usury has been committed. This means that usury laws’ protection, as a practical matter, extends to a broader swath of consumers. It is also more straightforward to establish in litigation. Although courts have allowed petitioners in CPA cases to establish procedural unconscionability based on a showing that the lender’s customers *as a class* had indicia of procedural unfairness such as low educational attainment and low income, without establishing that every individual borrower was disadvantaged,<sup>432</sup> even this requirement may constrain the types of loans that can be successfully attacked. In contrast, usury laws can be used to combat high prices even in the absence of apparent procedural unfairness.<sup>433</sup>

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goods or services were readily obtainable; (3) the fact the consumer had no prospect of receiving “a substantial benefit from the subject of the transaction”; (4) the fact that the consumer had “no reasonable probability of payment of the obligation”; (5) excessive one-sidedness in favor of the seller; and (6) “a misleading statement of opinion” by the seller “on which the consumer was likely to rely to his detriment”).

<sup>426</sup> See *supra* Part III.B.

<sup>427</sup> N.M. STAT. ANN. § 57-12-2(E) (2019); see also *Orozco*, *supra* note 402, 202 (noting that New Mexico’s statute therefore retains the U.C.C.’s inherent ambiguity as to what sorts of practices and prices violate these standards, making it vulnerable to vagueness challenges, but also permits flexibility in dealing with unjust business practices).

<sup>428</sup> *Bender*, *supra* note 329, at 772.

<sup>429</sup> For an extended discussion of this idea, see *id.* *Bender* points out that disputes do occasionally arise when both regimes are brought to bear—for example, can a court review an interest rate under the unconscionability standard when it does not violate the state’s usury law or when state usury law is preempted for that loan by federal law? But these are relatively narrow issues. See *id.* at 737.

<sup>430</sup> *De la Torre v. CashCall, Inc.*, 433 P.3d 1004 (Cal. 2018).

<sup>431</sup> *Id.* at 1010.

<sup>432</sup> See, e.g., *State ex rel. King v. B & B Inv. Grp., Inc.*, 329 P.3d 658 (N.M. 2014) (holding that a general practice on the part of the lender of targeting vulnerable borrowers could be deduced from the lender’s targeted marketing to low-income, low-educated groups who research showed could not understand key concepts such as annual percentage rate); see also *Orozco*, *supra* note 402, (summarizing the case).

<sup>433</sup> For an example of this problem outside the lending context, see *People ex rel. Hartigan v. Knecht Serv., Inc.*, 575 N.E.2d 1378, 1386 (Ill. App. Ct. 1991) (rejecting, in a suit against a plumbing, heating, and air conditioning business, the



A related advantage is that the usury standard is much clearer than the unconscionability standard.<sup>434</sup> As noted above,<sup>435</sup> even laws that peg the maximum interest rate to some shifting benchmark in the U.S. economy are exquisitely specific about what that benchmark is and how the interest-rate ceiling is to be calculated.

On the other hand, relative to the usury approach, the unconscionability standard arguably offers the contracting parties greater freedom to determine the terms of their agreement.<sup>436</sup> Additionally, usury laws have proven vulnerable to gaming on the part of regulated entities. As states have narrowed the range of covered transactions over time, lenders have found ways to evade these laws by restructuring transactions so that they are not covered.<sup>437</sup> For example, rent-to-own businesses can achieve lower interest rates while still exacting the same, high overall price from consumers by simply inflating the cash price of the item.<sup>438</sup> In contrast, CPAs ordinarily apply the unconscionability standard to consumer sales and loans generally, without regard for the specific type of transaction.

In summary, usury laws and CPAs take quite different approaches to defining impermissible consumer loans, mirroring the approaches taken in type-1 and type-3 emergency price-gouging laws. Each approach has important limitations, which may explain why states have tended to pursue them in tandem. The implications for prescription drug pricing laws are discussed shortly. Before reaching that discussion, we comment on how these laws have fared in the face of vagueness challenges.

## 2. Legal Challenges

Some facial challenges to usury laws have questioned whether these laws are permissible exercises of the state's police power. Courts' answer has been a resounding yes: they are constitutionally acceptable forms of economic regulation that do not violate substantive due process by interfering with freedom of contract.<sup>439</sup> States have wide latitude to regulate interest rates, as long as the classifications adopted in the statute satisfy basic equal-protection requirements.<sup>440</sup> In particular, courts have allowed legislatures wide discretion in selecting a maximum interest rate.<sup>441</sup>

Usury statutes have been challenged on vagueness grounds. Because these laws so clearly state the maximum interest rate, vagueness challenges have centered on issues other than what constitutes an excessive price. Some as-applied challenges have questioned whether particular aspects of the transaction at issue count toward the "interest" on the loan, but it appears that most concern whether the transaction fits within the scope of the usury law.<sup>442</sup> For example, is the

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contention that unconscionably high prices alone are sufficient to find a contract in violation of the Illinois Consumer Fraud Act).

<sup>434</sup> Cf. Bender, *supra* note 329, at 744 (noting criticisms that the unconscionability standard engenders too much uncertainty as applied to loan pricing).

<sup>435</sup> See *supra* note 413 and accompanying text.

<sup>436</sup> Bender, *supra* note 329, at 744-55.

<sup>437</sup> *Id.* at 739-40; Orozco, *supra* note 402, at 203.

<sup>438</sup> Bender, *supra* note 329, at 761. Unconscionability suits have often been brought in response to such practices. *Id.* at 746 & n.133.

<sup>439</sup> 75 AM. JUR. PROOF OF FACTS, *supra* note 404, at § 7 (citing cases).

<sup>440</sup> *Id.* at §§ 7, 8; see also Glenn v. State, 644 S.E.2d 826 (Ga. 2007) (finding that Georgia's criminal payday lending statute did not violate equal protection by confining its scope to loans by Georgia residents); Aros v. Beneficial Arizona, Inc., 977 P.2d 784, 789 (Ariz. 1999) (en banc) (finding a rational basis for treating consumer and commercial borrowers differently).

<sup>441</sup> Wooster, *supra* note 400, at § 14 (summarizing cases).

<sup>442</sup> See generally *id.* (collecting and summarizing cases relating to usury provisions in state constitutions).

transaction a “loan” or some other type of transaction?<sup>443</sup> Does the defendant’s conduct constitute a “scheme or business” of making usurious loans?<sup>444</sup>

In analyzing such claims in challenges to civil usury statutes, courts apply the comparatively lenient vagueness standard applicable to economic regulation.<sup>445</sup> Criminal usury statutes typically invite application of the tougher standard for criminal laws, but that has served as no bar to upholding these laws.<sup>446</sup> Courts have upheld usury statutes against vagueness challenges even where their holding required lenders to have a rather detailed knowledge of the state’s case law concerning what factors militate in favor of calling a transaction a loan rather than a sale.<sup>447</sup> Cases in which vagueness challenges have been sustained appear to be rare and connected to rather exotic issues.<sup>448</sup>

Case law also speaks to the clarity of CPAs’ “unconscionable” standard and the interrelationship between usury laws and general state CPAs. The Arkansas Supreme Court, in rejecting a vagueness challenge brought by a title-pawn business, held that one permissible vehicle for enforcing the state’s usury prohibition (contained in its constitution) was for the attorney general to bring an action under the state’s general CPA, which prohibited “unconscionable, false, or deceptive” business practices.<sup>449</sup> The contract at issue was unquestionably usurious; the issue was whether it could also be prosecuted as “unconscionable.” The court found that the “unconscionable” standard was not unconstitutionally vague because interpretations were available in the common law of contracts. Further, it found that it was consistent with the legislature’s purpose of protecting consumers against usury to permit the attorney general to bring enforcement actions relating to usurious loans under the state’s CPA.

Other case law, too, has upheld CPAs using the “unconscionable” standard against vagueness challenges. Courts have rebuffed claims of vagueness by pointing to the extensive fleshing out of its meaning in contracts cases, as well as provisions in some statutes and regulations that specify particular dimensions of unconscionability.<sup>450</sup> For example, Massachusetts issued regulations under its CPA prohibiting mortgage loans that “significantly deviate from industry-wide standards”<sup>451</sup>—a phrase calling to mind the reference to “reasonable market price” in the *Restatement*

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<sup>443</sup> See, e.g., 47 C.J.S. *Interest & Usury* § 169 (2019) (citing *Glenn*, 644 S.E.2d at 826, and *SAL Leasing, Inc. v. State ex rel. Napolitano*, 10 P.3d 1221 (Ariz. Ct. App. 2000)); see also *Fogie v. THORN Americas, Inc.*, 95 F.3d 645 (8th Cir. 1996) (applying the “more tolerant” vagueness standard to hold that Minnesota’s law was sufficiently clear in its definition of “consumer credit sales” as encompassing rent-to-own transactions).

<sup>444</sup> See, e.g., *People v. Lombardo*, 460 N.E.2d 1074, 1077 (N.Y. 1984) (holding that “scheme” and “business” are not vague because their legal meaning is the same as their dictionary definitions, and clearly applied to the defendant’s conduct); *People v. Di Raffaele*, 420 N.Y.S.2d 109, 111 (N.Y. Sup. Ct. 1979) (same).

<sup>445</sup> *Fogie*, 95 F.3d at 645; *United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 204 (D. Mass. 1998).

<sup>446</sup> See, e.g., *Di Raffaele*, 420 N.Y.S.2d at 111 (upholding criminal loansharking law).

<sup>447</sup> See *SAL Leasing*, 10 P.3d at 1229 (holding that state consumer lending law applied to a title-pawn business because “usury case law—including [two particular decisions]—gave appellees fair warning that their conduct was proscribed and made arbitrary prosecution impossible”); see also *Glenn v. State*, 644 S.E.2d 826, 828 (Ga. 2007) (rejecting claim that criminal payday lending law was unconstitutionally vague because it did not specifically name the particular lending schemes defendants used).

<sup>448</sup> See *Bisno v. Kahan*, 170 Cal. Rptr. 3d 709 (Cal. Ct. App. 2014) (concerning application of the usury state’s interest-rate cap to forbearance fees, which are a separate element of a loan contract); *Harvey v. Nissan North America*, 2005 WL 1252341 \*5-6, \*12-14 (N.J. Super. Ct. 2005) (sustaining an as-applied vagueness challenge to a state CPA where the attorney general sought to enforce the statute against a car maker which had not informed past buyers of the availability of a new anti-theft device); *State v. Roderick*, 704 So. 2d 49 (Miss. 1997) (finding no vagueness problem with the usury statute itself, but holding that its deployment as a predicate violation for prosecution under the state’s RICO statute raised vagueness problems).

<sup>449</sup> *State ex rel. Bryant v. R & A Investment Co., Inc.*, 985 S.W.2d 299 (Ark. 1999).

<sup>450</sup> See, e.g., *United Companies Lending Corp. v. Sargeant*, 20 F. Supp. 2d 192, 205 (D. Mass. 1998).

<sup>451</sup> *Id.*

(*Second*) of *Contract*'s definition of substantive unconscionability.<sup>452</sup> The district court examining those regulations also noted a policy concern favoring a tolerant posture toward the unconscionability standard: "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."<sup>453</sup> To summarize, vagueness challenges present little threat to either usury statutes or application of CPAs to high-interest consumer loans.

### 3. Applicability to Prescription Drug Prices

Sharp lending practices share some notable features with high-priced prescription drugs, making them an intuitive analogue in many respects. Most notably, the consumers availing themselves of these hard bargains are often in a desperate situation: in the case of predatory lending, because their credit history and assets are too poor for them to find credit in the mainstream market, and in the case of medications, because of serious health conditions. Further, both situations often involve little choice of alternative products—for borrowers, because they are excluded from the mainstream market, and for drugs, because of a lack of therapeutic alternatives. In both cases, opacity in the transaction makes it hard for consumers to understand the full cost of what they are buying. Finally, both circumstances can involve a cycle of dependence. Just as patients are reliant on medications for chronic conditions, high-interest loan customers often find they cannot repay their debt and must take out new debt to ease their obligations under the existing loan. Although it is arguably unfair to paint drug manufacturers with the same moral brush as predatory lenders, from the consumer's perspective the situations may feel similar.

Usury laws' approach of setting a maximum interest rate has clear applicability to drug price increases: legislation could specify a maximum allowable price increase over a specified time period. (Usury statutes do not address changes in interest rates over time, only absolute rates, but the approach of stating a maximum percentage is exportable to drug price increases.) As discussed earlier, recently introduced price-gouging legislation for medications has taken exactly that approach. Such bright-line rules create clear targets for enforcement action—any manufacturer who steps over the statutory line—and puts companies unambiguously on notice of how much is too much in terms of a price hike. Moreover, in reviewing usury statutes, courts have clearly signaled that legislatures have wide latitude in their choice of a ceiling rate. They can essentially select whatever rate they like; courts will not require them to provide a justification beyond the argument that it is reasonably related to a legitimate state interest.

The usury approach is also potentially applicable to drugs' launch prices: Congress (but not the states, given patent preemption issues) could establish a statutory maximum launch price. However, there is broad concern among experts that such crude price controls are undesirable from a standpoint of preserving incentives for innovation.<sup>454</sup> Particularly given the widely varying investments in R&D and anticipated market sizes for different drugs, imposing a single statutory cap is ill advised.

One advantage of the usury approach is its imperviousness to procedural-unfairness issues. It is a "consumer-blind" standard, in the sense that the characteristics of the particular consumers or group of consumers who are the target market do not matter in determining whether a violation has occurred. Not having to worry about showing procedural unfairness might allow attorneys general

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<sup>452</sup> See *supra* note 335.

<sup>453</sup> *Id.*

<sup>454</sup> See generally NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18.

more discretion about which drugs to target for enforcement actions—they do not need to worry about making out a claim that the drug is essential, for example, or that patients lack choice due to absence of competition in the market. Further, although usury statutes currently apply only to individual borrowers, the general approach could be deployed more broadly. Whereas the procedural-unfairness requirement makes it hard to persuade a factfinder that a sophisticated, corporate entity has been subjected to unconscionable practices, no comparable barrier precludes application of a usury approach to prices charged to drug wholesalers and mail-order pharmacies.

The usury approach has a slight advantage over CPAs using an unconscionability standard in terms of clarity, but neither has proved particularly vulnerable to vagueness challenges. Courts have felt comfortable relying on contract-law doctrine to interpret the standard. But importantly, CPAs or their implementing regulations may flesh out the term “unconscionable” so as to reduce ambiguity about the legislature’s intent. CPAs thus illustrate the potential for careful drafting to improve upon common-law understandings of unconscionability.<sup>455</sup> States and the Congress can write legislation with as specific a definition as desired to reduce the risk of vagueness challenges and send the clearest possible signals about what is expected of biopharmaceutical companies. In this sense, CPAs offer a highly appealing model for proscribing excessive drug prices.

State CPAs have already been used by two state attorneys general as well as private plaintiffs as a basis for suing drug companies over their pricing practices, illustrating the possibilities for a consumer-protection law approach to excessive prices. To date, such litigation has primarily emphasized a deception theory rather than an argument that prices are simply too high. In all of these cases, the plaintiffs allege that the three largest insulin manufacturers used a deceptive pricing scheme by “artificially inflating benchmark [list] prices to offer large rebates to PBMs”.<sup>456</sup> That is, they claim manufacturers raised and publicly disseminated their drug’s WAC so that they could give PBMs larger rebates, though they knew wholesalers and other organizations would use the WAC to set prices for some groups of consumers, such as the uninsured.<sup>457</sup> Despite the emphasis on deception, the latest filing, by the State of Kentucky, also characterizes the manufacturers’ conduct as an “unconscionable pricing scheme” involving “unconscionably and unreasonably inflated list prices,” an apparent reference to the “unfair” prong of Kentucky’s CPA.

Notwithstanding these strengths of the consumer-lending law model, three sticking points are worth bearing in mind when considering its potential applicability to prescription drugs. First, usury laws and CPAs have traditionally pegged enforcement to actual transactions. They do not prohibit merely offering a loan product at a usurious price; a transaction with a consumer must take place. If this approach were preserved, taking action against high-priced prescription drugs would require waiting for a sale to take place. This may be a relatively minor concern because although some patients may be unable to afford the medications, others with better insurance coverage will purchase them.

Second, part of the simplicity of usury statutes is that they announce a single price ceiling for all covered loans, regardless of who the borrower is. Drugs, of course, are not sold at a single price, nor are they typically sold at the list price. Price discrimination among payers is the norm, implemented through a series of rebates and discounts off the list price. How, then, to apply the

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<sup>455</sup> This observation is inspired by the discussion in Bender, *supra* note 329, at 746-803, of ways in which states can sharpen the language in their CPAs to clearly define unconscionability, thereby choosing how tightly to tether the statute’s definition of that terms to the default interpretation that courts will give it, which is based on U.C.C. 2-302.

<sup>456</sup> Complaint, *In re Insulin Pricing Litigation*, Civ. No. 17-699(BRM)(LHG) (D.N.J. filed Dec. 26, 2017). This lawsuit consolidated multiple suits initiated in federal court in other states.

<sup>457</sup> Complaint, *Minnesota ex rel. Swanson v. Sanofi-Aventis U.S. LLC*, No. 3:18-cv-14999 (D.N.J. filed Oct. 16, 2018); Complaint, *Kentucky ex rel. Beshear v. Novo Nordisk, Inc.*, No. \_\_\_\_ (Ky. Cir. Ct. filed May 13, 2019), [https://ag.ky.gov/pdf\\_news/20190513\\_Insulin-Pricing-Complaint.pdf](https://ag.ky.gov/pdf_news/20190513_Insulin-Pricing-Complaint.pdf).

usury model? Which price should it target? Imposing limitations that merely apply to the WAC is an obvious answer, but would not keep a manufacturer from imposing de facto price increases on particular payers by reducing the amount of discounts and rebates it is willing to give. The strong bargaining position of PBMs and large wholesalers may mitigate concerns about such behaviors, but the law would not address it directly.

This brings up a third, related concern: gaming. Usury statutes have inspired strategic behavior by lenders seeking to step out of the laws' scope.<sup>458</sup> It would be much more difficult for drug manufacturers to argue that their product is not covered by the statute, unless the statute applied only to a narrow class of products. But they could inflate a new drug's launch price so that they could painlessly remain within statutory ceilings on price increases, or could manipulate discounts and rebates to maintain or increase a drug's average net price. This is a significant concern that even careful drafting may be unable to eliminate.

In conclusion, although existing CPAs are not an optimal vehicle for redressing unconscionable drug pricing, the general approach they employ has considerable appeal. The usury model is also attractive, though its limitations suggest it should be thought of as a companion to a more general, CPA-like statute—as states have done for consumer lending. There is substantial potential to use such statutes to tailor a definition of unconscionability that makes sense for prescription drugs and avoids some of the baggage of the common-law unconscionability standard. Specifically, legislators can make clear that plaintiffs and attorneys general need not show any procedural unfairness.<sup>459</sup> We expand on this possibility in Part IV.

#### D. Public Utilities Rate Regulation

Public utilities have long been subjected to extensive regulation in the U.S.<sup>460</sup> In addition to price regulation via formal rate-setting processes, regulated aspects of public utilities include market entry and exit, the addition or abandonment of service offerings, service standards, financial structure, and accounting methods.<sup>461</sup>

State regulation of public utilities dates to the turn of the twentieth century, when widening economic inequality led to concern about Americans' ability to access essential products and services such as rail and other transit, telecommunications, electricity and gas, and finance.<sup>462</sup> The impetus for intervening into markets for these goods and services arose not only from their status as necessities, but also from realization that many of these industries tended toward natural monopolies<sup>463</sup>—and

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<sup>458</sup> See *supra* note 437 and accompanying text.

<sup>459</sup> Cf. Bender, *supra* note 329, at 796-97 (advocating this approach for CPAs relating to consumer lending).

<sup>460</sup> Public utilities are generally defined by reference to several characteristics: "(1) economies of scale, (2) the provision of an 'essential' service, (3) heavy capital requirements, (4) production of services or nonstorable goods, (5) demand and cost fluctuation, (6) exclusive franchises, and (7) the obligation to supply services to anyone willing to pay the price." William S. Brewbaker III, *Health Care Price Controls and the Takings Clause*, 21 HASTINGS CON. L.Q. 669, 705 n.149 (citing JAMES C. BONBRIGHT ET AL., PRINCIPLES OF PUBLIC UTILITY RATES 8-10 (1988)).

<sup>461</sup> *Id.* (citing BONBRIGHT ET AL., *supra* note 460, at 6).

<sup>462</sup> William Boyd, *Just Price, Public Utility, and the Long History of Economic Regulation in America*, 35 YALE J. REG. 721, 755 (2018); Sabeel Rahman, Essay, *Constructing Citizenship: Exclusion and Inclusion Through the Governance of Basic Necessities*, 118 COLUM. L. REV. 2447 (2019).

<sup>463</sup> REGULATORY ASSISTANCE PROJECT, ELECTRICITY REGULATION IN THE US: A GUIDE 3, 7 (2011); Adam Plaiss, *From Natural Monopoly to Public Utility: Technological Determinism and the Political Economy of Infrastructure in Progressive-Era America*, 57 TECH. & CULT. 806 (2006). A natural monopoly occurs when it is most efficient for an industry to consist of only one firm—for example, because the industry involves very high fixed costs. Paul Joskow, *Regulation of Natural Monopolies*, in A. MITCHELL POLINSKY & STEVEN SHAVELL, 2 HANDBOOK OF LAW AND ECONOMICS 1227-1348, 1227 (2007).

further, that well-regulated monopolies could actually be superior to competitive markets from a consumer-welfare perspective.<sup>464</sup> Public utility services tend toward natural monopoly because providing them is capital intensive, creating a barrier to market entry; and the marginal price of production continues to decrease as output increases, solidifying the position of large companies.<sup>465</sup> Further, the need for extensive physical facilities (for example, electrical wires) to distribute the utility to customers makes it more efficient for a geographic area to be served by a single provider. Thus, rather than resisting monopoly, the main regulatory move has been to protect retail customers against the consumer harms associated with monopolies, including supracompetitive prices and poor service.<sup>466</sup>

Regulation is executed by public utility commissions (PUCs) at the federal and state levels. In exercising their powers, PUCs seek to balance consumers' interest in affordable prices against the need to set rates at a level sufficient to motivate production and allow utilities to attract investment. They also aim to set rates in a manner that gives utilities incentives to operate efficiently.<sup>467</sup> Scholars have conceived of rate setting as reflecting a sort of "regulatory contract" between utilities and their customers, in which the utility commits to provide reliable, accessible service at minimum cost in exchange for the exclusive right to sell in a particular market, and customers (through the PUC) agree to compensate the utility for the costs it prudently incurs in meeting that commitment.<sup>468</sup>

Public utilities rate regulation spans many industries,<sup>469</sup> with some significant inter-industry differences in approach. We focus on retail electricity services as an illustrative example. Electricity is a useful case study<sup>470</sup> because methods of rate setting in that industry have been extensively reviewed by the courts and have evolved over time. Although the industry has undergone considerable deregulation since the 1980s, its history, and the rate-setting methods still applied in states that have not deregulated, provide insight into how rate setting might be carried out in the prescription drug industry. We conclude, however, that the approach through which electricity prices have been set, known as rate-of-return regulation, despite its merits, is pragmatically unsatisfactory for prescription drugs. By contrast, a distinct but related approach—setting rates that payers in a state will pay when a drug's market price exceeds some "affordability" threshold—has pragmatic appeal for controlling costs, albeit not insignificant normative vulnerabilities.

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<sup>464</sup> U.S. DEP'T OF ENERGY, A PRIMER ON ELECTRIC UTILITIES, DEREGULATION, AND RESTRUCTURING OF U.S. ELECTRICITY MARKETS § 5.3 (2002) ("[B]oth utilities and the public recognized that regulation of service territories and rates at the state level was preferable to continued customer competition, duplication of service, and different regulations in myriad municipalities.").

<sup>465</sup> Lino Mendiola, *The Erosion of Traditional Ratemaking Through the Use of Special Rates, Riders, and Other Mechanisms*, 10 TEX. TECH. ADMIN. L.J. 173, 174-75 (2008) (citing ELI CLEMENS, ECONOMICS AND PUBLIC UTILITIES 25 (Appleton-Century-Crofts 1950)).

<sup>466</sup> Timothy J. Brennan, *Entry and Welfare Loss in Regulated Industries*, in MICHAEL A. CREW, COMPETITION AND THE REGULATION OF UTILITIES 141 (1991).

<sup>467</sup> For some utilities, particularly energy, establishing rate levels and structures that encourage consumers not to overconsume is also a regulatory goal. BONBRIGHT ET AL., *supra* note 460, at 92-95.

<sup>468</sup> Paul L. Joskow & Richard Schmalensee, *Incentive Regulation for Electric Utilities*, 4 YALE J. REG. 1, 8-9 (1986).

<sup>469</sup> Aside from electricity and telecommunications, these include natural gas, water, oil pipelines, rail transportation, surface freight, and (until deregulation in the 1980s) air transportation. See William M. Capron, *Introduction to TECHNOLOGICAL CHANGE IN REGULATED INDUSTRIES* 1-12 (William M. Capron ed., 1971). Among the earliest targets of rate regulation in the U.S. were grain elevators, warehouses, and canals, for which nineteenth-century courts held that rate regulation was justified because they were "monopoly" providers of services "affected with a public interest." *Munn v. Illinois*, 94 U.S. 113, 150 (1876).

<sup>470</sup> Although a useful analogue to prescription drugs in many ways, retail electricity regulation does not face the same preemption challenges as drug regulation because it is specifically reserved to the states in the Federal Power Act, 16 U.S.C. § 791 (2018).

## 1. Approaches to Defining Excessive Price

About two thirds of the U.S. population is served by investor-owned (private) utility companies, with the remainder served by publicly-owned utilities, cooperatives, and other entities.<sup>471</sup> Electricity rates and terms of service for investor-owned utilities are set by state PUCs.<sup>472</sup> With regard to rate setting, state PUCs have two main functions: determining the utility's revenue requirements and then, based on that requirement, setting retail electricity rates for each class of customers.

Although a few states require periodic review of electricity rates, in most states rate review is initiated upon the request of the utility or an intervenor, such as a consumer organization.<sup>473</sup> Typically in these proceedings, known as “rate cases,” the utility submits a proposed rate change and the PUC conducts a review and approves or disallows the change. The basis for the PUC's decision is established by state statute; generally statutes require that rates be set at “just, reasonable and non-discriminatory” levels,<sup>474</sup> considering the utility's costs to provide service. Statutes sometimes provide more specific guidance—for instance, specifying which operating or investment costs may be taken into consideration.<sup>475</sup>

Two main approaches have dominated rate setting for utilities. Agencies may use a combination of these approaches (as well as others).<sup>476</sup> The first, and dominant, method is rate-of-return regulation. Reflecting the regulatory-contract idea, rate-of-return regulation seeks to quantify what it costs the utility to provide service and set rates at a level that permits the utility to recover its investment as well as a return on investment that is sufficient to attract investors. The PUC examines what the utility spends on operating expenses and investments and sets a valuation on its productive assets, taxes, and depreciation. It may disallow expenses and investments it deems imprudent.

The second approach is to impose a price cap. The PUC sets a baseline price ceiling that is intended to reflect prevailing costs in the industry. It then adjusts it upward annually for economy-wide inflation and certain changes that are outside the utility's control (for example, unusual events that make the inputs to its services more expensive), and downward to the extent that productivity in the industry is expected to improve faster, and/or input costs are expected to increase less, than in the economy as a whole.<sup>477</sup> A firm that increases its productivity over expected industry norms, or decreases its input costs below them, may keep the difference.<sup>478</sup> Whereas rate-of-return regulation

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<sup>471</sup> Jessica Shipley, *Traditional Economic Regulation of Electric Utilities*, RAP (Dec. 17, 2018), [https://www.raponline.org/wp-content/uploads/2018/12/rap\\_shipley\\_pucs\\_regulation\\_overview\\_2018\\_dec\\_17.pdf](https://www.raponline.org/wp-content/uploads/2018/12/rap_shipley_pucs_regulation_overview_2018_dec_17.pdf).

<sup>472</sup> In most states, public utilities are not subject to regulation; co-ops are subject to some form of regulation in about 20 states. REGULATORY ASSISTANCE PROJECT, *supra* note 463, at 24. Wholesale rates (i.e., prices that electricity retailers pay to generators) are regulated by the Federal Energy Regulatory Commission.

<sup>473</sup> U.S. DEP'T OF ENERGY, *supra* note 464, at § 5.4.

<sup>474</sup> Joskow & Schmalensee, *supra* note 468, at 4.

<sup>475</sup> *Id.* at 4-5.

<sup>476</sup> William M. Capron & Roger G. Noll, *Summary and Conclusion* of TECHNOLOGICAL CHANGE IN REGULATED INDUSTRIES, *supra* note 469, at 197-226 (going on to explain that “While rate-of-return control is commonly the principal device used in regulating prices and profits of electric utilities, transportation, and communications firms, the federal agencies responsible for regulating these sectors also regulate some prices directly”).

<sup>477</sup> James Ming Chen, *Price-level Regulation and Its Reform*, 99 MARQ. L. REV. 931, 943-4 (2016); David E.M. Sappington & Dennis L. Weisman, *The Price Cap Regulation Paradox in the Electricity Sector*, 29 ELECTRICITY J. 3, 3-4 (2016). Some states also factor in other adjustments (for instance, a major new investment that is necessary to serve customers' needs). Sappington & Wiseman, *supra*, at 3-4.

<sup>478</sup> Sappington & Wiseman, *supra* note 477, at 3-4.

involves regulatory scrutiny of the utility's spending decisions, under price-cap regulation the utility can "conduct its business as it sees fit, provided that its prices do not rise above a certain level."<sup>479</sup>

Although price-cap regulation was used for the telecommunications industry in the late 1980s and early 1990s,<sup>480</sup> electricity regulators historically have hewed closely to the rate-of-return approach.<sup>481</sup> In applying that approach in rate cases, PUCs begin by determining the company's revenue requirement—the amount of revenue it should be permitted to receive. The basic regulatory formula for the revenue requirement is: rate base x rate of return + operating expenses.<sup>482</sup> The rate base is the total of all investments made to serve customers (for example, buildings, wires, and computer software), net of depreciation.<sup>483</sup> The revenue requirement thus requires determining the amount of investment allowed in the rate base, a fair rate of return on that investment, and reasonable operating expenses—all based on some test year, which could be historical or a future year for which companies and regulators are making cost projections.<sup>484</sup> In determining the rate base, the regulator may choose to exclude investments it deems imprudent or not yet in use for the benefit of customers. Similarly, in determining recovery for operating expenses, the regulator can disallow any unreasonable or imprudent costs. Finally, once the test-year amounts are established, utilities, taxpayer representatives, and regulators may argue that the test-year data do not accurately represent the operating conditions that are likely to prevail in the future and that an upward or downward adjustment is appropriate.

Setting the rate of return is equally, if not more, challenging. The general standard is that the regulator must set a rate of return on investments in the rate base that is sufficient to allow the utility to attract additional capital under prudent management.<sup>485</sup> As is discussed below in subsection 2, PUC determinations as to appropriate rates of return have been subject to extensive legal challenges, and several Supreme Court decisions have provided guidance as to the standards and permissible range of methodological approaches for reaching such determinations.

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<sup>479</sup> James Ming Chen, *The Nature of the Public Utility: Infrastructure, the Market, and the Law*, 98 NW. U. L. REV. 1617, 1668-9 (2004) (reviewing JOSE GOMEZ-IBANEZ, *REGULATING INFRASTRUCTURE: MONOPOLY, CONTRACTS, AND DISCRETION* (2003)).

<sup>480</sup> JEAN-JACQUES LAFFONT & JEAN TIROLE, *COMPETITION IN TELECOMMUNICATIONS* 4-5, 86 (2000); Alexander Larson, *Predatory Pricing Safeguards and Telecommunications Regulation*, in CREW, *supra* note 466, at 51-70. The Federal Communications Commission switched from rate-of-return regulation to price caps for common carriers in 1989. State PUCs regulating local exchange telephone companies used rate-of-return regulation until the 1980s, when they began introducing reforms: some loosened their control over states, others moved to price caps, and others pursued different approaches. By the mid-1990s about half the states were using price caps. THOMAS W. BONNETT, *TELEWARS IN THE STATES: TELECOMMUNICATIONS ISSUES IN A NEW ERA OF COMPETITION* 59-63 (1996).

<sup>481</sup> Sappington & Wiseman, *supra* note 477, at 1-2 (noting that by 2003, 40 states had adopted price cap regulation for telecommunications, whereas by 2015 only 14 states employed multi-year rate plans in their electricity sectors). These authors posit that both institutional differences and implementation-related factors for price cap regulation account for the disparity. *Id.* at 2-5. Notably, California's experiment with price cap regulation was (wrongly) blamed for the "meltdown of unprecedented proportion" in the state's electricity sector in 2000. *Id.* at 3.

<sup>482</sup> REGULATORY ASSISTANCE PROJECT, *supra* note 463, at 38; BONNETT, *supra* note 480, at 62. The description of rate-of-return also relies on Mendiola, *supra* note 465, at 173-8, and Megan J. Hertzler & Mara N. Koeller, *Who Pays for Carbon Costs? Uncertainty and Risk in Response to the Current Patchwork of Carbon Regulation for Public Utilities*, 36 WM. MITCHELL L. REV. 904, 931-8 (2010). Those accounts, in turn, draw from two classic works in the field, BONBRIGHT ET AL., *supra* note 460, and CHARLES PHILLIPS JR., *THE REGULATION OF PUBLIC UTILITIES* (3d ed. 1993).

<sup>483</sup> Big investments such as a new power plant may be reflected in the test year so that the rates will allow the utility to recover the costs of that investment in the future when it will be "used and useful." REGULATORY ASSISTANCE PROJECT, *supra* note 463, at 38-39.

<sup>484</sup> *Id.* at 38-39. The utility proposes adjustments to the test-year data to reflect changes in costs that have occurred since then, or will occur in the forecasted test year. *Id.*

<sup>485</sup> *Id.* at 42. In satisfying that requirement, regulators consider what the utility must pay in interest on long-term debt and stock dividends, in addition to what a reasonable profit would be. Mendiola, *supra* note 465, at 177.



Rate-of-return regulation has endured as the preferred approach in regulated electricity markets<sup>486</sup> despite some widely recognized problems.<sup>487</sup> One problem relates to information asymmetries: “Relative to regulators, firm managers enjoy vastly superior access to information about the firm’s true costs and opportunities for profit.”<sup>488</sup> Regulators, who rely on submissions by the utilities for information, are therefore handicapped in their ability to accurately distinguish prudent expenses and investments from imprudent ones. A second problem is that the process of establishing the inputs to the rate-of-return formula is time consuming and expensive.<sup>489</sup>

A third, more fundamental issue is the perverse incentive inherent in setting rates based on operating costs: utilities have little reason to become more efficient if they can pass their expenses along to ratepayers and their revenue stream is based around building more infrastructure.<sup>490</sup> In theory, the threat of having particular costs disallowed during rate review should incentivize utilities to avoid imprudent spending and investment decisions; in reality, the informational-asymmetry problem means this prospect may impose insufficient discipline.<sup>491</sup> As a result, utilities may overinvest in infrastructure and operate less efficiently than they would in a competitive market or under alternative rate-setting schemes.<sup>492</sup>

These and other complaints about the traditional model of price regulation for electricity led to a deregulatory movement in the 1980s and 1990s.<sup>493</sup> Consumers were groaning under the burden of high electricity rates, and both consumer groups and utilities complained that rate cases had become protracted, adversarial, and expensive. Many states responded by partially or fully deregulating the retail electricity market.<sup>494</sup> Electric power generation was unbundled from power transmission and distribution, and retail customers were allowed to buy electricity from any supplier they chose.<sup>495</sup> As of 2018, 17 states and the District of Columbia had deregulated the retail electricity market to allow at least some choice of providers.<sup>496</sup>

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<sup>486</sup> However, a large number of retail electricity markets have been deregulated in some respects since the 1980s. *See* discussion *infra*.

<sup>487</sup> Among the reasons for the persistence of this approach is that the outcomes of forays into price-level regulation for natural gas and oil were “not encouraging.” Richard J. Pierce, Jr., *Price Level Regulation Based on Inflation Is Not an Attractive Alternative to Profit Level Regulation*, 84 NW. U. L. REV. 665, 680 (1990) (reviewing JORDAN J. HILLMAN & RONALD BRAEUTIGAM, *PRICE LEVEL REGULATION FOR DIVERSIFIED PUBLIC UTILITIES* (1989)).

<sup>488</sup> Chen, *supra* note 477, at 933.

<sup>489</sup> Chen, *supra* note 479, at 1669.

<sup>490</sup> *Id.* at 1669; Boyd, *supra* note 462, at 769.

<sup>491</sup> Joskow & Schmalensee, *supra* note 468, at 12. Moreover, if the PUC errs on the side of being too strict in disallowing expenses, it may scare off investors and jeopardize the utility’s ability to continue to provide service. *Id.* at 9.

<sup>492</sup> This phenomenon reflects the Averch-Johnson Effect—the tendency of regulated firms to overinvest capital to increase property when their allowed return is a function of the amount invested. REGULATORY ASSISTANCE PROJECT, *supra* note 463, at 61-62 (discussing Harvey Averch & Leland L. Johnson, *Behavior of the Firm Under Regulatory Constraint*, 52 AMER. ECON. REV. 1052 (1962)). For further discussion, see Chen, *supra* note 477, at 935-6 (citing several classic works in the field advancing this theory).

<sup>493</sup> Rebecca McNerney, *Overview: What’s Changing and Why*, WASH. POST, <http://www.washingtonpost.com/wp-adv/specialsales/energy/report/article10.html> (last visited June 30, 2019) (summarizing factors driving electricity deregulation).

<sup>494</sup> U.S. DEP’T OF ENERGY, *supra* note 464, at § 6.1.2. Additionally, at the federal level, the Federal Energy Regulatory Commission deregulated wholesale electricity and natural gas prices as well as long-distance delivery charges in the 1990s, but later backed off efforts to force states to restructure due a variety of problems encountered. *Id.* at § 7.1.1. For a general discussion of federal statutes that contributed to deregulation, see Chen, *supra* note 479, at 1638. For a summary of problems in federal restructuring, see Richard J. Pierce, Jr., *The Past, Present, and Future of Energy Regulation*, 31 UTAH ENV’T L. REV. 291, 295 (2011).

<sup>495</sup> U.S. DEP’T OF ENERGY, *supra* note 464, at § 6.1.2.2.

<sup>496</sup> *Map of Deregulated Energy States & Markets (Updated 2018)*, ELECTRIC CHOICE, <https://www.electricchoice.com/map-deregulated-energy-markets/> (last visited June 30, 2019).

Regulators in these states (and at the federal level) did not completely abdicate oversight of rates, however. They adopted rules and procedures to try to prevent utilities from engaging in market manipulation,<sup>497</sup> carved some components of a consumer's energy bill out of deregulation, and protected retail customers against price increases arising from volatility in the wholesale electricity market by maintaining default rates provided by the utility that dominated the market before deregulation (effectively, price caps).<sup>498</sup> Most retail-choice states have seen few consumers switch providers, suggesting that rate regulation remains important even in these markets.<sup>499</sup>

This deregulatory history teaches that price regulation in the electricity industry has been a bumpy ride. Litigation brought by utilities under the rate-of-return regime illuminates some of the reasons why.

## 2. Legal Challenges

The earliest challenges to rate regulation questioned whether it was permissible for states to regulate prices at all. This question was resolved definitively in *Munn v. Illinois*,<sup>500</sup> in which the Supreme Court found that price regulation of “businesses affected with public interest” sat squarely within states’ police powers.<sup>501</sup> However, because the Court articulated no test or standard to govern regulators’ rate setting,<sup>502</sup> litigation then turned to disputes over the basis on which regulators were setting rates. In the 1898 case of *Smyth v. Ames*,<sup>503</sup> concerning railroads, the Court articulated the basis that was to hold for more than a half century, the “fair value” standard. The *Smyth* standard held that the rate base should be set by reference to the fair value of the utility’s assets.<sup>504</sup>

Implementing this standard quickly became a morass, the untangling of which was repeatedly thrust back upon the courts. Among the standard’s problems was that the fair value of a utility’s assets depended in part on the rates it would be charging; thus, asset valuation and rate setting had a circular quality.<sup>505</sup> Further, when inflation skyrocketed during World War I and beyond, the fair-value method tilted away from the balance courts sought to achieve between the public’s interest and those of utility investors: the value of the utility’s assets far exceeded investors’ investments in the company, and the method could not adequately protect the public from high prices.<sup>506</sup>

Ultimately, in the 1944 case of *Federal Power Commission v. Hope Natural Gas*,<sup>507</sup> the Supreme Court abandoned the fair-value standard. Rather than looking at whether the regulator’s valuation of the rate base provided just compensation, the *Hope* Court held, courts should henceforth confine

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<sup>497</sup> One example of manipulation is restricting power generation to drive up price. U.S. DEP’T OF ENERGY, *supra* note 464, at § 6.2.1.2.

<sup>498</sup> U.S. DEP’T OF ENERGY, *supra* note 464, at § 7.1.3, A.35. Price caps were also adopted for wholesale markets in some states. *Id.* at A.35.

<sup>499</sup> *Electricity Residential Retail Choice Participation Has Declined Since 2014 Peak*, U.S. ENERGY INFO. ADMIN. (Nov. 8, 2018), <https://www.eia.gov/todayinenergy/detail.php?id=37452>.

<sup>500</sup> *Munn v. Illinois*, 94 U.S. 113, 150 (1876).

<sup>501</sup> *Boyd*, *supra* note 462, at 750.

<sup>502</sup> *Id.* at 741 (citing Walton Hamilton, *Affection with a Public Interest*, 39 YALE L.J. 1089, 1094 (1930)).

<sup>503</sup> 169 U.S. 466 (1898).

<sup>504</sup> *Id.* at 546-7 (“[T]he basis of all calculations as to the reasonableness of the rates to be charged by a corporation maintaining a highway under legislative sanction must be the fair value of the property being used by it for the convenience of the public.”).

<sup>505</sup> *Boyd*, *supra* note 462, at 762-63.

<sup>506</sup> John N. Drobak, *From Turnpike to Nuclear Power: The Constitutional Limits on Utility Rate Regulation*, 65 B.U. L. REV. 65, 81 (1985).

<sup>507</sup> 320 U.S. 591 (1944).

their review to whether the “end result”—the rate itself—was “just and reasonable,” as required by the governing statute.<sup>508</sup> Though *Hope* concerned federal regulation of natural gas rates, its standard has had enduring force in federal and state regulation of electricity providers and other utilities.

The *Hope* Court had little to say about the specific method through which a PUC could arrive at its result, so long as basic hallmarks of procedural due process in agency decision making were present (i.e., the decision was based on substantial evidence and was not an abuse of discretion).<sup>509</sup> It confined its review to ensuring that, whatever method was used, “the resulting rates were not so low as to be confiscatory.”<sup>510</sup> Subsequent cases have made clear that this constitutional bar is quite low: even a rate-setting scheme that results in some utility providers not receiving a fair rate of return may be permissible if it furthers the broad public interests that the PUC was created to promote.<sup>511</sup>

Although it declined to set forth a range of permissible approaches to rate setting, *Hope* did explicitly approve the use of the utility’s historical cost of providing service.<sup>512</sup> Under this “historical cost” standard, regulators set rates “at a level that allows the utility to recoup its reasonably and prudently incurred costs plus a reasonable rate of return; otherwise, the rate is held to constitute a taking.”<sup>513</sup> If this sounds like rate-of-return regulation, that is no accident: since *Hope*, historical cost ascended to dominance in utility rate setting and has become closely identified with rate-of-return regulation.<sup>514</sup>

The upshot of this brief history is that courts have moved over time from intensive review of the method and inputs into a PUC’s rate decisions to a high-level, deferential assessment of whether the end result is reasonable, and in some cases even lighter review.<sup>515</sup> A key purpose for establishing PUCs was ensuring universal access to a steady supply of electricity, so among PUCs’ considerations should be what rate of return is needed to attract investors, cover operating expenses, and keep utility providers in business. Rates set too low may benefit the public in the short term, but if they damage the provider too much, consumers suffer in the long term<sup>516</sup>—an issue with notable parallels to innovation incentives in the drug context. Nevertheless, courts will generally leave judgments about how low is too low to PUCs, stepping in only to prevent grossly unfair treatment

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<sup>508</sup> *Id.* at 600 (“Congress has provided . . . that all natural gas rates subject to the jurisdiction of the Commission ‘shall be just and reasonable . . . .’”); *id.* at 602 (“It is not theory but the impact of the rate order which counts. If the total effect of the rate order cannot be said to be unjust and unreasonable, judicial inquiry under the Act is at an end. The fact that the method employed to reach that result may contain infirmities is not then important.”).

<sup>509</sup> Basil L. Copeland, Jr. & Walter W. Nixon, *Procedural Versus Substantive Economic Due Process for Public Utilities*, 12 ENERGY L.J. 81, 81, 89 (1991).

<sup>510</sup> Boyd, *supra* note 462, at 767. Despite the language of confiscatory rates, *Hope* is generally read as having rejected *Smyth*’s view of rate setting through the lens of eminent domain. Instead, the *Hope* Court “treated ratemaking as one species of the legislative power and recognized that stringent ratemaking could be confiscatory. It did not adopt the regulatory takings doctrine . . . as the constitutional limit on ratemaking.” Drobak, *supra* note 506, at 85.

<sup>511</sup> *In re Permian Basin Area Rate Cases*, 390 U.S. 747 (1968) (upholding an area-wide rate for natural gas although some individual gas producers did not receive a fair rate of return); see also *Federal Power Comm’n v. Texaco*, 417 U.S. 380, 391-93 (1974) (reiterating that the Constitution requires only that the rate “be higher than a confiscatory level” and that courts need only assess whether the commission has balanced investors’ interests and the public’s interests in a reasonable way); Copeland & Nixon, *supra* note 509, at 99-100, 102 (discussing the relevance of the interests entrusted to the commission in the overall assessment of the reasonableness of a rate).

<sup>512</sup> *Hope Natural Gas*, 320 U.S. at 622 (Black, J., concurring).

<sup>513</sup> Brewbaker, *supra* note 460, at 703.

<sup>514</sup> Chen, *supra* note 479, at 1681 (citing *Verizon Communications, Inc. v. FCC*, 535 U.S. 467, 485, 500 (2002)).

<sup>515</sup> See Copeland & Nixon, *supra* note 509, at 104.

<sup>516</sup> Drobak, *supra* note 506, at 124-25.

of investors—that is, confiscatory rates.<sup>517</sup> And in addition to resolving disputes over rates that are purportedly too low, they are also called upon to review rates that consumers argue are too high.<sup>518</sup>

### 3. Applicability to Prescription Drug Prices

The public-utilities model has intuitive appeal as an analogue for prescription drugs<sup>519</sup> and has attracted interest from state lawmakers. Its appeal derives from its longstanding place in the American regulatory scheme and the prospect of applying “a persistent, ongoing practice of using state power to curb unfair and oppressive practices” in the market.<sup>520</sup> As discussed in Part I, Maryland and Maine have passed rate-setting legislation for prescription drugs and several other states have introduced similar bills,<sup>521</sup> encouraged by NASHP.<sup>522</sup> These rate-setting bills are often described as being modeled after public utilities regulation,<sup>523</sup> but there are important differences in the approaches, discussed below.

There are striking similarities between public utilities and prescription drugs. Both markets are plagued by the specter of monopoly pricing: utilities because of their tendency toward natural monopoly and drugs due to the government-granted patent monopoly and other regulatory exclusivities. Both involve essential products, and therefore are “affected with a public interest.”<sup>524</sup> States’ regulation of health insurance premiums and hospital charges over the last five decades buttresses the idea that the utilities model has application to healthcare.<sup>525</sup>

The appeal of the utilities model also springs from its potential reach: it provides a conceptual basis for regulation of the base price of a drug, in addition to price increases.<sup>526</sup> Although it is more straightforward to apply utility rate-setting methods to price increases, the “rate base” element of rate-of-return regulation<sup>527</sup> provides a way of thinking about how regulators could limit launch prices.

Another normatively appealing aspect of the traditional ratemaking model for utilities is the idea of setting explicit limits on sellers’ returns in a manner that strives to be fair to all parties.

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<sup>517</sup> *Id.* (citing JAMES BONBRIGHT, VALUATION OF PROPERTY 1155 (1937)).

<sup>518</sup> *See, e.g.,* Washington Gas Light Co. v. Baker, 188 F.2d 11 (D.C. Cir. 1950) (challenging high gas rates in the District of Columbia).

<sup>519</sup> *See* Nicholas Bagley, *Medicine as a Public Calling*, 114 MICH. L. REV. 57, 60 (arguing for the appropriateness of the public-utilities model for healthcare and concluding that “the fit is natural”).

<sup>520</sup> *Id.* at 61, 71 (discussing the approach’s suitability for healthcare generally); *id.* at 96-99 (summarizing the history of hospital rate regulation).

<sup>521</sup> *State Legislative Action to Lower Pharmaceutical Costs*, *supra* note 71 (listing and summarizing bills introduced through February 2019 in Connecticut, Illinois, Massachusetts, Minnesota, Missouri, New Jersey, and Oregon, in addition to Maryland).

<sup>522</sup> NASHP’S PHARMACY COSTS WORK GROUP, STATES AND THE RISING COST OF PHARMACEUTICALS: A CALL TO ACTION 7-8 (Oct. 2016), <https://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf>.

<sup>523</sup> *See, e.g., id.*; Ed Silverman, *A Growing Number of States Consider Legislation to Treat Pharma as a Utility*, STAT (Oct. 18, 2018), <https://www.statnews.com/pharmalot/2018/10/10/pharma-legislation-utilities-review-boards/>.

<sup>524</sup> *Munn v. Illinois*, 94 U.S. 113, 150 (1876); *see also* Bagley, *supra* note 519, at 75-79, 84-85 (discussing what makes a business imbued with a public interest).

<sup>525</sup> *See, e.g.,* Bagley, *supra* note 519, at 97-99 (briefly summarizing the history of insurance rate regulation). We have focused on electricity rather than insurance or hospitals because the regulatory approach originated in the energy sector. Additionally, rate regulation for hospitals has typically been implemented by limiting what particular payers will pay, rather than formal imposition of price controls that apply to all customers. For a useful review of the history of hospital rate setting, see John E. McDonough, *Tracking the Demise of State Hospital Rate Setting*, 16 HEALTH AFFAIRS 142 (1997).

<sup>526</sup> A limit on its reach, however, is that the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1001, may prevent application of the upper payment limit to ERISA plans.

<sup>527</sup> *See supra* note 483 and accompanying text.

Among the criticisms levied at biopharmaceutical companies is that their profit margins are too high. The industry is among the most profitable in the U.S.<sup>528</sup> Although there are large variations in margins across companies, in 2017 the average operating margin among the 25 largest drug companies was 22 percent.<sup>529</sup> Rate-of-return regulation strikes at the heart of this concern. It could also facilitate the curbing of high marketing and operational expenses. A recent study concluded that among 12 large biopharmaceutical companies, expenditures on marketing and administration (including executive pay) exceeded spending on R&D by up to 80 percent.<sup>530</sup> An estimated \$6.1 billion was spent on direct-to-consumer advertising alone in 2017, not counting social media promotion.<sup>531</sup> Regulators who deem these expenses imprudent or not in the public interest could disincentivize them by disallowing them in rate-setting calculations.

Given these benefits, how might the utilities model be applied to prescription drugs? At least two possibilities arise. First, rate-setting approaches from utilities could be used to evaluate whether a particular price increase is excessive. A federal statute of broad application or a state statute that (given likely patent-preemption challenges) focuses on medications for which federal exclusivities have expired<sup>532</sup> could peg the definition of an unconscionable increase to a formula for calculating a non-unconscionable price (akin to the formula for a reasonable rate of return or price ceiling for utilities). When a regulator suspects that a price increase is excessive, it could require the company to show that, to the contrary, it satisfies the demand of the formula. The rate of return, a key part of the formula, could be set by reference to what is allowed for utilities. In recent years, regulators have chosen rates converging around 10%<sup>533</sup> and courts have declined to intervene on the basis that those rates are too low. Because electricity is considered a low-risk investment, a higher rate of return would be appropriate for those biopharmaceutical companies funding high-risk R&D.

The second alternative would be to adopt a pure rate-setting model. Rather than simply prohibiting unconscionable or excessive prices, regulators would impose formal price controls as they do for utilities, informed by the guideposts from utilities cases about what sort of rate is legally permissible and statutory guidance as to the goals the rate-setting commission is meant to pursue.

In some respects, that approach resembles the rate-setting legislation in Maryland and similar bills proposed in other states. However, there are important differences. One technical distinction is that PUCs establish prices that may be charged to customers in the jurisdiction, whereas most state bills creating drug affordability boards (DAB) would establish maximum amounts that payers in the state will pay. Reportedly, one reason for this frame shift in Maryland's legislation is to minimize concerns about intruding on patentholders' ability to monopoly-price their products: the DAB leaves drug manufacturers free to charge whatever they wish, although payers in the state may not pay it.<sup>534</sup> A second difference is that the triggering conditions for review are different. PUCs in most jurisdictions review rates whenever a stakeholder initiates a rate case, while DAB review only occurs

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<sup>528</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS (2017).

<sup>529</sup> *Top 25 Global Pharma Companies by Market Cap (End of 2017)*, GLOBAL DATA (Apr. 3, 2018), <https://www.globaldata.com/top-25-global-pharma-companies-market-cap-end-2017/>.

<sup>530</sup> NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 88.

<sup>531</sup> Alison Kanski, *Pharma Advertising Up 14% Across All Media in October: Standard Media*, MM&M (Nov. 30, 2018), <https://www.mmm-online.com/home/channel/pharma-advertising-up-14-across-all-media-in-october-standard-media/>.

<sup>532</sup> Though even with a focus on generics, the dormant Commerce Clause could still pose challenges and may be foreclosed within the Fourth Circuit, as noted earlier in the discussion of *AAM v. Frosh*.

<sup>533</sup> Coley Girouard, *How Do Electric Utilities Make Money?*, ADVANCED ENERGY PERSPECTIVES (Apr. 23, 2015), <https://blog.aee.net/how-do-electric-utilities-make-money> (stating in 2015 that the average return on equity allowed for power companies was 10.13%).

<sup>534</sup> Horvath, *supra* note 179.

when certain trigger conditions occur. Specifically, the Maryland DAB is authorized to review launch prices that exceed a specified dollar amount and annual price increases that exceed a certain percentage amount,<sup>535</sup> an approach common in other states' bills.<sup>536</sup> The difference in trigger is substantive as well as procedural. Because PUCs have historically had to grapple with predatory pricing in some industries, they review downward as well as upward adjustments in prices. In contrast, DAB review as described in current legislation is only triggered by certain price increases or a high initial price.

Finally, the basis for making determinations that a price is excessive differs in the utilities and drug contexts. Unlike PUCs, DABs proposed in most states do not examine, in the first instance, the producer's costs or calculate a reasonable rate of return when setting upper payment limits. The task of Maryland DAB's, for example, is to determine whether a particular drug creates an "affordability challenge" for the state healthcare system or patients paying out-of-pocket costs. If it finds that an affordability challenge exists, then further regulatory action is triggered. NASHP's model-legislation approach calls for a payment ceiling to be imposed. In Maryland, that provision was substantially enervated in the final version of the legislation.<sup>537</sup>

The key point is that in taking further regulatory steps, the DAB does not focus on drug manufacturers' revenue or profit, but rather on indicators that patients and health insurers in the state may have difficulty affording the drug.<sup>538</sup> Biopharmaceutical companies' R&D costs, marketing costs, and gross and net revenues (as well as revenues realized by PBMs and wholesale distributors) are only considered if the DAB is unable to reach a determination whether the drug produces an affordability challenge based on the other factors. To date, only one state, New Jersey, has proposed a DAB model in which the board would focus on drug companies' costs and other metrics.<sup>539</sup>

Thus, except for New Jersey, the DAB approach focuses on burdens on consumers, while PUCs are supposed to balance the interest of the public with that of the utility. If the overall goal is cost containment, the affordability-based approach for drugs may be an effective strategy. As we describe below, applying rate-of-return regulation to drug companies would present numerous, intractable practical challenges. On the other hand, failing to consider the effect of an upper payment limit on producers' rate of return entails inherent risk of improperly balancing consumers' and companies' interests. That is, affordability standards have the normative deficiency that they do not require fair treatment of all parties. Furthermore, if DABs err on the side of strict payment limits in the short term, they risk discouraging investment in drug R&D if the limits were widely adopted—an issue of obvious import for consumer welfare.

Assuming these risks could be sufficiently mitigated in practice, the affordability-based rate-setting model is pragmatically preferable to the traditional utilities model. History teaches that rate-

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<sup>535</sup> As discussed earlier, *see supra* Part I.B.1, nearly all prescription drug rate-setting bills to date have taken this approach because they are patterned on model legislation developed by NASHP. *See An Act to Establish Rate Setting of Prescription Drugs in [State]*, *supra* note 160.

<sup>536</sup> *Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, *supra* note 151.

<sup>537</sup> Whereas early versions of the bill would have required the DAB to set an upper payment limit for all Maryland payers when it found that an affordability challenge exists or will occur, the adopted version directed it to undertake further study of policy options and, if it determined an upper payment limit was desirable, to "draft a plan of action for implementing the process" for setting such limits. It further provides that after January 1, 2022, with the approval of the state General Assembly's Legislative Policy Committee, the DAB may begin setting upper payment limits, but only for drugs purchased by the Maryland Medicaid program and other state or local government payers. The legislation also commissions a study on the legality of setting upper payment limits for other payers. *See* H.B. 768, 2019 Gen. Assemb. (Md. 2019).

<sup>538</sup> For details, *see supra* note 175 and accompanying text.

<sup>539</sup> *See Comparison of Bills Creating State Prescription Drug Affordability Review Boards*, *supra* note 151 (summarizing N.J. No. 583/983).

of-return regulation involves complex, technical determinations that invite legal challenges. Further, applying such an approach to pharmaceuticals would be substantially more challenging than applying it to electricity. In particular, calculating the rate base would be far more complex. Electricity companies produce a single product. Biopharmaceutical companies typically sell a range of products, and a price must be calculated for each. Does this mean a separate rate base should be calculated for each? How are the company's assets and R&D investment to be allocated among its products? There is general agreement among economists that in calculating the cost of bringing a drug to market it is appropriate to include not just the cost of developing that product, but the amounts the company invested in products that never succeeded in reaching FDA approval as well, because those amounts represent forgone investments.<sup>540</sup> The entire pool of R&D investment for a given year would have to be allocated across the marketed products in that year, and it is not clear how that allocation should be performed.

A related problem is how to think about historical cost for drugs. Since the *Hope* decision, a power company's historical cost in a test year has served as the foundation of rate setting in regulated retail electricity markets. Arguably, biopharmaceutical companies are subject to greater volatility in their year-to-year costs because of variations in their R&D costs depending on where their promising molecules are in the pipeline. Electricity regulators have evolved ways of dealing with lumpiness in investment and operating costs—for example, allowing power companies to present evidence of unusually high spending on large new construction projects and spread those costs over several future years of ratemaking. But it adds complexity to the rate-setting process.

A third challenge is what to do about entrants and exits in the pharmaceutical market. Rate setting for public utilities has been premised on the notion that one company will have the right to sell in a local retail market. In contrast, markets for treating particular health conditions will be subject to entries (and occasional exits) as new drugs are developed, older ones go off patent and generic competitors spring up, and existing sellers re-evaluate what constitutes the best use of their resources. This poses challenges for regulating price using a traditional utilities model. What, for example, should be done with a new company that has no historical costs to use to set the rate base? When the number of alternative drugs for treating a particular condition increases, should regulators ratchet the allowable rate of return downward, approximating what would be expected to occur under fully competitive market conditions? Electricity sales within a territory can be projected with reasonable certainty, so as to calculate the appropriate rate by dividing revenue requirement by sales; estimating future sales for a given drug is harder, given uncertainties about new market entries by competitors and other factors.

For these reasons, pursuing rate-of-return regulation for drugs faces significant hurdles on many fronts. The technical and conceptual (let alone political) challenges are formidable. Even if regulators were able to surmount them, they would also need to have an appetite for fighting what seem to be inevitable, recurrent court battles about the permissibility of their judgments. Judicial decisions affording electricity regulators a wide berth for rate-making decisions give cause for optimism about the eventual resolution of such disputes, but the fight may be long and expensive. Moreover, familiar concerns about the perverse incentive for inefficiency associated with rate-of-

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<sup>540</sup> NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 88. For two prominent studies that have taken this approach, see Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016); Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERNAL MED. 1569 (2017). But see Emanuel, *supra* note 396 (objecting that the DiMasi study assumed an excessive interest rate for capital invested in R&D, and noting that many failed drugs did not involve substantial investments in R&D because they failed at an early stage).

return regulation are likely to surface for pharmaceutical production as they did for electricity production—notwithstanding regulators’ best efforts to disallow imprudent expenses.

In summary, the public-utilities model is normatively attractive in its efforts to fairly regulate prices, and useful in inspiring initiatives that imagine similar rate-setting exercises for drugs. Yet, it is less conducive to suggesting particular methods by which prices for drugs ought to be set. Alternative approaches such as Maryland’s affordability-based rate-setting model may be more pragmatic for controlling drug prices, although, as already discussed, are vulnerable to normative criticism on fairness grounds.

#### **IV. Conclusions and Recommendations**

Our purpose is to identify approaches to imposing legislative restrictions on excessive drug prices that are likely to withstand void-for-vagueness challenges while substantially advancing the government’s purpose of curbing the “financial toxicity” of high drug costs. In this Part, we offer a series of recommendations for drafting new legislation and strengthening previously introduced bills at the state and federal levels. Our analysis is also summarized in Table 1 for easy reference.

In arriving at recommendations based on our review of four relevant areas of law, we bear in mind that the approach must not only be legally defensible, but should also satisfy the normative criteria previously articulated:<sup>541</sup> First, it must withstand legal challenge. Legislation that is constitutionally or otherwise legally vulnerable will ultimately be ineffective policy—and more immediately—a waste of state or Congressional resources. As discussed earlier, although our analysis focuses on vagueness challenges, state legislation in particular must also anticipate other potential avenues of challenge, such as patent preemption. Second, any plausible legal strategy must hold the promise of substantially advancing the objective of curbing excessive prescription drug costs. Third, it must not be unduly subject to gaming. Fourth, proposals must be operationally feasible. Fifth, they should be fair to biopharmaceutical companies. Across the fields we have surveyed, which approaches hold the greatest appeal when measured against these criteria? We begin by offering four major conclusions in answer to that question and then apply our findings to generate specific recommendations for legislation.

##### **A. Findings Concerning Analogous Areas of Law**

First, although emergency price-gouging laws would seem to be a natural model for price-gouging laws for prescription drugs, the approach would need to be stretched considerably in order to accommodate prescription drugs. On the one hand, even if agreement can be reached that it is reasonable to declare excessive prescription drug prices to constitute an emergency, the approaches taken in these statutes to benchmarking price increases would have to be adapted to be applied to prescription drugs (see Table). As we have discussed, it is difficult to find appropriate comparison prices for drugs. Further, because the pre-“emergency” prices arguably were already inflated, it is not as straightforward as it is for batteries or gasoline to deem a price increase of a given percentage reasonable. Supplementing this feasibility problem is a gaming concern that could undermine the approach’s effectiveness: it is not applicable to launch prices, and companies marketing new products likely will respond accordingly.

On the other hand, price-gouging laws are strong in the domain of legal defensibility—they set out very clear criteria, rarely draw legal challenges, and are durable in the face of vagueness

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<sup>541</sup> See *supra* Introduction.



arguments when challenged. Their clarity and specificity is appealing on procedural fairness grounds. And although they have not done so in the past, they could be drafted so as to set forth different allowable price increases for different kinds of products (e.g., more permissive ceilings for drugs with a low initial price). Overall, the maximum-percentage approach of emergency price-gouging laws hold appeal for drug price increases, but new methods would have to be generated for identifying benchmark prices.

Second, our review of contract law suggests that if legislators do not define the term “unconscionable” by statute, courts will apply common-law understandings of that term from contract disputes—and that is not optimal for advancing the goal of regulating drug prices. Although the contracts approach has several appealing aspects, overall, its disadvantages caution against relying too heavily upon it (see Table). Its appeal arises from its flexible standards. It can address situations of unfair pricing not expressly contemplated by legislative drafters. As discussed above, such flexibility would be advantageous because of the very different contexts surrounding prices for different drugs, which makes it challenging to simply “pick a number” and call prices above it excessive.<sup>542</sup> Flexibility in what factors can be incorporated into a calculus of what is “unconscionable” is also appealing for this reason.

However, a critical drawback of the common-law conception is that, in most jurisdictions, a showing of procedural unfairness is required. This requirement could foreclose taking action against high drug prices in a broad swath of circumstances in which it is hard to argue that buyers have been subject to oppression and surprise. A second disadvantage we have noted is that the traditional benchmarks courts use to assess the substantive unfairness of a price term—the seller’s markup of the product, the seller’s profit, and prices charged by competitors—will often be difficult to apply to manufacturers’ prices for drugs. The concept of reseller markup does not apply, there may not be other sellers of similar products to compare to, and drug-specific profit is hard to gauge because the production cost is not easily quantified. A third disadvantage is its heavy reliance on judges for interpretation. Judges may be too timid in applying the doctrine<sup>543</sup>—or overzealous—and, in either event, may not fully effectuate the legislature’s intent. They may also be inconsistent in their applications, undermining deterrence. For these reasons, the contract-law approach presents effectiveness and feasibility concerns.

Our third conclusion is that traditional methods of utilities regulation likely would be impracticable to apply to prescription drugs. Rate-setting commissions like Maryland’s may be an effective strategy for addressing affordability issues, but as discussed, they depart from the rate-making method employed by PUCs for electricity, rate-of-return regulation.<sup>544</sup> Despite its potential fairness to all parties—consumers and companies alike, its resistance to gaming, and its potential effectiveness in reducing excessively high drug costs by regulating companies’ profit (see Table), rate-of-return regulation for drugs fails the feasibility criterion. The history of electricity regulation demonstrates the difficulty of establishing a rate base even for simple products. The technical complexity involved in doing so for drugs would be much greater. New entries into the market by competitor companies present additional challenges in setting rates. Further, the electricity case suggests that although the prospects for withstanding vagueness challenges and other legal challenges are sunny, rate-of-return regulation invites costly and time-consuming litigation.

Our final conclusion is that, of the four areas of law reviewed, consumer lending law offers the most promising model for regulating excessive drug prices. The two-pronged approach states

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<sup>542</sup> See *supra* Part III.B.3.

<sup>543</sup> Beh, *supra* note 295, at 1013-14.

<sup>544</sup> As discussed above, Maryland’s rate-setting commission would set upper payment limits based on a different method. See *supra* Part I.B.1.b.

have taken to regulating loan prices—coupling a usury statute with a prohibition on unconscionable business practices under a more general consumer protection act—is a very attractive approach for prescription drugs. The analogue for usury in the drug context would be a statutory provision establishing a maximum percentage ceiling for increases in the price of the drug, annually or cumulatively over some time period, with an exception for situations where the company can show a larger increase is required by an acute market condition such as an ingredient shortage. This price-increase law would provide a first line of defense in policing high drug prices; it would be sufficient to address many of the pricing practices of greatest concern in the current environment; and given its straightforward, clear standard for violations, it would be relatively easy to implement.<sup>545</sup> But it would be supplemented by a backup strategy. Analogous to the role of general CPAs in consumer lending law, a consumer protection act specific to medicines could impose a general prohibition on “unconscionable” or “excessive” drug prices (either at launch or as a result of price increases). The statute would provide a definition of “unconscionable” or “excessive” in order to untether them from the U.C.C. and common-law understandings of unconscionability.<sup>546</sup> The general provision would be deployed where the price-increase provision is not suitable for addressing the price problem posed by a particular drug.

Before discussing what that definition might look like, we offer a few reflections on why this two-pronged model is attractive (see Table). Because it addresses both price increases and high base prices, it has strong potential to be effective in curbing drug costs and to limit opportunities for gaming. Further, the ability to write a definition of “unconscionable” into the statute that does not require a showing of procedural unfairness means that this approach can be consumer blind—that is, applicable to all purchasers of prescription drugs regardless of their sophistication. The legal defensibility of the approach against vagueness challenges is high: in the usury context, courts have repeatedly demonstrated their willingness to defer to legislatures’ choice of a maximum interest rate, and in the CPA context, they have rebuffed vagueness challenges to statutory definitions of unconscionable business practices. (It should not be forgotten, however, that for state laws other legal challenges could be problematic if the laws were not carefully drafted and applied.) Applying the standards does not raise significant feasibility problems, if appropriate benchmarks for the general standard are identified. It does, of course, raise the issue of which prices are to be evaluated—as do all price regulations.

Major objections to this proposed approach likely will relate to its fairness and collateral effects. Regarding the general unconscionability standard, companies will take a dim view of efforts

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<sup>545</sup> It may be noted that we recommend the usury approach here although we dismissed as infeasible the emergency price-gouging law approach, which bears some similarities to usury laws. The distinction is that the emergency price-gouging approach consists solely of a comparison of the price at a designated emergency time to the price of the same product at the pre-emergency time, or to the price of the same product in another market area or retail outlet (the latter two options are not helpful prescription drugs, as we have discussed). If the baseline price is already inflated, it is not a helpful benchmark. The usury approach also has this problem, but the problem can be overcome by coupling it with provisions allowing assessment of the excessiveness of the base price. Thus, although looking at price increases alone is not sufficient, it is useful as part of a broader regulatory scheme.

<sup>546</sup> Our recommendation in this regard is inspired by Bender, *supra* note 329 (discussing the advantages of statutory, as opposed to common-law, definitions of unconscionability in the consumer-lending context). Notably, Maryland took this approach in HB 631. However, the definition it provided in the statute was not a model of clarity. Further, in briefings responding to the AAM’s vagueness challenge, Maryland took the position that the provision was not vague because decades of common law in the contracts arena provided ample guidance as to the meaning of the term. That strategy muddies the waters as to what the legislature intended in establishing the statutory standard. If the statutory definition had been more specific (for example, if it had connected the general definition to the specific conditions that triggered a notification from the state Medicaid program of a potential affordability problem), an alternative defense that simply defended the clarity of the statutory language might have been more feasible to pursue.

to assess a substantively unreasonable base price, even when they are anchored in cost-effectiveness calculations or other transparent methods. Attempts to overtly cap drugs' base prices involve a risk of failing to reward companies for their investment at a level sufficient to ensure their continued commitment to innovation, and applying an unconscionability standard to the base price risks similar consequences. Regarding price increases, drug companies may, of course, also claim that capping price increases is unfair. If the law permits exceptions for situations where market disruptions justify larger increases as well as substantial discretion over setting the initial price, however, this objection appears weakened.

## B. Recommendations for Policy Design

We now turn to specific recommendations for legislators wishing to apply the consumer-lending-inspired, two-pronged model we have outlined. We discuss five important decisions that will need to be made.

First, *should the law be state or federal?* The approach could be implemented through either Congressional or state legislative action. Although states are the historical locus of consumer-protection law and in many ways the most natural choice to carry out the approach we have described, Congressional action is far preferable in light of the numerous legal challenges states are likely to face beyond issues of vagueness, depending upon how the law is written. One model for federal-state coregulation might be for states to address the excessive pricing of generic drugs while a federal statute focuses on products possessing federal exclusivities. Yet, Maryland's recent attempt at regulating unconscionable generic price increases was struck down. Given the Fourth Circuit's interpretation of the dormant Commerce Clause in that case and the U.S. Supreme Court's decision not to grant certiorari, a state-level consumer protection law focused on generic drug prices is still risky. At the very least, such laws ought to be explored within a different jurisdiction. Teeing up a circuit split attractive enough for the U.S. Supreme Court's attention may be a strategy to push for a final resolution of this issue.

Second, *what remedies should the statute provide?* A full discussion of remedies is beyond the scope of our analysis, but the importance of providing meaty remedies is clear. Given the size of many biopharmaceutical companies and the billions in revenue associated with sales of many drugs, laws that do not provide significant financial consequences for violations will be ineffectual. The types of remedies specified in the CURE High Drug Prices Act and Prescription Drug Price Relief Act, for example, have real bite.<sup>547</sup> Legislators should also ensure that the statute explicitly supplements other remedies at common law or under state or federal statutory law.<sup>548</sup>

Third, *which price should be evaluated?* Some federal bills propose to use the average manufacturer price (AMP), while most state price-gouging bills for medicines specify the WAC (some state bills do not define a specific price, however).<sup>549</sup> The WAC, which is often referred to as the list price, is the offering price set by the manufacturer for wholesalers and direct purchasers, before discounts and rebates. The AMP is the average price actually paid by wholesalers for drugs distributed to the retail pharmacy class of trade, after prompt-pay discounts but before rebates.<sup>550</sup> It

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<sup>547</sup> See *supra* Part I.A.

<sup>548</sup> This recommendation is offered by Bender, *supra* note 329, at 803, for consumer-lending laws.

<sup>549</sup> For details, see Gudiksen, *supra* note 82. A third alternative is the Average Wholesale Price (AWP), another representation of the list price, which includes no discounts or rebates. Colloquially known as "Ain't What's Paid," the AWP is the least meaningful of the alternatives, in terms of its relationship to actual acquisition costs, and has the disadvantage of not being publicly available.

<sup>550</sup> DANIEL R. LEVINSON, OFF. OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERVS., OEI-05-05-00240, MEDICAID DRUG PRICE COMPARISONS: AVERAGE MANUFACTURER PRICE TO PUBLISHED PRICES 4 (2005).

is calculated based on actual sales according to specifications set out by statute. AMP is, on average, considerably lower than both the WAC and AWP.<sup>551</sup>

The WAC is published in various private datasets and therefore, readily obtainable by anyone (albeit for a fee). It is also simple: it is one number, set by the manufacturer and adjusted periodically at its discretion. In contrast, AMP data are proprietary and nonpublic. However, drug manufacturers have long been required to report the AMP for all Medicaid-covered drugs to the federal Centers for Medicare and Medicaid Services on a quarterly basis.<sup>552</sup> The AMP thus has the benefit of already being in the hands of a key regulator. Further, manufacturers' AMP reporting is subject to audit from the Office of Inspector General to ensure compliance with Medicaid requirements, and is believed to be quite accurate.<sup>553</sup>

A third possibility is to peg price standards to the average net price after rebates and discounts paid by the first purchaser (for federal laws; to avoid dormant Commerce Clause challenges, state laws could specify the initial purchaser in the state). This approach more accurately represents the real prices paid—which can be substantially lower than either the WAC or the AMP. Another advantage is the avoidance of gaming. Under the rebate system, manufacturers can attempt to recoup lost revenue from a lower WAC or AMP by reducing the rebates they are willing to give, with the result that health plans and patients see little or no improvement in their own drug costs.<sup>554</sup>

For these reasons, targeting average net price is most consonant with the goals of drug price regulation. (We consider the AMP to be the second-best option, and, where the AMP is unavailable, the WAC as next best).<sup>555</sup> The price-regulation statute should set forth a detailed explanation of how this net price is to be calculated, including which purchasers are to be included, which discounts and rebates are to be netted out before the calculation is performed, and what the relevant time period for sales is.

Targeting net price is likely to encounter political resistance. Not only is that information not publicly available, many drug manufacturers and PBMs treat it as a trade secret.<sup>556</sup> Manufacturers also argue that having to reveal the discounts and rebates they offer to particular buyers would undercut their ability to offer them, because other purchasers would demand the same deal. Mitigating this concern is the fact that it is unnecessary to disclose average net price *publicly* in order for a price-gouging law's objectives to be carried out. Disclosure need only be made to the relevant oversight body.<sup>557</sup> Lawmakers who find the trade-secret argument credible can choose to protect it from further disclosure on that basis.

Fourth, *what should the maximum increase in price permitted by the price-increase provision be?* Here we do not have a strong recommendation other than that a numeric limit ought to be expressed clearly in the statute. However, we offer two points for consideration. First, if the ceiling is to be pegged to inflation, the Consumer Price Index for All Urban Consumers (CPI-U) is a better choice than the

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<sup>551</sup> *Id.* at ii.

<sup>552</sup> *Id.*

<sup>553</sup> See, e.g., BRIAN P. RITCHIE, OFF. OF INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERVS., A-06-13-0014, AVERAGE MANUFACTURER PRICE DETERMINATIONS BY SELECTED DRUG MANUFACTURERS GENERALLY WERE CONSISTENT WITH FEDERAL REQUIREMENTS, at i (2014) (concluding that “the methodologies that selected drug manufacturers used to determine AMPs generally were consistent with Federal requirements.”).

<sup>554</sup> Uninsured patients and patients paying coinsurance and deductibles at the pharmacy would, however, benefit from lower list prices, because their payments are typically pegged to the list price.

<sup>555</sup> Using either net price or the AMP would involve a delay in implementing the price-increase ceiling for newly launched products. The first price increase for a new product may not be observed until after twelve months after market entry, and then a year beyond that point would be required in order to calculate the average net price over the past year.

<sup>556</sup> Lee et al., *supra* note 15, at 865.

<sup>557</sup> NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 128-29.

CPI for Medical Care. Prescription drug prices comprise fifteen percent of the CPI for Medical Care,<sup>558</sup> so using that index as a benchmark involves a circularity. The CPI-U is a better measure of how much the prices of other goods in the economy are rising. Second, the statute ought to permit the manufacturer to provide evidence that an unanticipated shock necessitates a price increase above the statutory maximum. Such circumstances might arise, for example, in a time when key ingredients rapidly escalate in price or a problem at a particular manufacturing facility forces the company to switch facilities to avert a shortage.

A fifth question is *how should the general-CPA-style provisions of the statute define an excessive drug price* (for purposes of evaluating a drug's overall price rather than price hikes)? Our review of other areas of law using this type of standard suggests that if the statute uses the word "unconscionable," that term should be defined in a manner that explicitly requires no showing of procedural unfairness. Additionally, the statute should set forth a definition of substantive unconscionability that does not require comparisons that, though entrenched in the common law or general CPAs, are hard to make for drugs.<sup>559</sup> Value-based pricing models can vary,<sup>560</sup> but one reasonable approach would be to adopt a value-based pricing standard informed by, for example, the value assessment framework proposed by the Institute for Clinical and Economic Review (ICER).<sup>561</sup> Value-based pricing is based on the normative position that "there should be a relationship between price and benefits."<sup>562</sup> It pegs the price a payer is willing to pay for a drug to the amount of clinical value the drug is shown to generate—that is, the magnitude of the improvements in quality of life, functioning, and longevity the drug is shown to produce, either overall or for defined populations or indications. Value is typically established by using cost-effectiveness analysis to quantify gains in quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs).<sup>563</sup> Dividing a treatment's cost by the number of QALYs or DALYs generated produces a cost-effectiveness ratio. A price regulation statute employing a value-based standard could set forth a numeric cost-effectiveness ratio (or other measure of value) above which the drug's price would be considered excessive, or call for a broader assessment along the lines of ICER's framework.

Value-based pricing raises a thicket of difficult technical and normative issues,<sup>564</sup> which are beyond the scope of this Article to explore and resolve. For example, should value calculations be performed at the time of a drug's launch based on information from clinical trials, or should they await data from a broader group of real-world patients? Should value be measured based on clinical improvement alone, or also on the basis of whether improvement in functioning or longevity allows the person to contribute to society, as some have argued?<sup>565</sup> Are QALYs an ethically defensible

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<sup>558</sup> *Measuring Price Change in the CPI: Medical Care*, BUREAU OF LABOR STATISTICS (Mar. 21, 2019), <https://www.bls.gov/cpi/factsheets/medical-care.htm>.

<sup>559</sup> See *supra* Part III.

<sup>560</sup> See, e.g., Rachel Sachs et al., *Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule*, 43 J. HEALTH POL., POL'Y & L. 5 (describing different value-based pricing models).

<sup>561</sup> INST'T. FOR CLINICAL & ECON. REV., OVERVIEW OF THE ICER VALUE ASSESSMENT FRAMEWORK AND UPDATE FOR 2017-2019 (2018), <https://icer-review.org/wp-content/uploads/2017/06/ICER-value-assessment-framework-Updated-050818.pdf> (examining a drug's long-term value for money as a function of its estimated incremental cost-effectiveness, comparative clinical effectiveness, and other benefits and disadvantages, as well as contextual considerations).

<sup>562</sup> Ezekiel J. Emanuel, *When Is the Price of a Drug Unjust? The Average Lifetime Earnings Standard*, 38 HEALTH AFFAIRS 604, 606 (2019).

<sup>563</sup> *Id.* at 607; NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 54-55.

<sup>564</sup> NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 18, at 53-55, 58.

<sup>565</sup> See Emanuel, *supra* note 562, at 606 ("A drug that allows the average person to obtain a normal education or continue to work should be priced higher than one that merely keeps someone alive but not well enough to be employed ... because it saves costs in other nonmedical domains.").

metric given that in practice they value therapies for young, able-bodied persons higher than those for the aged and disabled?<sup>566</sup> Because of ongoing debates over these technical issues, a 2017 National Academies of Sciences, Engineering and Medicine consensus report concluded that value-based pricing approaches were not yet ready to take to scale.<sup>567</sup> However, it recommended the continued development and testing of these strategies.

We believe value-based pricing, particularly approaches grounded in cost-effectiveness, holds promise as a future basis for regulating excessive prices. It is worth noting, however, that the most valuable drugs may also be the most expensive. Thus, this approach could permit very high drug prices to persist, provided the drug offers commensurate benefits.<sup>568</sup> It simply provides a means of identifying prices that are excessive relative to the benefits delivered to the public.

Another possibility for defining substantive unconscionability would simply be to name a dollar amount above which the price may not rise—that is, establish a price cap (perhaps waivable if the company can show good value for money). Maryland’s HB 631, for instance, drew upon a price cap approach as a trigger for the state’s Medicaid program to report a drug to the attorney general for possible enforcement action. There are ethical arguments in favor of such an approach. Ezekiel Emanuel has argued, for example, that people should have enough earnings left over, after paying for their prescription drugs, to allow them to pursue “valuable life activities and life goals” beyond paying for necessities and their children’s college expenses.<sup>569</sup> After extensive calculations, he concluded that to satisfy this principle the cumulative lifetime cost of a drug must not exceed 11% of total lifetime disposable income for a college-educated male, or \$70,715.<sup>570</sup>

Despite the moral appeal of such arguments, our view is that the dangers of setting an absolute price cap either too high (thereby missing opportunities for regulatory action against nevertheless excessively-priced drugs, as measured by a value-based standard) or too low (thereby chilling investment in R&D) are, on balance, too great.<sup>571</sup> A price cap would also create clear incentives for manufacturers to set the price just below the statutory maximum, to the extent that market conditions allow it.

What about the possibility of pegging substantive unconscionability to the company’s investment in developing the drug? For example, one criterion for excessive price in Maryland’s HB 631 was whether increased drug prices were justified by the cost of producing the drug or expanding access to it. As we discussed in our review of other areas of law, definitions of excessive price that involve assessment of a company’s return on its investment are likely to be troublesome. Implementing Maryland’s approach, for instance, would require agreement about which costs are appropriate to include in these calculations, as well as agreement about a reasonable return on investment (though that is more a concern for novel drugs than for generics). Because the calculation also requires understanding the company’s expected revenue stream for the drug at

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<sup>566</sup> For a summary of this debate, see, e.g., David L.B. Schwappach, *Resource Allocation, Social Values and the QALY: A Review of the Debate and Empirical Evidence*, 5 HEALTH EXPECTATIONS 210 (2002); William S. Smith, *The U.S. Shouldn’t Use the ‘QALY’ in Drug Cost-Effectiveness Reviews*, STAT (Feb. 22, 2019), <https://www.statnews.com/2019/02/22/qaly-drug-effectiveness-reviews/>.

<sup>567</sup> NAT’L ACADS. OF SCIS., ENG’G, AND MED., *supra* note 18, at 72, 127.

<sup>568</sup> For example, the Hepatitis C drug, Sovaldi, was launched at a list price for a twelve-week course of treatment of \$84,000. Amidst the controversy over this price, experts pointed out that the higher cure rate of Sovaldi relative to alternative therapies for Hepatitis C meant that it would save more than it cost. See, e.g., John LaMattina, *What Price Innovation? The Sovaldi Saga*, FORBES (May 29, 2014), <https://www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/#33aab6277f67>.

<sup>569</sup> Emanuel, *supra* note 562, at 606.

<sup>570</sup> *Id.* at 608-09.

<sup>571</sup> The National Academies report also did not endorse “direct controls or setting limits on drug prices” because of concerns about chilling new drug development. NAT’L ACADS. OF SCIS., ENG’G, AND MED., *supra* note 18, at 132-33.

various prices, it also implicitly requires estimation of the size of the global market for the drug, the prices that the company will be able to get for the drug around the world, the range of current and future market exclusivities the company is likely to get, and the likelihood and timing of market entry by generic competitors. These bumpy roads are best avoided.

We turn now to a final question: among products covered by the statute, *how should agencies charged with enforcing the statute decide which drugs to target?* With the price-hike provision, the answer is clear: anything and everything above the maximum. Given the clear limit it imposes, this provision should not be complex or costly to enforce. Harder choices may have to be made about which products to target under the general unconscionability provision, the enforcement of which may involve higher complexity and more resources. High-priced, newly launched drugs are a natural target for regulatory scrutiny, especially since they are not yet subject to the price-increase provision. Among older drugs, priority should be placed on reviewing for possible enforcement products that (1) are most important from a public-health perspective; and/or (2) have the highest prices for a typical dose or course of treatment.<sup>572</sup> Drugs that meet both criteria should receive the highest priority.

Work by Mariana Socal and colleagues at Johns Hopkins University is helpful in analyzing factors relevant to assessing the public-health importance of a drug.<sup>573</sup> In recommending criteria for the Maryland Attorney General's office to act under HB 631, Socal and colleagues suggest that key considerations might include (1) whether the drug saves lives or averts serious harms; (2) the number of people dependent on the drug; and (3) how many alternative therapies are available for the health condition(s) the drug treats. Drugs used by children may merit particularly close monitoring "because of the smaller set of drugs available for use" in pediatric populations.<sup>574</sup> These criteria, in combination with the high-price criterion, would target scarce resources for enforcement to the drugs that present the most objectionable prices. Notably, they would point regulators toward drugs in the clinical area that are consistently identified as the most important driver of a national prescription drug bill: specialty oncology medicines.<sup>575</sup> To help foreclose vagueness challenges, these criteria should set them forth clearly in the statute text or implementing regulations.

### C. Conclusion

In this Article, we have investigated how federal and state legislation aimed at curbing excessive drug prices might be crafted so as to survive void-for-vagueness challenges. Insights are available from each of four adjacent areas of law we have reviewed in which a standard of "unconscionable" or "excessive" price has been operationalized: price-gouging laws relating to times of emergency, contract law, consumer lending laws, and public utilities rate regulation. Based on our examination of these areas, we have argued that there are viable and promising ways to pursue regulation of drug prices using a standard of unconscionable or excessive price. As we summarize in the Table 1, consumer lending law offers the most promising model, particularly if advanced via federal legislation. Any state legislation along these lines will have to run the gauntlet of litigation alleging dormant Commerce Clause and patent-preemption claims, which pose formidable

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<sup>572</sup> This review may determine that some very high-priced drugs should not be enforcement targets because they offer commensurately great clinical benefit.

<sup>573</sup> Policy Memorandum from Mariana Socal et al. to Assistant Maryland Attorney General Josh Auerbach (Oct. 16, 2017) (on file with authors).

<sup>574</sup> *Id.* at 3.

<sup>575</sup> See Vinay Prasad et al., *The High Price of Anticancer Drugs: Origins, Implications, Barriers, Solutions*, 14 NATURE REV. CLINICAL ONCOLOGY 381 (2017); Bradford R. Hirsch et al., *The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs*, 33 HEALTH AFFAIRS 1714 (2014).

challenges. But vagueness challenges can be headed off if legislators provide standards up front. Being clear will also increase the deterrent force of the statute.

In his classic 1967 article about the vagueness of unconscionability doctrine in contract law, Arthur Allen Leff urged drafters of legal standards to avoid the temptation of “saying nothing with words,”<sup>576</sup> citing Karl Llewellyn’s admonition that “Covert tools are never reliable tools.”<sup>577</sup> Heeding this advice will move lawmaking in the prescription drug pricing space toward policy that is effective, fair, and defensible.

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<sup>576</sup> Leff, *supra* note 288, at 559.

<sup>577</sup> *Id.* (quoting Karl N. Llewellyn, *The Standardization of Commercial Contracts in English and Continental Law*, 52 HARV. L. REV. 700, 703 (1939) (book review)).



**Table 1. Summary of Advantages and Disadvantages of Approaches to Defining Excessive Price**

	<b>Advantages</b>	<b>Disadvantages</b>	<b>Conclusion</b>
<b>Emergency price-gouging laws</b>	<ul style="list-style-type: none"> <li>• Rarely draw legal challenges; durable to vagueness arguments when challenged</li> <li>• Describe prohibited conduct with great specificity and clarity. Even type-3 statutes usually have criteria for what constitutes an excessive increase.</li> <li>• Conceivable to specify different allowable price increases for drugs with different base costs.</li> </ul>	<ul style="list-style-type: none"> <li>• Not possible to apply to launch prices</li> <li>• Hard to find appropriate benchmark (comparison) prices for drugs</li> <li>• Considering companies' increased operational costs as justification for price increases may encourage undesirable spending (e.g., marketing)</li> </ul>	Maximum-percentage approach is appealing for drug price increases, but approach to identifying benchmark prices is inapposite.
<b>Contract law</b>	<ul style="list-style-type: none"> <li>• Flexible standard; can address situations not expressly contemplated in statutes</li> <li>• Flexible proofs; elements can be shown through a wide variety of factors</li> </ul>	<ul style="list-style-type: none"> <li>• Requires showing of procedural unconscionability</li> <li>• Relies heavily on judges for interpretation</li> <li>• Traditional benchmarks for substantive unconscionability of price may be difficult to apply to drugs</li> <li>• Relies on contracting parties to bring claims (no public enforcement; court reviews one transaction at a time)</li> </ul>	Useful primarily for establishing a default definition of unconscionability that legislators can work from and adjust in statutes specific to prescription drugs.
<b>Consumer lending laws</b>	<ul style="list-style-type: none"> <li>• Durable in the face of vagueness challenges</li> <li>• Deference given to legislatures' choice of maximum interest rate</li> <li>• Usury approach has clear application to drug price increases</li> <li>• Enforcement need not require a showing of procedural unfairness</li> </ul>	<ul style="list-style-type: none"> <li>• Although potentially applicable to launch prices, setting maximum prices for new drugs may be unduly risky from an innovation standpoint.</li> <li>• Enforcement would take place after a drug sale, not when prices are announced.</li> <li>• Challenges determining which price would be regulated</li> <li>• Usury model is vulnerable to gaming by regulated entities</li> </ul>	Highly promising to couple a federal level usury-model approach for drug price increases with a consumer protection act specific to medicines that sets forth an unconscionability definition that is untethered from the U.C.C. definition.

<b>Public utilities (rate-of-return) regulation</b>	<ul style="list-style-type: none"> <li>• Utilities and drug markets share key features (monopolies, essential goods)</li> <li>• Potential applicability to both price increases and base prices</li> <li>• Concept of limiting companies' rate of return has public / moral appeal</li> <li>• Courts afford regulators broad discretion in setting rates, including levels and methods, so long as the rates are not so low as to be confiscatory</li> </ul>	<ul style="list-style-type: none"> <li>• Attracts extensive litigation</li> <li>• Potential for perverse incentives if allowances are made for high operational costs</li> <li>• Risk of erring in setting rates too low, discouraging investment and innovation</li> <li>• Rate setting is a complex, highly technical, information-intensive process</li> <li>• Regulators must rely on companies for key information, which companies have incentive to mischaracterize</li> <li>• Challenging to calculate a rate base for each drug</li> <li>• Challenging to deal with market entrants and exits</li> </ul>	<p>Rate-of-return regulation appears infeasible and inadvisable for prescription drugs.</p>
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