

Excessive Pricing in the Pharmaceutical Industry: How Much is Too Much?

Deirdre Carroll, Jeff Bank, and Marc Foto*

2-I. Introduction

In the pharmaceutical industry, the enforcement priority on both sides of the Atlantic over the last decade has been on pay-for-delay agreements between patent owners and generics rivals, and there has been little or no emphasis on excessive pricing (so-called “price-gouging”). In recent years, however, in the face of mounting public and political pressure, there has been increasing interest in regulatory and legislative solutions for rising drug prices.

Whether such solutions are needed and, if so, should be based on antitrust rules or statutes, is subject to debate. The widely held view is that to engage in *ex-post* enforcement against the pricing policies of companies rather than relying on *ex-ante* regulation may chill innovation and reduce the incentives to invest, to the ultimate detriment of consumers. The monopoly rights afforded to inventors encourage innovation and reward a corporation’s research and development effort. When that monopoly right has been exhausted, market forces kick in. Markets are generally deemed to be self-correcting: where there are no significant barriers to entry (and notably when patent protection has lapsed), the threat of new entry in response to raised prices ensures a competitive market.

However, rising drug prices have taken center stage in Europe and the United States and stimulated a flurry of regulatory and enforcement activity in both jurisdictions. At the federal level, the United States has resoundingly rejected the application of antitrust law to stand-alone excessive pricing cases. Moreover, the U.S. agency that supervises pharmaceuticals has no authority to regulate pricing. As it stands, therefore, there is neither antitrust enforcement nor federal level regulation to combat cases of alleged excessive pricing. Instead, states are attempting to step in to regulate pharmaceutical pricing in a bid to restrain spiraling costs. In 2017 alone, more than 130 pieces of legislation were introduced by states to face down high prices.¹ State statutes directly targeting price gouging in pharmaceuticals have failed to survive constitutional challenge, but several states have recently enacted “price transparency” laws to try to indirectly manage pricing by obligating companies to report, explain or justify to the state any price increases in drugs sold in the state. It remains to be seen whether even these lighter touch attempts to regulate pharmaceutical pricing at a state level will survive.

In sharp contrast to the hands-off ideological approach in the United States, and notwithstanding the fact that several EU member states have their own price regulation

* Deirdre Carroll is an associate at Wilson Sonsini Goodrich & Rosati in Brussels. Jeff Bank and Marc Foto are partner and associate, respectively, at Wilson Sonsini Goodrich & Rosati in New York. None of the opinions expressed in this article can or should be ascribed to the firm or any of its clients. The authors would like to thank Paul McGeown for his helpful comments on this article.

¹ Fran Quigley, ‘On Drug Pricing, States Step in Where Washington Fails,’ N.Y. TIMES (Feb. 27, 2018) available at <https://www.nytimes.com/2018/02/27/opinion/drug-pricing-states.html>.

regimes,² the EC's Directorate General for Competition, has demonstrated its willingness to step in where it believes that there has been a market or regulatory failure that has allowed pharmaceutical companies to implement abusively excessive pricing. This article seeks to compare both jurisdictions' approaches to excessive pricing through the lens of recent regulatory and enforcement developments.

2-II. European Union

Article 102 of the Treaty on the Functioning of the European Union ("TFEU"), the European equivalent of Section 2 of the Sherman Act, prohibits any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it, where it may affect trade between EU member states. Under EU law, dominance exists where a company's market position allows it to behave to an appreciable extent independently of its competitors, its suppliers, its customers and ultimately of consumers.³ Excessive pricing is an example of a breach of Article 102(a) TFEU, which prohibits a dominant firm from "*directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions.*"

In the EU, member state health authorities have primary responsibility for drug procurement and pricing regimes under their social security systems, and competition agencies are hesitant to play the role of an unofficial day-to-day price regulator. The Commission has rightly exercised discretion and clearly draws a distinction between new and innovative drugs (which tend to be highly regulated at a national level), and older, off-patent drugs, seriously contemplating intervention only when they have been the subject of significant price increases. Indeed, even when there is strong prima facie evidence of high prices and a sustained lobby from BEUC, the European Consumer Organization, the Commission has declined to pursue allegations that Gilead, an American pharmaceutical company, is engaging in excessive pricing of its hepatitis C medicine, Sovaldi.⁴ The European Commissioner for Competition, Vestager, has asserted that the market for hepatitis

² Most member states have some form of regulation addressing the maximum sale price of generics, for instance, or setting the maximum reimbursement rate for drugs. In the UK, for example, the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 (as amended) includes provisions governing the profit control of companies that supply branded drugs to the UK's National Health Service ("NHS"). Under Germany's Pharmaceutical Market Restructuring Act ("AMNOG"), when a new drug enters the market, manufacturers must submit studies demonstrating it is more effective than what was previously available. If it is not, public funds will only cover the price of the earlier version. Given the focus of the current article, state regulations in Europe are not addressed in detail.

³ Case C-85/76 *Hoffman-La Roche v. Commission*, judgment of Feb. 13, 1979, at § 38. The Commission treats market shares as a useful first indication of market power and has made it known that a share below 40 percent is unlikely to indicate dominance. The European Court of Justice, for its part, has stated that there is a rebuttable presumption of dominance if the company's share is above 50 percent. In all cases, the Commission also considers the overall market context including competitive constraints imposed by competitors, barriers to entry/expansion, and countervailing buyer power (Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C 45, Feb. 24, 2009, at §§ 13-18.).

⁴ Commissioner Vestager's response to a parliamentary question (E-000261/2015); letter from BEUC to Commissioner Vestager, May 3, 2017, available at http://www.beuc.eu/publications/beuc-x-2017-042_mgoipa_competition_in_the_pharmaceutical_sector.pdf.

C drugs is a “*rapidly moving*” and dynamic market, with new classes of drugs in advanced stages of development. She has also recognized that price-setting takes place at a national level in negotiations between pharmaceutical companies and healthcare systems where member states can exercise their bargaining power.⁵

Cognizant of the chilling effect on innovation that over-regulation might have, the commissioner has also publicly expressed the need for caution in this area, stating that: “When we do take action against excessive prices, we need to make sure we’re not taking away the rewards that encourage businesses to innovate.”⁶ A director in her agency noted more recently that the Commission is likely to focus on cases that tick certain boxes such as “no entry or very high barriers of entry [to the market], very sudden and very steep price increases, signs of market failure with possible regulatory failure.”⁷ However, there have been a few notable cases where the Commission has acted to restrain pharmaceutical pricing.

A. Legal framework: The *United Brands* and *AKKA/LAA* court judgments

i. *United Brands*

Given the limited number of excessive pricing cases taken by the Commission, the European courts have had relatively few opportunities to opine in this area. The seminal case on excessive pricing, *United Brands*, dates from 1978 and it took almost forty years after that decision before the courts would have the chance to add to their initial guidance in a meaningful way.

In *United Brands*, the European Court of Justice (“ECJ”) held that a price would be excessive where it “has no reasonable relation to the economic value of the product supplied.”⁸ The court also set out a two-part test to help identify abusive pricing:

1. whether the difference between the costs actually incurred and the price actually charged is excessive (*excessiveness*),

and, if the answer to this question is in the affirmative,

2. whether a price has been imposed which is either unfair in itself, or when compared to competing products (*unfairness*).⁹

The court underlined that this two-step test was meant merely as guidance and that “other ways may be devised [. . .] of selecting the rules for determining whether the price of a product is unfair.”¹⁰

While the judgment provided some parameters for the analysis to be applied, when exactly a high price would become “excessive” was still unclear and regulators were essentially left

⁵ Commissioner Vestager’s response to a parliamentary question (P-008636/2014).

⁶ Speech by Margrethe Vestager, ‘*Protecting consumers from exploitation*,’ Chillin’ Competition Conference, Brussels, Nov. 21, 2016.

⁷ Comments by Paul Csiszar (personal capacity), Innovation Economics for Antitrust Lawyers conference, Feb. 23, 2018. See PaRR article, available at https://app.parr-global.com/intelligence/view/prime-2596052?src_alert_id=128960.

⁸ Case C-27/76, *United Brands v. Commission*, judgment of Feb. 14, 1978, at § 250.

⁹ *Id.* at § 252.

¹⁰ *Id.* at § 253.

to take the “*I know it when I see it*” approach. As certain commentators note, even Commission officials accept that the *United Brands* judgment “highlights the major difficulties of proof associated with finding an abuse of excessive pricing, and probably explains the relative dearth of instances in which the Commission has intervened in those cases.”¹¹

ii. *AKKA/LAA*

In September 2017, the ECJ handed down its much-anticipated preliminary ruling in the case known as *AKKA/LAA*.¹² The case was a referral from the Latvian Supreme Court regarding a fine levied against the Latvian collective rights society by the Latvian Competition Council (“LCC”) for an abuse of dominance. In Latvia, *AKKA/LAA* was the sole entity authorized to manage the fees for Latvian and foreign copyright holders. The LCC found that *AKKA/LAA* had charged excessive fees following a comparison of its fees with those levied in the neighboring EU member states of Estonia and Lithuania. The LCC also compared the prices of twenty other member states using the purchasing power parity index (“PPP index”). *AKKA/LAA*’s fees were two to three times higher than those in its neighboring Baltic states, and between 50 and 100 percent higher in Latvia than in the member states where the PPP index was compared.

The ECJ’s judgment treated two broad points in particular: (1) establishing a benchmark price, and (2) establishing when a high price is excessive. Of particular note is the fact that the court acknowledged that the *United Brands* test was not meant to be determinative and that there are other methods by which it can be decided whether a price may be excessive—including a method solely based on a comparison of prices across member states.¹³

In determining what should be an appropriate comparator to establish a benchmark price, the court ruled that there is no minimum number of markets which must be compared and the choice of comparator markets will depend on the facts of each case. What matters is that the reference member states are selected in accordance with objective, appropriate and verifiable criteria, and that comparisons are made on a consistent basis and adjusted to take into account the PPP index (given the varying living standards in each country). Those criteria could include consumption habits, and other economic and sociocultural factors such as GDP per capita and cultural and historical heritage.¹⁴ The court also found that it is for the competition authority concerned to define its comparison framework and that a comparison of prices within one or several user segments is acceptable.¹⁵

In assessing when a high price would cross the line to abusively excessive, the court ruled that there is “no minimum threshold above which a rate must be regarded as ‘appreciably

¹¹ See R. O’Donoghue and J. Padilla, *The Law and Economics of Article 102 TFEU*, Hart Publishing (2013) (2nd ed.) at page 758, citing C. Esteva-Mosso and S. Ryan, ‘Article 82—Abuse of a Dominant Position,’ in J. Faull and A. Nikpay (eds.), *The EC Law of Competition*, Oxford University Press (1999).

¹² Case C-177/16 *Autortiesību un komunikācijas konsultāciju aģentūra/Latvijas Autoru apvienība v. Konkurences padome (AKKA/LAA)*, judgment of Sept. 14, 2017.

¹³ *Id.* at § 37.

¹⁴ *Id.* at §§ 38–46.

¹⁵ *Id.* at §§ 47–50.

higher,'” and advocated a case-by-case assessment. The court stated however that “a difference between rates may be qualified as ‘appreciable’ if it is both significant and persistent on the facts,” i.e., the difference must persist for “a certain length of time and must not be temporary or episodic.”¹⁶ With this criterion, the court may be signaling that excessive pricing cases should be limited only to markets where there are high barriers to entry and thus are precluded from self-correcting as proposed by Advocate General Wahl in his Opinion.¹⁷

Importantly, the court noted that the factors set out are “merely indicative” of an abuse of dominance. If a competition agency demonstrates that a dominant company’s prices are appreciably higher than the comparator benchmark, a dominant company then has the burden of proof to rebut this finding and may rely on “objective factors” to show its prices are in fact fair.¹⁸

While the judgment provided welcome clarity on when a high price becomes abusively excessive, the methodology for determining whether a price may be excessive will remain a source of angst for dominant companies and practitioners managing antitrust risk. It is now accepted that there are multiple acceptable methodologies, but what is not clear is whether any of these tests will be the preferred tool by default, or how parties should proceed where there is a conflict between the results depending on the methodologies employed in any given case.

Ultimately, the analysis of excessive pricing cases will remain dependent on the specific facts of each case and a large margin of maneuver is granted to the Commission and to national competition authorities in determining the most appropriate price comparison benchmark and methodology. The judgment is also not as helpful for cases in the pharmaceutical industry, where comparisons are likely to be particularly tricky and complex due to the marked differences in market conditions in the sector across member states.

Outside of the pharmaceutical context, however, the principles enunciated in the ECJ’s *AKKA/LAA* case are already being applied at a national level. In May 2018, the German competition agency confirmed that it would not be opening an abuse of dominance probe into Lufthansa’s price increases on certain routes following the collapse of Air Berlin. The national carrier had temporarily enjoyed a monopoly on some routes and had increased ticket prices on average by 25–30 percent. Echoing references to the difference in prices being “significant” and an excessive price needing to be “persistent” before it could be characterized as an abuse, the German agency noted that prices were quick to fall once easyJet entered the market and Lufthansa only used its monopoly position to achieve higher prices for a limited two-month period.¹⁹

B. The Commission’s Aspen Pharma Investigation

On May 15, 2017, the Commission launched its first excessive pricing investigation in the pharmaceutical sector when it opened formal proceedings over concerns that Aspen

¹⁶ *Id.* at §§ 55–56.

¹⁷ *AKKA/LAA*, Opinion of Advocate General Wahl, Apr. 6, 2017, at §§ 3–4, 48.

¹⁸ *AKKA/LAA*, at §§ 57–60.

¹⁹ ‘Price increase does not justify initiation of abuse proceeding,’ Bundeskartellamt press release, May 29, 2018.

Pharmacare Holdings Limited (“Aspen”), a South African multinational company, had breached Article 102 TFEU by engaging in excessive pricing concerning five off-patent life-saving cancer medicines in the EEA.²⁰ Aspen acquired the drugs at issue from GlaxoSmithKline (“GSK”) in 2009 after their patent protection expired. The Commission has also said that it is investigating allegations that Aspen Pharma, in order to impose the price increases, made use of unfair, abusive negotiation practices with national authorities and/or hindered parallel trade between the member states. These practices allegedly included reducing the direct medicine supply and/or threatening supply reductions, as well as defining EEA-wide stock allocation strategies and implementing them in cooperation and/or agreement with local wholesalers.²¹ The Commission’s investigation excludes Italy, where Aspen was already subject to a €5.2 million fine for similar conduct (*see* section III. A).

The launch of this investigation serves to highlight the Commission’s continued reluctance to run a *pure* excessive pricing case—given the practical and conceptual difficulties—and its focus instead on instances where there are cumulative abuses or aggravating factors (such as the abusive negotiation tactics) and/or core Single Market issues involving the hindrance of parallel trade or market integration.²² The Commission may feel more comfortable that its decisions will survive challenge where they are grounded in additional, and more recognized, enforcement bases.

2-III. European National Level

While the Aspen investigation may be the first excessive pricing investigation in the pharmaceutical industry at an EU level, other national competition agencies had already turned their scrutiny on the sector. The UK’s Competition and Markets Authority (“CMA”) has a number of ongoing investigations into excessive pricing allegations in the pharmaceutical industry, and the Italian competition authority (“AGCM”) found Aspen in breach of competition law around eight months before the Commission opened proceedings against the company.

A. Italy

i. Aspen Pharma

Aspen’s problems in Europe began before it fell into the Commission’s crosshairs. On September 29, 2016, the AGCM levied a fine of almost €5.2 million (\$5.7 million at then-current rates) on the pharmaceutical company for infringing Article 102(a) TFEU.²³

The AGCM found that Aspen had abused its dominance to obtain a high increase in the pricing of four of its life-saving onco-hemathological drugs, the rights for which it had

²⁰ Case COMP/AT.40394—*Aspen*, Commission press release IP-17-1323, May 15, 2017.

²¹ Case COMP/AT.40394—*Aspen*, Opening of Proceedings, May 15, 2017.

²² *See* Cases C-26/75—*General Motors v. Commission*, judgment of Nov. 13, 1975 and C-226/84—*British Leyland v. Commission*, judgment of Nov. 11, 1986 for issues of legal monopoly, parallel trade, and excessive pricing. For issues of discrimination, refusal to supply, hindering the development of markets, and excessive pricing see Case COMP/36915—*Deutsche Post AG—Interception of cross border mail*, Commission decision of July 25, 2001.

²³ ‘Price increases for cancer drugs up to 1500%: the ICA imposes a 5 million Euro fine on the multinational Aspen,’ AGCM press release, Oct. 14, 2016.

acquired from GSK. Their market value was limited, the patents had long expired, and there was no real competing drug on the market. In its negotiations with the Italian Medicines Agency (“AIFA”) in 2013, Aspen sought to change the classification of the drugs so that it could freely set prices, rather than be reimbursed. It threatened to interrupt the direct supply of the drugs to the Italian market in order to impose the re-classification and its price increases, which ranged from between 300 percent and 1500 percent of the initial price.

The AGCM investigated Aspen’s behavior and carried out a two-fold *United Brands*-type analysis to assess whether the price increases amounted to unfair pricing, focusing on profit margin and cost-plus criteria. The AGCM established that there was a disproportionate discrepancy between the production costs of the drugs and the price increase which Aspen attempted to force through. The agency’s task was made simpler as it had a clear benchmark for the price comparison: the prices charged by the previous registration holders prior to Aspen’s acquisition of rights. The AGCM found that there were no justifications—economic or otherwise—for the price increase. In particular, the R&D investments in the drugs at issue had been recouped years before by previous registration holders.

It is important to note that this case was not simply a case of excessive pricing, but a case of excessive pricing coupled with clear abusive intent through Aspen’s aggressive negotiation tactics with the AIFA to force its increases through. Aspen’s appeal against the AGCM decision was rejected on June 14, 2017.

As noted in OECD Roundtable discussions, monitoring the implementation of a remedy over time is rife with practical difficulties. Intervening against excessive prices may risk a competition authority finding itself in the situation of a:

semi-permanent quasi-regulator, [. . .] something that a ‘generalist’ competition authority is much less equipped for than proper regulators with their deep knowledge of and continuous involvement in their industries.²⁴

The AGCM cannot mandate drug prices, but it did monitor Aspen’s compliance with the AIFA’s drug-pricing framework post-decision and ran non-compliance proceedings in parallel to Aspen’s renewed negotiations with AIFA. The AGCM only closed those proceedings once AIFA was satisfied with the negotiations and an agreement signed between AIFA and Aspen which stated the drug prices were now fair and non-discriminatory. By using its antitrust enforcement tools as leverage in conjunction with AIFA’s regulatory powers and industry knowledge, the AGCM ensured Aspen’s excessive pricing was remedied effectively.²⁵

B. United Kingdom

i. The Pfizer and Flynn Pharma Case

In December 2016, the CMA fined Pfizer £84.2 million and Flynn Pharma (“Flynn”) £5.2 million (\$110 million and \$6.5 million, respectively), finding that Pfizer’s supply prices to Flynn and Flynn’s selling prices for its Epanutin phenytoin sodium capsules, an epilepsy

²⁴ OECD Working Party Roundtable document, ‘Article 102 and Excessive Prices,’ Oct. 4, 2011.

²⁵ As reported in Global Competition Review, ‘Italy ends Aspen pharma monitoring,’ July 6, 2018.

treatment drug, were excessive (equating to increases of up to 2,600 percent) and in breach of Article 102 TFEU and Chapter II of the UK Competition Act 1998.²⁶

The prices of Epanutin were regulated as part of Pfizer's portfolio of branded drugs through the UK's Pharmaceutical Price Regulation Scheme ("PPRS"). Pfizer sold the UK distribution rights for Epanutin to Flynn in 2012 for a nominal fee but continued to produce and sell the drug to Flynn at prices that were 790 percent to 1,600 percent higher than its historic resale price. Flynn, for its part, took the drug outside the PPRS by de-branding it and sold it on to the UK's National Health Service ("NHS") at prices 2,300 percent to 2,600 percent higher than the pre-2012 prices. This led to an increase in the NHS's spending on the drug from £2 million to £50 million.

Both Pfizer and Flynn appealed the decision to the Competition Appeal Tribunal ("CAT"), which set aside the CMA's decision in June 2018.²⁷ It is worth noting that the CMA's decision was issued before the *AKKA/LAA* judgment, on which the CAT relies heavily.

The CAT upheld the CMA's findings of dominance, but quashed its rulings on abuse together with the penalties imposed. The CMA ran the case as a pure excessive pricing case, and did not ground its reasoning on a combination of the two companies' exclusionary and exploitative conduct. According to the CAT, the CMA failed to correctly apply the two-part *United Brands* legal test.

In terms of excessiveness, the CAT found, *inter alia*, that the CMA placed too much reliance on whether the price exceeded cost plus a certain arbitrary profit margin percentage (the "cost-plus" approach), using a 6 percent return-on-sales ("ROS") as a reasonable return, on the basis that it was the highest allowable ROS under the PPRS. The CMA thus sought to identify a benchmark in circumstances of "idealized competition" rather than in circumstances of "normal and sufficiently effective competition." Leaving aside the correctness of a comparison with a ROS set by a regulatory scheme, a 6 percent return seems an unreasonable benchmark and unworkably low by any metric.

Importantly, in its judgment the CAT underlined that it was not concluding that the benchmark price, with the right methodology, "would not have given rise to a finding of excessiveness" but that it did not consider the approach adopted a "sufficient basis for that finding." The tribunal stressed that an authority "cannot simply choose that method of calculating the excess that was most favorable to establishing an infringement, to the exclusion of other methods."²⁸

In identifying the price which would be obtained under normal and effective competition, the CAT ruled that the CMA should have more carefully assessed the comparators proposed by the parties, in particular the prices of phenytoin sodium tablets²⁹ and should have given

²⁶ Case CE/9742-13, *Unfair pricing in respect of the supply of phenytoin sodium capsules in the UK*, decision of Dec. 7, 2016.

²⁷ Cases 1275-1276/1/12/17, *Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v. CMA and Pfizer Inc. and Pfizer Limited v. CMA*, judgments of June 7, 2018.

²⁸ *Id.* at §§ 310-314.

²⁹ *Id.* at §§ 345, 370 *et seq.*

due weight to the therapeutic value that epilepsy patients attach to the drug in its assessment of the economic value of the product.³⁰ The CMA has sought permission to appeal the CAT's judgment.

The CMA has a number of ongoing cases in the pharmaceutical area, and the judgment provides ample guidance as to how the CMA should conduct its assessment in those investigations—in particular in terms of the use of meaningful comparators—and may inform the CMA's decision to prosecute all or only some of those cases to a negative decision.

The legal “loophole” in the UK which enabled Flynn to avoid the pricing constraints of the PPRs has been closed by the recent Health Service Medical Supplies (Costs) Act 2017 which gives the government broad power to compel pharmaceutical companies to reduce the price of a generic medicine or introduce other controls on branded products in cases where charges are “unreasonable,”³¹ and may reduce the need for antitrust investigations.

ii. Actavis UK

Building on an investigation initially opened in March 2016, the CMA issued a charge sheet against Actavis UK in December 2016. The agency issued further charge sheets against Intas Pharmaceuticals Limited and Accord Healthcare Limited, which acquired Actavis UK in January 2017, proposing to find them jointly and severally liable for the alleged infringements for their period of ownership. The agency alleges that Actavis engaged in excessive and unfair pricing for hydrocortisone tablets. Once Actavis acquired the rights to the drug, it de-registered the branded product, sold it as a generic (*i.e.*, outside of the UK's PPRS regime, as had occurred in the *Pfizer/Flynn* case) and implemented increases of over 12,000 percent compared to the branded version of the drug sold by the previous registered holder prior to April 2008. The NHS had paid £0.70 for 10mg packs of the drug, and £1.07 for 20mg packs. This had increased to £88.00 and £102.74, respectively, by March 2016, and the aggregate amount spent on hydrocortisone tablets by the NHS went from £522,000 a year to £70 million a year.³²

iii. Concordia

In October 2016, the CMA launched an investigation into Concordia International covering price increases for liothyronine tablets, a drug used to treat hypothyroidism. The UK agency sent a statement of objections to the company in November 2017, setting out its provisional findings that Concordia abused its dominant position to overcharge the NHS by millions for the essential thyroid drug. According to the CMA, the amount the NHS paid per pack rose from around £4.46 before it was de-branded in 2007 to £258.19, meaning the NHS's spend on liothyronine tablets increased from £0.6 million to £34 million between 2006 and July 2017—a hike of almost 6,000 percent.³³

³⁰ *Id.* at § 419 *et seq.*

³¹ The Health Service Medical Supplies (Costs) Act 2017 (c 23), Apr. 27, 2017.

³² ‘Pharmaceutical company accused of overcharging NHS,’ CMA press release, Dec. 16, 2016.

³³ ‘Drug company accused of abusing its position to overcharge the NHS,’ CMA press release, Nov. 21, 2017.

C. Other EU Member States

In January 2018, the Danish Competition Authority found that CD Pharma, an Italian pharmaceutical distributor, abused its dominant position on the Danish market for the sale of Syntocinon, an off-patent labor stimulant containing oxytocin. CD Pharma had an exclusive distribution agreement with the producers of the drug, and when Amgros, a wholesale buyer for hospitals, approached it as it had sourcing problems, CD Pharma increased the price in April 2014 from DKK 45 (€6) to DKK 945 (€127)—a price increase of 2,000 percent. CD Pharma was ordered to refrain from similar conduct and its case has been referred to the public prosecutor for further action.³⁴

In November 2017, the French competition authority announced the launch of a sector inquiry in the healthcare sector. One focus is likely to be pricing by pharmaceutical companies.³⁵

The Dutch Authority for Consumers and Markets (“ACM”), for its part, set out its four key enforcement priorities for 2018–2019 in its agenda published in February 2018, one of which was the pricing of prescription drugs.³⁶ Less than a month later, three high-ranking officials of the ACM published a working paper on competition and IP law in the pharmaceutical sector which touched on excessive pricing.³⁷ Given the clear focus on pricing in the pharmaceutical sector, an abuse of dominance case in the Netherlands in the coming months would not be entirely surprising.

2-IV. United States

Rising drug prices have long been the subject of debate in the United States. Measures such as the Hatch-Waxman law (more formally known as the Drug Price Competition and Patent Restoration Act) are intended to encourage development and use of cheaper generic drugs without stifling innovation.³⁸ However, neither the Food and Drug Administration, which supervises drug products, nor the U.S. antitrust agencies, has authority to control drug pricing. As with all products and services, charging exorbitant prices for drugs is not unlawful under federal or state antitrust laws. On the contrary, a bedrock principle of U.S. antitrust law is that “[t]he opportunity to charge monopoly prices—at least for a short period—is what attracts business acumen in the first place; it induces the risk taking that produces innovation and economic growth.”³⁹ Recent FTC Commissioner Maureen Ohlhausen re-affirmed this principle in early 2017, stating, “[s]tanding alone, a high pharmaceutical

³⁴ Press release, Danish Competition Council, Jan. 31, 2018.

³⁵ Press release, French Competition Authority, Nov. 21, 2017.

³⁶ ‘ACM’s key priorities for 2018 and 2019,’ ACM press release, Feb. 13, 2018.

³⁷ ‘Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse,’ ACM working paper, Mar. 7, 2018.

³⁸ Drug Price Competition and Patent Restoration Act, 21 U.S.C. § 355.

³⁹ *Verizon Commc’ns v. Law Offices of Curtis Trinko, LLP*, 540 U.S. 398, 407 (2004) (“The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an essential element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts ‘business acumen’ in the first place; it induces the risk taking that produces innovation and economic growth.”).

price is not an antitrust violation if it simply reflects a legally obtained intellectual property right.”⁴⁰ The director of civil enforcement at the Department of Justice’s antitrust division, Patricia Brink, in a recent discussion on whether excessive prices are a matter for competition regulation stressed that “in the United States, both historically and at present, the answer is an unequivocal no.”⁴¹ These public statements merely serve to echo the jurisprudence in this area, which has made it abundantly clear that a:

natural monopolist that acquired and maintained its monopoly without excluding competitors by improper means is not guilty of ‘monopolizing’ in violation of the Sherman Act . . . and can therefore charge any price that it wants . . . for the antitrust laws are not a price-control statute . . .⁴²

The approach in the United States is thus heavily premised on the idea that companies are entitled to reap the benefits of their innovation and business acumen, and that the normal workings of the free market (with high prices essentially acting as a signal to new entrants, which will force prices down) will ultimately correct any perceived anti-competitive pricing. An appeals court previously stressed that judges are simply not designed to be regulators, commenting that “[j]udicial oversight of pricing policies would place the courts in a role akin to that of a public regulatory commission.”⁴³

The former FTC General Counsel, William Blumenthal, expressed similar sentiments regarding the antitrust agencies’ ability to determine prices, noting:

[I]n cautioning against even limited intervention by competition agencies against high prices, I am focusing . . . principally on considerations of institutional design Simply put, we need to question whether competition agencies have the competence to engage in classical price-and-profits public-utility-style regulation.⁴⁴

Even if antitrust law is not a viable remedy in the United States, many believe that other types of regulation can be enacted to slow, or reverse, the trend of increasing drug prices, and in a broader context, increased health care spend overall. The issue is acute: a 2016 study found that prescription drug spending had ballooned to \$457 billion, nearly 17 percent of all

⁴⁰ Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Mallinckrodt ARD Inc., FTC File No. 131-0172 (Jan. 18, 2017), available at https://www.ftc.gov/system/files/documents/public_statements/1054983/170118_mallinckrodt_statement.pdf.

⁴¹ Comments of Patricia Brink at the 2017 ICN Annual Conference, Porto May 10–12 as reported by Global Competition Review. Article available at <https://globalcompetitionreview.com/article/1141425/excessive-pricing-continues-to-divide-us-from-peers>.

⁴² *Blue Cross and Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1413 (7th Cir. 1995), citing *National Reporting Co. v. Alderson Reporting Co.*, 763 F.2d 1020, 1023–24 (8th Cir. 1985); *U.S. v. Aluminum Co. of America*, 148 F.2d 416, 430 (2d Cir. 1945); *Ball Memorial Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1339 (7th Cir. 1986); *Berkey Photo*, 603 F.2d at 296–98.

⁴³ *Berkey Photo, Inc. v Eastman Kodak Co.*, 603 F 2d 263, 294 (2nd Cir. 1979), cert. denied, 444 U.S. 1093 (1980).

⁴⁴ William Blumenthal, former FTC General Counsel, ‘Discussant Comments on Exploitative abuses under Article 82 EC,’ Robert Schuman Centre of the European University Institute, Twelfth Annual Competition Law and Policy Workshop: ‘A Reformed Approach to Article 82 EC’ (June 9, 2007), available at <http://www.ftc.gov/speeches/blumenthal/070731florence.pdf>.

personal health care services.⁴⁵ This trend does not show signs of reversing. Experts estimate that prescription drug spending will climb to over \$600 billion in the next three years.⁴⁶ Despite this forecast, Congress has not prioritized legislation curbing prescription drug spending. For example, the Improving Access to Affordable Prescription Drugs Act proposed on March 29, 2017 has sat idle in the Senate since that date.⁴⁷ In response, states have proposed legislation attempting to regulate spiraling costs. Two common types of proposed legislation have targeted price gouging and sought to promote price transparency.

A. Price Gouging Statutes

There have been efforts to curb the price of both patented and off-patent drugs through price gouging statutes in a handful of states. Such price gouging legislation seeks to control drug prices directly, by creating a cause of action against a manufacturer for either excessive prices or a large price spike (even if the drug is patent protected). If a manufacturer were to be found liable, the manufacturer could be enjoined from selling the drug at that price, be forced to pay civil penalties, or both. There has not been an opportunity to test whether these statutes are contrary to United States antitrust law—no statute has yet passed constitutional muster.

i. District of Columbia

In 2005, the District of Columbia passed the Prescription Drug Excessive Pricing Act.⁴⁸ This act made it:

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.⁴⁹

In line with European precedent, which acknowledges that there are multiple acceptable methodologies to determine whether a price is excessive, the Act provided that while it was not the exclusive way to make a *prima facie* case of an excessive price, a plaintiff could make a case by establishing that the wholesale price of a drug in D.C. is “30 percent higher than the comparable price in either the United Kingdom, Germany, Canada, or Australia, if the drug is protected in those countries by patents or other exclusive marketing rights.”⁵⁰ If a manufacturer were to be found in violation of this law, a judge could issue civil penalties and issue:

⁴⁵ Yale Global Health Justice Partnership, *Curbing Unfair Drug Prices: A Primer for States*, (Aug. 2017), https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf.

⁴⁶ Bill Berkrot, *U.S. Prescription Drug Spending as High as \$610 billion by 2021: Report*, REUTERS, (May 4, 2017), <https://www.reuters.com/article/us-usa-drugspending-quintilesims/u-s-prescription-drug-spending-as-high-as-610-billion-by-2021-report-idUSKBN1800BU>.

⁴⁷ *Id.*; S.771—*Improving Access to Affordable Prescription Drugs Act*, U.S. CONGRESS, (July 4, 2018), <https://www.congress.gov/bill/115th-congress/senate-bill/771/all-actions?overview=closed#tabs> (seeking to lower the cost of drugs by, amongst other methods, expanding reporting requirements for price spikes, and creating civil penalties for noncompliance).

⁴⁸ *Pharm. Research & Mfrs. of Am. v. District of Columbia*, 406 F. Supp. 2d 56, 59 (D.D.C. 2005).

⁴⁹ *Id.* at 60.

⁵⁰ *Id.* at 61.

(1) Temporary, preliminary, or permanent injunctions to enjoin the sales of prescription drugs in the District at excessive prices; (2) Appropriate fines for each violation; (3) Damages; including treble damages; (4) Reasonable attorney's fees; (5) The cost of litigation; or (6) Any other relief the Court deems proper.⁵¹

The plaintiffs in that case, Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Innovation Organization (BIO), sued in the D.C. District Court for a declaratory judgment that the Act was unconstitutional, and sought to enjoin D.C. from enforcing the statute.⁵² The plaintiffs put forth three theories of harm. First, that the Act violated the Supremacy Clause; second, that the Act violated the Commerce Clause; and third, that it violated the Foreign Commerce Clause.⁵³ The plaintiffs prevailed on their first two challenges—the Court found that the Act was preempted by the rights conferred by the federal patent laws, and that the statute attempted to regulate wholly out of state transactions.⁵⁴ The District appealed the decision on the basis that the law did not violate the Supremacy Clause, but the Federal Circuit affirmed the District Court's decision.⁵⁵

ii. Maryland

In 2017, Maryland passed HB 631, a bill targeted at protecting Marylanders “from the imposition of unconscionable price increases for certain off-patent or generic drugs in circumstances of market failure or dysfunction.” This bill was a departure from the legislation attempted in DC more than a decade earlier, as this bill did not implicate the federal patent laws, and instead focused on off-patent drugs: “[u]nder HB 631, ‘a manufacturer or wholesale distributor may not engage in price gouging in the sale of an essential off-patent or generic drug.’”⁵⁶ HB 631 also contained a provision that allowed the Maryland Medical Assistance Program to notify the Attorney General when there is an:

increase in a drug price that amounts to an increase of 50 percent or more in the wholesale acquisition cost (“WAC”) of the drug within the preceding one year, or if a 30-day supply or full course of treatment would cost more than \$80 at the drug's wholesale acquisition cost.⁵⁷

The statute authorized the Attorney General to:

compel the violating party to produce certain records, to restrain or enjoin a violation, to restore to any consumer money lost as a result of the violation, to require a violating party engaging in price-gouging to make the drug available at the pre-violation price for one year, and to impose a civil penalty of up to \$10,000 per violation.⁵⁸

In 2017, the Association for Acceptable Medicines (“AAM”), an industry trade association composed of mostly generic drug manufacturers, brought an action for injunctive relief under

⁵¹ *Id.*

⁵² *Id.* at 59.

⁵³ *Id.* at 64–71.

⁵⁴ *Id.* at 71.

⁵⁵ *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

⁵⁶ *Ass'n for Accessible Meds. v. Frosh*, 2017 U.S. Dist. LEXIS 161168, at *4 (D. Md. Sept. 29, 2017), *rev'd* 887 F.3d 664 (4th Cir. 2018).

⁵⁷ *Id.*

⁵⁸ *Id.* at *3.

the Commerce Clause and the 14th Amendment's Due Process Clause.⁵⁹ Specifically, AAM alleged that that HB 631 "violates the dormant Commerce Clause as applied to the sales of drugs between out-of-state manufacturers and out-of-state wholesale distributors."⁶⁰

If a state statute "discriminates against" interstate commerce, the statute will be struck down as violating the dormant Commerce Clause.⁶¹ If a statute indirectly affects interstate commerce, then the court will conduct a balancing test.⁶² The District Court found the Maryland price gouging statute to be constitutional, as the effect of the law would be applicable only on prices for drugs sold within Maryland.⁶³ The District Court stated, "because HB 631 does not 'insist on price parity' with drugs sold outside the state, it does not have the 'practical effect' of regulating commerce occurring wholly outside the state . . ."⁶⁴ Furthermore, AAM "has not shown that any burden imposed by the law does not clearly exceed the local benefits to Maryland consumers . . ."⁶⁵

In 2018, the Fourth Circuit reversed and struck down the entire statute, stating:

First, the Act is not triggered by any conduct that takes place within Maryland. Second, even if it were, the Act controls the prices of transactions that occur outside the state. Finally, the Act, if similarly enacted by other states, would impose a significant burden on interstate commerce involving prescription drugs.⁶⁶

The lynchpin of the statute was that it was not focused on what a Maryland consumer pays for the drug, but rather "the price the manufacturer or wholesaler charges in the initial sale of the drug."⁶⁷

iii. Other States

Eleven other states have proposed price-gouging legislation attempting to limit the prices of generic or off-patent drugs, many of which are similar to Maryland's HB 631,⁶⁸ but these bills are not faring well. Currently, there are no states with a price gouging law in effect, and proposals in at least four states have already died in committee.⁶⁹ Legislative action has

⁵⁹ *Id.* at *1.

⁶⁰ *Id.*

⁶¹ *Id.* citing *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 579 (1986) ("When a state statute directly or indirectly regulates or discriminates against interstate commerce, or when its effect is to favor in-state economic interests over out of state interests, we have generally struck down the statute without further inquiry.").

⁶² *Id.*; see *Pike v. Bruce Church Inc.*, 397 U.S. 137, 142 (1970); *Brown Forman*, 476 U.S. at 579 ("[W]hether the State's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.").

⁶³ *Id.* at *5.

⁶⁴ *Id.*

⁶⁵ *Id.* at *8.

⁶⁶ *Frosh*, 877 F.3d at 670.

⁶⁷ *Id.* at 671.

⁶⁸ *State Legislative Action to Lower Pharmaceutical Costs*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (July 5, 2018), <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>.

⁶⁹ *Id.*

shifted towards price transparency laws, in the hopes that imposing reporting requirements on drug manufacturers may impose some constraints on pharmaceutical pricing without falling afoul of constitutional concerns.

B. Price Transparency Laws

To date, seven states have enacted price transparency legislation covering both on and off patent drugs. These are notification statutes—thus their effect on drug prices is indirect because they do not dictate what a manufacturer may charge for a drug. The states currently with this legislation in force are: California, Connecticut, Louisiana, Nevada, New York, Oregon, and Vermont.⁷⁰ The statutes are generally similar in substance: they require drug manufacturers to explain or justify to the state rises in prices charged in the state. The viability of these price transparency laws, however, is very much in doubt. The laws in California and Nevada are already being challenged as unconstitutional. Plaintiffs allege similar flaws to those of Maryland's HB 631.

i. California

On October 9, 2017, California passed Senate Bill 17.⁷¹ This bill imposes a number of reporting obligations to the Department of Managed Health Care (DMHC). Effective October 1, 2018, this bill requires reporting: "(A) The 25 most frequently prescribed drugs; (B) The 25 most costly drugs by total annual plan spending; and (C) The 25 drugs with the highest year-over-year increase in total annual plan spending."⁷² The Department will then publish a report of this information by January 1 of the following year.⁷³

Furthermore, the bill also imposes new requirements on drug manufacturers. First, a prescription drug manufacturer for a drug with a whole acquisition cost above \$40 must give each purchaser 60 days' notice before an increase in the WAC if the increase for that year is more than 16 percent, "including the proposed increase and the cumulative increases that occurred within the previous two calendar years prior to the current year."⁷⁴ The effect of this statute is that drug companies cannot raise their federal WAC price until California's notice period is over. For these drugs, a manufacturer must then notify California's Office of Statewide Health Planning and Development (OSHPD) a description of factors used to make the decision to increase price, including any "change or improvement in the drug, if any, that necessitates the price increase."⁷⁵ Second, a manufacturer must notify the DHMC in writing

⁷⁰ Alan M. Kirschenbaum, 'Connecticut Becomes Seventh State to Enact Drug Price Transparency Law,' FDA L. BLOG (June 6, 2018), available at: http://www.fdalawblog.net/2018/06/connecticut-becomes-seventh-state-to-enact-drug-price-transparency-law/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+FdaLawBlog+%28FDA+Law+Blog%29.

⁷¹ HEALTH & SAFETY § 1367.243.(2) (A)–(C); see also McKenzie E. Cato et al., 'California Enacts Law to Increase Drug Pricing Transparency,' FDA L. Blog (Oct. 13, 2017), available at <http://www.fdalawblog.net/2017/10/california-enacts-law-to-increase-drug-pricing-transparency/>.

⁷² *Id.* at (d).

⁷³ *Id.*

⁷⁴ HEALTH & SAFETY § 127677(a).

⁷⁵ *Id.* at (c)(2).

within three days after the release of the drug if it is introducing a new drug to the market at a WAC that exceeds the Medicare Part D threshold for a specialty drug.⁷⁶

On December 8, 2017, PhRMA challenged the law as unconstitutional on three distinct grounds. First, PhRMA alleged that SB 17 violated the Commerce Clause by restricting the price nationwide—that a manufacturer could not raise WAC anywhere until the 60-day notice period had expired in California.⁷⁷ Second, PhRMA asserts that requiring manufacturers to communicate with “potentially thousands of registered purchasers” compels speech and thus violates the First Amendment.⁷⁸ Finally, PhRMA alleges that SB 17 is unconstitutionally vague.⁷⁹ This challenge remains outstanding.

ii. Nevada

On June 15, 2017, Nevada enacted S.B. 539, a transparency and reporting law targeted at the rising costs of diabetes treatments.⁸⁰ The new law requires: (1) the Department of Health and Human Services to compile a list of prescription drugs that the Department determines to be essential for treating diabetes in this State, and (2) the preparation of a list of such drugs that have been subject to a significant price increase within the immediately preceding two calendar years.⁸¹ If a manufacturer’s drug is included on part 1 of the list, the manufacturer must submit an annual report that contains information concerning the cost of the drug. If a manufacturer’s drug is on part 2 of the list, then the manufacturer must submit a report justifying the cost increase.⁸²

Nevada’s new law is notable, however, for its effect on Pharmacy Benefit Managers (“PBMs”). For any drug that a PBM sells that is on the list described above, that PBM must submit: “(a) The total amount of all rebates that the PBM negotiated with manufacturers during the immediately preceding calendar year for prescription drugs . . . (b) the total amount of all rebates described in paragraph (a) that were retained by the PBM; and (c) the total amount of all rebates described in paragraph (a) that were negotiated for purchases of such drugs for use by: (1) Recipients of Medicare; (2) Recipients of Medicaid; (3) Persons covered by third parties that are governmental entities which are not described in subparagraph (1) or (2) . . .”⁸³ Given the impact that PBMs in the United States can have on the ultimate price paid by consumers (or their insurance companies), it is logical that a state would have an interest in collecting information throughout the distribution chain.⁸⁴

⁷⁶ HEALTH & SAFETY § 127681(a)–(h).

⁷⁷ Compl. ¶ 7, *Pharm. Research & Mfrs. of Am. v. Brown*, No. 2:17-at-01323, ECF No. 1 (E.D. Cal. 2017).

⁷⁸ *Id.* at ¶ 8.

⁷⁹ *Id.* at ¶ 11.

⁸⁰ Alan M. Kirschenbaum & David C. Gibbons, 2017: A Banner Year for State Laws on Drug Pricing, Price Reporting, and Discounting, FDA L. BLOG (Nov. 2, 2017), <http://www.fdalawblog.net/2017/11/2017-a-banner-year-for-state-laws-on-drug-pricing-price-reporting-and-discounting/>.

⁸¹ NEV. REV. STAT. § 439 s. 3.6 (2017).

⁸² *Id.* at s.4(1)–(4).

⁸³ *Id.* at Sec. 4.2(1)(a)–(c).

⁸⁴ Judi Buckalew, *Pharmacy Benefit Managers Play Significant Role in Drug Pricing*, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, <https://www.aaos.org/AAOSNow/2017/Oct/Cover/cover02/?ssopc=1>.

On September 1, 2017, the plaintiffs, PhRMA and BIO alleged that S.B. 539 is unconstitutional on four grounds.⁸⁵ First, they alleged that SB 539 violates the Supremacy Clause; second, that SB 539 is preempted by federal trade secret law; third, that it violates the Takings Clause of the Fifth Amendment; and fourth, that it violates the Dormant Commerce Clause.⁸⁶

On September 13, 2017, the plaintiffs moved for a Temporary Restraining Order and Preliminary Injunction on the basis that the disclosures necessary for drugs published on the lists would strip away trade secret protection.⁸⁷ Both motions were denied.⁸⁸

In response to the plaintiff's constitutional and trade secret concerns, Nevada enacted LCB File No. R042-18 on May 31, 2018.⁸⁹ The updated regulation permits Nevada manufacturers to claim confidentiality over trade secrets and delays any enforcement action against manufacturers that were non-compliant with their reporting duties until January 15, 2019.⁹⁰ Based on this, the parties agreed to file a voluntary dismissal of their complaint without prejudice, reserving all rights to assert any claims in the future.⁹¹

iii. New York

In April 2017, New York enacted Senate Bill S02007B, Part D of which amended New York's Public Health Law.⁹² This bill goes a step further than the other transparency laws. It requires manufacturers to provide rebates to the New York Department of Health for any drug:

that has increased more than three hundred percent of its state maximum acquisition cost [SMAC] during the period April 1, 2016 through March 31, 2017, or that has increased more than seventy-five percent of its SMAC after April 1, 2017.⁹³

For these drugs, the newly formed Drug Utilization Review Board will attempt to negotiate a rebate with the drug manufacturer.⁹⁴ If the drug manufacturer and the Board are unable to negotiate an acceptable rebate, the manufacturer must provide the following information: (1) actual cost of developing and distributing the drug; (2) research and development costs of the drug; (3) administrative, marketing, and advertising costs; (4) the

⁸⁵ Complaint at 1-7, *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM-CWH, ECF No. 1 (D. Nev. Sept. 1, 2017).

⁸⁶ *Id.*

⁸⁷ Pl.'s Mot. TRO & Preliminary Injunction at 3, *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM-CWH, ECF No. 27 (D. Nev. Sept. 13, 2017).

⁸⁸ Order Denying Pl.'s Mot. TRO at 4, *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM-CWH, ECF No. 28 (D. Nev. Sept. 14, 2017); Order Denying Pl.'s Mot Preliminary Injunction at 1, *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM-CWH, ECF No. 61 (D. Nev. Oct. 17, 2017).

⁸⁹ Joint Status Report at 2, *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM-CWH, ECF No. 95 (D. Nev. June 28, 2018).

⁹⁰ *Id.*

⁹¹ *Id.* at 4.

⁹² S. 02007-B, 2017 Leg. Sess. (N.Y. 2017); *see also supra* note 32.

⁹³ S. 02007-B at § 280(17)(1).

⁹⁴ *Id.* at § 280(3)(A)-(E).

extent of utilization; (5) prices for the drug that are charged to purchasers outside the United States; (6) prices charged to typical purchasers in the state, including but not limited to pharmacies, pharmacy chains, wholesalers, and other direct purchasers; (7) average rebates and discounts per payer type in the state; and (8) average profit margin of each rebate eligible drug over the prior five year period, and the projected profit margin anticipated for such drug.⁹⁵

Unsurprisingly, the industry reaction to this bill has been negative. At the time the bill was first announced, Priscilla VanderVeer, a spokeswoman for PhRMA, said that the group has “significant concerns” about the New York proposal;⁹⁶ PhRMA, for its part, warned of a “chilling effect” on the New York economy as New York had more than 240,000 industry jobs.⁹⁷

iv. Connecticut

Connecticut is the most recent state to pass a price transparency law, doing so on May 31, 2018.⁹⁸ Beginning on January 1, 2020, the executive director of the OHS may conduct a study no more than once a year, “of each pharmaceutical manufacturer of a pipeline drug that, in the opinion of the executive director in consultation with the Comptroller . . . may have a significant impact on state expenditures for outpatient prescription drugs.”⁹⁹ Following the study, and starting no later than March 1, 2020, the director of OHS will prepare a report of no more than ten prescription drugs that the director determines are: “(A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health.”¹⁰⁰

A drug will not be included on this list unless the “wholesale acquisition cost of the drug, less all the rebates paid to the state in the last calendar year, (A) increased by at least (i) twenty per cent during the immediately preceding calendar year; or (ii) fifty per cent during the immediately preceding three calendar years; and (B) was not less than 60 dollars for (i) a thirty-day supply”¹⁰¹ It is possible that the language “less all the rebates paid to the state” may save the statute should there be a dormant Commerce Clause challenge. By adding that limiter, it ensures that the statute does not regulate commerce outside of Connecticut. A manufacturer’s ability to change its WAC and charge whatever price it deems necessary is in no way encumbered by this statute.

⁹⁵ *Id.* at § 280 6(A)(I)–(VII).

⁹⁶ Julie Appleby, *New York State Wants Its Prescription Drug Money Back—Or Else*, USA TODAY (May 18, 2017), <https://www.usatoday.com/story/news/2017/05/18/kaiser-new-york-state-wants-its-prescription-drug-money-back---else/101845050/>.

⁹⁷ *Id.*

⁹⁸ Alan M. Kirschenbaum, ‘*Connecticut Becomes Seventh State to Enact Drug Price Transparency Law*,’ FDA L. BLOG (June 6, 2018), available at http://www.fdalawblog.net/2018/06/connecticut-becomes-seventh-state-to-enact-drug-price-transparency-law/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+FdaLawBlog+%28FDA+Law+Blog%29.

⁹⁹ 2018 Conn. Acts 18-41 § 10(c)(1).

¹⁰⁰ *Id.* at § 10(d)(1).

¹⁰¹ *Id.* at § 10(d)(2).

Connecticut's law also imposes reporting requirements on PBMs. Starting in 2020, each PBM shall report their aggregate rebates from drug formularies for the preceding calendar year.¹⁰² This law is an example of the future of state-level price transparency legislation. Currently, there are 84 bills in various stages of development in 35 states that seek to regulate PBMs.¹⁰³

2-V. Conclusion

The purchase price of any given drug is not merely a function of the R&D investment made in its development, testing and manufacture, but also of the costs sunk into other candidate drugs of the company which never made it to market. Some drugs are "hits" for pharmaceutical companies and allow them to reap profits far greater than their initial investment. However, for every hit there are numerous R&D project failures which can "tank" the average profit measure of the company and mean that optimizing the profits on the successful products is crucial for a business's overall innovation strategy. Engaging in an assessment of the discrepancies between the manufacturing costs and purchase prices of drugs can thus be inherently flawed in an industry characterized by high-risk marketing strategies.

The European Commission and national competition authorities appear, rightly, to be limiting excessive pricing investigations to certain extreme and "unfair" cases where there are perceived market and regulatory failures. There is clearly a general reluctance by the Commission to step-in if there is no additional exclusionary conduct or other abusive behavior present and it seems unlikely that the European regulator will intervene in an excessive pricing case in the pharmaceutical sector absent such "plus factors," or indeed turn its focus beyond off-patent drugs to those still under protection. The recent cases in Europe have involved similar fact patterns:

1. The drugs were old and had not been subject to recent R&D or other investments;
2. The drugs were off-patent and being marketed by a company other than the original rightholder;
3. The price increases often occurred in small markets with limited patient groups to target and where entry may thus not be attractive;
4. The price increases were coupled with an abusive element or aggravating factor, such as steps to take a drug outside a national pricing regime or aggressive negotiation tactics.

Notwithstanding the political pressure, not least from public finance ministries, to manage healthcare costs—and therefore the cost of drugs—we do not sense that the Commission's current caseload is likely to foreshadow a more-generalized enforcement trend beyond these "plus factor" circumstances.

In the United States, the rejection of antitrust law as a tool for price control and reliance instead on *ex-ante* regulation has resulted in states being significantly more active than the

¹⁰² *Id.* at § 2.

¹⁰³ *State Legislative Action to Lower Pharmaceutical Costs*, NATIONAL ACADEMY FOR STATE HEALTH POLICY (July 5, 2018), <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>.

federal government in enacting legislation to tackle excessive pricing. However, even regulation has had limited impact in this area as several state statutes have already succumbed to constitutional challenge or have cases pending against them. Whether this approach of leaving excessive pricing solely to regulation is preferable to the combination of price regulation and selective antitrust enforcement in the EU will remain a matter for debate.

There is an argument that we should seek to use the best of both worlds: the EU should hold to its current focus on excessive pricing cases in off-patent drugs and/or where there is an aggravating “plus factor” and leave companies to enjoy their well-earned monopoly benefits for patented drugs, and the United States should consider embracing antitrust enforcement in addition to its regulatory efforts addressing excessive pricing.

While the antitrust enforcers on either side of the Atlantic tackle excessive pricing in very different manners—one through price regulation, and the other through targeted antitrust enforcement—their aims are clearly aligned: protect the incentive to innovate while defending consumers where the market fails.