

PREVENTING DRUG PRICE GOUGING: GOVERNMENT POWER AND INITIATIVES

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INTRODUCTION

The continuously rising cost of prescription drugs in the United States is unsustainable and, in some cases, unconscionable. Drug spending is increasing at a faster rate than any other component of health care spending. Pharmaceutical companies inexplicably raise prices not only gradually but often dramatically over the course of a short number of years and, with seemingly increasing frequency, even overnight. Across the country, public outcry against pharmaceutical drug price gouging rings loud and clear. The anger towards pharmaceutical companies and bad actors like Martin Shkreli burns across party lines. Yet corresponding support for appropriate federal action invariably extinguishes along those same party lines. Without congressional action, federal agencies, such as the Food and Drug Administration (“FDA”), are powerless to act directly. In lieu of federal action, individual states have moved to protect drug consumers by experimenting with new forms of legislation, fair pricing and transparency laws. In response to these legislative initiatives, states will likely face legal challenges brought by the federal government and pharmaceutical companies in protest of these new restrictions.

I. BACKGROUND

A. Media Attention on the Issue

Over the past 30 years, the media have constantly focused on the public’s concern about increasing drug prices,¹ and recently, drug consumers, healthcare providers, and policymakers alike have vocalize their increasing concern over, or rationale in support of, high drug prices.² Multiple media outlets have reported that drug price increases have outpaced inflation – some studies estimate a 75 percent increase since 2007 alone.³ While documenting this trend, the media

¹ Christine Leopold et al., *Thirty Years of Media Coverage on High Prices in the United States – A Never-Ending Story or a Time for Change?*, ELSEVIER 14, 14 (2016).

² *Id.*

³ *Id.* at 15.

have highlighted the evermore-common outliers, such as instances of deliberate drug price gouging that steeply and deliberately raise the cost of drugs for the pharmaceutical companies' profits at the drug consumers' expense. The media focused on one such outlier in 2015 when former Turing Pharmaceuticals CEO Martin Shkreli invoked public outrage when he spiked the price of a 62-year old drug by 5,000 percent overnight, raising the price from \$13.50 to \$750 per tablet.⁴ Two years later, in 2017, Mylan Pharmaceutical incited the public's ire when reports revealed that the company inexplicably and repeatedly raised the price of EpiPen, a drug delivery device used to treat severe allergic reactions, from \$100 to \$600 per pack of two pens in just under the span of 10 years.⁵ Thanks to increased media attention, these examples of price gouging are familiar to most Americans. Unfortunately, these are not isolated incidents but are representative of an uncontrolled and unmanaged trend.

B. Effects of High and Increasing Cost of Drugs

The effects of high and increasing costs of drugs impact drug consumers and Americans on both a macro and micro level. Such results may be expected in light of the research published by the Tufts Center for the Study of Drug Development that illustrates how drug costs have skyrocketed over the last half century,⁶ climbing an estimated 145 percent between 2003 and 2013 alone.⁷

1. Effects of High and Increasing Cost of Drugs on the Cost of Healthcare as a Whole

The increasing cost of drugs has a comprehensive effect of making American health care costlier nationwide and taxing existing resources

⁴ Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

⁵ See generally Nate Raymond, *Mylan, U.S. finalize \$465 million EpiPen settlement*, REUTERS (Aug. 17, 2017), <https://www.reuters.com/article/us-mylan-epipen/mylan-u-s-finalize-465-million-epipen-settlement-idUSKCN1AX1RW> [<https://perma.cc/3WH6-P6L2>].

⁶ See generally Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New Estimates of R&D cost*, ELSEVIER (2016).

⁷ *Id.* at 12.

dedicated to offsetting those exact healthcare expenditures. As of 2013, the United States spends twice the national average on drugs than 19 other industrialized nations.⁸ In fact, research shows that drug spending is growing faster than any other component of the U.S. healthcare industry.⁹ In response to this market growth and the prevalence of the increasing cost of drugs, many private insurers have resorted to modifying healthcare plans by increasing premiums, deductibles, and out-of-pocket expenses.¹⁰ As a result, in 2017 one in three Americans reported to struggle to afford their health insurance payment requirements.¹¹ Moreover, in the public sphere, high drug prices exacerbate the impact of any reduction in federal funding in the healthcare sector.¹² The macro effects of high drug costs increase the cost of health care as a whole and drain resources created to diminish the cost of health care for Americans.

2. Effects of High and Increasing Cost of Drugs on Individuals

Subsequently, the industry's increasing drug costs significantly affect many drug consumers and healthcare patients individually. Between 2008 and 2015, the U.S. prices of nearly 400 generic drugs alone increased by more than 1,000 percent.¹³ As a result, 20 percent of patients in 2016 reported that they or a family member did not fill a prescription due to high cost.¹⁴ Similarly, one in eight Americans claim

⁸ David Morgan, et al., *Health at a Glance 2015: OECD Indicators*, ORG. FOR ECON. CO-OPERATION AND DEV., 30 (2015).

⁹ See generally CTR. FOR SUSTAINABLE HEALTH SPENDING, *Health Sector Economic Indicators: Health price growth remains at 2.1%; Prescription price growth moderating* (Price Brief #17-03), ALTARIUM INSTITUTE, 2 (2017), https://altarium.org/sites/default/files/uploaded-related-files/CSHS-Price-Brief_March_2017_0.pdf.

¹⁰ AARON BERMAN ET AL., CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES, 1, 5 (2017).

¹¹ *Id.*

¹² *Id.* at 9.

¹³ Elizabeth O'Brien, *Why drug prices remain insanely high and 6 things you can do to save*, MARKETWATCH, (Sept. 21, 2015), <http://marketwatch.com/story/six-tips-for-fighting-rising-prescription-drug-costs-2015-09-15>.

¹⁴ U.S. FED. TRADE COMM'N, UNDERSTANDING COMPETITION IN PRESCRIPTION DRUG MARKETS: ENTRY AND SUPPLY CHAIN DYNAMICS, WORKSHOP PRESENTATION SLIDES 8 (2017), https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf.

that they or a family member have split or skipped dosages due to high drug costs.¹⁵ The rampant increase of drug costs are having a direct effect on Americans' ability to afford, and in some cases, take their prescribed medications.

C. Difficulty of Pricing Drugs and Lack of Consumer Purchasing Power

At the root of the problem of runaway drug prices is the lack of established standards by which pharmaceutical companies and other groups calculate the cost and prices of individual drugs and the average cost of drug development. As of 2014, the Tufts Center for the Study of Drug Development estimated the cost of developing a new drug to be \$2.6 billion.¹⁶ This astonishing figure is not without controversy. First, this figure comes from a study based on unverifiable data provided to the study by the very drug companies sponsoring the study, and second, the most accurate methodology to derive the cost of development is hotly contested by experts and market participants in the field.¹⁷ Because there are no set standards, pharmaceutical companies may, and regularly do, attribute hikes in drug prices to research and development ("R&D"), and these pharmaceutical companies may manipulate the methodology used to calculate such cost to present the highest value possible. The method for calculating the cost of R&D and the method for manipulating numbers to calculate cost are both crucial because instilling a public belief in the extraordinary expense of R&D is often in pharmaceutical companies' best interest.¹⁸ This belief helps drug companies justify the ever increasing prices of their products.¹⁹ In addition to an increasing legal incentive in the wake of new state legislation, pharmaceutical

¹⁵ BERMAN ET AL., *supra* note 10, at 6.

¹⁶ Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK, (Mar. 17, 2017), <https://www.newsweek.com/2017/04/14/prescription-drug-pricing-569444.html> [<https://perma.cc/YQ22-J3PS>].

¹⁷ Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES, (Nov. 18, 2014), <https://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html>.

¹⁸ BERMAN ET AL., *supra* note 10, at 7.

¹⁹ *Id.*

companies have an undeniable financial incentive to manipulate the methodology to show the highest possible cost of R&D. The absence of a set standard for the method of calculating the cost and price of drugs contributes to the current high market prices.

A lack of consumer market power and understanding of how drugs are priced endures as a root factor that promotes unreasonable prices of pharmaceuticals. Typically, in the course of treatment, the patient taking the drug is not the decision-maker on what drug to use for treatment. The physician controls the decision of what drug the patient will use, and the patient's insurance company controls the price that the patient pays for the drug.²⁰ Many patients do not question the suitability or cost of a prescribed drug, as many patients do not consider themselves to be in the position to ask questions or exercise consumer purchase power when it comes to drugs prescribed to them, and many patients do not seek to develop an understanding of the drug pricing process and do not use their consumer power to fully evaluate competing drug products.²¹ Unlike when people shop for the best deal available when buying electronics, drug consumers, more often than not, simply accept the drug that is prescribed to them, rather than taking their business elsewhere if they think the cost is too high.²² This lack of true market decision-making power prevents consumers from driving drug pricing practices down through common marketplace interactions.²³ Furthermore, by keeping as much of the pricing process as secret as possible, companies perpetuate a general lack of understanding that supports the public's willingness to buy overpriced medications—similar to preserving the public's perception of the excessive cost of R&D—that directly benefits pharmaceutical companies.

Some industry experts remain unconvinced that the Trump administration's plan to lower prescription drug prices by requiring drug makers to display the list price "in a legible textual statement at the end of the advertisement" will work because of the limited

²⁰ Wapner, *supra* note 16.

²¹ *Id.*

²² Wapner, *supra* note 16.

²³ *Id.*

purchasing power of the healthcare consumer.²⁴ The new regulation would apply to prescriptions that cost more than \$35 per month or courses of treatment covered by Medicare and specifically requires that the price be displayed “for sufficient duration and in a size and style of font that allows the information to be read easily.”²⁵ Alex Azar, Secretary of U.S. Department of Health and Human Services, defended the new rule, stating, “We have for over 50 years required that car manufacturers and car dealers post the sticker price of cars on the windows of their cars and be transparent about—even though there are negotiations and everything else—because [it is] a starting point [that is] an important part of consumer fairness.”²⁶ Yet, Adrienne Faerber, lecturer at the Dartmouth Institute for Health Policy and Clinical Practice disagrees, explaining that “[w]hen you go to the car dealer and you see that sticker price and you can negotiate a better price that can fit your budget directly with the car dealership.”²⁷ Rather, Faerber says, drug prices are negotiated through layers of middlemen, “[s]o you [do not] get to negotiate based on these prices like you would with a car.”²⁸ The impact the new regulation is still uncertain. However, unlike most consumer markets, the drug market clearly does not grant decision making power to the consumer, which ultimately facilitates the permissible setting of unreasonable prices.

II. CURRENT FEDERAL REGULATION, ACTION, AND INACTION

A. Congressional Action

In 2017, the U.S. Senate introduced a bill to rein in drug pricing, but, to date, the bill has not gained momentum. In March 2017, the Senate proposed a bill called the Improving Access To Affordable

²⁴ See Selena Simmons-Duffin, *Will Displaying Drug List Prices In Ads Help Lower Costs?* NPR POLICY-ISH (May 8, 2019, 5:48 PM), <https://www.npr.org/sections/health-shots/2019/05/08/721574626/will-displaying-drug-list-prices-in-ads-help-lower-costs>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

Drugs Act.²⁹ If passed, the bill would impose a progressive rebate on any price increases greater than the rate of inflation.³⁰ The premise was that the rebate would not only penalize drug manufacturers that increase prices without justification but would also generate billions of dollars in revenue for the federal government.³¹ To avoid paying the rebate, a drug manufacturer would be required to justify the price increase based on manufacturing costs.³² The bill represents progress on the congressional level but does not yet have bipartisan support – nor is it expected to gain any soon.³³ Despite the introduction of legislation aimed at lowering drug costs in the U.S. Senate, Congress has yet to produce their own federal solution to combat directly price gouging.

B. Executive Action

In wake of his criticism of pharmaceutical drug price gouging, President Donald Trump had chosen to pursue administrative action in coordination with FDA to address the issue of high drug prices, yet he has – so far – stopped short of using his executive powers to take direct action. In October 2017, President Trump publicly criticized pharmaceutical companies and pronounced that they are “getting away with murder.”³⁴ Despite his harsh criticism of the pharmaceutical industry’s pricing practices, President Trump has yet to invoke his executive power to unilaterally lower costs.³⁵ Should he choose to do so, it would be within the presidency’s executive power to employ federal patent-use authority, which is the ability to push

²⁹ BERMAN ET AL., *supra* note 10, at 3.

³⁰ *Id.* at 14.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ Leandra Bernstein, *Trump attacks drug companies for high prices, weighs options to curb monopolies*, WJLA ABC 7, (Oct. 17, 2017), <https://wjla.com/news/nation-world/trump-attacks-drug-companies-for-high-prices-weighs-options-to-curb-monopolies> [<https://perma.cc/XS3C-9HHE>].

³⁵ BERMAN ET AL., *supra* note 10, at 3.

prices down for federally funded inventions, and the power to authorize the importation of cheaper foreign drugs.³⁶

In addition to the President's refrain from using his executive power to address the growing unconscionable drug pricing practices, he also has not publicly backed any proposed legislation.³⁷ Instead, the President has chosen to pursue administrative action in coordination with FDA and other agencies.³⁸ For example, in May 2018, the Trump administration published a "blueprint" containing proposals to combat rising prescription drug prices that are clearly meant to be implemented through federal agency action.³⁹ The most notable of these proposals describes efforts at transparency and simplification: eliminating some rebates paid out by drug companies that obscure the price of drugs, using international comparisons for pricing Medicare drugs, and requiring drug companies to include prices in advertising.⁴⁰ In response to the drug price gouging problem, President Trump currently limits his use of executive action to administrative action through the executive agencies.

C. FDA Action

While FDA's mission statement provides that the agency will bear the responsibility for protecting public health by ensuring the safety, efficacy, and security of pharmaceutical products,⁴¹ FDA possesses no legal authority to investigate or control the prices set by drug manufacturers, distributors, and retailers.⁴² Plainly stated, the ability

³⁶ *Id.* at 6.

³⁷ Bernstein, *supra* note 34.

³⁸ *Id.*

³⁹ *Fact Sheet: President Donald J. Trump's Blueprint To Lower Drug Prices*, THE WHITE HOUSE (May 11, 2018), <https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/>.

⁴⁰ *See id.*

⁴¹ U.S. FOOD & DRUG ADMIN., *What We Do*, (Accessed Jan. 6, 2018), <https://www.fda.gov/about-fda/what-we-do> [<https://perma.cc/8QER-5THE>] [hereinafter FDA *What We Do*].

⁴² U.S. FOOD & DRUG ADMIN., *Frequently Asked Questions about CDER*, (last visited Oct. 30, 2017), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research/frequently-asked-questions-about-cder> [<https://perma.cc/V3US-VG6N>] [hereinafter FDA *FAQ*].

to regulate drug pricing is not under the agency's purview. In January 2018, FDA Commissioner Dr. Scott Gottlieb recognized this lack of agency power when he claimed that such lack of jurisdiction did not relieve FDA of any duty, saying: "While we don't have the authority to regulate prices, we do have the authority – and the responsibility – to ensure that the agency's policies are not impeding competition that could ultimately be a check to rising drug prices and patient access."⁴³ In practice, FDA does not concern itself with the pricing of drugs, as the agency does not consider price in its drug approval process, nor does it negotiate with pharmaceutical companies over drug pricing.⁴⁴ Although drug pricing does not fall squarely within FDA's purview, the agency may use its existing powers to create or modify regulations that indirectly affect drug pricing. For example, FDA may change controlling regulations to expedite the drug approval process, which boosts market competition, thereby reducing prices. FDA's purview does not enable it to directly control drug pricing but allows the agency to pass regulations that indirectly affect drug pricing.

Another way in which FDA is using the power it does have to regulate pharmaceutical drugs and address the drug price gouging problem is through its newly launched Drug Competition Action Plan ("DCAP"). In May 2017, FDA Commissioner Scott Gottlieb committed the agency to contributing to the solution by announcing the launch of DCAP.⁴⁵ FDA estimates that past and ongoing efforts to boost competition in the pharmaceutical market and facilitate approval of generic drugs have saved the American healthcare system approximately \$1.67 trillion in the past decade.⁴⁶ DCAP aims to capitalize on these methods and introduce new ones to incur even

⁴³ Scott Gottlieb, *Reflections on a Landmark Year for Medical product Innovation and Public Health Advances and Looking Ahead to Policy in 2018*, FDA NEWSROOM (Oct. 1, 2018, 12:06PM), <https://www.fda.gov/NewsEvents/Newsroom/FDAVoices/ucm611998.htm>.

⁴⁴ Zachary Brennan, *What FDA Can and Can't Do to Help Lower Rising Drug Prices*, REGULATORY AFFAIRS PROF'LS SOC'Y (Nov. 18, 2015), <https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2015/11/what-fda-can-and-can%E2%80%99t-do-to-help-lower-rising-drug-prices> [<https://perma.cc/DHD2-7ZRY>].

⁴⁵ U.S. FOOD & DRUG ADMIN., *FDA Tackles Drug Competition to Improve Patient Access*, FDA PRESS ANNOUNCEMENT (June 27, 2017), <https://perma.cc/P57B-UD9E> [hereinafter FDA June 27, 2017 PRESS ANNOUNCEMENT].

⁴⁶ Scott Gottlieb, *FDA Working to Lift Barriers to Drug Competition Drug Competition*, FDA VOICE (June 21, 2017), <https://perma.cc/UVB3-3S4E>.

greater savings in the future by launching concentrated efforts to reduce drug prices. In June 2017, FDA took its first steps under DCAP by (1) publishing for the first time a complete list of off-patent, off-exclusivity drugs without approved generics and (2) implementing a new policy to expedite the review of generic drug applications where competition is limited until three approved generics are available for the given drug.⁴⁷

1. Publication of Drugs without Approved Generics to Boost Market Competition

As a part of DCAP, FDA published a list of off-patent, off-exclusivity drugs without an approved generic.⁴⁸ The agency published the list “to improve transparency and encourage the development and submission of abbreviated new drug applications (“ANDAs”) in markets with no competition.”⁴⁹ The agency anticipates that the publication of this list will facilitate the release of new generic drugs that will drive down the collective prices of pharmaceuticals.⁵⁰ Prior to the publication of this list, FDA had no clear, centralized information as to which drugs had generics and which were eligible to be developed into generics.⁵¹ Furthermore, the lack of centralized information made it difficult to track upcoming opportunities for development and made it easy for drug companies to buy the original brand-name product and spike prices.⁵² DCAP prompted FDA to publish a list of off-patent, off-exclusivity drugs in hopes of stimulating free market competition to rein in drug prices.

⁴⁷ FDA June 27, 2017 PRESS ANNOUNCEMENT, *supra* note 45.

⁴⁸ U.S. FOOD & DRUG ADMIN., OFFICE OF GENERIC DRUG, LIST OF OFF-PATENT, OFF-EXCLUSIVITY DRUGS WITH NO APPROVED GENERIC (2017) 1, 1, https://www.scribd.com/document/352372747/List-of-Off-Patent-Off-Exclusivity-Drugs-with-No-Approved-Generic?irgwc=1&content=10079&campaign=Skimbit%2C%20Ltd.&ad_group=35871X943606X53333e60a6fcd05ad0024f5d965aafd0&keyword=ft750noi&source=impactradius&medium=affiliate#from_embed [https://perma.cc/K2HG-V5D7].

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Lydia Ramsey, *The FDA just made a move that could prevent the next drug price gouger*, BUS. INSIDER (June 27, 2017), <http://www.businessinsider.com/fda-list-of-drugs-without-generic-competition-to-prevent-price-gouging-2017-6>.

⁵² *Id.*

2. *Priority Review to Reduce ANDA Backlog and Increase Market Competition*

Another goal of DCAP is to expedite the lengthy generic drug approval process.⁵³ In 2016, the lengthy approval process created a backlog of applications that FDA struggled to process.⁵⁴ Of the approximately 4,000 ANDAs pending approval, 2,200 were eligible for immediate review.⁵⁵ DCAP aims to resolve this issue by giving priority review to generic drug applications for drugs with limited competition,⁵⁶ particularly those with no more than three approved generics and that do not contain any exclusive patents.⁵⁷ DCAP also authorizes priority review for products that have only one existing, approved drug.⁵⁸ If FDA determines that the approval of the submission could help mitigate or prevent a drug shortage, which may cause prices to increase, then DCAP may grant priority review as well.⁵⁹ When DCAP grants a submission priority review, “FDA will either (1) give a shorter goal date or (2) grant an expedited review.”⁶⁰ When FDA gives a shorter goal date, it commits to completion of review in a set amount of time that is shorter than the standard time allotted for processing.⁶¹ Alternatively, when FDA grants expedited review, the agency “will strive to act on an ANDA as soon as possible, including prior to the goal date if possible. An expedited review, though, does not result in a shorter goal date.”⁶² DCAP’s prioritization

⁵³ Zachary Brennan, *Generic Drug Backlog at FDA: A Dive Into the Confusing Numbers*, REGULATORY AFFAIRS PROF’LS SOC’Y (Nov. 1, 2016), <https://www.raps.org/regulatory-focus/e2%84%a2/news-articles/2016/11/generic-drug-backlog-at-fda-a-dive-into-the-confusing-numbers#/>. [<https://perma.cc/RX58-Y49E>].

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Gottlieb, *Reflections*, supra note 43.

⁵⁷ U.S. FOOD & DRUG ADMIN., OFFICE OF GENERIC DRUG, MANUAL OF POLICIES AND PROCEDURES (MAPP 5240.3 REV. 4), PRIORITIZATION OF THE REVIEW OF ORIGINAL ANDAs, AMENDMENTS, AND SUPPLEMENTS (June 27, 2017) 1, 3.

⁵⁸ *Id.* at 6.

⁵⁹ *Id.* at 4.

⁶⁰ *Id.* at 7.

⁶¹ *Id.*

⁶² *Id.*

for expedited review of drugs without three approved generic counterparts should accelerate generic drug approval that consequently brings all drug prices down.

Published in early 2019, the 2018 Annual Report of the Office of Generic Drugs, part of FDA's Center for Drug Evaluation and Research, seems to indicate that DCAP is making a positive impact.⁶³ In fact, nearly 10% of drug approvals in 2018 were generic products for branded drugs that had no FDA-approved generics.⁶⁴ In total, more than 1,000 generic drugs received FDA approval or tentative approval in 2018—October and November represented peak months for approvals and tentative approvals with 128 each.⁶⁵ Specifically, the report recognized FDA:

made significant progress in the three major components of the DCAP: (1) streamlining the ANDA review process to increase efficiency, effectiveness, and output of approvals; (2) enhancing development and review of complex generic drug products; and (3) reducing the "gaming" that frustrates and delays generic drug approvals and extends brand monopolies beyond what Congress intended with the Hatch-Waxman Amendments of 1984.⁶⁶

Critically, the agency reiterated its commitment to DCAP and "doing all [it] can, within [its] jurisdiction, to advance the critically important public health mission of providing the American public with more affordable medicines."⁶⁷

⁶³ See generally U.S. FOOD & DRUG ADMIN, 2018 OFFICE OF GENERIC DRUGS ANNUAL REPORT, <https://www.fda.gov/drugs/2018-office-generic-drugs-annual-report> (last visited July 14, 2019) [hereinafter FDA 2018 Annual Report].

⁶⁴ Laura Jostz, *FDA Makes Progress on Improving Drug Competition, Transparency, According to 2018 Report*, AM. J. OF MANAGED CARE IN FOCUS BLOG (Mar. 1, 2019), <https://www.ajmc.com/focus-of-the-week/fda-makes-progress-on-improving-drug-competition-transparency-according-to-2018-report>.

⁶⁵ *Id.*

⁶⁶ FDA 2018 Annual Report, *supra* note 63.

⁶⁷ *Id.*

D. Federal Trade Commission (“FTC”) Action and Coordinated Action with FDA

Like FDA, FTC wields limited jurisdiction over drug prices and may only assert its jurisdiction in certain circumstances related to federal antitrust and consumer laws that fall within its purview.⁶⁸ FTC has an indirect regulatory relationship with the pharmaceutical drug industry.⁶⁹ On the one hand, FTC’s congressional mandate is to ensure that the nation’s markets function competitively,⁷⁰ yet the agency holds no authority to regulate the price of any product, including pharmaceutical drugs.⁷¹ However, on the other hand, Congress empowered FTC to prohibit unfair methods of competition, which enables the agency to prevent illegal agreements among pharmaceutical companies to increase prices, restrict supply, or employ exclusionary practices that would prevent others from entering the market.⁷² For example, in the past, FTC worked with state attorney generals to bring antitrust charges against pharmaceutical companies that enter into illegal agreements to raise drug prices and restrict competitor access.⁷³ FTC’s jurisdiction may not directly regulate drugs prices, but its jurisdiction enables the agency to act to protect consumers from price gouging when the actions taken by pharmaceutical manufacturers and suppliers violate federal antitrust and consumer protection laws.

To address the issue of increasing drug prices and price gouging, FTC targets practices that impede the entry of generic drugs into the pharmaceutical market and has committed itself to acting to aid in lowering drugs costs, much like FDA’s efforts to combat price gouging. In November 2017, FTC partnered with FDA to host a

⁶⁸ See Alan Friedman, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, U.S. FED. TRADE COMM’N BLOG (May 18, 2015, 12:31 PM), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription> [<https://perma.cc/XR8G-KBU6>] [hereinafter Friedman, *From the antitrust mailbag*]; see also FDA *What We Do*, *supra* note 41.

⁶⁹ See Friedman, *From the antitrust mailbag*, *supra* note 68.

⁷⁰ See *id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

workshop titled, “Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics.”⁷⁴ These discussions built on the bedrock concept that, as Acting FTC Chairman Maureen K. Ohlhausen said, “Competition is key to containing prescription drug costs.”⁷⁵ FDA Commissioner Dr. Scott Gottlieb expounded on this idea in his opening remarks, saying, “Although FDA and the FTC have very different responsibilities relating to healthcare, among our shared goals is a critical one of ensuring that all Americans are able to benefit from competition [in the market] when it comes to the medical products that they use.”⁷⁶ The workshop was free, open, and webcasted live to the public.⁷⁷ FTC invited and accepted public comments on the topic one month after the workshop⁷⁸ and received 324 comments from a wide variety of interested persons—private citizens, political representatives, medical and pharmacy associations, and healthcare supply chain companies alike.⁷⁹ FTC continues to use the powers within its purview and work with FDA to combat and reduce drug prices.

In November 2018, in conjunction with the Organisation for Economic Co-operation and Development, FTC and the U.S. Department of Justice Antitrust Division released a position paper analyzing why excessive pricing of pharmaceuticals is not an antitrust violation under U.S. antitrust law.⁸⁰ The paper posited that “U.S.

⁷⁴ U.S. FED. TRADE COMM’N, *FTC to Conduct Workshop on November 8, Examining Competition Issue Related to Prescription Drug Market*, FTC RELEASE (Oct. 3, 2017), <https://www.ftc.gov/news-events/press-releases/2017/10/ftc-conduct-workshop-november-8-examining-competition-issues>.

⁷⁵ *Id.*

⁷⁶ U.S. FED. TRADE COMM’N, *UNDERSTANDING: COMPETITION IN PRESCRIPTION DRUG MARKETS: ENTRY AND SUPPLY CHAIN DYNAMICS WORKSHOP, TRANSCRIPT SEGMENT 1: INTRO AND KEYNOTE REMARKS*, (2017).

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ U.S. FED. TRADE COMM’N, *FTC Announces Agenda for November 8 Workshop on Examining Competition Issues Related to Prescription Drug Markets*, FTC RELEASE #725 (2017), <https://www.ftc.gov/policy/public-comments/2017/11/initiative-725>.

⁸⁰ ORG. FOR ECON. CO-OPERATION AND DEV., *Excessive Pricing in Pharmaceutical Markets – Note by the United States*, U.S. FED. TRADE COMM’N (Nov. 23, 2018) https://www.ftc.gov/system/files/attachments/us-submissions-oecd-2010-present-other-international-competition-fora/excessive_prices_in_pharmaceuticals_united_states.pdf.

antitrust law does not recognize excessive pricing as an antitrust violation in and of itself, allowing legitimate market participants acting independently to set their prices as high as they choose.⁸¹ The agency identified that the policy choice stems from “the legislature’s determination that ultimately competition will produce not only lower prices, but also better goods and services.”⁸² Crucially, the paper underscored the importance of FDA’s DCAP and emphasized that “FTC and FDA are working together to improve access to affordable drugs, including finding ways to keep drug companies from gaming the regulatory system to deter generic and biosimilar competition.”⁸³ Though it may be too soon to identify measurable results from their coordinated efforts, FTC has indicated that it remains committed to its partnership with FDA to control prescription drug prices.

III. STATE-LEVEL SOLUTIONS

In light of a lack of cohesive federal action, states have led the charge in undertaking a range of legislative efforts to lower increasingly high drug pricing and prevent drug price gouging, including implementation of fair pricing and transparency laws. As pharmaceutical companies engage in interstate commerce across all 50 states, citizens stand to benefit from each state’s experimentation in legislation, even if they do not reside in a state with such laws. For example, one state may require pharmaceutical companies to disclose certain information that citizens in another state may be able to use as the basis for a call to action for stronger drug pricing regulations in their own state. The biggest roadblock that states seeking to make progress this way will face is the power of the pharmaceutical lobby.⁸⁴ The pharmaceutical lobby will inevitably attempt to block state-level action by pointing to the potential for loss of innovation and damage to one of America’s largest industries.⁸⁵

⁸¹ *Id.* at 13.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ BERMAN ET AL., *supra* note 10, at 9–10.

⁸⁵ *Id.*

A. Fair Pricing Legislation

Fair pricing legislation seeks to directly constrain the cost of drugs.⁸⁶ Typically, legislation of this kind requires drug manufacturers to either (1) justify price increases or face penalties for failure to do so or (2) provide rebates when prices surpass a certain threshold.⁸⁷ To effectively implement these laws, states will need to select a method to establish fair prices.⁸⁸ Given the complexity of deriving drug prices that pharmaceutical industry leaders must contend with (even when acting in good faith), creating a method for fair drug pricing is likely to be a significant challenge for state legislatures.⁸⁹ Three viable approaches exist: (1) set price benchmarks based on the costs of development, (2) rely on a reference price that is publicly available, or (3) price drugs according to their therapeutic value.⁹⁰

In May 2017,⁹¹ Maryland passed the nation's first law designed not only to deter increasing drug prices but also to punish practitioners of drug price gouging.⁹² This law, Maryland House Bill 631 ("H.B. 631"), exemplifies the second approach described above and penalizes unjustifiable price increases.⁹³ H.B. 631 applies to any generic drug⁹⁴ *made available for sale* in Maryland and was "enacted in response to two government reports detailing price-gouging of off-patent drugs under specific market conditions."⁹⁵ Under Maryland state law, "pricegouging" is defined as "an unconscionable increase in the price of a prescription drug."⁹⁶ To be considered unconscionable, a

⁸⁶ BERMAN ET AL., *supra* note 10, at 9–10.

⁸⁷ *Id.*

⁸⁸ *Id.* at 13.

⁸⁹ *Id.* at 4.

⁹⁰ *Id.* at 13.

⁹¹ *Id.* at 18.

⁹² *Id.* at 14.

⁹³ *Id.* at 13–14.

⁹⁴ *Id.*

⁹⁵ Ass'n. for Accessible Medicines v. Frosh, No. MJG-17-1860, 2017 WL 4347818, at *1 (D. Md. Sept. 29, 2017).

⁹⁶ *Id.* at *2 (citing H.R. 631, 2017 Leg., 437th Sess. § 2-801(c) (Md. 2017)).

drug price increase must satisfy two elements.⁹⁷ First, the increase must be excessive and not justified by the cost of production or expansion of access of the drug to promote public health, and second, it must result in no meaningful choice about purchasing the drug at an excessive price because of (1) the importance of the drug to consumers' health and (2) insufficient competition in the market.⁹⁸ Should a court determine that a drug price increase satisfies this definition, the law authorizes the court to compel the violating party to produce certain records, to restore to a drug consumer any money lost as a result of an unconscionable price increase, and to impose a civil penalty of up to \$10,000 per violation.⁹⁹ Importantly, the law's reach is incredibly broad as it targets *any generic made available* in the state.¹⁰⁰

The Maryland law's reach is extremely powerful because the law provides no defense for manufacturers whose drugs were made available in Maryland but who never directly dealt with Maryland drug consumers.¹⁰¹ Theoretically, *any* manufacturer may be subject to suit in Maryland, regardless of typical jurisdictional limitations. Maryland's aggressive fair pricing law is poised to affect practitioners of drug price gouging across the country and seeks to do so by applying an unconscionable standard to price increases.

Since H.B. 631's enactment, proponents have begun encouraging the use of Maryland's new fair pricing law, while opponents have already taken legal action to strike it down. In favor of the law and in preparation of Maryland's first drug price gouging case, the Maryland Attorney General, the Maryland State Medical Society, and the Maryland Healthcare for All Coalition have been actively encouraging citizens to share their stories of how escalating drug prices have hurt them or their families.¹⁰² In response, the Association for Accessible Medicines ("AAM"), a lobbying group that represents manufacturers

⁹⁷ *Id.* (citing H.R. 631 § 2-801(f)).

⁹⁸ *Id.*

⁹⁹ *Id.* at *3 (citing H.R. 631 § 2-803(d)).

¹⁰⁰ *Id.* (citing H.R. 631 § 2-803(g)).

¹⁰¹ *Id.*

¹⁰² Deborah Weiner, *State seeks stories of prescription drug price gouging*, WBAL TV 11, (Nov. 1, 2017, 5:32 PM), <https://www.wbaltv.com/article/state-seeks-stories-of-prescription-drug-price-gouging/13136386> [<https://perma.cc/F4R6-LNAQ>].

and distributors of generic drugs, filed suit against Brian Frosh, the Maryland Attorney General, and Dennis Schrader, the Secretary of the Maryland Department of Health,¹⁰³ in July 2017, just two months after the law's enactment.¹⁰⁴ AAM challenged the fair pricing law as a (1) violation of the dormant Commerce Clause as applied to the sale of drugs between out-of-state manufacturers and distributors and (2) unconstitutionally vague under the Due Process Clause of the Fourteenth Amendment.¹⁰⁵

To its first claim, AAM asserted that H.B. 631 violates the Dormant Commerce Clause because as it pertains to *any* generic drug that is *made available for sale* in Maryland, it regulates "commercial activity that occurs wholly outside" of Maryland.¹⁰⁶ To support its argument, AAM presented two hard-hitting points: (1) not one of the three generic drug wholesalers that account for approximately 90 percent of the market are domiciled in Maryland and (2) none of the country's twenty largest generic drug manufacturers operate within Maryland's borders.¹⁰⁷ To its second claim, AAM asserts that H.B. 631 is unconstitutionally vague because it fails to define or describe the terms used to supposedly denote "price-gouging,"¹⁰⁸ as the law provides no guidance on how to interpret or apply such language,¹⁰⁹ and as the legislation does not define the scope of the discretion the Maryland Attorney General possesses in applying the law over the course of an investigation.¹¹⁰

In September 2017, the Maryland District Court held that AAM's two arguments failed and that the law would stand.¹¹¹ On appeal in

¹⁰³ See generally Complaint, Ass'n for Accessible Medicines v. Frosh, No. 1:17-cv-1860 (D. Md. filed July 6, 2017) [hereinafter AAM Complaint].

¹⁰⁴ Docket, Ass'n for Accessible Medicines v. Frosh, No. MJG-17-1860, 2017 WL 4347818 (D. Md. Sept. 29, 2017) [hereinafter Maryland Court Docket].

¹⁰⁵ See generally AAM Complaint, *supra* note 103.

¹⁰⁶ *Id.* at ¶ 4.

¹⁰⁷ *Id.* at ¶ 51.

¹⁰⁸ AAM Complaint, *supra* note 103, at ¶ 59.

¹⁰⁹ *Id.* at ¶ 60.

¹¹⁰ *Id.* at ¶ 61–63.

¹¹¹ See Ass'n for Accessible Medicines v. Frosh, No. MJG-17-1860, 2017 WL 4347818, at *15 (D. Md. Sept. 29, 2017).

April 2018, the Fourth Circuit held the law to be unconstitutional because it regulated commerce beyond the borders of Maryland.¹¹² In February 2019, the Supreme Court formally declined to hear the appeal filed by Maryland's attorney general.¹¹³ The Supreme Court's declination to hear the case will likely affect the viability of fair pricing laws in other states and may deter other states' experimentation with similar laws. Nevertheless, Maryland legislature prepares to pass new legislation that would "install a 'Prescription Drug Affordability Board'" to "set payment levels for drugs" – a true signal that state-level initiatives to combat prescription drug pricing will continue to push forward in the face of adversity.¹¹⁴

B. Transparency Legislation

Transparency legislation seeks to pierce the mysterious veil hiding exactly how drugs are priced and why those prices change.¹¹⁵ The goal of transparency legislation is to provide the public and policymakers with the information needed to inform future policy and legislative efforts.¹¹⁶ By unveiling precise R&D costs, the public and government entities can identify incidences of truly unjustified price gouging separate from truly justified price increases and act accordingly. Typically, drug manufacturers impose confidentiality requirements on states and other purchasers when negotiating sale agreements.¹¹⁷ In order to be successful, a states' transparency legislation must operate around these agreements and compel manufacturers to disclose private information without implicating the other parties to the contracts.¹¹⁸ Many of the strongest transparency bills require disclosure of a wide range of information including a combination of manufacturer prices offered to other payers; R&D costs, including

¹¹² Lev Facher, *Supreme Court deals a fatal blow to Maryland drug 'price gouging' law*, STAT (Feb. 19, 2019), <https://www.statnews.com/2019/02/19/supreme-court-declines-case-on-maryland-drug-price-gouging-law/>.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ BERMAN ET AL., *supra* note 10, at 7.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 8.

¹¹⁸ *Id.* at 7.

clinical trial financial assistance; manufacturing costs; marketing and advertising costs; patient financial assistance and rebates; intellectual property status; acquisition costs; settlement cost; regulatory approval costs; state and federal tax benefits; off-short profits; donations to patient disease advocacy groups; and grants, subsidies, and costs paid for with public funds or by third-parties.¹¹⁹

Notably, this type of legislation greatly differs from legislation requiring the disclosure of information to regulators, which already exists in many forms in the healthcare space. Public reception to transparency legislation will likely be largely positive, as a Kaiser Family Foundation poll found that 86 percent of Americans “favor requiring drug companies to release information to the public on how they set drug prices.”¹²⁰ By passing transparency laws, states will be able to compel pharmaceutical companies to disclose information about how they set drug prices and provide the public information on which they can base their calls to action.

Not all transparency legislation is created equal. The impact on the pharmaceutical companies may vary greatly depending on what the legislation requires of the companies. Lawmakers may draft a transparency bill so that it calls for disclosure of information that is neither central to many drug companies’ business model nor qualifies as comprehensively secret.¹²¹

Transparency legislation differs as to (1) what type of drugs the law applies to, (2) the reporting requirements, and (3) available disclosure exemptions.¹²² First, transparency legislation may pertain to either brand name or generic drugs, rather than all drugs regardless of patent status; drugs priced above a certain acquisition cost; drugs most frequently prescribed by physicians; or a combination of these requirements.¹²³ In contrast, some states have drafted bills that broadly impose disclosure requirements on “all drugs.”¹²⁴ Second, legislation

¹¹⁹ BERMAN ET AL., *supra* note 10.

¹²⁰ *Id.*

¹²¹ *Id.* at 11.

¹²² *Id.* at 15–19.

¹²³ *Id.* at 15–17.

¹²⁴ *Id.*

varies as to specific disclosures required of pharmaceutical companies. Reporting requirements may include reporting the cost of R&D, manufacturing, marketing, clinical trials, and acquisition; the history of the drug's price increases; and the value of grants, subsidies, and profits to the company.¹²⁵ Finally, available public disclosure exemptions vary state to state. For example, public disclosure exemption legislation passed in Louisiana permits no public disclosure exemptions whatsoever; in contrast, the public disclosure exemption legislation enacted in Vermont prohibits the identification of individual drugs and companies in disclosures and protects all disclosed information from state-level public records requests.¹²⁶ A 2017 study on the Vermont transparency law illustrated that the prohibition of public disclosure of any information released to the state by drug manufacturers substantially reduced the value of the information released through the law.¹²⁷ Because states have many different variables to address when drafting transparency legislation, some laws will require a far greater number of disclosures than others and, as a result, have more teeth.

In June 2017, Nevada passed into law a bill that focuses on ensuring drug pricing transparency. The law, Nevada Senate Bill 265 ("S.B. 265") was initially introduced in February 2017 with the intent to "to lower the cost of certain essential diabetes drugs, such as insulin, by requiring companies that manufacture them [to] report costs of producing and marketing the drug along with any rebates that they provide for the drugs."¹²⁸ S.B. 265 aimed to do so by including three specific transparency provisions: one directing the Nevada Department of Health and Human Services ("Nevada DHHS") to compile a list of drugs "essential" for treating diabetes;¹²⁹ a second compelling drug manufacturers to submit to the Nevada DHHS a

¹²⁵ BERMAN ET AL., *supra* note 10.

¹²⁶ *Id.* at 16–17.

¹²⁷ *Id.* at 10.

¹²⁸ Complaint at ¶ 34, Pharm. Research & Manufacturers of Am. et al v. Sandoval et al, No. 2:17-cv-02315-JCM-CWH, (D. Nev. filed Sept. 1, 2017) (citing Megan Messerly, *Sandoval Vetoes Major Pharmaceutical Transparency Litigation Citing Concerns Over "Nascent, Unproven and Disruptive" Changes*, NEV. INDEP. (June 2, 2017)).

¹²⁹ S. Res. 265, 2017 Leg., 79th Sess. § 6 (Nev. 2017), https://www.leg.state.nv.us/Session/79th2017/Bills/SB/SB539_EN.pdf [<https://perma.cc/A4LR-WFCZ>].

report disclosing cost and pricing information for such drugs;¹³⁰ and a third requiring the Nevada DHHS to compile and publish a report containing the prices of essential diabetes drugs and the effect of those prices on healthcare spending in Nevada.¹³¹ After the Governor of Nevada vetoed S.B. 265, the Senate resurrected it by attaching it in a moderately modified form to S.B. 539.¹³² The Nevada legislature passed S.B. 539 into law and enacted the provisions included in the original S.B. 265.¹³³ In its final form, the law identifies drug manufacturers' trade secrets as public disclosure exemptions¹³⁴; however, the law also amends the Nevada Revised Statutes Section 600A.030 to redefine "trade secrets" to exclude "any information that a [drug] manufacturer is required to report pursuant to [the law] . . . to the extent that such information is required to be disclosed by [the corresponding] section[]." ¹³⁵ If S.B. 539 survives future legal challenges, it will stand as a model for future state-level initiatives to rein in increasing drug prices by requiring transparency from drug manufacturers.

As one of five transparency bills successfully passed into law on the state level as of 2017,¹³⁶ the Nevada law was destined to receive pushback from the pharmaceutical industry and its advocates. Three months after Nevada enacted the law, the Pharmaceutical Research and Manufacturers of America ("PhRMA") and Biotechnology Innovation Organization ("BIO"), the nation's largest pharmaceutical lobbying groups, filed suit against the Governor of Nevada, Brian Sandoval; the Director of the Nevada DHHS, Richard Whitley; and the Nevada Legislature, challenging the law on constitutional grounds.¹³⁷

¹³⁰ *Id.* § 7(1).

¹³¹ *Id.* §§ 6(1), 7(2).

¹³² See generally S. Res. 539, 2017 Leg., 79th Sess. (Nev. 2017), https://www.leg.state.nv.us/Session/79th2017/Bills/SB/SB539_EN.pdf [<https://perma.cc/A4LR-WFCZ>].

¹³³ *Id.*

¹³⁴ BERMAN ET AL., *supra* note 10, at 16.

¹³⁵ S. Res. 539 § 9(5)(b).

¹³⁶ BERMAN ET AL., *supra* note 10, at 15-17 (identifying transparency laws passed by California, Florida, Louisiana, Nevada, and Vermont).

¹³⁷ Docket, Pharm. Research & Mfrs. of Am. v. Sandoval, No. 2:17cv2315 (D. Nev. filed Sept. 1, 2017) [hereinafter Nevada Court Docket].

PhRMA and BIO raised challenges based on (1) federal patent law preemption grounds; (2) federal trade-secret law preemption grounds; (3) the Fifth Amendment's Takings Clause of the Fifth Amendment to the U.S. Constitution; and (4) the dormant Commerce Clause of the U.S. Constitution.¹³⁸ On the patent law preemption claim, the plaintiffs argued that the Nevada transparency law violates federal patent law and eliminates the protections provided by the Hatch-Waxman Act.¹³⁹ They also contended it nullifies the protection of trade-secrets provided by the federal Defend Trade Secrets Act of 2016 ("DTSA")¹⁴⁰ as the law compels manufacturers to disclose proprietary advertising, cost, marketing, pricing, and production information that are all generally classified as DTSA trade-secrets.¹⁴¹ Their third claim asserted that the Nevada law violates the Takings Clause by depriving affected drug manufacturers of trade-secret protection for their confidential information, which forces them to disclose their confidential information to the state, and ensures that much of their confidential information will be disseminated third-party payers and competitors on the Internet.¹⁴² Previous to the passage of the Nevada transparency law, this type of confidential information was protected as trade secrets in Nevada and all other states.¹⁴³ The plaintiffs' final claim suggested the law violates the dormant Commerce Clause because

¹³⁸ Complaint at ¶ 4-7, *Pharm. Research & Mfrs. of Am v. Sandoval*, No. 2:17cv2315 (D. Nev. filed Sept. 1, 2017) [hereinafter PhRMA Complaint].

¹³⁹ PhRMA Complaint at ¶ 4; *see also* U.S. FOOD & DRUG ADMIN., *Hatch-Waxman Amendments*, FDA.Gov, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters> (last accessed July 13, 2019) ("The 'Drug Price Competition and Patent Term Restoration Act of 1984,' also known as the Hatch-Waxman Amendments [or the Hatch-Waxman Act], established the approval pathway for generic drug products." By doing so, the Hatch-Waxman Act effectively established the legal and economic foundation for the generic drug industry.).

¹⁴⁰ PhRMA Complaint at ¶ 5; *see also* AM. BAR ASS'N, *Explaining the Defend Trade Secrets Act*, ABA BUSINESS LAW TODAY BLOG, https://www.americanbar.org/groups/business_law/publications/blt/2016/09/03_cohen/ (last accessed July 13, 2019) (The Defend Trade Secrets Act of 2016 "creates a federal, private, civil cause of action for trade-secret misappropriation in which '[a]n owner of a trade secret that is misappropriated may bring a civil action . . . if the trade secret is related to a product or service used in, or intended for use in, interstate or foreign commerce.'").

¹⁴¹ PhRMA Complaint at ¶ 124.

¹⁴² *Id.* at ¶ 6.

¹⁴³ *Id.*

complying by disclosing trade-secrets would eviscerate the value of proprietary protection in all states.¹⁴⁴

In June 2018, the plaintiffs, PhRMA and BIO, the two national drug lobbying organizations, voluntarily dismissed their suit challenging the constitutionality of Nevada's pricing transparency law less than a month after the state approved regulations allowing drug companies to protect certain information they submitted the state from public disclosure.¹⁴⁵ The Nevada DHHS-approved regulation "allows drug manufacturers and [pharmacy benefit managers] to request that information they report to the state be kept confidential if they believe its disclosure would constitute a misappropriation of a trade secret."¹⁴⁶ The regulation provides that if DHHS receives a public records request, state officials would make an initial determination about whether the information requested to be disclosed constitutes a trade secret and should be released while allowing manufacturers 30 days to take action in court to prevent the disclosure if they disagree.¹⁴⁷ Nevada Senate Leader Michael Roberson, a key supporter of the legislation, called the dismissal "a tremendous victory for all Nevadans." Such victory will hopefully encourage other states to implement laws encouraging transparency regarding prescription drug pricing.

IV. FEDERAL RESPONSE TO STATE-LEVEL SOLUTIONS

While FDA is charged with overseeing the complex regulatory scheme imposed on the pharmaceutical drug industry, FDA is not likely to attempt to, nor is not likely able to, preempt state law designed to regulate drug pricing and drug price gouging. Federal preemption is a doctrine of American constitutional law, rooted in the Supremacy Clause, under which state and local governments' power

¹⁴⁴ *Id.* at ¶ 7.

¹⁴⁵ Megan Messerly, *Big Pharma abandons lawsuit over Nevada's insulin pricing transparency law after state approve trade secret protection regulations*, NEV. INDEP. (June 28, 2018, 6:01 PM), <https://thenevadaindependent.com/article/big-pharma-abandons-lawsuit-over-nevadas-insulin-pricing-transparency-law-after-state-approves-trade-secret-protection-regulations>.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

to act yields when it conflicts with federal law. Under the Supremacy Clause, state law that conflicts with its federal counterpart is “without effect.”¹⁴⁸

In determining whether federal law preempts a state-law claim, two “cornerstone” principles guide courts engaging in such analysis.¹⁴⁹ First, in fields traditionally occupied by the states, such as health and safety regulations, preemption analysis starts with the “assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.”¹⁵⁰ Second, analysis of the scope of the statute’s preemption is guided by the bedrock concept that “[t]he purpose of Congress is the ultimate touchstone.”¹⁵¹ Express preemption occurs in cases where Congress’ purpose is made clear through statutory language that explicitly states whether it is meant to preempt a lower-level lawmaking authority.¹⁵² For example, the federal Medical Device Amendments expressly preempt state regulation of medical devices.¹⁵³

In the absence of express language, preemption may also be implied, and in implied preemption cases, “[t]he agency’s own views should make a difference” even though the text of the statute or the agency rule does not address preemption expressly.¹⁵⁴ The U.S. Supreme Court directly applied and affirmed the validity of implied preemption as applied to FDA regulatory matters in its 2000 decision, *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120

¹⁴⁸ *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

¹⁴⁹ *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (citing *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

¹⁵⁰ *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

¹⁵¹ *Id.* (citing *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)).

¹⁵² FUNDAMENTALS OF PREEMPTION, NAT’L POLICY & LEGAL ANALYSIS NETWORK TO PREVENT CHILDHOOD OBESITY & PUB. HEALTH LAW CTR. AT WILLIAM MITCHELL COLL. OF LAW, <https://publichealthlawcenter.org/sites/default/files/resources/nplan-fs-fundamentals-2010.pdf> (last accessed July 13, 2019).

¹⁵³ 21 U.S.C. § 360k(a) (2017) (prohibiting any state from establishing any requirement “different from, or in addition to” a federal requirement relating “to the safety or effectiveness” of a medical device).

¹⁵⁴ *Geier v. American Honda Motor Co.*, 529 U.S. 861, 883 (2000).

(2000).¹⁵⁵ In *Brown & Williamson Tobacco Corp.*, the Supreme Court held that the Court's deference to an agency's interpretation of Congress' purpose is justified because "[t]he responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones."¹⁵⁶ Additionally, the Court reasoned that the agency, not Congress, is more familiar with "the ever-changing facts and circumstances surrounds the subjects."¹⁵⁷ In accordance with this ruling, FDA's interpretation controls "unless [it is] plainly erroneous or inconsistent with the regulation[s]."¹⁵⁸ In any challenge to the constitutionality of states' anti-drug price gouging legislation, courts will have to address FDA's preemptive authority to bring suit challenging state law.

FDA has not yet challenged fair pricing or transparency legislation enacted at the state level, and the agency is not likely to do so. In FDA's enabling statute, the Food, Drug, & Cosmetics Act ("FDCA"), Congress gave FDA a specific mandate to regulate the drug field, and this specific mandate defeats any presumption against preemption. However, FDA's enabling statute does not speak directly to the agency's ability to set or regulate drug prices, and Congress has not passed legislation that grants the agency the ability to do so. Without these specific grants of power, the argument that Congress explicitly stated FDA's purpose regarding drug price that would act as "touchstone." Congress' purpose as "touchstone" may be derived by identifying the purposes of the FDCA.

Past FDA cases generally recognize safety and effectiveness as the primary objectives of the FDCA, yet *United States v. Lane Labs – USA Inc.*, 427 F.3d 219 (3d Cir. 2005), exists as a compelling outlier. In *Lane Labs*, the Third Circuit found the powers enshrined in the FDCA, such as the ability to regulate advertising, and the legislative history "make it clear that Congress intended the statute to protect the financial interests of consumers as well as their health."¹⁵⁹ The legislative

¹⁵⁵ See generally *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

¹⁵⁶ *Id.* at 132 (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984)).

¹⁵⁷ *Id.* at 132.

¹⁵⁸ *Auer v. Robbins*, 519 U.S. 452, 461 (1997).

¹⁵⁹ *United States v. Lane Labs–USA Inc.*, 427 F.3d 219, 227 (3d Cir. 2005).

history of the act may act as a touchstone as the court highlights how the history identifies the statute's purpose was to protect "the consumer's health and pocketbook."¹⁶⁰ The court's holding in *Lane Labs* that financial protection is a core principle of the FDCA satisfies the "purpose" element of implied preemption.

Applying the *Lane Labs* holding to a challenge of the states' legislation gives a preview of how a court may handle those cases. Because FDA can likely prove that Congress' purpose in creating the FDCA was for FDA to protect drug consumers' financial interests as a public health concern, a reviewing court would likely defer to the agency's own view as to whether it has necessary authority. In cases of implied preemption, the U.S. Supreme Court has made it clear that an agency's views should receive deference. Moreover, in the case of drug price regulation, FDA has already determined that it does not have jurisdiction over drug prices, and it has made this determination clear in its guidance and public statements.¹⁶¹ Should FDA change its determination, which it may do because "authority granted by Congress" cannot "evaporate through lack of administrative exercise"¹⁶² and decide it has the ability to regulate drug pricing, – FDA would not be precluded from doing so based on past inaction or rare action.

Should FDA change its position and assert that it does have jurisdiction without Congress amending the FDCA, however, it will likely face many of the same challenges it did in *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). In *Brown & Williamson Tobacco Corp.*, FDA was unsuccessful in persuading the court that it had jurisdiction over an area of law not expressly within its purview when the agency had previously asserted it had no authority over such matters in public committee hearings.¹⁶³ With respect to drug pricing regulation, FDA has given no indication that it will attempt to preempt state laws aimed at restricting increasing drug prices and drug price gouging. If FDA did attempt to regulate this industry, it will likely fail to persuade a court that it has the authority to do so – without congressional action

¹⁶⁰ *Id.* at 228 (citing H.R. Rep. No. 74-2755 at 2 (1936)).

¹⁶¹ See FDA *What We Do*, *supra* note 41; see also FDA *FAQ*, *supra* note 42.

¹⁶² *BankAmerica Corp. v. United States*, 462 U.S. 122, 131 (1983).

¹⁶³ See generally *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000).

to amend the FDCA. Under the current regulatory scheme, FDA has no power to preempt state-level initiatives to combat drug price gouging and does not claim to have such power.

CONCLUSION

Ever increasing drug prices and drug price gouging pose an incredible risk and expense to Americans. In lieu of cohesive federal action, states have been emboldened to tackle the problem by passing innovative fair pricing and transparency legislation. On the federal level, the President and Congress have refrained from taking direct action. FDA—the federal agency with the most experience and direct authority to regulate drugs—does not believe it possesses the jurisdiction to address the problem and has not intervened to thwart state-level initiatives. Even if FDA should choose to intervene, courts would likely determine that FDA's regulations and enabling statute do not preempt these novel state laws. Instead, the biggest threat to state-level solutions will be legal challenges raised by the pharmaceutical industry based on violations of federal patent law, federal trade-secrets law, the dormant Commerce Clause, the Takings Clause, and the Due Process Clause.