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Drug Pricing—The Next Compliance Waterloo

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DRUG PRICING—THE NEXT COMPLIANCE WATERLOO

Dr. Seth Whitelaw,[†] Nicodemo Fiorentino,^{††} & Jennifer O’Leary^{†††}

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I. INTRODUCTION

“Drug prices are too high.”¹

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1. See Rachel Roubein, *HHS Nominee: Prescription Drug Prices Too High*, THE

With these five simple words, Alex Azar II, former president of Lilly USA LLC, and now the Department of Health and Human Services (HHS) Secretary, captured the essence of the drug pricing war.² It is a conflict that pits the pharmaceutical companies against doctors, hospitals, insurers, regulators, and consumers.³ The pharmaceutical industry has fought this war for over two decades,⁴ but inevitably, it will lose because both facts and public opinion weigh in favor changing the status quo.⁵ In this industry, life science

HILL (Nov. 29, 2017, 10:46 AM), <http://thehill.com/policy/healthcare/362325-hhs-nominee-prescription-drug-prices-too-high> [<https://perma.cc/S443-C6FN>] (quoting the opening statement of Alex Azar before the Senate Health, Education, Labor, and Pensions Committee).

2. *Id.*

3. See Toon van der Gronde et al., *Addressing the Challenge of High-Priced Prescription Drugs in the Era of Precision Medicine: A Systematic Review of Drug Life Cycles, Therapeutic Drug Markets and Regulatory Frameworks*, 12 PLOS ONE 2 (Aug. 16, 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559086/pdf/pone.0182613.pdf> [<https://perma.cc/2GXQ-RGTE>] (discussing the need for pharmaceutical “regulatory reform to curtail prices and safeguard equitable access to innovative medicines”); David Ferry, *The New War on (Overpriced) Drugs*, WIRED (June 10, 2017, 10:06 AM), <https://www.wired.com/story/fighting-high-drug-prices/> [<https://perma.cc/S9MX-7CKN>] (analyzing the conflict between drug pricing stakeholders); Carolyn Y. Johnson, *Pharma, Under Attack for Drug Prices, Started an Industry War*, WASH. POST (Jan. 2, 2018), https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html?utm_term=.7e3efc2d94f7 [<https://perma.cc/3T3G-FGNA>] (analyzing public outcry, academic analysis, political concerns, and the battle between insurers and drug companies).

4. Compare Donald L. Barlett & James B. Steele, *Why We Pay So Much for Drugs*, CNN (Jan. 27, 2004, 5:57PM), <http://www.cnn.com/2004/ALLPOLITICS/01/27/timep.drugs.tm/> [<https://perma.cc/E2EC-7LPA>] (chronicling public outcry amid the 2004 presidential campaign regarding high priced drugs and the cozy relationship between the FDA and pharmaceutical companies), and Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1995 (Nov. 15, 2007), <http://www.nejm.org/doi/pdf/10.1056/NEJMp078193> [<https://perma.cc/D96W-JWCS>] (discussing tactics pharmaceutical companies engage in when subverting public policy goals of lower prices), with Ferry, *supra* note 3 (analyzing the modern conflict between drug pricing stakeholders), and Jill Disis, *Lawmakers Say EpiPen Hikes Made Executives ‘Filthy Rich’*, CNN MONEY (Sept. 22, 2016, 8:22 AM), <http://money.cnn.com/2016/09/21/news/companies/mylan-epipen-house-oversight-committee/> [<https://perma.cc/8KFH-QX8V>] (chronicling the ongoing public policy battle for cheaper drugs between pharmaceutical companies and lawmakers).

5. See, e.g., Andrew Pollack, *Big Price Increase for Tuberculosis Drug is Rescinded*, N.Y. TIMES (Sept. 21, 2015), <https://www.nytimes.com/2015/09/22/>

compliance officers have prepared for the confrontation for over twenty years. In this time, these officers have become vetted with unique knowledge and experience that will benefit all stakeholders. This is their Waterloo.

The article will first discuss the pattern of prescription drug price increases from major pharmaceutical companies, the complexities of prescription drug pricing, and political responses to recent major cases involving drug pricing.⁶ This is followed by a review of legislative solutions aimed to fix prescription drug price increases.⁷ Finally, the article concludes by recommending tools that compliance officers can use to help regulate the price of pharmaceutical drugs.⁸

II. HOW DID IT GET THIS BAD?

As with most issues, the current drug pricing situation did not occur overnight. Rather, it progressed over many years.⁹ For example, since 2013, the prices of many generic drugs rose sharply; in some cases by as much as 600% to 1,000%.¹⁰ Over much of the past two decades, opinion polls and surveys have consistently shown that pharmaceutical companies are held in low esteem, on par with oil and gas companies.¹¹ The perceived arrogance of the industry has

business/big-price-increase-for-tb-drug-is-rescinded.html [https://perma.cc/Y4GS-M4NP] (documenting public outcry causing a change in pricing by a pharmaceutical company). *But see* Max Nisen, Opinion, *Why Pharma May Not Fear the Latest Drug-Price Probe*, BLOOMBERG GADFLY (Aug. 18, 2017, 10:03 AM), <https://www.bloomberg.com/gadfly/articles/2017-08-18/biogen-and-pharma-may-not-fear-multiple-sclerosis-drug-price-probe> [https://perma.cc/573Z-8EA7] (arguing that public outcry will not change the pharmaceutical industry's pricing practices).

6. See discussion *infra* Section II.

7. See discussion *infra* Section III.

8. See discussion *infra* Section IV.

9. See generally Alex Kacik, *Drug Prices Rise as Pharma Profit Soars*, MOD. HEALTHCARE (Dec. 28, 2017), <http://www.modernhealthcare.com/article/20171228/NEWS/171229930> [https://perma.cc/FT7P-7F6M] (detailing the rise of prescription drug prices).

10. See *Generic Drug Price Spikes Demand Congressional Hearing, Pharmacists Say*, NCPA (Jan. 8, 2014), <http://www.ncpanet.org/newsroom/news-releases-2017/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say> [https://perma.cc/L4M3-3C4S] (citing a survey of members).

11. See, e.g., Jim Norman, *Americans' Views of Pharmaceutical Industry Take a Turn*, GALLUP (Sept. 14, 2015), http://www.gallup.com/poll/185432/americans-views-pharmaceutical-industry-tumble.aspx?g_source=pharmaceutical+industry&g_

only served to strengthen the negative perceptions.¹² When coupled with rising healthcare costs that many people attribute to high drug prices,¹³ the result is a rallying cry that American politicians find irresistible.¹⁴ “A greater degree of government oversight is needed to defend public health” because the pharmaceutical industry is “controlled by economic managers who regard medicine simply as a business and who ignore human needs and responsibilities.”¹⁵

medium=search&g_campaign=tiles [https://perma.cc/XF9E-667T].

12. See, e.g., JAGDISH N. SHETH, *THE SELF-DESTRUCTIVE HABITS OF GOOD COMPANIES: ...AND HOW TO BREAK THEM* (Wharton Sch. Publ'g ed., 1st ed. 2007) (discussing Merck); Brian Mahany, *Big Pharma and Corporate Arrogance—Baxter International*, MAHANY L. (Apr. 22, 2015), https://www.mahanyertl.com/2015/big-pharma-corporate-arrogance/ [https://perma.cc/U4F8-4RKE] (discussing Baxter International and the 2007 heparin scandal that ended in tragedy).

13. See, e.g., Blaire Briody, *Medicaid's Ticking Bomb Could Wipe Out State Budgets*, FISCAL TIMES (June 23, 2010), http://www.thefiscaltimes.com/Articles/2010/06/23/Medicaid-Ticking-Time-Bomb-Could-Wipe-Out-State-Budgets [https://perma.cc/JQ2E-WPBD] (“Medicaid costs as a percentage of state budgets will nearly double by 2030, from the current 20 percent to 35 percent in some states.”); Norman, *supra* note 11 (“[Seventy-three percent] of Americans said they considered the high cost of prescription drugs an important reason for rising healthcare costs.”).

14. See Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 680 (2011).

“Catastrophes are probably the most important catalysts of new regulation.” Legislators in our media-oriented world “transform individual acts of malfeasance into social problems requiring society-wide solutions.” Legislators write prohibitory legislation, which places them “on the side of the angels without having to vote for higher taxes.” Once regulatory bureaucracies are established, their growth is determined in part by failure of current policy, and in part by new risks and new situations that develop. Noteworthy events spark that growth, including “scandals that expose presumptive laxity, corruption, or incompetency in the regulatory agency.”

EUGENE BARDACH & ROBERT A. KAGAN, *GOING BY THE BOOK: THE PROBLEM OF REGULATORY UNREASONABLENESS* 23 (Transaction Pubs. 2d prtg. 2003).

15. See Lawrence Grouse, *Physicians for Sale: How Medical Professional Organizations Exploit Their Members*, 10 MEDSCAPE J. MED. 169 (2008); see also Timothy S. Jost, *Oversight of Marketing Relationships Between Physicians and the Drug and Device Industry: A Comparative Study*, 36 AM. J. L. & MED. 326, 330 (2010), (describing the “troubling relationships between [drug and medical device] manufacturers and [medical] professionals” through a business marketing framework).

A. *Pattern of Prescription Drug Price Increases*

A pattern of price increases can be seen across the pharmaceutical industry. For example, the drug Daranide was originally approved in 1958 to treat glaucoma and is now used to treat a rare illness called periodic paralysis.¹⁶ Over the past seventeen years, the price of the drug has ranged from \$0 to more than \$13,000 for 100 pills.¹⁷

The behavior of some pharmaceutical companies and their executives demonstrates the pricing problem.¹⁸ For example, former hedge fund manager Martin Shkreli organized Turing Pharmaceuticals (“Turing”) with the specific purpose to acquire and raise the price of older drugs.¹⁹ In late August 2015, Turing procured the drug Daraprim from Impax Pharmaceuticals for \$55 million and raised the price of the drug from \$13.50 to \$750—a 5,455% increase.²⁰ In the midst of the outrage over Turing’s actions, Shkreli declared that the drug was priced where the company “could make a comfortable profit,” and “that he had no plans to

16. Carolyn Y. Johnson, *At One Time This Drug Was Free. Now, 100 Pills Are \$15,000*, WASH. POST (Dec. 19, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/12/18/this-old-drug-was-free-now-its-109500-a-year/?utm_term=.2b98ff1d946d [<https://perma.cc/56MJ-5K43>].

17. *Id.*

18. See, e.g., James Hamblin, *Pharma Bro Is the Face of U.S. Health Care*, ATLANTIC (Sept. 23, 2015), <https://www.theatlantic.com/health/archive/2015/09/martin-shkreli-in-the-mirror/406888/> [<https://perma.cc/B7X8-K2BF>]; Matthew Herper, *Why Did that Drug Price Increase 6,000%? It's the Law*, FORBES (Feb. 10, 2017, 1:52 PM), <https://www.forbes.com/sites/matthewherper/2017/02/10/a-6000-price-hike-should-give-drug-companies-a-disgusting-sense-of-deja-vu/#5d4997e471f5> [<https://perma.cc/SH27-GBYJ>]; Carolyn Y. Johnson, *This Old Drug Was Free. Now It's \$109,500 a Year*, WASH. POST (Dec. 18, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/12/18/this-old-drug-was-free-now-its-109500-a-year/?utm_term=.1cc1a947d580 [<https://perma.cc/E82D-CD8B>]; Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone Is Missing the Point*, NEW YORKER (Feb. 5, 2016), <https://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point> [<https://perma.cc/893E-JZ6G>].

19. See Laura Lorezetti, *This 62-Year-Old Drug Just Got 5,000% More Expensive*, FORTUNE (Sept. 21, 2015), <http://fortune.com/2015/09/21/turing-pharmaceuticals-drug-prices-daraprim/> [<https://perma.cc/35N5-8KTU>]; Luke Timmerman, *A Timeline of the Turing Pharma Controversy*, FORBES (Sept. 23, 2015), <https://www.forbes.com/sites/luketimmerman/2015/09/23/a-timeline-of-the-turing-pharma-controversy/#44a84d72771d> [<https://perma.cc/HXH9-UNVU>].

20. See Lorezetti, *supra* note 19; see also Timmerman, *supra* note 19.

lower [the price].”²¹ Simultaneously, Hillary Clinton tweeted from the campaign trail that, “[p]rice gouging like this in the specialty drug market is outrageous. Tomorrow, I’ll lay out a plan to take it on.”²²

The public backlash caught the attention of Valeant Pharmaceuticals and its CEO Mike Pearson, who pursued a quiet strategy similar to Turing.²³ Pearson’s plan leveraged the company to purchase small but established drug makers.²⁴ He raised prices and slashed non-essential components, including research and development.²⁵ After the Clinton tweet, Valeant shares fell in value by 20%.²⁶ During the subsequent months, information surfaced about the misstatement of financial results and Valeant’s uniquely cozy arrangement with specialty pharmacy, Philidor,²⁷ which led to allegations that the company’s real success resulted from a combination of price gouging, a secret network of specialty pharmacies, and fraud.²⁸ These accusations sent Valeant stock into a free fall and caused Pearson’s

21. Interview by Meg Tirrell with Martin Shkreli, CEO, Turing Pharms., CNBC (Sept. 21, 2017), <https://www.cnbc.com/video/2015/09/21/turing-ceo-drug-priced-where-we-could-make-comfortable-profit.html> [<https://perma.cc/6JLV-7B9R>].

22. See Matt Egan, *Hillary Clinton Tweet Crushes Biotech Stocks*, CNN MONEY (Sept. 21, 2017), <http://money.cnn.com/2015/09/21/investing/hillary-clinton-biotech-price-gouging/?iid=EL> [<https://perma.cc/8CZG-KS2D>].

23. See Lydia Ramsey & Andy Kiersz, *Here’s Former Stock Market Darling Valeant Crashing in One Chart*, BUS. INSIDER (Nov. 13, 2015, 9:24 AM), <http://www.businessinsider.com/why-have-valeant-pharmaceuticals-shares-collapsed-2015-11> [<https://perma.cc/MG2Q-KYDW>]; Ed Silverman & Jonathan Rockoff, *Pharmaceutical Companies Buy Rivals’ Drugs, Then Jack Up the Prices*, WALL STREET J. (Apr. 26, 2015), <https://www.wsj.com/articles/pharmaceutical-companies-buy-rivals-drugs-then-jack-up-the-prices-1430096431> [<https://perma.cc/7R6K-D3WM>].

24. See Silverman & Rockoff, *supra* note 23.

25. *Id.*

26. *Id.*

27. Bob Bryan & Linette Lopez, *The Disastrous Valeant Document Everyone’s Been Waiting for is Finally Here*, BUS. INSIDER (Apr. 29, 2016, 7:42 AM), <http://www.businessinsider.com/valeants-annual-report-is-finally-out-2016-4> [<https://perma.cc/PQ57-MJEK>].

28. See Kaitlin Wildoner, *Valeant and Philidor Controversy Comes to a Head*, 3.2 LIFE SCI. COMPLIANCE UPDATE 16–19 (2017).

resignation.²⁹ Between August 2015 and January 2016, the company's value declined by 29.6%.³⁰

The cascading events began for Mylan Pharmaceuticals (“Mylan”) in 2016, when it raised the price of the EpiPen from about \$103.50 to \$608.61.³¹ Facing a tidal wave of criticism, Mylan pivoted and announced the launch of a generic EpiPen that cost half the branded product price, but still three times the 2009 price.³² In response, Sarah Jessica Parker resigned as the company's spokesperson and stated she was “disappointed, saddened and deeply concerned by Mylan's actions.”³³ The New York Attorney General evinced its concern by launching an antitrust investigation, and Congress called for hearings to consider Mylan's actions regarding the EpiPen.³⁴ Even Martin Shkreli weighed in, saying

29. *Id.*

30. Brian Feroldi, *Why Valeant Pharmaceuticals Intl. Inc. Crashed in 2015*, MOTLEYFOOL.COM (Jan. 8, 2016, 4:59 PM), <https://www.fool.com/investing/general/2016/01/08/why-valeant-pharmaceuticl-crashed-in-2015.aspx> [https://perm a.cc/VXG2-RLZ9].

31. *Mylan CEO on EpiPen Drug Price Controversy: “I get the Outrage,”* CBS NEWS (Jan. 27, 2017, 6:54 AM), <https://www.cbsnews.com/news/epipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out/> [https://perma.cc/GK7H-HUXS]; see also Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG BUSINESSWEEK (Sept. 23, 2015, 9:00 AM), <https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-th-e-epipen-into-a-billion-dollar-business> [https://perma.cc/W32L-WEKM] (stating how Mylan's marketing and lobbying efforts facilitated EpiPen price increases).

32. Press Release, Mylan, *Mylan Launches the First Generic for EpiPen (epinephrine injection, USP) Auto-Injector as an Authorized Generic* (Dec. 16, 2016), <http://newsroom.mylan.com/2016-12-16-Mylan-Launches-the-First-Generic-for-EpiPen-epinephrine-injection-USP-Auto-Injector-as-an-Authorized-Generic> [https://perma.cc/TS9E-JSGM]; see also Charles Duhigg, *Outcry Over EpiPen Prices Hasn't Made Them Lower*, N.Y. TIMES (June 4, 2017), <https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html> [https://perma.cc/9C5S-QHNG] (explaining that the price of the generic version was still \$370).

33. See Jenna Amatulli, *Sarah Jessica Parker Ends Mylan Partnership Over EpiPen Price Hike*, HUFFINGTON POST (Aug. 25, 2016, 12:53 PM), http://www.huffingtonpost.com/entry/sarah-jessica-parker-ends-relationship-with-mylan-after-epipen-price-hike_us_57bf0730e4b02673444eb374 [https://perma.cc/HH5Q-RU7X].

34. Press Release, N.Y. State Office of the Attorney Gen., A.G. Schneiderman *Launches Antitrust Investigation into Mylan Pharmaceuticals Inc., Maker of EpiPen* (Sept. 6, 2016), <http://www.ag.ny.gov/press-release/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker> [https://perma.cc/N9VL-8XJW].

“[t]hey had one product, and they finally started making a little bit of money and everyone is going crazy over it.”³⁵

Mylan also came under scrutiny for allegations that it teamed with prominent activists to have EpiPen added to the federal list of preventative medical services.³⁶ In 2016, the company contributed \$227,500 towards lobbying efforts aimed at garnering the listing.³⁷ The next year Mylan reached an agreement with the United States Department of Justice to pay \$465 million to settle a lawsuit, alleging that the company violated the False Claims Act.³⁸ Under the terms of the settlement, Mylan admitted to “knowingly misclassifying EpiPen as a generic drug to avoid paying rebates owed primarily to Medicaid.”³⁹

B. *Complications of Drug Pricing*

The pharmaceutical drug pricing system is a labyrinth of pricing mechanisms that ultimately leads to conflict. “Behind the seemingly simple act of buying a bottle of pills, a host of players—drug companies, pharmacies, insurers and pharmacy benefit managers—are taking a cut of the profits, even as consumers are left to fend for themselves, critics say.”⁴⁰ A 2016 study exposed just how complicated drug pricing is, revealing that “[a]lthough price growth for protected brands was 12.4% on an invoice price basis, net price growth is estimated to have increased 2.8% in 2015 on average.”⁴¹

35. Vinita Nair, *Ex-Pharma CEO Martin Shkreli Weighs in On Skyrocketing EpiPen Prices*, CBS NEWS (Aug 23, 2016), <http://www.cbsnews.com/news/ex-pharma-ceo-martin-shkreli-weighs-in-on-skyrocketing-epipen-prices/> [https://perma.cc/8J4P-UMBP].

36. Eric Lipton & Rachel Abrams, *EpiPen Maker Lobbies to Shift High Costs to Others*, N.Y. TIMES (Sept. 16, 2016).

37. *Id.* In 2016, Mylan made a total of \$1.8 million in total donations. *Id.*

38. Press Release, Dep’t of Justice Office of Pub. Affairs, Mylan Agrees to Pay \$465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates (Aug. 17, 2017), <https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates> [https://perma.cc/MY73-LP]6].

39. *Id.*

40. Charles Ornstein & Katie Thomas, *When Buying Prescription Drugs, Some Pay More with Insurance Than Without It*, PROPUBLICA (Dec. 9, 2017, 12:01 PM), <https://www.propublica.org/article/when-buying-prescription-drugs-some-pay-more-with-insurance-than-without-it> [https://perma.cc/LBX5-CWJH].

41. See IMS INST. FOR INFORMATICS, MEDICINES USE & SPENDING IN THE U.S.: A REVIEW OF 2015 & OUTLOOK TO 2020, 8 (2016), <https://morningconsult.com/wp->

Moreover, the study noted that the invoice versus net price spread “reflects higher levels of off-invoice discounts, price protection, rebates and price concessions since 2013.”⁴²

A recent study from the National Academies of Sciences, Engineering, and Medicine makes similar observations on the complexities of drug pricing.⁴³ The consensus report concluded that “[t]he relevant data needed to conclusively analyze this system do not exist at present, and, . . . some of the participants . . . argue that revealing their transactions would actually increase the drug prices paid by patients.”⁴⁴ As a result, each side blames the other.

C. Political Responses

The Turing, Valeant, and Mylan cases have generated a predictable backlash and a flurry of activity by politicians. In 2017, United States Senators started pressing the Government Accountability Office (GAO) to investigate potential abuses of the Orphan Drug Act,⁴⁵ and President Trump demanded that the “artificially high price of drugs” be brought down “immediately.”⁴⁶ In both the House and Senate, Democrats presented the Improving Access to Affordable Prescription Drugs Act, but the bills have yet to progress out of committee.⁴⁷

content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf [https://perma.cc/WW3X-Z8GL].

42. *Id.*

43. NAT’L ACAD. OF SCI., ENGINEERING, & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 62 (Norman R. Augustine, Guru Madhavan, & Sharyl J. Nass, eds., 2017) [hereinafter MAKING MEDICINES AFFORDABLE].

44. *Id.* at 60. *Contra* Ornstein & Thomas, *supra* note 40 (“[P]eople are shocked to discover they can sometimes get better deals than their own insurers.”).

45. Sarah Jane Tribble & Sydney Lupkin, *Three Key Senators Ask GAO to Investigate Possible Abuses of the Orphan Drug Act*, KAISER HEALTH NEWS (Mar. 7, 2017), <http://khn.org/news/three-key-senators-ask-gao-to-investigate-possible-abuses-of-the-orphan-drug-act/>. [https://perma.cc/3ZBZ-WUUF]. The GAO is an independent agency under the United States Congress.

46. 163 CONG. REC. H1388 (Feb. 28, 2017) (message of President Trump), <https://www.govinfo.gov/content/pkg/CREC-2017-02-28/pdf/CREC-2017-02-28-pt1-PgH1386-3.pdf> [https://perma.cc/XGT4-S687]; *see also* Thomas Sullivan, *President Trump Meets with Democrats on Drug Prices*, POL’Y & MED. (Apr. 13, 2017, 5:05 AM), <http://www.policymed.com/2017/04/president-trump-meets-with-democrats-on-drug-prices.html> [https://perma.cc/WN6A-JZJ6] (discussing the meeting between President Trump, several Democratic lawmakers, HHS Secretary Tom Price, and others regarding rising drug prices).

47. Improving Access to Affordable Prescription Drugs Act, H.R. 1776, 115th

In 2018, the debate continues as pharmaceutical companies forge ahead, increasing the costs of drugs.⁴⁸ Examples of the ongoing pricing behavior include Allergan PLC's attempt to transfer a patent to the Saint Regis Mohawk tribe (to take advantage of the group's status as a sovereign nation),⁴⁹ and Avondale Pharmaceutical's 800% price hike for a daily vitamin.⁵⁰ In reaction to the increases, states such as California, Louisiana, New York, and Nevada have successfully enacted price transparency laws, while Maryland has enacted an anti-price gouging law with a cost disclosure component.⁵¹ With the exception of Louisiana and New York, the industry's trade groups continue to lobby against these regulatory measures.⁵² One recent success for the lobbyists include

Cong. (2017); Improving Access to Affordable Prescription Drugs Act, S. 771, 115th Cong. (2017); Zachary Brennan, *Democrats Propose Wide-Ranging Bill to Lower Drug Costs*, RAPS (Mar. 30, 2017), <http://www.raps.org/Regulatory-Focus/News/2017/03/30/27223/Democrats-Propose-Wide-Ranging-Bill-to-Lower-Drug-Costs/#sthash.xT7h7S3e.dpuf>. [https://perma.cc/4JHH-DN37].

48. Katie Thomas & Reed Abelson, *Lower Drug Prices: New Proposals Carry Lots of Promises*, N.Y. TIMES (Feb. 9, 2018), <https://www.nytimes.com/2018/02/09/health/trump-drug-prices-medicare.html> [https://perma.cc/SF82-CQMA].

49. Joe Mullin, *Judge Throws Out Allergan Patent, Slams Company's Native American Deal*, ARS TECHNICA (Oct. 16, 2017, 7:16 PM), <https://arstechnica.com/tech-policy/2017/10/judge-throws-out-allergan-patent-slams-companys-native-american-deal/> [https://perma.cc/AB4G-73VV]; Meg Tirrell, *More Scrutiny for Allergan Over Native American Tribe Deal*, CNBC (Oct. 2, 2017, 7:35 PM), <https://www.cnn.com/2017/10/02/more-scrutiny-for-allergan-over-native-american-tribe-deal.html> [https://perma.cc/U2X9-48TF].

50. Jennings Brown, *A Pharma Company Raised the Price of a Daily Vitamin by 800 Percent*, GIZMODO (Dec. 12, 2017, 12:15 PM), <https://gizmodo.com/a-pharma-company-raised-the-price-of-a-daily-vitamin-by-1821217649> [https://perma.cc/EN9P-L4VT].

51. See 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/> [https://perma.cc/56PD-EBNF].

52. See Alan M. Kirschenbaum & David C. Gibbons, *Another State Drug Pricing Law . . . Another Legal Challenge; Trade Group Sues California in Latest Lawsuit Against Drug Pricing Transparency Bill*, FDA L. BLOG (Dec. 17, 2017), <http://www.fdalawblog.net/2017/12/another-state-drug-pricing-law-another-legal-challenge-trade-group-sues-california-in-latest-lawsuit-against-drug-pricing-transparency-bill/> [https://perma.cc/P9LN-BPA4]; Stephen Bartlett, *Trade Organizations Challenge Nevada's Drug Price Transparency Law*, DRUG PRICING POL'Y WATCH (Sept. 19, 2017), <http://www.drugpricingpolicywatch.com/2017/09/19/trade-organizations-challenge-nevadas-drug-price-transparency-law/> [https://perma.cc/7DAK-2QXS]; Erin Cox, *Drug Firms Challenge Maryland Price-Gouging Law*, BALTIMORE SUN (July 6, 2017, 8:16

the defeat of a Ohio ballot measure designed to allow the state to renegotiate drug prices.⁵³ Nevertheless, legislatures are beginning to enact measures to increase drug pricing transparency that will likely reveal that pricing decisions are neither rational nor methodical. Further, the United States Senate hearings on Gilead's pricing decision for Solvadi have already provided a glimpse behind the curtain.⁵⁴ Similar legislative efforts will likely continue to expose pricing methods contrary to public policy, which will leave the pharmaceutical manufacturers fighting a rearguard action against a tidal wave of regulatory efforts. Ultimately, the legislators, payers, and public will prevail in their effort to stabilize and reduce the price of prescription drugs.

III. THE APPROACH OF THE STATES AND LOCALITIES

A. *The Advocates Behind a Legislative Solution*

“86% of Americans support actions requiring drug companies to release information to the public on the process of setting drug prices”⁵⁵

PM), <http://www.baltimoresun.com/news/maryland/politics/bs-md-price-gouging-suit-20170706-story.html> [<https://perma.cc/G35K-E7SH>]; Kevin Schweers, *MYTH/FACT on PBM Arguments Against Bipartisan MAC Legislation*, NAT'L COMMUNITY PHARMACISTS ASS'N: THE DOSE (Mar. 13, 2017), <http://www.ncpanet.org/newsroom/ncpa's-blog—the-dose/2017/03/13/myth-fact-on-pbm-arguments-against-bipartisan-mac-legislation> [<https://perma.cc/83MB-J8XH>].

53. See *Drug Companies Spend \$57M to Defeat Ohio Ballot Issue*, U.S. NEWS (Dec. 16, 2017, 2:26 PM), <https://www.usnews.com/news/best-states/ohio/articles/2017-12-16/drug-companies-spend-57m-to-defeat-ohio-ballot-issue> [<https://perma.cc/HDH7-FKCB>]; Casey Ross, *Ohio Voters Reject Measure to Rein in Drug Costs*, STAT (Nov. 7, 2017), <https://www.statnews.com/2017/11/07/ohio-drug-costs-ballot/> [<https://perma.cc/3DXV-8HNC>].

54. See generally S. COMM. ON FIN., 114TH CONG., *THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTHCARE SYSTEM* (Comm. Print 2015) (discussing the negative impacts of Sovaldi's pricing decisions).

55. See Aaron Berman et al., *Curbing Unfair Drug Prices: A Primer for States*, GLOBAL HEALTH JUST. PARTNERSHIP OF THE YALE L. SCH. & YALE SCH. PUB. HEALTH 1, 7 (2017), https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf [<https://perma.cc/9YUR-9Z4N>] (citing Ashley Kirzinger et al., *Kaiser Health Tracking Poll—Late April 2017: The Future of the ACA and Health Care & the Budget - Rx Drugs*, THE HENRY J. KAISER FAM. FOUND. (2017)), <https://www.kff.org/report-section/kaiser-health-tracking-poll-late-april-2017-the-future-of-the-aca-and-health-care-the-budget-rx-drugs/> [<https://perma.cc/YS97-4AAF>]).

While there has been inaction at the federal level, there is a myriad of local initiatives and highly influential advocacy groups calling for transparency in drug pricing.⁵⁶ This landscape includes some of the “most powerful trade organizations,”⁵⁷ spending near record amounts to affect change amidst a multitude of failing state legislative bills,⁵⁸ and new requirements that increase compliance risks at both the state and local level.⁵⁹

The National Coalition on Health Care (NCHC)⁶⁰ and the Campaign for Sustainable Rx Pricing (CSRxP) are examples of affiliations that have provided aid to state legislatures with the goal of increasing transparency.⁶¹ The CSRxP is a “nonpartisan coalition of organizations informing the debate on drug pricing and finding bipartisan, market-based solutions to lower drug prices in the U.S.”⁶² The CSRxP is not alone in its efforts with patient advocacy groups,

56. See generally *Prescription Drug State Database*, NAT'L CONF. ST. LEGISLATURES, <http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx> [https://perma.cc/QF87-PXW7] (last visited July 31, 2018) (discussing current initiatives for drug pricing transparency).

57. Jay Hancock, *Drug Industry Spent Millions to Squelch Talk About High Drug Prices*, KAISER HEALTH NEWS (Dec. 19, 2017), <https://khn.org/news/drug-industry-spent-millions-to-squelch-talk-about-high-drug-prices/> [https://perma.cc/RVT7-H9UZ]. For example, Research and Manufacturers of America (PhRMA) is “one of the most powerful trade organizations in any industry” and is spending near record amounts on lobbying efforts. *Id.*

58. See Nicodemo Fiorentino, *Whack a Mole Pricing Bills Keep Popping Up Everywhere*, 3.5 LIFE SCI. COMPLIANCE UPDATE 1, 2 (2017).

59. See, e.g., Thomas Sullivan, *Chicago Proposes Drug Pricing Transparency Ordinance*, POL'Y & MED. (Sept. 1, 2017), <http://www.policymed.com/2017/09/chicago-proposes-drug-pricing-transparency-ordinance.html> [https://perma.cc/W5XV-8UK6] (explaining a new drug pricing transparency ordinance and how, “if enacted, the proposal will likely have an effect on the bottom line of pharmaceutical companies”).

60. *About Us*, NCHC, <http://www.nchc.org/> [https://perma.cc/Y7U4-99X5] (last visited July 31, 2018) (defining NCHC as a “nonpartisan, nonprofit organization of organizations” that “represents more than 80 participating organizations, including medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers, and groups representing consumers, patients, women, minorities and persons with disabilities”).

61. *The Campaign*, CSRxP, <http://www.csrpx.org/about-the-campaign/> [https://perma.cc/26P2-TCLE] (last visited July 31, 2018).

62. *Our Mission*, CSRxP, <http://www.csrpx.org/about-the-campaign/> [https://perma.cc/26P2-TCLE] (last visited July 31, 2018); *Who We Are*, CSRxP, <http://www.csrpx.org/about-the-campaign/> [https://perma.cc/26P2-TCLE] (last visited July 31, 2018).

such as Patients for Affordable Drugs,⁶³ also lobbying legislatures for the same goal.⁶⁴ As an example of recent success, Maryland’s consumer advocacy group, Maryland Citizens’ Health Initiative and its Health Care for All! Coalition⁶⁵ actively contributed to Maryland enacting the first price gouging law in the nation.⁶⁶

Another highly influential group is the National Academy for State Health Policy (NASHP), which is an “independent academy of state health policymakers.”⁶⁷ Through its Pharmacy Costs Work Group (PCWG), NASHP is comprised “of state leaders from governors’ staffs, state legislatures, Medicaid, public employees’ health insurance programs, offices of attorney generals, state-based insurance exchanges, comptrollers’ offices and corrections departments.”⁶⁸ Funded by the Laura and John Arnold Foundation and Kaiser Permanente,⁶⁹ the PCWG began its task of “look[ing]

63. *About Us*, PATIENTS FOR AFFORDABLE DRUGS, <https://www.patientsforaffordabledrugs.org/about/> [https://perma.cc/4266-E3AM] (last visited July 31, 2018).

64. *Solutions*, PATIENTS FOR AFFORDABLE DRUGS, <https://www.patientsforaffordabledrugs.org/solutions/> [https://perma.cc/G87Z-7UE5] (last visited July 31, 2018).

65. *About*, HEALTH CARE FOR ALL, <http://healthcareforall.com/about/> [https://perma.cc/4HKT-THGK] (last visited July 31, 2018).

66. Len Lucchi, *How the Drug Industry Blew it in Md.*, BALTIMORE SUN (June 27, 2017, 10:40 A.M.), <http://www.baltimoresun.com/news/opinion/oped/bs-ed-op-0628-drug-industry-md-20170627-story.html> [https://perma.cc/C9EL-7NNS].

67. *About NASHP*, NASHP, <https://nashp.org/about-nashp/> [https://perma.cc/3SVB-RNSN] (last visited July 31, 2018).

68. Pharmacy Costs Work Group, *States and the Rising Cost of Pharmaceuticals: A Call to Action*, NASHP 1, 4 (Oct. 2016), <https://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf>. [https://perma.cc/P9AR-4GVD]; see also Trish Riley, *NASHP Announces Pharmacy Costs Work Group*, NASHP (May 10, 2016), <https://nashp.org/nashp-announces-pharmacy-costs-work-group/> [https://perma.cc/EFL2-K75V].

69. *Center for State Rx Drug Pricing*, NASHP, <https://nashp.org/center-for-state-drug-rx-pricing/> [https://perma.cc/6J6M-GXP8] (last visited July 31, 2018); Riley, *supra* note 68. The Laura and John Arnold Foundation also provided funds to NASHP to establish the Center for State Drug Price Action. Press Release, Laura & John Arnold Found., *Laura and John Arnold Found. Announces \$7.2 Million in Grants to Address the Rising Cost of Pharm. Drugs* (Feb. 17, 2016), <http://www.arnoldfoundation.org/laura-and-john-arnold-foundation-announces-7-2-million-in-grants-to-address-the-rising-cost-of-pharmaceutical-drugs/> [https://perma.cc/AX2 Z-WJ39] (providing additional information related to other grants the foundation has given “for research and pilot projects aimed at addressing the rising cost of pharmaceutical drugs and reducing the financial barriers that can make it difficult to obtain life-saving treatments”). With the support of the Laura and John Arnold Foundation, NASHP has also awarded grants of its own to

beyond the strategies currently used in states to identify and develop new ideas which address the growing problem of Rx costs.⁷⁰ In October 2016, the PCWG issued a call to action to “[i]ncrease price transparency to create public visibility and accountability.”⁷¹ Part of this strategy included the following types of disclosure:

- (1) Drug development cost reporting, requiring justification of price increases;
- (2) Public disclosure of price discounts and rebates to states; and
- (3) Confidential disclosure of price discounts and rebates to states.⁷²

With PCWG’s guidance, NASHP developed a model transparency bill blueprint for states that would require manufacturers to disclose how a drug is priced and publish price justification documents obtained from manufacturers.⁷³

In August 2017, the Yale Global Health Justice Partnership (GHJP),⁷⁴ in collaboration with the National Physicians Alliance (NPA)⁷⁵ and the Universal Health Care Foundation of

Colorado, Delaware, and Oklahoma to enable the states to study ways to address prescription drug pricing practices. Jennifer Reck, *NASHP Awards Grants to Colorado, Delaware, and Oklahoma to Tackle Rising Rx Drug Prices*, NASHP (Oct. 10, 2017), <https://nashp.org/nashp-awards-grants-to-colorado-delaware-and-oklahoma-to-tackle-rising-rx-drug-prices/> [<https://perma.cc/ARJ5-FYE3>].

70. Riley, *supra* note 68.

71. Pharmacy Costs Work Group, *State Leaders Offer Solutions to Address Rapid Increase in Prescription Drug Spending*, NASHP (Oct. 18, 2016), <https://nashp.org/state-leaders-offer-solutions-to-address-rapid-increase-in-prescription-drug-spending/> [<https://perma.cc/X5TF-NVD4>].

72. *Id.*

73. Jane Horvath et al., *NASHP Releases Model Rx Transparency Legislation*, NASHP (Mar. 7, 2017), <https://nashp.org/nashp-releases-model-rx-transparency-legislation/> [<https://perma.cc/TR2L-RZ44>]; see also *An Act to Promote Prescription Drug Price Transparency and Cost Control*, NASHP, <https://nashp.org/wp-content/uploads/2017/03/Transparency-Model-Legislation.pdf> [<https://perma.cc/272J-FQF3>] (last visited July 31, 2018).

74. *About Us*, GHJP, <https://law.yale.edu/ghjp> [<https://perma.cc/N8H9-DDK4>] (last visited July 31, 2018) (describing GHJP as “a program hosted jointly by Yale Law School (YLS) and Yale School of Public Health (YSPH) that tackles contemporary problems at the interface of global health, human rights, and social justice”).

75. *About*, NPA, <http://npalliance.org/about/> [<https://perma.cc/77E6-YFY3>] (last visited July 31, 2018) (describing NPA as “a non-partisan, non-profit organization” that “creates research and education programs that promote health and foster active engagement of physicians with their communities to achieve high

Connecticut,⁷⁶ joined in the transparency effort with a white paper entitled “Curbing Unfair Drug Prices: A Primer for States,” which provides various strategies for state legislatures to “rein in prescription drug prices.”⁷⁷ Two of these strategies are for states to “pass laws that address unfair launch prices and price increases” and “pass legislation that mandates public release of as much information as possible about drug prices and development, manufacturing, and marketing costs on a drug-by-drug basis.”⁷⁸

Many of these advocacy groups appear to be centered on the same reasoning—“[o]perating with transparency sends a message that there’s nothing to hide.”⁷⁹ Several of these entities also argue that a lack of transparency ultimately permits market participants such as pharmacy benefit managers (“PBMs”) to engage in anticompetitive behavior,⁸⁰ such as kickbacks from drug manufacturers in exchange for exclusivity arrangements (that allegedly keep less expensive drugs off the market), as well as securing preferential rebates that are not passed on to patients.⁸¹

quality, affordable health care for all”).

76. *About Us*, UNIVERSAL HEALTH CARE FOUND. OF CONN., <http://www.universalhealthct.org/en/aboutus> [https://perma.cc/4KAL-SZX9] (last visited July 31, 2018) (describing the foundation as “a 501(c)(3) research, development and education organization dedicated to assuring that the health care needs of all Connecticut residents are met”).

77. *New GHJP Report Examines Curbing Unfair Drug Prices*, YALE L. SCH. (Aug. 8, 2017), <https://law.yale.edu/yls-today/news/new-ghjp-report-examines-curbing-unfair-drug-prices> [https://perma.cc/V3S4-389U].

78. Berman et al., *supra* note 55, at 13–14.

79. Press Release, Chuck Grassley, Iowa Senator, Grassley Works to Have Drug Company Payments Disclosed (Oct. 23, 2009), <https://www.grassley.senate.gov/news/news-releases/grassley-works-have-drug-company-payments-disclosed> [https://perma.cc/Q4DX-UVTT]. Senator Grassley (R-Iowa) is one of the chief proponents of pharmaceutical transparency and disclosure. *See, e.g.*, Press Release, Chuck Grassley, Iowa Senator, Grassley Works for Disclosure of Drug Company Payments to Medical Groups (Dec. 8, 2009), <https://www.grassley.senate.gov/news/news-releases/grassley-works-disclosure-drug-company-payments-medical-groups> [https://perma.cc/PWV6-MRZH].

80. Troy Parks, *Drug Pricing Need Transparency, Physicians Say*, AMA WIRE (Jan. 26, 2017), <https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say> [https://perma.cc/5RM8-NCKX]; *see also* *What is a PBM?*, PBM WATCH, <http://www.pbmwatch.com/> [https://perma.cc/XDU5-4DET] (last visited July 31, 2018) (providing background information about PBMs).

81. *See* MAKING MEDICINES AFFORDABLE, *supra* note 43, at 61; *Hearing on Section 408(b)(2) Regulation: PBM Compensation and Fee Disclosure*, U.S. DEP’T OF LABOR (2014) (citing testimony of David A. Balto), <https://www.dol.gov/sites/default/>

Some researchers, however, challenge the notion that transparency is an effective remedy. They contend that the premise that disclosure curbs so-called “bad behavior” is based more on the public’s negative perception of pharmaceutical companies and concerns over the mounting costs of healthcare, than on empirical research demonstrating the ability of money to change individual behavior.⁸² Other researchers contend that disclosure alone is not the answer, suggesting that “disclosure is a sham; a way of deluding ourselves that we have cleansed the problem of conflict of interest and bias.”⁸³

Many policymakers are also opposed to a transparency remedy. For example, the Federal Trade Commission has consistently expressed concern that pushing for disclosure might have the opposite effect and drive pharmaceutical prices higher.⁸⁴

files/ebsa/about-ebsa/about-us/erisa-advisory-council/ACBalto061914.pdf [https://perma.cc/AC4V-MXU8].

82. Adam Licurse et al., *The Impact of Disclosing Financial Ties in Research and Clinical Care: A Systematic Review*, 170 ARCHIVES OF INTERNAL MED. 675 (2010) (discussing the lack of data connecting “financial ties” and professional behaviors); see also Kathleen Boozang et al., *The Limits of Disclosure as a Response to Financial Conflicts of Interest in Clinical Research*, SSRN 11 (Dec. 5, 2010), <http://ssrn.com/abstract=1720564> [https://perma.cc/77EE-ZSP4].

83. See PETER SNYDER ET AL., SCIENCE AND THE MEDIA: DELGADO’S BRAVE BULLS AND THE ETHICS OF SCIENTIFIC DISCLOSURE 79, 87 (1st ed. 2009); Paula Dalley, *The Use and Misuse of Disclosure as a Regulatory System*, 34 FLA. ST. U. L. REV. 1089, 1093 (2007) (“Disclosure is a ‘soft’ form of intervention that does not directly mandate change in the underlying behavior.”).

84. Brief for Fed. Trade Comm’n as Amicus Curiae Supporting Respondent, *Mylan Pharm., Inc. v. Celgene Corp.*, Civil Action No. 2:14-CV-2094-ES-MAH (D. N.J. May 20, 2014), 2014 WL 2968348.

AB 1960’s mandated disclosure of information may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies and by raising the cost of generic substitution and clinical interchange. Any such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.

Letter from Fed. Trade Comm’n to Assembly Member Greg Aghazarian, (Sept. 7, 2004), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v04_0027.pdf [https://perma.cc/G52F-88V5].

Additional disclosure and contract responsibilities, including the imposition of a fiduciary duty on a PBM in certain of its dealings with pharmacies, are likely to increase administrative costs and legal liability

Furthermore, while transparency is the most common remedy, the states, local governments, and local watchdog groups are adopting a mixed approach—combining disclosure, enforcement, and oversight (e.g., task forces)—in an effort to achieve the desired end goal of rational drug pricing.⁸⁵

B. Explosive Growth of State and Local Legislative Initiatives

The elevation of Donald Trump to the White House, and the resulting gridlock in Washington, has made it increasingly unlikely that the federal government will take definitive action to address escalating drug prices in the near future.⁸⁶ Given the lack of action by the federal government, states and other local governments are promulgating their own rules and regulations.⁸⁷ These efforts by the

for performing the PBM's core functions. All of these legislative requirements are likely to cause the prices that PBMs charge for their services—and concomitantly, the price of pharmaceutical coverage—to rise.

Letter from Fed. Trade Comm'n to Delegate Terry G. Kilgore (Oct. 2, 2006), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-hon.terry-g.kilgore-concerning-virginia-house-bill-no.945-regulate-contractual-relationship-between-pharmacy-benefit-managers-and-both-health-benefit/v060018.pdf [<https://perma.cc/7TAE-X2SC>]; *see, e.g.*, Letter from Fed. Trade Comm'n to the Honorable Mark Formby (Mar. 22, 2011), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-letter-honorable-mark-formby-mississippi-house-representatives-concerning-mississippi/110322mississippi-pipbm.pdf [<https://perma.cc/6MLN-QNY9>]; Letter from Fed. Trade Comm'n to Senator James L. Seward (Mar. 31, 2009), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf [<https://perma.cc/AUS2-3HPZ>].

85. Berman et al., *supra* note 55, 6–8 (discussing current legislative approaches for controlling drug prices).

86. *See* Jonathan D. Rockoff & Thomas M. Burton, *Congressional Democrats Object to White House's Drug-Cost Plans*, WALL ST. J. (June 21, 2017, 6:54 PM), <https://www.wsj.com/articles/congressional-democrats-object-to-white-houses-drug-cost-plans-1498085664?mg=prod/accounts-wsj> [<https://perma.cc/E6JG-986A>]; Jonathan D. Rockoff, *Trump Administration Makes Drug and Medical-Device Companies Nervous*, WALL ST. J. (Jan. 24, 2017, 3:07 PM), <https://www.wsj.com/articles/trump-administration-makes-drug-and-medical-device-makers-nervous-1485288454> [<https://perma.cc/TH2Y-DE3M>].

87. *See* Lydia Ramsey, "More is Possible": A Bunch of States are Taking on High Drug Prices, and It Could Start Hitting Drugmaker Profits, BUS. INSIDER (June 4, 2017, 3:36 PM), <http://www.businessinsider.com/states-with-drug-pricing-transparency-bills-2017-6/#maryland-is-tackling-generic-drug-price-hikes-1> [<https://perma.cc/3D42->

states and other municipalities are not new, however, as there was substantive legislative activity on the topic of drug pricing dating back to 2015.⁸⁸ Nevertheless, both the sheer volume of legislative proposals and the increasing likelihood of passage in 2018 are new.⁸⁹

In December 2017, NASHP noted that some of the recommendations made by the National Academies were “already getting trial runs in states.”⁹⁰ Vermont, in 2016, became the first state in the nation to require price transparency reporting, while, in 2017, California, Louisiana, Maryland, New York, and Nevada signed into law their versions of pricing legislation.⁹¹ Since 2015, the number of states putting forth cost transparency legislation targeting prescription drug costs has increased over 200%.⁹² At the same time, the number of transparency bills introduced in those states exploring pricing transparency increased over 475%.⁹³ However, it

4LNM] (detailing the state laws addressing drug prices).

88. See generally RICHARD CAUCHI, 2015–2016 LEGISLATION TO REQUIRE PRESCRIPTION DRUG COST AND PRICE TRANSPARENCY (Nat’l Conference State Legislatures ed., 2016) (discussing state drug price transparency legislation from 2015–2016).

89. See Jill Wechsler, *Drug Pricing and Quality are Top Issues for 2018*, 42 PHARMACY TECH. 20, 20 (2018) (explaining upcoming medical legislation and its effect on the medical industry).

90. Jennifer Reck & Trish Riley, *Academy of Sciences Recommends Federal Strategies to Lower Rx Prices, But Some States Are Already Taking Action*, NASHP (Dec. 1, 2017), <https://nashp.org/academy-of-sciences-recommends-federal-strategies-to-lower-rx-prices-but-some-states-are-already-taking-action/> [https://perma.cc/4WA2-J664].

91. *Id.*; see also Alan M. Kirschenbaum & David C. Gibbons, *2017: A Banner Year for State Laws on Drug Pricing, Price Reporting, and Discounting*, FDA LAW BLOG (Nov. 2, 2017), <http://www.fdalawblog.net/2017/11/2017-a-banner-year-for-state-laws-on-drug-pricing-price-reporting-and-discounting/> [https://perma.cc/8ZKQ-DF6E] (providing summaries of California’s S.B. 17, Nevada’s S.B. 539, and Vermont’s S.B. 216).

92. See Fiorentino, *supra* note 58, at 2. There were two additional states that introduced cost transparency bills and five additional cost transparency bills in 2017 that were released after publication.

93. The legislation discussed below accounts for legislation targeting pharmaceutical manufacturers only. *Id.* Thus, legislation that would require pharmacy benefits managers to disclose rebates and similar type of legislation is excluded. *Id.*

is not just the volume of bills that is important, but the requirements they seek to impose on the industry.

Chart 1 - Number of States Cost Transparency Bills Introduced

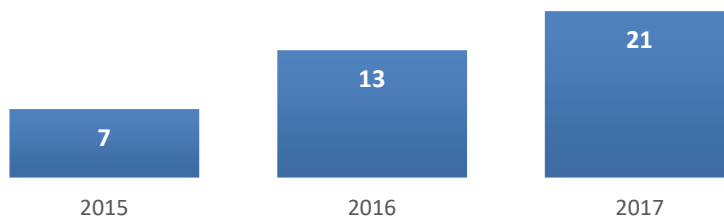
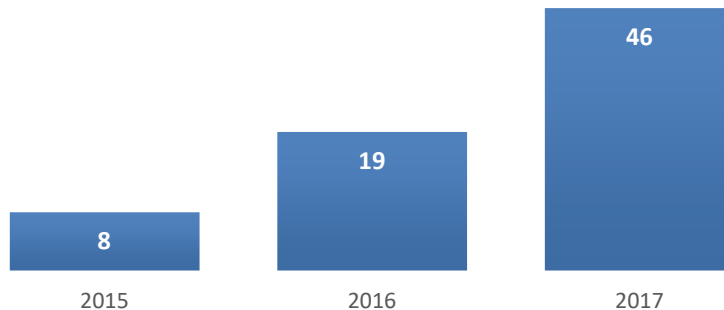


Chart 2 - Number of Congressional Cost Transparency Bills Introduced



C. The Categories of Pricing Legislation

In the last two years, the states' bills generally can be broken down into two main categories. The first is pricing transparency and the second, broadly speaking, is fair pricing (e.g., cost justification).⁹⁴ Within each of these two main categories there are

94. Berman et al., *supra* note 55, at 6–8.

several unique state variants.⁹⁵ However, all the individual state proposals seem to start with a transparency component.⁹⁶

To get even more granular, within the pure transparency legislation camp, there are three main subgroups. The first subgroup, the *Cost Reporting Bills*, would require “manufacturers to file annual reports on the cost of the drugs.”⁹⁷ “Costs” would include “research and development costs, costs of clinical trials and other regulatory costs, total costs for materials, manufacturing and administration of the drug, [and] costs associated with the drug’s acquisition.”⁹⁸ Manufacturers would also have to submit information on the “total marketing and advertising costs for the promotion of the drug directly to potential prescribers and consumers.”⁹⁹ The second subgroup of bills, the *Price Disclosure Via Advertising Bills*, “would require all manufacturers to disclose the wholesale price of their drugs in any advertisement occurring within the state.”¹⁰⁰ The third subgroup, “the *Fine Print Cost Disclosure Bills*, would require some type of disclosure, such as costly new drug notification . . . but also tack on additional requirements.”¹⁰¹ For example, the manufacturer might be responsible “for hiring independent auditors to verify the information in the report,” or additional requirements “unrelated to price, such as pharmaceutical representative licensure.”¹⁰²

In the fair pricing legislation camp, there are also three main subcategories of legislative initiatives. The first subcategory, the *Cost Increase Notification & Reporting Bills*, would require manufacturers planning to increase the costs of prescription drugs above a certain threshold to notify the state and payors (i.e., insurance companies) of a planned increase.¹⁰³ In addition, manufacturers would also need to provide “a justification report to the state and/or payors that

95. See *infra* Sections III.D–III.E.

96. See *id.*

97. Fiorentino, *supra* note 58, at 4.

98. *Id.*; see, e.g., S.B. 737, 2017 Leg., 2017 Jan. Sess. (Conn. 2017) (requiring every manufacturer of a prescription drug made available in the state to file a report regarding each such drug that contains the total cost to produce the drug).

99. Fiorentino, *supra* note 58, at 4.

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.*

includes other information relating to spend[ing] for the particular drugs.”¹⁰⁴

The second subcategory, the *WAC/AWP Reporting Bills*, “would require manufacturers with a certain increase in the drug’s [Whole Sale Acquisition Cost (“WAC”)] or [Average Wholesale Price (“AWP”)] to justify the increase and provide a cost report that includes other information relating to spending for the drug.”¹⁰⁵

The third fair pricing subcategory, the *Costly New Drug Notification & Justification Reporting Bills*, is “composed of bills that would require a manufacturer which is set to receive U.S. Food and Drug Administration approval of a drug, that will be costly, to notify the state and/or payors . . . as well as provide a justification report to[them].”¹⁰⁶

D. Vermont Leads the Way

Vermont has a strong activist-history when it comes to targeting the pharmaceutical industry with laws, ranging from its unique gift ban to its disclosure law on spending with healthcare professionals and drug samples.¹⁰⁷ Vermont’s pharmaceutical pricing legislation combines the elements of transparency with fair pricing and requires a state commission.¹⁰⁸ Under the Vermont variant, “a state entity or a commission would be responsible for creating a public list of prescription drugs, [and] require the manufacturer to report” to a state regulatory agency or commission.¹⁰⁹ The state agency or commission would also be responsible for submitting a public report to the legislature.¹¹⁰ In addition to a price-marketing disclosure law,¹¹¹ Vermont now requires cost transparency for certain “high-cost” prescription drugs.¹¹² Vermont’s Attorney General’s Office (AGO) identified manufacturers who are required to justify the cost of certain prescription drugs, which the AGO will report to the legislature by December 1 of each year.¹¹³

104. *Id.*

105. *Id.*

106. *Id.*

107. *See, e.g.*, VT. STAT. ANN. tit. 18, § 4631a (2016).

108. *See* Fiorentino, *supra* note 58, at 4–5.

109. *Id.* at 5.

110. *Id.*

111. VT. STAT. ANN. tit. 18, § 4633 (2016).

112. *Id.* § 4635.

113. *Id.* §§ 4635(c)(1), 4635(d).

E. California, Louisiana, Maryland, New York, and Nevada Follow Suit

California's Governor approved Senate Bill 17 in October 2017.¹¹⁴ The law requires manufacturers of a prescription drug with a WAC of \$40 or more for a thirty-day supply to provide written notification at least sixty days prior to any price increase to state purchasers, health plans or insurers, and PBMs, if the WAC's increase is at least 16%.¹¹⁵ Manufacturers providing WAC increase notifications will also be required to report additional information quarterly, such as a description of the financial and nonfinancial factors that contributed to the increase, to the Office of Statewide Health Planning and Development (OSHPD).¹¹⁶ Further, all manufacturers must notify OSHPD in writing before introducing a new prescription drug into the commercial market if the WAC exceeds a specified threshold.¹¹⁷ In November 2017, OSHPD published its implementation plan.¹¹⁸ Although the reporting requirements do not go into effect until 2019,¹¹⁹ PhRMA has already challenged the law for constitutional violations.¹²⁰

In Louisiana, two laws were enacted during the 2017 Regular Session of the Louisiana Legislature addressing prescription drug price transparency: Act 220 and Act 236. Act 220 added a law requiring prescription drug manufacturers who engage in "prescription drug marketing" to disclose to the Louisiana Board of Pharmacy (BOP) the WAC for the Food and Drug Administration (FDA) approved drugs marketed in the state.¹²¹ While quarterly

114. S. 17, 2017. Leg., Reg. Sess. (Cal. 2017).

115. CAL. HEALTH & SAFETY CODE § 127677(a)-(b) (West 2018).

116. *Id.* § 127679.

117. *See id.* § 127681 (requiring reporting if the WAC "exceeds the threshold set for a specialty drug under the Medicare Part D program (Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173))").

118. *Cost Transparency Rx Implementation Plan*, OSHPD (Nov. 2017), <https://www.oshpd.ca.gov/documents/LawsRegs/SB-17-Implementation-Plan.pdf> [<https://perma.cc/7LR9-TRQS>].

119. *See id.*

120. Greg Langlois, *Pharma Group Sues to Block California's New Drug Pricing Law*, BLOOMBERG BNA (Dec. 11, 2017), <https://www.bna.com/pharma-group-sues-n73014473040/> [<https://perma.cc/5YKC-FNEQ>].

121. LA. STAT. ANN. § 40:2255.11 (2017). The term "prescription drug marketing" is broadly defined and "means to provide educational or marketing information or materials regarding a prescription drug in any form including but not limited to all of the following: (a) Face-to-face meetings[;] (b) Physical mailings[;] (c) Telephone conversations[; and] (d) Electronic mail or facsimile." *Id.*

reporting is required,¹²² there are no penalties attached for non-compliance.¹²³ Act 236 directs the BOP to develop a website that will allow prescribers to access prescription drug pricing information.¹²⁴ Act 236 also specifies, among other provisions, information the BOP will collect from manufacturers and how marketers may provide the required information.¹²⁵

Maryland was successful in enacting a law prohibiting price gouging, which also contained a WAC disclosure component.¹²⁶ The state has focused its efforts on “essential off-patent or generic drug[s].”¹²⁷ These drugs are defined as prescription drugs for which all exclusive marketing rights have expired.¹²⁸ They are available for sale in the state and either appear on the World Health Organization’s most recent Model List for Medicines¹²⁹ or have been

§ 40:2255.1(2) (alterations added). It should be noted that New Mexico has had a similar price reporting law on the books since 2007.

A person who manufactures a prescription drug, including a generic prescription drug, that is sold in New Mexico shall file with the human services department: (1) the average manufacturer price for the drug; (2) the price that each wholesaler or pharmacy benefit manager doing business in this state pays the manufacturer to purchase the drug; and (3) the price paid to the manufacturer by any entity in an arrangement or contract that sells or provides prescription drugs in New Mexico without the services of a wholesaler.

N.M. STAT. ANN. § 27-2E-1(A) (2016).

122. LA. STAT. ANN. § 40:2255.11.

123. *Compare* H.B. 436, 2017 Leg., Reg. Sess. (La. 2017) (illustrating that the original proposed bill included § 2255.14 “Rulemaking; enforcement”), *with* LA. STAT. ANN. § 40:2255.11 (illustrating the absence of the enforcement clause).

124. LA. STAT. ANN. § 37:1251(A)(1) (2017).

125. *Id.* § 37:1251(A)(2)–(3). Section (A)(2) specifies that “[t]he website shall include, at a minimum, the following data elements, separated by therapeutic category: (a) Name of the product[;] (b) Whether the drug is a brand name or a generic[;] (c) Drug strength[;] (d) Per-unit wholesale acquisition cost of the drug[; and] (e) Any disclaimers deemed appropriate by the board.” The Louisiana Board of Pharmacy has developed a dedicated page on the agency’s website, which provides an overview of the laws, the information to be reported, and how companies should submit the information. *Pharmaceutical Cost Transparency*, LA. BOARD PHARMACY, <http://www.pharmacy.la.gov/index.cfm?md=pagebuilder&tmp=home&pid=403> [<https://perma.cc/5DGP-ENFV>] (last visited July 31, 2018).

126. H.B. 631, 2017 Leg., Reg. Sess. (Md. 2017).

127. *See id.*

128. *Id.* § 2-801(B)(1)(i).

129. *WHO Model Lists of Essential Medicines*, WORLD HEALTH ORG., <http://www.who.int/medicines/publications/essentialmedicines/en/> [<https://perma.cc/V23G-FWJQ>] (last visited July 31, 2018).

designated by Maryland's Secretary of Health and Mental Hygiene as an "essential medicine."¹³⁰

Under Maryland's concept of price gouging, the Maryland Medical Assistance Program (MAP) is directed to notify the state attorney general of any increase that would result in:

- (1) an increase of 50% or more in the WAC within the previous year; *or*
- (2) an increase of 50% or more in the price paid by MAP in the previous year; *and*
- (3) either a thirty-day supply, full course of treatment, or the only available quantity that does not correspond to a thirty-day supply of an essential off-patent or generic drug would cost more than \$80.¹³¹

Following a request from the Maryland Attorney General, manufacturers of these drugs would be required to submit a report within forty-five days of the request containing information such as the cost of production and reasons for the price increase.¹³² Additionally, the attorney general was granted the authority to require the manufacturer to reimburse consumers, including a third-party payor, any money it acquired as a result of a price increase violation.¹³³ In June 2017, the Association for Accessible Medicines (AAM)¹³⁴ filed suit against the state of Maryland claiming that HB 631 violates the United States Constitution (the Commerce Clause and Fourteenth Amendment), seeking both a temporary restraining order and permanent injunction prohibiting the implementation or enforcement of HB 631.¹³⁵ But by April 2018, the U.S. Court of Appeals for the Fourth Circuit held the law "violat[e]d

130. H.B. 631, 2017 Leg., Reg. Sess., § 2-801(B)(1)(ii) (Md. 2017).

131. *Id.* §§ 2-803(A)(1)(i)–(2)(ii).

132. *Id.* §2-803(B).

133. *Id.* § 2-803(D)(3).

134. AAM was formerly known as the Generic Pharmaceutical Association.

135. Compl. ¶ 8, *Ass'n for Accessible Meds. v. Frosh*, No. 1:17-cv-1860, 2017 WL 4347818 (D. Md. July 6, 2017); *see also The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?*, NASHP (Nov. 14, 2017), <https://nashp.org/the-dormant-commerce-clause-what-impact-does-it-have-on-the-regulation-of-pharmaceutical-costs/> [<https://perma.cc/BV68-F7MW>] (providing multiple dormant clause resources, such as insights and analysis, a blog, and an "easy-to-understand table featuring Dormant Commerce Clause's 'Dos and Don'ts'").

the dormant commerce clause because it directly regulates the price of transactions that occur outside Maryland.”¹³⁶

New York’s transparency law, on the other hand, comes with a twist.¹³⁷ In the New York variant, the legislature established a Medicaid drug cap to address drug expenditures.¹³⁸ To address costs, the Commissioner of the New York State Department of Health (Commissioner) is responsible for setting a year-to-year Medicaid drug expenditure growth target.¹³⁹ Quarterly, the Department of Health and Division of the Budget must assess “the projected total amount to be expended in the year on a cash basis by the Medicaid program for each drug, and the projected annual amount of state funds Medicaid drug expenditures on a cash basis for all drugs” and submit a report to the Drug Utilization Review (“DUR”) Board that provides, among other information, projected Medicaid drug expenditures.¹⁴⁰ In the event the expenditures from the previous

136. *Ass’n for Accessible Meds. v. Frosh*, No. 17-2166, 2018 WL 1770978, at *1 (4th Cir. Apr. 13, 2018). Not willing to concede defeat, Maryland Attorney General Brian E. Frosh has asked the full Fourth Circuit to rehear the case *en banc*. Ovetta Wiggins, *Frosh Asks a Federal Appeals Court to Rehear Case on Md. Drug Price-Gouging Law*, WASH. POST (Apr. 27, 2018), https://www.washingtonpost.com/local/md-politics/frosh-asks-a-federal-appeals-court-to-rehear-case-on-drug-price-gouging-law/2018/04/27/cbc014fe-4a5e-11e8-827e-190efaf1f1ee_story.html?utm_term=.83ec460f6306/ [https://perma.cc/28XJ-SYRB].

137. A. 2939, 2017 Assemb., Reg. Sess. (N.Y. 2017); S. 2007B, 2017 Leg. Gen. Assemb. (N.Y. 2017); N.Y. PUB. HEALTH LAW § 280 (McKinney 2017).

138. *See* N.Y. PUB. HEALTH LAW § 280(1) (finding that “[s]ince two thousand eleven, the state has taken significant steps to contain costs in the Medicaid program by imposing a statutory limit on annual growth. Drug expenditures, however, continually outpace other cost components causing significant pressure on the state, providers, and patient access operating under the Medicaid global cap”).

139. *See id.* § 280(2). The year-to-year growth targets for 2017 through 2019 are as follows:

- (a) for state fiscal year 2017–2018, be limited to the ten-year rolling average of the medical component of the consumer price index plus five percent and minus a pharmacy savings target of \$55 million;
- (b) for state fiscal year 2018–2019, be limited to the ten-year rolling average of the medical component of the consumer price index plus four percent and minus a pharmacy savings target of \$85 million; and
- (c) for state fiscal year 2019–2020, be limited to the ten-year rolling average of the medical component of the consumer price index plus four percent and minus a pharmacy savings target of \$85 million.

Id.

140. *See id.* § 280(3) (providing that the other information “includ[es] the amounts, in aggregate thereof, attributable to the net cost of: changes in the

quarter indicate that the annual growth limit will be exceeded, the Commissioner can recommend that the drug(s) be referred to the DUR Board.¹⁴¹ In turn the DUR Board will determine “whether a target supplemental Medicaid rebate should be paid by the manufacturer of the drug to the department and the target amount of the rebate.”¹⁴² If the DUR Board recommends a target rebate, the Commissioner will require the manufacturer to pay the supplemental rebate.¹⁴³ However, price reporting is triggered only if the manufacturer refuses to provide supplemental Medicaid rebates to the New York Department of Health.¹⁴⁴ In April 2018, Vertex

utilization of drugs by Medicaid recipients; changes in the number of Medicaid recipients; changes to the cost of brand name drugs and changes to the cost of generic drugs”).

141. *Id.* § 280(3)(a).

142. *Id.* It should be noted that under Section 3(b), prior to the DUR Board is notified, “the [Department of Health] shall notify the manufacturer of such drug and shall attempt to reach agreement with the manufacturer on a rebate for the drug.” *Id.* § 280(3)(b). If a rebate is agreed upon, then the drug will not be referred to the DUR Board. *Id.* § 280(3)(c); *see also id.* § 280(4), (5)(e) (providing how the DUR Board should determine whether to recommend a target supplemental rebate for a drug and how the DUR Board should formulate a recommendation concerning a target rebate).

143. *See id.* § 280(5)(a).

144. *See id.* § 280(6)(a). Reporting would include the following:

- i) the actual cost of developing, manufacturing, producing (including the cost per dose of production), and distributing the drug;
- ii) research and development costs of the drug, including payments to predecessor entities conducting research and development, such as biotechnology companies, universities and medical schools, and private research institutions;
- iii) administrative, marketing, and advertising costs for the drug, apportioned by marketing activities that are directed to consumers, marketing activities that are directed to prescribers, and the total cost of all marketing and advertising that is directed primarily to consumers and prescribers in New York, including but not limited to prescriber detailing, copayment discount programs, and direct-to-consumer marketing;
- iv) the extent of utilization of the drug;
- v) prices for the drug that are charged to purchasers outside the United States;
- vi) prices charged to typical purchasers in the state, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, or other direct purchasers;
- vii) the average rebates and discounts provided per payer type in the State; and

Pharmaceuticals' costly cystic fibrosis drug, Orkambi, became the test case of the state's new law as the Department of Health unanimously voted to negotiate a rebate; the outcome remains to be seen and the company "plans to take a hard line".¹⁴⁵

The passage of Nevada's pricing transparency law, Senate Bill 539, is perhaps the best illustration of why the pharmaceutical manufacturers will ultimately lose this war.¹⁴⁶ In Nevada's case, a major union became a powerful force against the pharmaceutical industry. Nevada's Culinary Health Fund is a labor management trust fund that provides health benefits to approximately 55,000 workers and their 70,000 dependents in the Las Vegas area.¹⁴⁷ In an effort to contain rising health care costs for its members, the Culinary Health Fund contributed greatly to legislators advocating for the successful passage of SB 539.¹⁴⁸

While SB 539 contains numerous provisions targeting the pharmaceutical industry, the primary focus of the bill concerns pricing transparency of diabetes medication.¹⁴⁹ By February 1, 2018, the Nevada Department of Health and Human Services (NDHHS) must create a master list of all insulins and biguanides, and their

viii) the average profit margin of each drug over the prior five-year period and the projected profit margin anticipated for such drug.

Id. § 280(6)(a)(i)-(viii).

145. See Ed Silverman, *New York Panel Votes to Lower the Cost of a Pricey Vertex Drug for Cystic Fibrosis*, STAT (Apr. 26, 2018), <https://www.statnews.com/pharmalot/2018/04/26/new-york-vertex-cystic-fibrosis-price/> [<https://perma.cc/8TA9-S7G9>].

146. See Megan Messerly, *Labor Health Fund Says Attorney General's Office, Legislature Could 'Potentially Eviscerate' Insulin Transparency Law*, NEV. INDEP. (Oct. 15, 2017, 2:05 AM), <https://thenevadaindependent.com/article/labor-health-fund-says-attorney-generals-office-legislature-could-potentially-eviscerate-insulin-transparency-law> [<https://perma.cc/5YAV-2MN3>] (according to an official from the Nevada Department of Health and Human Services, the local Nevada Culinary Union was able to best the industry's lobbyists).

147. *About Us*, CULINARY HEALTH FUND, <https://www.culinaryhealthfund.org/about-us/> [<https://perma.cc/WAZ5-4LDY>] (last visited July 31, 2018).

148. See Culinary Union, *Culinary Union Thanks Governor Brian Sandoval for Signing Historic Pharmaceutical Transparency Bill into Law and Senator Yvanna Cancela for Pioneering the Landmark Legislation*, CISION (June 15, 2017, 4:09 PM), <http://www.prnewswire.com/news-releases/culinary-union-thanks-governor-brian-sandoval-for-signing-historic-pharmaceutical-transparency-bill-into-law-and-senator-yvanna-cancela-for-pioneering-the-landmark-legislation-300475004.html> [<https://perma.cc/ZW4P-33VQ>]; Messerly, *supra* note 146.

149. See S.B. 539 § 28(3), 2017 Leg., 79th Sess. (Nev. 2017) (setting the effective date for §§ 1 to 6.5 to be Oct. 1, 2017).

corresponding WAC.¹⁵⁰ Using the list, NDHHS will then create a secondary list of those drugs with an increase in the WAC equal to or greater than the percentage increase in the Consumer Price Index, Medical Care Component (CPI-M) from the previous year, or twice the CPI-M in the preceding two years.¹⁵¹

Manufacturers named on the secondary list must file a report that contains information, such as drug production costs, manufacturer profit, and costs associated with coupons.¹⁵² They also must state a rationale justifying the WAC increase.¹⁵³ Also, unlike the Vermont pricing legislation, any information that a manufacturer reports to the state is not considered a trade secret and can be disclosed to the public.¹⁵⁴

Currently, the pricing transparency provisions are the subject of a lawsuit filed by PhRMA and the Biotechnology Innovation Organization (“BIO”).¹⁵⁵ PhRMA and BIO contend that, among other things, SB 539 “interferes with the federal patent and trade-secret laws, deprives manufacturers of their property interest in their trade secrets, and improperly overrides the regulatory choices of every other state.”¹⁵⁶ While it is unclear whether PhRMA and BIO will prevail, initial indications do not look promising. For example, the industry representatives failed to meet the burden for granting a temporary restraining order (TRO).¹⁵⁷ This is another clear indication that drug pricing transparency and fairness are topics that are not going away.

Additionally, states have begun to seek legal action to control drug costs. The Connecticut Attorney General’s office launched an

150. *Id.* § 3.6(1).

151. *Id.* § 3.6(2).

152. *Id.* § 3.8.

153. *Id.* § 4.

154. *See id.* § 9 (revising the definition of “trade secret” to exclude information manufacturers report under §§ 3.8 and 4 of SB 539).

155. *Pharm. Research & Mfrs. of Am. v. Sandoval*, No. 2:17-cv-02315-JCM (CWH), 2017 U.S. Dist. LEXIS 149468 (D. Nev. Sept. 14, 2017); *see also* David C. Gibbons & Alan M. Kirschenbaum, *PhRMA and BIO Team Up Again to Challenge a State Drug Pricing Law*, FDA LAW BLOG (Sept. 7, 2017, 4:17 PM), <http://www.fdalawblog.net/2017/09/phrma-and-bio-team-up-again-to-challenge-a-state-drug-pricing-law/> [<https://perma.cc/Q6KN-SL38>] (providing a summary of the complaint).

156. *Compl. at 2, Pharm. Research & Mfrs. of Am. v. Sandoval*, 2017 U.S. Dist. LEXIS 149468 (D. Nev. Sept. 1, 2017) (No. 2:17-cv-02315 JCM (CWH)).

157. *Order at 1, Pharm. Research & Mfrs. of Am. v. Sandoval*, 2017 U.S. Dist. LEXIS 149468 (D. Nev. Oct. 17, 2017) (No. 2:17-cv-02315 JCM (CWH)).

investigation, culminating in a coalition of forty-five states who brought suit, alleging that generic pharmaceutical companies engaged in price-fixing.¹⁵⁸ The multi-district litigation claims that generic pharmaceutical manufacturers provided incentives to large purchasers like McKesson Corp., Cardinal Health Inc., and AmerisourceBergen Corp., to keep prices artificially high.¹⁵⁹ To support the contention of price-fixing, the coalition cites the companies' 10-k and other regulatory filings required by the SEC, some of which contain troubling statements about the relationships between generic manufacturers and purchasers.¹⁶⁰

IV. LEVERAGING COMPLIANCE

There are no easy answers to the dilemmas and trade-offs posed by the current need to curb rising healthcare costs, while continuing to find and produce new medicinal treatments. Ultimately, it will involve complex ethical decisions, pitting the value of life against the costs to achieve it. However, these issues are outside the scope of this article.

In the short term, for the pharmaceutical manufacturers facing an onslaught of pricing legislation, it comes down to trust, which is something that compliance professionals know a great deal about.¹⁶¹

158. See Press Release, Conn. Attorney General's Office, AG Jepsen Leads Coalition in New, Expanded Complaint in Federal Generic Drug Antitrust Lawsuit (Oct. 31, 2017), <http://portal.ct.gov/AG/Press-Releases/2017-Press-Releases/AG-Jepsen-Leads-Coalition-in-New-Expanded-Complaint-in-Federal-Generic-Drug-Antitrust-Lawsuit> [<https://perma.cc/9XMH-3N4B>]; Nathan Vardi, *States Focus on Incentives of Wholesalers & Pharmacies in Drug Price-Fixing Probe*, FORBES (Nov. 6, 2017, 8:04 AM), <https://www.forbes.com/sites/nathanvardi/2017/11/06/states-focus-on-incentives-of-wholesalers-and-pharmacies-in-drug-price-fixing-probe/#5605e55c402b> [<https://perma.cc/HBV4-Z9FG>].

159. See Vardi, *supra* note 158.

160. *Id.* For example, McKesson stated its deals “include an inflation-based compensation component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices,” and, according to AmeriSourceBergen, “[i]f the frequency or rate of generic pharmaceutical price deflation accelerates, our results of operations could be adversely affected.” McKesson Corp., Annual Report (Form 10-K), at 10 (May 5, 2016); AmeriSourceBergen Corp., Annual Report (Form 10-K), at 8 (Nov. 25, 2014).

161. See Deann M. Baker, *Compliance Professionals Trust and Verify—It's What We Do*, HEALTH CARE COMPLIANCE ASS'N (Jan. 2016), <https://www.hcca-info.org/Resources/View/tabid/451/ArticleId/5561/Compliance-Professionals-Trust-and-Verify-Its-what-we-do.aspx> [<https://perma.cc/S54H-A8YQ>].

Compliance professionals also have the tools and processes to help companies demonstrate social responsibility and trustworthiness.¹⁶² In other words, they have tools that will allow drug companies to demonstrate that they understand the “social contract” of their industry.¹⁶³ Finally, the tools that life science compliance professionals wield have been honed and tested successfully over the past two decades.¹⁶⁴ We believe that several of these tools can be effective in this situation as well.

A. *Adopting a Voluntary Pricing Code*

At the outset, we proposed that the industry create and adopt a voluntary pricing code. Companies have adopted these voluntary pricing codes.¹⁶⁵ In fact, several states have mandated compliance with the Code as a prerequisite for selling pharmaceuticals to their citizens.¹⁶⁶ Various executives within the industry have begun to call

162. See *id.* (discussing how the compliance professional can use auditing and monitoring within their own corporations).

163. See Eric Sherbet, *The Top Five Business Benefits of Compliance*, PHARMACEUTICAL COMPLIANCE MONITOR (July 14, 2014), <http://www.pharma.compliancemonitor.com/top-five-business-benefits-compliance/7233/> [https://perma.cc/TRF5-HW4G]. See generally Jan C. Heller & Mark E. Meaney, *Integrating Ethics into a Compliance Program*, in THE HEALTH CARE COMPLIANCE PROFESSIONAL'S MANUAL 62,001, ¶ 60,180 (Health Care Compliance Ass'n, 2017) (“A compliance professional’s language and style of communication should convey a message of trust and support for shared corporate values.”).

164. See Joseph E. Murphy & Debbie Troklus, *Compliance Officers and Infrastructure*, in THE HEALTH CARE COMPLIANCE PROFESSIONAL'S MANUAL, 51,011, ¶¶ 50,205–40 (Health Care Compliance Ass'n, 2017).

165. See, e.g., *Code on Interactions with Healthcare Professionals*, PHRMA (Feb. 2, 2017), <http://www.phrma.org/codes-and-guidelines/code-on-interactions-with-health-care-professionals> [https://perma.cc/6MMD-3ZVP] (announcing adoption of a voluntary code of conduct).

166. See MASS. GEN. LAWS ANN. ch. 111N, § 2 (West 2014) (adopting standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth); *Compliance Packet for Manufacturers and Wholesalers of Drugs, Medicines, Chemicals, Devices, or Appliances*, NEV. STATE BD. OF PHARMACY (June 25, 2013), http://bop.nv.gov/uploadedfiles/bopnvgov/content/resources/all/ab_128_compliancepacket.pdf [https://perma.cc/A323-QWP2] (requiring wholesalers or manufacturers who employ a person to sell or market a drug or medicine must comply with certain model codes of conduct); Erik Snapp & Monika Blacha, *Mandatory Compliance with “Voluntary” Codes*, LAW360 (Oct. 30, 2008), <https://www.law360.com/articles/74986/mandatory-compliance-with-voluntary-codes> [https://perma.cc/P6GR-V28B] (stating that although industry codes are often

for what amounts to a voluntary pricing code. In September 2016, at the height of the Mylan EpiPen controversy, Brent Saunders called upon the industry to honor its unwritten social contract with patients.¹⁶⁷ After condemning “those outliers who have taken dramatic price increases—or engaged in what the public thinks of as price gouging,” Saunders stated, “we must keep this social contract in mind as we make business decisions that ultimately improve wellbeing, and as a result, address the hopes others place in us.”¹⁶⁸ To aid his company and other drug makers in making those business decisions, Saunders outlined five key activities:

- (1) Pricing products based on the value they create,
- (2) Avoiding price gouging or predatory pricing,
- (3) Limiting price increases as to both frequency (once per year) and amount (slightly above the annual inflation rate),
- (4) Avoiding major price increases when products near patent expiration, and
- (5) Disclosing the impact of price on the company.¹⁶⁹

While not formally presented as such, Saunders’ ideas, nevertheless, amount to the tenets of a *de facto* voluntary code.¹⁷⁰

Recently, John Maraganore, CEO of Alnylam Pharmaceuticals, pledged, “[w]e will not arbitrarily increase prices beyond the price of inflation [because] [w]e think the most difficult practice to explain to payors and patients is drug price increases.”¹⁷¹ While two

described as “voluntary,” they have become mandatory minimum standards of conduct in a growing number of states); Joseph H. Zwicker & Dara Z. Kesselheim, *Stringent Requirements for Pharmaceutical and Medical Device Companies in Massachusetts*, CHOATE, <https://www.acc.com/chapters/ne/upload/Stringent-Requirements-for-Health-Care-Practitioners-in-Mass.pdf> [<https://perma.cc/AXX5-TBLG>] (last visited July 31, 2018) (evaluating impact of strict marketing code of conduct on pharmaceutical and medical device companies doing business in Massachusetts).

167. Brent Saunders, *Our Social Contract with Patients*, ALLERGAN: CEO BLOG (Sept. 6, 2016), <https://www.allergan.com/news/ceo-blog/september-2016/our-social-contract-with-patients> [<https://perma.cc/NL6F-U5ZW>].

168. *Id.*

169. See Seth Whitelaw, *Pharma Pricing & One Bold CEO*, WHITELAW COMPLIANCE GROUP (Sept. 6, 2016), <https://www.whitelawcompliance.com/blog/pharma-pricing-one-bold-ceo/> [<https://perma.cc/3ZQR-RAJ6>].

170. *Id.* (calling Saunders’ approach “alien,” but also “achievable and necessary”).

171. See Matthew Herper, *Alnylam Chief Makes Pricing Pledges Before Drug is Even Approved*, FORBES (Nov. 30, 2017, 10:00 AM), <https://www.forbes.com/sites/matthewherper/2017/11/30/alnylam-chief-makes-pricing-pledges-before-drug-is->

CEOs do not constitute a trend, there seems to be a glimmer of recognition among pharmaceutical CEOs of the need to address price increases in a straight forward manner.¹⁷²

Creation and adoption of a voluntary code by the drug industry would constitute a substantial step towards defusing the current acrimonious environment. The National Academies agree that this is necessary as “[a]dvocacy for cooperation and collaboration is likely to be more productive when making recommendations that will require sacrifice across many components of the health care sector.”¹⁷³ It also would be a step towards providing increased transparency to the system, which the National Academies consensus study supports and recommends.¹⁷⁴

B. Standardizing the Price Setting Process

In addition to the creation and adoption of a voluntary code, we believe that another set of compliance tools—needs assessments and standard review processes—would help the industry address the ongoing perception that price increases are arbitrary. The recent examples of aggressive price increases have served to strengthen that perception.¹⁷⁵ If the industry critics and activists only had a few egregious examples to point to, it is unlikely that we would be seeing the sustained level of legislative activity at all levels of government. However, there is a more robust source that outlines the extent to which the pharmaceutical industry’s pricing house is in disarray.¹⁷⁶

The Senate Finance Committee undertook an investigation on the pricing of Solvadi and its impact on the United States health care

even-approved/#4cb7cba26265 [https://perma.cc/6TEJ-VLUN] (discussing Alnylam’s pledge to “put patients first”).

172. See, e.g., Henry Waxman et al., *Getting to the Root of High Prescription Drug Prices*, COMMONWEALTH FUND (July 2017), http://www.commonwealthfund.org/~media/files/publications/issue-brief/2017/jul/waxman_getting_to_root_high_rx_drug_prices_ib_v2.pdf [https://perma.cc/7KGM-GKH8] (discussing high prescription drug prices, concluding, “[d]rug manufacturers should be able to clearly articulate and justify their drug pricing decisions in a clear, straightforward manner to the public”).

173. MAKING MEDICINES AFFORDABLE, *supra* note 43, at 159.

174. See *id.* at 160 (“[T]ransparency likely will reduce bad behavior and abuse in the market. Participants in the markets will perform better.”).

175. See *supra* discussion Section II.A.

176. See S. COMM. ON FIN., 114TH CONG., *supra* note 54 (discussing the various factors that affect the pharmaceutical industry’s pricing determinations).

system.¹⁷⁷ Solvadi is a pill to treat Hepatitis C and is manufactured and marketed by Gilead Sciences, Inc. (Gilead).¹⁷⁸ Gilead priced Solvadi at \$1,000 per pill, costing the average patient approximately \$84,000.¹⁷⁹ Critics and physicians alike vilified Gilead for price gouging.¹⁸⁰ The Committee determined that the pricing decision for Solvadi was based on “setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni [Solvadi’s successor] and its even higher price.”¹⁸¹ Furthermore, the Committee concluded that “Gilead’s goal throughout its pricing decision process appears to have been to identify the price just below the level where payors would place significant restrictions on patient access.”¹⁸² As a result, the company and its consultants developed multiple pricing scenarios to find that optimal level.¹⁸³

The elements that were not included in the pricing decision were just as important as those elements that were included. Based on the Committee’s review:

Gilead acquired access to its sofosbuvir-based drugs through a multi-billion dollar acquisition and spent hundreds of millions of dollars more completing clinical trials and FDA approvals. While there were extensive

177. See *id.* at 114–20.

178. See Melanie Haiken, *FDA Approves Breakthrough New Drug for Hepatitis C—2nd in Two Weeks*, FORBES (Dec. 10, 2013, 3:20 PM), <https://www.forbes.com/sites/melaniehaiken/2013/12/10/fda-approves-breakthrough-new-drug-for-hepatitis-c-2nd-in-two-weeks/#7e2557aa2b2d> [https://perma.cc/UVT7-GDPJ] (stating how John Ward, CDC director of the Division of Viral Hepatitis, called Sovaldi “a landmark advance in the treatment of Hepatitis C”).

179. See Margot Sanger-Katz, *\$1,000 Hepatitis Pill Shows Why Fixing Health Costs is so Hard*, N.Y. TIMES (Aug. 2, 2014), <https://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html?mtrref=www.google.com> [https://perma.cc/3WAS-C6ST].

180. See John LaMattina, *Gilead’s CEO Admits to ‘Failures’ in Setting Price of \$1,000-A-Pill Breakthrough*, FORBES (Dec. 8, 2016, 8:00 AM), <https://www.forbes.com/sites/johnlamattina/2016/12/08/gileads-ceo-apologetic-about-sovaldis-1000-per-pill-price-tag/#541ea2f61a97> [https://perma.cc/8PQX-WUYM]; Brendan Pierson, *Gilead Sued Over ‘Exorbitant’ Hepatitis C Drug Prices*, REUTERS (Dec. 10, 2014, 2:55 PM), <https://www.reuters.com/article/health-sovaldi/gilead-sued-over-exorbitant-hepatitis-c-drug-prices-idUSL1N0TU27W20141210> [https://perma.cc/R4YT-M74E]; Lisa Schencker, *Antitrust Suit Accuses Sovaldi Maker Gilead of Price-Gouging*, MODERN HEALTHCARE (Dec. 10, 2014), <http://www.modernhealthcare.com/article/20141210/NEWS/312109945> [https://perma.cc/EUU7-JXEQ].

181. *Id.* at 117.

182. *Id.*

183. See *id.*

discussions regarding return on those investments while Gilead was considering the acquisition of Pharmasset, there is scant evidence that return on these investments played a significant role in determining the pricing of these drugs. Similarly, the cost of manufacturing Sovaldi, which was nominal, played no part in establishing the price. In an interview, Gilead executive Jim Meyers, who played a lead part in making the pricing recommendation did not know the cost of manufacturing the drug.¹⁸⁴

Therefore, it appears that traditional pricing rationales often touted by the pharmaceutical industry, such as recouping R&D and manufacturing costs while making a reasonable profit, were not at work in this situation.¹⁸⁵ While Solvadi is only one case study, it outlines perhaps the most significant challenge for the pharmaceutical industry when it comes to price—there is no standard price setting process.¹⁸⁶ This is where compliance can help.

Less than ten years ago, the industry faced a similar situation in setting compensation for healthcare professionals, institutions, and organizations. While everyone got paid, most drug companies did not know what was paid each year by the type of service.¹⁸⁷ That changed with the government's increased anti-kickback enforcement efforts and the Physician's Payment Sunshine Act (Sunshine Act) that was part of the Affordable Care Act.¹⁸⁸ What emerged was a scripted process that began with a needs assessment and concluded with a cross-functional review session.¹⁸⁹

184. *Id.*

185. *See, e.g., Ads: Let's Talk About Cost*, <http://www.phrma.org/media/ads-let-s-talk-about-cost> [<https://perma.cc/PG9E-LRWV>] (last visited July 31, 2018).

186. *See* Jessica Wapner, *How Prescription Drugs Get Their Prices, Explained*, NEWSWEEK (Mar. 17, 2017, 8:00 AM), <http://www.newsweek.com/prescription-drug-pricing-569444> [<https://perma.cc/HY63-YTGA>] (stating that there is no formula to set prescription drug prices).

187. *See generally* Elizabeth Richardson, *The Physician Payments Sunshine Act: New Regulations Require Medical Product Manufacturers to Publicly Report Payments Made to Physicians and Teaching Hospitals*, HEALTH AFF. 1, 1–2 (2014) (discussing how many physicians somehow received compensation from pharmaceutical companies).

188. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6002, 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h (2010)) (amending Part A of title XI of the Social Security Act by adding section 1128G).

189. *See generally* Ilyssa Levins, *Seeing the Sunshine in the Sunshine Act*, PHARMACEUTICAL COMPLIANCE MONITOR (June 27, 2014), <http://www.pharma-compliancemonitor.com/seeing-sunshine-sunshine-act/7146/> [<https://perma.cc/2A8U-VZUJ>]; Katherine Norris, *The Future's So . . . Corporate Integrity Agreements Then*

While the needs assessment document varies by company, “the important questions of ‘why,’ ‘what,’ and ‘how’ [are] a critical part of the needs assessment process in determining whether the proposed services fulfill a legitimate business need.”¹⁹⁰ Although these needs assessments were originally developed in context of engaging the services of healthcare providers, we believe that using the needs assessment tools and techniques will work well for pricing decisions.

Using a needs assessment tool imposes rigor and enforces discipline. For the needs assessment to be adequate, all the necessary supporting information must be assembled and analyzed.¹⁹¹ Moreover, a needs assessment process requires a disciplined approach that transcends the creation of the final, finished document. Therefore, if a needs assessment was integrated as part of the pricing determination process, companies would have basic information, such as R&D and manufacturing costs, and could avoid embarrassing “Jim Meyers” type situations or worse.¹⁹² The same holds true for the cross-functional review session. Multidisciplinary team reviews are commonplace within pharmaceutical companies.¹⁹³ Consequently, the concept and operations of multi-disciplinary review teams are well-settled constructs.

In the case of a pricing review team, pharmaceutical companies will face the difficulty of determining team membership. Product pricing, as distinguished from the discipline of government pricing,

and Now, 2.2 Life Sci. Compliance Update 12 (2016).

190. See Tynan Olechny & Christina Hummel, *Feeling Needy—The Why, What and How of Needs Assessments*, 3.1 LIFE SCI. COMPLIANCE UPDATE 2 (2017) (discussing what constitutes an effective-needs assessment). See generally Michelle Cooper & Margaret Hambleton, *Risk Assessment Basics for Compliance Officers*, in THE HEALTH CARE COMPLIANCE PROFESSIONAL’S MANUAL, 41,001, ¶ 40,100 (Health Care Compliance Ass’n 2017) (discussing risk assessment and mitigation strategies).

191. RYAN WATKINS ET AL., A GUIDE TO ASSESSING NEEDS 277 (World Bank 2012) (eBook), <https://openknowledge.worldbank.org/bitstream/handle/10986/2231/663920PUB0EPI00essing09780821388686.pdf?sequence=1&isAllowed=y> [https://perma.cc/M6KB-4SVF].

192. See S. COMM. ON FIN., 114TH CONG., *supra* note 54. Meyers was Gilead’s Vice President of North American Commercial Operations in 2015 and should have known how much it cost to produce Solvardi. See *id.*

193. See Denise Myshko, *Cross-Functional Teams: Models of Success*, PHARMAVOICE (Sept. 2006), <http://www.pharmavoices.com/article/2006-09-cross-functional-teams/> [https://perma.cc/4NU7-7UVX] (“[T]he most effective organizations structure themselves using multidisciplinary teams.”).

is spread over many areas in most organizations.¹⁹⁴ However, most organizations will likely involve their compliance, legal, and finance officers. Beyond this core, including additional disciplines is a matter of organizational design and culture.

C. *Managing Disclosure*

Based on our review of the legislative landscape, mandatory pricing disclosure will continue to expand beyond the handful of states and local jurisdictions that presently require it. Also, absent an intensive and successful lobbying effort at the congressional level, preemptive relief—if there is any potential for it—is a long way off. Therefore, drug companies will face a myriad of price disclosure frameworks, at least in the near future. It is naïve to believe compliance can guide these various legislative regimens toward a meaningful disclosure frame. Rather, managing the overall disclosure process to minimize the impact on the company is a more realistic role for compliance. Once more, compliance officers have a great deal of experience with this.¹⁹⁵

Despite the existence of the federal Sunshine Act, there is no single, harmonized payment disclosure framework. While individual states cannot require separate disclosure of the same federal information, they are free to pursue and require the disclosure of additional information.¹⁹⁶ Therefore, states such as California, Massachusetts, Minnesota, and Vermont, maintain their own separate disclosure schemes.¹⁹⁷ Pharmaceutical compliance officers

194. See Wendy Goldstein, *Insight: Life Science Compliance Considerations for 2016*, PHARMACEUTICAL COMPLIANCE MONITOR (Feb. 8, 2016), <http://www.pharmacompliancemonitor.com/insight-life-sciences-compliance-considerations-for-2016/10376> [<https://perma.cc/5MCV-G7EY>] (“The time is ripe to ensure that all processes and systems are current (including training on such processes and systems) to maintain compliance with applicable U.S. and foreign pricing laws and marketing laws relevant to communicating prices and value propositions.”).

195. See, e.g., Matt Weber & Armin Sarabi, *The Role of Internal Investigations and Self-Disclosure in Effective Compliance Programs*, COMPLIANCE TODAY, Nov. 2008, at 4.

196. See Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6002, 124 Stat. 119, 689 (codified as amended at 42 U.S.C. § 1320a-7h (2010)).

197. Alan M. Kirschenbaum & David C. Gibbons, *2017: A Banner Year for State Laws on Drug Pricing, Price Reporting, and Discounting*, HYMAN, PHELPS, & MCNAMARA PC: 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/> [<https://perma.cc/8TD2-3JEW>] (describing the recently adopted reporting requirements in California and Vermont, among other states); Lydia Ramsey, ‘More is Possible’: A

and their departments routinely operate within this complex, tangled web of transparency requirements.

In our estimation, their experience designing and deploying processes and technical solutions to meet various physician payment transparency requirements makes compliance officers ideally suited to address new pricing disclosure schemes. Pharmaceutical compliance officers could implement programs by employing the following steps currently used in Sunshine Act compliance:

- (1) Determine what information needs to be gathered and locate the sources of that information;
- (2) Collect all the information and place it into some type of repository;
- (3) Develop and deploy tools to monitor completeness of the information and extract the data as required for each report;
- (4) Create the necessary quality control, review, and, if necessary, attestation process; and
- (5) Establish the necessary processes, complete with timelines for each succeeding round of reports.

Although each step seems simple and obvious on its face, it requires an expert's knowledge of the laws and regulations, the industry, and the company's unique structures, systems, and processes to achieve success. This is where compliance officers excel.

V. CONCLUSION

As federal, state, and local governments cope with ever higher pharmaceutical prices that seem to defy logic and common sense, various state and local governments have seized the concept of pricing transparency to restore the missing balance. In doing so, they are discovering that pharmaceutical pricing is an extremely complicated and interdependent system of healthcare providers, payors, manufacturers, and patients. Governments continue to persist in their efforts after seeing a glimpse of the irrational world of drug pricing, knowing that current approaches are untenable.

Bunch of States are Taking on High Drug Prices, and It Could Start Hitting Drugmaker Profits, BUS. INSIDER (June 4, 2017, 3:36 PM), <http://www.businessinsider.com/states-with-drug-pricing-transparency-bills-2017-6/> [https://perma.cc/P3EH-U7QP] (discussing pharmaceutical transparency legislation in Maryland, New York, Nevada, Ohio, California, and Vermont).

Likewise, the pharmaceutical industry continues to fight against the inevitable tide, arguing that regulators and the public do not need to understand how prices are set. Although arguing strenuously that additional legislation—including pricing transparency—is not the answer to rising costs, the pharmaceutical industry and its lobbyists fail to propose alternatives that attempt to meet the needs of all constituents. Therefore, without offering a plausible alternative, like physician payment transparency, pricing transparency will likely become a permanent fixture.

For industry compliance officers, coping with a radically new landscape is something which they are eminently familiar. With battle-tested experience and tools, the industry's compliance officers are best suited to demonstrate the value of compliance by helping their companies manage the new reality, while minimizing its disruptive impacts. They need to have the courage to step to the front of the line and lead.

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