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STATE AND FEDERAL POLICY SOLUTIONS TO RISING PRESCRIPTION DRUG PRICES IN THE U.S.

WILLIAM V. PADULA, PHD*

I. INTRODUCTION

Right now is the greatest opportunity in over 30 years to curb the rising prices of prescription drugs. One of the last major pieces of federal legislation passed solely to reduce drug spending was the Drug Price Competition and Patient Term Restoration Act (aka the “Hatch-Waxman” Act) of 1984.¹ Hatch-Waxman is estimated to have introduced more than \$1 trillion in savings over the past decade alone due to the availability of low cost generics.² However, the U.S. has recently witnessed the prices of generics increasing, particularly older generics with little competition such as Daraprim and EpiPen.³ Coverage of these price hikes by politicians and popular media has invigorated a national push to reform many aspects of the system that regulates drug pricing – a system that all but exists in a free market economy.⁴

In addition to price hikes on generics, new branded drugs have consistently become more expensive. Thankfully, new life-saving technologies have been introduced in recent history such as imatinib mesylate (brand name: Gleevec®; manufacturer: Novartis) for chronic myeloid leukemia, as well as cures for hepatitis C virus such as sofosbuvir (brand name: Solvaldi®; manufacturer: Gilead) and ledipasvir/sofosbuvir (brand name: Harvoni®; manufacturer:

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1. Drug Price Competition and Patient Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

2. Letter from John E. Dicken, Health Care Director, GAO, to Senator Orin Hatch, Drug Pricing: Research on Savings from Generic Drug Use (Jan. 31, 2012) (on file with GAO).

3. SPECIAL COMM. ON AGING U.S. SENATE, SUDDEN PRICE SPIKES IN OFF-PATENT PRESCRIPTION DRUGS: THE MONOPOLY BUSINESS MODEL THAT HARMS PATIENTS, TAXPAYERS, AND THE U.S. HEALTH CARE SYSTEM 39–41 (2016).

4. Corrina Sorenson, et al., *Advancing Value Assessment in the United States: A Multistakeholder Perspective*, 20 VALUE IN HEALTH. 299, 299–300 (2017).

Gilead).⁵ Given the investment that pharmaceutical manufacturers make to develop these life saving technologies, many economists claim that the prices may be justifiably high.⁶ Nonetheless, these drugs seriously impact payers' budgets when trying to cover the costs of newly introduced health technologies in addition to existing health services.⁷ And more so, the cost of high-priced drugs can be paralyzing to patients who are underinsured and must tradeoff out-of-pocket copays for other necessities.⁸

II. PRIORITY POLICY SOLUTIONS TO HIGH DRUG PRICES

A lack of fluidity in Washington, D.C. currently to pass federal legislation to address most concerns surrounding the rising costs of drugs has directed most actionable items to the state-level in the past three years. States are addressing drug pricing issues through one of two domains. First, states are targeting drug pricing directly for both branded and generic products.⁹ These policies are focused primarily on capping annual price increases so that the price at which a drug is introduced to the market remains relatively close to future prices. Some state policies are also addressing launch prices considered too high by some, but this latter issue is more difficult to address and might require emulating price regulation practices implemented by other Western countries.¹⁰ Second, states are exploring topics in drug price transparency. While constituents may know

5. See Rena M. Conti, et al., *Changing the Cost of Care for Chronic Myeloid Leukemia: the Availability of Generic Imatinib in the USA and EU*, 94 ANNALS OF HEMATOLOGY 249, 249 (2015) (explaining that imatinib was introduced for the treatment of chronic myeloid leukemia and other malignant diseases); Jay H. Hoofnagle & Averell H. Sherker, *Therapy for Hepatitis C—the Costs of Success*, 370 N. ENGL. J. MED. 1552, 1552 (2014) (explaining that ledipasvir and sofosbuvir are used for the treatment of hepatitis C); William V. Padula, et al., *Cost-effectiveness of Tyrosine Kinase Inhibitor Treatment Strategies for Chronic Phase After Generic Entry of Imatinib in the United States*, 108 J. NAT'L CANCER INST., Mar. 2016, at 1, 2 (explaining that generic imatinib is used to treat chronic myeloid leukemia).

6. Joseph A. DiMasi, et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180–81 (2015).

7. See Rena M. Conti & Meredith B. Rosenthal, *Pharmaceutical Policy Reform – Balancing Affordability with Incentives for Innovation*, NEW ENG. J. MED. (2016) (describing the prohibitive costs that payers must assume).

8. William V. Padula et al., *Paying for Drugs After the Medicare Part D Beneficiary Reaches the Catastrophic Limit: Lessons of Cost Sharing from Other US Policy Partnerships Between Government and Commercial Industry*, APPLIED HEALTH ECON. & HEALTH POL'Y, July 2018, at 2 (stating that copays can be quite prohibitive to people paying out of pocket).

9. See Shashi N. Kapadia et al., *Strategies for Improving Hepatitis C Treatment Access in the United States: State Officials Address High Drug Prices, Stigma, and Building Treatment Capacity*, J. PUB. HEALTH MGMT & PRAC. (2018) (describing how high drug prices constitute a barrier to accessing hepatitis c treatments and offering solutions for states to undertake to combat this barrier).

10. See generally Jaume Puig-Junoy, *Impact of European Pharmaceutical Price Regulation on Generic Price Competition*, 28 PHARMACOECONOMICS 649 (2010) (providing examples and statistics of price regulation practices among other countries and the impact on drug price competition).

what the price of the drug is in a particular market, the elements that go into pricing the drug are relatively obscure.¹¹ A drug's price is estimated to consist of the investment in research and development, marketing, profit sharing, charitable contributions, and potentially a cost component that is used to reinvest in future innovations within the manufacturer.¹² However, few consumers, if any understand the breakdown of what the price of a drug goes towards these different elements. On top of that, drugs change hands several times between the manufacturer and the transaction at the interface between the pharmacy and the patient. In particular, commercial payers, wholesalers and pharmacy benefit managers (PBMs) potentially play a large role in determining the price of a drug, but their influence is unknown.¹³ Transparency laws would mandate the public release of information about components of the price of a drug; which include development, manufacturing and marketing costs.¹⁴

In addition to transparency laws, states and the federal government are attempting to address a common issue created by PBM "gag" clauses. Under these "gag" clauses, a pharmacist is not allowed to disclose differences in the out-of-pocket costs a patient may face when filling a prescription.¹⁵ On the one hand, a patient would have to pay a certain amount based on the co-pay their plan has contracted through the PBM. Alternatively, there are potential out-of-pocket savings for the patient for certain prescriptions if they pay for it in cash rather than through their insurance plan.¹⁶ Thus, some prescriptions have greater insurance for out-of-pocket co-pays than the acquisition price of the drug. Many people consider these laws, which gag pharmacists from disclosing price information to the consumer to be unfair. Therefore, states and the federal government are exploring ways to lift gag laws and grant patients access to information that allows them to pay the lowest price for the drug in terms of personal out-of-pocket costs. The challenge to lifting these gag laws is ensuring

11. See Sabine Vogler & Kenneth R. Paterson, *Can Price Transparency Contribute to More Affordable Patient Access to Medicines?*, 1 PHARMACOECONOMICS 145, 145–47 (2017) (describing some of the factors that go into drug pricing in different healthcare systems, such as individual negotiations and agreements on products between payers and the pharmaceutical industry).

12. See Michael Dickson & Jean Paul Gagnon, *Key Factors in The Rising Cost of New Drug Discovery and Development*, 3 NATURE REV. DRUG DISCOVERY, 417, 421, 425–27 (2004) (describing how the value between pharmaceutical innovation and conventional production mechanisms cannot be accurately measured with common accounting).

13. T. Joseph Mattingly II et al., *Estimating Drug Costs: How do Manufacturer Net Prices Compare with Other Common US Price References*, 36 PHARMOECONOMICS 1093 (2018).

14. David B. Ridley, *Price Differentiation and Transparency in the Global Pharmaceutical Marketplace*, 23 PHARMOECONOMICS 653, 654–55 (2005).

15. Robert Pear, *Why Your Pharmacist Can't Tell You That \$20 Prescription Could Cost Only \$8*, N.Y. TIMES (Feb. 24, 2018), <https://www.nytimes.com/2018/02/24/us/politics/pharmacy-benefit-managers-gag-clauses.html>.

16. KAREN VAN NUYS, ET AL., *OVERPAYING FOR PRESCRIPTION DRUGS: THE COPAY CLAWBACK PHENOMENON* 1 (2018).

that the business transaction between PMBs and pharmacists is not negatively impacted.

Given these multiple domains in drug pricing policy, states and the federal government have prioritized many pieces of legislation over the past 12-36 months to benefit patients.¹⁷

III. UNCONSCIONABLE PRICE INCREASES ON DRUGS AND DEVICES

States have begun presenting legislation to prevent egregious increases in the prices of different health technologies, both generic and branded, referred to as “price gouging.”¹⁸ To establish that a manufacturer or distributor is engaged in price gouging, state officials will need to show that the price increases are not only unjustified but also legally unconscionable (as “unconscionability” is defined by doctrine in contract law).¹⁹ A relationship between buyer and seller is deemed unconscionable if it is based on terms so egregiously unjust and so clearly tilted toward the party with superior bargaining power that no reasonable person would freely agree to them. This standard includes cases in which the seller vastly inflates the price of goods.

A classic case of price gouging is *Williams v. Walker-Thomas Furniture Co.*, which involved a layaway furniture plan under which the customer, after missing a single installment payment on a stereo, lost all the furniture she had purchased from the store over the course of 5 years.²⁰ The appellate court ruled that contracts may be found unconscionable if the transaction entails “an absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party.”²¹

Laws protecting consumers against unconscionable price increases have had different levels of success within states. Massachusetts has achieved perhaps the most comprehensive legislation by enacting a price gouging protections law that applies to both generic and branded drugs.²² The State of New York enacted a price-gouging law on drugs with an increase in price of 75% or greater.²³ In

17. National Academy for State Health Policy, 2018

18. Jeremy A. Greene & William V. Padula, *Targeting Unconscionable Prescription-Drug Prices—Maryland Anti-Price Gouging Law*, 377 NEW ENG. J. MED. 101, 101 (2017).

19. RESTATEMENT (SECOND) OF CONTRACTS §§153, 208 (AM. LAW INST. 1979) (stating that when one party makes a mistake the contract is voidable if the mistake(s) makes the enforcement of the contract unconscionable (defined in §208) or the other party knew of the mistake or caused the mistake).

20. 350 F.2d 445, 447 (D.C. Cir. 1965) (explaining where the terms of a sale agreement provided that the company maintain title on previous items purchased by the customer until all subsequent purchases were paid in full).

21. *Id.* at 449.

22. S. 2202, 190th Gen. Ct., Reg. Sess. (Mass. 2017).

23. S. 2007, 240th Leg., 2017 Sess. (N.Y. 2017).

addition, Rhode Island, Illinois, Massachusetts, Oregon, and New Jersey²⁴ also introduced price-gouging legislation that has not yet been passed. A number of states have filed failed legislative attempts to address price gouging: Washington, Colorado, Minnesota, Wisconsin, Mississippi, Louisiana, Virginia, Vermont, and New Hampshire.²⁵

The State of Maryland has played an important role in the passage of price gouging legislation, but also has illustrated some weaknesses of the law. In 2017, Maryland passed anti-price-gouging legislation bipartisan in both the House of Delegates and the Senate.²⁶ The legislation reached the Governor's desk, but was never signed into law. However, the bill was automatically written into law as of October 2017 since it remained unsigned on the Governor's desk for more than 6 months. This law required pharmaceutical companies to submit price increases of 50% or more to the state Attorney General's office prior to implementing such price hikes.²⁷ The Attorney General would then have the right to freeze the price hike if he/she would deem it unconscionable.

The Maryland anti-price-gouging law was held up in lawsuits brought against the state by pharmaceutical manufacturing advocacy groups. As of spring 2018, the lawsuit has been upheld, thereby making the anti-price-gouging law in Maryland moot. In a 2-1 ruling, the 4th Circuit Court of Appeals found the anti-price-gouging law unconstitutional because it regulated trade outside Maryland's borders, which is prohibited by the "Dormant Commerce Clause."²⁸

IV. DRUG PRICE TRANSPARENCY

A number of states have introduced transparency bills in order to better understand what components of a manufacturer's costs go into the price of the drug. These transparency bills also would help consumers understand where prices might be manipulated by other stakeholders in the series of transactions between the manufacturer and consumer, such as influence by PBMs, payers, pharmacies and wholesalers.

24. H. 5390, 2017 Gen. Assemb., Jan. Sess. (R.I. 2017); S. 496, 2017 Gen. Assemb., Jan. Sess. (R.I. 2017); H. 4900, 100th Gen. Assemb., Reg. Sess. (Ill. 2018); S. 652, 190th Gen. Court., Reg. Sess. (Mass. 2017); H.B. 2387, 79th Legis. Assemb., Reg. Sess. (Or. 2017); S. 1590, 2018 Leg., 218th Sess. (N.J. 2018).

25. S.B. 5995, 2018 Leg., 65th Sess. (Wash. 2018); ; S.B. 152, 71st Gen. Assemb., 2nd Reg. Sess. (Colo. 2018); S.B. 2841, 2018 Leg., 90th Sess. (Minn. 2018); S.B. 874, 2018 Leg., Reg. Sess. (Wis. 2018); H.B. 137, 2018 Leg. Reg. Sess. (Miss. 2018); H.B. 243, 2018 Leg., Reg. Sess. (La. 2018); S.B. 223 2018 Leg., Reg. Sess. (Va. 2018); H.B. 713 2018 Leg., Reg. Sess. (Vt. 2018); H.B. 1780 2018 Leg., Reg. Sess. (N.H. 2018).

26. MD. CODE ANN., HEALTH-GEN. § 2-801(c) (West 2018).

27. Jeremy A. Greene & William V. Padula, *Targeting Unconscionable Prescription-Drug Prices—Maryland's Anti-Price-Gouging Law*, 377 NEW ENGL. J. MED. 101, 102 (2017).

28. See *Ass'n for Accessible Med. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018) (holding that the Maryland price gouging statute dealing with the sale of prescription drugs violates the dormant commerce clause).

Nevada has passed multiple bills into law to address complete drug transparency. The first law requires that manufacturers and PBMs submit annual reports to the state on their separate influences on both their operating costs and how the prices of drugs are influenced by these costs.²⁹ Manufacturers must also submit all planned price increases to the state in advance of such changes. The second law is targeted specifically at insulin, a treatment for diabetes.³⁰ Given the concerning epidemiology of obesity and diabetes in the U.S., Nevada is concerned about the budget impact of insulin on local payers. Thus, they have required that all diabetes therapies with raised prices must disclose costs associated with marketing and production of these drugs. In addition, PBMs and manufacturers must disclose all rebates to the state; sales representatives must log all conversations with provides; and, nonprofits must disclose funding received from pharmaceutical manufacturers related to diabetes treatments.

California has introduced legislation requiring transparency for drug prices.³¹ The terms of this law require that manufacturers notify the state of raises in the price of a drug by greater than 16%. This price increase applies to anything above that threshold over a 2-year period.

A number of other states have explored various styles of legislation to tackle drug price transparency. Florida has passed legislation to require transparency on the prices of the 300 most frequently prescribed drugs.³² Vermont passed a transparency bill on drugs with a wholesale acquisition price above \$670 per course of treatment.³³ Other states with price transparency bills in draft are Colorado, Connecticut, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Oregon, Rhode Island, Virginia and Washington.³⁴

29. S.B. 91, 79th Leg., 2017 Sess. (Nev. 2017) (enacted); S.B. 539, 79th Leg., 2017 Sess. (Nev. 2017) (enacted).

30. S.B. 539, 79th Leg., Reg. Sess. (Nev. 2017).

31. S.B. 17, 2017 Leg., Reg. Sess. (Cal. 2017).

32. H.B. 589, 219th Leg., Reg. Sess. (Fla. 2017).

33. S.B. 92, 74th Gen. Assemb., Reg. Sess. (Vt. 2018) (enacted).

34. H.B. 16-1102, 70th Gen. Assemb., 2nd Reg. Sess. (Colo. 2016); S.B. 737, 2017 Gen. Assemb., Jan. Sess. (Conn. 2017); S.B. 73, 100th Gen. Assemb., Reg. Sess. (Ill. 2017); H.B. 1150, 120th Gen. Assemb., 1st Reg. Sess. (Ind. 2017); H.B. 436, 2017 Leg., Reg. Sess. (La. 2017) (enacted); S.B. 59, 2017 Leg., Reg. Sess. (La. 2017) (enacted); MD. CODE ANN., HEALTH-GEN. §§ 2-801-803 (West 2018); S. 1048, 189th Leg., Reg. Sess. (Mass. 2016); S.F. 934, 89th Leg., Reg. Sess. (Minn. 2015); H.F. 1060, 89th Gen. Assemb., Reg. Sess. (Minn. 2015); S. 983, 218th Leg., Reg. Sess. (N.J. 2018); S. 7686, 240th Leg., 2016. Sess. (N.Y. 2016); H.B. 839, 2015 Gen. Assemb., Reg. Sess. (N.C. 2015); H.B. 3486, 78th Legis. Assemb., Reg. Sess. (Or. 2015); S. 2560, 2016 Gen. Assemb., Jan. Sess. (R.I. 2016); H.B. 1113, Gen. Assemb., 2017 Sess. (Va. 2017); S.B. 487 Gen. Assemb., 2017 Sess. (Va. 2017); S.B. 6471, 64th Leg., Reg. Sess. (Wash. 2016).

V. ELIMINATING THE GAG LAW

Of all legislations on drug pricing introduced, gag laws appear to have the strongest momentum towards bipartisan support. At the federal level, the bipartisan bill *The Patient Right to Know Drug Prices* to eliminate gag clauses was passed into law. This bill was sponsored by Sen. Susan Collins (R-ME) and Sen. Claire McCaskill (D-MO) and was passed on October 10, 2018.³⁵ This law allows communication between pharmacists and patients on information transfer about out-of-pocket expenses, with or without use of a health plan.³⁶

In the past year, most states also passed laws to lift gags on pharmacists: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Mississippi, Nevada, North Carolina, North Dakota, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia.³⁷ In 2018, legislation regarding gag laws was considered, but failed in: Missouri, New York, Pennsylvania, and Washington.³⁸ In addition, the Governor of Arkansas recently called a special session to order to look at ways of effectively eliminating the gag law.³⁹

35. S.2554 — 115th Congress (2017-2018) – *Patient Right to Know Drug Prices Act*

36. See *Trending now: State Legislation that Bans Pharmacy Benefit Managers' 'Gag Clauses'*, NAT'L ACAD. FOR ST. HEALTH POL'Y: STATE HEALTH POLICY BLOG, <https://nashp.org/trending-now-state-legislation-that-bans-pharmacy-benefit-managers-gag-clauses/> (last visited Nov. 4, 2018) (identifying states that have recently enacted a ban on 'gag clauses' that forbid pharmacists from discussing cheaper prescription options with customers).

37. H.B. 240, 30th Leg., Reg. Sess. (Alaska 2018); H.B. 2107, 52nd Leg., 2nd Reg. Sess. (Ariz. 2018); H.B. 1010, 91st Gen. Assemb., 2nd Extraordinary Sess. (Ark. 2018); S.B. 1021, 2017-2018 Gen. Assemb., Reg. Sess. (Cal. 2018); H.B.18-1284, 71st Gen. Assemb., Reg. Sess. (Colo. 2018); S.B. 445, 2017 Reg. Sess. (Conn. 2017); H.B. 425, 149th Gen. Assemb., Reg. Sess. (Del. 2018); H.B. 351, 2018 Leg., Reg. Sess. (Fla. 2018); H.B. 276, 2017-2018 Gen. Assemb., Reg. Sess. (Ga. 2017); H.B. 1317, 120th Gen. Assemb., 2nd Reg. Sess. (Ind. 2018); S.B. 351, 2017-2018 Leg., Reg. Sess. (Kan. 2018); H.B. 463, 2018 Gen. Assemb., Reg. Sess. (Ky 2018); S.B. 241, 2018 Leg., Reg. Sess. (La. 2018); S.P. 10, 128th Leg. Reg. Sess. (Me. 2017); S.B. 576, 438th Gen. Assemb., Reg. Sess. (Md. 2018); H.B. 426, 2018 Leg., Reg. Sess. (Miss. 2018); S.B. 539 78th Leg., Reg. Sess. (Nev. 2017); H.B. 1791, 2018 Gen. Assemb., Reg. Sess. (N.H. 2018); H.B. 466, 2017 Gen. Assemb., Reg. Sess. (N.C. 2017); S.B. 2258, 65th Leg., Reg. Sess. (N.D. 2017); H.B. 5038, 122nd Leg., Reg. Sess. (S.C. 2018); S.B. 141, 93rd Leg., Reg. Sess. (S.D. 2018); S.B. 2362, 110th Gen. Assemb., Reg. Sess. (Tenn. 2018); S.B. 1076, 85th Leg., Reg. Sess. (Tex. 2017); S.B. 208, 2018 Leg., Gen. Sess. (Utah 2018); S.B. 92, 2018 Gen. Assemb., Reg. Sess. (Vt. 2018); H.B. 1177, 2018 Gen. Assemb., Reg. Sess. (Va. 2018); S.B. 46, 83rd Leg., Reg. Sess. (W. Va. 2018)

38. S.B. 466 99th Gen. Assemb., 1st Reg. Sess. (Mo 2018); S.B. 7191, 2017-2018 Gen. Assemb., Reg. Sess. (N.Y. 2017); S.B. 637 2017 Gen. Assemb., 2017 Sess. (Pa 2017); H.B. 2623 65th Leg., Reg. Sess. (Wash. 2018)

39. Erika Ferrando, *State of Arkansas to Fight for Oversight on Pharmacy Benefits Managers in Special Session*, THV11 (March 12, 2018, 6:46 PM), <https://www.thv11.com/article/news/local/state-of-arkansas-to-fight-for-oversight-on-pharmacy-benefits-managers-in-special-session/91-527956457>.

VI. OTHER EFFECTIVE DRUG PRICING POLICIES

The State of New York recently passed a law establishing an expenditure cap on drugs prescribed for Medicaid patients.⁴⁰ Above a particular threshold of expenditures for Medicaid eligible patients, the state now requires manufacturers to provide rebates for the excessive cost of certain drugs.⁴¹ This threshold is based on the total cost of drug expenditures per patient, and is not limited to only certain classes of drugs.⁴² Thus, every drug manufacturer must be prepared to provide rebates to the New York State Medicaid program if they wish to have their drugs on the Medicaid formulary.

The City of Chicago created a new city ordinance requiring pharmaceutical sales personnel to log conversations with all providers regarding the marketing and prescribing of drugs they represent.⁴³ In addition, sales personnel wishing to market to providers in Chicago must obtain a city license. This policy is the first of its kind to monitor interactions between pharmaceutical sales and providers.

VII. OTHER CURRENT POLICY PROPOSALS

The U.S. is the only Western country that does not use price regulation at onset at a national level. In the fall of 2018, the Trump Administration proposed a change to this with the introduction of foreign valuations on drug prices, known as “external reference pricing” on drugs administered in U.S. doctors’ offices and hospitals, otherwise known as Medicare Part B.⁴⁴ External reference pricing would mainly reference prices calculated by other countries using methods in health technology assessment (e.g. cost-benefit analysis) to determine the price of the drug valued by its target outcome.

European countries have used methods such as cost-effectiveness analysis at societal willingness-to-pay thresholds.⁴⁵ For instance, the National Institute for Health and Care Excellence (NICE) in the U.K. uses cost per quality-adjusted life year (QALY) willingness-to-pay thresholds that vary by the priority of the drug indication.⁴⁶ Drugs for managing common chronic and acute conditions such as hypertension or influenza may have lower thresholds in the range of £20,000-25,000 per QALY. Whereas, drugs with life-saving indications such as

40. S. 2007B/A. 3007B, 240th Sen. Assemb., 2017 Sess. (N.Y. 2017).

41. *Id.*

42. *Id.*

43. CITY OF CHICAGO RULES, PHARMACEUTICAL REPRESENTATIVE LICENSE § 4 (2017).

44. Rachel Sachs, *Administration Outlines Plan to Lower Pharmaceutical Prices In Medicare Part B*, HEALTH AFFAIRS BLOG (October 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full/>.

45. See Laura Vallejo-Torres et al., *On Estimating the Cost-Effectiveness Threshold: Why, What, How?*, 19 VALUE IN HEALTH 558 (2016) (identifying methodologies for estimating cost-effectiveness thresholds in healthcare systems).

46. Adrian Towse & Clive Pritchard, *National Institute for Clinical Excellence (NICE): Is Economic Appraisal Working*, 20 PHARMACOECONOMICS 95, 99 (2002).

for cancer, HIV/AIDS and hepatitis C virus may be assigned greater thresholds near £30,000 per QALY.

While the approach has never been applied explicitly by U.S. payers such as Medicare programs, the Trump Administration views this proposal as a negotiation process between drug manufacturers and commercial payers to establish rates of some drugs. It could be used effectively by Medicare to establish a place to initiate negotiation, perhaps with binding arbitration. However, owning this critical task has tradeoffs. External reference pricing could protect American patients while restraining price hikes domestically, however the pricing would be based on non-U.S. values of drug outcomes. There is concern that external reference pricing could stymie innovation as it has done in other international markets since the prices would unlikely account for the cost of research and development.

VIII. CONCLUSIONS

As a nation, the U.S. has not been effective at addressing some of the greatest concerns of rising expenditures and prices on drugs. In lieu of federal action, states have successfully introduced and passed several laws that appear to be making a difference. The introduction of rate setting and transparency programs at the state level, as well as gag laws at the federal and state levels is effectively providing patients with a better outlook for lower priced drugs. However, there will continue to be disparities in accessibility to drugs based on price between states as some states achieve progression in drug pricing policies while others lag behind.

A unified effort to implement new drug pricing policies across the U.S. will ultimately continue to depend on federal action. It may be possible to witness federal adoption of some of these rate setting and transparency policies in the near future if multiple states can pass consistent laws, which is being witnessed. For instance, the passage of the federal gag law came after the same legislation passed across Nevada, Connecticut and Maryland. Likewise, the same anti-price-gouging law that appeared in Maryland is being presented as a bill in Wisconsin and Illinois among other states.⁴⁷ However, industry reaction to these laws in the form of effective lawsuits has created a “whack-a-mole” scenario for states, such that as Wisconsin and Illinois may have effective anti-price-gouging legislation in the next year, while Maryland’s is currently held up in a legal battle. Sustained unification of these policies across many states is the most likely way that federal government will take notice and introduce new drug pricing legislation in the future.

47. *State Actions to Halt Price Gouging for Generic Drugs*, NATIONAL CONFERENCE OF STATE LEGISLATURES, (July 20, 2018), http://www.ncsl.org/Portals/1/Documents/Health/Generic_drug_antiprice_gouging_Maryland_31894.pdf.

One element of these policies to note is the level of bipartisan support seen state by state with the introduction of these bills. Drug pricing does not appear to be an argumentative issue across party lines. Most of the legislation mentioned above has passed bipartisan in conservative states including Florida and Montana, purple states like Michigan, and progressive states including Maryland and Massachusetts.⁴⁸ Concerted efforts to pass drug pricing legislation simultaneously will make single-state legal battles less likely.

48. H.B. 351, 25th Leg., 2d Reg. Sess. (Fla. 2018); H.B. 628, 65th Leg., Reg. Sess. (Mont. 2017); S.B. 502, 49th Leg., Reg. Sess. (Mich. 2015); S.B. 1079, 438th Gen. Assemb., Reg. Sess. (Md. 2018); S. 221, 198th Gen. Court, Reg. Sess. (Mass. 2017).