

Curbing Unfair Drug Prices

A Primer for States



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The high cost of prescription drugs in the United States is unsustainable. Spending on prescription drugs is increasing at a faster rate than any other component of health care spending, and a growing number of Americans report difficulty affording their medications. High drug prices are forcing some patients to skip doses of critical medicines, and others to choose between their health and necessities like food and rent. Meanwhile, the pharmaceutical industry continues to launch new drugs at exorbitant prices, increase prices of many old drugs without justification, and reap record profits.

Evidence has unequivocally shown that high drug prices are not linked to the actual costs of research, development and manufacturing. Instead, inflated drug prices are a result of drug manufacturers' power to charge whatever price the market will bear. The need for legislative action is urgent.

To date, however, the federal government has failed to take—and many policymakers have not even considered—meaningful steps to curb drug prices. A leaked draft executive order on drug pricing by the Trump Administration contemplates cutting regulations, but mentions no serious action to lower costs. Instead, it seeks to eliminate mandated discounts for hospitals and clinics that serve low-income patients, and fulfill several other long-time requests of the pharmaceutical industry.¹ The executive order reflects the enormous lobbying influence of pharmaceutical companies at the federal level, where they spent \$2.3 billion over the past decade and where there remains a partisan divide around action to address drug pricing.² While some recently proposed federal measures, including the 2017 Improving Access to Affordable Prescription Drugs Act, are promising first steps, their passage and implementation remain uncertain in the current political environment.

As often occurs, state legislatures have stepped in to fill the policy vacuum. In 2017, more than 80 pharmaceutical pricing bills were proposed in over 30 states around the country.³ Recently, path-breaking drug pricing legislation has passed in Maryland, New York, and Nevada. Several other states have considered bills mandating the study of options to lower drug prices, and some significant legislation could pass within the next year.⁴ Clearly, drug pricing will remain high on state legislative agendas next year, with many now poised to follow up on these initial forays.

This document aims to inform these state legislative efforts by identifying key steps that states can and should take to reduce drug prices. Intended for legislators, government officials, advocates, and constituents concerned about high drug prices, this document focuses, as state legislatures have, on two promising categories of legislative efforts: unfair pricing bills, which are intended to directly regulate drug prices or drug price increases, and transparency and reporting bills, which seek to clarify the rationale for high drug prices by requiring manufacturers to disclose information relevant to pricing decisions. We also identify strategic lessons and best practices drawn from an assessment of recent state-level price reform efforts. We conclude with a set of specific recommendations for legislators seeking to protect patients by preventing pharmaceutical companies from engaging in harmful pricing practices. (Our full set of recommendations can be found in the final section of this report.) In particular, we believe that:

- **States should target excessive pricing for both generic and brand-name drugs, both by prohibiting unfair launch prices and by capping annual price increases.**
- **States should mandate the public release of as much information as possible about pricing, as well as development, manufacturing, and marketing costs on a drug-by-drug basis.**

While the capacity of each state to carry out these recommendations will vary, we intend for this document to identify promising possibilities for reform in a policy area that is currently primed for another wave of legislative activity.

The high cost of U.S. health care today faces more scrutiny than ever before. State legislatures across the country, confronted with rising costs and potential funding shortfalls, are trying to balance budgets while preserving access to services. Unfair drug pricing represents a particularly egregious problem. High drug prices are straining state health budgets, leading to the rationing of new medicines by curtailing their use, and ultimately harming patients.

Research shows that prescription drug spending is growing faster than any other part of the health care dollar.⁵ In 2015, prescription drug spending reached \$457 billion, accounting for roughly 17 percent of total health care costs.⁶ Patients are increasingly feeling the effects of these rising costs:

- **More than one in four Americans currently taking prescription medications report difficulty affording them.**⁷
- **One in eight report that they or a family member have cut pills in half or skipped doses due to high drug costs.**⁸
- **Nearly two-thirds of Americans – regardless of political affiliation – believe that lowering the cost of prescription drugs should be a top policy priority.**⁹
- **86% of Americans support actions requiring drug companies to release information to the public on the process of setting drug prices.**¹⁰
- **Nearly 80% of Americans want government to limit what companies charge for high-cost drugs for illnesses like cancer or hepatitis.**¹¹

In recent years, multiple cancer drugs have launched at a price of more than \$120,000 for one year of treatment; a hepatitis C drug for \$84,000 for a course of treatment; and a genetic neuromuscular disease drug for \$750,000 for the first year of treatment alone.¹² The problem is not just limited to brand-name drugs. Some generic drugs have also seen sharp price increases with no accompanying changes in their formulation that could justify the increase.¹³ For example, the price for doxycycline, a commonly prescribed antibiotic approved in 1967, rose by more than 8,281% between 2013 and 2014.¹⁴ Devices used to deliver drugs have also been subject to price hikes. The price of a two-pack of Mylan's EpiPen (epinephrine), a drug-device combination, increased six-fold in less than a decade, from \$100 to over \$600.¹⁵ In the midst of an opioid epidemic Kaleo increased the price of its overdose treatment, Evzio (naloxone), from \$690 to \$4,500 over two years.¹⁶

While these individual examples spark outrage and make headlines, they reflect a deeper, systemic problem. The United States has long spent more on prescription drugs than have other countries. In 2013, the per capita prescription spending in the U.S. was more than double the average of 19 industrialized nations.¹⁷ Moreover, between 2008 and 2015, the U.S. prices of nearly 400 generic drugs increased by more than 1000%.¹⁸

States are increasingly finding the status quo unsustainable. States account for 17% of all health spending and bear a significant share of the costs of prescription drugs for millions of Americans, including Medicaid beneficiaries, state employees, and incarcerated persons.¹⁹ Medicaid alone accounts for 9% of all prescription drug spending.²⁰ Rising drug prices have forced states to limit coverage. For example, the introduction of new hepatitis C drugs increased the cost of treating an individual patient by about 400% between 2011 and 2015.²¹ Confronted with rising demand for these treatments, some states have restricted access to sofosbuvir, a new drug to treat hepatitis C, to control costs.²² For example, fewer than 1 percent of prisoners with hepatitis C in state prisons are currently being treated due to the high price of these medicines.²³ Taken together, spending on health care poses a severe budgetary problem for states, as 49 states have some form of balanced budget requirements.²⁴

Patients themselves are also bearing the burden of unfair drug prices. Insurers, responding to the increasing number and prevalence of high-cost drugs, have resorted to increasing premiums, deductibles, and out-of-pocket drug payments not covered by insurance plans.²⁵ In a 2017 poll, about 1 in 3 Americans reported having trouble affording their cost-sharing and premium requirements.²⁶ Financial burden due to expensive medical treatment is a major cause of reported distress among patients and their families, who may be forced to make treatment decisions according to affordability concerns.²⁷ As it stands, Americans have few laws to protect them against unfair pricing practices, and little information about why drug prices are so high.

In this primer, we assess state-based legislative efforts to better inform the public about the price of medicines and to limit price gouging by the industry. In doing so, we describe recent efforts; assess political, legal and administrative considerations; and recommend potential legislative options for states. We focus on transparency and limits on unfair prices because long-term solutions will require public information and awareness about the basis for drug prices, as well as legislation that directly addresses the main driver of high drug prices—the ability of pharmaceutical manufacturers to set prices at whatever the market will bear.²⁸ These two options also offer a comprehensive approach that tackles drug prices across the board and will benefit *all* constituents, not merely a subset of beneficiaries.²⁹ We expound our recommendations in the final section of this report. Together, increased transparency and limits on unfair pricing represent an important first step in protecting American patients from exorbitant health care costs and ensuring affordable access to life-saving treatments.

There is much that the federal government could do to lower drug prices via both legislative and executive action. Over the past few years, there has been some discussion about the problem of high drug prices in Congress, but few serious proposals for drug price reform. The only comprehensive proposal to garner significant support at the federal level is a bill spearheaded by Senator Franken (D-MN) and released in March 2017. The bill, titled the “Improving Access To Affordable Prescription Drugs Act,”³⁰ has the support of more than a dozen other Senators, including Senators Warren (D-MA), Blumenthal (D-CT) and Booker (D-NJ).³¹ Although this represents a major step forward, Republicans in Congress have yet to embrace drug pricing as a legislative priority. While President Trump has expressed support for increasing the affordability of prescription drugs,³² and has discussed joining forces with Democrats to support giving Medicare the authority to negotiate drug prices,³³ he has made no concrete legislative proposals to date. The Trump Administration already possesses several potentially powerful means to unilaterally lower drug prices: its federal patent use power,³⁴ its power to push prices down for federally funded inventions under Bayh-Dole,³⁵ and the power to authorize the importation of cheaper drugs from abroad.³⁶ But Trump has made no move to use these powers, and his Secretary of Health and Human Services, Tom Price—who would be key to the use of any of these options—has expressed reluctance to use these powers to curb drug prices.³⁷

Seizing the initiative, states over the last several years have undertaken a range of legislative efforts to address high drug pricing. Certain remedies for high drug prices can come only from the federal government. For example, only the federal government can authorize Medicare to negotiate drug prices for Part D of the program that covers millions of seniors, or reduce patent terms and so shorten the time during which drug companies can exclude competitors and enjoy monopoly pricing power.³⁸ But states do possess significant authority to take a range of measures to regulate drug pricing.³⁹ Within the federal framework, states have the autonomy and power to enact laws for the protection and security of its citizens, allowing states to serve as laboratories for “novel social and economic experiments.”⁴⁰ Collectively, states can provide direct relief to millions of American citizens and residents. They can also generate the political momentum for a federal response. Historically, state legislation has both motivated and informed subsequent federal laws.⁴¹ In addition, some state laws, such as those mandating transparency about factors influencing drug prices, provide benefits to the public and to policymakers around the country and even abroad.

Fair Pricing Bills

Fair pricing bills seek directly to constrain the soaring prices of pharmaceuticals. Several states have proposed—and two states have passed—legislation requiring drug manufacturers (1) to justify certain price increases or face penalties; or (2) to provide rebates when prices exceed a certain threshold.⁴²

As an example of the first approach, a recent bill passed in Maryland prohibits “unconscionable” price increases for essential generic drugs and drug-device combinations used to deliver generic drugs.⁴³ The Maryland bill requires manufacturers that impose significant price increases to provide a justification for such increases to the Attorney General, specifying an increase of over 50% in one year as a suggested benchmark for a significant increase.⁴⁴ The Attorney General, in turn, may petition the Circuit Court to enjoin an “unconscionable” price increase, restore money to patients and third-party payers, and impose a penalty on the manufacturer.⁴⁵ Similar bills have been proposed in Massachusetts, Montana, Oregon, Rhode Island, and Tennessee.⁴⁶

A recent bill passed in New York takes the second approach. It sets a Medicaid expenditure cap by directing the state Department of Health to require manufacturer rebates for drugs which would otherwise exceed the Department’s projected spending targets.⁴⁷ The bill instructs the state Department of Health to make annual projections for Medicaid drug spending, and to assess, on a quarterly basis, whether drug expenditures will exceed these targets.⁴⁸ If overall spending is anticipated to exceed these targets, the Department may negotiate additional supplemental Medicaid rebates for specific drugs from drug manufacturers.⁴⁹ If an agreement cannot be reached, the drug may be referred to the state’s Drug Utilization Review Board for review, further manufacturer negotiations, and possibly formulary and prior authorization sanctions.⁵⁰

These bills are very significant: they represent path-breaking efforts to address drug prices, and show that such laws can be enacted at the state level. But they are also limited – Maryland by its focus on generic drug price increases and lack of public disclosure of information collected by the Attorney General, and New York by its limitation to Medicaid. In other states, such as Massachusetts and Oregon, ambitious bills targeting all prescription drugs, whether patented or generic, are still pending as of this writing.⁵¹

Transparency bills provide the public and policymakers with the information needed to understand how drug prices are set. Their aim is to better inform future policy-making and legislative efforts, as well as help identify specific instances where action to bring prices down is justified. Transparency legislation should, we believe, be distinguished from what we term “reporting” legislation: the former provides information to the public, while the latter provides information to regulators alone. The former is more valuable because it informs both policymakers and the public debate.

Transparency legislation has been introduced in many states over the past two years, and Nevada recently passed a significant transparency law focused on insulin.⁵² The Nevada law requires manufacturers of drugs essential for the treatment of diabetes to report annually on information including the costs of producing the drug, the marketing and advertising costs related to the drug, the profit the manufacturer has earned from the drug, information about patient assistance programs, the wholesale acquisition cost of the drug over the last several years, and the aggregate amount of rebates provided. The law directs the Department of Health and Human Services to compile an annual report based on this information. The law also requires manufacturers to submit information to the state about price increases and sales representatives.

Transparency bills enjoy widespread popular support: a recent Kaiser Family Foundation poll found that 86% of Americans “favor requiring drug companies to release information to the public on how they set drug prices.”⁵³ Transparency will significantly aid in efforts to understand how extensive over-pricing in fact is, and understand where drug prices need to be set to ensure that developers are appropriately compensated for their investment and risks.

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Drug manufacturers sometimes justify their exorbitant prices based on the costs of research and development and the difficulty of introducing a new drug. However, evidence suggests that drug prices today generally are not set with reference to the cost of innovation.⁵⁴ Furthermore, these costs can be accounted for if drug manufacturers provide information regarding public funding of R&D costs (including tax benefits) and granular data by clinical trial phase.⁵⁵ More information about R&D costs, as well as public investments in R&D and other influences on pricing will help inform both fair prices for particular drugs and future legislative approaches to drug pricing.

Additionally, if the development and production costs for particular medicines are publicly known, patients and the public can more readily identify the most egregious examples of price gouging, and demand action. Requiring disclosures can also have a direct effect on drug manufacturers’ behavior, as manufacturers may avoid pricing drugs at costs that would trigger disclosure requirements. In this way, transparency legislation can act as a disincentive to overprice drugs.

The strongest transparency bills require disclosure of many different kinds of information that may be relevant in price determinations. The recently introduced federal bill and various recent state bills require manufacturers to disclose a wide range of information, including:⁵⁶

- Manufacturer prices offered to other payers;
- Research and development costs including clinical trial costs;
- Manufacturing costs;
- Marketing and advertising costs;
- Patient financial assistance and rebates;
- Intellectual property status;
- Acquisition costs (if relevant);
- Pay-for-delay settlements;
- Regulatory approval costs;
- State and federal tax benefits;
- Off-shored profits and jobs;
- Donations to patient disease advocacy groups; and
- Grants, subsidies, and costs paid with public funds or by third parties.

Although manufacturers often impose confidentiality requirements on states and other purchasers when negotiating purchase agreements, states can prospectively compel manufacturers themselves to disclose this information.

Legislatures have taken many different approaches to the scope of disclosures required. The approaches with the most potential to inform public debate and facilitate long-term policy change are those that require drug manufacturers to publicly disclose detailed accounts of the major costs associated with drug development and marketing.⁵⁷ While less ambitious and valuable to the long-term need for policy-relevant information, reporting bills can provide vital information to regulators, and are valuable especially if they are paired with increased regulatory power to address excessive prices. Most bills exist on a spectrum somewhere between these two options, for example requiring disclosure of only some pricing factors or limiting reporting requirements to only certain classes of drugs.⁵⁸

In developing drug pricing legislation, lawmakers and advocates should take into account a range of political, legal and administrative considerations. Below, we identify several key considerations, drawn from an analysis of recent state-level efforts with which we are familiar (in particular, Maryland and Connecticut). We also highlight ways that states may help successfully tailor legislation to their specific context.

Political Considerations

Supporters of state reforms may encounter two key political challenges: the uncertainty in the federal health care landscape and the strength of the pharmaceutical lobby. Building a broad political coalition may help address these challenges.

1. The Uncertain Federal Landscape

The health policy environment in the United States today is volatile, with particular uncertainty about the future of the Affordable Care Act and Medicaid. These debates have enormous stakes and demand significant attention from advocates and policymakers alike. In the shadow of these debates, state legislators and civil society groups may not see the problem of high drug prices as a top health care priority.

Turning Medicaid into a block grant without curbing the rising cost of drugs would likely force states to restrict access to needed medical care, including drugs and other medical products.

However, the current intense focus on health care costs and issues also presents an opportunity to link issues, build a broad coalition, and generate political momentum. High drug prices are deeply connected to other systemic problems in the health care system. High drug prices lead to higher health care costs, which, in turn, contribute to higher insurance premiums. High drug prices also exacerbate the health impact of any reduction in federal funding, or loss in insurance coverage. For example, turning Medicaid into a block grant without curbing the rising cost of drugs would likely force states to restrict access to needed medical care, including drugs and other medical products. Similarly, individuals who lose insurance coverage under a replacement for the Affordable Care Act would face exorbitant costs for drugs, curbing their access to essential treatments. By linking high drug prices with these broader issues, advocates and legislators can build multi-stakeholder coalitions of patient and consumer advocacy groups, insurers, academic researchers, and health care practitioners. In addition, there is strong bipartisan support from the public for serious measures to lower drug prices.

2. The Pharmaceutical Lobby

The strength of the pharmaceutical lobby at the federal level is well-documented.⁵⁹ Pharmaceutical companies have also invested heavily in some states to fight the recent set of legislative and ballot initiatives.⁶⁰ A detailed analysis of their advocacy strategy is beyond the scope of this paper, but advocates and legislators can expect the industry to vigorously oppose legislative action to address drug pricing. A frequent talking point of the pharmaceutical industry is that legislation targeting high drug prices will hurt innovation. Evidence shows, however, that companies spend far more on marketing than on research and development,⁶¹ and that research and development costs do not explain elevated US drug prices.⁶² (Price increases on old medicines, of course, also cannot be justified by R&D costs.) Public tax dollars also play a significant role in innovation: more than half of the most transformative drugs in the last 25 years had their origins in publicly funded research.⁶³

Industry may also seek to shift the blame for high drug prices to unfair practices by pharmacy benefit managers (PBMs). While PBMs and their role in pricing deserve attention,⁶⁴ the prices set by manufacturers fundamentally reflect their unchecked power to charge whatever the market will bear. Companies seeking to shift the blame should be pressed to be more transparent about their after-rebate prices and overall profits. One report found that the median revenue of the top-100 prescription drugs has risen sevenfold between 2003 and 2014, reflecting money solely earned by the pharmaceutical industry.⁶⁵ Targeting unfair PBM practices is not a substitute for addressing egregious pharmaceutical practices that result in unfair drug prices.

The industry may also focus on the potential for job loss, particularly if they have extensive research or manufacturing presence in the state. In addition to publicly deploying arguments about innovation and jobs, industry may also privately threaten legal challenges and the withdrawal of medicines from state markets.

The success of the Maryland campaign highlights several strategies available to advocates to challenge these arguments. Advocates may wish to:

- Build a multi-stakeholder coalition of patient and consumer advocacy groups, insurers, academic researchers, and health care practitioners;
- Assess the economic and political footprint of the pharmaceutical industry in their state, including the number of jobs created, campaign contributions and key political allies;
- Research and identify the specific impact of high drug prices on the state budget and local patients;
- Disseminate existing advocacy documents that refute common pharmaceutical lobby myths, such as the notion that high drug prices reflect the high cost of innovation;⁶⁶ and
- Act in concert with other states to reduce the risks associated with legislation, such as the threat of withdrawal.

Legal Considerations

Industry sometimes argues that transparency bills interfere with their trade secrets and that predatory pricing bills are preempted by federal patent law. Trade secrecy law prohibits unauthorized disclosure to competitors of economically valuable information not generally known by others. Federal preemption refers to the invalidation of state law that conflicts with federal law. In both areas, consistent with these laws, states have substantial authority to write effective legislation. States may permit sufficient disclosure of information to the public and to regulators, and regulate exorbitant prices of patented and generic drugs without risking preemption. Possible legal arguments are presented below.

1. Trade Secrecy

Drug manufacturers sometimes claim that transparency bills that make information available to the public (and therefore to competitors) risk unconstitutional “takings” of their trade secrets.⁶⁷ Some states in response have curbed their transparency bills, turning them into reporting bills that require companies to report information only to regulators, or to hybrid bills that require regulators to share only very limited information with the public. For example, the Vermont bill passed in 2015 prohibits public disclosure of any information provided by manufacturers if it identifies an individual drug or manufacturer.⁶⁸ The first report was released in 2017,⁶⁹ and shows that this limitation on disclosure substantially reduced the usefulness of the information released. Under the prevailing legal standard, however, states can make any information available to the public without providing compensation to the owner 1) if it is not a trade secret or 2) if it is a trade secret, but certain fact-intensive determinations indicate that no “taking” has occurred.

Courts have not ruled consistently—if at all—on whether information considered under transparency bills would be considered trade secrets. In simplified terms, when making a trade secret determination, courts look to the degree of secrecy of the information and to its economic value. We know that pharmaceutical companies vigilantly protect some of their information. But some information required by transparency bills—such as patent status—is already in the public domain (though burdensome for the public to collect). Such information will not be “secret” enough to qualify as a trade secret. Other information that transparency bills target may not have economic value in the relevant sense. For example, detailed research and development costs for a particular drug may be sufficiently “secret” to qualify as a trade secret, but not of sufficient economic value to competitors, particularly if disclosure applies uniformly across companies and occurs years after these costs were accrued. Other information, like marketing costs, may be more likely to qualify as a trade secret.

States can, however, sometimes require companies to disclose trade secrets, because takings law involves a close consideration of the circumstances. There are very few cases where companies have sued government for taking a trade secret, and existing cases can be read narrowly or broadly. On a narrow reading of the sole Supreme Court case in this area, the government is liable for taking a trade secret only when it explicitly has assured a company submitting data that it will not be released to the public.⁷⁰ On this reading, states would be free to make trade secrets public as long as they had not previously assured companies submitting the data that it would not be made public. A broader reading of the case would suggest instead that states must defend such prospective disclosures under a multi-factor test that considers the character of the governmental action, its interference with reasonable investment-backed expectations, and its economic impact. If a state requires public disclosure of a very valuable and highly protected trade secret, like a secret product formula, and does not have good evidence of public benefit, under this test it may be found to have taken a trade secret, so that compensation must be afforded.⁷¹

Unlike ingredient or formula disclosures, drug transparency bills require the disclosure of information that is neither central to drug companies’ business model, nor in most cases comprehensively secret.

Unlike ingredient or formula disclosures, drug transparency bills require the disclosure of information that is neither central to drug companies’ business model, nor in most cases comprehensively secret. Given their significant budgetary and public health interest, states are well-positioned to require public disclosure of substantial information, but will strengthen their hand by building a record of the value of the information to the public.

If a state demands transparency of categories of information where it deems trade secrecy to be a genuine concern, it can do two things to protect the public interest. The first is to mandate public disclosure *unless* companies make a strong, detailed showing of trade secrecy to a state entity. Companies are in the best position to provide the evidence needed to assess arguments about economic benefit and secrecy, and concessions to secrecy should not be made without specific, clear evidence of this sort. To further promote transparency, states may give the public the legal right to object to the withholding of specific information by state entities.

Second, states may also provide for disclosures to a group that is narrower than the public, but configured to include those that make key contributions to the policy debate. Trade secrecy is about protecting information from *competitors*. Courts have thus found that disclosure to a discrete group of non-competitors does not implicate trade secrecy.⁷² In this context, rather than make disclosures to regulators alone, states should identify specific groups, such as academics and patient advocates, who are permitted access to the required information. These groups could then analyze the data and release it in a sufficiently aggregate basis such that they no longer constitute trade secrets.

2. Federal Patent Law Preemption

Drug manufacturers may also claim that state laws regulating drug prices are preempted by federal patent law. States have broad authority to regulate health, safety and welfare for the common good. Under the Supremacy Clause of the Constitution, however, states may not act inconsistently with the federal Constitution or with federal laws.

The Supreme Court has long recognized the state power to tax manufactured patented goods, as well as the ability to control or even ban patented articles.⁷³ In a much-criticized case before the US Federal Circuit called *BIO v. DC*, one appellate court concluded that a law regulating the prices of patented drugs was preempted by federal patent law. The court reasoned that the law rebalanced “the statutory framework of rewards and incentives insofar as it relates to inventive new drugs,” and so interfered with the execution of federal patent law.⁷⁴ However, the law in question applied *only* to patented medicines, and the court explicitly limited its holding to that context, leaving room for price control laws that cover both patented and unpatented drugs alike.⁷⁵ This is presumably because it has long been assumed – and the federal government has explicitly recognized – that states have broad power to regulate prices, including of goods and services that implicate patents, such as gasoline⁷⁶ and electricity.⁷⁷

States also have broad tax authority and regularly tax or impose rebates on products that implicate patents. Some states, such as New York, are avoiding patent preemption arguments by implementing price restrictions via rebates or taxes instead of directly regulating the prices of drugs. Taxes and rebates set at less than 100% of the excessive price do not strictly limit the price that a drug manufacturer can set, as a drug manufacturer can always set the price higher to compensate.⁷⁸ In this system drug manufacturers may still exercise their exclusive rights to set drug prices, creating additional arguments against preemption.

States have broad authority to regulate health, safety and welfare for the common good.

It should be noted, finally, that generic drugs are not subject to patent law. This means that states can without question regulate the prices of generic drugs.⁷⁹

Administrative Considerations

States introducing drug pricing legislation may also face administrative challenges. Because states vary considerably in their administrative capacity and drug pricing expertise, certain types of legislation may not be feasible for some states to implement. For example, some states may not have the capacity to analyze transparency data, assess research and development costs and risks, and independently establish fair prices across a broad range of medicines. Similarly, if state attorney generals are empowered to challenge unfair drug pricing,⁸⁰ some may not have the capacity to pursue all but the most egregious and clearly defined violations.

To minimize administrative challenges, advocates can push for increased staff and resources (noting, for example, that new positions could potentially pay for themselves via budget savings).⁸¹ Another alternative is to adjust the scope, ambition, and structure of a bill to reflect administrative constraints, and to ensure buy-in from relevant actors. Administrative burdens could be minimized by using simple and clear standards (e.g., using benchmarks for prices rather than a tailored, drug-by-drug analysis).⁸² States can also take advantage of outside resources by increasing public participation. For example, states could publish all transparency data, supplementing regulatory review of unfair prices with public review. States might also give standing to individuals to challenge unfair drug prices, and more formally rely on external expertise when analyzing data, ranging from non-profit organizations to expert committees.

Part 4: Recommendations

Based on our analysis of state level legislative proposals and efforts, and their potential implications, we have developed a set of recommendations designed to identify key steps to address high drug prices that state should take. The set of solutions each state pursues may be different but should share some key features to have a meaningful impact.

States should consider implementing both fair pricing and transparency legislation. These two prongs of potential legislation are complementary and address both short-term and long-term concerns about drug pricing. Prohibitions on unfair pricing, if well-crafted, can provide immediate relief to patients and state budgets, while transparency can help lay the groundwork for broader reforms, and better-informed policy, in the future.

Recommendation 1: States should pass laws that address unfair launch prices and price increases of patented and brand-name drugs.

- **Legislation should cover the prices of both generic and patented drugs.**
 - Addressing unfair pricing for only generic drugs skirts any possibility of legal challenge on the basis of preemption, but would not address the largest drains on state budgets. Covering only generics also would not provide relief from high insurance premiums and out-of-pocket costs derived from the high prices of patented medications. States have strong arguments to prevail in a potential legal challenge to state laws regulating both generic and patented drugs.
- **Establishing limits on prices requires a method to establish fair prices. States might approach this task in varied ways:**
 - **The most rigorous approach would be to set price benchmarks based on the costs of developing a drug.** States could ensure companies earn only reasonable compensation and do not profit at the expense of patient access. This approach would entail disallowing prices that would capture excessive profits relative to the manufacturer's risk-adjusted investments.
 - **A second approach relies on a reference price that is publicly available.**
 - States with more limited administrative resources could approximate a fair price by using reference prices. The bill in Oregon, for example, uses the highest price offered in another developed country as a referent.
 - Implementing this approach requires reference prices to be available to the state. California's Proposition 61 would have set reference prices to the lowest price by the U.S. Department of Veterans Affairs. States using non-public prices should mandate disclosure to facilitate implementation.
 - **A final approach would be to price drugs according to their therapeutic value.**
 - An example of the value-based approach can be found in a Massachusetts bill. The bill uses analysis from the Institute for Clinical and Economic Review (ICER) to set a price. ICER compares different treatments based on their clinical benefits and uses this information to set value-based benchmark prices. This approach may not always lead to more affordable prices, however, because ICER sets a high price threshold for some drugs. ICER compares interventions to the cost of existing interventions, and so may overcompensate when R&D costs are taken into account.
 - Governor Cuomo's proposal as enacted for Medicaid in New York sets a rebate target for certain drugs, in part, based on the affordability and cost of the drug to the Medicaid program and any significant and unjustified price increases. The rebate might also incorporate information about the drug's therapeutic value.
 - **Given limited resources, states might choose to prioritize particular high-cost drugs** by setting a threshold for regulation based on the drug's price for a course of treatment, total state spending on the drug, or the drug's importance for patient care.

- **States should also constrain unfair price increases. This will have a smaller impact than setting prices, but will still provide meaningful relief for patients.**
 - **One model is the federal drug-pricing bill, the “Improving Access To Affordable Prescription Drugs Act,”⁸³ which would impose a progressive rebate on any price increases greater than the rate of medical inflation.** Although stalled at the federal level, this proposal has the potential to generate billions of dollars in government revenue.⁸⁴ To avoid this rebate, a manufacturer would need to justify the increase based on changes in manufacturing costs. This approach systematically addresses the problem of price increases by imposing a penalty on price increases above the rate of medical inflation.
 - **The Maryland law targets generic drug price increases. The law gives discretion to the Attorney General to prosecute drug companies that engage in unconscionable price increases for “essential generic drugs.”** It also suggests a threshold of, but not limited to more than 50% over a two-year period. Violators may be required to offer their products at a lower price and/or return profits to patients and payers. Violators may also face civil penalties. While more limited in scope than the proposed federal law, it is an important first step in establishing a state’s authority to rein in high drug prices.

Recommendation 2: States should 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.

- **Disclosure of detailed information about drug prices and development, manufacturing, and marketing costs on a drug-by-drug basis is critical. To estimate expenditures adjusted for the risk of failure and assess the validity of existing estimates, this information must include granular data by clinical trial phase. This information is a key input into public debate about drug prices.⁸⁵ Though manufacturers argue drug prices are high because of the costs of development and the value drugs provide, it is difficult to assess these claims without this information.**
 - Understanding what prices are and how they are set will allow both patients and regulators to make more informed decisions about whether prices are excessive, and introduce some rationality and evidence into pricing debates. In the current environment, manufacturers’ arguments are frequently based on exaggerated and unsubstantiated claims.
 - States may want to include transparency requirements for pharmacy benefit managers (PBMs), as Nevada did in its insulin drug pricing transparency bill.⁸⁶ Information about which rebates PBMs negotiate will help ensure PBMs are acting in the best interests of insurers and patients. However, it is important to remember that pharmaceutical companies, without disclosing research and development costs to PBMs, set the prices that PBMs then negotiate down. Laws that require disclosure of drug prices set by pharmaceutical companies would also help in evaluating the pricing practices of industry middlemen.
- **At a minimum, state transparency laws should release all information to non-competitors (including regulators, payers, academic researchers, and patient advocacy groups).**
 - These groups should have allowances to release analyses using aggregated data.
- **States should have a presumption of public release for all information, subject to rebuttal only if companies demonstrate that a specific fact is a trade secret.**
 - Companies are in the best position to provide the evidence needed to assess arguments about economic benefit and secrecy, and concessions to secrecy should not be made without specific, clear evidence.
 - The legislation can also give the public the legal right to object to the withholding of specific information.

Appendix: List of State Bills (as of June 1, 2017)

Transparency Bills

State	Status	Type of Drug	Reporting Requirements	Public Disclosure Exemptions
California	Introduced in 2015, died in committee in 2016	Drugs with a wholesale acquisition cost of \$10,000 or more annually or per course of treatment	<ul style="list-style-type: none"> - R&D (including costs paid to any predecessor) - Manufacturing - Marketing - Clinical trials - Acquisition - Price history - Profit 	Confidential and proprietary information
California	Passed in 2017	All covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use	<ul style="list-style-type: none"> - All factors contributing to price increase - Marketing - Acquisition - Clinical efficacy 	Specifically requires publishing of reported data in a “manner that identifies the information that is disclosed on a per-drug basis” and prohibits aggregation.
Connecticut	Passed Senate, pending on House calendar	All drugs	Prohibits health carriers and PBMs from prohibiting or penalizing a pharmacist’s disclosure to individual purchasers of (1) the cost of a drug to the individual, (2) therapeutically equivalent drugs, and (3) alternative, less expensive methods of purchasing a drug	None
Connecticut	Introduced in 2017	All drugs	<ul style="list-style-type: none"> - R&D - Clinical Trials - Manufacturing - Acquisition - Marketing 	None
Florida	Passed in 2017	300 most frequently prescribed drugs	<ul style="list-style-type: none"> - Retail prices (including generics) 	None
Illinois	Introduced in 2017	Drugs which have increased in wholesale price by 25% or more in any 12-month period, or by more than \$10,000	<ul style="list-style-type: none"> - Notice of price increase - Price history - Marketing - Acquisition 	Pricing information prior to date of price increase
Indiana	Introduced in 2017	Drugs in Medicaid program with an annual wholesale cost or per course cost of at least \$10,000	<ul style="list-style-type: none"> - R&D (including predecessors) - Clinical trials - Regulatory - Manufacturing - Marketing - Acquisition - Profit - Grants and subsidies 	Proprietary information, only summary of report is published

Transparency Bills (continued)

State	Status	Type of Drug	Reporting Requirements	Public Disclosure Exemptions
Louisiana	Passed in 2017	All drugs	<ul style="list-style-type: none"> - Manufacturers and PBMs who market directly to prescribers must provide the current WAC information for all FDA approved drugs marketed in that state 	None
Maryland	Introduced in 2017, died in committee in 2017	Drugs with a wholesale acquisition cost of \$2,000 or more annually or per course of treatment	<ul style="list-style-type: none"> - R&D (including predecessors) - Grants and subsidies - Intellectual property - Pay-for-delay - Regulatory - Manufacturing - Marketing - Tax benefits - Foreign income - Patient financial assistance and co-pay coupons 	None
Massachusetts	Introduced in 2017	Up to 20 prescription drugs, determined by the Health Policy Commission	<ul style="list-style-type: none"> - All factors contributing to price increase - Percentage of price increase attributable to each factor 	Confidential commercial information and trade secrets
Nevada	Introduced in 2017, declared exempt	Drugs costing \$10,000 or more per year or course of treatment, or has increased in price by 25% or more over the past year.	<ul style="list-style-type: none"> - R&D (including predecessors) - Clinical trial - Regulatory - Post-approval study - Manufacturing - Grants and subsidies - Acquisition - Marketing - Patient financial assistance - Profits - Price history - Similar information required from PBMs 	Information that would cause competitive harm to the manufacturer
Nevada	Passed into law in 2017	Insulin and biguanides for which the WAC increases by more than: (1) the percentage increase in the state Consumer Price Index, Medical Care Component in the previous calendar year or (2) two times the percentage increase in the Consumer Price Index, Medical Care Component in the previous two calendar years	<ul style="list-style-type: none"> - Any factor, without limitation, that has contributed to the price increase - The percentage of total increase attributable to each factor - An explanation of the role of each factor in the price increase - Marketing 	Trade secrets

Transparency Bills (continued)

State	Status	Type of Drug	Reporting Requirements	Public Disclosure Exemptions
New Jersey	Introduced in 2016, referred to committee	List of “critical prescription drugs” developed by committee established by bill	<ul style="list-style-type: none"> - R&D (including predecessors) - Grants and subsidies - Prices (including prices for other payors) - Regulatory - Manufacturing - Marketing 	Reported information must be aggregated, not public or government record
New York	Introduced in 2017	Drugs with a wholesale acquisition cost of \$1,000 or higher for 30-day supply, or has increased in price by more than three times in the past three months	<ul style="list-style-type: none"> - R&D (including predecessors) - Clinical trial - Regulatory - Post-approval study - Acquisition - Marketing - Prescriber education - Lobbying - Patient financial assistance - Donations to advocacy groups - Price history 	Confidential and proprietary information, all data is exempt from state FOIA
Oregon	Introduced in 2017	Drugs which have an introductory average wholesale price of \$10,000 or more per year, or has increased in price by 3.4% over a 12-month period	<ul style="list-style-type: none"> - R&D (including predecessors) - Anticipated return on investment - Description of measures against off-label use - Clinical trial - Regulatory - Patient financial assistance - Post-approval study - Acquisition - Marketing 	Information likely to compromise financial or competitive position
Vermont	Enacted in 2016	Drugs with a wholesale acquisition price of \$2,500 or more annually or per course of treatment	<ul style="list-style-type: none"> - R&D (including predecessors) - Grants and subsidies - Intellectual property - Reverse payment patent settlements - Regulatory - Manufacturing - Marketing - Revenues - Price history - Tax benefits - Patient financial assistance 	Data must not allow identification of an individual drug or company, information is exempt from state Public Records Act
Washington	Passed in House, read in Senate in 2017	The 25 prescription drugs most frequently prescribed, 25 costliest drugs, and 25 drugs with highest year-over-year increase in spending	<ul style="list-style-type: none"> - R&D - Price history (U.S. and Canada) - Clinical trials - Regulation - Acquisition - Profit - Justification for price 	Report is limited to costs and price increases based on utilization and cost data reported by health plans

Fair Drug Pricing Bills

Bill	Current Status	Requirements	Process
Fair Pricing Act	Introduced September 15, 2016	Both generic and brandname -Qualifying drugs that experience an increase of 10% in the AMP over a 12-month period. -Qualifying drugs are FDA approved, commonly administered by hospitals (as determined by the Secretary of Dept of Health and Human Services), not designated as a drug for a rare disease or condition, not designated as a vaccine, and for which at least \$1 of total sales were purchased by Medicare or State Medicaid plan.	-Manufacturer required to submit a report to the Secretary for justification. -Inspector General of Department of Health and Human Services determines reporting requirements.
California	Failed	<u>Both generic and brandname</u> -Sets price ceiling for the net cost of any drug to the same as or less than the lowest price paid for by the referent: Dept of VA.	Reference pricing
Connecticut	Passed Senate, pending on House Calendar	All drugs	- Limits out of pocket payments to the lowest of applicable copayment, allowable claim amount, or uninsured cost of drug - Allows third party payers to recover damages in antitrust suits against drug manufacturers
District of Columbia	Enacted into law; challenged; struck down	Brand name only -Patented drugs with wholesale price 30% or more than the comparable price in other high income countries that also has patent protection for the product.	-Any affected party can file suit including, but not limited to, the state AG
Maryland	Enacted into law on May 26, 2017	Generic only -Price increase of 50% or more of the AMP or the WAC within a 2-year period. -Price increase of 50% or more of the price paid by the Maryland Medicaid Assistance Program.	-Maryland Medical Assistance Program notifies both manufacturer and the State AG. -Manufacturer is compelled to produce report for AG justifying price increase. -AG office determines if the price increase is unjustified and eligible for injunction through circuit court.
Maine	Introduced in 2017	Drugs whose (i) WAC is \$2,500 or more annually or for a course of treatment, or whose (ii) WAC of the drug has increased by 50% or more over the previous 5 years or increased by 15% or more over the previous 12 months.	- Manufacturer must notify AG of information related to the price of qualifying prescription drugs from manufactures including total cost of production and cost per dose, research and development funds, retail prices charged outside of the United States, and the true net typical prices charged to PBMs.
Massachusetts	Adopted June 2, 2016	Both generic and brandname -Applies to drugs whether the following four conditions must be considered: (1) cost of drug to public health care programs (2) current cost of drug in the commonwealth (3) extent of utilization of the drug within the commonwealth (4) potential impact of the cost of drug on the commonwealth's achievement of the statewide health care cost growth benchmark.	-Manufacturer is required to submit report for price justification. -The Commission and the Center is required to prepare a report that is provided to the legislation and available to the public.

Fair Drug Pricing Bills (continued)

Bill	Current Status	Requirements	Process
Massachusetts	Introduced in 2017	Any drug that has experienced a WAC increase of 15% or more over a 12-month period	- Manufacturer must file a report including the current WAC, the amount of most recent increase to WAC, the five-year history of the WAC, as well as R&D costs and revenue from the drug.
Montana	Died in committee in 2017	Any drug that has experienced a WAC increase more than twice the increase in the consumer price index	- Manufacturer is required to submit all relevant information necessary to justify price increase to state AG
Nevada	No action as of 2017	Drugs with a WAC price of at least \$10,000 or drugs with a price increase of at least 25% over 12 months	Requires manufacturer to report to the Division of Insurance the factors causing the price increase
New Jersey	Introduced in 2017	Creates a Prescription Drug Review Commission to determine whether the cost of any drug is excessive	- The Commission can establish a maximum allowable price for a drug
New York	Signed into law; Current bill to lower threshold to 75% introduced January 23, 2017	Generic only -Applies to prescription drugs that have increased 300% more than their State Maximum Acquisition Cost (SMAC) to Medicaid over the preceding 12 months.	-Center for Medicare and Medicaid Services create and adopt the methodology that would determine the additional rebates.
New York	Enacted in 2017	All drugs. The Department and the Division of the Budget shall assess on a quarterly basis the projected total amount to be expended in the year on a cash basis by the Medicaid program for each drug, and the project annual amount of drug expenditures for all drugs	Implements a Medicaid drug spending cap as a separate component within the Medicaid global cap
Ohio	Indirect state statute that will be voted on November 7, 2017	Both generic and brandname -Sets price ceiling for the net cost of any drug to the same as or less than the lowest price paid for by the referent.	-Reference pricing
Oregon	Referred to Health Care Committee January 17, 2017	Both generic and brandname -Sets price ceiling for the average wholesale price as the highest price paid in any country other than the US that is a member of the OECD. -Applies to drugs that experience a price increase by a manufacturer of 3.4% or more in the average wholesale price over preceding 12 months. -This applies to drugs approved by the FDA that have an introductory average wholesale price of \$10,000 or more annually.	- Manufacturer creates process by which reimbursement for excess costs may be dispensed to the payer. - Manufacturer is required to produce written notice 60 days in advance before increase in average wholesale price. - Manufacturer is required to submit report justifying introductory price to Dept of Consumer and Business Services.
Pennsylvania	Referred to Insurance Committee on April 21, 2015	Both generic and brandname -Prescription drug with an AWP of \$5,000 or more annually or per course of treatment.	-Manufacturer required to file report with the Insurance Department for price justification. -Manufacturer also required to have an independent third-party auditor review prior to filing report.

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²⁸ Targeting discount negotiations between pharmaceutical manufacturers and pharmaceutical benefit managers (PBMs) may also be helpful, but the precise impact of such an intervention on drug prices remains unclear. More fundamentally, targeting these negotiations does not address the unconstrained power of pharmaceutical companies to set unfair prices.

²⁹ Expanding the 340(B) program, which provides discounts for eligible healthcare organizations, is one example of a more limited approach. “340B Drug Pricing Program,” Department of Health and Human Services Health Resources and Services Administration (March 2017), <https://www.hrsa.gov/opa/>.

³⁰ S. 771, 115th Cong. (2017); H.R. 1776, 115th Cong. (2017).

³¹ “As Health Care Debate Shifts, Senator Franken and Senate Colleagues Lead Milestone Effort to Bring Down Prescription Drug Prices,” Press Release (March 29, 2017), https://www.franken.senate.gov/?p=press_release&id=3655

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³⁵ Goldman, Andrew, “KEI, UACT Request that Trump Administration Reevaluate Xtandi Petition,” Knowledge Ecology International (April 19, 2017), <http://keionline.org/node/2756>; Love, James, “Xtandi 2016 March-In Request,” Knowledge Ecology International (January 13, 2016), <http://keionline.org/node/2412>. The Bayh-Dole Act enables the patenting and commercialization of inventions developed under federally funded research programs. The Act gives the federal government a royalty-free right to any patent claimed by a grant recipient as well as “march-in” rights to require licenses be granted under special circumstances. 35 U.S.C. § 202-03.

³⁶ Wu, Tim, “How to Stop Drug Price Gouging,” *New York Times* (April 20, 2017), <https://www.nytimes.com/2017/04/20/opinion/how-to-stop-drug-price-gouging.html>.

³⁷ Scott, Dylan, “Tom Price sidesteps question on Medicare drug-pricing negotiations,” *STAT* (January 18, 2017), <https://www.statnews.com/2017/01/18/tom-price-drug-prices/>.

³⁸ The Franken bill aims to do both. See: “As Health Care Debate Shifts, Senator Franken and Senate Colleagues Lead Milestone Effort to Bring Down Prescription Drug Prices,” Press Release (March 29, 2017), https://www.franken.senate.gov/?p=press_release&id=3655.

³⁹ See: U.S. Const. amend. X. See also: *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475, 116 S. Ct. 2240, 2245 (1996) (“Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. Because these are ‘primarily, and historically, . . . matter[s] of local concern,’ the ‘States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.’” (quoting *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985) and *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985))).

⁴⁰ *New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932) (Brandeis, J., dissenting).

⁴¹ For example, the Employee Retirement Income Security Act of 1974 (ERISA) resulted from Congress’ desire to unify and harmonize multiple state laws regulating pension and health plans. Pub. L. No. 93-406, 88 Stat. 829. See also: *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016) (“[T]he central design of ERISA . . . is to provide a single uniform national scheme for the administration of ERISA plans without interference from laws of the several States”); Flint, Jr., George Lee, “ERISA: Fumbling the Limitations Period,” *Nebraska Law Review* 84, no. 1 (2005): 313–368 (discussing the legislative history of ERISA and the intent of Congress to preempt varying state laws).

⁴² See Appendix for a list of state bills.

⁴³ H.R. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017), <http://mgaleg.maryland.gov/2017RS/bills/hb/hb0631E.pdf>.

⁴⁴ Id.

⁴⁵ While “unconscionable” is usually a legal term of art, here it is defined as relating to a price increase that is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health, and results in patients who need the drug having no choice but to purchase the drug at the increased price. Id.

⁴⁶ See S. 627, 190th Gen. Court, Reg. Sess. (Mass. 2017), <https://malegislature.gov/Bills/190/S627>; H.R. 326, 65th Leg., Reg. Sess. (Mont. 2017), <http://leg.mt.gov/bills/2017/BillPdf/HB0326.pdf>; S. 793, 79th Legis. Assemb., Reg. Sess. (Or. 2017), <https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/SB793/Introduced>; H.R. 5323, 2017 Gen. Assemb., Jan. Sess. (R.I. 2017), <http://webserver.rilin.state.ri.us/BillText17/HouseText17/H5323.pdf>; H.R. 1327, 110th Gen. Assemb., Reg. Sess., (Tenn. 2017), <https://legiscan.com/TN/bill/HB1327/2017>.

⁴⁷ See: S. 2007B, 2017 Leg. Gen. Assemb. (N.Y. 2017), <https://www.nysenate.gov/legislation/bills/2017/s2007/amendment/b>.

⁴⁸ For 2017-2018, this is based on the “ten-year rolling average of the medical component of the consumer price index plus 5% and minus a pharmacy savings target of fifty-five million dollars.” For 2018-2019, the adjustment factor of five percent is reduced to four percent. Id.

⁴⁹ Id.

⁵⁰ Id. If an agreement cannot be reached based on the Drug Utilization Review Board recommendation, the manufacturer may be required to submit extensive information regarding its drug product, including actual costs of research & development, manufacturing, production, and distribution. Id. This information would be kept confidential by the state. Id.

⁵¹ See: S. 627, 190th Gen. Court, Reg. Sess. (Mass. 2017), <https://malegislature.gov/Bills/190/S627>; S. 793, 79th Legis. Assemb., Reg. Sess. (Or. 2017) <https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/SB793/Introduced>.

⁵² See: S. 539, 2017 Assemb., 79th Sess. (Nev. 2017), <https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5822/Text>.

⁵³ Kirzinger, Ashley, Wu, Bryan, and Brodie, Mollyann, “Kaiser Health Tracking Poll: September 2016,” The Henry J. Kaiser Family Foundation (September 29, 2016), <http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>.

⁵⁴ See, e.g.: Ron Wyden and Charles E. Grassley, “The Price of Sovaldi and its Impact on the U.S. Health Care System,” Senate Committee on Finance (December 1, 2015), [https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf) (concluding that Gilead had set the price of Sovaldi with the goal of maximizing revenue and preparing the market for Harvoni); Alton, Gregg, “Re: Betting on Hepatitis C: How Financial Speculation in Drug Development Influences Access to Medicines,” *BMJ* (July 29, 2016), <http://www.bmj.com/content/354/bmj.i3718/> (“Giead [sic] conducted extensive research with a broad group of private and public payers to determine a fair and reasonable price.”). doi: 10.1136/bmj.i3718; Yu, Nancy, Helms, Zachary and Bach, Peter, “R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices,” *Health Affairs Blog* (March 7, 2017), <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>. Advocacy materials from the pharmaceutical industry also suggests that companies consider factors beyond the research and development cost of new drugs when setting prices. “Four Facts: Value and Cost of Medicines,” The Catalyst - A PhRMA Blog (May 21, 2014), <http://catalyst.phrma.org/four-facts-value-and-cost-of-medicines>.

⁵⁵ See Love, James, “The 2016 Tufts estimates of the risk adjusted out-of-pocket costs to develop a new drug,” Knowledge Ecology International (April 12, 2016), <http://keionline.org/node/2464>.

⁵⁶ “As Health Care Debate Shifts, Senator Franken and Senate Colleagues Lead Milestone Effort to Bring Down Prescription Drug Prices,” Press Release (March 29, 2017), https://www.franken.senate.gov/?p=press_release&id=3655; See also H.R. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017), <http://mgaleg.maryland.gov/2017RS/bills/hb/hb0631E.pdf>.

⁵⁷ See S. 652, 190th Gen. Court, Reg. Sess. (Mass. 2017), <https://malegislature.gov/Bills/190/SD2051.Html>; H.R. 2387, 79th Legis. Assemb., Reg. Sess. (Or. 2017) <https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/HB2387/Introduced>; H.R. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017), <http://mgaleg.maryland.gov/2017RS/bills/hb/hb0631E.pdf>.

⁵⁸ See generally: S.B. 17, 2017 Assemb., Reg. Sess. (Cal., 2017) http://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB17; S. 0073, 110th Gen. Assemb., Reg. Sess. (Ill. 2017), <http://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=91&GA=100&DocTypeId=SB&DocNum=73&GAID=14&LegID=99589&SpecSess=&Session=>; H.R. 1150, 120th Gen. Assemb., Reg. Sess. (Ind. 2017), <https://iga.in.gov/legislative/2017/bills/house/1150#document-258865dd>; S. 3088, 217th Leg., Reg. Sess. (N.J. 2017), <https://legiscan.com/NJ/bill/S3088/2016>; A. 2939, 2017 Assemb., Reg. Sess. (N.Y. 2017), https://custom.statenet.com/public/resources.cgi?id=ID:bill:NY2017000A2939&ciq=ncslcd3&client_md=bdd731af894edb2d07b5c473f5a1a1e&mode=current_text. The National Academy for State Health Policy set forth model transparency legislation with this hybrid nature in 2017. See “Model Drug Price Transparency Legislation,” National Academy for State Health Policy (2017), <http://nashp.org/pharmacy-costs-workgroup-model-drug-price-transparency-legislation/>.

⁵⁹ Lazar, Alex, “Pharmaceuticals/Health Products: Background,” The Center for Responsive Politics, (August 2015), <https://www.opensecrets.org/lobby/background.php?id=h04&year=2016>.

⁶⁰ Roll, Carrie, “States’ Efforts for Drug Price Transparency Stymied by the Pharmaceutical Industry,” *Health Law & Policy Matters* (August 2, 2016), <https://www.healthlawpolicymatters.com/2016/08/02/states-efforts-drug-price-transparency-stymied-pharmaceutical-industry/>.

⁶¹ Gagnon, Marc-Andre and Lexchin, Joel, “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States,” *PLoS Med* 5, no.1 (2008): e1.

⁶² Yu, Nancy et al., “R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices,” *Health Affairs Blog* (March 7, 2017), <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>.

⁶³ Kesselheim, Aaron et al., “The roles of academia, rare diseases, and repurposing in the development of the most transformative drugs.” *Health Affairs* 34, no. 2 (2015): 286–293.

⁶⁴ A new class-action lawsuit brought by diabetes patients represents this skewed dynamic: patients allege that insulin manufacturers inflated prices of treatments to provide PBMs with wider spreads between benchmark and real prices, resulting in higher profits. In re INSULIN PRICING LITIGATION, Amended Class Action Complaint, Civil Action No. 3:17-cv-00699, (D.N.J. 2017).

⁶⁵ “Budget-Busters: The Shift to High-Priced Innovator Drugs in the USA,” EvaluatePharma (2014).

⁶⁶ See, e.g.: “Prescription Drug Affordability Initiative Frequently Asked Questions (FAQs): HB 631/666 and SB 415/437,” Maryland Citizens’ Health Initiative Education Fund, Inc. (February 2017), http://healthcareforall.com/wp-Content/uploads/2017/02/RxDrugAffordability_FAQ_revised_final.pdf.

⁶⁷ The Takings Clause of the Fifth Amendment prohibits the government from taking private property for public use, without just compensation. U.S. Const. amend. V. The Supreme Court has held that trade secrets may be protected under the Fifth Amendment, so long as the applicable state law recognizes property rights in trade secrets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-1004 (1984) (“We therefore hold that to the extent that Monsanto has an interest in its health, safety, and environmental data cognizable as a trade-secret property right under Missouri law, that property right is protected by the Taking Clause of the Fifth Amendment.”).

⁶⁸ VT Stat. Ann. Tit. 18, § 4635 (e), <http://legislature.vermont.gov/statutes/section/18/091/04635>.

⁶⁹ Vermont Attorney General, “Report of Attorney General to the Legislature Regarding Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635” (December 2016), <http://legislature.vermont.gov/assets/Legislative-Reports/AGO-Report-Pharma-Cost-Transparency-12-01-2016.pdf>

⁷⁰ See: *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (U.S. 1984) (“In an industry that long has been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest.”)

⁷¹ *Philip Morris v. Reilly*, 312 F.3d 24, 44 (1st Cir. Mass. 2002) (“Frankly, for a state to be able to completely destroy valuable trade secrets, it should be required to show more than a possible beneficial effect.”).

⁷² See: *Pharm. Care Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 315 (1st Cir. Me. 2005) (holding that a Maine law requiring pharmacy benefit managers to disclose their contract terms with drug companies to customers did not constitute a taking).

⁷³ See: *Rockwood v. Comm’r of Corps. & Taxation*, 257 Mass. 572, 574, 154 N.E. 182, 183 (1926) (“A patented article, when manufactured, may be taxed by the State.”); *Fox Film Corp. v. Doyal*, 286 U.S. 123, 131, 52 S. Ct. 546, 548 (1932) (holding that taxes on copyrights and patents were not taxes on a federal governmental instrumentality, and that copyrights and patents were not entitled to exemption from state tax).

⁷⁴ *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007).

⁷⁵ *Id.* at 1373. See also: *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1347 (concurring in the denial of hearing en banc, Fed. Cir. 2007) (“[The] issue before the panel was not premised on whether D.C. has the authority to impose price discrimination restrictions in general.”). See also: Lipski, Serena, “Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices,” *University of Toledo Law Review* 39, no. 4 (2008): 913–940 (suggesting that *BIO v. DC* must be read narrowly to only apply to laws specifically targeting patented drugs); Sarnoff, Joshua D., “*Bio v. DC* and the new need to eliminate federal patent law preemption of state and local price and product regulation,” *Patently-O Patent Law Journal* (2007): 30–35. (“The Court’s holding also did not address a state or local price or product regulatory law of general application, and its decision did not expressly include or exclude such laws.”)

⁷⁶ See, e.g.: Vann, Adam and Ruane, Kathleen A., “Gasoline Price Increases: Federal and State Authority to Limit ‘Price Gouging,’” Congressional Research Service RS22236 (2011).

⁷⁷ Knittel, Christopher R., “The Adoption of State Electricity Regulation: The Role of Interest Groups,” *The Journal of Industrial Economics* 54, no. 2 (2006): 201–222. doi:10.1111/j.1467-6451.2006.00280.x.

⁷⁸ Note that full rebates are still prohibited, since they effectively set an upper limit to prices.

⁷⁹ In addition, if a court were to find preemption by federal patent law, it will only find the part of the legislation that affects patented drugs to be preempted. *United Distribution. v. FERC*, 319 U.S. App. D.C. 42 (1996) (“Even where Congress has not entirely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law.”).

⁸⁰ H.R. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017), <http://mgaleg.maryland.gov/2017RS/bills/hb/hb0631E.pdf>.

⁸¹ Proposed legislation could also include penalties for nondisclosure of information. See, e.g.: S. 771, 115th Cong. § 201 (2017); H.R. 1776, 115th Cong. § 201 (2017). The revenue from these penalties could offset increased costs and fund institutions facing increased administrative burdens or related government programs.

⁸² The Ohio Ballot initiative, for example, requires state agencies and programs to purchase prescription drugs at prices no higher than what the U.S. Department of Veterans Affairs (VA) pays for them. McTigue, Donald J., “‘Ohio Drug Pricing Relief Act’ Summary Petition,” Ohio Secretary of State (July 21, 2015), <http://www.sos.state.oh.us/sos/upload/ballotboard/2015/2015-07-21-petition.pdf>.

⁸³ S. 771, 115th Cong. § 202 (2017); H.R. 1776, 115th Cong. § 202 (2017).

⁸⁴ Hwang, Thomas and Kesselheim, Aaron S., “Taxing Drug Price Spikes: Assessing The Potential Impact,” *Health Affairs Blog* (May 12, 2017), <http://healthaffairs.org/blog/2017/05/12/taxing-drug-price-spikes-assessing-the-potential-impact/>.

⁸⁵ States must request detailed data to understand the economics of marketing, research, and clinical trials. See Love, James, “Contribution to United Nations Secretary-General’s High-Level Panel on Access to Medicines No. 82” (February 29, 2016), <https://highlevelpaneldevelopment.squarespace.com/inbox/2016/2/29/james-lovec>.

⁸⁶ See: S. 539, 2017 Assemb., 79th Sess. (Nev. 2017), <https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5822/Text>.

Curbing Unfair Drug Prices

A Primer for States

August 2017

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www.yaleghjp.org

National Physicians Alliance

www.npalliance.org

Universal Health Care Foundation of Connecticut

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