

# ARE DRUG PRICES DRIVING HEALTHCARE COST GROWTH?

*By Jim Stergios, Executive Director &  
Gregory Sullivan, Research Director, Pioneer Institute*



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## INTRODUCTION

Anyone who regularly pays health insurance bills knows that little progress has been made in bending the healthcare cost curve, and that failure makes prescription drug costs a tempting target. But frustration with continuing healthcare cost increases is not a legitimate justification for proposals that single out pharmaceuticals, could adversely affect patients and increase long-term costs. This white paper examines why state-level regulatory reactions to short-term increases in drug prices are not supported by the evidence and could produce negative consequences for patients and other purchasers.

A number of lawmakers and advocates have called for the federal and/or state governments to force private pharmaceutical companies to disclose how much they spend on research, production, and marketing. Some have even called for controls on drug prices. The Health Policy Commission (HPC), an independent Massachusetts state agency established in 2012, issued its *2015 Cost Trends Report* in January 2016, which advocates for state legislative changes to give the HPC authority to mandate that pharmaceutical manufacturers appear before the Commission as witnesses and disclose proprietary information regarding drug pricing,<sup>1</sup> and for Massachusetts' state Medicaid agency, MassHealth to use "value-based benchmarks" in determining how much it will pay pharmaceutical companies for drugs.<sup>2</sup> The report identifies several bills that have been proposed by Massachusetts legislators that seek to limit the impact of drug price increases on consumers, including one (S. 1048) sponsored by Senator Mark Montigny that would require drug manufacturers to provide the methodology behind their pricing and potentially cap the prices of certain drugs.

The HPC's *2015 Cost Trends Report*, issued pursuant to its enabling statute, is a far-reaching, data-laden 102-page document with many well-supported and excellent recommendations. In an important supplemental report, entitled *Cost Trends Report: Provider Price Variation*, the HPC highlights the possible impact of "unwarranted price variations" — and the opacity of pricing — on healthcare cost trends.<sup>3</sup> The purpose of this Pioneer study is not to disparage the HPC's overall effort, which is a significant contribution to our understanding of the healthcare market in the aftermath of considerable policy changes. Rather, it is to take issue with two recommendations in the *2015 Cost Trends Report* concerning government controls on pharmaceutical companies and, potentially, pricing.

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### **HPC's 2015 Cost Trends Report is a far-reaching document with many well-supported recommendations. This paper takes issue with one recommendation on pharmaceutical pricing.**

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The pros and cons of price controls on drugs have been widely debated. The pro, simply stated, is that price controls will reduce drug prices, at least in the short term. The con is that price controls will discourage the development of new and improved drugs that (1) treat diseases and (2) potentially lessen the need for more expensive non-pharmaceutical medical care, such as hospitalizations. Government policies concerning the price of Food and Drug Administration-approved drugs have an inherent effect on the financing of research and development of new generations of drugs. A National Bureau of Economic Research report notes that only one in several thousand compounds investigated ever makes it through the full development process to gain FDA approval, and that the entire process from discovery to launch takes an average of about 15 years.<sup>4</sup>

Finally, it is worth noting that efforts by specific states to regulate drug prices would likely produce unintended consequences elsewhere in the U.S. market. The far-reaching economic impact of this form of price regulation should not be overlooked. Pioneer urges policymakers to closely examine how these controls could harm consumers by potentially generating barriers to the development of new treatments.

### **SOVALDI AND THE 13 PERCENT RISE IN MASSACHUSETTS' 2014 DRUG EXPENDITURES: THE IMPLICATIONS**

One headline from the HPC's January report is that Massachusetts' 4.8 percent growth in healthcare spending in 2014 exceeded its 3.6 percent spending benchmark by approximately one-third. The HPC offered two principal reasons for this excessive spending growth: (1) MassHealth expenditures grew more than was projected, and (2) drug expenditures increased by 13.1 percent.

Regarding cost inflation at MassHealth, a substantial portion of the increase is attributable to a one-time event: the botched rollout of the Connector website, which ultimately led to the inclusion of hundreds of thousands of non-determined Medicaid recipients.<sup>5</sup> The program has since undergone a thorough eligibility redetermination and administrative overhaul.

The other main driver of Massachusetts' excessive 2014 increase in healthcare costs, according to the HPC report, is the precipitous 13 percent increase in pharmaceutical costs after what the report described as "more than a decade of overall low pharmaceutical spending growth rates." The report described its concern as follows:

After more than a decade of overall low pharmaceutical spending growth rates, dramatic jumps in spending in 2014 in both Massachusetts and the U.S. — driven in part by the high-profile introduction of new high-cost drugs for the Hepatitis C virus (HCV) — have focused attention on issues of drug prices and utilization, for new cutting-edge therapies as well as generic products. Pharmaceutical innovation has led to important advancements in patient longevity and quality of life. Manufacturers assert that high prices for new drugs reflect the costs of research and development, including research for products that fail to reach the market, and that high prices are necessary to support continued innovation. Further, some suggest that costs for preventative or curative treatments may lead to overall savings. However, with trends in Massachusetts largely mirroring national trends, drug spending has become an increasing concern for payers, providers — especially those engaging in new risk-based payment models — and patients facing out-of-pocket costs for medications. The impact of high-cost drugs on the state's healthcare cost growth benchmark has encouraged the Health Policy Commission (HPC) to closely examine the issue of pharmaceutical spending.<sup>6</sup>

The report highlighted in particular the 354 percent rise in sales of drugs that treat Hepatitis C, as follows:

Among the new drugs impacting spending in 2014, much attention has focused on the introduction of new Hepatitis C virus (HCV) therapies led by Gilead Sciences' Sovaldi, which became the nation's top-selling drug in 2014. Introduced at the end of 2013, Sovaldi offered a significant advancement for people with HCV, with a high cure rate and substantially fewer toxic side effects and shorter treatment course than previously available options. However, Sovaldi entered the market with a list price of \$84,000 per patient for a 12-week treatment, rivaling the high prices more typical of "orphan drugs" for rare diseases. The combination of high price and relatively high prevalence of HCV (3.2 million Americans were estimated to be infected in 2013) resulted in Sovaldi earning over \$10 billion in sales in 2014. In Massachusetts, the introduction of Sovaldi and other new HCV drugs caused spending on HCV drugs (non-HIV antivirals) to rise from \$96 million in 2013 to \$436 million in 2014, more than a 350 percent increase.<sup>7</sup>

### SOVALDI: THE REST OF THE STORY

The report relies in large part on the 13 percent rise in pharmaceutical costs in 2014 to support its recommendation for legislative changes in Massachusetts that would give the HPC authority to mandate disclosure of proprietary information regarding drug pricing, and for the Massachusetts state Medicaid agency, MassHealth, to use "value-based benchmarks" in determining how much it pays pharmaceutical companies for drugs.

## Three HPC Recommendations on Drug Pricing

The HPC report recommends that

- 1 **“All payers should pursue the use of value-based benchmarks when negotiating prices”** (HPC, 92) The HPC cites the value-based benchmarking methodology of ICER, which is synonymous with “dollars-per-quality adjusted life year (QALY) gained” in determining the value of a pharmaceutical or other health product, describing it as follows:

“For each drug, ICER seeks to determine a “value-based price benchmark” that takes into account how much better the drug is at improving patient outcomes over the long-term, tempered by thresholds at which additional new costs would contribute to growth in healthcare costs exceeding growth in the overall national economy. The value-based price benchmark represents a cost-effective price at which payers and providers would not be forced to limit the treatment’s availability to patients” (HPC, 32).

During the acrimonious debate over the Affordable Care Act (ACA), this approach was compared by some to healthcare rationing. In establishing the Patient-Centered Outcomes Research Institute (PCORI) as part of the ACA, the Senate Finance Committee “forbade PCORI from using “dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of healthcare is cost effective or recommended.” ([https://en.wikipedia.org/wiki/incremental\\_cost-effectiveness\\_ratio](https://en.wikipedia.org/wiki/incremental_cost-effectiveness_ratio) and <http://www.healtheconomics.com/uncategorized/pcori-head-vows-not-to-do-cost-effectiveness-studies-but-notes-gray-areas/>)

Sovaldi is a case study as to why the QALY, or ICER’s methodology, can be problematic. According to the HPC report, “[ICER] found that despite Sovaldi’s “very-cost effective” performance at \$20,000 per QALY (quality-adjusted life year) gained versus the previous standard of care, its long-term value does not translate into budgetary feasibility for payers.” The report, which reported cost trends for pharmaceuticals through 2014, noted that “any long-term cost-offsets” for Sovaldi “could require as long as 20 years to manifest for payers” (HPC, 31). Just weeks after the period studied by the HPC came to a close, the price of Sovaldi was cut by 46 percent in response to market competition. One would imagine that the price reduction would significantly impact Sovaldi’s QALY.

- 2 **“The Legislature should add pharmaceutical and medical device manufacturers to the list of mandatory market participant witnesses at the HPC’s annual healthcare Cost Trends Hearing”** (HPC, 92). This recommendation calls for legislative changes in Massachusetts to give the HPC authority to mandate that pharmaceutical manufacturers appear before it as witnesses and disclose proprietary information regarding drug pricing. This proposal would amend Chapter 6D, Section 8, of the Health Policy Commission’s enabling statute to allow the HPC to compel pharmaceutical manufacturers to give testimony under oath, subject to cross-examination and production of documents, regarding cost structures, administrative and labor costs, and other information in any manner and form the HPC may determine.

This recommendation aligns with calls in the report to “increase[e] transparency regarding manufacturer methodology for setting prices for specific drugs (with respect to costs to develop and distribute)” in order to “support efforts for value-based pricing” (HPC, 39). S. 1048, and the HPC report would compel private drug companies under force of law to disclose proprietary cost information and pricing methodology in order to facilitate “value-based pricing.”

- 3 **“The Legislature should require increased transparency in drug pricing and manufacturer rebates”** (HPC, 92). Pioneer strongly supports this recommendation for reasons set forth in this report.

The HPC report states that its estimates of drug spending do not reflect rebates and other discounts that occur after the initial acquisition price due to the lack of availability of this information. Pioneer Institute strongly supports the recommendation that the HPC be granted the ability to determine how much manufacturers charge for their products, net of pre- and post-sale discounts in order to allow state officials to determine whether MassHealth is paying a fair price. This is differentiated from the question of whether HPC should be given authority to compel disclosure under oath of proprietary information concerning costs, development, operations, labor, marketing and other aspects of private firms’ business.



**Weeks after the end of the 2014 period reviewed in the report (and a year before the report’s final public release) Sovaldi’s manufacturer cut the drug’s price by 46 percent.**

In framing its legislative recommendations around rising drug costs, the HPC report relies extensively on the 13 percent increase in pharmaceutical costs from 2013-2014 attributable in large part to the introduction of Sovaldi. By focusing on the 2013-2014 time period, the report does not adequately factor into its financial analysis a significant event that occurred soon after. In February 2015, just weeks after the end of the 2014 period considered in the report and almost a year before the report’s final public release, Sovaldi’s manufacturer of cut the drug’s price by 46 percent after U.S. pharmacy groups and insurers threatened to switch to a cheaper alternative. This is a significant consideration because more than half of Massachusetts’ 13.1 percent rise in pharmaceutical costs in 2014 was attributable to sales of Sovaldi, which was introduced at the end of 2013. The report includes a description of the February 2015 price drop but does not factor into its analyses the extent of the financial impact.

As mentioned above, the HPC report states that the introduction of Sovaldi and other new HCV drugs in 2014 caused spending on non-HIV antiviral drugs to jump from \$96.4 million in 2013 to \$436.0 million in 2014, accounting for 42 percent of the total growth in drug spending in Massachusetts. By this measure, total drug spending grew by \$808.6 million, with Sovaldi contributing approximately \$339.6 million of the total increase (see Figure 1).

**Figure 1. Pharmaceutical spending growth 2013-14, Non-HIV Antivirals and all other (millions)**

	Spending growth 2013-14	Share of increased spending
Non-HIV Antivirals (includes Sovaldi in 2014)	\$339.6	42%
All other pharmaceuticals	\$469.0	58%
All pharmaceuticals	\$808.6	100%

According to the HPC report, commercial payers received a median discount of around 14 percent for Sovaldi in 2014 and Medicaid programs received

minimal discounts above the required 23 percent.<sup>8</sup> The report then explains that “As competition increased, Gilead announced that discounts from list price for their HCV drugs would average 46 percent in 2015, and rebates would exceed 50 percent for certain Medicaid programs and the Department of Veteran Affairs.” According to the HPC, MassHealth collected supplemental rebates from Gilead in 2015 at a discount exceeding 50 percent. The report also explains that 25 state Medicaid agencies jointly negotiated for a discount on Viekira Pak in exchange for designating it the preferred option over Sovaldi, but that MassHealth was not among the 25 agencies so doing.

As Figure 2 shows, had the February 2015 discount of 46 percent been applied in 2014, Massachusetts’ spending growth for HCV drugs from 2013-14 would have been reduced substantially from \$339.6 million to \$213.3 million.

**Figure 2. Pharmaceutical spending growth 2013-14, factoring in 46% Sovaldi discount (millions)**

	Spending growth had 46% Sovaldi discount been applied in 2014	Share of increased spending
Non-HIV Antivirals (includes Sovaldi in 2014)	\$213.3	31%
All other pharmaceuticals	\$469.0	69%
All pharmaceuticals	\$682.2	100%

According to industry analysts, Gilead Sciences Inc., the manufacturer of Sovaldi, cut its prices when groups that buy medication for U.S. patients demanded bigger concessions after AbbVie Inc. received approval for its rival hepatitis C drug, Viekira Pak in December 2014.<sup>9</sup> According to *The Financial Times Limited*, Express Scripts, the largest U.S. pharmacy benefits manager, announced in December that it would exclusively carry AbbVie’s drug exclusively, wiping \$20 billion off Gilead’s market capitalization in a single day and sparking a broad sell-off in the biotech sector. Since then, Gilead has unveiled its own exclusive deals with groups including CVS/Caremark and UnitedHealth, the largest U.S. health insurer, although it is now clear it had to offer significant price cuts to win the business. AbbVie’s drug is just as effective but requires the patient to take between three and six pills per day, resulting in a more cumbersome treatment. Merck has said it will file for approval of an alternative single-pill treatment later this year.<sup>10</sup>

What should be of great interest to policymakers when they consider the HPC’s drug price recommendations

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## Market competition, not government-required disclosures of costs or price controls, resulted in the 46 percent reduction in the price of Sovaldi.

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is that market competition from another drug manufacturer, not government-required disclosures around private company cost structures or price controls, resulted in the 46 percent reduction in the price of Sovaldi. Further reductions are possible if Merck wins the above-mentioned request for FDA approval of another competing drug product.

Also of note to policymakers is that the HPC-cited 13.1 percent rise in Massachusetts' 2014 pharmaceutical costs does not reflect price increases alone. That increase includes the purchase by the Commonwealth of a new medical invention, Sovaldi, beginning in 2014, with a high cure rate, substantially fewer toxic side effects and shorter treatment course than previously available options.<sup>11</sup> As *The Atlantic* has noted about Hepatitis C, "Left untreated, [it] attacks the liver and can lead to cancer or liver failure."<sup>12</sup> The *2015 Cost Trends Report* states, "Sovaldi is very effective clinically, as well as cost-effective in the long-term relative to earlier HCV treatments."<sup>13</sup>

Notwithstanding its conclusion concerning Sovaldi's long-term cost savings impact, the HPC bases its recommendations for legislative reforms on Sovaldi's short-term impact:

Any long-term cost-offsets could require as long as 20 years to manifest for payers. In the meantime, Sovaldi's potential short-term budget impact was calculated to represent a per-member per-month premium increase of 5 percent, which is an increase at least five times higher than what [The Institute for Clinical and Economic Research] ICER estimated state budgets can manage for individual new drugs without pushing up premiums at an unsustainable rate.<sup>14</sup>

The HPC's call for new legislative requirements that force private companies to make proprietary cost, marketing and drug development information public is based disproportionately on the short-term rather than long-term cost implications of newly introduced pharmaceutical products. If inventions like Sovaldi can bring about long-term but not short-term savings, state

leaders should think twice before adopting policies that would hinder research and development of new generations of such drugs. Short-term analysis also discounts the effect that market competition can have on short and medium-term costs, as happened in the case of Sovaldi.<sup>15</sup>

Moreover, an inherent limitation in HPC's analysis of the year-to-year increase in pharmaceutical prices, acknowledged in the report, is that the data upon which its analysis relies "do not reflect rebates and other discounts that occur after the initial acquisition price." The report concludes: "More data is needed on rebate amounts to produce more accurate estimates of total spending and growth."

Because the HPC was unable to take into account rebates and discounts negotiated by insurers and pharmacy benefit managers, or statutorily required for Medicaid, the reliability of analysis and conclusions are inherently compromised. Had the HPC been unable to review actual hospital costs and instead had to rely on hospital charge master rates ("sticker prices") to determine how much Massachusetts spent on hospital care in a given year, its analysis would likewise have been undermined. This flaw is highlighted by a February 2016 announcement by CVS Health that its active pharmacy benefit management led to a dramatic drop in the growth of its "prescription drug trend, a measure of growth in prescription spending" from "a high of 11.8 percent in 2014" to "5 percent in 2015," after accounting for rebates and discounts.<sup>16</sup> The HPC report itself underscores the extent to which the Center for Health Information and Analysis's neglect of discounts and rebates might impact estimates of total healthcare expenditure:

According to a 2011 report from the Office of the Inspector General at the Department of Health and Human Services, Medicare Part D recoups about 19 percent of its spending on brand-name drugs through off-invoice discounts and rebates, while Medicaid programs recoup about 45 percent of their costs for brand-name drugs. Rebate levels for MassHealth are higher than this national average. The value of rebate invoicing for the MassHealth Primary Care Clinician

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## An inherent limitation in HPC's analysis is that the data upon which its analysis relies do not reflect rebates and other discounts.

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**One-year “trends” are not a reasonable standard of analysis for the formulation of policy recommendations that will have impacts for years to come.**

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(PCC) and Fee-For-Serve (FFS) plans was 50.1 percent of the pharmacy spending in FY 2015.<sup>17</sup>

If Medicare Part D plans to recoup, on average, 19 percent of costs in rebates, and MassHealth recoups 50.1 percent,<sup>18</sup> it is unclear why the HPC report does not adjust its total cost estimates using these data.

HPC’s heavy reliance on the significance of the one-time 2014 rise in drug expenditures also inherently limits the report’s findings. Relying on a single year-to-year cost increase to capture the dynamic realities of any sector or market, where any number of factors can influence production, demand, and therefore pricing, is inherently problematic. A single year’s experience, especially one impacted significantly by the introduction of a drug like Sovaldi, as happened in 2014, should not be deemed to constitute a trend meriting legislative intervention. This is especially true in industries where innovation plays such a significant role. At the very least, one-year “trends” are not a reasonable standard of analysis for the formulation of policy recommendations that will have impacts for years to come. Again, page 29 of the HPC report notes,

After more than a decade of overall low pharmaceutical spending growth rates, dramatic jumps in spending in 2014 in both Massachusetts and the U.S.—driven in part by the high-profile introduction of new high-cost drugs for the Hepatitis C virus (HCV) — have focused attention on issues of drug prices and utilization, for new cutting-edge therapies as well as generic products.

In the commercial market, for example, between 2010 and 2013, prescription drug spending grew by less than one percent per year on average in Massachusetts and the U.S. (0.5 percent and -0.8 percent, respectively).<sup>19</sup>

Thus, it is difficult to understand the logic behind the HPC’s claim that “[a]side from increases in prescription drug spending,” healthcare cost growth in Massachusetts’ commercial sector “was near 1 percent from 2013 to 2014.” The implication is that drug spending increases accounted for almost two thirds of the overall commercial rate increases year-to-year (2.9 percent).<sup>20</sup> Without a complete and accurate picture of the true rate

of pharmaceutical price growth, including discounts, the HPC is limited in its ability to discern the true drug pricing trends — and also in its ability to provide a firm foundation for drug pricing policy recommendations.

Going forward, it would be wise for the HPC to seek additional price information from the carriers. For example, it would be important to obtain from carriers the net pricing data after discounts to complement the HPC and CHIA’s calculations, which separate drug price increases from total costs (and thereby show drug cost inflation as a major driver of overall healthcare cost inflation). Perhaps the net cost data will demonstrate that CHIA, the HPC and insurers are painting an accurate picture in their statements about the impact of drug price trends. Alternatively, the data might show that drug price increases are less dramatic, or even that cost increases are being driven by a small subset of drugs.<sup>21</sup>

As previously stated, HPC’s *2015 Cost Trends Report* presents valuable analysis of a broad and detailed range of critical issues in addition to its analysis of pharmaceutical cost trends, but its policy prescription for legislatively mandated drug cost disclosure and potential price restrictions deserves closer examination.

## **BROADER OBSERVATIONS ABOUT THE COST OF DRUGS**

While drugs are certainly part of the cost growth equation, it is easy to understand why drug companies are today squarely in the crosshairs of policymakers. The healthcare world has been abuzz since Martin Shkreli, the head of a small and little-known generic drug company, Turing Pharmaceuticals, jacked up the price of Daraprim to 50 times its previous market price. A generic drug that has been in the marketplace for decades and had no competitors, Daraprim is used to fight parasitic infections and has proven helpful with AIDS patients.

Closer to home, the biotech company Vertex Pharmaceuticals Inc. was recently criticized for charging patients over \$259,000 annually for its new breakthrough cystic fibrosis treatment, Orkambi.<sup>22</sup>

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**In healthcare, as in any market, price determines the level of access one may or may not have to a treatment.**

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The debate over drug prices is a serious one. It is clear that in healthcare, as in any market, price determines the level of access one may or may not have to a treatment under or even beyond patent protection. Unfortunately, proponents of S. 1048, which would require unique disclosures in Massachusetts regarding research and development, marketing, and manufacturing costs, among many other items, ignore some important facts.

1. **Competition on price, not public disclosure of proprietary information on cost and operations, is what eventually drives down prices in every market sector.** Semiconductors, computers, cell phones and many other innovative products have seen steep price declines because consumers, whether businesses or individuals, know what the final price is and can shop for value. There was no need in any of these sectors to disassemble the price to component parts of a specific company's production and operation, or even its individual cost centers. In fact, applying the word "transparency" to the operation of a private company is something of a misnomer. Transparency is a concept for the public sector; because the public sector is supported by tax dollars, the public expects and demands transparency. That same sort of mechanism is not part of a free society, where private individuals and private companies are protected by privacy and property rights. To function well, the private sector must inform the public with prices. In a free enterprise system, other companies who believe they can provide a higher quality product or produce a similarly effective product at a lower price will enter the marketplace. Applying the language of public transparency to private companies — or private individuals — can lead to dangerous violations of privacy and property rights.

While there are exceptions to the rule, usually due to the lack of a competing treatment or in some cases patent or exclusivity abuses, both the drug development market and patients have benefited from new market participants. As a result of competition, the last half century has been an unprecedented period of discovery of needed treatments even as, over time, it has seen these treatments sold at ever lower prices. That is the story of almost every drug, from Avapro to Lipitor, to Seroquel and even Sovaldi.<sup>23</sup>

2. **Shkreli-style price-gougers are not driving runaway healthcare costs.** Two facts are worth remembering as regards the impact of drug prices and the overall market. First, drugs account for just 10 percent of overall U.S. healthcare spending. Second, while what

Shkreli did was reprehensible, exploitative actors are the outliers — and healthcare industry cost increases, while certainly impacted by drugs, are hardly attributable to outlier cases. Unlike most innovators in the pharmaceutical industry, Turing's pricing was unrelated to research and development costs, or new information about the value of the drug to patients. It reflected nothing more than price gouging leveraged because of his company's market monopoly. S. 1048's proposal to require multiple unique disclosures in Massachusetts will have no impact on the Shkreli and will negatively affect everyone else. Finally, as noted above, putting a newly developed drug on the market can, in addition to providing a new or more effective treatment, increase short-term costs even as it lowers long-term costs.<sup>24</sup>

3. **The Shkreli of the world are a problem that can be effectively addressed through public pressure and adequate policing.** Shkreli was rightly publicly shamed, resulting in promises from Turing to lower the price of Daraprim. Outside of whether Turing followed (or ever intended to follow) through on the company's stated intentions, an important result was that Imprimis Pharmaceuticals reacted to the situation by announcing that it will sell the same drug for one dollar per pill (far below the original price Turing was charging).

But far more important than such promises and announcements is the antitrust investigation by New York Attorney General Eric Schneiderman, who is investigating whether Turing was restricting competition by reducing the availability of Daraprim to thwart generic competition. Schneiderman's action is both responsible and an effective remedy. What Massachusetts needs is a market where short-term artificial barriers to generics are taken down, and long-term solutions to high prices that facilitate the entry of more competitors to counterbalance the first developer of a treatment are encouraged.

Competition on price works very well, but it assumes appropriate market policing by state attorneys general and the federal government to ensure that

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**Shaming works. And so does appropriate market policing by state attorneys general.**

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companies are not restricting market participation by other companies. As demonstrated in a 2005-2006 investigation by Attorney General Thomas Reilly, market policing should not limit itself to drug pricing by drug companies but should also extend to drug pricing by hospitals and other provider organizations. Reilly's probe investigated "excessive billing by hospitals to the state's \$800 million free-care pool" and an audit by the Inspector General's Office "documented unusually high charges, including prescription drug prices routinely inflated by as much as 300 percent and radiology exams billed at many times the normal rate."<sup>25</sup>

With transparent pricing and adequate market policing, pharmaceutical prices tend to drop significantly as generics enter the marketplace when patents expire. Federal and state officials are only doing their jobs when they police private companies with patents so the companies do not game the system, for example, by manipulating their patent rights.

4. **Proponents of S. 1048 do not give due consideration to supply and demand; that is, respectively, the extreme costs of developing drugs and the sometimes very small populations benefited by the development of those new treatments.** The case of Vertex Pharmaceuticals' drug Orkambi points to a very different and important set of realities in the drug industry. While its annual cost of treatment is high, it must be put into the context of the cost of developing and getting federal approval, which is enormous. A 2014 Tufts University report notes that the average cost of getting a drug to market today stands at a whopping \$2.6 billion — 145 percent more than what it cost in 2003.<sup>26</sup>

So what is the value of treating individuals with cystic fibrosis? Certainly, the value of the Orkambi treatment to the fewer than 10,000 individuals (0.003 percent of the U.S. population) suffering from this devastating disease is life-changing. At tens and even hundreds of thousands of dollars per treatment, perhaps some will say the cost is too high. If it is "too high," meaning another company can develop and produce a treatment with the same or more efficacy for less, then there will in all likelihood be another market entrant.

That is how the market works within other innovation sectors; if prices are too high, new competitors enter the market, providing more choices and reducing costs. Healthy competition takes place without

intruding on private company information and creating a less welcoming environment to bioscientific discovery.

5. **There is a big difference between federal and state disclosure requirements.** How would the state disclosure requirements work under S. 1048? Would pharmaceutical companies have to make disclosures to state government only if they sold here? Would that lead companies to consider pulling their products from Massachusetts to avoid expensive reporting requirements or disclosing financially proprietary information? It is one thing for the federal government, in providing a patent, to require disclosures from public pharmaceutical companies; the Massachusetts-specific application of such disclosure requirements would have a whole different order of negative effects.
6. **The provisions of the S. 1048 "reform" bill being debated will entail enormous administrative costs for biopharmaceutical companies.** Breaking out and tracking all the data for a specific state is an enormous undertaking that takes time and money away from research and development. The economic toll will be particularly high on Massachusetts, where so much of the research is conducted. The Commonwealth is one of the nation's leading centers for new drug development, with a robust employment base — in 2013, there were 232 drug development firms in Massachusetts.<sup>27</sup> The negative impacts of the broad brush approach proposed in the legislation will also create a disincentive for future investment in the Commonwealth's biosciences sector.

The provisions of the S. 1048 "reform" bill being debated will result in a less attractive marketplace for innovation — the exact opposite of the bill's stated intent — and have no impact on healthcare costs. Finally, it is worth stating that Massachusetts residents want these new treatments, just as patients around the country and the world do.

## THE NEED TO FOCUS POLICYMAKERS ON PRICE TRANSPARENCY AND STRONGER MARKET MECHANISMS

Almost a decade has passed since the Massachusetts healthcare reform law (Chapter 58) went into effect. Four years later, the federal Affordable Care Act (2010) was signed; six years later, Chapter 224 (2012) was put into law. All three of these reforms place significant emphasis

## Is the lack of transparency — and rampant price variations — the real issue for policymakers?

on greater price transparency in the healthcare market, and yet our progress thus far in Massachusetts has been modest at best. This fact, together with the analyses in the HPC’s important supplemental report on *Provider Price Variation*, go a long way toward explaining why seven of the Commission’s recommendations underscore value shopping, the transparency of data on quality and pricing, and variations in pricing in different care settings.

The supplemental report recognizes that provider prices vary across payment methods, as well as in different care settings. The variations are present in global payment as well as fee-for-service settings, in both hospitals and physician groups. The report finds that the level of variation has not diminished, notwithstanding the above-mentioned legislative actions taken at the federal and state levels. As the report notes,<sup>28</sup>

[U]nwarranted price variation contributes to higher healthcare spending due both to the prices and to the large share of volume at higher-priced providers. Price variation has a significant impact on total spending not only because some providers receive far higher prices than others for the same sets of services, but also because the providers with high prices tend to have high volume. For the three major commercial payers, hospitals with the highest inpatient relative prices had approximately six to eight times as many inpatient stays as hospitals with the lowest relative prices, and approximately 18 to 23 times as much inpatient revenue, adjusting for differences in the number of hospitals.

As the supplemental report further finds, the variation in prices does not reflect higher value, and “the HPC’s rigorous multivariate analysis shows that a substantial portion of hospital price variation is associated with market structure,” and is not going to change. As the report concedes, “less competition is associated with higher prices,”<sup>29</sup> and

[T]here has not been meaningful progress in reducing unwarranted variation in provider prices over the past six years, and current reforms do not hold significant promise for meaningfully reducing this variation.<sup>30</sup>

The lack of transparency and the rampant unwarranted price variation may, in fact, prove to be the real issue for policymakers.

## RECOMMENDATIONS

Massachusetts must lower the barriers that prevent patients from accessing information and understanding who provides high-value care. Quality of care in the Commonwealth is among the best in the world, but it comes at a cost that is killing the middle class. Pioneer recommends that state leaders undertake the following approaches to monitor and ensure fair competition among drug companies:

1. **Policymakers should obtain data on drug expenditure trends using multi-year, rebated data before considering policy changes that could affect drug development.**
2. **The Attorney General should aggressively enforce consumer protection and antitrust laws so as to minimize the abuse of patent and exclusivity protections.**
3. **Policymakers should delve more deeply into the potential impact of pricing opacity as a driver of overall healthcare cost inflation. Here, two actions are important:**
  - a. **Advance regulatory actions to enforce existing provisions in legislation to expand healthcare pricing transparency.** While it is important to recognize the differences between the drug industry and the healthcare industry at-large and how prices are determined within each, consumers would benefit most from policies that ensure all transactions for health-related services and products are subject to high standards of transparency. State (Chapter 58 and Chapter 224) and federal law (the Affordable Care Act) include clear calls for greater price transparency — it is important that these laws are enforced vigilantly in all areas of healthcare with which consumers interact.

Multiple Pioneer reports overwhelmingly demonstrate that only very modest progress has been made in the insurer and provider communities. Though not directly connected to problems with opacity in provider pricing, issues with transparency in drug pricing adversely affect consumers in similar ways. Problems with lack of information on pharmaceutical pricing for consumers therefore demand a similar policy prescription as ensuring that providers clearly disclose prices for medical services.

Massachusetts should lead this policy conversation, and learn from states that are

moving faster on this front. Oklahoma is just one example. For the last six years the Oklahoma Surgery Center in Oklahoma City has offered services at one-eighth to one-tenth the cost of the local hospital, even though they are using the same surgeons. Thus far, they are producing better clinical outcomes. They are the Henry Fords of their time, focused on delivering high-value care to those who need surgery but often do not possess the financial means.

- b. **Promote competition and embrace consumer tools like health savings accounts**, which allow consumers more control over their care and provide incentives to choose more cost-effective care. A more flexible system is needed that, for example, allows lower-cost nurse practitioners to do more when they see a patient. Massachusetts needs more Minute Clinics or urgent care centers that are open long hours, and telehealth that can provide services remotely, both of which can handle easily treatable cases and cost a fraction of the price of a hospital emergency room visit. Policymakers should also work to reduce the barriers for the healthcare equivalents of Southwest and JetBlue — high-value providers that want to enter the market with a model that embraces competitive pricing.

A legislative “fix” focusing on pharmaceutical operations that neither helps patients nor lowers costs while retarding the development of new drugs by increasing development costs is the wrong medicine. Pioneer

believes the legislature must focus its efforts on pricing, not the decomposition of costs in any sector of the market. The Institute understands that the carrier and provider communities have not complied with repeated legislative state and federal requirements that they provide prices, which are, at bottom, the most basic element of any marketplace. The reaction from the legislature to this lack of compliance should not be to turn on one innovative sector and require that it provide both prices (which is largely does already) and also a decomposition of its cost structures, which include proprietary information. If representatives on Beacon Hill want to reduce the cost burden on Massachusetts citizens and improve service quality, they should focus on opening the entire healthcare market to publicly knowable prices and more competition.



## ENDNOTES

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2. *2015 Cost Trends Report*, 32. “For each drug, [the Institute for Clinical and Economic Review] seeks to determine a “value-based price benchmark” that takes into account how much better the drug is at improving patient outcomes over the long-term, tempered by thresholds at which additional new costs would contribute to growth in healthcare costs exceeding growth in the overall national economy. The value-based price benchmark represents a cost-effective price at which payers and providers would not be forced to limit the treatment’s availability to patients.”
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13. *2015 Cost Trends Report*, 31.
14. *2015 Cost Trends Report*, 31.
15. *2015 Cost Trends Report*, 31. “Comparative effectiveness analysis suggests that Sovaldi is very effective clinically, as well as cost-effective in the long-term relative to earlier HCV treatments... [ICER] found that despite Sovaldi’s “very-cost effective” performance at \$20,000 per QALY (quality-adjusted life year) gained versus the previous standard of care, its long-term value does not translate into budgetary feasibility for payers... Any long-term cost-offsets could require as long as 20 years to manifest for payers. In the meantime, Sovaldi’s potential short-term budget impact was calculated to represent a per-member per-month premium increase of 5 percent, which is an increase at least five times higher than what ICER estimated state budgets can manage for individual new drugs without pushing up premiums at an unsustainable rate.”
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17. *2015 Cost Trends Report*, 29.
18. MassHealth receives best price plus a minimum of 23.1percent in rebates plus additional rebates if prices increased beyond the consumer price index (the so-called “CPI penalty”), which translated into the 50.1 percent rebate figure.
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20. *2015 Cost Trends Report*, 15-16.
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28. *2015 Cost Trends Report: Provider Price Variation*, 2.
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## ABOUT THE AUTHORS

**Jim Stergios** is Executive Director of Pioneer Institute. Previously, Jim was Chief of Staff and Undersecretary for Policy in the Commonwealth's Executive Office of Environmental Affairs, where he drove efforts on water policy, regulatory and permit reform, and urban revitalization. His prior experience includes founding and managing a business, teaching at the university level, and serving as headmaster at a preparatory school. Jim holds a doctoral degree in Political Science from Boston University.

**Gregory W. Sullivan** is Pioneer's Research Director, and oversees the Centers for Better Government and Economic Opportunity. Prior to joining Pioneer, Sullivan served as Inspector General of the Commonwealth of Massachusetts and was a 17-year member of the Massachusetts House of Representatives. Greg is a Certified Fraud Investigator, and holds degrees from Harvard College, the Kennedy School, and MIT.

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