



OnPoint: Issue Brief

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Rx Reality Check: 2018 Update

Pharmaceutical Industry Driving US Health Care Costs

Despite the clinical benefits prescription drugs provide to patients, the cost of drugs continues to increase both nationally and in the Commonwealth. Recent National Health Expenditure data from the Centers for Medicare & Medicaid Services (CMS) indicate that national spending on drugs will increase by 6.6% for 2018 compared to 2.9% in 2017, totaling roughly \$360 billion. By 2026, CMS predicts the U.S. will spend more than \$600 billion a year on pharmaceutical drugs, accounting for a little more than 8% of the nation's health expenditures¹. CMS attributes this increase in spending to reduced rebates from drug manufacturers to benefit managers, which have shielded consumers from increases the past several years.² Prescription drug spending in the U.S. now accounts for 22% of commercial spending, which exceeds the costs of inpatient care.³ Another projection from the U.S. Department of Health and Human Services (HHS) Assistant Secretary of Planning and Evaluation put prescription drug spending at \$535 billion in 2018.⁴

Massachusetts has not been immune to these trends in increased prescription drug spending. According to the Health Policy Commission's (HPC) *2017 Cost Trends Report*, point-of-sale spending on prescription drugs in Massachusetts grew 6.4% in 2016, from \$8.6 billion to \$9.2 billion.⁵ In its *2017 Annual Report of the Massachusetts Health System*, the Center for Health Information and Analysis (CHIA) found that prescription drug spending comprised 6.4% (\$9.2 billion) of the \$59 billion total health care expenditure (THCE) for 2016. Along with outpatient hospital spending, prescription drug spending was the largest cost driver of the increase in THCE from 2015 to 2016.⁶ This latest *OnPoint* will take a closer look at state and national trends in pharmaceutical manufacturing, examine initiatives being considered at both the state and federal levels to address the rising costs of prescription drugs, and propose recommendations for policymakers as they consider solutions to address rising costs.

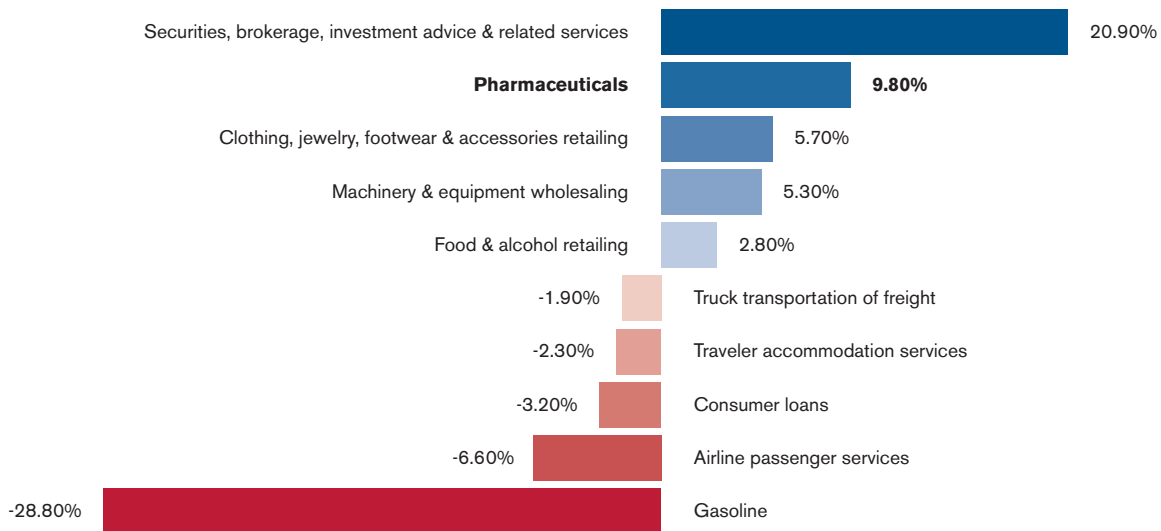
Pricing Increases – Beyond Sovaldi

While the high cost of specialty drugs has garnered significant attention, prices have increased across all segments of the pharmaceutical industry – specialty, brand name and generics. Despite the suggestion that the drastic price increases for drugs that have been on the market for decades represent the actions of a few bad actors, price hikes are pervasive and can occur multiple times a year for certain drugs.

According to the *Wall Street Journal*, from 2015 to 2016, drug manufacturers' prices rose the second most among the 20 largest components in the Producer Price Index. Based on data from the Bureau of Labor Statistics, the chart on the following page shows the largest price increases and decreases for products and services from May 2015 to May 2016, noting that pharmaceutical prices have increased 9.8% during that period.⁷

Price increases are not limited to the list price or the original selling price before discounts are applied; health plans and pharmacy benefit managers (PBMs) are also seeing triple-digit price increases after rebates and discounts are applied. In general, rebates are offered for drugs with competition in their class, and often, for oncology drugs, rebates are not available. Drug manufacturers argue that list prices are not an accurate barometer of a drug's price, since the manufacturers often provide discounts to health plans or PBMs. But even with these discounts, a recent *Bloomberg* report found that 30 of 39 drugs with global sales over \$1 billion showed increases of more than double the rate of inflation from 2009 to 2015. Only six of the 39 drugs had price increases in line with or below inflation.⁸ The brand-name drugs Humira and Enbrel demonstrate the minimal impact that discounts have on prices. Even with the manufacturers' discounts, both drugs saw triple-digit price growth far exceeding the rate of inflation from 2009 to 2015. For Humira, even with a 23% discount, the rebate price increased 111% during this period.

Select Price Increases* – Producer Price Index



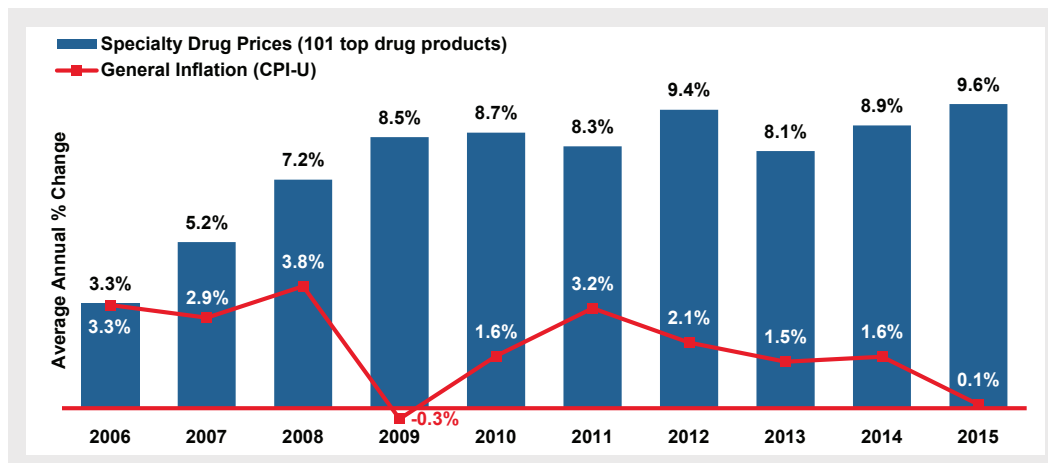
*source: Wall Street Journal, June 14, 2016 based on data from the Bureau of Labor Statistics

The difference was greater with Enbrel, with its rebate price increasing 142% despite a 20% discount.⁹ As the Massachusetts Attorney General’s examination on specialty drugs noted, “Even after accounting for all discounts and rebates, growth in the health plans’ spending on prescription drugs has significantly outpaced overall health care spending growth.”¹⁰

Increases in Specialty Drug Prices

Spending on specialty drugs has doubled and accounted for two-thirds of prescription drug spending from 2010 to 2015 in the U.S.¹¹ In 2017, specialty drug spending, which accounted for about 41% of drug spending in commercial plans, increased by about 11%.¹² This increase was not limited to commercial plans. As seen below, retail prices for 101 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, increased by an average of 9.6% – the highest average annual increase since 2006 and substantially more than general inflation in every year from 2006 to 2015.¹³

In 2015, Average Annual Specialty Drug Price Change Was the Highest since 2006



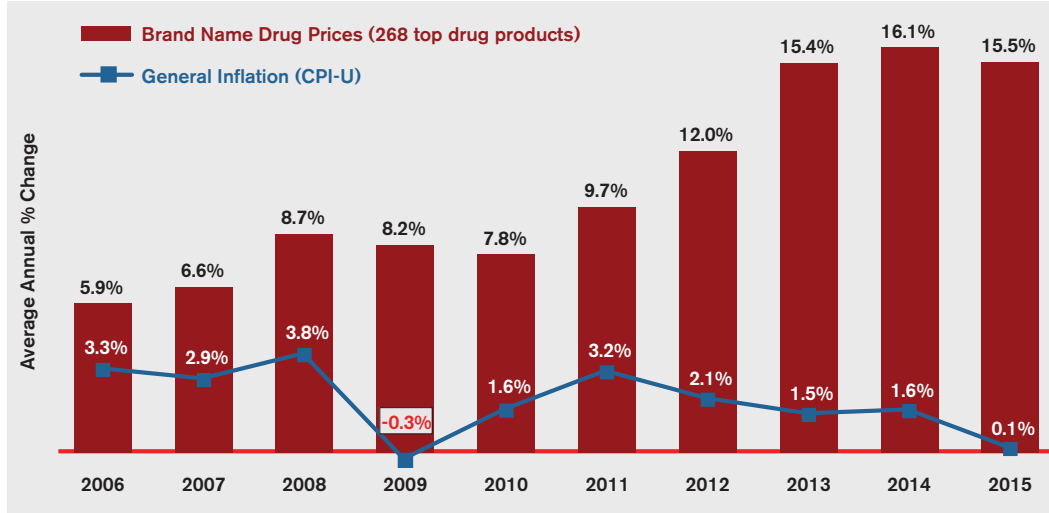
With new specialty drugs like chimeric antigen receptor T-cell (CAR-T), immunotherapy tisagenlecleucel (Kymriah) or injectable LDL-lowering drugs known as PCSK9 inhibitors (Repatha and Praluent), this trend will continue. When Kymriah received FDA approval in the summer of 2017, it was hailed as a breakthrough for pediatric and young adult acute lymphoblastic leukemia. However, the drug came with a hefty price tag of \$475,000, which represents only a portion of the total cost of the overall treatment, as patients receiving Kymriah require supplementary care such as hospitalization and possible concomitant intravenous infusion of the anti-IL-6-receptor tocilizumab, which is estimated to cost an additional \$500,000.¹⁴

The price for Luxturna, a one-time gene therapy treatment for retinal dystrophy that costs upwards of \$850,000 (\$425,000 per eye), is another example of how specialty drugs come with very high price tags.¹⁵ In an effort to address the high prices, a large Massachusetts-based health plan has entered into a “value-based” contract with the manufacturer of Luxturna, Spark Therapy, which will provide rebates to the health plan if the drug does not meet certain targets in full-field sensitivity testing results.¹⁶

Increases in Brand Name Drug Prices

Increases in prescription drug costs have not been restricted to specialty drugs. While branded drugs make up only 10% of all drug prescriptions, they accounted for almost 75% of spending. From 2008 to 2016, the price of branded drugs in the U.S. doubled.¹⁷ The increases in prices for branded drugs have exceeded inflation over several years, including 2014 and 2015, which saw prices 15 times higher than the rate of the Consumer Price Index (CPI-U), as illustrated in the chart below.¹⁸

Average Annual Brand Name Drug Prices Compared to Inflation from 2006 to 2015



A Reuters’ analysis of proprietary drug price data of the top 10 selling drugs sold in the U.S. in 2014 revealed large price increases for these drugs in recent years. Some examples of recent substantial price increases include:

- Enbrel – A typical weekly treatment for the injectable rheumatoid arthritis drug increased by 118% from 2010 to 2016. Its list price increased from \$427 to \$932 during this period.
- Crestor – The popular cholesterol-reducing drug saw a 113% increase in its list price for a three-month supply of the drug, from \$350 to \$745 over 2010 to 2015.
- Abilify – An antipsychotic drug saw its list price increase by 96% for a typical month-long supply, from \$454 in 2010 to \$891 in 2016.¹⁹

In Massachusetts, brand name abuse-deterrent opioids will also contribute to significantly higher costs. Under Chapter 258 of the Acts of 2014, health plans in the Commonwealth are required to provide coverage for abuse-deterrent opioid drug products on a basis not less favorable than non-abuse-deterrent formulations. Today, most non-abuse-deterrent formulations are low-cost generics, typically covered at a lower copay on Tier 1. As a result of Chapter 258, health plans will have to cover new to market expensive, brand name only, abuse-deterrent formulations on Tier 1 as well. In many plan designs, Tier 1 is reserved for lower-cost generics.

Increases in Generic Drug Prices

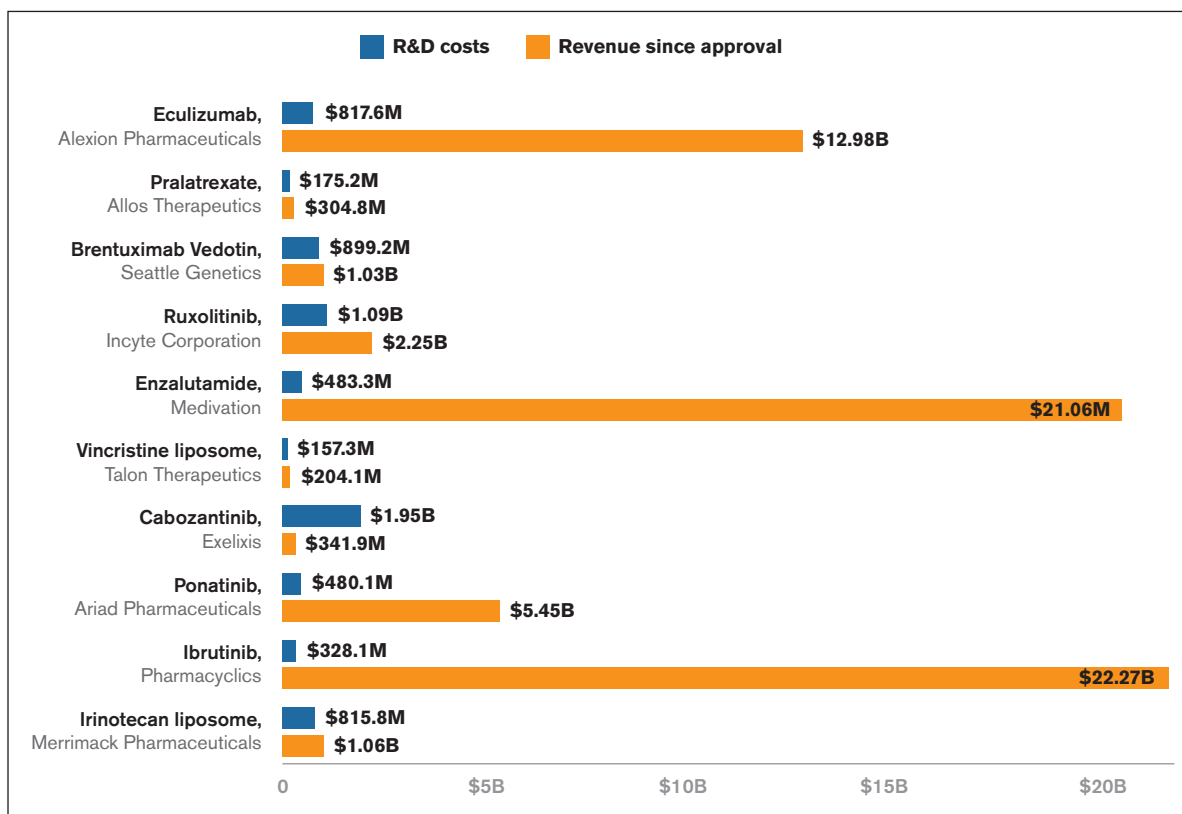
Increases in pharmaceutical spending have not been limited to brand name and specialty drugs. Generic drug prices have also soared, significant because almost 90% of all prescriptions written in the U.S. are for generic drugs. The lower costs of generic drugs serve an important role in keeping health care costs down. When a generic version of a drug enters the market, the original drug sees a steep reduction in price as the original manufacturer seeks to compete with lower-cost competitors. In 2016, a General Accountability Office study found that out of approximately 1,400 generic drugs analyzed, about 300, or 20%, saw an increase in price of at least 100%.

It also found 48 cases of generic drug prices increasing 500%.²⁰ One reason for the steady increase in prices for generics can be attributed to the lack of competition. This has resulted in drugs that have been on the market for some time seeing significant price increases. Doxycycline hyclate, an antibiotic used to treat a variety of infections, saw an increase of 8,000%, from \$20 to \$1,849.²¹ Often, manufacturers of brand medications will increase their prices in the few years before a generic version is released. That helps explain the rising drug costs seen with Abilify and Crestor when generic versions were released in 2015 and 2016, respectively. It should be noted that when a generic version of the drug is released, the price is not dramatically lower at first, particularly if there is only one manufacturer of the generic. The cost is not much different from the brand until competition from other manufacturers begins. One recent example is Syprine, which treats a rare condition called Wilson disease. A generic alternative from Teva Pharmaceutical, which was touted as a lower-cost alternative, was priced at \$18,375 for a bottle of 100 pills. This is 28 times what Syprine cost in 2010.²² Often generics remain relatively costly for the first several months, up to a year, they are on the market. Furthermore, generic drugs often “automatically” receive significant market share from health plan formulary changes and generic substitution laws such as Massachusetts General Law Chapter 112, Section 12D, which provides an incentive to offer the generic version at a lower price than the brand name version at the outset.

The Myth That High Prices Are Needed to Fund Research and Development

The pharmaceutical industry has argued that high prices are justified to support the cost of development and to ensure innovation. Yet numerous studies have shown that the link between high prices and funding development is dubious at best. First, there is evidence that the cost of developing drugs has been overstated. The industry has cited the cost of developing a drug and bringing it to market at \$2.6 billion.²³ But according to a recent *Journal of the American Medical Association (JAMA)* study, the median cost of developing a cancer drug was about \$648 million.²⁴ Second, there is a body of evidence showing that drug manufacturers’ marketing and administrative costs are greater than research and development costs. Analysis from the research firm Global Data found that nine out of the big 10 pharmaceutical companies spend more on marketing than on research.²⁵ Finally, many of the drugs garner profits that far exceed their research and development costs. A recent *Health Affairs* study found that higher margins from higher drug prices charged in the U.S. generates more than enough revenue compared to their global research and development budgets.²⁶ In the *JAMA* study mentioned above, for 10 of the cancer drugs approved by the FDA between 2010 and 2015, several of the drugs made 10 times as much as the biotech companies spent on research and development costs, as seen in the chart below.

How Cancer R&D Costs Stack Up to Drug Revenue



Impact on the Commonwealth

Public programs are vulnerable to higher-than-expected drug costs. Between 2014, when Sovaldi came on the market, and January 2016, the state's Medicaid program, MassHealth, spent \$318 million on hepatitis C drugs for its members. This unanticipated cost threatened to put public health plans at severe financial risk, with the state's Medicaid managed care organizations (MCOs) experiencing hundreds of millions of dollars in losses during 2014 and 2015. In response to the losses experienced by the state, the Massachusetts Attorney General's office used the state's consumer protection laws to threaten possible legal action for unethical pharmaceutical pricing. This drove Gilead and Bristol-Myers Squibb to negotiate supplemental rebate agreements with the state to provide hepatitis C drugs to MassHealth enrollees at a significantly lower cost.²⁷ The financial impact on the Commonwealth and MCOs is expected to continue as the market sees breakthrough drugs with high initial prices.

Public Perceptions of Prescription Drug Prices

The rising prices for prescription drugs have led many Americans to support changes to keep prescription drugs affordable. A March 2018 survey by the Kaiser Family Foundation of 1,212 Americans found that eight of 10 (80%) of respondents perceived drug costs as unreasonable, compared to 77% in September 2016. The Kaiser survey also found half of the public (52%) say passing legislation to bring down the cost of prescription drugs should be a "top priority" for Congress and the current administration.²⁸ Among policy ideas to address prescription drug costs, 86% of respondents supported requiring drug companies to explain how they set drug prices. Further, 78% supported limiting the amount drug companies can charge for high-cost drugs for illnesses like hepatitis or cancer.²⁹ In a recent Harvard School of Public Health Survey conducted in February 2018, 81% of respondents supported requiring pharmaceutical companies to provide advance notice of price increases of more than 15%.³⁰

Greater Transparency Is Needed

The current state of prescription drug pricing and the projections of continued increases in drug spending in the years ahead have prompted a variety of proposals from both federal and state lawmakers. In 2018 alone, 20 state legislatures are considering 43 bills that address the rising costs of prescription medications. This is on top of 100 pharmaceutical pricing bills that were introduced in 30 states in 2017, 25 of which became law. The aim of many of these efforts focused on greater transparency into how drug companies set their prices. Another category of these bills targets PBMs. These bills seek to limit how much consumers pay and to ensure consumer and pharmacy communications by banning so called "gag rules" that limit pharmacists' ability to inform consumers about lower-cost prescription options. Finally, some state legislatures are also considering bills that seek to import drugs from Canada. Efforts of three states on price transparency are highlighted in the text box.

Transparency Initiatives in 3 States

- **Maryland** – Proposed legislation establishing a Drug Cost Commission that would recommend how much payers should pay for brand-name drugs. Separately, in 2017, it passed a drug price-gouging law that limits growth in generic drug costs.
- **California** – Drug manufacturers will notify and justify to the state and health plans any price increases in drug prices of 16% or more.
- **Nevada** – Manufacturers of drugs essential for the treatment of diabetes will be required to report increases in prices exceeding medical inflation.

Recommendations

Prescription drug costs continue to outpace all other health care spending categories, and multiple state reports have pointed to prescription drug spending as the major driver of rising health care costs in Massachusetts. It is necessary to hold the entire system accountable in our state's efforts to make health care more affordable. As the Massachusetts legislature considers legislation to address health care costs, we strongly encourage consideration of the following recommendations, which will increase the transparency of drug costs and enable policymakers to understand changes in prescription drug spending and pharmaceutical prices:

1. **Transparency of Prescription Drug Price Increases.** The HPC, in collaboration with CHIA, should identify a list of prescription drugs for which the state spends significant health care dollars and for which the prices have increased significantly over the past 12 months. The HPC should require those manufacturers to provide an explanation for the increase, including disclosing the research, development, marketing and manufacturing costs as well as the profits attributable to those drugs.

Additionally, pharmaceutical companies that propose to raise their prices by 10% or more should be required to provide notice to the HPC before the new price is to take effect and explain the rationale for the increase so that consumers, employers, providers, health plans and the state have notice before the increase takes effect.

There is widespread support for increased transparency of prescription drug prices in the U.S. The National Academy of Sciences, Engineering, and Medicine's recent report, *Making Medicines Affordable: A National Imperative*, recommends greater transparency of financial flows in the biopharmaceutical supply chain. The report recommended, "Assure greater transparency of financial flows and profit margins in the biopharmaceutical supply chain." As a recent Commonwealth Fund study concluded, "Aside from this complicated distribution system, a lack of price transparency and availability of information about the comparative value of similar therapeutic drugs makes the drug marketplace less efficient."³¹ Greater transparency was included in the 2017 HPC *Cost Trends Report*, which recommended "... increasing price transparency and accountability, adding pharmaceutical and medical device manufacturers as Cost Trends Hearing witnesses."

- 2. Participation in the Commonwealth's Annual Cost Trends Hearings.** As part of the Commonwealth's annual health care cost trends hearings, pharmaceutical and biotech companies and PBMs should be required to submit data to the HPC and to be called as witnesses to testify under oath. Requiring drug manufacturers to be part of the annual hearings would be an important step toward understanding the impact pharmaceutical pricing has on the statewide cost benchmark, whether the costs associated with these therapies offer value in comparison to other therapies and treatments, and whether they are improving patient care. Health plans and providers have been accountable for meeting the state's cost benchmark but increases in prescription drug prices continue to threaten the ability of the state to meet the cost benchmark.
- 3. Promotion of Comparative Effectiveness in Examining Treatments and Technologies.** Understanding the medical efficacy and cost of new prescription drugs is critical to determining whether the added benefits of more expensive drug treatments are sufficient to warrant the additional costs and the price is appropriate. This principle was reflected in the recommendation from the Massachusetts Attorney General's 2016 *Examination of Health Care Cost Trends and Cost Drivers* to "Improve measurement and transparency of the comparative efficacy of different drugs that treat the same disease." The HPC could utilize a third party like the Institute for Clinical and Economic Review (ICER) to evaluate the safety, effectiveness and cost of new therapies to determine whether the added benefits of more expensive drug treatments are sufficient to warrant the additional costs, as well as to determine appropriate standards of care so that best practices are followed in deciding when to use different therapies.
- 4. Greater State Flexibility.** The state should have the authority to directly negotiate for rebates with manufacturers. The governor's proposed Fiscal Year (FY) 2019 budget includes language that would give Massachusetts the authority to directly negotiate with drug manufacturers for rebates and allow the state, in the event the negotiations are unsuccessful, to impose rules for greater transparency in drug pricing and monetary penalties. A similar provision was included in President Trump's FY19 HHS budget that gave five states authority to negotiate rebates directly with manufacturers. As the Massachusetts legislature debates the FY19 state budget, the governor's proposal should be considered as a measure to help address high drug costs.
- 5. Early Dissemination of Information on New Drugs Coming to Market.** Currently, the Food and Drug Administration (FDA) prohibits pharmaceutical manufacturers from sharing information about drugs in development until they are approved. However, this restriction leaves little time for health plans, employers and government payers to understand the potential cost of new medications or to develop appropriate clinical criteria, as was the case with Sovaldi. To provide more notice and give payers an opportunity to prepare before new therapies are brought to the marketplace, the FDA should permit pharmaceutical manufacturers to share clinical and pricing information with health plans and other purchasers prior to a drug's approval.

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