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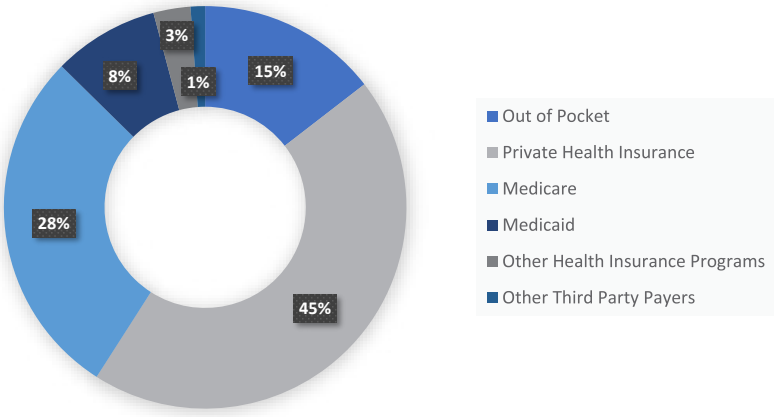
Rx Reality Check

Prescription Drug Spending: Driving Health Care Costs at the State and Federal Levels

Pharmaceutical innovations provide significant opportunities for patients; however, prescription drug costs continue to skyrocket, which creates affordability challenges and ultimately results in limited access for many patients. A January 2021 RAND Corporation report found that United States drug prices were 256% higher than those in the 32 comparison countries combined.[1] In 2019, prescription drug spending increased by 5.7% to reach $369.7 billion, faster than the 3.8% growth in 2018. See Figure 1. The Centers for Medicare & Medicaid Services (CMS) projects that prescription drug spending will grow at an average annual rate of 5.3% for 2019–2028 to reach $560 billion by 2028.[2] High drug prices contribute to health insurance premium increases and high out-of-pocket costs, placing a financial burden on patients, families, and the health care system.

Figure 1

Total U.S Retail Prescription Drug Spending, 2019 = $369.7 Billion

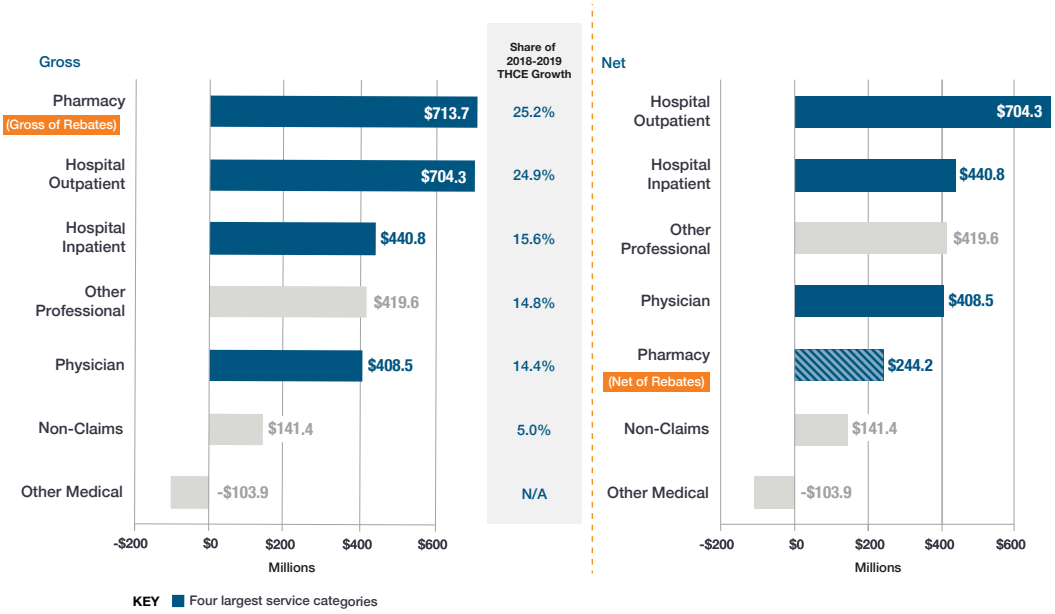


Source: MAHP's analysis of 2019 CMS National Health Expenditure data.
Note: Private health insurance, Medicare, and Medicaid account for 81% of total retail prescription drug spending.

In Massachusetts, prescription drug spending continues to grow. According to the Center for Health Information and Analysis' (CHIA) 2021 Annual Report on the Performance of the Massachusetts Health Care System, pharmacy expenditures are the largest service categories of total health care expenditures (THCE). Pharmacy spending totaled $10.7 billion in 2019, a 7.2% increase from $9.9 billion in 2018. Prescription drug rebates are estimated to have grown over the past three years, from $1.6 billion in 2017 to $2.3 billion in 2019. Net of rebates, expenditures for prescription drugs grew 3.0% in 2019, a percentage point lower than the 2018 trend (+4.0%). [3] See Figure 2 next page.

Figure 2

Change in Total Health Care Expenditures by Service Category, 2018–2019



Increases in pharmacy and hospital outpatient spending were the largest drivers of THCE growth between 2018 and 2019.

Source: CHIA Annual Report on the Performance of the Massachusetts Health Care System, 2021

From 2018 to 2019, THCE in Massachusetts increased by $2.7 billion gross of pharmacy rebates. Gross of prescription drug rebates, pharmacy spending was the largest component of medical expenditure growth, accounting for 25.2% of the increased spending. Importantly, consumers typically pay their cost-sharing (deductibles and coinsurance) based on the list price of the drug and do not benefit directly from rebates.[4]

In Massachusetts, the CHIA noted that 10 therapeutic classes of drugs, which include antivirals, anti-asthmatics, cardiovascular, and psychotherapeutic drugs, accounted for over 70% of pharmacy expenditures. For 2017, the CHIA report highlighted the top 20 drugs, 18 of which were brand-name drugs that had contributed to the increased pharmaceutical spending.[5] These drugs have contributed most significantly to the increase in pharmaceutical spending. See Figure 3.

Figure 3

2017

Top 10 Therapeutic Classes vs All Other	Expenditures PMPM	% of Total Expenditures
ANTI-INFLAMMATORY TNF INHIBITING AGENTS	$12.00	13.27%
ANTIVIRALS	$8.55	9.46%
CNS DRUGS	$8.13	9.00%
ANTIHYPERGLYCEMICS	$7.51	8.31%
PSYCHOTHERAPEUTIC DRUGS	$5.63	6.22%
ANTINEOPLASTICS	$5.46	6.04%
UNCLASSIFIED DRUG PRODUCTS	$5.26	5.81%
HORMONES	$5.07	5.61%
ANTIASTHMATICS	$4.83	5.35%
CARDIOVASCULAR	$2.74	3.04%
Top 10 Therapeutic Classes	$65.17	72.10%
All Other Classes Combined	$25.21	27.90%

Source: CHIA report on commercial prescription drug use and spending, 2015-2017

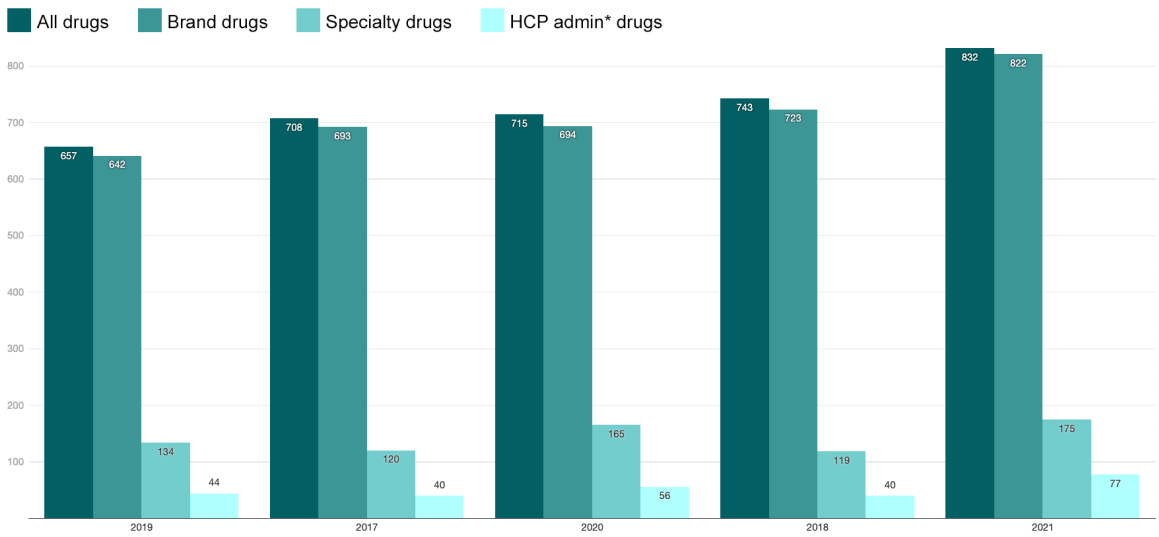
The Massachusetts Association of Health Plans' (MAHP) latest OnPoint examines state and national trends in prescription drug cost growth and offers sound recommendations to policymakers on ways to curtail spending growth while continuing to foster innovation.

Rising Prices for Specialty and Brand-Name Drugs

January 2021 saw the largest number of price increases for prescription drugs. A recent analysis from GoodRx found that a total of 832 drugs increased in price by an average of 4.5% in 2021 alone. Out of these, 822 were brand-name drugs for which prices increased by an average of 4.6% and 10 were generic drugs for which prices increased by an average of 4.2%. Of all the drugs that evidenced increases, 822 were brand-name drugs, 175 were specialty drugs (which are already expensive drugs in the U.S.), and 77 were health care practitioner-administered (HCP admin) drugs. See Figure 4.

Figure 4

January List Price Increases, by Drug Type



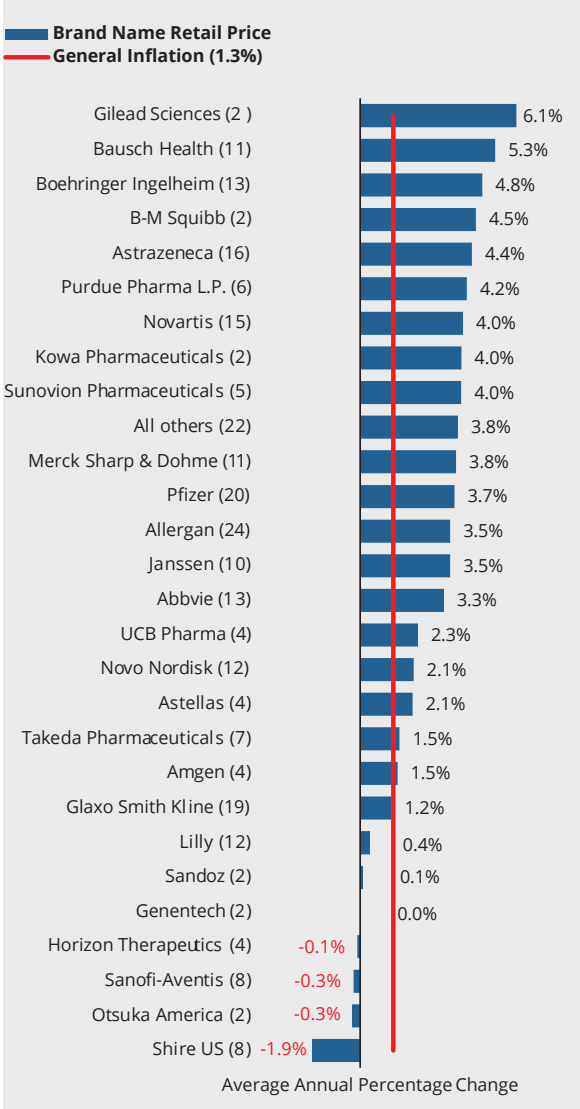
**HCP admin drugs are those that you can only get under the supervision of the healthcare practitioner. Chart: GoodRx*

Many drugs that went up in cost have seen substantial price increases over the past three years. For instance, Idhifa — a cancer treatment specialty drug — increased its list price by 13%. A few other popular and expensive brand-only medications include Humira (21%), Nucynta (30%), Cosentyx (24%), and Skyrizi (15%). These price increases might impact consumers' ability to afford these medications.[6]

Between 2006 and 2020, price increases for widely used brand-name prescription drugs consistently exceeded the rate of general inflation (1.3%), and the increase was twice as fast as inflation in 2020 (2.9%). Retail prices for the 260 brand-name drug products most widely used by older Americans rose 2.9% in 2020 compared to their 2019 prices.[7] See Figure 5 next page.

Figure 5

Retail Prices for Widely Used Brand-Name Drug Products Increased by More Than General Inflation for the Majority of Manufacturers in 2020.



Note: Calculations of the average annual brand name drug price change include the 260 drug products most widely used by older Americans (see Appendix A). Manufacturers with only 1 drug product in the market basket of 260 most widely used brand name prescription drugs were included in the "All Others" category. The number in parentheses after a manufacturer's name indicates the number of drug products in the market basket for that manufacturer. The general inflation rate is based on CPI-U All Items for 2020.

Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from IBM MarketScan® Research Databases.

Source: Rx Price Watch Report; Trends in Retail prices of brand-name prescription drugs widely used by older Americans, 2006-2020.

In many instances, these price increases are not supported by clinical evidence. In January 2021, the Institute for Clinical and Economic Review (ICER) found that substantial price increases for seven out of nine select drugs in 2019 were not supported by new clinical evidence. The researchers at ICER provide an explicit and independent approach to determining whether certain price increases are justified by new clinical evidence or other factors. Figure 6 below highlights the price increases for those seven drugs. The price increases for these drugs, which are unsupported by clinical evidence, led to increases in prescription drug spending that amounted to $1.2 billion, raising prices for employers and consumers without any additional clinical benefit.[8]

Figure 6

Treatment	Q42016 to Q42018 Wholesale Acquisition Cost (WAC) Increase	Q42016 to Q42018 Estimated Average Net Price Increase	US Spending Impact of Net Price Increases in 2017 and 2018 (in Millions)
Humira	19.1%	15.9%	$1,857
Lyrica	28.3%	22.2%	$688
Truvada	14.3%	23.1%	$550
Rituxan*	17.0%	13.8%	$549
Neulasta	14.6%	13.4%	$489
Cialis	26.2%	32.5%	$403
Tecfidera	16.7%	9.8%	$313

In addition, new and pricey drugs have begun to enter the market at a more rapid pace, raising concerns about effectiveness and the impact on insurance costs for employers and consumers. The rate of approvals for specialty drugs has dramatically increased in the past few years.[9] For example, in June 2021, the U.S. Food and Drug Administration (FDA) approved Aduhelm (aducanumab), a new Alzheimer's medication whose list price is set at a staggering $56,000 for one year of treatment. Patients receiving Aduhelm would be on this medication for an extended period of time, taking it in perpetuity from the time of the initial prescription. As of July 12, the FDA has requested an investigation of drug reviewers involved in the approval and further updated label information for the drug. Critics of the FDA approval noted that the trial data for the drug was inconclusive, and they highlighted the FDA advisory committee's nearly unanimous decision, which stated that there was not enough evidence that the drug provided clinical benefits. ICER's revised evidence report calculated a fair annual price ranging between $3,000 and $8,400 for Aduhelm and noted insufficiency of evidence of its health benefits.[10]

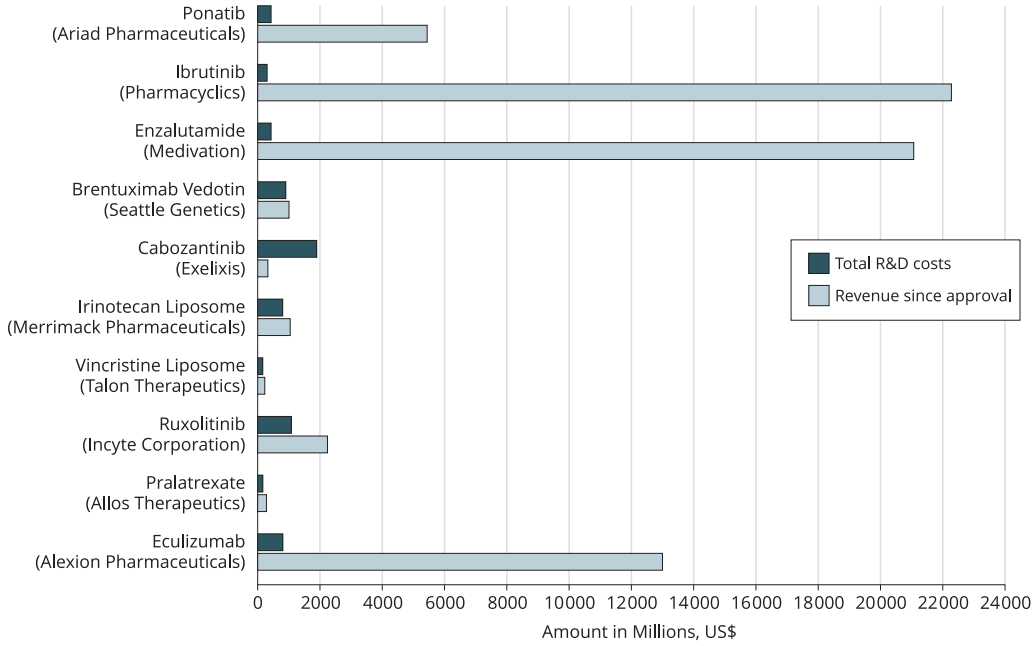
Research and Development

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.[11] But according to a recent study by the Journal of the American Medical Association (JAMA), the median cost of developing a cancer drug was about $648 million.[12] Second, there is a body of evidence showing that drug manufacturers' marketing and administrative costs are greater than research and development (R&D) 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.[13]

Figure 7

How Cancer R&D Costs Stack Up to Drug Revenue



In addition, many of the drugs garner profits that far exceed their R&D costs. A recent Health Affairs study found that higher margins from higher drug prices charged in the U.S. generate more than enough revenue compared to their global R&D budgets.[14] The JAMA study mentioned above noted that for 10 of the cancer drugs approved by the FDA between 2010 and 2015, several of these drugs made 10 times as much as the biotech companies spent on R&D costs, as seen in Figure 7 above. Finally, research from the Congressional Budget Office confirmed that pharmaceutical research and development costs do not have a relationship to the prices drug companies set on their products.[15] The report states, "Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug's sunk R&D costs —that is, the costs already incurred in developing that drug — do not influence its price."

Insights from COVID-19 Vaccines and Treatments

The COVID-19 pandemic spurred the rapid development of vaccines and treatments. While R&D costs for COVID-19 vaccines and treatment were partially covered through governmental funding, revenue far exceeds costs. With support from the U.S. federal government and $445 million in funding from the German government, drug manufacturers developed, trialed, and received emergency use authorization for vaccines to prevent the novel virus, and as of June 2021, 45.8% of the population in the U.S. has been vaccinated. According to the first-quarter financial results for Pfizer alone, their COVID-19 vaccine made $3.5 billion in revenue, and the company forecasts $26 billion of revenue in 2021 from COVID-19 vaccine sales.[20] The COVID-19 vaccines are highly effective at keeping individuals from getting COVID-19 and reducing the risk of people spreading the coronavirus that causes COVID-19.

Researchers and drug manufacturers continue to explore the use of existing drugs for coronavirus treatment, including the widely publicized Remdesivir, previously evaluated for treatment of SARS and Ebola. According to a recent study in the Journal of Virus Eradication, Remdesivir can be produced for approximately $9 per 10-day course of treatment if produced as a generic through an India-based manufacturer. In May 2020, Gilead Sciences set the price for Remdesivir at $520 per vial, or $3,120 per patient for a typical course of treatment. The Institute for Clinical and Economic Review (ICER) contends that the Remdesivir pricing must be reassessed, and it further encouraged policymakers to explore alternatives to the existing drug pricing systems. Additionally, they updated their pricing model for Remdesivir and highlighted that the "cost-effectiveness" benchmark price changed for Remdesivir based on new data on the drug, additional assumptions regarding the manufacturer's development expenses, uptake of Remdesivir, and generic prices.[21]

Unwarranted Factors Contributing to Price Increases

Product Hopping and Pay-for-Delay Settlements

Product hopping refers to when a brand-name drug company moves patients to a new reformulated version of a drug when an existing drug's patent exclusivity is close to expiring.[16] Generic drugs are launched after the patent expiration of the original brand-name drug and are lower-cost alternatives used by consumers in place of brand-name drugs. The cost savings from generic drug use are the most effective tool in holding down overall pharmacy benefit costs for individuals and employers. The practice of product hopping is a strategic move that brand-name drug companies use to prevent generic competition in the market. The study by Alex Brill of Matrix Global Advisors, commissioned by the Coalition for Affordable Prescription Drugs, finds that product hopping for the brand-name drugs Prilosec, TriCor, Suboxone, Doryx, and Namenda cost the U.S. health care system $4.7 billion annually.

"Pay-for-delay" refers to the patent settlements between drugmakers and the generic companies wherein generic companies are offered settlements to restrict introduction of lower-cost alternative drugs to the market. These pay-for-delay patent settlements effectively block all other generic drug competition for a growing number of branded drugs. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year. Since 2001, the FTC has filed several lawsuits to stop these deals, and it supports legislation to end such pay-for-delay settlements.[17]

Biologic Brand Drugs versus Biosimilars

There is a growing body of literature highlighting how regulatory barriers to competition lead to increases in drug spending. Biologic brand drugs, such as Humira, are made from living cells from humans, animals, or other microorganisms. These drugs include a variety of specialty medicines and vaccines and are typically expensive and available at specialty pharmacies.

On the other hand, biosimilars are drugs with structure, functions, and effectiveness similar to those of biologic brand drugs that are utilized interchangeably in clinical practice. Biosimilars, such as Inflectra, are comparatively cheaper than biologic brand drugs. Both biologic brands and their biosimilars are often used for complex conditions such as, but not limited to, rheumatoid arthritis, cancer, Crohn's disease, and multiple sclerosis.

The growth of biologic brand drugs continues, and biosimilars now compete for market share among medicines with $11.5 billion in spending. Spending on biologic brand drugs grew by 12.6% in 2017, averaging 11.2% growth for the past five years as a variety of biologic brand treatments for autoimmune disorders, immunology, and cancer came to the market.[18] Despite the availability of biosimilars, there are barriers to marketing them, which lead to price and spending increases. When traditional, small-molecule drugs' patents expire, they are subject to vigorous price competition from generic drugs; hence, overall spending on small-molecule drugs is steadily declining. However, most biologic drugs are not subject to the same competitive forces, leading to rapid price and spending increases.[19]

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. In our state's efforts to make health care more affordable, it is necessary to hold the entire system accountable. 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 in prescription drug pricing —** The Health Policy Commission (HPC), in collaboration with the CHIA, should identify a list of prescription drugs for which the state spends significant health care dollars and for which prices have increased significantly over certain time periods or drugs that are new to the market that have significantly impacted the cost-growth benchmark. The HPC should require those manufacturers to provide an explanation for the increase, including disclosures of research, development, marketing, and manufacturing costs as well as the profits attributable to those drugs. Likewise, pharmaceutical companies that propose to raise their prices by 10% or more should be required to provide notice to the HPC 30 days before the new price is to take effect, explaining the rationale for the increase, so that consumers, employers, providers, health plans, and the state have notice before the increase takes effect.

2. **Regulatory checks on excessive drug pricing —** The state has seen evidence of price increases of branded, generic, and specialty drugs nationally and locally, which contribute to spending by health plans and employers. Policymakers should have a regulatory oversight and check on excessive price increases on prescription drugs by performing cost-effective analyses and evaluation of specific prescription drugs. MAHP supports the drug pricing review process established in 2020. Under this authority, the HPC assists in managing pharmaceutical spending by conducting reviews of high-cost drugs referred to it by MassHealth. They assess them to determine whether the pricing is unreasonable or excessive in relation to the value. MAHP supports a similar review process for the commercial market.

3. **Participation in the cost trends hearings —** As part of the commonwealth's annual health care cost trends hearings, pharmaceutical and biotech companies 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.

4. **Encourage cost effectiveness research for drugs and treatments —** Consumers have a right to know about the efficacy and costs associated with their drug regimen and treatments so they are able to make informed decisions for their health. Understanding the medical efficacy and cost of new treatments, including prescription drugs, is essential for patients and providers to be able to make informed health care decisions. In the absence of a national process for measuring both the cost and clinical effectiveness of new procedures and drugs, states can fill that void. The HPC or a collective of interested organizations should bring together stakeholders — clinicians, patients, health plans, academics, and pharmaceutical and device manufacturers — 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.

5. **Early dissemination of information on new drugs coming to market —** Currently, the FDA prohibits pharmaceutical manufacturers from sharing information about drugs in development until they are approved. This restriction leaves little time and information for health plans, employers, and government payers to understand the potential cost of new medications or to develop appropriate clinical criteria. To provide more notice and to 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.

6. **Encourage Competition —** Policymakers should explore and adopt strategies that encourage competition while discouraging monopolies. The pharmaceutical industry has monopolies over many drugs due to patents, marketing restrictions, and other regulatory barriers that lead to high drug prices. Drug companies highlight their revenue and profits for future R&D of new therapies. We recommend reforms at the federal level; for instance, reforms to stop evergreening of patent protections and to shorten the exclusivity period for biologics in order to increase biosimilars competition that would encourage competition, create consumer choices, and ensure an open and honest discussion of the factors that go into drug pricing. We further propose legislative reforms to address the pharmaceutical practice of product hopping as a violation of antitrust laws.

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