



**mahp**  
Michigan Association  
of Health Plans

**Senate Insurance Committee**  
**January 27, 2016**

*Testimony of Michigan Association of Health Plans in opposition of SB 625*

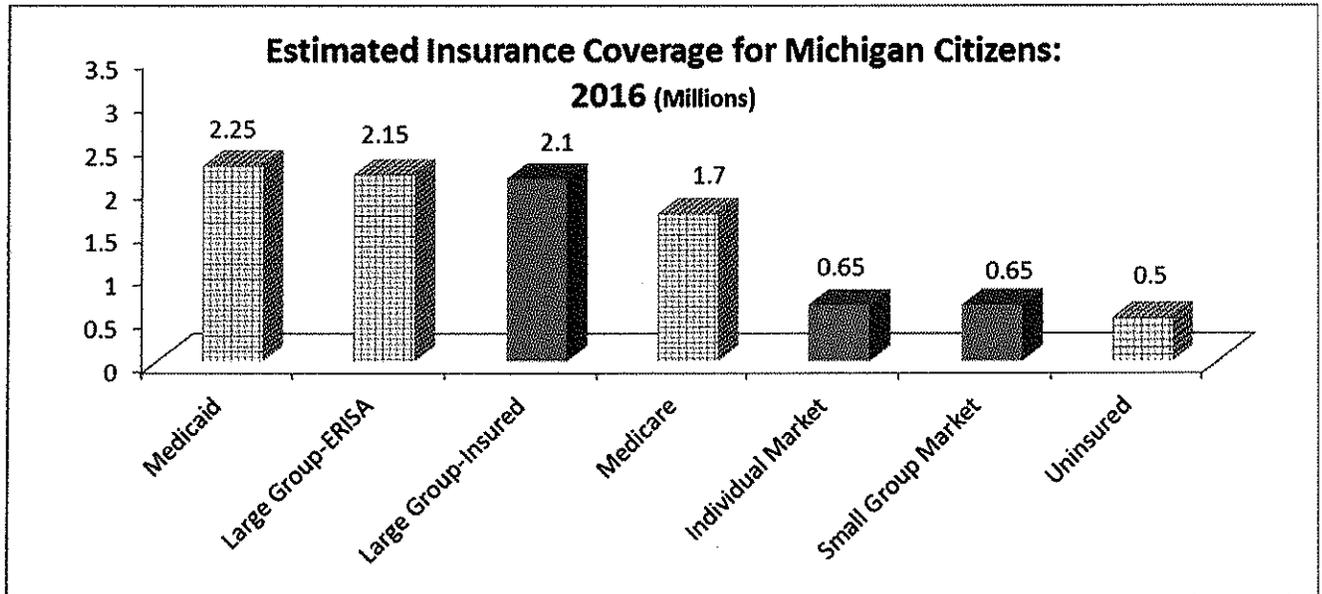
Good afternoon Chairman Hune and members of the committee, my name is Christine Shearer, Deputy Director, of Legislation and Advocacy for the Michigan Association of Health Plans. With me today is Dr. Vanita Pindolia, VP Ambulatory Clinical Pharmacy Programs, Health Alliance Plan.

As many of you already know, we are opposed to Senate Bill 625. However, we don't want anyone to misinterpret our position as one of insensitivity. I bet if we asked everyone in this room to raise their hands if they personally (either themselves or a loved one) have been impacted by cancer, we would have an overwhelming demonstration that illustrates the scope and prevalence of this disease. MAHP will continue to work with Senator Hansen on this very important issue.

As health plans, we understand the physical, emotional and financial toll that cancer can have on people. That is why we provide coverage for all FDA-approved antineoplastic drugs – including the oral chemotherapy treatments that are the focus of SB 625.

The purpose of our testimony is not questioning the benefits or efficacy of orally-administered chemotherapy treatments. Instead, we hope to provide some background on high-cost specialty drugs and the unintended consequences that may result if Senate Bill 625 were effectuated into law.

The graph below illustrates our estimate of where Michigan Citizens are grouped related to insurance coverage. The solid blue color bars represent the 3.4 million Michigan citizens (or about one-third of the states population) that would potentially be affected by the legislation in the large group-insured, small market and individual market. All other segments of our population are outside of purview of the legislation.



I will now turn it over to Dr. Vanita Pindolia.

Senate Bill No. 625 specifically addresses the desire to lower out-of-pocket costs for cancer treatments.

Diagnosis and treatment of cancer places a tremendous physical and emotional toll on both the patient and caregivers/family members/loved ones.

Due to the high price associated with cancer treatment drugs, a financial toll is added to the burden.

Majority of the oral cancer drug treatment drugs used today are classified as 'Specialty Drugs'.

**Specialty drugs** are large molecule drugs used to manage complex chronic and/or life threatening conditions that usually require close monitoring for safety and effectiveness and are typically priced much higher than traditional drugs (for reference, traditional drugs are used to treat high blood pressure, diabetes, etc.).

**What are common disease states Specialty Drugs Manage?**

Rheumatoid Arthritis, Plaque Psoriasis, Multiple Sclerosis, Cancer, Hepatitis C, HIV, Growth deficiency, Hemophilia, Pulmonary Arterial Hypertension and Orphan drugs for rare diseases

**Approximate Monthly Cost of Commonly Used Specialty Medications, 2014**

<b>Medication</b>	<b>Sample indication for medication use</b>	<b>Monthly cost for sample indication</b>
Provenge (sipuleucel-T)	Metastatic prostate cancer	\$105,800
Solvaldi (sofosbuvir)	Hepatitis C	29,900
Olysio (simeprevir)	Hepatitis C	23,600
Rituxan (rituximab)	Non-Hodgkin's lymphoma	21,900
Gleevec (imatinib)	Chronic myeloid leukemia	11,900
Avastin (bevacizumab)	Metastatic colorectal cancer	11,600
Revlimid (lenalidomide)	Multiple myeloma	9,300
Neulasta (pegfilgrastim)	Neutropenia	5,700
Copaxone (glatiramer)	Multiple sclerosis	5,000
Tecfidera (dimethyl fumarate)	Multiple sclerosis	4,900
Humira (adalimumab)	Rheumatoid arthritis	4,000
Remicade (infliximab)	Rheumatoid arthritis	4,000

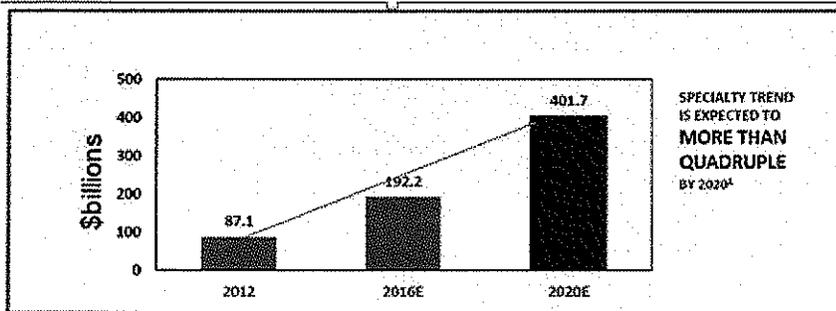
*Health Affairs October 2014 vol. 33 no. 10 1736-1744.*

**NOTE: Drugs highlighted in yellow are used to treat cancer.**

**All health plans contract with a Specialty Drug Pharmacy to provide these drugs to negotiate the best reimbursement fees, increase drug adherence and improve care through monthly engagements with patient to assure side effects are being managed and collaborate with physicians when necessary.**

**Specialty Pharmacies dedicate time and resources to identifying drug copay assistance programs for patients. Approximately 90% of the patients obtaining specialty drugs, that do not have regulations precluding use of patient assistance programs, receive monetary assistance to offset their out-of-pocket costs; the financial assistance is usually for full year periods and covers nearly full amount of out-of-pocket costs.**

**Specialty drug spending trend from 2012-2020 shows 2020 expectation of \$401.7 billion spend:**

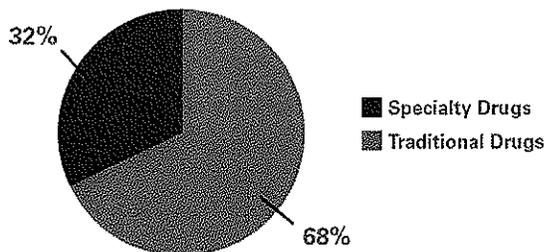


<http://pwchealth.com/cgi-local/hregister.cgi/reg/pwc-hri-medical-cost-trend-2015.pdf>

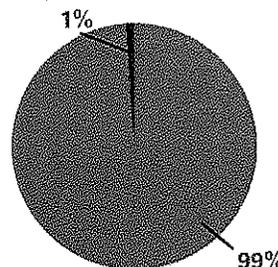
**How much of total prescription drug spend does specialty drug make up?**

**The 1% of the US prescriptions written in 2014 for specialty drugs comprised 32% of the total US prescription drug spend in 2014:**

Prescription Drug Spending in 2014



Prescriptions Written in 2014



Source: The Express Scripts 2014 Drug Trend Report, March 2015. Available at: <http://lab.express-scripts.com/drug-trend-report/>

**Drug Pipeline and FDA Approvals: We now are seeing more FDA drug approvals for specialty drugs over traditional drugs each year.**

**Unlike traditional drugs, specialty drugs enter the US market at a very high price and then continuously increase prices over the course of their patent protection. Gleevec, the first oral targeted cancer drug to enter the market, is a great example of what happens with drugs costs at market entry and over the course of patent protected life:**

Novartis first sold Gleevec in 2001 for an annual cost of \$30,000, a price the company acknowledged was steep. "We agree with those who say the price we have set for Gleevec is high. But given all the factors, we believe it is a fair price," Daniel Vasella, Novartis' CEO at the time, wrote in *Magic Cancer Bullet*, a 2003 book he penned about his company's wonder drug.

That "fair price" nearly tripled over the past decade. An annual course of Gleevec now wholesales for more than \$76,000 in the U.S., according to Novartis. The retail price that patients or their insurers pay is typically much higher.

## **WHAT DOES ALL THIS MEAN for Bill No 625:**

- 1. The chemotherapy parity laws do NOT address the underlying issue of high drug costs that has led to employer groups having to either increase premiums, provide higher copayment/deductible benefit designs or move employees to individual health plans.**

**Per Drs. Wang, Joffe and Kesselheim (from Brigham and Women's Hospital and Harvard Medical School) published their comments on chemotherapy parity laws after Ohio became the 34<sup>th</sup> state to enact theirs:** "Chemotherapy parity laws may have substantial benefits for some patients. The laws, however, only apply to the limited number of private insurance plans with large discrepancies in cost-sharing arrangements for oral and intravenous chemotherapy; thus, it is unclear how many patients may actually benefit. Moreover, parity laws merely shift the responsibility for the cost of chemotherapeutic agents to insurers who presumably pass along their additional costs to all policyholders. The laws do not address the underlying issue: the high cost of oral cancer drugs. By not distinguishing between higher- and lower-value agents, these laws sidestep the emerging national debate about the appropriateness of using expensive therapeutics that demonstrates only limited marginal benefit compared with less costly alternatives." *JAMA Nov 2014;174(11):1721-2.*

- 2. The Chemotherapy parity bill does not take into account other unintended consequences:**
  - a. Although removing/reducing the out-of-pocket costs of cancer drugs in 2016 may have a smaller impact on overall healthcare costs that will need to shift to the purchasers of healthcare (individuals for QHP and private insurers) in other forms, this is a continuously moving target.**

**Looking at Gleevec as a great example of an alarmingly high drug entry price and then continuous price increases.**
  - b. Patients with other disease states requiring specialty drugs can also request to have bills barring them from having to pay their employer group's negotiated benefit design**
    - i. With more of the US drug spend being comprised of specialty drugs, specialty drugs entering the market at whatever price they feel is an appropriate compensation, specialty drugs continuously increasing their drug prices over the course of their patent protection, and specialty drugs making up majority of the FDA approvals, the 'smaller impact' on overall healthcare costs that WILL shift to the purchasers of healthcare, will be TREMENDOUS.**
  - c. Majority of the patients consuming majority of the US drugs have 'regular' chronic diseases - such as high blood pressure, diabetes and high cholesterol - and require multiple drugs for disease management. All of these patients would also see a shift increase in their 'non-specialty' drug copayment fees to offset the provided specialty drug out-of-pocket decrease.**
    - i. Patients with diabetes and asthma/COPD struggle with their drug costs. Insulins used to treat diabetes now cost \$350 to \$500 per month**

**and inhalers used to treat asthma/COPD drugs cost over \$300 per month.**

- 3. The Chemotherapy parity bill does not address out of pocket spend seen with the primary cancer population – elderly on Medicare; nor the self-insured population for which the use of high deductible plans continue to increase.**

**Drug price controls are the heat of many republican and democratic discussions these days. For any type of chemotherapy parity bill to be considered in Michigan, we should do our due diligence of assuring price transparency is included in the bill by having each drug manufacturer report on pharmaceutical costs for each cancer medication that is made available in Michigan. The report should include the wholesale acquisition cost of the drug, for each drug, a five-year history of wholesale acquisition cost and the month each price change took effect. All Michigan residents should have access to the report; thereby allowing patients, physicians, payers and healthcare purchasers to understand financial constraints each drug will have on each entity.**

I will now turn it back to Christine for summary.

In conclusion

Price controls on health plans are the wrong way to address the soaring cost of prescription drugs. In fact, price controls would make the cost challenges facing patients and the health system even worse.

Ironically, some of the most vocal companies supporting price controls on insurers are drug makers themselves. In states across the country, drug companies are backing legislation that would force insurers to cap co-payments on prescription drugs. In typical form, rather than addressing the underlying price of medications and treatments, drug makers are looking to hide their record-breaking costs increases behind insurance providers. Capping co-pays, as this legislation would do, without addressing the underlying price of the drug and their profit margins will only drive up the cost of coverage and premiums. With most new treatment carrying a six-figure price tag, shouldn't drug companies be upfront and transparent about why we're paying so much than other countries for their products?

Michigan cannot no longer afford to walk around the problem of drug pricing. Shifting blame may have worked in the past, but when public health and access to vital medicines continue to be threatened by these excessive increasing prices, we all need to step up and work toward a better way to solve this problem for patients.

Thank you for allowing us to testify, we would be happy to answer any questions you may have.

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### *The heart of the matter*

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***The five-year contraction in healthcare spending growth comes to an end next year as the stronger economy releases a pent-up demand for care. Despite some higher utilization and expensive new cures, the rise in the expected growth rate in 2015 is modest compared to prior increases.***

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### *An in-depth discussion*

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***For 2015, PwC's Health Research Institute (HRI) projects a medical cost trend of 6.8%. Taking into account likely adjustments to benefit design such as higher deductibles, HRI anticipates a net growth rate of 4.8%.***

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### *What this means for your business*

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***A stronger economy and newly insured Americans mean an uptick in spending growth for healthcare. But the fact that health spending continues to outpace GDP underscores the need for a focus on productivity, efficiency, and better value for purchasers.***

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of Pennsylvania's Wharton School of Business. The result in 2015 is expected to be a small, but measurable increase in medical spending growth because some of the expected increase will be tempered by deflators as described below.

Low unemployment rates are another indicator of economic health. In 2015, the national unemployment rate is expected to settle in at about 6.5%.<sup>12</sup> As more people become employed, job stability increases a family's discretionary income and allows family members to turn their attention to long-postponed health needs. Between September 2013 and March 2014, 8.2 million people gained coverage from employer-sponsored insurance plans.<sup>13</sup> Once individuals get coverage, they are more inclined to seek care.

### No slowing down for specialty drugs

For years, the budgetary impact of drug spending has been a mixed bag, drawn in sharp relief again in 2015. As blockbuster medications go off patent, the switch to generic drugs brings with it considerable cost reductions for purchasers. But at the same time, the rise of high-priced specialty drugs is sparking anxiety and fierce debate among purchasers over pricing strategies and whether the high cost will be worth it over the long term. One thing is certain: In 2015, several expensive specialty therapies will likely increase the healthcare spending growth rate. (Figure 5).

Only 4% of patients use specialty drugs, but those drugs account for 25% of total US drug spending.<sup>15</sup> Specialty drugs for cancer, respiratory conditions, central nervous system disorders, and inflammatory conditions such as rheumatoid arthritis and psoriasis are expected to increase drug spending growth in 2015.<sup>16</sup>

In 2013, 70% of the 27 drugs approved by the FDA were specialty medications, raising the specter of a series of expensive treatment decisions in future years.<sup>17</sup> Nine of these therapies were oncology drugs.<sup>18</sup>

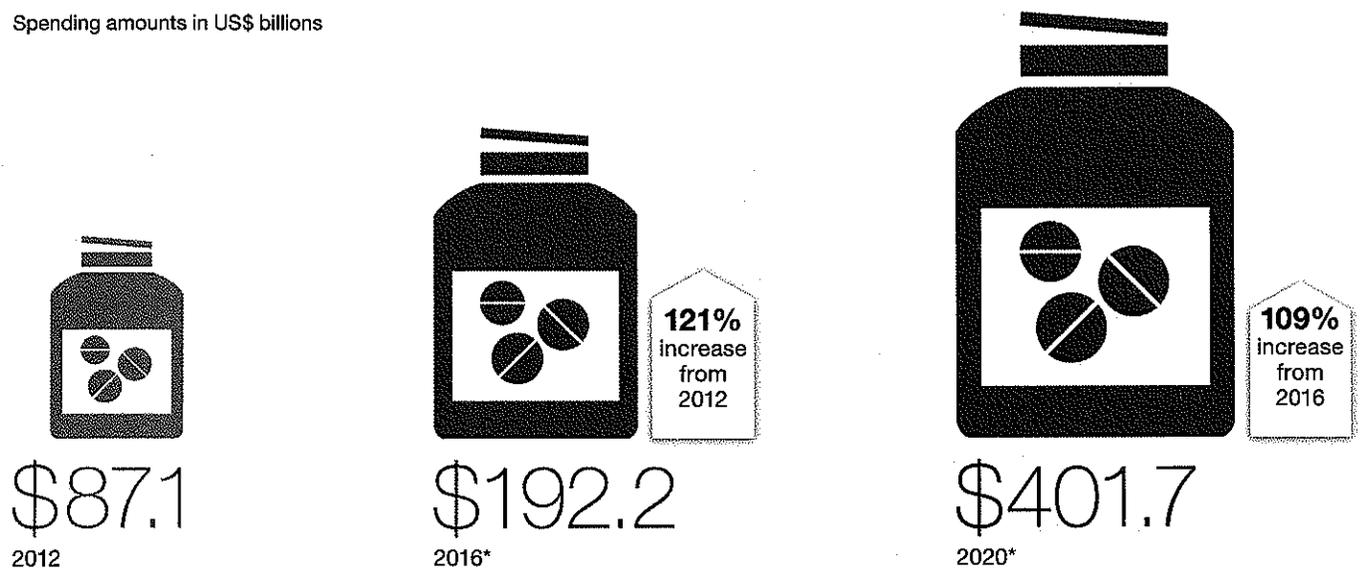
The average cost of branded oncology treatments has doubled over the past decade from \$5,000 to \$10,000 per month.<sup>19</sup> In 2013, two of the first drugs to be approved through the FDA's breakthrough therapy process—an expedited review process for serious or life-threatening conditions—were cancer drugs now on the market for between \$7,000 and \$11,000 a month.<sup>20</sup> While treatment costs are high, they can result in extended life span, improved quality of life, and, in some cases, savings over many years.

No drug category has gotten more attention in recent months than the new Hepatitis C therapies, which are expected to increase total Hepatitis C drug spending 209% by 2015.<sup>21</sup> About 3.2 million Americans have Hepatitis C, a life-threatening viral infection—about a million of those

Figure 5. US specialty drug spending will quadruple by 2020

### Projected specialty drug spending from 2012 to 2020

Spending amounts in US\$ billions



Source: PwC Health Research Institute estimates based on data from CVS Caremark<sup>14</sup>

Offsetting the spike in specialty drugs is about \$17 billion less in spending as big-name branded drugs lose patent protection in 2015.<sup>31</sup>

**Physician-based payments become more lucrative hospital-based payments in acquisitions**

The rapid acquisition of physician groups by hospitals will likely continue into 2015. Hospitals pursue these acquisitions in search of economies of scale, controlled referrals, bargaining power with suppliers, and more coordinated care. A recent survey by the American Medical Association (AMA) found that 43.6% of multi-specialty physician practices have a business model that includes some type of hospital ownership.<sup>32</sup>

Additionally, the share of physicians in a solo practice has decreased 20% during the past 30 years.<sup>34</sup>

As physician practices are acquired, they may be reclassified as “hospital-outpatient” departments, which allow hospitals to charge a “hospital facility fee” even though services are not performed in a hospital. Hospitals say they charge the fee to cover higher operating costs.

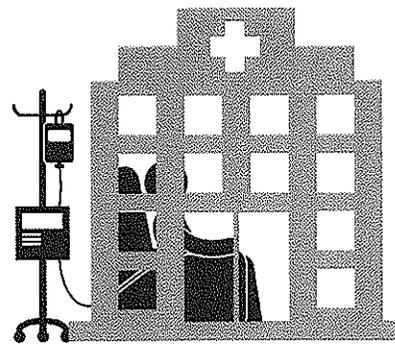
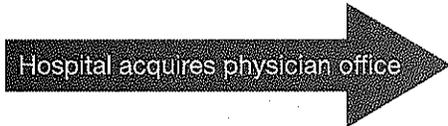
According to a recently published study, this not only affects hospital prices for services and drugs, but can ultimately be passed on to patients who may end up with a higher bill.<sup>35</sup> According to a report by the Medicare Payment Advisory Commission, Medicare paid about 80% more per office visit in a hospital outpatient department than at a freestanding physician office.<sup>36</sup>

This shift has been commonly observed in cancer care. Between 2011 and 2012, the number of oncology practices owned by hospitals increased by 24%.<sup>37</sup> The result: hospital oncology outpatient costs were more than double physician office costs during the same time period (Figure 7).<sup>38</sup>

In April 2014, Highmark, a Pennsylvania-based insurance company, announced that it would no longer reimburse at the hospital-based rate for cancer treatments performed in outpatient offices.<sup>39</sup> The insurer believes that it will subsequently reduce claims by \$200 million per year. Other insurance executives told HRI they are watching this trend closely and may renegotiate contracts to pay doctors and hospitals the same regardless of where the drugs are administered.

**Figure 7. Oncology drugs cost more when administered in a “hospital-outpatient” department**

Oncology drugs administered in a “hospital outpatient” department can cost twice as much as a physician office



Oncology drug Z costs \$1,000 in a **physician office** setting

Oncology drug Z costs \$2,000 in a **hospital-outpatient** setting

Example oncology drugs  
Total payment (\$) per claim

	Physician office	Hospital outpatient	Percent difference
Allimta	\$5,460	\$9,710	78%
Herceptin	\$2,740	\$5,350	95%
Avastin	\$6,620	\$14,100	113%

Source: PwC Health Research Institute analysis based on 2012 Truven claims data.<sup>33</sup>

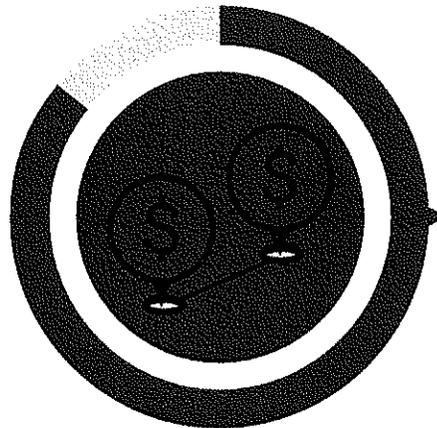
revenue challenges.<sup>43</sup> Now community and regional hospitals are gaining these same savings. The results can be powerful. “By centralizing key support functions, CHRISTUS will be able to save \$20 million over 5 years in facilities management efficiencies, reduce costs to collect payments by 0.35% per transaction, and will project seven-figure savings by centralizing accounting, procurement, and accounts payable,” CHRISTUS Health System’s Generale told HRI.

When hospitals and doctors work together to cut costs and share in savings, the result is reduced supply costs due to greater standardization and improved ability to negotiate prices. Health systems that work closely with doctors can more easily limit the range of implants they must stock to get bulk pricing discounts. For example, the average price paid for femoral knee implants, an implant choice determined by physician preference, decreased 6.6% between 2013 and 2014.<sup>44</sup> Scottsdale Healthcare saved \$24 million by reducing its number of suppliers.<sup>45</sup>

Standardizing medical practices also yields significant savings. “The term ‘cookbook medicine,’ which used to have a negative connotation, is now leading to better quality and better outcomes,” said Grealy of the Healthcare Leadership Council.

“We have embraced standardized care processes. It is not just paying less for supplies; it is picking a treatment protocol with proven outcomes,” said Mark D. Birdwhistell, VP for administration and external affairs of UK Healthcare system in Kentucky. In 2015, these operational efficiencies will play a role in lowering healthcare spending growth by reducing waste.

**Figure 10. Employer survey shows a strong interest in increasing employee cost sharing through plan design changes**



Source: PwC 2014 Touchstone Survey

**85%**

of employers have already implemented or are considering an increase in employee cost sharing through plan design changes over the next 3 years

### **Consumers become cost-conscious healthcare shoppers**

The ongoing growth in high-deductible plans ultimately influences consumer behavior on the number and type of health services purchased. Eighty-five percent of employers in PwC’s 2014 Touchstone Survey have already implemented or are considering an increase in employee cost-sharing through plan design changes over the next three years, and 44% of employers are considering offering high-deductible plans as the only insurance option for their employees over the next three years (Figure 10).

While increased cost sharing and high-deductibles do not affect medical inflation directly, consumer behavior does. Cost remains a top concern for consumers and affects the health choices they make. According to a December 2013 HRI survey, 40% of consumers said that healthcare expenses put a strain on their budget. And a recent study in the journal *Health Affairs* about families with high-deductible health plans observed deliberate changes in those families’ use of health services. Families

enrolled in high-deductible plans used fewer brand name drugs, had fewer doctor visits, and spent less per visit.<sup>46</sup>

Increased price transparency can also play a role in driving down prices. In 2011, CalPERS, a large California administrator of health and retirement benefits for state employees, demonstrated that consumers shop differently when given cost and quality information and a financial incentive to select wisely. When CalPERS set its reimbursement rate for hip and knee replacements at \$30,000, its members switched to lower-cost providers. In response, other providers dropped their prices to compete, and CalPERS saved \$5.5 million in the first two years.<sup>47</sup>

Consumers are starting to hunt for more pricing information on their own. Based on HRI’s latest consumer survey, 45% of consumers who shopped for medical procedures or health services in 2013 called around to get prices. Many consumers say they want more user-friendly pricing information. According to the same survey, 43% of consumers who would like to shop for health and medical services prefer to use an online



# ISSUE Brief

## Specialty Drugs: Issues and Challenges

**Advancing Effective Strategies to  
Address Soaring Drug Costs  
While Ensuring Access to Effective  
Treatments and Promoting  
Continued Medical Innovation**

### TWEETS

@AHIPCoverage

- ✎ Specialty drugs account for 1% of prescriptions but 32% of all Rx drug spending
- ✎ Issue brief explores the unsustainable cost trend of specialty drugs
- ✎ Learn about health plan strategies to promote access to specialty drugs while managing costs

## KEY TAKEAWAYS

**27**  
of  
**51**

Specialty drug approvals by the FDA exceeded traditional drug approvals for the first time in 2010—a trend that has continued each year since. In 2014, 27 of the 51 drugs approved by the FDA were specialty drugs.

**6%**

The Centers for Medicare & Medicaid Services (CMS) projects sustained increases in drug spending of 6% or more annually from 2015 to 2022, as both drug prices and utilization increase.



Anti-competitive strategies used by some drug manufacturers, such as “evergreening” and “product hopping,” restrict access to less costly, high-value generics and therapeutic alternatives.



Health plans have developed a number of innovative strategies to address unsustainable increases in the prices of specialty drugs.

# Background

Spending on specialty drugs represents an increasing share of U.S. prescription drug spending and is growing at a rapid and unsustainable rate. Addressing these cost trends is critical to ensuring a sustainable health care system and achieving affordability for businesses and consumers. In 2014, U.S. spending on prescription drugs totaled nearly \$379 billion—almost a third of which was spent on specialty drugs.<sup>1</sup>

Specialty drugs—which are generally understood to be drugs that are structurally complex and often require special handling or delivery mechanisms—are typically priced much higher than traditional drugs. While some of these drugs have been groundbreaking in the treatment of cancer, rheumatoid arthritis, multiple sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed tens of thousands of dollars a year. The treatment regimen for some of the most expensive specialty drugs can cost \$750,000 per year.<sup>2</sup> Compounding the financial impact of these drugs is the changing demographics of those who use them. Historically these drugs have targeted diseases affecting very small populations—sometimes as few as a thousand individuals nationally. But over time and with breakthroughs in the understanding of disease and clinical pathways, these drugs are now used to treat chronic conditions affecting tens of millions of patients.

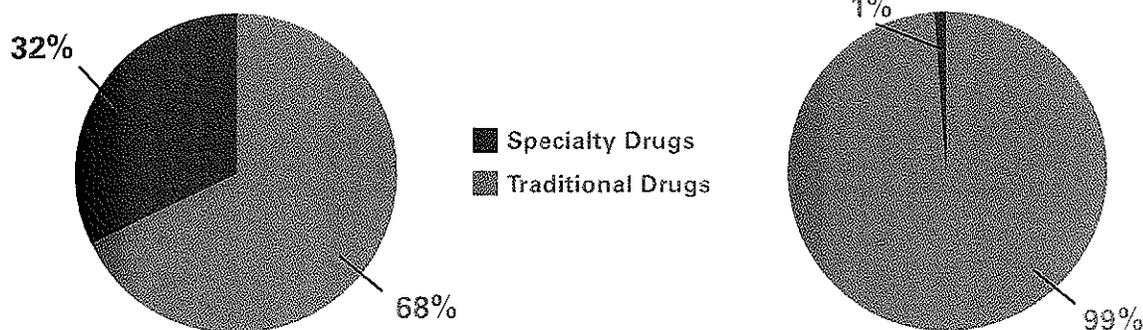
Although these drugs offer tremendous promise when medically necessary, their high costs and use for treatment of chronic conditions in large populations has upended traditional assumptions about prescription drugs and threatens the availability of affordable coverage options nationwide. Health plans, employers, and other stakeholders are searching for innovative, market-based strategies to restrain cost growth while simultaneously maintaining access to safe and effective drugs for patients.

This issue brief explores recent trends in the specialty drug market, highlights some of the innovative strategies health plans are adopting to provide patients with access to specialty drugs while managing costs, and recommends additional policy solutions to further promote high-value, high-quality care.

**Figure 1: U.S. Spending on Prescription Drugs, 2014**

Prescription Drug Spending in 2014

Prescriptions Written in 2014



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: <http://lab.express-scripts.com/drug-trend-report/>

## Prescription Drug Cost Trends

Express Scripts and the IMS Institute for Healthcare Informatics estimate that overall spending on prescription drugs grew by 13.1% in 2014 to \$373.9 billion—the largest year-over-year increase since 2001.<sup>3</sup>

Because of their extremely high cost, specialty drugs account for a disproportionate share of overall drug spending (Figure 1). For some specialty drugs, the monthly treatment cost can exceed tens of thousands of dollars (Figure 2).

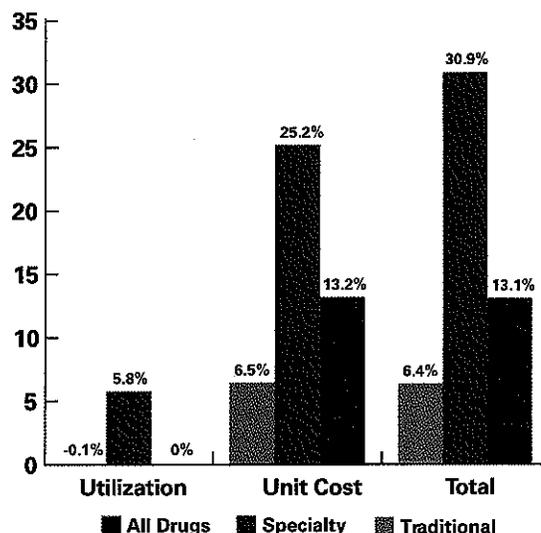
**Figure 2: Approximate Monthly Cost of Commonly Used Specialty Medications, 2014**

Medication	Sample indication for medication use	Monthly cost for sample indication
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Avastin (bevacizumab)	Metastatic colorectal cancer	\$11,600
Revlimid (lenalidomide)	Multiple myeloma	\$9,300
Neulasta (pegfilgrastim)	Neutropenia	\$5,700

Source: Adapted from Specialty Medications: Traditional And Novel Tools Can Address Rising Spending On These Costly Drugs, Exhibit 1. Health Affairs, 33, no. 10 (2014).

In the area of oncology, the median price for new cancer drugs approved in the past 5 years now exceeds \$10,000 per month (up from \$4,500 a decade earlier), according to data from Memorial Sloan Kettering Cancer Center.<sup>4</sup> Moreover, prices for many existing brand-name and specialty drugs may not even fall when faced with competition from other drugs. Prices have been known to double for dozens of established drugs to treat serious chronic conditions such as diabetes, cancer, and multiple sclerosis, when a single manufacturer produces a number of drugs in a specific therapeutic area.<sup>5</sup>

**Figure 3: Commercially Insured: Components of Trend, 2014**



Source: The Express Scripts 2014 Drug Trend Report. March 2015. Available at: <http://lab.express-scripts.com/drug-trend-report/>

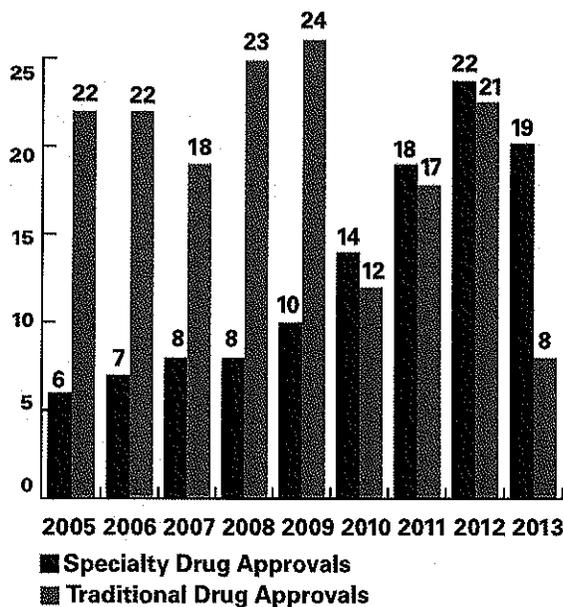
These prices drive the growth in prescription drug spending. While the growth rate in spending for traditional medications (non-specialty, small molecules) in 2014 was just 6.4%, spending on specialty drugs increased by more than 30% (Figure 3).

Many of the highest-cost specialty drugs are a unique subset of specialty drugs known as biologics. Unlike traditional medications made from chemical compounds, biologics are complex molecules derived from living or biological sources. Biologic medications can include vaccines, gene therapies, recombinant protein products, antibodies, and hormones. Advances in the understanding of how these medications work and their potential to help treat and cure disease have led to dramatic growth in the biologic market—eight of the 10 top-selling drugs are estimated to be biologics by 2016, while only one biologic was in the top 10 only a decade ago.<sup>6</sup> And these drugs come to market with a significant price tag. Some biologics can be 22 times more expensive than traditional medications.<sup>7</sup>

Unlike their traditional counterparts, spending on specialty drugs has shown no signs of moderation. An increase of 16% each year is forecast for the 2015–2018 period, with total spending comprising more than 50% (\$235 billion) of total drug spending by 2018.<sup>8</sup>

Growing introduction, use, and price of specialty drugs in the pharmaceutical market further explain their position as the driver of drug spending. In 2010, specialty drug approvals by the Food and Drug Administration (FDA) exceeded traditional drug approvals for the first time (Figure 4), a trend that has continued each year since. And in 2014, 27 of the 51 drugs approved by the FDA—53%—were specialty drugs.<sup>9</sup> As of early 2015, 42% of drugs in the late stage of the FDA approval process were specialty medications.<sup>10</sup> A report by health care accrediting agency URAC noted that the marked increase of chronic illnesses in Americans (such as cancer, obesity, and diabetes) coupled with the pharmaceutical industry’s ability to quickly identify and develop new and more personalized drugs has positioned the specialty drug market for continued growth.<sup>11</sup>

**Figure 4: FDA Traditional and Specialty Drug Approvals, 2005-2013**



Source: Adapted from Medical Cost Trend: Behind the Numbers 2015,” PricewaterhouseCoopers Health Research Institute, Specialty Drug Infographic, June 2014. Slide 5.

## The Broken Prescription Drug Market

Unsustainable growth of specialty drug spending is due to many complex factors but can be explained, in part, by the legal and regulatory treatment of these therapies. Under

current law, brand-name biologic drugs are given a 12-year exclusivity period upon approval from the FDA—in effect a government-approved monopoly. This period of exclusivity is typically longer than the patent protection remaining for traditional drugs by the time they are brought to market. Although these exclusivity periods give pharmaceutical manufacturers the incentive to take on the risk of developing groundbreaking drugs, they also precipitate a number of negative policy consequences.

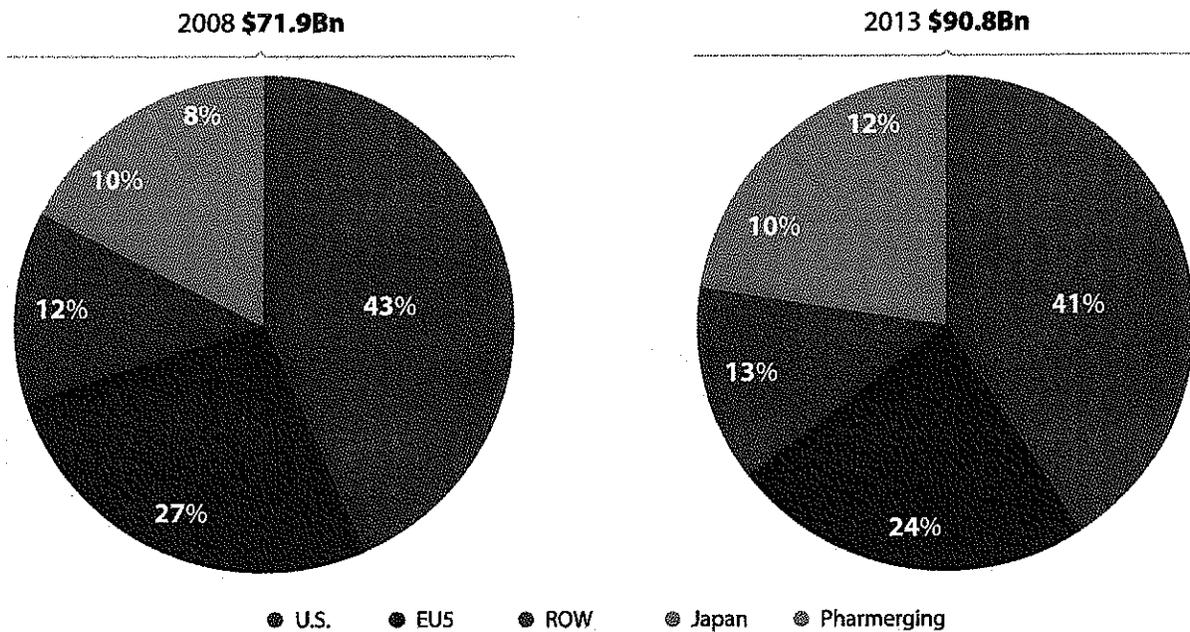
Granting lengthy exclusivity periods to specialty drugs removes the economic benefits of price competition, resulting in higher prices relative to what they would be in a perfectly competitive market. This phenomenon can be seen in Medicare spending for Part B drugs, which more often are biologics requiring physician administration and therefore covered through the medical, rather than pharmacy benefit.<sup>12</sup>

The Government Accountability Office released a report examining trends in Part B spending in 2010 with two notable findings: (1) only 10 drugs accounted for 44% of all Part B spending; and (2) none of these 10 drugs had a generic version also approved by the FDA.<sup>13</sup> The lack of adequate substitutes for these drugs constrains efforts by all payers’ (health plans, public programs, employers) to implement effective policies to promote access and manage costs. Health plans have developed expertise in using value-based purchasing or cost-sharing designs that provide incentives for prescribers and patients to select high-quality, high-value treatments and care. But when generic or therapeutic alternatives do not exist, the options available for encouraging high-value are limited.

There is growing evidence that prescription drug manufacturers have gamed this regulatory process to artificially prolong the exclusivity period for some drugs and prevent less costly generic versions from reaching the market.<sup>14</sup> By making minor changes to a drug’s chemical composition or delivery mechanism (e.g., an extended release version of a previously-patented drug that had to be taken twice a day), manufacturers can extend patents that would have otherwise expired. These so called “evergreening” schemes do not typically provide any enhanced clinical benefit for consumers—rather they are aimed at maintaining monopolistic pricing for products that are just as effective as their less expensive, generic counterparts. Other anti-competitive strategies such as

## Oncology spending is still dominated by the U.S. and EU5

Proportion of oncology spending by global market share, 2008-2013



Source: IMS MIDAS, MAT Sep 2013. Pharmerging includes retail only for Brazil and Mexico. Oncology includes Therapeutic treatments as well as supportive care, radiotherapy and immunotherapies.

- U.S. share of total spending declined by 2% but remains the largest oncology market.
- The five largest European markets also reduced their share of the global spending by 3%.
- While the pharmerging share of total spending has grown by 12%, 75% of total sales are represented by the U.S., EU5, and Japan alone.
- The U.S. relevance in global oncology extends beyond its size but also because the access and pricing associated with the U.S. health care system have encouraged use of innovative treatments.

## Varied discount mechanisms are in place in the EU5, allowing for a lower net price paid by payers

	 U.S.	 France	 Germany	 Italy	 Spain	 U.K.
<b>National</b>	—	✗ PV Agreements	✓ National rebate	✓/✗ Mandatory discounts, Payment by results, PV agreements	✗ Confidential discounts	✓/✗ Patient access schemes
<b>Regional</b>	—	—	—	✗ Discounts	✗ Discounts	—
<b>Local</b>	—	✗ Contracting	✗ Contracting	✗ Contracting	✗ Contracting	✗ Contracting
<b>MSP (per course, indexed to US)</b>	1	—	1.03	1.03	1.08	0.98
<b>National Discounts</b>	—	—	24% MSP	40% MSP	29% list price	31% list price
<b>Net Price (indexed to US MSP)</b>	1	—	0.79	0.62	0.77	0.63

✓ Published and transparent    ✗ Not publicly disclosed/confidential    — No discount at this level

- Final prices are between 21% to 38% lower in European countries when compared to the U.S.
- In the U.S., there are very minimal, if any, discounts there are, however, rebates.
- In France the cost of oncologic drugs not included in the T2A lists (i.e. the Diagnosis Related Group system through which public hospitals get funded in France) is borne nationally and there may be price/volume agreements in place, but these are not publically disclosed and are confidential. Discounting agreements are possible at local level.
- In Germany, for intravenous (IV) drugs, additional discounts and rebates for office-based practices are available in some regions and offered by some payers. For open care units of hospitals the conditions are negotiated for every region.

**Chart notes:**

All countries in the E.U. feature discount mechanisms at the national level, with those in Italy being the most varied. Discount mechanisms are less prevalent at the regional level. At the local level, non-publically disclosed contracting arrangements are in place for all countries in the E.U.

# The average monthly cost of branded oncology drugs has doubled over the past decade

## U.S. cost per month of branded oncology drugs (2003-2013)



Source: 1. Adapted from Bach PB. *N Engl J Med.* 2009;360:626-633. 2. IMS MIDAS ex-manufacturers sales data.

- The average monthly cost of branded oncology drugs was ~\$5,000 in 2003 compared with ~\$10,000 in 2013.
- Certain individual branded oncology agents cost upwards of \$30,000 per month.
- These costs do not include discounts, or patient payment shares.