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Rising Cost of Specialty Drugs in Michigan and the United States: A Case Example for Multiple Sclerosis

The Center for Healthcare Research & Transformation (CHRT) illuminates best practices and opportunities for improving health policy and practice. Based at the University of Michigan, CHRT is a non-profit partnership between U-M and Blue Cross Blue Shield of Michigan to promote evidence-based care delivery, improve population health, and expand access to care.

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Introduction

Specialty drugs continue to be a growing component of the prescription drug market and have fueled increases in overall prescription drug spending. These drugs are used to treat complex and chronic medical conditions such as cancer, hepatitis C, multiple sclerosis (MS), and rheumatoid arthritis. They typically require special handling, administration, and monitoring, adding to their cost.

Spending on non-specialty drugs has decreased in Michigan in recent years, yet total drug spending has increased because of increased spending on specialty drugs, especially with the release of new, high-cost MS and hepatitis C drugs. Treatments for these two conditions rely greatly on prescription drug medication that can save lives and improve patients' quality of life. But, recent cost increases for drugs like these can often lead to high out-of-pocket costs. Generic drugs offer an alternative to costly branded drugs, with savings up to 80 percent for consumers. However, generics are not available for most specialty drugs.

This issue brief examines overall specialty drug cost trends in the United States and Michigan, focusing on high-cost specialty drugs for MS patients, and explores policy implications. The analysis is based on prescription drug data for privately insured patients with prescription drug coverage.[1]

[1] The Michigan data includes privately insured patients with prescription drug coverage through Blue Cross Blue Shield of Michigan (BCBSM). The national data is from Express Scripts Drug Trend Reports, 2011-2014, and is also limited to privately insured patients. Specialty drugs covered under a patient's medical benefit are not included in this analysis (generally includes drugs administered in hospital or institutional settings).

Key Findings

- From 2011 to 2014, specialty drug spending increased substantially as a proportion of total drug spending, both in Michigan (from 14 percent to 22 percent) and the United States (from 18 percent to 32 percent).
- While Michigan's specialty drug costs did not grow as fast as the national average during this time period, Michigan spent more per member per year (PMPY) than the U.S. average in 2014 for seven of the top eight specialty drugs.
- In Michigan, higher PMPY spending on specialty drugs used to treat multiple sclerosis (MS), including Copaxone and Tecfidera, is explained in part by the higher MS prevalence rates in Midwestern states[2], including Michigan, compared to the United States.
- Specialty drug price increases are also a factor in the escalating overall cost increases. For example, annual per patient spending in the United States for Copaxone, an MS drug, grew five-fold from its introduction in the mid-1990s to 2013 ($12,000 to $60,000, respectively). Most recently, annual per patient spending reached nearly $90,000.

[2] Regions in this brief used for MS prevalence data are defined by P. Dilokthornsakul et al.'s article, **"Multiple sclerosis prevalence in the United States commercially insured population."** This definition was used as it provides the most current, region specific prevalence data available. MS prevalence data defines the following states as Midwestern states: North Dakota, South Dakota, Nebraska, Kansas, Minnesota, Iowa, Missouri, Wisconsin, Illinois, Michigan, Indiana, and Ohio.

Overall Specialty Drug Spending in Michigan and the United States

From 2011 to 2014, spending on specialty drugs increased rapidly in Michigan and the United States. Nationally, specialty drug spending accounted for 18 percent of total drug spending in 2011, increasing to 32 percent by 2014.[3] In Michigan, specialty drug spending accounted for 14 percent of total drug spending in 2011, increasing to 22 percent by 2014.[4] FIGURE 1

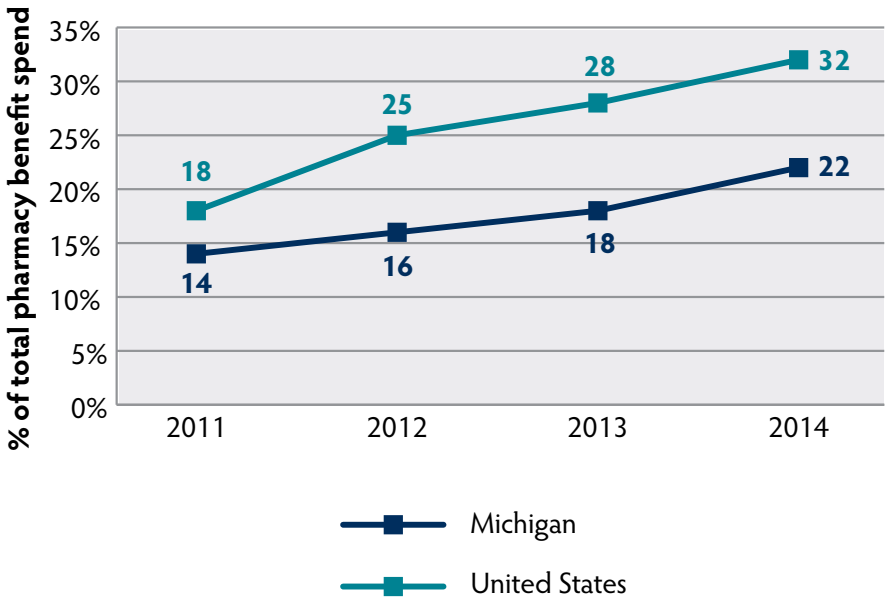
In both the United States and Michigan, specialty drug spending increased sharply from 2013 to 2014, largely due to the release of two specialty drugs: Sovaldi, a curative treatment for hepatitis C, and Tecfidera, an oral medication for MS. Michigan's overall prescription drug spending grew by 12.2 percent in 2014, compared to only 2.4 percent in 2013.[5]

Since 2014, national trends for hepatitis C drugs are starting to show declines in both utilization and cost.[6] As patients with advanced hepatitis C were cured, utilization decreased. Additional hepatitis C drugs were introduced in 2016, including Zepatier, Epclusa, and Viekera XR, lowering unit cost nationally by 6.7 percent.[7]

For MS treatment, the unit cost of MS drugs increased by 7.4 percent in 2016, driven by price increases for Copaxone and Tecfidera[8], while utilization stayed relatively flat.

FIGURE: 1

Specialty Drug Spending as a Proportion of Total Drug Spending, Michigan and the United States, 2011-2014



Sources: Express Scripts Drug Trend Reports, 2011-2014, and CHRT analysis of BCBSM claims data.

[3] Express Scripts Drug Trend Reports, 2011-2014.

[4] CHRT analysis of Blue Cross Blue Shield of Michigan (BCBSM) data.

[5] Ibid.

[6] Express Scripts Drug Trend Report, 2016.

[7] Ibid.

[8] Ibid.

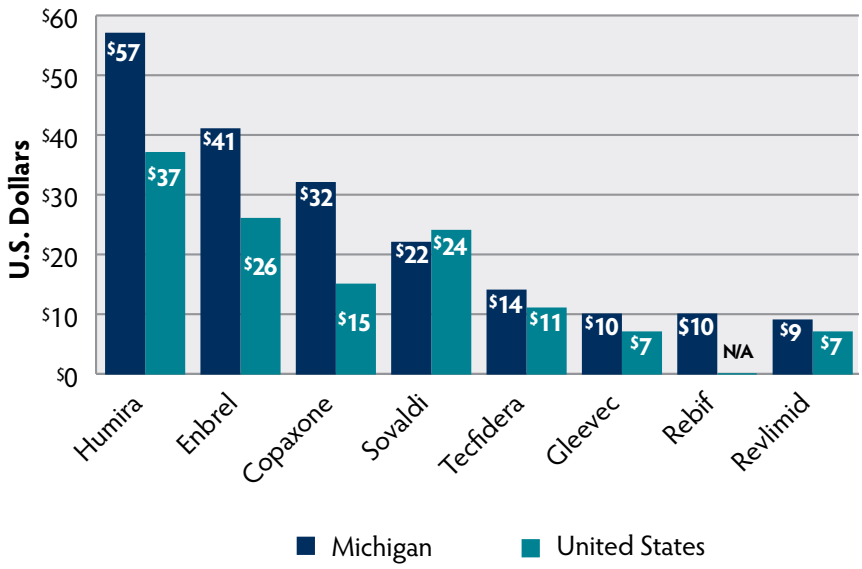
Top High-Cost Specialty Drugs: Comparison of Michigan to the United States Within an Insured Population

The top eight specialty drugs (ranked by Michigan PMPY spending) represented 70 percent of specialty pharmacy spending in 2014. On a population basis, Michigan generally had higher annual spending per member for the top specialty drugs compared to the national average. The greatest differences in PMPY among these top drugs were for Humira, Enbrel, and Copaxone. FIGURE 2

The per member per year (PMPY) spending for both Copaxone and Tecfidera was higher in Michigan compared to the United States, with Copaxone more than twice the national PMPY rate.[9] Michigan's higher PMPY spending for Copaxone may indicate that more patients needed the drugs and/or that the cost per patient was higher.

FIGURE:2

Spending on Top Specialty Drugs per Member per Year, Michigan and the United States, 2014



Sources: Express Scripts Drug Trend Reports, 2011-2014, and CHRT analysis of BCBSM claims data.

Notes: Humira and Enbrel treat inflammatory conditions (most notably rheumatoid arthritis); Copaxone, Tecfidera, and Rebif treat multiple sclerosis; Sovaldi treats hepatitis C; and Gleevec and Revlimid are oncology drugs. National data for Rebif in 2014 was not available.

[9] PMPY spending calculates the cost of a drug across an insured population, including patients who received the drug and people with similar health insurance who did not require it.

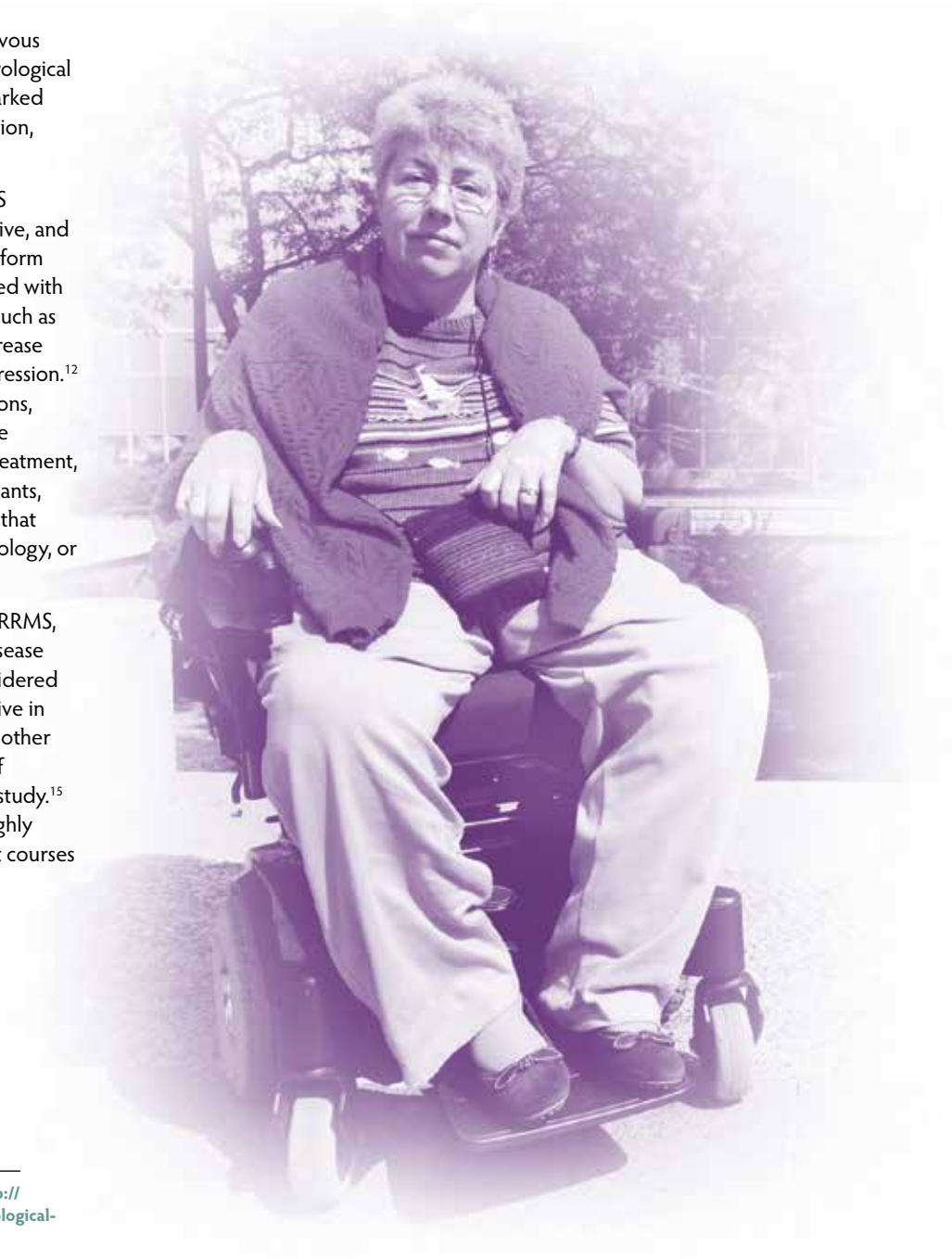
Specialty Drug Case Example: Multiple Sclerosis (MS)

MS Overview

MS is a chronic disease that affects the central nervous system and is the most widespread disabling neurological condition in young adults. This disease is often marked by problems with muscle control and strength, vision, balance, feeling, and thinking.[10]

There are four types of MS: relapsing-remitting MS (RRMS), primary progressive, secondary progressive, and progressive relapsing. RRMS is the most common form of MS and 85 percent of MS patients are diagnosed with RRMS at onset.[11] Available treatments for RRMS, such as disease modifying therapies (DMTs), work to decrease the frequency of relapses and delay disease progression.[12] MS treatments include injectable or oral medications, depending on a patient's need. Medication can be supplemented with various forms of alternative treatment, such as vitamin D supplements, yoga, medicinal plants, and physical therapy. There is not good evidence that alternative treatments such as acupuncture, reflexology, or occupational therapy are effective.[13]

Copaxone, Tecfidera, and Rebif are used to treat RRMS, which is characterized by relapses of increased disease activity followed by remissions. Copaxone is considered one of the best treatments for RRMS and is effective in decreasing relapses by 30 percent.[14] Tecfidera, another top MS drug, was shown to reduce the number of relapses by 53 percent during a two-year clinical study.[15] However, the effectiveness of MS treatments is highly variable among individual patients, and treatment courses can vary greatly from patient to patient.[16]



[10] "Multiple Sclerosis," University of Michigan Neurosciences. **http://www.uofmhealth.org/conditions-treatments/brain-neurological-conditions/multiple-sclerosis** (accessed 3/24/2017).

[11] "Multiple Sclerosis: The 4 Types of MS," **https://www.multiplesclerosis.com/us/treatment.php** (accessed 3/24/2017).

[12] "Understanding Multiple Sclerosis (MS)", healthline. **https://www.healthline.com/health/multiple-sclerosis#symptoms1** (accessed 10/18/2017).

[13] Observation from meeting with MS clinician, 7/18/2017.

[14] K. Koriem. "Multiple sclerosis: New insights and trends," *Asia Pacific Journal of Tropical Biomedicine*, Feb. 2016.

[15] **https://www.tecfidera.com** (accessed 9/12/17).

[16] Observation from meeting with MS clinician, 7/18/2017.

Specialty Drug Case Example: Multiple Sclerosis (MS) *(continued)*

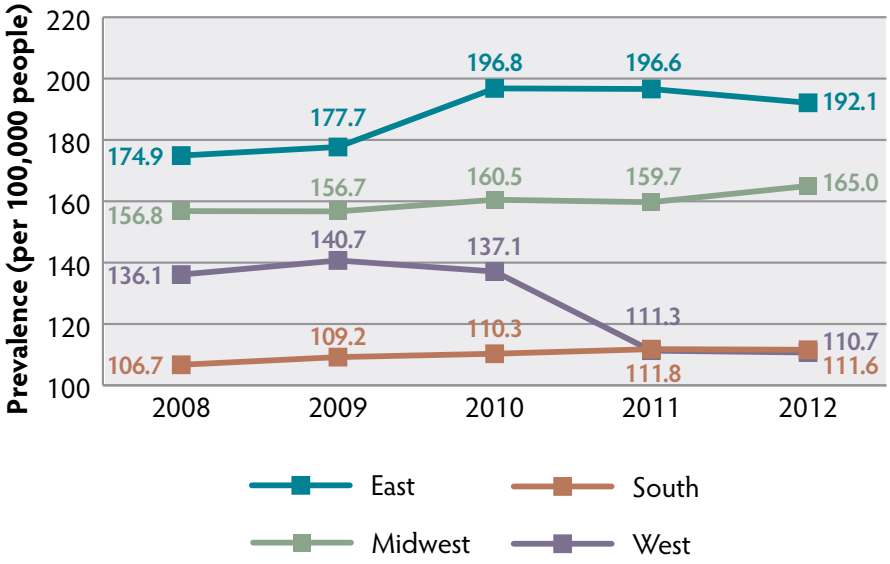
MS Prevalence

Midwestern states have higher prevalence rates of MS than the United States as a whole[17] (165 cases per 100,000, compared to 149.2 cases per 100,000).[18] The Midwestern region also has higher prevalence rates than both the Western region[19] (110.7 cases per 100,000 people) and the Southern region[20] (111.6 cases per 100,000).[21] From 2008-2012, prevalence among Midwestern states has increased, while both the Western and Southern regions either saw declines or little change. FIGURE 3

Research suggests that these regional differences in prevalence rates may be related, in part, to climate and sunlight exposure. This higher prevalence rate of MS in the Midwest is a significant factor explaining Michigan's higher PMPY spending for MS compared to the national average.

FIGURE 3

Multiple Sclerosis Prevalence Rates among the U.S. Insured Population, by Geographic Region, 2008-2012



Source: P. Dilokthornsaul, R. Valuck et al., "Multiple sclerosis prevalence in the United States commercially insured population," American Academy of Neurology (2016).

[17] Updated U.S. prevalence statistics to be released later this year.

[18] P. Dilokthornsaul, R. Valuck et al. "Multiple sclerosis prevalence in the United States commercially insured population," *Neurology* (March 2016).

[19] MS prevalence data defines the following as Western states: Washington, Oregon, California, Idaho, Nevada, Utah, Arizona, Colorado, New Mexico, Montana, and Wyoming.

[20] MS prevalence data defines the following as Southern states: Texas, Oklahoma, Arkansas, Louisiana, Mississippi, Alabama, Georgia, Kentucky, Tennessee, West Virginia, Virginia, Maryland, Delaware, North Carolina, South Carolina, and Florida.

[21] P. Dilokthornsaul, R. Valuck et al., "Multiple sclerosis prevalence in the United States commercially insured population," *Neurology* (March 2016).

Challenges and Implications for Consumers

Unexplained Price Increases

For many patients who need specialty drugs, increases in price translate to higher out-of-pocket costs. Some specialty drugs have had significant price increases since they were released to the market. For example, when the MS drug Copaxone was introduced in the mid-1990s, its annual cost per patient was approximately $12,000 (in 2013 dollars). By 2013, Copaxone's annual cost per patient was nearly $60,000.[22] Most recently, Copaxone reached an annual cost per patient of $89,213.[23] Copaxone is considered a first generation disease modifying therapy (DMT) for MS. Since it was introduced, its annual cost increase has averaged 36 percent. Tecfidera, an MS treatment released in 2013, has had cost increases of nearly 14 percent annually.[24] Both of these treatments outpaced the price inflation of 3 to 5 percent annually for overall prescription drugs. Most interesting is the fact that even with the introduction of new treatments for MS, the cost for first generation DMTs continues to increase, a trend that goes against traditional economic theory, which suggests more competition in the market should stabilize costs.[25] A recent study suggests that one explanation may be that the current U.S. health care system does not have a way to limit price increases, as compared to other industrialized countries.[26]

Generic Availability and Patent Protection

In 2015, the FDA approved the first generic drug for Copaxone, called Glatopa. This drug is a generic equivalent for one of the Copaxone dosage levels and is a step toward more affordable treatment options for MS patients. Compared to daily Copaxone, Glatopa had estimated annual cost savings of $17,000 per patient in 2016.[27] However, savings are not expected to be as dramatic as generics for traditional brand name drugs. This is because cost savings from generics are typically higher when there are more available generics on the market. [28] In the case of MS drugs, Glatopa is the only generic available for Copaxone. Most MS drugs have no generic versions on the market.

Some of the more recently introduced MS drugs are classified as "biologic" drugs.[29] These medications are derived from animals, humans, or microorganisms such as bacteria or yeast. Biologic drugs are granted 12 years of market exclusivity, compared to the five years given to most brand name drugs.[30] For some biologic drugs, biosimilar drugs have been developed. These drugs are designed to be similar to biologic drugs, but they are not exact replications and cannot be true generics because it is impossible to create exact copies of biologic drugs.[31] The U.S. Food and Drug Administration (FDA) is now able to approve biosimilar drugs, but there are few on the market.

While biosimilar drugs can be more cost-effective than biologic drugs, they are discounted much less than generic drugs.[32] Price reductions for potential future biosimilar drugs might be only between 20 and 40 percent, compared to about 80 percent for traditional generics.[33]

[22] D. M. Hartung, D. N. Bourdette, S. M. Ahmed et al., "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry," *Neurology*, May 2015, 84: **http://www.neurology.org/content/early/2015/04/24/WNL.0000000000001608.abstract** (accessed 1/11/2017).

[23] K. Gohil, "Multiple Sclerosis: Progress, but No Cure," Pipeline Plus, Sept. 2015, 40: **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4571850/** (accessed 10/18/2017).

[24] D. M. Hartung, D. N. Bourdette, S. M. Ahmed et al., "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry," Neurology, May 2015, 84: **http://www.neurology.org/content/early/2015/04/24/WNL.0000000000001608.abstract** (accessed 1/11/2017).

[25] Ibid.

[26] Ibid.

[27] B. Weinstock-Guttman, K. Nair, J. Glajch et al., "Two decades of glatiramer acetate: From initial discovery to the current development of generics," *Journal of the Neurological Sciences*, March 2017, 376: **https://www.ncbi.nlm.nih.gov/pubmed/28431621** (accessed 10/17/2017).

[28] A. Pollack, "Generic Version of Copaxone, Multiple Sclerosis Drug, is Approved," *The New York Times*, April 16, 2015, **https://www.nytimes.com/2015/04/17/business/generic-version-of-copaxone-multiple-sclerosis-drug-is-approved.html?mcubz=3** (accessed 9/13/2017).

[29] MS biologic drugs include: alemtuzumab (brand name Lemtrada), ocrelizumab (brand name Ocrevus) and natalizumab (brand name Tysabri).

[30] L. Purvis and C. Kuntz, "Is High Prescription Drug Spending Becoming Our New Normal?" *Health Affairs Blog*, May 2016: **http://healthaffairs.org/blog/2016/05/17/is-high-prescription-drug-spending-becoming-our-new-normal/** (accessed 1/11/2017).

[31] P.K. Patel, C.R. King, and S.R. Feldman, "Biologics and biosimilars," *The Journal of Dermatological Treatment*, June 2015, 26 (4): 299-302.

[32] B.R. Hirsch, S. Balu, and K.A. Schulman, "The impact of specialty pharmaceuticals as drivers of health care costs," *Health Affairs (Project Hope)*, October 2014, 33 (10): 1714-1720.

[33] "Is There a Cure for High Drug Prices?" Consumer Reports. July, 2016, **http://www.consumerreports.org/drugs/cure-for-high-drug-prices** (accessed 1/16/2017).

Proposed Policies to Manage Specialty Drug Prices

Increases in specialty drug spending are driving cost increases for prescription drugs overall. Additionally, high out-of-pocket costs create financial burdens and may limit access for patients who depend on these drugs. Current and new specialty drugs can save lives and improve patients' quality of life. However, the ongoing high price increases are not sustainable. Two recent policy proposals aim to manage specialty drug costs:

- **Increase price transparency** – Requiring drug manufacturers to disclose estimated prices prior to FDA approval could help to inform regulators, the public, and purchasers about the cost structure planned prior to a drug's market entry. Additionally, drug manufacturers could be required to report on subsequent price increases over certain thresholds. Where generics or biosimilar drugs are available, price transparency for consumers could enable comparative shopping. The bipartisan Fair Accountability and Innovative Research Drug Pricing Act (S. 1131), introduced in the U.S. Senate in May 2017, would require manufacturers of certain drugs and biological products with a wholesale cost of $100 or more per month to report price increases of 10 percent or more in a year or 25 percent or more over a three-year period to the U.S. Department of Health and Human Services.[34] Price transparency reporting under this legislation likely would include MS drugs. At the state level, California Governor Jerry Brown signed a high-profile drug price transparency bill, Senate Bill 17, in October of 2017. This bill requires drug manufacturers to notify health plans and other purchasers 60 days in advance of a planned drug price increase if the increase exceeds certain thresholds.[35] Heath plans will also be required to submit annual reports to the state of California, providing details on the most frequently prescribed drugs, the most expensive drugs, and drugs that have the greatest year-to-year price increases.
- **Reimportation** – Importing prescription drugs back to the United States, that were originally manufactured in the United States and exported for sale in another country, could help lower out-of-pocket costs for consumers. Consumer surveys show widespread support to allow Americans to buy prescription drugs from Canada.[36] Buying medications from a certified Canadian pharmacy could save Americans between 20 percent to 80 percent on brand name drugs.[37] In fact, MS drugs Copaxone and Tecfidera cost significantly less in Canada: Copaxone has an annual cost of approximately $15,000 in Canada, roughly one-fourth of its cost in the United States, and Tecfidera has an annual cost of $21,510 in Canada, less than half its cost in the United States.[38] While the FDA has expressed concerns with counterfeits and drug safety—especially with injectable drugs such as Copaxone—the possibility of limited reimportation of drugs, including oral drugs that treat MS, could be further explored. Some experts say that it's possible that the ability to import drugs from countries that have regulatory systems similar to the United States could help moderate drug prices.[39]

  This year, members of Congress have discussed several drug reimportation bills. In February 2017, senators introduced the Affordable and Safe Prescription Drug Importation Act (S. 469), a bill on drug reimportation. This bill also would allow Americans to buy prescription drugs from Canada. In August 2017, the Congressional Budget Office (CBO) estimated that S. 469 would save consumers $7 billion over the next 10 years.[40]

[34] Summary: S.1131 – 115th Congress (2017-2018), "Fair Accountability and Innovative Drug Pricing Act of 2017," **https://www.congress.gov/bill/115th-congress/senate-bill/1131** (accessed 8/11/2017).

[35] M. Mason, "Californians will get more information on what's driving prescription drug prices under law signed by governor," *LA Times*, October 9, 2017: **http://www.latimes.com/politics/la-pol-ca-prescription-drug-price-disclosure-20171009-story.html** (accessed 10/11/2017).

[36] A. Kirzinger, B. Wu, and M. Brodie, "Kaiser Health Tracking Poll: September 2016." Kaiser Family Foundation, Sep. 29, 2016: **http://kff.org/health-reform/report/kaiser-health-tracking-poll-september-2016/**, (accessed 2/242017).

[37] M. J. Bhosle and R. Balkrishnan, "Drug reimportation practices in the United States," *Therapeutics and Clinical Risk Management*, 2007. Vol. 3(1): 41-46.

[38] D. M. Hartung, D. N. Bourdette, S. M. Ahmed et al., "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry," *Neurology* May 2015, 84: **http://www.neurology.org/content/early/2015/04/24/WNL.0000000000001608.abstract** (accessed 1/11/2017).

[39] "Is There a Cure for High Drug Prices?" *Consumer Reports*. July, 2016, **http://www.consumerreports.org/drugs/cure-for-high-drug-prices/** (accessed 1/11/2017).

[40] D. Mills, "Fight Continues this Summer to Lower Prescription Drug Prices," *healthline* News. August 16, 2017: **http://www.healthline.com/health-news/fight-continues-this-summer-to-lower-prescription-drug-prices#1** (accessed 8/21/2017).

Conclusion

High-cost specialty drugs are expected to continue to have a substantial impact on total prescription drug spending both nationally and in Michigan. Lack of price competition in the market and challenges with developing generics for specialty drugs contribute to market exclusivity for specialty drugs and higher prices. These high prices limit access and increase out-of-pocket costs for patients. For many patients who depend on these drugs to effectively treat their medical conditions, limited access and high costs can seriously impair their lives. Policy intervention and collaboration among stakeholders in the prescription drug market will be increasingly important to address the growing cost burden of specialty drugs.

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