

Written Statement of Bari Talente, J.D.
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Before the Committee on Education and Labor
Subcommittee on Health, Employment, Labor, and Pensions
United States House of Representatives
Making Health Care More Affordable: Lowering Drug Prices and Increasing Transparency
September 26, 2019

Background and Introduction:

Good Afternoon. Chairwoman Wilson and Ranking Member Walberg, thank you for the opportunity to participate in this hearing on lowering drug prices and increasing transparency. My name is Bari Talente, Executive Vice President of Advocacy with the National Multiple Sclerosis Society. I think it is important to note who is not here today – the many people living with MS who have employer sponsored insurance and who because of high drug costs are worried about the cost to their employers and the effect that has on co-workers in the form of higher premiums, increased cost sharing, lost wages, or reduced benefits. In fact, we hear from many with MS who are reluctant to disclose their diagnosis publicly because they don't want to be "that person" with their coworkers or they fear their job may be in jeopardy because they are a driver of rising health insurance costs.

Nearly 1 million people are living with MS in the United States. Given that the average age of MS diagnosis is between the ages of 20 and 50, this is a disease that hits people during prime employment years. In fact, various surveys and studies tell us that nearly 60% of people living with MS have employer sponsored insurance.

But before we get into that let me tell you a little bit about multiple sclerosis, the Society and the impact of high drug prices, affordability and access for people living with MS. MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS.

The National MS Society's vision is a world free of MS. Our mission is to ensure that people affected by MS can live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever. We work with all ethical stakeholders, companies, organizations and individuals that share our mission to end MS forever. To that end, in 2018, the Society received \$7.5 million USD from the pharmaceutical industry. This represented less than 4% of the organization's revenue in 2018. As we call for transparency across the prescription drug supply chain, we live this value and post this information on the Society's website. **It is important to note that we do not accept pharmaceutical support for our advocacy work.**

The Society is also an employer, with nearly 1,000 staff across the country. It should not surprise you that we have a higher percentage of employees living with MS than many employers. People directly affected by MS- whether they themselves live with MS or a loved one does- are drawn to our work. We also provide robust benefits to our staff and have also been directly impacted by rising health insurance costs due to the high price of drugs and the costs of treating MS. Over the past two years, our

organization's health insurance has increased by about 15% each year- after negotiating down from initially proposed increases of 19% and higher. Our leadership has affirmed our commitment to living our health care principles and ensuring our staff and their family members living with MS have affordable access to the medications they need. Choosing to support our employees has consequences and our organization has had to shift resources from priority work that benefits all people living with MS in the United States.

Cost of MS Disease Modifying Therapies & Impact on People with MS

A growing body of evidence indicates that early and ongoing treatment with a Food and Drug Administration (FDA) approved Disease Modifying Therapy (DMT) is the best way to manage the MS disease course, prevent accumulation of disability and protect the brain from damage due to MS. These medications have transformed the treatment of MS over the last 25 years. Fortunately, there are now over fifteen FDA-approved DMTs for relapsing forms of MS. No single agent is 'best' for all people living with MS. As MS presents differently in each individual, every person's response to a DMT will vary and these treatments are not interchangeable. It is not uncommon for people to work their way through several of the medications as they find the one that stabilizes their disease, or as different medications stop working for them.

Unfortunately for people affected by MS, the price of MS treatments has dramatically risen since the first DMT was approved in 1993 (appendix 1). The first medication, so anxiously awaited for, was approximately \$11,500 when it came on the market. That same medication today has a list price of more than \$98,000. It's not the only one. In the MS DMT market, price increases occurring one or more times per year for almost all DMTs have become the norm. Between 2004 and 2015, the average price of MS disease modifying treatments increased 300%. Those trends have continued. In 2013, the annual median price was less than \$60,000. In 2019, the median price for brand MS DMTs is \$88,853. While some of these increases are associated with new treatment options entering the market, the MS space is a prime example of escalating prices for products already on the market- some for a considerable amount of time. For almost all of these medications, they must be taken continuously. For a person with MS diagnosed at age 25, they could experience 50 plus years of DMT costs.

Today, people with MS report high and rapidly escalating medication prices, increasing out-of-pocket costs, confusing and inconsistent formularies, and complex payer approval processes that stand in the way of getting the treatments they need. Many people with MS tell us that without copay assistance, they would not be able to afford their medications to slow the progression of their disease. Further, we hear from healthcare providers and people with MS about barriers to treatment imposed by insurers rather than a shared decision-making process between the person with MS and their healthcare provider. One of these examples is so called "co-pay accumulators", which prohibit the application of copay assistance from counting towards an individual's deductible or out-of-pocket maximum.

Additionally, we have seen increased use of step therapy, or fail first, people have to "fail" on a medication that is preferred by an insurer before moving to a medication that is right for them. We have heard of people required to fail on treatments they already know don't work for them, or to try multiple similar treatments before being able to move to a different mechanism of action or route of administration. These policies are designed to discourage the use of costly medications. People with MS also report delays in treatment as they wait for prior authorization, or approval from their insurer for their medication. Each time there is a gap in care or someone fails on a medication, they are at risk for a relapse, disease progression and worsening of symptoms from which they may not fully recover.

Medications do not work if people cannot access them. In a recent survey of people with MS conducted by our organization, 40% shared that they have altered their use of their DMT because of costs. They may have stopped treatment for a period of time, they may skip or delay filling a prescription, maybe they skip or delay a treatment, or they don't take the medication as prescribed to try and make it last longer.

I would like to share just a few of the direct experiences of people with MS, who have shared with us the impact the cost of their medications have on their lives.

- Kristine from Georgia, who after her divorce, was forced to switch insurance plans. Her new plan required her to fail on some treatments before she could access the more aggressive treatment that her doctor prescribed. Because the average price of MS therapies is around \$88,000 a year, it is common for insurers to implement utilization management practices like step therapy in order to control costs. Kristine shared the impact failing on a drug had on her life - "There were several times I was hospitalized for days at a time receiving high doses of IV steroids and unable to work. My symptoms ranged from electrical shock type pain in my face to having trouble walking to losing my speech for almost six months."
- Jenna from Massachusetts told us that after her medication stopped working for her, her doctor prescribed a different, more aggressive medication. This medication worked for her but is extremely expensive at over \$80,000 a year. She wrote to us about the worry she felt about affording this medication if her insurance didn't cover it and about the terror she and her husband face about having to change jobs – and therefore change insurance. She wrote "My husband and I are both hard workers. He is a building maintenance tech in a union, and I am self-employed, helping other small business owners with their marketing. His insurance currently covers my medication, but not all insurances will. In fact, we are terrified for him to change jobs, because we cannot afford my medication if it is not covered. We struggle financially and he has to weigh new opportunities for employment, which would pay more and help us greatly, over the issue of health insurance coverage. Because all health insurances won't cover my treatments, he has had to turn down a better paying job, with better hours, in order to keep our current insurance."
- And Keisha from Pennsylvania, who was diagnosed with MS as a sophomore in college. Over the last decade, Keisha has tried many disease-modifying therapies to help manage her MS. She has commercial insurance through her employer and receives financial assistance through a manufacturer-sponsored program, but the expenses still add up because of copays and needing to meet deductibles. Keisha is especially concerned about the rising costs of disease-modifying therapies. She says, "If I'm on super expensive meds, I'm hurting my company's bottom line in the end. I would choose a different medicine if there were one that was significantly lower in price". Keisha has a message for you- as policymakers and decisionmakers: "do something" to help with the cost. It's not a selfish thing to want to be well, to want to contribute," she says. "All people deserve a chance to be contributing members of society, they need to be able to function just as much as I do."

Solutions for People with MS

Drug prices, affordability and access are complex problems that will require multiple solutions and shared commitment by all stakeholders. There is no silver bullet solution and we have to look at solutions across the entire prescription drug supply chain. The Society has advocated for Congress to

advance policies that will lower drug costs and improve access for those living with MS. The current trajectory is unsustainable for government, taxpayers, and those living with chronic conditions such as MS.

In 2016, the National MS Society released comprehensive recommendations to Make MS Medications Accessible (Recommendations), which call on all stakeholders across the healthcare and drug supply chain system to work together **to make medications more affordable, and the process for getting them simple and transparent.** We believe there is no single solution that can fully reverse the trend toward ever-increasing drug prices and payer policies that inhibit or delay access to medically necessary therapies. We have consistently called on all stakeholders to engage in conversations to drive solutions and to bring forward solutions for their industry. Congress is one of these stakeholders that must act.

Current Legislative Proposals

Reining in Price Increases

As shared above, price increases in the MS space have been particularly problematic. The National MS Society supports various proposals to address price increases.

- The CURE High Drug Prices Act (S.637/H.R.4158), introduced by Sen. Richard Blumenthal and Representative Pingree, would require pharmaceutical manufacturers to justify to the Department of Health and Human Services price increases of 10% or more within the previous year; 20% or more over 3 years; and 30% or more over the preceding 5 years. If the increases are found unreasonable, HHS could require the company to reimburse consumers and payors (including Medicare & Medicaid); provide the product for the price before the increase for up to one year; and pay civil penalties if the price gouging was done knowingly.
- The Fair Accountability and Innovative Research (FAIR) Drug Pricing Act (S.1391/H.R. 2296), sponsored by Representatives Jan Schakowsky (D-IL) and Francis Rooney (R-FL), and U.S. Senators Tammy Baldwin (D-WI) and Mike Braun (R-IN). The bipartisan, bicameral legislation would require transparency from pharmaceutical manufacturers who increase drug prices by more than 10% per year or more than 25% over a three year look-back period and justification for each price increase, including manufacturing, research and development costs for the qualifying drug and other information that is deemed appropriate.
- The Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act (H.R. 2213), which includes the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019. The SPIKE Act requires manufacturers to report detailed information to the Secretary of the Department of Health and Human Services (HHS) for certain drugs if their prices exceed certain thresholds. Beginning in 2021, if a drug price increases by more than 10 percent or \$10,000 over one year, 25 percent or \$25,000 over three years, or has a launch price higher than \$26,000, pharmaceutical manufacturers would be required to submit a justification for the price or price increase to the HHS Secretary. This justification would have to explain the causes of a price increase or high launch price, which could include information on expenses pertaining to developing, manufacturing, licensing, and marketing the drug. The STAR Act also includes language that would make information on PBM rebates public on the Department of Health and Human Service's website.

While the FAIR Drug Pricing Act and the SPIKE Act legislation have similar intent, the Society believes that the language in the FAIR Drug Pricing Act will go further to level the playing field in regard to information that people with MS need to make more informed choices. While the SPIKE Act requires the

manufacturer (once a SPIKE is triggered) to submit information on individual factors that have contributed to the increase in the cost of the drug, the manufacturer would be able to make the determination on what factors have contributed to the price increase of the drug and submit information only on those factors. The Society's recommendations call for increased transparency in all levels of the prescription drug supply chain, so that all stakeholders are operating with the same information and we believe that the requirements outlined in the FAIR Drug Pricing Act move us closer to that goal.

Incentivizing generics and promoting competition

The Society is concerned with anticompetitive practices that may be delaying the entry of lower cost generics into the market and we have supporting the following legislation to help put an end to these practices.

- We support the Creating and Restoring Equal Access To Equivalent Samples Act (CREATES) Act, (S.340/H.R.965), which allows the FDA more discretion to approve alternative safety protocols, rather than requiring parties to develop shared safety protocols. It also creates a mechanism by which the generic manufacturers can seek a civil action against the brand company if that company refuses to provide samples within commercially reasonable, market-based terms. This legislation has bi-partisan, bi-cameral support, and we have urged Congress to swiftly pass it to ensure that bad actors cannot further delay needed therapies to the market.
- Additionally, the Society believes that Congress should pass legislation that prohibits "pay-for-delay" settlements and other anticompetitive tactics that prevent lower-cost generic medications from coming to market.
- We support the Preserve Access to Affordable Generics and Biosimilars Act (S.64) from Senators Chuck Grassley and Amy Klobuchar. This bill would prohibit brand name drug companies and biologic manufacturers from compensating generic companies or biosimilar manufacturers to delay the entry of a generic drug or biosimilar into the market. According to a recent Kaiser Health News data analysis the FDA has approved over 1,600 generic drug applications since January 2017, yet more than 700 (43%) were not on the market as of January 2019.vi According to that same analysis, 36% of generics that would be the first to compete in the marketplace against the branded drug are not yet for sale. FDA approval is one important step to improving access to lower cost medications, but these products need to be available for patients and the healthcare system to benefit and we urge you to consider this legislation for inclusion in your larger drug pricing package.
- The Society also supports the Biologic Patent Transparency Act (S.659), sponsored by Senators Collins and Kaine. This bill aims to provide transparency around patents, promote competition in the biosimilar space in order to expedite lower cost biosimilar treatments. The Society believes that issues surrounding patents need to be examined more broadly, and we urge Congress to thoroughly examine patent issues and the role they play in high prescription drug costs. The Society believes that novel innovation and intellectual property must be protected in order to foster better therapies, but that protection needs to be balanced with the goals of the Hatch-Waxman act to ensure that after the protection period, that both biosimilar and generic therapies have an uninterrupted pathway to market.

The Prescription Drug Pricing Reduction Act of 2019

The Society supports provisions within the Senate Finance Committee's *The Prescription Drug Pricing Reduction Act of 2019 (PDPRA)* to reduce beneficiaries' out-of-pocket drug costs in Part D. Medicare

beneficiaries living with MS have high out-of-pocket costs and typically reach the catastrophic phase early in the year (appendix 2). Once they reach the catastrophic phase in Part D they are still responsible for 5% of the costs of their medications.

The Society also supports provisions to require drug manufacturers to pay additional rebates if they raise prices above the inflation rate. Studies have indicated potential shadow pricing in the MS DMT class over the past several yearsⁱ, and we urge Congress to include provisions to help alleviate it. We believe that this legislation will help limit price increases for existing MS medications.

As people with MS need relief now from high out of pocket costs, the Society have urged implementation of this provision before 2022. Further, we encourage Congress to consider options such as a monthly cap or other alternatives to smooth out-of-pocket cost burdens for beneficiaries throughout the year. We also urge that Congress consider equalizing manufacturer liability in both the catastrophic phase and the coverage gap. Placing manufacturer liability in just the catastrophic phase could have unintended and unforeseen effects on the market for specialty medications.

Lower Drug Costs Now Act of 2019 (H.R. 3)

The National MS Society supports the goals and many provisions of the Lowering Drug Costs Now Act of 2019 (H.R. 3) and applaud Chairmen Scott, Pallone and Neal for their leadership in advancing policies that will result in lower drug costs for many Americans.

The Society's 2016 recommendations to make MS medications accessible for people with MS called for Congress to allow the Secretary of Health and Human Services to negotiate the prices of medications. We are pleased that this is a fundamental provision of H.R. 3 and is a positive step to address high drug prices. It's important that those negotiated prices will be offered to commercial plans. MS DMTs are some of the most expensive medications. In 2017, two of the MS disease-modifying therapies (DMTs) rank in the top 25 medications by total spending and accounted for over \$2.5 billion in total spending, according to the Centers for Medicare and Medicaid Services (CMS) dashboard. The idea of negotiating prices for Medicare Part D could have a real-life impact on people living with MS on Medicare, because the actual price of medications matters to them. Depending on how much a person has paid towards their drug costs for the year, they could be paying coinsurance based on the price of the drug. Negotiating a lower price on their behalf could yield real savings for both individuals and the health care system.

We do have a suggestion related to medications eligible for negotiation. According to the Food and Drug Administration, "On average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer. However, the appearance of a second generic manufacturer reduces the average generic price to nearly half the brand name price. As additional generic manufacturers market the product, the prices continue to fall, but more slowly. For products that attract a large number of generic manufacturers, the average generic price falls to 20% of the branded price and lower."ⁱⁱ

We have noted above our support for bipartisan legislation that will promote bringing additional generics to the market. Currently, only one MS brand DMT has generic competition. There are two generics for this DMT, which are also expensive (especially when considered in price with traditional generics) and to date, these generics have had little impact on both overall costs within the class or on people's out-of-pocket costs. These generics entered the market with list prices more than \$60,000 per

year, and though one drastically reduced its list price more than a year ago, access to this generic has not followed general market trends for generics. Additionally, the cost of these generics often means that they are placed in the specialty tier of a formulary, removing any incentive for their use. As more specialty medications go generic, it is important to ensure access to these generics can drive prices downward. Therefore, we urge that H.R. 3 is modified so that competition from a single generic is not a sole reason to exclude a drug from consideration in negotiation. It is also unclear if complex/specialty generics work as traditional generics, and the legislation may want to include flexibility to address this group of medications.

We appreciate that H.R. 3 does not include a formulary. As stated previously, MS medications are not interchangeable and a formulary could restrict access to certain medications. We also appreciate that those on commercial and employer sponsored plans could benefit from the negotiated price. However, we urge that the inflation rebates in Parts B and D be applied to commercial plans as well.

We also support the provisions to establish an out-of-pocket cap in Medicare Part D and are encouraged by the significant bipartisan support for this cap. We appreciate the various legislative efforts to ease the burden on Medicare beneficiaries and that H.R. 3 includes a Medicare Part D out of pocket cap of \$2,000 in 2022. As stated above, we believe that this could be implemented earlier and that smoothing out-of-pocket costs throughout the year be considered. As you can see from appendix 2 those living with MS face high out-of-pocket costs at the beginning of the year and smoothing these costs along with an out-of-pocket cap could provide predictability for those Medicare beneficiaries living with MS. People with MS on Medicare currently pay approximately \$6,000 out-of-pocket just for their MS DMT. Then, there are symptom management medications for MS and medications for other health conditions an individual may have. An out-of-pocket cap is needed to bring predictability, affordability and access to Medicare beneficiaries.

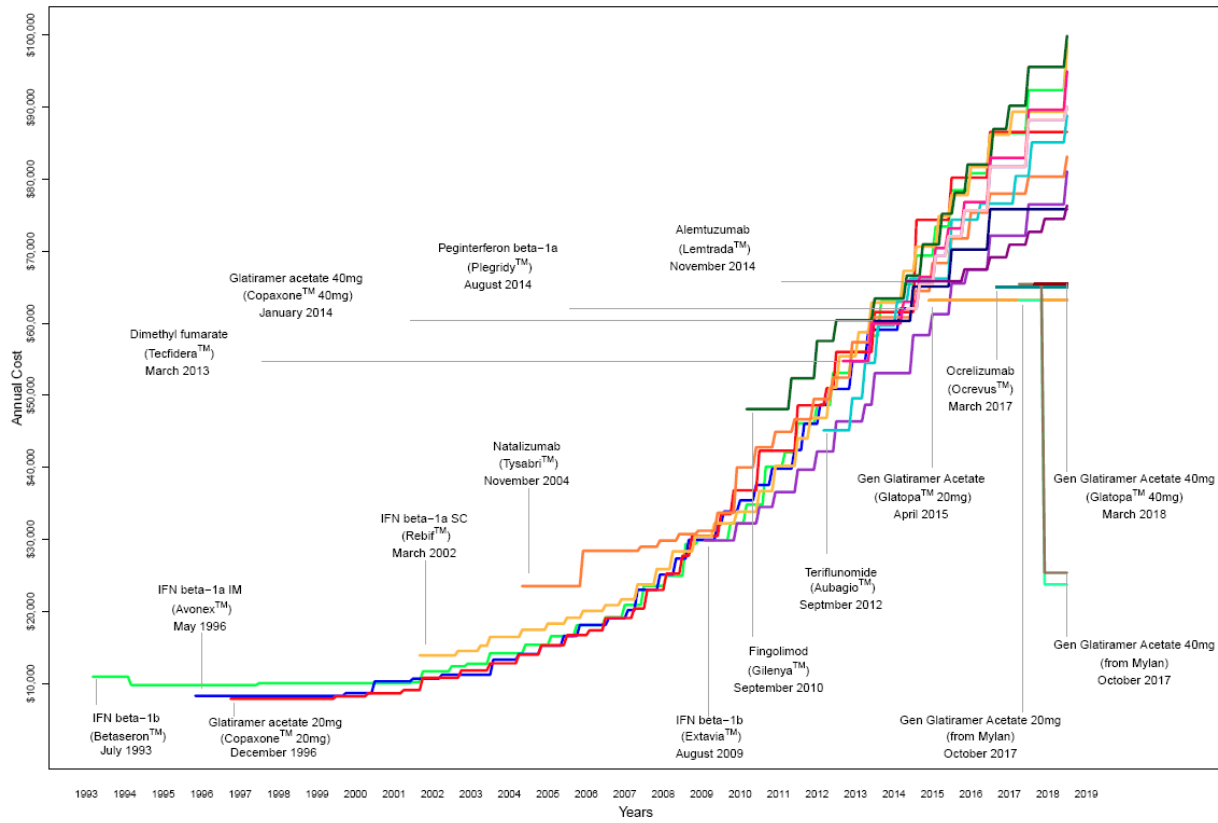
Much discussions has been raised around the impact of any sort of legislation to address prescription drug prices on innovation in drug development; however, recent analysis shows that price increases of brand name drugs are largely driven by year-over-year price increases of drugs that already in the market vs. new products.ⁱⁱⁱ We recommend that H.R. 3 be amended to include the FAIR Drug Pricing Act, to address this issue.

We thank the Committee for your attention to these important and complicated issues that cross all types of health insurance, employers and all aspects of individuals trying to live their best lives. The National MS Society is committed to working with all committees of jurisdictions to find solutions for people with MS.

I look forward to your questions on this important issue.

Appendix 1

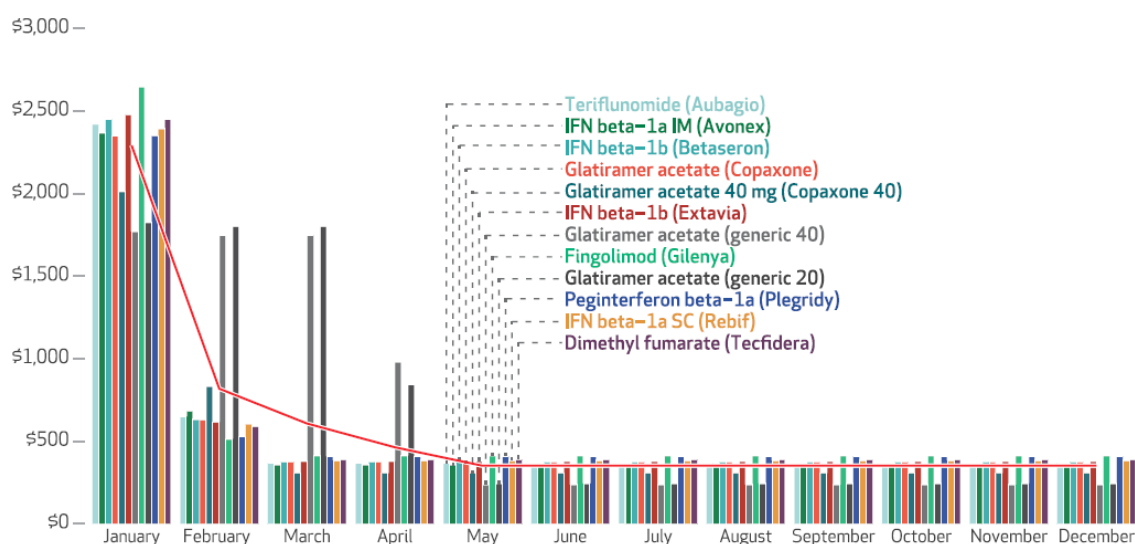
Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University



Appendix 2

EXHIBIT 4

Projected out-of-pocket spending for beneficiaries without a low-income subsidy for multiple sclerosis disease-modifying therapies, by month, 2019



SOURCE Authors' analysis of data from the Prescription Drug Plan Formulary files of the Centers for Medicare and Medicaid Services (CMS), and CMS enrollment data in 2016 (the most recent data available); and 2019 basic Part D benefit plan parameters. Drug prices are derived from the Medicare Plan Finder, using the nationwide plan that reported the lowest retail costs in the Portland, Oregon, metropolitan area. **NOTES** The solid line is average projected out-of-pocket spending across drugs. Appendix exhibit A6 shows details by drug (see note 20 in text). IFN is interferon. SC is subcutaneous. IM is intramuscular.

ⁱ Hartung, DM, Bourdette DN, Ahmed SM, Whitham RH. "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail?". *Neurology*. 2015 May 26;84(21):2185-92. doi: 10.1212/WNL.0000000000001608. Epub 2015 Apr 24. <https://www.ncbi.nlm.nih.gov/pubmed/25911108>. (Accessed 9/24/2019).

ⁱⁱ <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>

ⁱⁱⁱ Hernandez, Inmaculada. et. al. The Contribution of New Product Entry Versus Existing Product Inflation In The Rising Costs of Drugs. *Health Affairs*. January 2019. <https://doi.org/10.1377/hlthaff.2018.0514> . <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2018.05147>. (Accessed 9.24.2019)