

#### Testimony: Steffany Stern, Vice President of Advocacy, National Multiple Sclerosis Society

Chairman Wyden, Ranking Member Crapo, and Members of the committee: Thank you for the opportunity to testify at this important hearing. My name is Steffany Stern, and I am the Vice President of Advocacy for the National Multiple Sclerosis Society. I joined the Society as a staff member seven years ago, but have been part of the MS community since I was a year old, in 1981, when my mom, Joan, was diagnosed with MS.

My mom's diagnosis has shaped nearly all aspects of my life. I watched as she dealt with the physical challenges of this devastating disease, the emotional ramifications of living with constant uncertainty about her future, and decades of financial burden. MS, like so many other chronic health conditions, is a family disease, and it hasn't been easy for any of us.

We have come a long way since my mom was diagnosed, on her 24<sup>th</sup> birthday. My family is incredibly grateful for research innovation and the collaboration of research that has been funded by the public, the Society, and industry that led to it. In the 1980s and half of the 90s, all my mom could do to treat her MS was take vitamins, try to take care of herself, and hope that her relapses didn't take too much away from her life, in the short-term or the long-term. But once the MS disease-modifying therapies (which we refer to as DMTs) came to market, she's been able to take four of them, all of which have helped her manage the course of her disease.

Today, evidence shows that early and ongoing treatment with a DMT is the best way to manage the MS disease course, prevent accumulation of disability, and protect the brain from damage due to MS. There are now more than twenty DMTs on the market, including generic options, and these medications have transformed the treatment of MS over the last 29 years. When a person is diagnosed with relapsing forms of MS, they can choose between several effective medications to manage the course of their disease. Or, more accurately—they can make that choice if they can afford it. It is unconscionable that in 2022, people with MS and other health conditions who cannot pay for their medications would be in the same position my mom was in during the 1980s: left with no treatment option. For those who cannot afford their medications, all this innovation is simply meaningless.

The Society's vision is a world free of MS and our mission is that we will cure MS while empowering people affected by MS to live their best lives. To achieve this mission, we work with all companies, organizations and individuals that share our goal. On average, financial support from pharmaceutical companies over the last five years has accounted for less than 5% of Society income. The Society independently develops public policy positions on issues that are important to people affected by MS, and we do not accept pharmaceutical support for our advocacy work. Additional detailed information on our financial relationships with the pharmaceutical sector can be found on the <u>Society's website</u>.

Every day the Society hears from people struggling to afford their medication, making hard choices as families and too often going without medication for days, or months, or even stopping their treatment all together. I am grateful for the chance to share some of their experiences with you today.

### What is multiple sclerosis (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. Nearly one million Americans live with this disease, and most people are diagnosed between the ages of 20 and 50, when they are in their prime working years. 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.

MS is a highly expensive disease. The average total cost of living with multiple sclerosis is \$88,487 per year<sup>i</sup>. **The total estimated cost to the U.S. economy is \$85.4 billion per year<sup>ii</sup>.** Disease-modifying therapies are the biggest cost of living with the disease, with individuals with MS spending an average of \$65,612 more on medical costs than individuals who don't have MS.

### Prices are too high and still rising—even for drugs that have been on the market for decades.

The full range of MS DMTs represent various mechanisms of action and routes of administration with varying efficacy, side effects and safety profiles. No single agent is 'best' for all people living with MS<sup>iii</sup> and, as MS presents differently in each person, every person's response to a DMT will vary. It is common for people with MS to move through several different DMTs throughout their life with MS, as they may "break-through" on a medication, or have disease activity, and need to try a different DMT.

With all this progress, people diagnosed today have the potential of a better course of MS than my mom. Yet, the price of these medications makes them out-of-reach for a growing number of people in the MS community.

While not identical, most brand MS DMTs have seen similar pricing trajectories. The price of MS therapies has dramatically risen since the first MS disease-modifying therapy was approved in 1993. When the first MS DMT came to market, the price range was \$8,000 to \$11,000 for one year of treatment. The annual median price for MS DMTs has increased nearly \$34,000 in less than 10 years. As of February 2022 (see appendix), the median annual price of the brand MS DMTs is close to \$94,000. Six of the MS DMTs have increased in price more than 200% since they came on market, with nine now priced at over \$100,000. This trajectory is not sustainable for people with MS or the US healthcare system as a whole. Recent analysis of the MS DMTs shows that price increases of brand name drugs are largely driven by year-over-year price increases of drugs that are already in the market vs. new products.<sup>iv</sup>

My mom's first medication, Betaseron, came on the market in 1993 priced at \$11,532. That same medication is now priced at \$111,721. It has increased in price by \$100,000 since it came to market. And this medication is nearly 30 years old and has not been improved, and is the same medication it was back then.

### Generics alone will not improve the affordability of or access to MS medications.

Generic medications play a critical role in prescription drug affordability, yet generics for specialty drugs, like MS DMTs, are still unaffordable for many patients. These generics are often covered by health plans, including Medicare plans, more like specialty medications rather than other generics, still resulting in high cost-sharing for people with MS. The brand product, despite its higher price, can receive favorable or equal treatment in specialty tiers, which disincentives the use of the lower-cost generic alternatives.

Generics are relatively new to the MS market, but the addition of generics to the MS class has not driven down the cost of DMTs substantially, as would be expected in a normal competitive market. When including generics, the median price of MS DMTs only falls to \$80,412 a year and our experience with MS generics has demonstrated that they present their own unique set of access issues. Our experience has solidified our belief that we cannot rely on generics alone to improve affordability for people with MS. Congress must play a role in ensuring access to these lower cost medications.

As detailed in the 46brookyn report "Wreck-fidera: How Medicare Part D has hidden the benefits of generic competition for a blockbuster Multiple Sclerosis treatment," in the third quarter of 2021, Medicare Part D plans covering most U.S. seniors didn't even make the generic equivalent to Tecfidera available, and only offered them the brand-name Tecfidera<sup>v</sup>. The generic system worked as it should have, and within a few months of Tecfidera going generic, more than 10 generic drug manufacturers were able to bring generic equivalents to the market; however, incentives within Part D made access to these lower-cost alternatives challenging at best.

The Society has seen this same dynamic play out in private plans as well. We have heard directly from people with MS and MS healthcare providers that some people do not have access to MS generics or are unable to afford the cost-share of their generic MS DMT—which may still be several hundred dollars each month. It can also be more difficult to obtain patient assistance funds for generic medications, which leaves people with MS and healthcare providers few choices. When generics are unaffordable, people with MS may switch to a different DMT, one that is higher cost to the system but may have a lower out-of-pocket cost for the person with MS due to insurance design or available patient assistance supports. **The Part D redesign proposed by Congress is the right first step in addressing the distorted incentives for prescription drug plans that leads to lower generic uptake.** Additionally, as there is still limited evidence around real-world utilization of specialty generics, we urge Congress to ensure access to lower cost generics and biosimilars by creating a specific generic and biosimilar formulary tier in Medicare Part D and prescription drug plans.

# MS DMT prices are staggering, and are directly linked to unaffordable out-of-pocket costs for people living with MS.

As the prices of MS DMTs increase, health plans and pharmacy benefit managers (PBMs) with little ability to negotiate better prices employ increasingly strict utilization management practices (prior authorization, step therapy and formulary restrictions) to minimize their use and cost liability for these therapies instead. These practices present significant hurdles for prescribers and real barriers for people with MS. Utilization management tools can result in delays or disruptions in treatment as patients wait for their health plan to determine whether they will cover care as prescribed. Any delay or disruption in treatment is particularly problematic for people with MS as delays may result in worse health outcomes, increased healthcare costs over time and disease progression that cannot be reversed.

# Every day, people with MS and other chronic conditions must make impossible decisions when their doctor prescribes them a medication that is high-priced.

Since I joined the Society seven years ago, I have heard too many stories about the hardships associated with drug costs to possibly be able to count. I have heard of people making excruciating choices that affect not only their lives, but the lives of everyone they care about—just to be able to pay what they owe to take their medications. I'm not exaggerating when I say that for many people with MS, the thought of being without their medication is terrifying. Any time that lapses because a person is not taking their medication could mean disease progression, and that could mean a loss of mobility that

becomes permanent. It could mean losing the ability to walk, to run, to live independently, to remember the moments you want to remember, to live your life the way you want to live it.

People with MS take numerous medications, in addition to their DMTs, to manage their MS symptoms. The increasing costs of prescription drugs create numerous access challenges for people with MS, which can be financially devastating, and creates constant stress for people who already live with the uncertainty and challenges of a chronic health condition.

Like Laurie from Oregon, who had to change her MS medication twice after joining Medicare because the out-of-pocket cost of her original DMT would have bankrupted her and her husband. During these changes, Laurie's MS symptoms increased substantially, and she transitioned from the relapsing form of MS to a progressive form of the disease. In Laurie's words, "I'm furious about this. I've been living in fear about access to my DMTs in the future, at a time I am losing ground with my disease."

Therese in Indiana was forced to change DMTs after the costs for hers soared to \$6,000 a month. But the next DMT didn't work for Therese; her MS progressed, bringing lingering cognitive issues, some dizziness and tingling in her hands and feet. By the time Therese had to switch to a different DMT, she had already burned through her savings.

Or Kenya in Louisiana, who occasionally rations medicine or skips it all together if she can't cover her Medicare out-of-pocket cost.

Every day, Bob in Minnesota and Diane in Wisconsin roll the dice. They each made the difficult decision to completely stop taking their MS DMT once they went on Medicare because they didn't want to financially devastate their families. For several years now, each has been without a DMT.

Sadly, these stories are not unique. In a 2019 survey of people with MS about their experience with their DMTs, more than half of those surveyed said they were concerned about being able to afford their DMT over the next few years and 40% had altered the use of their DMTs due to cost, with some skipping or delaying treatment<sup>vi</sup>.

Additionally, 40% stated that they experience stress or other emotional impact due to high out-ofpocket costs and are making lifestyle sacrifices to be able to pay for their DMT. This snapshot of realworld experiences shows why 85% of those surveyed said that the federal government should do more to control the high costs of MS DMTs.<sup>vii</sup>

What does it really mean when we say people are making lifestyle sacrifices? It can range quite a bit, but in our survey<sup>viii</sup> people reported:

- Spending less on entertainment and dining out,
- Saving less for future (college or retirement),
- Using a credit card more often,
- Spending less on their family,
- Spending less on groceries,
- Postponing paying other bills,
- Postponing retirement,

• And working a second job.

A couple of real-life examples of these sacrifices include:

Lisa in Michigan told us: Her out-of-pocket medication expenses average approximately \$9000/year, and on a fixed income, these expenses are quite debilitating. She often uses her charge cards to cover the costs and relies on her family to pay for her food as well as other living expenses. She could not get coverage for the new, efficacious DMT she was prescribed and had to switch to a more financially accessible medication because she could not afford her copay.

And Wayne, a senior in South Carolina, who still owns and operates a small business, now takes around \$13,000 out of his 401(k) account every year to pay his Medicare out-of-pocket costs.

Holly in New Mexico, who doesn't want to have to choose whether her family eats or she gets her medication.

## Many people with MS must rely on financial assistance from drug manufacturers to pay their out-ofpocket costs so they can afford to get their medication.

A key piece of the prescription drug access puzzle for many people with MS comes in the form of patient assistance funding. Seventy percent of people with MS have relied on patient assistance programs to be able to afford and stay on their disease-modifying treatment. The Society believes that the current status quo which makes medications largely unaffordable without patient assistance programs is unsustainable and in many ways, harmful to people with MS.

Reliance on patient assistance programs places undue stress and burden on people who rely on lifechanging medications. Individuals are particularly challenged when they transition to Medicare, where patient assistance programs from manufacturers are not allowed. Charitable foundations exist for Medicare beneficiaries to apply to for some assistance affording their medication, but the need is far greater than supply. From 2018 to 2020, the various nonprofit programs serving Medicare beneficiaries with MS opened only 16 to 20 times for just a total of 87 to 98 days out of the entire year approximately 25 to 30% of the year. In 2021, these funds opened only four times, for just 25 days out of the year. And to date in 2022, the funds opened only once in January, for just three days.

This is a nerve-wracking process for Medicare beneficiaries with MS, as an individual has to apply every year for the assistance, and it is never guaranteed even if life circumstances remain constant. People with MS often experience debilitating fatigue and cognitive challenges as common symptoms, setting them up to fail in a system that requires them to repeatedly call different assistance programs and hope to get through on a day where funds are available. This process compounds the stress and anxiety people with MS face on top of already managing a life-long chronic condition.

Ms. Dixon from Ohio relies on these nonprofit foundations to help cover her Medicare out-ofpocket expenses—about \$2,000 for a monthly supply of her DMT. She describes having to call the various 1-800 numbers each year and ask if they are helping people. In 2019, she didn't get there in time, and went several months without her DMT until she was finally able to find assistance. She is frustrated by the system, saying "I didn't ask for this disease. Why should we, as people who worked all our lives, pay so much for medicine, when we're on a fixed income and you know that we can't pay for it?" Kenya from Louisiana calls out the need to reapply each year, and since it can take several months for approval, she has to remember to apply early or risk a disruption in her treatment. Kenya says it is challenging because she has to have the energy and mental clarity to navigate and track the complex approval process.

My mom is among the group of people living with MS who could not access her medication without charitable assistance. Her current medication has a list price of nearly \$104,000. I talked to my parents, and they said that right away in January, they face a bill of \$5000 a month for my mom's medication. Her Medicare Advantage-Part D plan pays \$2600 of that and charitable assistance pays \$2400, and the charitable assistance continues covering her out-of-pocket throughout the year. My parents painstakingly select their plans every year to find one with the best coverage for their medications and health care providers and yet somehow, this is their best option. They cannot pay thousands of dollars a month, for months on end, between my mom's Social Security Disability Insurance, my dad's Social Security check, and the hourly wage he makes driving a city bus to make ends meet. When my mom went onto this medication she now takes, my parents called and called through a list of charitable funds I got from the National MS Society, finding them all to be closed and not accepting new patients; my dad remained persistent and with some good timing, he finally got the assistance they needed. The process of seeking and finding assistance is immensely stressful and uncertain, requiring time and diligence. Luckily, my dad got through and got what they needed to access my mom's drugs. People like my parents should not have to face this process just to fill her most-necessary prescription. The patient assistance should not be necessary in the first place. If my parents cannot secure that assistance, my mom is unable to continue to take her drug. They also struggle to afford the medications my dad—a 40+ year care partner and now senior with chronic health conditions—takes each month; he anticipates having to pay around \$4,000 out of pocket for his medications this year.

Health care costs have been a cause of stress and a burden for my parents since my mom was diagnosed. They were small-business owners for decades and my mom's care has always been a major line-item in their budget. I'll never forget the day he started looking at the costs he would have to pay out-of-pocket as he was transitioning to Medicare; he told me over the phone, "Steffany, I can't afford Medicare." My parents are on a fixed income and live in a very small town, but even in a low cost-of-living area, their health care costs are unsustainable for them on Social Security. My dad is 69 years old with his own health challenges and had to get a job driving a city bus in their town, to pay their bills, and they have had to cut every possible corner—even moving to a smaller home and getting less-expensive cars. I try to help out however I can, but this is a situation no one should have to be in—health care and drug costs making retirement security out-of-reach.

#### It is not enough to only address out-of-pocket costs. People with MS need drug pricing reform.

Congressional action to address drug pricing would have the real-life impact of reducing what people with MS pay for medicines. An out-of-pocket cap and smoothing mechanism would be transformative for people who rely on Medicare to get their medications. Right now, too many people with MS and other health conditions pay much more than they can afford, and some even make the decision to go off their life-changing medications. Recent analysis confirms their experience. Cumulative annual out-of-pocket spending for Medicare beneficiaries with MS just for their MS DMT was \$6,894 in 2019, including an average of \$352 in out-of-pocket cost per month for those already in the catastrophic coverage phase<sup>ix</sup>. We strongly support the concept of capping out-of-pocket costs and restructuring the Medicare Part D program to reduce beneficiaries' out-of-pocket costs. As noted above, Medicare beneficiaries living with MS have high out-of-pocket costs and typically reach the catastrophic phase early in the year. Under current law, once they reach the catastrophic phase in Part D, they are still responsible for 5% of

the costs of their medications. These reforms would have an immediate impact on improving affordability of medications, upon implementation.

But to truly improve affordability and access to MS medications, we believe that the price of the medications must be addressed. Given the escalating prices of the MS DMTs, we support provisions that would limit how much pharmaceutical companies can increase drug prices each year. Last year, when the Society was analyzing drug prices of MS therapies, we found that five MS DMTs had increased in price by more than 30%. MS therapies are also incredibly expensive, so even smaller increases of three or four percent have a noticeable impact. With co-insurance very common for specialty medications like the MS DMTs, the list prices are directly linked to increased out-of-pocket costs for people with MS. Medicare is the single largest payer of MS-related costs in the United States, and as such the high prices for the DMTs mean higher costs across the entire system<sup>x</sup>.

The Society has had a comprehensive set of <u>recommendations</u> on actions to address the high cost of MS DMTs since 2016, and one of those recommendations is to allow Medicare to negotiate the prices of prescription drugs. The Medicare program consistently spends around \$5 billion on MS DMTs<sup>xi</sup>. Allowing Medicare to potentially negotiate for lower DMT prices could result in significant cost savings for both the program and people affected by MS, who would pay lower out of pocket costs and less for their premiums.

### The Society supports – and people with MS need—meaningful innovation.

There is a narrative that drug prices reflect innovation and allowing Medicare to negotiate drug prices will result in fewer new products on market. This narrative is flawed. We believe that people with MS should not have to face a choice between unaffordable medications and supporting innovation.

The innovation argument cannot explain why six MS DMTs have increased in price more than 200% since coming to market, nor can it justify medications still increasing in price more than 20 years after entering the market. Rather, these experiences directly point to the need for inflationary rebates. Further, the innovation narrative does not align with direct statements from biotech leaders who were involved in MS DMT pricing or marketing in an article published in 2019.<sup>xii</sup> This Society-funded study suggested that the price ecosystem, overall corporate growth, international pricing disparities and supply chain-related distortions may play a more central role in drug pricing decisions than innovation. Those interviewed indicated that strategy related to initial list pricing focused on the prices of competitors in the therapeutic area. While one participant described the need to recoup development costs and incentive investments as reasons for price increases, more common responses cited corporate growth as more of a driver for price increases.

Follow-on products that simply build on previous products should not be priced as first-in-class therapies. We have seen this first-hand in MS where there are multiple treatment options, many of which have little or no innovation associated with the agent, but are all priced similarly. We believe there is a place for improved products to provide additional options for patients, but they must be priced appropriately and not as "first-in-class" innovation.

Despite the influx of successful DMTs in the MS space in the past twenty-nine years, more is needed because we still don't have a cure for this disease. While we have more than twenty DMTs to treat relapsing forms of MS, we have limited options for treating progressive MS. The Society is leading collaboration in this space. In 2014, we partnered with five other MS organizations to establish what is known today as the International Progressive MS Alliance, which has advanced the development of

treatment for progressive MS by removing scientific and technological barriers. Currently, this Alliance includes members of MS organizations from Australia, Belgium, Canada, Denmark, Germany, Italy, the Netherlands, Spain and the United Kingdom, as well as the MS International Federation.

It will take continued partnership from all stakeholders to move us to "best-in-class" products for both relapsing forms of MS and progressive MS. This type of innovation is happening every day and people with MS need true innovation to develop a cure. Innovation will allow for more treatments with different mechanisms, will provide novel solutions and drive better outcomes for people with MS. These are the incentives that must drive the development of novel solutions for people with MS—not supply-chain distortions or international pricing disparities. It is vital that we maintain an environment that creates opportunities to take the scientific and financial risks needed to drive development of treatments that can have life-changing benefits.

We believe Medicare negotiation will not limit innovation but has the potential to drive innovation and make space for the next wave of innovative treatments. For example, an exciting development in the MS therapy pipeline is a group of treatments known as Bruton's tyrosine kinase inhibitors, or BTKi. BTKi is important for the activity and survival of antibody-producing B-cells. These immune cells are thought to be one of the key drivers of brain and spinal cord inflammation in people living with MS. This is a brand-new line of treatment, and this class of inhibitors can act on immune cells in peripheral circulation, but also directly on cells within the brain and the spinal cord to reduce inflammation. The treatments have shown great promise in Phase 2 clinical trials and now there are multiple Phase 3 clinical trials for various BTKi molecules in both relapsing and progressive forms of MS. There's optimism that this approach may stop MS progression, but we won't know until the trials are completed. This is the kind of innovative therapies we need in the MS space and this type of innovation should be rewarded in the market. As stated previously, people must be able to afford and access innovation for it to have impact. In our healthcare system, as products reach the end or pass their life cycle, prices should stagnate and decrease to free healthcare dollars for the next wave of innovation. We believe that Medicare negotiation has a role in this cycle and the potential to promote uptake of truly innovative products.

# My mom is one of the 85% of people with MS across the United States who want the federal government to do more to control the high cost of MS medications.

The Society urges the members of this committee to work together in a bipartisan fashion and pass meaningful reform that will lower the price of medications and out-of-pocket costs for people with MS. We appreciate that there are fundamental differences of opinion in the role of government to help facilitate lower drug prices, as well as the impact of those policies on innovation and the U.S. healthcare system—but we believe that now is the time for Congress to act to make meaningful change for people with MS and millions of others who struggle to afford the medications they need to live their lives.

Medications must be affordable, and the process for getting them simple and transparent. We urge Congress to act now and allow Medicare to negotiate for prescription drugs, redesign Medicare Part D to better work for Medicare beneficiaries by capping out of pocket costs and allowing beneficiaries to smooth costs within the plan year and enact an inflationary rebate that would prevent the cost of medications from rising over the cost of inflation.

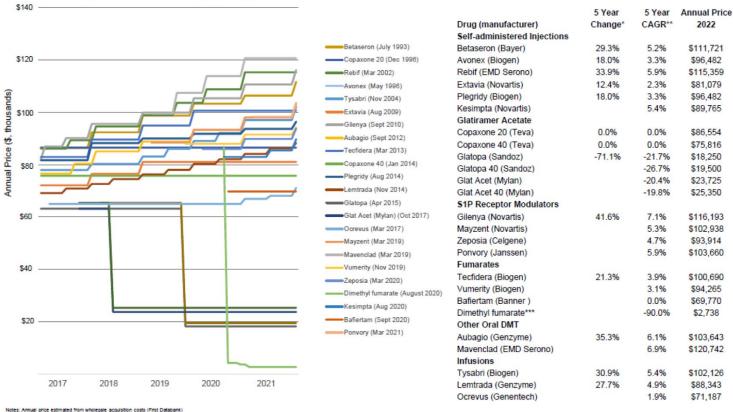
No single solution will fully address the multiple factors that work together to contribute to the high prices of medications in the U.S. We believe these policies are a good first step and will make an immediate impact on people with MS and others. **The current system does not work in the best** 

**interest for people with MS and other chronic health conditions and the status quo is not sustainable**. Medications cannot change the lives of people who need them if they cannot access them.

Patients have waited long enough. We look forward to working with Congress as it works towards enacting meaningful change for people affected by MS.

#### Appendix

#### Trends in annual price for disease-modifying therapies for multiple sclerosis; 2017 to 2022



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<sup>&</sup>lt;sup>i</sup> "B. Bebo et al. A Comprehensive Assessment of the total economic burden of multiple sclerosis in the United States. ECTRIMS 2021. 15, October, 2021.

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<sup>vi</sup> National Multiple Sclerosis Society. "Quantifying the Effect of the High Cost of DMTs" Market Research Report. August 2019.

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<sup>ix</sup> Daniel M Hartung, Kirbee A. Johnson, Adriane Irwin, Sheila Markwardt, and Dennis N. Bourdette, '*Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis In Medicare Part D'*, Health Affairs, February 2019, Vol.38, No.2.

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