National
Multiple Sclerosis
Society

May 4, 2021

The Honorable Frank Pallone
Chairman
House Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
House Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
Chairman
Subcommittee on Health
House Energy & Commerce Committee
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
Subcommittee on Health
House Energy & Commerce Committee
Washington, DC 20515

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo and Ranking Member Guthrie:

On behalf of the National Multiple Sclerosis Society (Society), thank you for the opportunity to provide a statement for the record for the hearing "Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs." The Society is glad that Congressional leaders are turning their attention to addressing the high cost of prescription drugs—in a survey of people with MS, 85% want the federal government to do more to control the high costs of MS disease-modifying treatments. We urge this Committee to work together in a bipartisan fashion and pass meaningful reform that will lower the cost of medications for people with 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.

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. We have been a leading voice in advocating for policies that will reduce the cost of medications that people with MS rely on to live their best lives. In 2016, the Society released comprehensive recommendations to Make MS Medications Accessible (Society 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[i]. We know that there is no single solution that can fully reverse the trend toward ever-increasing drug costs and payer policies that inhibit or delay access to medically necessary therapies. These Recommendations continue to form the basis of our support for any legislation that seeks to address the high cost of prescription drugs.

One of the core components of the Society's Recommendations is transparency. We work with all companies, organizations and individuals that share our mission. On average, financial support from pharmaceutical companies over the last three years has accounted for less than 4% of Society funds. 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 Society's website.

MS-DMTs: A case study that shows why Congress must act to address drug pricing

The cost of MS therapies has dramatically risen since the first MS disease- modifying therapy (DMT) was approved in 1993. Data and analysis confirm the experience of people with MS- continuously increasing medication prices and out-of-pocket costs, confusing and inconsistent formularies and complex payer approval processes that stand in the way of getting the treatments they need.

Growing evidence shows that early and ongoing treatment with a Food and Drug Administration (FDA) approved 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 25 years. 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[ii] and, as MS presents differently in each person, every person's response to a DMT will vary. Further, most of the MS DMTs are not therapeutically interchangeable.

While not identical, most brand MS DMT's have seen similar pricing trajectories. When the first MS DMT came on the market in 1993, the price range was $8,000 to $11,000 for one year of treatment. Since that time, price increases occurring one or more times per year for almost all DMTs have become the norm. In 2013, the annual median price for MS DMTs was less than $60,000, today the median price for brand MS DMTs is $93,672. Five MS DMTs are now priced at more than $100,000 per year and almost all these treatments must be taken each year. Recent analysis 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. [iii]

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 $88,212 a year and our experience with MS generics has demonstrated that they have their own unique set of access issues.

Impact of high prices of MS DMTs

As the prices of MS DMTs increase, health plans and pharmacy benefit managers (PBMs) employ increasingly strict utilization management practices (prior authorization, step therapy and formulary

restrictions) to minimize their use and cost liability for these therapies. 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.

Increasingly, people with MS are faced with higher out-of-pocket costs due to high deductibles and co-insurance rather than a flat co-pay for their MS DMT. These insurance plan designs make it more difficult for people to stay on their life-changing medication as they can face several hundreds of dollars or more each month. 70% of people with MS have relied on patient assistance programs to be able to afford and stay on their disease-modifying treatment.

People affected by MS want the federal government to enact meaningful change

People with MS take numerous medications, apart from their DMTs, to manage their MS symptoms. The increasing costs of prescription drugs create numerous access challenges for people with MS, which impacts their financial well-being and creates constant stress for people who already live with a chronic health condition. The Society surveyed people with MS about their use of 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[iv]. Additionally, 40% stated that they experience stress or other emotional impact due to high out-of-pocket costs and are making lifestyle sacrifices to be able to pay for their DMT. This snapshot of real-world experiences shows why 85% of those surveyed said that the federal government should do more to control the high costs of MS DMTS.[v]

The Society's Recommendations address the interconnectivity within the current U.S. health care system that limits the effectiveness of piecemeal approaches. We believe the bills under consideration by this Committee include many of the fundamental changes that are necessary so that the system protects patient's interests while allowing innovation and development of new therapies. While much discussion has focused on the impact of Medicare negotiation on access and innovation, we believe proposals around transparency, improving generic access and availability, and addressing price increases are just as crucial to ensuring timely solutions for people with MS, and the sustainability of the U.S. healthcare system and the research and development pipeline.

Improving transparency throughout the pharmaceutical supply chain

As noted above, a core component of the Society's Recommendations is about improving transparency in all areas of the pharmaceutical supply chain so that all stakeholders operate with the same level of information. We support the provisions included within the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) and the Lower Cost, More Cures Act (H.R. 19) that would improve transparency throughout the pharmaceutical supply chain to help level the playing field around information used to set the prices of medications and price increases. Leveling the playing field involves transparency from the manufacturer on which factors are used to set prices; the rationale, frequency and implementation of plans for anticipated price increases; the relationship of price increases to research and development of new therapies; the marketing of products to both

physicians and the public; as well as details about patient assistance programs, including amount of funds provided and number of patients assisted with those programs.

Justifying Significant Price Increases

The Society also supports provisions within H.R. 3 and H.R. 19 that require manufacturers to justify significant price increases, above 10 percent annually or 25 percent over 36 months. The Society also endorses the bipartisan Fair Accountability and Innovative Research (FAIR) Drug Pricing Act of 2019 (S. 898) which has similar goals. This provision is a critical component to leveling the playing field for all stakeholders and allows the public to better understand the factors that have a direct impact on price increases. The Society also supports provisions to require drug manufacturers to pay additional rebates if manufacturers raise prices above the inflation rate. Studies have indicated potential shadow pricing in the MS DMT class over the past several years[vi], and we urge Congress to include provisions to help alleviate this practice.

Allowing Medicare Negotiation and Capping Out of Pocket Costs for Medicare Beneficiaries

The Society's recommendations directly call for Congress to allow Medicare to negotiate prices for beneficiaries and we support the provisions within H.R. 3 that would enact this policy. Medicare beneficiaries with MS have long reported significant difficulty accessing their medications affordably and recent analysis confirms their experience. Cumulative annual out-of-pocket spending for Medicare beneficiaries with MS 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[vii]. Additionally, the Medicare Part D program spent over $5 billion on MS DMTs in 2017. Allowing Medicare to negotiate for lower DMT prices will result in significant cost savings for both the program and people affected by MS.

We also support proposals in H.R. 3 and H.R.19 that would restructure 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. Additionally, we support the provisions proposed by both H.R. 3 and H.R. 19 that would allow for those beneficiaries who are projected to reach the catastrophic phase to spread the out-of-pocket cost over the course of the plan year, sometimes referred to as "smoothing". We believe these policies are essential to improving the accessibility of MS DMTs for Medicare beneficiaries that live with MS.

Address Regulatory Gaming to Increase Availability of Generics and Biosimilars

The Society appreciates the attention from the Committee around improving the regulatory process to ensure speedy regulatory approval and access to generic medications and biosimilars. We believe that industries should be compensated fairly for the research and development required to bring innovative products to market. However, market exclusivity and patent protections are vital tools created by Congress to reward innovation, and our Recommendations state that minor tweaks to existing products should not receive lengthy patent protections.

The 2020 House Oversight and Government Reform Committee reports revealed that a brand product's pricing strategy is often dependent on when a generic competitor is expected to enter the market and demonstrated how companies have misused patents and the regulatory process to manipulate the market, keep lower cost products from coming to market, which keep prices artificially high. We believe Congress should act now to ensure these practices end.[viii] We support the Stop The Overuse of Petitions and Get Affordable Medicines to Enter Soon (STOP GAMES) Act (H.R.2843) and provisions within H.R.19 that would explicitly prohibit pay-for-delay agreements. These provisions are necessary to ensure fundamental fairness to ensure swift approval of lower cost generic options when brand products reach the end of their patent protections. We urge Congress to work closely with the Food and Drug Administration and the Federal Trade Commission to guarantee that the system is working with the scope and intent of the Hatch-Waxman Act.

Improving Access to Generics and Biosimilars

The Society appreciates the Committee's focus to not only ensure that generics therapies can get to market, but that people have access to those therapies. Generic medications play a critical role in prescription drug affordability, yet generics for specialty drugs, like MS DMTs, are still unaffordable for many patients (See Appendix 1).

These generics are often covered by health plans more like specialty medications rather than other generics, creating high cost-sharing for people with MS. The brand product, despite its higher price, receives favorable or equal treatment in specialty tiers, which disincentives the use of the lower-cost generic alternatives. We are pleased that the H.R. 2846 creates a specific generic and biosimilar formulary tier in Medicare Part D and prescription drug plans. We specifically called for this addition in the 116th Congress and believe that this will improve access and utilization of MS generics. We have heard directly from people with MS and MS healthcare providers that some people with MS 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 become 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 to the person with MS due to insurance design or available patient assistance supports. As there is still limited evidence around real-world utilization of specialty generics, we urge the Committee to continue examining the specialty generic market with the goal of ensuring patients can affordably access these medications as they continue to come to market in higher numbers.

Innovation

Some criticism of H.R. 3 is that it would stifle innovation, with fewer new products coming to market. We support a meaningful conversation and exploration as to whether this would be the case and what the true impact of this would be. Is every newly approved product truly innovative? Innovation brings scientific discoveries into life-changing medications for individuals and families. Continued innovation also has an important role in helping to reach a "best-in-class" product, that may offer greater health benefits or less side effects than a first in class product did. 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. These innovators should be rewarded.

However, today's environment also includes product approvals that are "me too" products that simply build on previous products and which do not benefit from scientific innovation nor do they demonstrate meaningful additional benefits for patients. 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. We believe there may be a place for marginally improved products to provide additional options for patients, but they must be priced appropriately and not as "first-in-class" innovation.

Conclusion

The Society appreciates 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. We also know that the current system does not work in the best interest for people with MS and other chronic health conditions and is not sustainable. MS medications have transformed the lives of people with MS, but medications cannot change the lives of people that need them if they cannot access them. We look forward to working with this Committee as it works towards enacting meaningful change for people affected by MS.

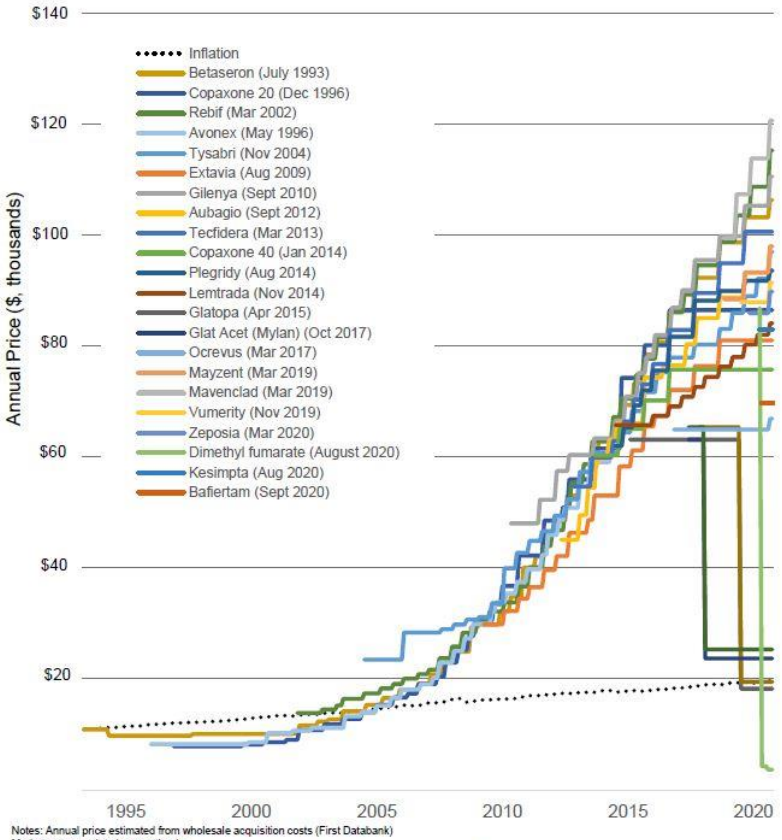
If you have any questions about our recommendations, please contact Leslie Ritter, Associate Vice President of Federal Government Relations, at Leslie.Ritter@nmss.org.

Sincerely,

Bari Talente, Esq.
Executive Vice President, Advocacy and Healthcare Access
National Multiple Sclerosis Society

APPENDIX I

Trends in annual price for disease-modifying therapies for multiple sclerosis; 1997 to 2021



Drug	5 Year Change*	1 Year Change**	Annual Price 2021
Self-administered injections			
Betaseron	35.6%	3.0%	$106,401
Avonex	30.0%	2.0%	$93,672
Rebif	48.3%	11.3%	$115,359
Extavia	23.7%	0.0%	$81,079
Plegridy	30.0%	2.0%	$93,672
Kesimpta			$83,000
Glatiramer Acetate			
Copaxone 20	7.9%	0.0%	$86,554
Copaxone 40	7.9%	0.0%	$75,816
Glatopa	-71.1%	0.0%	$18,250
Glatopa 40		0.0%	$19,500
Glat Acet (Mylan)		0.0%	$23,725
Glat Acet 40 (Mylan)		0.0%	$25,350
Oral DMTs			
Gilenya	41.6%	5.0%	$110,660
Aubagio	31.8%	5.1%	$98,054
Tecfidera	37.6%	0.0%	$100,690
Mayzent		5.0%	$98,036
Mavenclad		12.4%	$120,742
Vumerity		4.0%	$91,520
Zeposia		4.5%	$89,870
Bafiertam			$69,770
Dimethyl fumarate***			$3,650
Infusions			
Tysabri	35.2%	8.9%	$97,032
Lemtrada	27.9%	4.8%	$84,168
Ocrevus		3.0%	$66,950

Notes: Annual price estimated from wholesale acquisition costs (First Databank)
Market entrance date in parenthesis
Dashed line is projected annual price of Betaseron assuming only inflationary increases in price (CPI)
Lemtrada is based on four 12 mg vials (Package insert dosing: 12 mg/day (5 vials) for five consecutive days in first year; 12 mg/day (3 vials) for three days in year 2);
*2016 to 2021 (Februrary); **2020 to 2021 (Februrary), ***lowest price dimethyl fumarate reported
Updated 2.18.2021 (Data through February 2021)
Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University

National Multiple Sclerosis Society

[i] National MS Society. Make MS Medications Accessible: Recommendations. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/Recommendations-Make-MS-Meds-Accessible.pdf. Accessed February 27, 2019.

[ii] MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. Accessed December 26, 2018.

[iii] Hernandez, Inmaculada et all. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." Health Affairs. Vol.38, No. 1. https://doi.org/10.1377/hlthaff.2018.05147

[iv] National Multiple Sclerosis Society. "Quantifying the Effect of the High Cost of DMTs" Market Research Report. August 2019. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/NMSS-Research-Report-Full-Access-to-MS-Medications.pdf. (Accessed April 27, 2021).

[v] National Multiple Sclerosis Society. "Quantifying the Effect of the High Cost of DMTs" Market Research Report. August 2019. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/NMSS-Research-Report-Full-Access-to-MS-Medications.pdf. (Accessed April 27, 2021).

[vi] Hartung, DM, et al. 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,

[vii] 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.

[viii] Committee Releases Additional Staff Reports on Skyrocketing Drug Prices for Day 2 of Landmark Hearings with CEOs." Oct. 1, 2020. https://oversight.house.gov/news/press-releases/committee-releases-additional-staff-reports-on-skyrocketing-drug-prices-for-day