National
Multiple Sclerosis
Society

June 6, 2019

The Honorable Richard E. Neal
Chairman
House Ways and Means Committee

The Honorable Kevin Brady
Ranking Member
House Ways and Means Committee

The Honorable Frank Pallone, Jr.
Chairman
House Energy and Commerce Committee

The Honorable Greg Walden
Ranking Member
House Energy and Commerce Committee

Dear Representatives Neal, Pallone, Brady, and Walden:

Thank you for providing this opportunity to comment on the House Ways and Means and Energy and Commerce Committee draft legislation to improve the Medicare Part D program by capping out-of-pocket costs for beneficiaries once they've reached the catastrophic coverage spending threshold. On behalf of Medicare beneficiaries living with multiple sclerosis (MS) and their caregivers, the National Multiple Sclerosis Society (the Society) applauds the Committees' ongoing efforts to help lower the cost of prescription drugs and eliminate coverage-related barriers to care. We hope that this Congress will succeed in promoting the affordability and accessibility of drug treatments by reforming the current drug pricing system and fostering improvements in the design and administration of prescription drug benefits. In addition to addressing out-of-pocket drug costs for Medicare beneficiaries, we also support policies that would bring added transparency to drug pricing and accelerate access to generics. However, we will limit our comments here to the need to relieve Part D enrollees' out-of-pocket costs.

MS and the Cost of MS Treatments

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. A new study funded by the National MS Society has confirmed that nearly one million people are living with MS in the United States, more than twice the original estimate.

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. Fortunately, there are now over a dozen FDA-approved DMTs for different forms of MS. 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[i]. As MS presents differently in each individual, every person's response to a DMT will vary. In fact, as supported by the American Academy of Neurology's' Practice Guideline Recommendations: Disease Modifying Therapies for Adults with Multiple Sclerosis, it is critically important that payers, payment models and delivery systems recognize that despite similarities in their indications, these therapies are not interchangeable.[ii]

Unfortunately for people affected by MS, the cost of MS therapies has dramatically risen since the first DMT was approved in 1993. 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.

When MS DMTs first 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 2019, the median price for brand MS DMTs is $88,853[iii] and several pharmaceutical companies have already raised prices this year (see Appendix 1 and 2).

Impact on Medicare Beneficiaries with MS

Recent analyses of trends in Part D plans' coverage of DMTs and corresponding out-of-pocket costs for their enrollees provide damning evidence of the severe cost burdens for Medicare beneficiaries with MS. Hartung and colleagues have projected cumulative annual out-of-pocket spending for 2019 of $6894, including an average of $352 in out-of-pocket costs per month for those already in the catastrophic coverage phase.[iv] The implications of these findings are most revealing in light of earlier research showing that MS patients whose specialty drug prescription cost-sharing amount was between $100 and $250 were 80% more likely to abandon their treatment than those with lower cost-sharing requirements. [v]

Unfortunately for Part D enrollees with MS and limited financial means, Medicare's anti-kickback statute puts most patient assistance program (PAP) funding out of reach. Although limited financial assistance funding to help Medicare beneficiaries pay for needed medications and with the approval of the Office of Inspector General (OIG) does exist, the demand for these funds far exceeds their supply. In fact, it is typical for these programs to announce funds to help people with MS have been exhausted within 24 to 28 hours following announcement of their availability. Additionally, Part D enrollees relying on specialty drugs, which are typically covered at the highest cost tier, are prohibited from requesting an exception to these tiering arrangements and the cost-sharing requirements associated with them.

Because MS is not one of the six 'protected classes', Part D plans can and often do exclude some DMTs from their formularies, as Hartung and colleagues also revealed in their study of coverage trends in Medicare drug plans from 2007 to 2016. Additionally, these authors examined prior authorization and step therapy requirements, concluding that throughout the study period, the share of plans with at least one therapy available without limitations declined from 39 percent to 17 percent. The rate of prior authorization use increased from 61–66 percent of plans to 84–90 percent. For beneficiaries with MS and their health care providers, these formulary exclusions and utilization management practices result

in significant barriers to timely access to medically necessary treatment, threatening treatment relapses and worsening disease and disability. [vi]

Although additional MS-specific data on the impact of rising DMT prices and out-of-pocket costs for Medicare beneficiaries is not available, the personal experiences of people with MS are well known to us through our relationships with many thousands of them, their family caregivers and healthcare providers. The Society's Navigator services, which provide information, referral and benefits counseling to hundreds of thousands of people with MS and others in the MS community each year, report the need for help paying for MS medications is among the most common reasons for calling our toll free help line and reviewing our online information and resources. Despite our best efforts to help Medicare beneficiaries navigate their health plan choices and prescription drug benefits, we believe many like MS Activist and retired Wisconsin school teacher Diane Whitcraft, have made the painful decision to stop taking their MS medications altogether due to un-affordable cost-sharing requirements.

Additional Recommendations for Improving Medicare Drug Benefits

The price of MS DMTs has skyrocketed in the 16 years since passage of the Medicare Modernization Act of 2003, which created the Part D drug benefit. As a result, so have the out-of-pocket costs for beneficiaries living with MS because co-insurance is a percentage of the list price of the medications. For the reasons described above, **the Society supports capping annual out-of-pocket costs for Medicare beneficiaries at the catastrophic coverage phase of their Part D plan.** Additionally, we urge you to consider options – such as a monthly cap or other mechanism, as some large employer plans have done voluntarily -- to allow out-of-pocket costs to be distributed more evenly throughout the year. This would alleviate the financial strain experienced by so many people with MS in the earliest months of the year, before they reach the catastrophic coverage phase.

We thank the Committees for capping out-of-pocket expenses for Part D beneficiaries in the draft legislation. There is widespread support for capping the out-of-pocket expenses in Part D, which is supported by MedPAC and included in the President's Budget proposal for Fiscal Year 2020. Congress came together in a bipartisan way to address the coverage gap, also known as the donut hole, and we hope that Congress can once again come to consensus on capping expenses in Medicare Part D.

As much as Medicare beneficiaries are relieved to see the end of the coverage gap, we urge the Committee to assure enrollees on generic drug treatments don't face a higher cost-sharing requirement as is currently the case for people with MS on generic forms of glatiramer acetate – currently the only DMT with a generic equivalent on the market. With the full closure of the coverage gap, we see no reason not to eliminate the distinction between coverage phases within the program, as their continuation will only extend the confusion about an already confusing benefit program. Further encouraging the use of generics among LIS-eligible beneficiaries could be accomplished by eliminating cost-sharing requirements for generics by these individuals. This measure would likely prove cost-effective to the Medicare program in the long run while helping a vulnerable population maintain adherence to their treatment regimens.

Absent additional data on the implications of prescription drug costs for people with MS, it is difficult to make informed recommendations about the share of costs that should be required of beneficiaries, especially those not eligible for the low income subsidy (LIS). Nonetheless, we do urge you and the Congress to address the substantial increase in the catastrophic threshold due in 2020 when Medicare Part D beneficiaries will experience an increase of $1450 to reach the catastrophic coverage phase.

Additionally, we support the Medicare Extra Rx HELP Act (S. 691) which would eliminate the asset test in determining eligibility for these subsidies, streamline the application process and update the benefit by extending it to beneficiaries living at or below 200% of the federal poverty level (about $25,000 for an individual in 2019). This would put the Extra Help Program more on par with Marketplace subsidies and more accurately reflect the reality of prescription drug expenses for this population. Also, we believe Part D beneficiaries should have the ability to seek a lower cost share for specialty medications. The Committees should explore ways and approaches for beneficiaries taking these high-cost medications to seek a lower cost share amount.

Additionally, as we have observed many times over, the lack of real transparency in the presentation of coverage and care costs harms beneficiaries, as the transition from cost-sharing in the form of flat copay amounts to co-insurance illustrates. The requirement to pay a percentage of an unknown price does not provide anyone with the information they need to make an informed choice. We agree with the National Council on Aging's recommendations for improving the Part D Plan Finder, and appreciate efforts to give them your serious consideration.

In sum, while the affordability and accessibility of prescription drugs for Medicare beneficiaries with MS has dramatically improved with the Medicare Modernization Act, the cost of treatments has resulted in un-affordable cost-sharing and administrative burdens for many. We are grateful for this opportunity to share the experiences and needs of beneficiaries with MS with the Committee as you consider improvements to the Part D program.

Sincerely,

Bari Talente

Bari Talente, Esq.
Executive Vice President of Advocacy
National MS Society

[i] 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.

[ii] American Academy of Neurology, 'Practice Guideline Recommendations Summary: Disease Modifying Therapies for Adults with Multiple Sclerosis', viewed online June 6, 2019

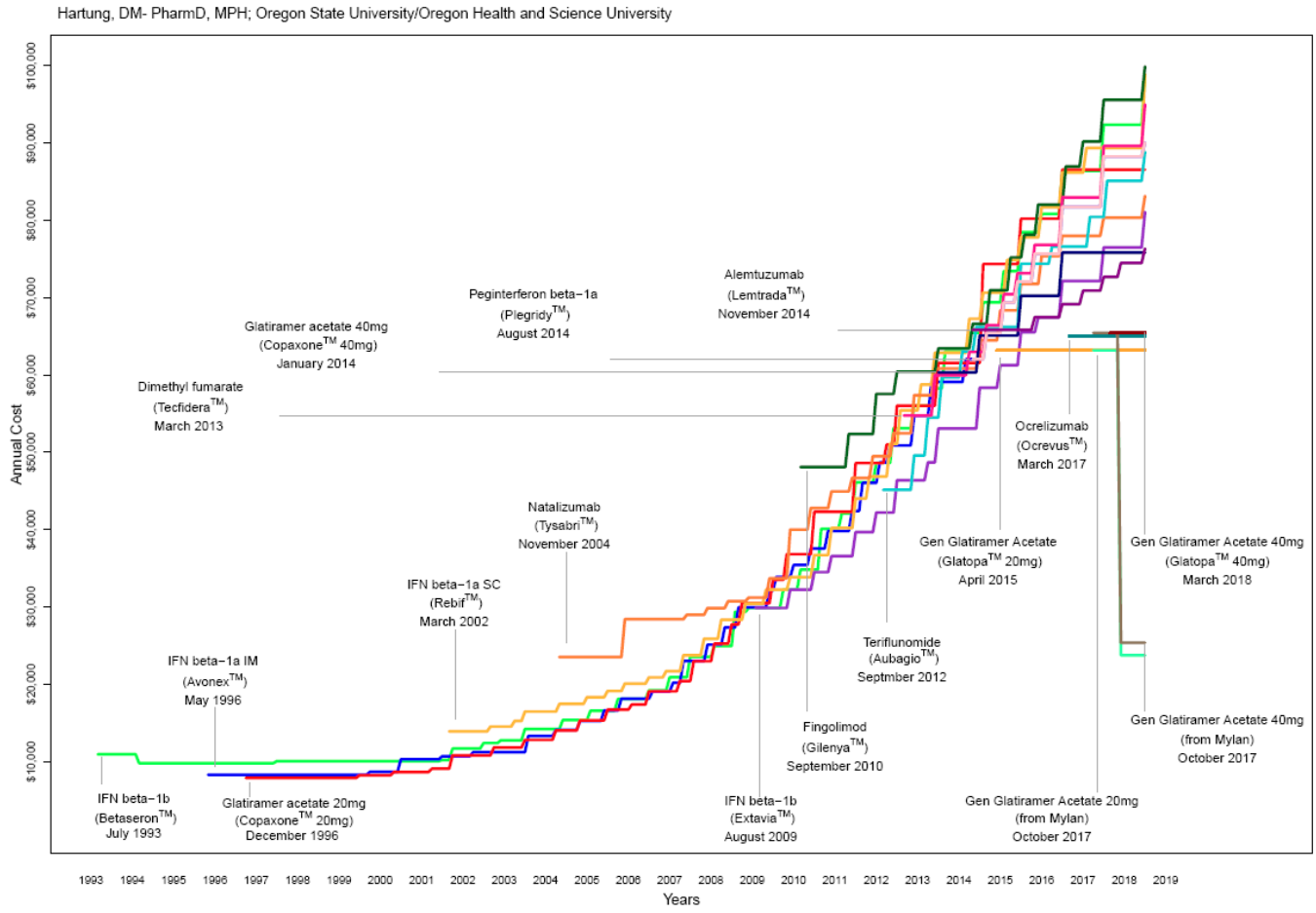
[iii] Hartung DM. *Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA.* Neurotherapeutics. 2017 Oct;14(4):1018-1026. doi: 10.1007/s13311-017-0566-3. **https://www.ncbi.nlm.nih.gov/pubmed/28812229**

[iv] 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.

[v] Gleason PP, CI Starnor, BW Gunderson, et. al., '*Association of Prescription Abandonment with Cost-Share for High-Cost Specialty Pharmacy Medications'*, Journal of Managed Care Pharmacy 2009: 15 (8) 648-58.

[vi] 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.

Appendix 1


Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University
Annual Cost
$10,000
$20,000
$30,000
$40,000
$50,000
$60,000
$70,000
$80,000
$90,000
$100,000
1993
1994
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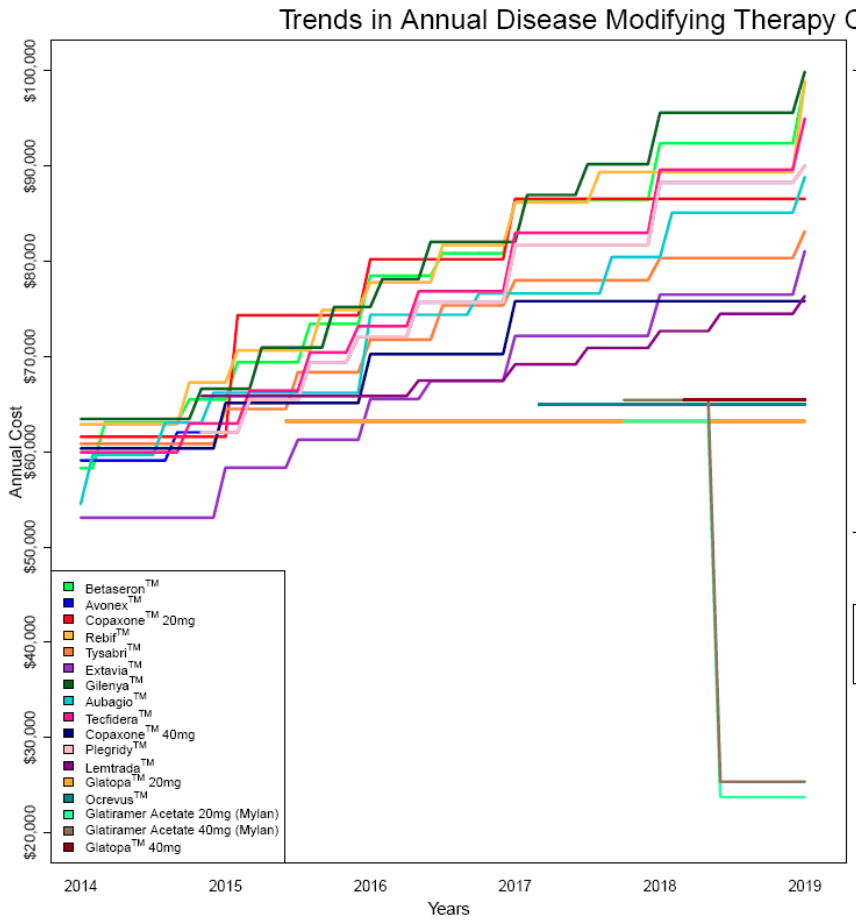
Years
IFN beta−1b (Betaseron™) July 1993
IFN beta−1a IM (Avonex™) May 1996
Glatiramer acetate 20mg (Copaxone™ 20mg) December 1996
IFN beta−1a SC (Rebif™) March 2002
Natalizumab (Tysabri™) November 2004
Peginterferon beta−1a (Plegridy™) August 2014
Glatiramer acetate 40mg (Copaxone™ 40mg) January 2014
Dimethyl fumarate (Tecfidera™) March 2013
Alemtuzumab (Lemtrada™) November 2014
IFN beta−1b (Extavia™) August 2009
Fingolimod (Gilenya™) September 2010
Teriflunomide (Aubagio™) Septmber 2012
Gen Glatiramer Acetate (Glatopa™ 20mg) April 2015
Ocrelizumab (Ocrevus™) March 2017
Gen Glatiramer Acetate 20mg (from Mylan) October 2017
Gen Glatiramer Acetate 40mg (from Mylan) October 2017
Gen Glatiramer Acetate 40mg (Glatopa™ 40mg) March 2018

Appendix 2



Drug	2019 Cost*	2014 Cost**
Betaseron™	$98,759	$58,265
Avonex™	$90,035	$59,085
Copaxone™ 20mg	$86,554	$61,567
Rebif™	$98,899	$62,873
Tysabri™	$83,152	$60,827
Extavia™	$81,079	$53,080
Gilenya™	$99,896	$63,444
Aubagio™	$88,853	$54,500
Tecfidera™	$94,991	$59,957
Copaxone™ 40mg	$75,816	$60,336
Plegridy™	$90,035	$62,036†
Lemtrada™	$76,346	$65,833†
Glatopa™ 20mg	$63,193	$63,193†
Ocrevus™	$65,000	$65,000†
Glatiramer Acetate 20mg (Mylan)	$23,725	$63,193†
Glatiramer Acetate 40mg (Mylan)	$25,350	$65,432†
Glatopa™ 40mg	$65,433	$65,433†

*January 2019
**January 2014
†Market entry cost if approved after January 2014

We estimated annual costs using wholesale acquisition cost. Package insert for Lemtrada™ states initial dose is five consecutive daily infusions with three consecutive daily infusions in subsequent year. We estimated the annual cost for Lemtrada™ based on the use of four vials.

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