



National  
Multiple Sclerosis  
Society

December 8, 2017

Maureen K. Ohlhausen  
Acting Chairwoman  
Federal Trade Commission  
400 7th St., SW  
Washington, DC 20024

Scott Gottlieb, MD  
Commissioner  
U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Re: Federal Trade Commission Workshop on “Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics”

Dear Acting Chairwoman Ohlhausen and Commissioner Gottlieb:

On behalf of the National Multiple Sclerosis Society (Society), thank you for the opportunity to submit comments to the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) in conjunction with the FTC’s public workshop on “Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics.” The Society works to provide solutions to the challenges of multiple sclerosis (MS) so that everyone affected by this disease can live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

MS is an unpredictable, often disabling disease of the central nervous system, which interrupts the flow of information within the brain and between the brain and the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, severity and specific symptoms of MS in any one person cannot yet be predicted, but advances in research and treatment are moving us closer to a world free of MS. Access to MS medications, including disease modifying therapies (DMTs) has transformed MS treatment over the last two decades. Today there are 15 FDA-approved DMTs that reduce disease activity and disease progression for many people with relapsing forms of MS, including the recent approval of the of the first ever therapy for primary progressive MS.

MS DMTs are crucial to people living with MS; yet too often high prices, escalating price increases, a complex and opaque supply chain growing out-of-pocket costs, and confusing and inconsistent formularies create real barriers between people living with MS and their ability to access the medications they need to live their best lives. As there are no easy answers to this complex issue, the Society’s Advisory Committee on Access to MS Medications – comprised of people with MS, family members, health policy experts and healthcare providers – released [recommendations](#) (also attached) as a part of the Society’s “Make MS Medications Accessible Initiative” (Initiative) to ensure that MS medications are affordable and formularies are simple and transparent. The Initiative calls on all parties involved – pharmaceutical companies, insurance providers, pharmacy benefit managers, specialty pharmacies, health care providers, policy makers, and patients – to work together to address escalating prices and other issues that are creating significant barriers to treatment.

## **Price Increases**

This Initiative calls on government agencies to intervene when the free market does not appear to be working to reduce the cost of medications for a single disease class. Current industry incentives are based on a simple supply and demand economic model, which is not what we see for specialty medications like MS disease modifying therapies. While the pharmaceutical industry states that products are based on “what the market will bear”, this ignores the complexity of the specialty drug market, the perverse incentives within the supply chain and the blurred lines between the numerous “purchasers” and end users of the product.

We believe that heightened scrutiny is needed to regulate markets that do not fit the expectations of a typical competitive market, like those for specialty drugs. All of the top 10 specialty medication classes, which includes MS, increased in spend and all had increases in the price of the medications<sup>1</sup> In 2014, the average wholesale price of available MS disease-modifying therapies (DMT) was \$16,000. In 2013, the average price was \$61,000; at the beginning of 2017, the average price of an MS DMT is \$83,688 (all average wholesale prices). We see significant price increases in most new products on market, but more troubling is that we see continuing escalating prices for DMTs that have long been on market, with some even off-patent. Between 2012 and 2017, the mean annual percent increase in cost ranged from 0 to 14.4%. Nearly three-quarters of the MS DMTs average more than one price increase per year.

We believe the FTC has a role to explore continual price increases that are significantly above the rate of the national health expenditure for medications that have long been on the market. Additionally, as noted during the public workshop, the prescription drug market should not be viewed as a single market and instead should be viewed as smaller disease markets, and each should be examined as its own independent market and not necessarily as reflective of the larger pharmaceutical market. There can be nuanced differences within disease states that add challenges to the expectation of performance as a typical competitive market. For example, MS is a heterogenous disease, and patients with the same type of MS and disease course may respond differently to each treatment. A patient that is stable on one medication may not have the ability to choose to switch to a cheaper medication because they may react negatively, find the side effects to be unmanageable, or the treatment may conflict with the patient’s desired treatment outcome. While there are more than a dozen DMTs, these treatments are not interchangeable for people with MS. We encourage FDA and FTC to explore whether within a therapeutic class, there needs to be a narrowing of markets based on lack of interchangeability among products.

## **The Role of Generics**

Recently, the FDA hosted a public meeting to gain input on how best to preserve Congress’ intended balance in the Hatch-Waxman Amendments between encouraging innovation in drug development and accelerating the availability of lower-cost alternatives to innovator drugs to the public. The Society responded to that request, joining many of the public statements submitted to the Agency in commenting that some manufacturers have leveraged current FDA regulations to delay or prevent generic competition. These actions, including “pay-for-delay”, product hopping, evergreening, or utilizing Citizens Petitions and risk evaluation and mitigation strategies (REMS) with the goal of delaying generic entry, are all examples of harmful strategies that have been utilized and were discussed at the public meeting. If a practice is intended to prevent generic competition, the Society believes that such practices should be considered anti-competitive and the FTC should take appropriate enforcement action to curtail their use.

Many MS medications have REMS both with and without elements to assure safe use (ETASU). These therapies are vital to people with MS, and without REMS, would not be able to be approved by the

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<sup>1</sup> 2015 Drug Trend Report. The Express Scripts Lab: Express Scripts; March 2016.

FDA. While legally REMS are not supposed to restrict competition, stakeholders and participants at the FTC workshop and the FDA Hatch-Waxman meeting acknowledged that REMS programs have been used to delay competitors from market entry. There has been legislation offered in Congress that would help ensure that the use of REMS programs align with Congressional intent.

- The Creating and Restoring Equal Access To Equivalent Samples Act (CREATES Act, S. 974/H.R. 2212) allows the FDA more discretion to approve alternative safety protocols, rather than require parties to develop shared safety protocols.
- The Fair Access for Safe and Timely Generics Act (FAST Generics Act, H.R. 2051) states that for a medication subject to a REMS, a generic developer must have FDA authorization to obtain the medication before brand company must provide it. The FDA may authorize a product developer to conduct testing and clinical trials with the medication and may prohibit or limit transfer of a medication to a product developer if the transfer poses an imminent hazard to public health. Further, the FAST Generics allows FDA to waive the requirement that a medication use a single, shared system of ETASU with a comparable approved medication if the generic and brand manufacturers are unable to agree.

We recommend that both FDA and FTC work with Congressional leaders to ensure that both Agencies have the means and enforcement authority to ensure that REMS programs are not used to delay generic entry.

Additionally, the Society's Initiative calls on the FDA to eliminate market exclusivity protections for minor modifications of existing products that only serve to extend the life cycle of the product. Ensuring that market exclusivity is granted to products and therapies that are truly innovative and show significant clinical improvement or value over the current available treatments is vital to preserving the Congressional intent of the Hatch-Waxman framework. Extending market exclusivity protections for minor changes likely has a chilling effect on the introduction of lower-cost generics or biosimilars into the market.

Furthermore, our recommendations call for the FDA to prioritize approving multiple generic products per reference product. MS DMTs are very new to the generic space, so we know that multiple generics are required on the market before prices begin to be significantly impacted. We are pleased that the FDA plans to implement a Drug Competition Action Plan to increase generic competition and to expedite the review of generic drug applications until there are three approved generics for a given drug product, and we encourage the FDA and FTC to work collaboratively to address issues related to generic entry, transparency of generic prices and supply chain dynamics. We also encourage the FDA and FTC to closely watch generics in the specialty drug space as our initial experience indicates some differences between specialty drug generics and the more traditional generic medications. The FTC might consider an evaluation of various state laws and both federal and state regulations that may impact the mandatory use of generics, formulary coverage of specialty drug generics and whether out-of-pocket costs for the use of generic specialty medications are actually lower than for brand specialty medications.

### **Supply Chain**

Determining the role that pharmacy benefit managers (PBM's) and group purchasing organizations (GPOs) play in prescription drug pricing, consumer access, and quality is currently difficult to assess given the lack of information that is publicly available. The Society's recommendations call for increased transparency throughout the pharmaceutical system and supply chain- from manufacturers, insurers and pharmacy benefit managers and we urge the FTC to investigate the role of intermediaries and road blocks that impact pharmaceutical prices, access, and quality within the pharmaceutical supply chain.

We believe the FTC should explore the perverse incentives within the supply chain for manufacturers to charge higher prices and then rebate more extensively. It appears that when this happens, many within the supply chain benefit- except for the patient who may be faced with a higher cost-share per month and/or during a deductible period or Medicare's coverage gap.

Additionally, we urge the FTC and the FDA to consider the impact of mergers and consolidations within the health system and supply chain in decreasing competition and limiting choices for consumers (of insurers and distribution options). Do mergers and consolidations meet some of the stated goals of improving health outcomes? Are people with chronic illnesses impacted differently? Are there savings throughout the supply chain and health system due to mergers and consolidations? We encourage the FTC to examine these questions as the consolidation trend is continuing.

The Society appreciates this opportunity to comment to both the FDA and the FTC on the issues and questions that were posed at the public workshop. If you have any questions, please contact Leslie Ritter, Senior Director of Federal Government Relations at 202.408.1500 or [Leslie.Ritter@nmss.org](mailto:Leslie.Ritter@nmss.org).

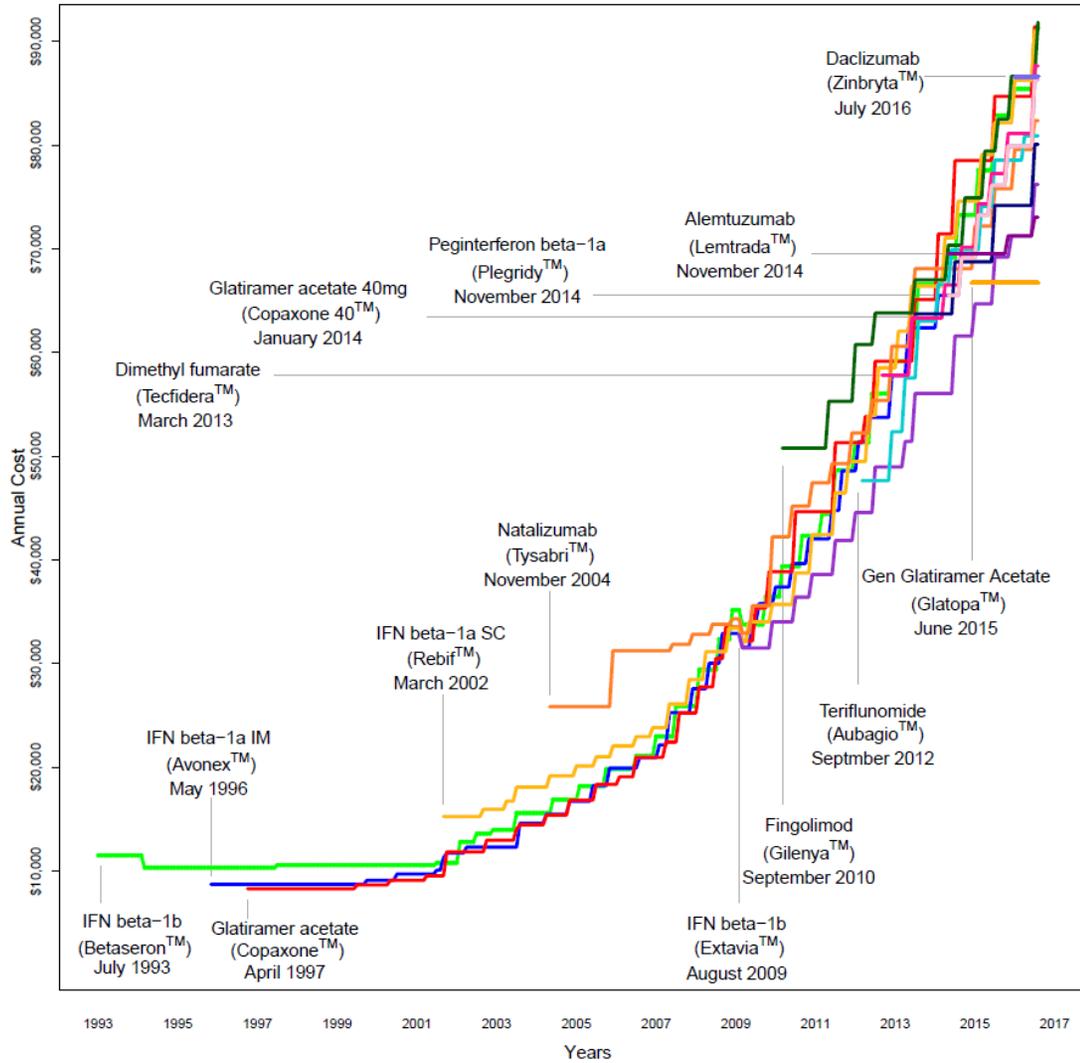
Sincerely,



Bari Talente  
Executive Vice President, Advocacy  
National Multiple Sclerosis Society

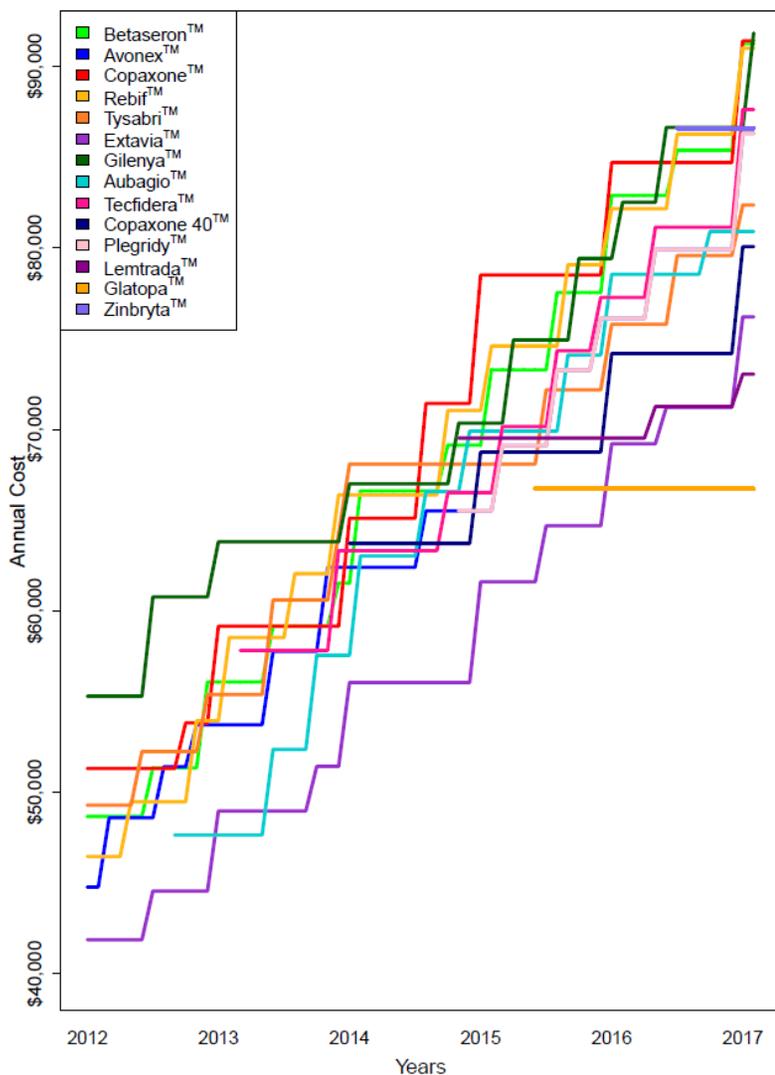
## Appendix

Trends in Annual Disease Modifying Therapy Costs 1993–2017



Drug	Approval Cost	Current Cost
Betaseron™	\$11,532	\$91,261
Avonex™	\$8,723	\$86,308
Copaxone™	\$8,292	\$91,401
Rebif™	\$15,262	\$91,005
Tysabri™	\$25,850	\$82,368
Extavia™	\$32,826	\$76,201
Gilenya™	\$50,775	\$91,836
Aubagio™	\$47,651	\$80,902
Tecfidera™	\$57,816	\$87,623
Copaxone 40™	\$63,715	\$80,062
Plegridy™	\$65,510	\$86,308
Lemtrada™	\$69,520	\$73,039
Glatopa™	\$66,731	\$66,731
Zinbryta™	\$86,592	\$86,592

## Trends in Annual Disease Modifying Therapy Costs 2012–2017



Drug	2017 Cost*	2012 Cost**	Mean Annual % Increase in Cost	Mean Number of Increases per Year	Mean % Change per Increase
Betaseron™	\$91,261	\$48,676	13.4%	2.2	5.9%
Avonex™	\$86,308	\$44,781	14%	2.2	6.2%
Copaxone™	\$91,401	\$51,315	12.2%	1.4	8.6%
Rebif™	\$91,005	\$46,464	14.4%	2.2	6.3%
Tysabri™	\$82,366	\$49,294	10.8%	1.8	5.9%
Extavia™	\$76,201	\$41,883	12.7%	1.8	6.9%
Gilenya™	\$91,836	\$55,295	9.4%	1.6	5.8%
Aubagio™	\$80,902	\$47,651†	14.2%	1.6	6.8%
Tecfidera™	\$87,623	\$57,816†	11.4%	1.8	6.1%
Copaxone 40™	\$80,062	\$63,715†	7.9%	1	7.9%
Plegridy™	\$86,308	\$65,510†	9.6%	1.7	5.7%
Lemtrada™	\$73,039	\$69,520†	1.7%	0.7	2.5%
Glatopa™	\$66,731	\$66,731†	0%	0	0%
Zinbryta™	\$86,592	\$86,592†	0%	0	0%

\*February 2017

\*\*January 2012

†Market entry cost if approved after 2012

Methodology adapted from Hartung et al.<sup>1</sup> We estimated acquisition costs using average wholesale price (AWP) published by First DataBank. AWP reporting was phased out in 2011 and acquisition costs were then estimated using wholesale acquisition cost (WAC) with the conversion  $AWP = 1.2 \times WAC$ . We applied a 12% discount to AWP, the median discount that state Medicaid programs reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers. Package insert for Lemtrada™ states initial dose is five consecutive daily infusions with three consecutive daily infusions in subsequent year. We estimate the annual cost for Lemtrada™ based on the use of four vials.

1. 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;84(21):2185–2192.