

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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August 17, 2017

Mr. Gary Zieziula
President
EMD Serono
1 Technology Place
Rockland, MA 02370

Dear Mr. Zieziula:

We are launching an in-depth investigation to determine why drug companies are dramatically increasing their prices for drugs used to treat Multiple Sclerosis (MS), which is a disease of the central nervous system that often has devastating and disabling effects on patients. We believe no American should be forced to struggle to afford lifesaving medical treatments, especially when drug companies increase prices without warning, cause, or justification.

According to experts, some drug companies appear to be increasing their prices and setting new, higher prices in lockstep with competitors—a strategy known as “shadow pricing.” When a company increases its price or introduces a new, more expensive drug into the market, other companies increase their prices to match—or shadow—these higher prices.

For example, a study on MS drug prices published by the *American Academy of Neurology* reported that “the dramatic increases in the costs of the first-generation DMTs [disease-modifying therapies] may have been a response to the introduction of competing treatments with higher prices.”¹ The study found:

Why the costs of MS DMTs in the United States have risen so dramatically is uncertain. However, the simplest explanation is that pharmaceutical companies raise prices of new and old MS DMTs in the United States to increase profits and our health care system puts no limits on these increases.²

According to this study, annual sales of MS drugs doubled from \$4 billion to nearly \$9 billion from 2008 to 2012. At the same time, the cost of the average annual disease-modifying

¹ Dr. Daniel Hartung et al., *The Cost of Multiple Sclerosis Drugs in the U.S. and the Pharmaceutical Industry: Too Big To Fail?*, *American Academy of Neurology* (May 26, 2015) (online at www.ncbi.nlm.nih.gov/pubmed/25911108).

² *Id.*

MS therapy was \$16,050 per patient in 2004, while the average annual cost of the disease-modifying therapy interferon increased to more than \$60,000 in 2015.³

As the study noted: “Classic economic theory asserts that competition should reduce or stabilize costs for the consumer as more products enter the market.”⁴

Unfortunately, this has not been the case in the MS drug market. The prices of more than a dozen MS therapies have increased sharply in the past decade, nearly in lockstep with new, more expensive entrants into the market.⁵

The MS market also lacks robust competition from the generic market. Currently, the only generic alternative is for the brand drug Copaxone 20 mg, and it is priced at \$66,731.⁶ Shortly before this generic was launched, however, the company that sells Copaxone developed a new 40 mg formulation that could be taken less frequently, and it switched approximately 70% of patients to this new formulation—which faces no generic competition.⁷ The generic reportedly captured only 25% to 30% of the 20 mg market by 2015.⁸

Your company appears to be following the market’s pricing pattern. Rebif has increased in price by 496% since it was approved in 2002, and has nearly doubled in price in just five years—between 2012 and 2017.⁹

³ *Id.*

⁴ *Id.*

⁵ *A Market-Based Proposal For Controlling Drug Prices*, Forbes Magazine (June 20, 2016) (online at www.forbes.com/sites/matthewherper/2016/06/20/a-market-based-proposal-for-controlling-drug-prices/); National Multiple Sclerosis Society, *Access to MS Medications* (online at www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/2017-PPC-Access-to-MS-Meds-Leavebehind.pdf) (accessed on Aug. 15, 2017); Office of the Attorney General, Commonwealth of Massachusetts, *Examination of Health Care Cost Trends and Cost Drivers* (Oct. 7, 2016) (online at www.mass.gov/ago/docs/healthcare/cc-pharma-100716.pdf); *Insurers Pay More for Multiple Sclerosis Drug Because Rebates Don't Help, Report Says*, Stat (Oct. 13, 2016) (online at www.statnews.com/pharmalot/2016/10/13/multiple-sclerosis-drug-prices-teva/).

⁶ National Multiple Sclerosis Society, *Access to MS Medications* (online at www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/2017-PPC-Access-to-MS-Meds-Leavebehind.pdf) (accessed on Aug. 15, 2017).

⁷ Express Scripts, *2015 Drug Trend Report* (Mar. 2016) (online at <https://lab.express-scripts.com/lab/drug-trend-report/~media/e2c9d19240e94fcf893b706e13068750.ashx>).

⁸ *How Teva Defended Copaxone From Generic Competition*, Drug Channels (Apr. 5, 2016) (online at www.drugchannels.net/2016/04/how-teva-defended-copaxone-from-generic.html); *Take the Generic, Patients Are Told. Until They Are Not*, New York Times (Aug. 6, 2017) (online at www.nytimes.com/2017/08/06/health/prescription-drugs-brand-name-generic.html).

⁹ Data in table from National Multiple Sclerosis Society, *Access to MS Medications* (online at www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/2017-PPC-Access-to-MS-Meds-Leavebehind.pdf) (accessed on Aug. 15, 2017) (“Methodology adapted from Hartung et al. 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 x WAC. We applied a 12% discount to AWP, the median discount that state Medicaid programs

<u>Brand Name</u>	<u>Year Approved</u>	<u>Approval Price</u>	<u>2012 Price</u>	<u>2017 Price</u>	<u>Total % Increase</u>
Rebif	2002	\$15,262	\$46,464	\$91,005	496%

In order to evaluate the underlying causes of the skyrocketing prices for MS drugs, we request you provide by August 31, 2017, the following information and documents from 2010 to the present:

- (1) A list of your company's profits and expenses for Rebif, including, but not limited to:
 - (a) profit (including operating and net);
 - (b) sales;
 - (c) cost of goods sold;
 - (d) operating cost;
 - (e) rebates (including commercial, Medicare Part D, and Medicaid rebates);
 - (f) discounts;
 - (g) allowances;
 - (h) coupons;
 - (i) patient co-pay;
 - (j) charge backs;
 - (k) direct selling expenses;
 - (l) medical affairs;
 - (m) marketing;
 - (n) research and development;
 - (o) Patient Assistance Programs;
 - (p) taxes; and
 - (q) any other expenses or costs;
- (2) all documents, including internal analyses or memoranda, that have been provided to, or prepared for, your company or your Board of Directors, referring or relating to sales, profits, and pricing strategies for Rebif;
- (3) all documents and communications relating to any tax deductions or benefits related to patient assistance programs, eligibility requirements and total number of applicants and recipients for Rebif;
- (4) all documents and communications concerning any efforts to extend the patent life of Rebif, including through the development of new drug strengths or formulations;

reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers.'').

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- (5) all documents and communications concerning your company's use of limited, restricted, or specialty distribution systems for Rebif; and
- (6) all agreements, contracts, and communications to or from suppliers, distributors, wholesalers, insurers, pharmacy benefit managers, retail pharmacies, and any other partner in the distribution channel for Rebif.

If you have any questions about this request, please contact Francesca McCrary with Ranking Member Cummings' staff at (202) 225-5051. Thank you for your consideration.

Sincerely,



Elijah E. Cummings
Ranking Member



Peter Welch
Member of Congress

cc: The Honorable Trey Gowdy, Chairman