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—those 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

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\(^2\) *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.\(^9\)

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\(^3\) Id.

\(^4\) Id.


\(^9\) 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
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.”).
(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

cc: The Honorable Trey Gowdy, Chairman

Peter Welch
Member of Congress
August 17, 2017

Mr. Philip Blake
Senior Bayer Representative and President
Bayer Healthcare Pharmaceuticals, Inc.
100 Bayer Boulevard
P.O. Box 915
 Whippany, NJ 07981

Dear Mr. Blake:

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


² Id.
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 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 seems to be following the market’s pricing pattern. The price of your MS medication Betaseron has increased by 691% since it was approved 1993, and has nearly doubled in price over the past five years.9

3 Id.
4 Id.
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
Mr. Philip Blake  
Page 3

<table>
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<th>Brand Name</th>
<th>Year Approved</th>
<th>Approval Price</th>
<th>2012 Price</th>
<th>2017 Price</th>
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<td>Betaseron</td>
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<td>$11,532</td>
<td>$48,676</td>
<td>$91,261</td>
<td>691%</td>
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</table>

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 Betaseron, 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 Betaseron;

(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 Betaseron;

(4) all documents and communications concerning any efforts to extend the patent life of Betaseron, including through the development of new drug strengths or formulations;

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 reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers.”).
(5) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for Betaseron; 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 Betaseron.

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 cooperation with this request.

Sincerely,

Elijah E. Cummings  
Ranking Member

Peter Welch  
Member of Congress

cc: The Honorable Trey Gowdy, Chairman
Mr. Michel Vounatsos  
Chief Executive Officer  
Biogen  
601 Pennsylvania Avenue NW  
Washington, DC 20004  

Dear Mr. Vounatsos:

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

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’s five MS drugs appear to be following the market’s pricing pattern. Four of your company’s MS drugs have seen at least double-digit percent price increases since they were approved, and one drug has increased in price by nearly 1,000%. Biogen’s newest drug, Zinbryta, was introduced in 2016 at the staggering price of $86,592 per year. By 2017, Biogen’s other four drugs had risen in price to match Zinbryta. The table below shows these price increases.\(^9\)

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\(^3\) Id.

\(^4\) Id.


\(^9\) 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-
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 that details the sale of each individual MS drug your company currently markets, 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 each individual MS drug your company currently markets;

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

*Zinbryta is co-promoted by Biogen and AbbVie.*
(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 each individual MS drug your company currently markets;

(4) all documents and communications concerning any efforts to extend the patent life of any MS drug your company currently markets, including through the development of new drug strengths or formulations;

(5) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for each individual MS drug your company currently markets; 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 each individual MS drug your company currently markets.

If you have any questions about this request, please contact Francesca McCrory 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
August 17, 2017

Mr. Paul Hudson  
Chief Executive Officer  
Novartis Pharmaceuticals Corporation  
1 Health Plaza  
East Hanover, NJ 07936

Dear Mr. Hudson:

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 MS therapy was $16,050 per patient in 2004, while the average annual cost of the disease-

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² Id.
modifying therapy interferon increased to more than $60,000 in 2015.\textsuperscript{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.”\textsuperscript{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.\textsuperscript{5}

The MS market also lacks robust competition from the generic market. Currently, your company’s drug Glatopa, which is priced at $66,731, is the only generic alternative for a brand MS drug—Copaxone 20 mg.\textsuperscript{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.\textsuperscript{7} Glatopa reportedly captured only 25% to 30% of the 20 mg market by 2015.\textsuperscript{8}

Your company’s brand MS drugs appear to be following the market’s pricing pattern. Your company’s first brand MS drug, Extavia, has increased in price by more than 130% since it was approved in 2009. Your company’s other brand MS drug, Gilenya, has nearly doubled in price in less than ten years. The table below shows these pricing developments.\textsuperscript{9}

\textsuperscript{3} Id.
\textsuperscript{4} Id.

\textsuperscript{6} Id.

\textsuperscript{7} Id.


\textsuperscript{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
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 that details the sale of each individual MS drug your company currently markets, 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 each individual MS drug your company currently markets;

(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 each individual MS drug your company currently markets;

reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers.”).
(4) all documents and communications concerning any efforts to extend the patent life of any MS drug your company currently markets, including through the development of new drug strengths or formulations;

(5) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for each individual MS drug your company currently markets; 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 each individual MS drug your company currently markets.

If you have any questions about this request, please contact Francesca McCrery 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
August 17, 2017

Mr. Daniel O’Day
Chief Executive Officer
Roche Pharmaceuticals
Konzern-Hauptsitz
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

Dear Mr. O’Day:

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.

Genentech, a member of the Roche Group, introduced Ocrevus—a drug used to treat relapsing-remitting and primary progressive MS—in March 2017, with a Wholesale Acquisition Cost (WAC) price of $65,000.\(^1\) The company was praised for setting the price of Ocrevus approximately 20% lower than other brand MS drugs currently on the market, but questions have been raised about whether Ocrevus—which is similar to Roche’s 2006 cancer drug Rituxan—is truly a new, breakthrough product or simply the reformulation of an old drug that may soon face biosimilar competition in in the U.S.\(^2\) One researcher described Ocrevus as an “expensive, overdosed version of Rituxan” and characterized Genentech’s commercialization of the drug as “shameless.”\(^3\)

Although the price of Ocrevus has remained stable since its introduction five months ago, experts have raised concerns that some drug companies appear to be increasing their prices and setting new, higher prices in lockstep with competitors—a strategy known as “shadow pricing.”

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\(^1\) MS Society, *FDA Approves Ocrevus™ (ocrelizumab) for People with Primary Progressive MS or Relapsing MS—First Disease-Modifying Therapy for Primary Progressive MS* (Mar. 29, 2017) (online at www.nationalmssociety.org/About-the-Society/News/FDA-Approves-Ocrevus).


\(^3\) Id.
Mr. Daniel O’Day
Page 2

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.” 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.

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 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.

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

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.

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.

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5 Id.

6 Id.

7 Id.


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.\textsuperscript{10} The generic reportedly captured only 25% to 30% of the 20 mg market by 2015.\textsuperscript{11}

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 Ocrevus, 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 Ocrevus;

(3) all documents and communications, including internal analyses or memoranda, relating to the use of clinical data or other information about the drug Rituxan (rituximab) in the development of Ocrevus,


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 Ocrevus;

(5) all documents and communications concerning any efforts to extend the patent life of Ocrevus, including through the development of new drug strengths or formulations;

(6) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for Ocrevus; and

(7) 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 Ocrevus.

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
August 17, 2017

Mr. Bill Sibold
Executive Vice President
Sanofi Genzyme
500 Kendall Street
Cambridge, MA 02142

Dear Mr. Sibold:

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

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\(^2\) *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.\(^\text{3}\)

As the study noted: "Classic economic theory asserts that competition should reduce or stabilize costs for the consumer as more products enter the market."\(^\text{4}\)

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.\(^\text{5}\)

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.\(^\text{6}\)

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.\(^\text{7}\) The generic reportedly captured only 25% to 30% of the 20 mg market by 2015.\(^\text{8}\)

Sanofi recently announced that it would limit future annual price increases across its portfolio to the National Health Expenditures (NHE) growth rate.\(^\text{9}\) This is a step in the right direction, given that your company’s MS drugs have historically followed the pattern of staggering launch prices and significant price increases. Aubagio has nearly doubled in price

\(^{3}\) Id.

\(^{4}\) Id.


since it was approved in 2012. Lemtrada’s 2014 approval price was 45% higher than Aubagio’s approval price just two years prior.  

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Year Approved</th>
<th>Approval Price</th>
<th>2012 Price</th>
<th>2017 Price</th>
<th>Total % Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aubagio</td>
<td>2012</td>
<td>$47,651</td>
<td>$47,651</td>
<td>$80,902</td>
<td>70%</td>
</tr>
<tr>
<td>Lemtrada</td>
<td>2014</td>
<td>$69,520</td>
<td>N/A</td>
<td>$73,039</td>
<td>5%</td>
</tr>
</tbody>
</table>

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 that details the sale of each individual MS drug your company currently markets, 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 each individual MS drug your company currently markets;

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10 Data in table from National Multiple Sclerosis Society, Access to MS Medications (online at www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy2017-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 reimburse pharmacies, to estimate the amount paid to pharmacies by third-party payers.”).
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 each individual MS drug your company currently markets;

(4) all documents and communications concerning any efforts to extend the patent life of any MS drug your company currently markets, including through the development of new drug strengths or formulations;

(5) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for each individual MS drug your company currently markets;

(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 each individual MS drug your company currently markets; and

(7) all documents and communications concerning Sanofi’s Pricing Principles as they relate to the MS drugs your company currently markets and any additional MS drugs in development, as well as responses to the following:

(a) Does Sanofi plan to limit future price increases for Aubagio and Lemtrada to the NHE growth rate?
(b) Does Sanofi plan to increase the prices of Aubagio and Lemtrada every year?
(c) Does Sanofi intend to place any total dollar limits on the future prices of Aubagio or Lemtrada?
(d) Please provide the annual gross and net price increases for Aubagio and Lemtrada since their introduction.

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

Sincerely,

Elijah E. Cummings  Peter Welch
Ranking Member  Member of Congress

cc: The Honorable Trey Gowdy, Chairman
Dr. Yitzhak Peterburg
Chief Executive Officer
Teva Pharmaceutical Industries
1090 Horsham Road
North Wales, PA 19454

Dear Dr. Peterburg:

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

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 Teva’s brand drug Copaxone 20 mg, and it is priced at $66,731.\(^6\) Shortly before this generic was launched, however, your company 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.\(^7\)

Your company’s MS drugs appear to be following the market’s pricing pattern. Copaxone 20 mg has increased in price by more than 1,000% since it was approved in 1997. Copaxone 40 mg, a new formulation of the same drug, was launched at a staggering price of $63,715 per year, and has seen a double-digit percent increase in price in just three years. The table below shows these price increases.\(^9\)

\(^3\) Id.
\(^4\) Id.


\(^9\) 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
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(o) Patient Assistance Programs;
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(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 each individual MS drug your company currently markets;

(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 each individual MS drug your company currently markets;

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(4) all documents and communications concerning any efforts to extend the patent life of any MS drug your company currently markets, including through the development of new drug strengths or formulations;

(5) all documents and communications concerning your company’s use of limited, restricted, or specialty distribution systems for each individual MS drug your company currently markets;

(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 each individual MS drug your company currently markets; and

(7) the rebate percentages and average rebate amounts paid by Teva to pharmacy benefit managers and/or commercial, Medicare Part D, and Managed Medicaid plans, for Copaxone 20 mg and Copaxone 40 mg, from 2014 to the present.

If you have any questions about this request please contact Francesca McCrary 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