

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

UNITED STATES of AMERICA; STATE of CALIFORNIA; STATE of COLORADO; STATE of CONNECTICUT; STATE of DELAWARE; DISTRICT of COLUMBIA; STATE of FLORIDA; STATE of GEORGIA; STATE of HAWAII; STATE of ILLINOIS; STATE of INDIANA; STATE of IOWA; STATE of LOUISIANA; STATE of MARYLAND; COMMONWEALTH of MASSACHUSETTS; STATE of MICHIGAN; STATE of MINNESOTA; STATE of MONTANA; STATE of NEVADA; STATE of NEW JERSEY; STATE of NEW MEXICO; STATE of NEW YORK; STATE of NORTH CAROLINA; STATE of OKLAHOMA; STATE of RHODE ISLAND; STATE of TENNESSEE; STATE of TEXAS; COMMONWEALTH of VIRGINIA; STATE OF WASHINGTON and STATE of WISCONSIN, ex rel. MICHAEL BAWDUNIAK,

Plaintiff-Relator,

v.

BIOGEN IDEC INC.,

Defendant

Civil Action No.:  
12-CV-10601-FDS

Filed Under Seal Pursuant  
to 31 U.S.C. § 3730(b)(2)

**PLAINTIFF-RELATOR  
DEMANDS A TRIAL BY  
JURY ON ALL COUNTS**

**SECOND AMENDED COMPLAINT**

On behalf of the United States of America, 28 States, \* and the District of Columbia (collectively, the "States"), Plaintiff-Relator Michael Bawduniak (the "Relator") hereby files this Amended Complaint against Defendant Biogen Idec, Inc. ("Biogen") under the False Claims Act, and alleges as follows:

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\* The States on whose behalf the Plaintiff-Relator brings this action are: California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington and Wisconsin.

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## INTRODUCTION

1. This action concerns false and fraudulent Medicare and Medicaid reimbursement claims that Biogen caused through a massive scheme to pay millions of dollars in kickbacks to the highest volume prescribers of its two leading products. For several years, Biogen has been defrauding Medicare, Medicaid, and other federal programs by providing financial rewards to physicians to induce them to prescribe Biogen's multiple sclerosis (MS) treatments. The goal of this kickback scheme was to preserve the eroding market share of its older biological product Avonex and to increase the market share of its newer biological product Tysabri. Biogen knowingly identified the top prescribers of its drugs and paid them millions to keep their prescriptions at profitable levels. The return on Biogen's investment in this kickback scheme was significant, and came largely at the expense of federal and state coffers.

2. Biogen's kickback scheme was and continues to be massive. In just 2009 and 2010, for example, the company paid a total of \$18 million to 1,500 doctors and nurses, who collectively write prescriptions totaling approximately 60% of the MS market. Rather than waste its time and money marketing to the other 16,000 neurologists who only account for 40% of the market, Biogen found it more cost effective and profitable to simply buy commercial loyalty from the minority that writes a majority of the prescriptions.

3. This multimillion dollar kickback scheme capitalized on the unique nature of multiple sclerosis. MS is an incurable disease which can lead to complete debilitation. A small group of products known as immunomodulating agents (IMA) are approved to



treat MS. Not surprisingly, given the severe and incurable nature of the disease, these treatments are enormously expensive. The annual cost of an IMA drug for a single patient is between \$35,000 to \$70,000. Thus, once a patient is placed on one drug company's MS drug, that company stands to receive hundreds of thousands of dollars over the course of the patient's life. And because there is a relatively small number of neurologists who treat MS, each prescriber has the ability to direct millions of dollars in revenue to one company's benefit or another. The obvious temptation is to influence these decisions through kickbacks.

4. Due to the nature of the disease and its treatment, a high percentage of Avonex, Tysabri and other MS drugs are paid for by federal health care programs. MS frequently disables its sufferers and those who are totally disabled can qualify for Medicare, even if they are not yet 65 years old. Nearly a quarter of all non-cancer enrollees in Medicare (at least in 2005) were MS patients and approximately 30% of all MS drug payments are paid for by Medicare. MS therapies represent Medicare's second largest drug expenditure, after cancer treatments. In 2006 and 2007, Medicare spent more than \$500 million on MS treatments; Avonex alone accounted for roughly \$170 million of these expenditures for those two years. Others who are unable to work or who cannot afford the expensive care are enrolled in the Medicaid program, a joint program of the federal government and the states. A 2007 study found that an additional 10.5% of MS patients were covered by Medicaid. Thus the federal government and the individual states pay for close to half of all funds paid for multiple sclerosis drugs.

5. Prior to 2010, six different IMAs were used to treat MS, and for most patients these biological products were highly interchangeable. All carried essentially the same FDA-approved indication. Five of the six products were injected, and four of those contained indistinguishable proteins called interferons. But the problem with interferon is that it commonly produces flu-like side-effects. This left Teva's Copaxone, which did not contain interferon, as the emerging marketing leader. By early 2008, Copaxone surpassed Avonex in sales, dealing a tremendous blow to Biogen, which claimed to be a market leader in MS.

6. Even with the addition of Tysabri to its portfolio, Biogen could do little to reclaim its former position at the top of the market. If anything, Biogen's two products were at a slight disadvantage. Of the injectable products, Avonex was the only one that required injection deep into muscle tissue, rather than the more convenient injection just under the skin. Avonex also had the lowest perception of efficacy among doctors. Tysabri was even less convenient because it is only administered by infusion and has the possibility of a more severe and potentially fatal side effect called PML.

7. Biogen had a plan. It had been studying the MS market since Avonex's approval in 1996, and knew the most important fact: a relatively small number of prescribers dominate the entire market. Six thousand doctors write over 90% of the prescriptions for MS drugs, and just 1,200 doctors wrote 60% of the IMA prescriptions. The economics and demographics of multiple sclerosis make it a fertile ground for a kickback scheme. Pharmaceutical companies, over the years, have recognized that occasional payments of a few thousand dollars (or, alternatively, the granting of

expense paid trips to resorts) have strongly motivated the recipients to prescribe the payor's drug for their patients.

8. Kickbacks, however, are illegal. By 2008 enhanced enforcement and revised industry guidelines had curtailed the use of this tactic in most of the industry. Over the years, however, Biogen had honed its ability to distribute large amounts of money to large numbers of physicians without appearing to have engaged in illegal kickback activity. Biogen exploited two mechanisms for making payments to physicians – retaining them as consultants and hiring them as speakers – that were permissible if performed in a reasonable and limited fashion. Biogen expanded these exceptions well beyond permissible boundaries so that its sham consulting and speaking schemes were mere conduits for the channeling of illegal payments to the maximum number of high prescribers.

9. Pursuant to the sham consulting scheme, the Department of Regional Marketing discerned that the company required "consultation" was needed on a number of similar topics relating to the marketing of its well-established drugs. The documented need for such consulting was purely imaginary, as neither the company's market research department (which was responsible for holding legitimate consultant meetings) nor its brand managers had ever made inquiries on the topics that supposedly required consultation. Biogen then held dozens of consultant meetings that required the attendance of hundreds of doctors across the country, liberally paying consulting fees to the physicians who attended. Unsurprisingly, "consultants" were effectively selected by local sales officials, who based their selection on the consultant's



prescribing volume as opposed to their supposed expertise on the topic of the meeting. From any legitimate perspective, the meetings made little sense. The average consultant attended more than one consulting event a year. It would have been more cost effective for Biogen to ask all of its questions to a particular consultant at just one meeting, rather than at two or three. Nor was it necessary to ask the same questions in 15 different cities. Biogen hired so many consultants that it could not have acted on the advice it received even if it had intended to do so.

10. The illegal purpose of these payments was manifest. Biogen did not pay doctors to consult unless they were high prescribers; academic affiliations, educational pedigree, and published works were irrelevant. The only criteria that mattered were the physician's prescribing volume and ability to influence peers. Not surprisingly, the sales force routinely suggested that certain doctors be selected as consultants. Biogen carefully documented its purported need for such consulting to make the consultations appear legitimate on paper. But ultimately it retained far more consultants than it required, and never did anything with the expensive "consulting product" that it received.

11. A second method of funneling funds was the training of "speakers" to talk to other physicians about Biogen's drugs. Speakers are paid when they obtain training and paid again when they are supposed to present, even if no one attends the scheduled meeting. Biogen constantly trained speakers for both Avonex and Tysabri, even though most speakers would only present twice (or less) a year and many presented to only a single person—often someone they already worked with. Given that there was no

demand for additional presentations about these established drugs and that there were many experienced speakers who could handle what little demand existed, the expansion of the speaking program was a complete sham operated solely to pay physicians to remain loyal to Biogen. Importantly, Biogen selected speakers based on their prescribing ability, not their speaking ability.

12. The scope of the kickback scheme was staggering. In 2009 alone, Biogen paid 820 physicians a total of \$8.8 million to speak or consult, \$10,600 per physician. Faced with the market entry of the first oral treatment for MS, Gilenya, Biogen expanded these programs in 2010. In that year, Biogen paid 1,200 physicians a total of \$9.1 million to speak or consult. Biogen's kickback payments were distributed fairly evenly between excessive, duplicative, and redundant consulting meetings on one hand, and training an excessive number of unnecessary speakers on the other.

13. Biogen's internal Compliance Department, which was responsible for preventing the payment of kickbacks, had no ability to stop them. The Compliance Department often criticized the suspect nature of these payments but was overruled by marketing executives. Compliance reviewed every single proposal and routinely expressed concerns that there were too many meetings, too many consultants, and too many payments. Each time, these concerns were disregarded by Tony Kingsley, Senior Vice President of US Commercial Operations (and the member of senior management who instructed the Relator to create the consulting programs) or a marketing vice president.

14. The kickback program was a success. Avonex was able to stop its loss of market share and hold sales constant, despite FDA approval of a new MS drug that is taken orally. With price increases, Biogen pushed its US sales of Avonex to \$1.5 billion annually. And Tysabri sales continued to grow, despite a black box warning of deadly side effects. The kickback program was so successful that Biogen continues to use sham consulting meetings and unnecessary speaking engagements to pay favored physicians. Moreover, with Biogen now introducing its own oral MS medication, BG-12 (also known as Tecfidera), to the market, it has once again turned to its proven strategy to motivate physicians to prescribe its products.

#### PARTIES

15. Relator Michael Bawduniak is an individual who resides in New Hope, Pennsylvania. He has been an employee of Biogen since 2004. Between 2004 and 2006, he was an Area Business Manager, the title given to Biogen sales representatives. From 2007 to 2009, he was a Regional Senior Marketing Manager (RSMM). He was promoted to the position of Director of Regional Marketing on an interim basis in 2009. In 2011, after he attempted to halt the payment of kickbacks to physicians that Biogen feared would transfer their brand loyalty to Gilenya, he was demoted to his former position, now known as Thought Leader Liaison. Mr. Bawduniak left Biogen in 2012.

16. Defendant Biogen Idec Inc. ("Biogen") is a Delaware corporation with a principal place of business in Weston, Massachusetts. Biogen conducts business in each and every state in the United States on a daily basis.

**JURISDICTION & VENUE**

17. Pursuant to 28 U.S.C. § 1331, this District Court has original jurisdiction over the subject matter of this civil action since it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"). In addition, the FCA specifically confers jurisdiction upon the United States District Court. 31 U.S.C. § 3732(b).

18. Pursuant to 28 U.S.C. § 1367, this District Court has supplemental jurisdiction over the subject matter of the claims brought pursuant to the false claims acts of the States on the grounds that the claims are so related to the claims within this Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.

19. This District Court has personal jurisdiction over Biogen pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Biogen has sufficient minimum contacts with the United States of America.

20. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because Biogen's corporate headquarters are located in this judicial district and it transacts business here on a daily basis.

21. The is unaware of any public disclosure of the information or allegations that are the basis of the Complaint or Amended Complaint. In the event that there has been a public disclosure, the Relator is the original source of the information and allegations contained in this Complaint. Prior to the filing of this action, the Relator voluntarily provided the United States Government with information regarding the

false claims that are the subject of this Complaint as early as November 18, 2011. The Relator further sent notice of the false claims to the States alleged in this Complaint on April 4, 2012.

### NATURE OF ACTION

22. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), makes “knowingly” presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim.

23. The False Claims Act makes “knowingly” making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim.

24. The False Claims Act makes any person who conspires to commit a violation of the FCA liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim.

25. The False Claims Act defines a “claim” to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient. Any claim



submitted by a Medicare or a Medicaid provider for a payment constitutes a claim under the False Claims Act. Any claim submitted by a provider for payment by a federal insurance plan, such as Tricare, is also a "claim" for purposes of the False Claims Act.

26. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), makes it a felony to pay or receive gifts or remuneration that can influence healthcare decisions. Specifically, the Anti-Kickback Statute prohibits anyone from:

knowingly and willfully...pay(ing) any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . .order, or arrange for or recommend ...any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

27. A transaction may violate the Anti-Kickback Statute even when a payor's unlawful intent is not its exclusive intent. It is enough that "*any one purpose* of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program." *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 3, 2003) (emphasis added). In other words, even "a lawful purpose will not legitimize a payment that also has an unlawful purpose."

28. Every provider who enters into a contract with Medicare agrees to comply with Medicare's laws, regulations and program instructions. Each provider specifically acknowledges in its provider contract that the provider understands "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not

limited to, the Federal anti-kickback statute and the Stark law), and on the [provider]'s compliance with all applicable conditions of participation in Medicare." Upon information and belief, each of the States' provider agreements in their respective Medicaid programs contains comparable provisions agreeing to comply with the Anti-Kickback statute and acknowledging that their receipt of payment is conditioned upon compliance with such provisions.

29. Medicare and Medicaid claims for reimbursement of any goods or services that were the subject of a kickback constitute false claims. This is because compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a condition of payment for any goods or services reimbursed by Medicare or Medicaid, including drugs and, in the case of MS drugs, office or outpatient visits to inject or infuse such drugs.

30. Additionally, a recent amendment to the Anti-Kickback Statute, effective on March 23, 2010, states: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Consequently, any kickbacks paid by Biogen on or after March 23, 2010 constitute False Claims regardless of the provisions of any provider agreement or state Medicaid statute.

31. When a kickback has been paid, the measure of damages is the full amount of the claim caused by the kickback—such as the amount of payments billed to Medicare or Medicaid as a result of an Avonex or Tysabri prescription induced by a kickback. Every Avonex or Tysabri prescription written by a physician to whom Biogen paid a kickback is tainted, and the full cost of all amounts paid due to such prescriptions is owed back to the government. From 2009 through the present, Medicare and the state Medicaid programs have paid hundreds of millions of dollars for Avonex and Tysabri prescriptions written by physicians to whom Biogen had knowingly paid kickbacks.

### **FACTUAL ALLEGATIONS**

#### **A. Multiple Sclerosis**

32. Multiple Sclerosis is a chronic, autoimmune, inflammatory, demyelinating disease of the central nervous system, which is made up of the brain, spinal cord, and optic nerves. MS damages the myelin sheath surrounding nerve fibers in the brain and spinal cord, impairing conductivity, and causing visual, sensory, and motor disturbances. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. The progress, severity, and specific symptoms of MS are unpredictable and vary from one person to another. Nevertheless, the disease is chronic, and for many of the 400,000 Americans with MS, the disease is disabling. MS is the leading cause of disability among young adults.

33. While the cause of MS is not known, it is thought to be an autoimmune disease where the body's own defense system attacks myelin, the fatty substance that

surrounds and protects the nerve fibers in the central nervous system, and often damages the nerve fibers themselves. The damaged myelin forms scar tissue (sclerosis), which gives the disease its name. When any part of the myelin sheath or nerve fiber is damaged or destroyed, nerve impulses traveling to and from the brain and spinal cord are distorted or interrupted, producing the variety of symptoms that can occur.

34. Multiple Sclerosis typically presents in one of four courses, each of which can be mild, moderate, or severe: (1) People with *relapsing-remitting* MS experience clearly defined attacks of worsening neurologic function. These attacks – which are called relapses, flare-ups, or exacerbations – are followed by partial or complete recovery periods (remissions), during which no disease progression occurs. Approximately 85% of people are initially diagnosed with relapsing-remitting MS. (2) People with *primary-progressive* MS suffer slowly worsening neurologic function from the beginning – with no distinct relapses or remissions. The rate of progression may vary over time, with occasional plateaus and temporary minor improvements. Approximately 10% of sufferers are diagnosed with primary-progressive MS. (3) People with *secondary-progressive* MS experience a steadily worsening condition that follows the initial period of *relapsing-remitting* MS. Before the disease-modifying medications became available, approximately 50% of people with relapsing-remitting MS developed this form of the disease within 10 years. However, long-term data are not yet available to determine whether the use of disease-modifying medications significantly delays this transition. (4) People with *progressive-relapsing* MS, one of the rarest courses of MS, experience steadily worsening disease from the beginning, but

with clear attacks of worsening neurologic function along the way. They may or may not experience some recovery following these relapses, but the disease continues to progress without remissions.

**B. The Market for MS Drugs in the United States**

35. There is no cure for MS, but the FDA has approved some drugs, including Avonex and Tysabri, to treat MS symptoms. The FDA has approved these drugs for the treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. All of the approved treatments are biologicals that fall under the class of agents known as immunomodulating agents (IMAs).

36. All of the IMAs approved for treatment of MS are still under patent protection. Their manufacturers, including Biogen, have priced these medications to maximize their profits at the expense of Medicare, Medicaid, and private insurance programs. As a result of these pricing policies, the annual mean cost of treating MS is \$47,000, nearly all of which goes to drug therapy. The total annual cost for the United States' health care system is \$13 billion.

37. Because of the inelastic market for MS treatments, increased competition has resulted in increased prices, not lower prices. For example, Biogen has doubled the price of Avonex since 2007. When Novartis announced that the price for Gilenya in 2010 would be set at almost \$50,000 a year, Biogen's response was to raise the price for both Avonex and Tysabri.



38. The following table lists the FDA approved treatments for MS in 2011, and their estimated annual cost at that time:

| <b>Product</b>          | <b>Company</b>          | <b>FDA approval</b>     | <b>Annual price</b> |
|-------------------------|-------------------------|-------------------------|---------------------|
| Betaseron               | Bayer                   | 1993                    | \$37,000            |
| <b>Avonex</b>           | <b>Biogen Idec</b>      | <b>1996</b>             | <b>\$37,500</b>     |
| Copaxone                | Teva                    | 1996                    | \$42,000            |
| Novantrone <sup>2</sup> | Serono/Immunex          | 2000                    | \$3,000             |
| Rebif                   | Serono, Inc./Pfizer     | 2002                    | \$37,000            |
| <b>Tysabri</b>          | <b>Biogen Idec/Elan</b> | <b>2006<sup>3</sup></b> | <b>\$43,000</b>     |
| Extavia                 | Novartis                | 2009                    | \$35,000            |
| Gilenya                 | Novartis                | 2010                    | \$48,000            |

### C. Biogen's MS Products and Their Competition

39. Avonex (interferon beta-1a) was approved by the FDA in May 1996 and is indicated for the treatment of patients with relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Avonex is administered through weekly intramuscular injections. Many patients self-inject the medication, but some require weekly doctor's visits for their therapy.

40. Interferons such as Avonex are amino acid glycoproteins released by host bodies in the presence of pathogens such as viruses, bacteria, parasites, or tumor cells. Interferon proteins can be derived from various sources. Those that are derived from mammalian cells—like Avonex and Rebif—are called interferon beta-1a; those that are

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<sup>2</sup> Novantrone is chemotherapeutic agent, and thus is not considered part of the disease-modifying class of biological products approved to treat MS. And as its sales are negligible, it is generally ignored by the MS industry and thus will be ignored for purposes of this Amended Complaint.

<sup>3</sup> Tysabri was initially approved in 2004, but was withdrawn early in 2005 due to safety concerns.

derived from *E-coli* – like Betaseron and Extavia – are called interferon beta-1b. It is believed that biological products containing interferon beta are beneficial in treating MS because of their anti-inflammatory properties. One of the most common side-effects of interferons such as Avonex is flu-like symptoms.

41. Avonex sales in the United States have exceeded \$1 billion annually for many years. Between 2009 and 2011, Biogen received more than \$4.5 billion in revenue from US sales of Avonex.

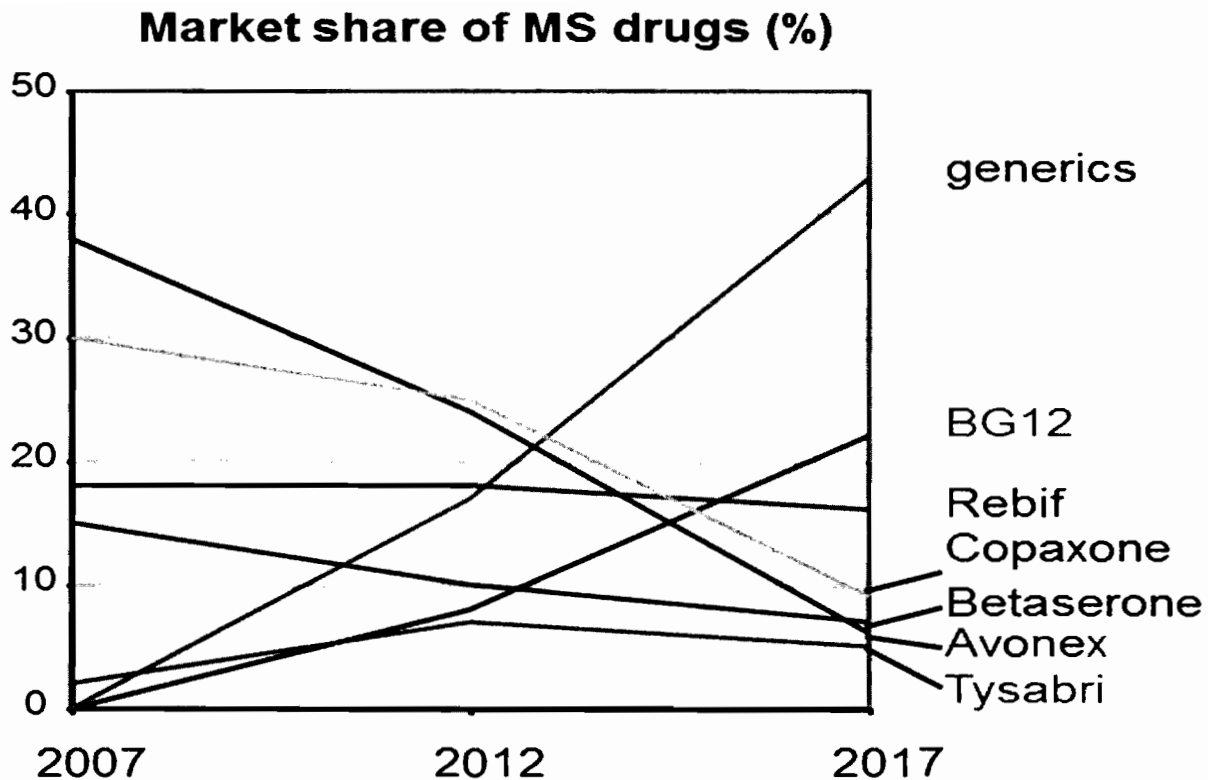
42. Tysabri (natalizumab) was approved by the FDA in November 2004 and is indicated for the treatment of patients with relapsing forms of multiple sclerosis to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations. Tysabri is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate MS therapy. Tysabri is administered through infusion. Patients being treated with Tysabri must receive treatments at an outpatient infusion therapy clinic once every four weeks. Tysabri cannot be self-administered or taken in one's home.

43. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. For this reason, Biogen withdrew Tysabri from the market until such safety concerns could be addressed to the satisfaction of the FDA. In June 2006, Biogen re-launched Tysabri, with availability restricted to patients enrolled in the TOUCH Risk Minimization Action Plan. Despite the TOUCH program, there have been 212 PML cases and 46 deaths in Tysabri MS patients as of March 1, 2012.

44. Tysabri sales in the United States have exceeded \$200 million annually for several years, and exceeded \$300 million in 2011. Domestic sales between 2009 and 2011 exceeded \$840 million.

45. Prior to the launch of the more recent IMAs, Biogen's products dominated the MS market. In 2004, Avonex had 40% market share, outselling the other three biological products in its class: Betaseron, Copaxone, and Rebif. When Tysabri was re-launched in 2006, Biogen still dominated the MS market. Avonex alone accounted for 37% of US sales, which was more than Copaxone's 32% market share, and more than Betaseron and Rebif's combined 30% market share.

46. By 2007, Avonex had been on the market for over a decade and was beginning to lose market share to newer competitors. Tysabri could not protect Biogen's market position because of its safety concerns. A Yale School of Management analysis predicted Avonex dropping to below a 30% market share by 2010, and freefalling to less than 10% by 2016. In 2009 a new competitor, Novartis, would enter the market and in 2010 it would introduce the first oral treatment for MS, Gilenya. Gilenya posed a particularly serious threat to Biogen's market dominance because patients unquestionably preferred taking a daily pill to receiving a weekly shot or a monthly infusion, as the following table from the analysis shows:



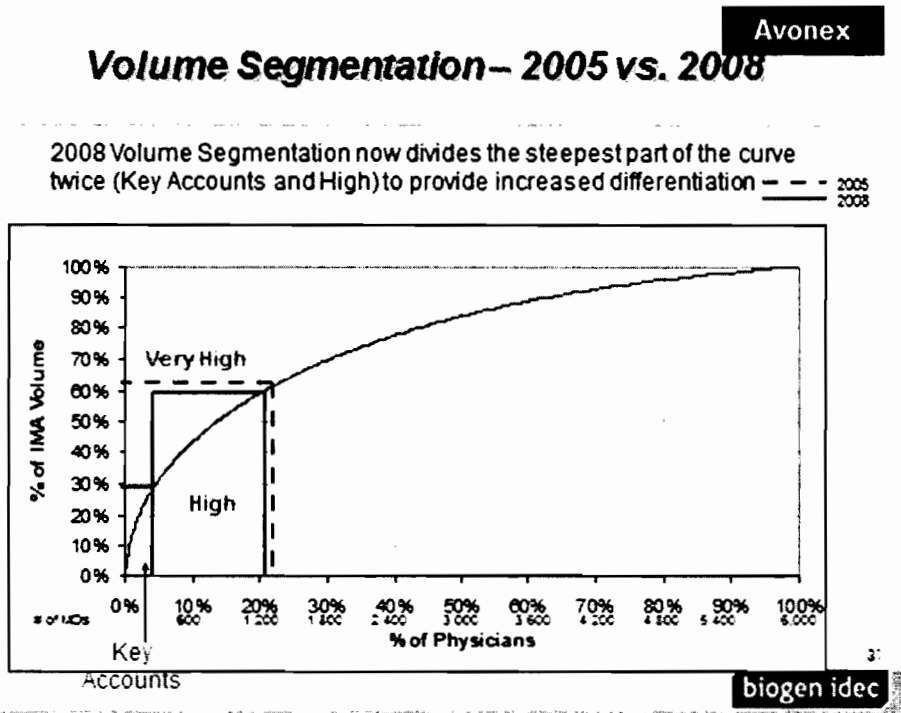
47. By 2008, it was clear that Avonex was losing market share to the other injectibles, which had better perceived efficacy and were more comfortable for patients because they could be injected subcutaneously, rather than intramuscularly. Copaxone in particular had an advantage, because it did not contain interferon and thus lacked the flu-like side-effects associated with those products. In fact, by early 2008, Copaxone surpassed Avonex in sales, knocking it out of the top position it had held for most of the decade.

48. The gloomy forecast got worse for Biogen in 2009. In mid-2009, Novartis launched its own interferon called Extavia. While this product had little anticipated impact, its launch was intended to pave the way for Novartis's launch in late 2010 of Gilenya. Gilenya was expected to cause Biogen's market share to decline even further

because it was the first oral treatment for MS. Assuming comparable safety and efficacy, a patient would naturally opt for a pill over needles.

**D. A Small Number of Physicians Determine the Treatments that MS Patients Receive**

49. Most of the 400,000 MS patients in this country receive their treatment from the 13,000 to 17,000 neurologists in the United States. Just 300 neurologists, however, write 30% of all IMA prescriptions for the treatment of MS. 1,200 prescribers write 60% of IMA prescriptions, and the top 6,000 wrote 90%. Biogen was well aware of this concentration in the market, as demonstrated by the following slide, and deliberately focused its marketing efforts on the lucrative prescribers – those neurologists who were either in the top 20% of prescribers, or, even better, those in the top 5%:





50. Biogen devised a way to identify and target the doctors who wrote 60% of prescriptions for MS (depicted in the red boxes above) and thus would provide the “most bang for the buck.” This plan was summarized in the 2008 Physician Segmentation and Call Plan, which called for Biogen to focus only on the top 6,000 prescribing neurologists, and ignore the other roughly 10,000 who offered little return on investment. Biogen divided these top 6,000 prescribers into four groups based on their prescription volume. These volume groups were called “key accounts,” “high,” “medium,” and “low.” The “key accounts,” as the label implies, were the most coveted prescribers – these were the 300 neurologists whose prescriptions accounted for 30% of the market. When added together with the “high” volume prescribers, Biogen could target 60% of the MS market through just 1,200 physicians.

51. Biogen then divided these same 6,000 physicians a different way, by product loyalty. Those already loyal to Biogen were “Avonex advocates,” while those trending towards Biogen were “Avonex opportunity.” Those loyal to a competitor – and thus disloyal to Biogen – were labeled “Competitor Advocates”; those trending away from Biogen were labeled “Avonex Risk.” In terms of past and present economic value to Biogen, “Avonex Advocates” and “Avonex Risk” were the most valuable, and “Avonex Opportunity” and “Competitor Advocates” had the least value to Biogen.

52. Having identified the volume potential and loyalty of each of the top 6,000 physicians, Biogen then overlaid these categorizations, assigning each physician to the 16 resulting groups:

## ***Number of MDs in Each Avonex Segment***

|                     | Volume Segment |              |              |              | Total        |
|---------------------|----------------|--------------|--------------|--------------|--------------|
|                     | Low            | Medium       | High         | Key Accounts |              |
| Avonex Advocate     | 259            | 237          | 77           | 36           | 609          |
| Competitor Advocate | 388            | 315          | 99           | 34           | 836          |
| Avonex Opportunity  | 781            | 998          | 368          | 92           | 2,239        |
| Avonex Risk         | 593            | 1,011        | 452          | 117          | 2,173        |
| None*               | 17             | 81           | 45           | 0            | 143          |
| <b>Total</b>        | <b>2,038</b>   | <b>2,642</b> | <b>1,041</b> | <b>279</b>   | <b>6,000</b> |

\*None = "Exception" physicians identified by ABMs that are Kaiser, VA/DoD, etc. writers with total volume not fully reported in available data. The ABMs designated the Volume Segment.

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53. The primary goal of paying doctors was to preserve existing market share. Given that every new patient placed on a Biogen MS drug could generate between \$30,000 to \$45,000 per year for an indeterminate number of years, Biogen further knew that losing even a small percentage of a high writer's prescription share could cause significant revenue loss. For example, losing just a 2% market share of a key account who placed 500 patients on IMA therapy would translate to an annual loss of 10 patients and more than \$300,000 in lost annual revenue. It was imperative not to allow such a neurologist to transition even a small percentage of his patients from Avonex's weekly intramuscular injections to an oral medication or subcutaneous injection.

**E. Biogen Uses Kickbacks to Secure its Market Position**

54. It is an open secret that drug companies have routinely used disguised payments to physicians to induce the doctors to prescribe their drugs over those of a competitor. Under the guise of providing “consulting services,” for example, drug companies have frequently provided high-level prescribers all-expenses-paid junkets to expensive resorts where they might attend a program presented by the company while enjoying the sunshine and cuisine. No *bona fide* effort would be made in these trips to actually obtain the opinions of the “consultants,” despite the considerable expense paid, supposedly, to obtain such advice. There was no question that such largesse was doled out in order to induce prescriptions of Biogen products, a clear violation of the Anti-Kickback Statute.

55. In recent years, enforcement of the Anti-Kickback Statute has increased, and pharmaceutical company guidelines have closed down the most egregious violations. But the fact remains that the easiest way to acquire brand loyalty is to purchase it. For years, Biogen engaged in marketing programs that had no real corporate purpose other than to distribute money to high-level prescribers with the expectation that the physicians would express their gratitude by placing their patients on Biogen’s biologicals.

56. Biogen’s kickback strategy focused on two types of payments: (1) payments for consulting programs, and (2) payments for promotional speaking engagements, which included both payments for speaking and payments for receiving training on how to speak. Both forms of payment served no other corporate purpose

than to distribute cash to physicians. Biogen scheduled consulting and speaking engagements at an unnecessarily high frequency. Given the small number of neurologists that treat MS, Biogen could have conducted legitimate consulting and promotional events for much less money. Put another way, the company would never authorized such massive outlays of cash if the money had gone directly to people other than the prescribers of its MS drugs.

57. Biogen's kickback strategy was approved at the highest levels of corporate headquarters. On several occasions, the strategy was confirmed and reaffirmed by Tony Kingsley, former Senior Vice President of Commercial Operations, who is now Executive Vice President reporting directly to CEO George Scangos.

**1. Biogen Conducts Hundreds of Sham Consulting Events**

58. The voluntary guidelines that the pharmaceutical industry adopted in 2006 prohibited drug companies from making excessive payments to physicians and required the companies to receive some feedback or advice when they paid physicians to act as "consultants." These measures may have eliminated the worst abuses, but they did not, and have not, stopped expenditures that are made solely for the purpose of putting cash into physicians' hands to induce future prescriptions. Although window dressing may have been added to make Biogen's payments appear to be consideration for traditional consulting services, in reality any consulting arrangement was a sham: the payments purchased advice that was not needed and never used. Biogen's consulting arrangements at all times were a pretext for kickbacks.

59. The ostensible purpose of the consultant meetings organized by Biogen was to obtain market research regarding physicians' use of Avonex and Tysabri. Biogen maintained a permanent Market Research department whose work was vital in shaping the marketing and sales campaigns that Biogen conducted. But the consultant meetings were not organized, monitored, or even requested by the Market Research department. The physician consultant meetings were initiated and administered by the Regional Marketing department. The Relator was the Director of this department between November 2009 and February 2011.

60. As the Director of Regional Marketing, almost 50% of the Relator's efforts were devoted to the physician consultant meetings. Physician consultant meetings were not initiated because Biogen required physician input on specific inquiries. Instead, senior marketing officials decided how many meetings (and how much money it wanted to pay out to doctors) and the Regional Marketing Department was expected to come up with topics and programs. In other words, it was not the need for consulting that drove the process; it was the need to direct cash to physicians who could initiate new prescriptions. The 2010 RSMM Strategic Plan instructed marketing personnel to "drive the meetings that seek feedback." In other words, the meetings—and the payments to physicians that necessarily accompanied the meetings—were more important than any product generated by the meetings.

61. The Relator, like prior directors before him, came up with the subjects for the physician consultant meetings on his own, without any input from Market Research or the marketing managers of the two drugs. His superiors told him the number of



programs the company wanted to hold and how many physicians it wanted to have in attendance, and he and his staff determined what matters might require consultation.

62. In theory, Biogen's Compliance Department was supposed to prevent the abusive use of consultant meetings. In reality, it was nothing more than a rubber stamp. Its requirement for an annual consulting plan, which would have blocked the proliferation of obviously duplicative consultant meetings, was ignored. So too were its concerns that that there were too many consultants attending too many meetings. Examples of the routine circumventing of Compliance are detailed below.

63. The only area where Compliance succeeded was in requiring that the feedback received at these so-called consultant meetings was recorded. But Compliance could not require anyone to read or use the opinions, and no one within the company did. At the conclusion of each program, a Biogen employee duly summarized the opinions and an Executive Summary was generated and circulated by rote. But the market research generated by these programs had no effect on Biogen's marketing; the marketing plans for the foreseeable future had already been drafted and were not affected by the results of the conference. Only once or twice did anyone ever acknowledge that they had received reports from the consulting meetings, much less use them. The fact that Biogen spent millions of dollars every year on physician consulting meetings but never used the product of the meetings is further evidence that their sole purpose was to be a vehicle to get payments to prescribers.

64. The selection process Biogen employed to determine which neurologists would be its paid consultants confirms that the purpose of these programs was to

benefit high prescribers who could direct hundreds of patients to Biogen's MS products. If the true purpose of the meetings was to obtain information from knowledgeable practitioners, the most experienced and insightful neurologists would have been chosen, with teaching hospital physicians likely being overrepresented in the sample. But the attendees were almost uniformly the highest volume prescribers. And although they were not supposed to have any influence in the selection, in reality senior sales representatives exerted substantial influence over who would be invited to attend the meetings.

65. The physician attendees were aware that the purpose of these meetings was to pay doctors in exchange for brand loyalty. An email from a Biogen sales representative, reporting the concerns of Dr. Robert Giombetti, a neurologist from Marina Del Rey, California, makes this clear. Dr. Giombetti was "one of our good doctors" and "our friend." He wanted to let Biogen know that it "was falling behind on competitiveness in both number of consultant meeting [sic] held annually and honorariums paid." Moreover, Biogen's competitor, Teva, was paying his nurse to attend meetings twice a year (including one in New Orleans) and was also paying them both to attend monthly dinner consultants' meetings. Dr. Giombetti helpfully informed Biogen of the amounts he was receiving from Teva to attend all of these meetings. The not so subtle subtext of Dr. Giombetti's warning was that if Biogen did not match what Teva was paying, it would lose prescriptions. As will be discussed below, especially in connection with the challenge faced by the entry of Gilenya, Biogen had no intention of allowing that to happen.

66. Sham consulting meetings were not the brainchild of the Relator. For years Biogen had held an annual national consultants' meeting where Biogen invited roughly 200 of its top prescribers to warm weather resorts in places like Miami and San Diego in the middle of winter. These annual meetings were nothing more than junkets for Biogen's most loyal and lucrative "customers." The event was highly suspect in an era of enhanced kickback enforcement and there was pressure within Biogen to discontinue the practice. However, once Biogen decided to implement its strategy to preserve market share through widespread kickbacks, Biogen continued holding them. In 2009 and 2010, despite having recognized that the annual meeting was an indefensible kickback that should be discontinued, Biogen nonetheless invited 200 consultants to a lavish resort, and paid each of them approximately \$6,500 each, in addition to hotel, meals, and airfare for the minimal "consulting" provided. Unsurprisingly, just about all of the invitees were either "key accounts" or "high" prescribers.

67. As the launch of Novartis's Gilenya approached, Biogen saw consultant meetings as key "blunting tactics" to minimize the loss of market share to the new oral medication. The Relator was personally informed by Tony Kingsley, the Senior Vice President of Commercial Operations, that physician consultant meetings would be an important tactic to maintain Biogen's market share in the face of a formidable market entry. Kingsley wanted the Relator and his staff to set up an unprecedented series of consultant meetings across the country that would allow Biogen to pay as many physicians as possible. Kingsley told the Relator that the purpose was "keep all key

customers busy” during the Gilenya launch. “If customers are busy attending our programs they will not be able to attend the competition’s programs.” Moreover, if Biogen was paying them to attend lavish conferences, the attendees would be less inclined to switch their patients from Avonex or Tysabri.

68. Legitimate market research only requires a small number of participants, particularly when the market is as small as the one Biogen served: the 6,000 neurologists who prescribed the vast majority MS medications. Guidelines from the Office of the Inspector General warned firms that consultant meetings with numerous consultants (such as Biogen’s annual national consultant meeting) were suspect. But there was no explicit rule against a drug company holding the same type of consultants meeting on multiple occasions in multiple locations. Thus while a single meeting with 150 consultants was generally impermissible, nothing prohibited Biogen from inviting 150 physicians to 10 different meetings held in 10 different locations, with each meeting hosting only 15 invitees. And by holding the meetings across the country it was easier to spread the payments out geographically. This is precisely the type of program that Biogen set up in 2010 to blunt the Gilenya market entry.

69. For example, in the fall of 2009 Biogen scheduled an MS Franchise Feedback Consultant Meeting for 15 physician attendees. It then repeated the event in 11 additional locations, expecting to pay 180 neurologists in total. In the first and second quarter of 2010, the Relator designed a General Community Neurologist Consultant Meeting for 5-10 consultants. However, it was repeated 24 times, with Biogen seeking to pay as many as 240 community neurologists. A Nurse

Practitioner/Physician Assistant Consultant Meeting was designed by the Relator for 5-10 consultants. It was repeated in 23 locations. The most expansive program was the Risk Benefit Decisions Consultant Meeting held in the 2<sup>nd</sup> and 3<sup>rd</sup> quarters of 2010. It sought 140 to 280 consultants for 28 meetings in 28 locations. And two months after it was approved, the Relator sought approval for another 3 meetings and to raise the total of consultants to 310. The expansion was also approved.

70. None of the feedback from any of these meetings was ever used by Biogen. After an Executive Summary was prepared, no one expressed any interest in the opinions of Biogen's expensive consultants.

71. Physician consulting programs had to be approved by Biogen's Compliance Department, which was supposed to ensure that Biogen complied with all applicable federal statutes and regulations, including the Anti-Kickback statute. Compliance regularly expressed reservations regarding Biogen's physician consultant meeting programs. For example, in response to the proposal to host 24 General Community Neurologist Consultant Meetings, Compliance warned that Marketing "should consider if 24 meetings are required to meet needs." It also realized that it "(a)ppears that intent is to invite all community neurologists, in area. . . ." When Regional Marketing sought approval to retain 280 consultants in connection with its proposal to hold 28 Risk Benefit Decisions consultant meetings, Compliance warned:

Request is for a very high # of HCP consultants (up to 280) + meetings (28). Policy states that only the minimum # of consultants necessary shall be employed. Strongly recommend that approver consider whether this need can be met w/ fewer consultants + mtgs. (emphasis in original).



72. As the note above indicates, although Compliance could make recommendations and notify management of the consequences of paying kickbacks, Compliance did not ultimately decide whether the programs would go through. The person who told the Relator to set up the programs, Tony Kingsley, was the "approver," who decided whether the consultant meetings would be held. And Kingsley, time and again, approved the proposed programs regardless of Compliance's express reservations.

73. Thus, in March 2010 and May 2010, respectively, Kingsley approved the General Community Neurologist consultant meetings and the Risk Benefit Decisions Consultant Meetings. In July 2010, when Regional Marketing sought to expand the Risk Benefit Decisions series to 31 meetings using as many as 310 consultants, Kingsley approved the payments again, despite Compliance's comment that "Request is for a very high # of HCP [Health Care Provider] consultants overall." For several other programs Compliance strongly recommended that the "approver" and the "submitter" reconsider whether the need could be met with fewer consultants. But such reconsiderations never occurred and the programs were routinely approved, usually by Kingsley.

74. In addition to the high number of consultants and meetings, Compliance frequently raised other concerns. For example, Compliance questioned of whether it was possible to hold a "New Therapy Entrant Strategy" consultants meeting with 25 consultants in late July 2010 and have "enough time to apply the feedback obtained at

this meeting to slide decks to be used at upcoming speaker training mtgs in August.” Kingsley ignored this concern and approved the meeting.

75. As recently as 2011, Compliance’s Amy Zahler also raised concerns that many of the consultants for the Global Thought Leader Consultant Meeting “are frequently utilized by various depts... [and] may have provided recent feedback on similar topics.” The concern was that Biogen was “soliciting duplicate feedback at this meeting.” But Zahler took no action to determine whether such duplication took place, leaving it instead to Marketing to worry about such details. Marketing, of course, was not troubled by this, since the goal of increasing consultant meetings required that consultants get paid to go to more than one meeting per year. Francisco Granata, Biogen’s Executive Vice President of Global Commercial Operations, approved the meeting.

76. A final example is the duplicative and balkanized speaker training. Rather than simply training speakers in one fell swoop, Biogen found ways to make speaker training a full time activity. There were national speaker training meetings and regional speaker training meetings, and Avonex speaker training meetings and Tysabri speaker training meetings. In July 2011, Amy Zahler was asked to review a regional Avonex speaker training meeting with 75 consultants. She worried about the “public perception” of the excessive and fragmented speaker training, having just reviewed a proposal to train 75 consultants to speak on Tysabri, as well as a proposal to train an equivalent number of national speakers for both drugs. Zahler expressed concern that there was “potential duplication of content at this meeting” and asked “whether [it is]

necessary for HCPs who are speakers for both Avonex and Tysabri to attend both meetings.” Marketing VP Andi Bruell ignored these concerns and approved the consulting event.

77. Pursuant to its kickback strategy, Biogen held close to 100 consultant meetings each year—so many that the selected neurologists frequently consulted more than once, usually on nearly identical topics. To combat Gilenya’s market entry in 2010, the Relator increased the number of consultant meetings over those held the prior year by 280%. In those meetings, Biogen paid 864 physicians to “consult,” paying a total of \$4.7 million in consulting fees, in 1,625 separate payments. The average single consulting fee was \$2,900 and the average doctor attended nearly 2 meetings.

78. Biogen used consultant meetings as part of its blunting tactics to combat the launch of Gilenya. In 2010, Biogen identified prescribers of their drugs who it believed were at the highest risk of placing patients on Gilenya (which Biogen frequently abbreviated as FTY) within a year. On August 19, 2010, Biogen’s Business Intelligence Department circulated a “Top 50 At Risk MDs” spreadsheet, which contained a list of 50 high volume prescribers that the company believed were most likely to adopt Gilenya. Marketing began to focus attention on how to maintain these critical accounts as Biogen prescribers.

79. On September 2, 2010, the Director of Avonex Marketing, Lisa Hickey, sent the Relator and other senior marketing officials an email referencing the Top 50 At Risk MDs spreadsheet and informing the recipients that “TK (Tony Kingsley) has asked us to pull together a holistic view of our engagement with this group.” She asked the

marketing officials to determine how many of the listed high prescribers “have participated in our consultant/steering committee meetings,” and wanted to know from the Relator what types of programs the targeted doctors had attended.

80. Ten days later, Hickey sent the Relator a second email containing a new spreadsheet setting forth the Top 50 At Risk MDs. Hickey wanted the Relator to provide “all the activity we have against these HCPs [health care providers],” letting her know which doctors had attended local consultant meetings, and which doctors were slated to receive speaker training in the next 60 days. She also wanted to know what activities the Relator’s staff was planning for each doctor on the list. Shortly thereafter the Relator received an email from his own boss, Bill Ames, asking him to also identify which doctors on the Top 50 at Risk list had attended a consultant meeting.

81. On September 15, 2010, the Relator met with Bill Ames to discuss the requests he had received from Ames and Hickey. In the meeting Ames admitted that the “holistic approach” senior management was considering was to target important prescribers whose business Biogen did not want to lose and to pay them to attend meetings with the hope that such treatment would influence them to keep prescribing Avonex and Tysabri. Ames confirmed that the spreadsheets Hickey sought from the Relator were to be used to track the payment opportunities being offered to the Top 50 At Risk MDs and to ensure they were receiving opportunities to receive payments from Biogen.

82. The Relator knew that providing a list of completed and anticipated payments to major prescribers who the company had identified as priority accounts

would constitute evidence of unlawful payments for the purpose of obtaining prescriptions. He warned Ames that the existence of such lists would raise serious compliance problems. The Relator also contacted the Compliance Department and asked “hypothetically” if such information was requested from a senior executive would it be proper to provide it. The Relator was informed that the “hypothetical” requests violated two of Biogen’s compliance policies: one which prohibited any “agreement with an individual with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, (or) sell . . . any Biogen Idec product or to reward any past such behavior”; and a second that “strictly prohibited” Biogen employees “from completing return on investment analyses or from other tracking of business in connection with a Consultant Meeting.”

83. The Relator informed Hickey and Ames that providing the requested information would make it clear that Biogen was making payments for prescriptions. Hickey, in particular, still pressed for the requested information and found it from sources other than the Relator.

84. In February 2011, the Relator was removed from his position as Director of Regional Marketing and given his current position as a Thought Leader Liaison. The new position was a distinct demotion, and the Relator no longer had any direct reports or line responsibilities. The Relator had received excellent reviews as the Director of Regional Marketing. Biogen demoted him because it no longer viewed him as a team player and viewed him as being more concerned with compliance than generating profits for Biogen.



85. When it came time for Biogen to promote its own oral treatment for MS, Tecfidera (which was internally identified as BG-12 while the Relator was working on its advisory board meetings), it continued to use sham advisory boards as excuses to pay off doctors. In 2011, more than a year before Tecfidera was approved for use by the FDA, Biogen knew that two sets of clinical trials for the drug, DEFINE and CONFIRM were positive. It wanted to publicize those results and prime the market for immediate adoption once the drug was authorized. However, Biogen could not promote BG-12 before it was approved, such conduct blatantly violates the Food Drug & Cosmetic Act. Biogen had to find a method of publicizing results without appearing to engage in promotion.

86. Biogen elected to use "consultants," just as it had used consultants to try to blunt its competitors' market entries. On November 4, 2011, Douglas Gill, the Thought Leader Liaison for Biogen's US Marketing Department submitted a Consultant Needs Assessment to Biogen's Compliance Department seeking authorization to pay 96 high prescribing physicians to attend six regional meetings as "consultants." The Needs Assessment asserted that Biogen needed to obtain the consultants' perspective regarding the DEFINE clinical data, what a BG 12 Treatment Algorithm would look like, feedback on Biogen's theory of the mechanism of action of BG-12, what commercial activities would assist a successful launch, and to determine whether there was any regional differentiation in response to Biogen's data.

87. All of these grounds were pretextual. With regard to the first three reasons, none of the "consultants" had any experience with the unapproved drug, and

the only information they had received had come from Biogen—any “consultation” they would provide would solely be a regurgitation of marketing materials they had received from Biogen. As to whether the “consultants” could identify commercial activities that could assist a successful launch of BG-12, Biogen had an entire marketing department with special (and extensive) expertise in the successful launch of MS medications—Biogen did not need to retain dozens of physicians with absolutely no marketing qualifications to learn about commercial launch applications. Similarly, due to its extensive experience in the field, Biogen already was well versed in any differences between marketing to community based practitioners and those centered in teaching hospitals, or any regional distinctions. Indeed, the Needs Assessment form sheepishly acknowledged that there may be no regional distinctions—a fact already well known to the professional marketers at Biogen.

88. Moreover, as with “consulting product” it received in connection with the Gilenya consultant meetings described above, Biogen never intended to do anything with the information it paid to receive. Biogen’s marketing team had already developed its rollout marketing plans for the expected approval of BG-12, and the DEFINE consulting meetings were being held too late to alter them. Biogen never had any intent to use the “consulting” it would receive from the regional consultant meeting in developing its BG-12 marketing program and never, in fact, used it.

89. Notwithstanding the lack of any objective need to pay some of its most important customers to hear about a new product that could not legally be promoted, Biogen’s Compliance Department approved the request to retain 96 consultants. On

November 14, 2011 Amy Zahler, a manager of compliance operations approved the request to retain consultants. She acknowledged that the "(t)otal number of consultants is significant at 96 HCPs," and urged the Marketing Department to "(c)onsider whether need can be met w/ fewer." After receiving compliance approval, Biogen held six regional consultant meetings relating to the DEFINE clinical studies in Atlanta, Chicago Dallas, Detroit, New York and San Francisco between February and March 2012.

90. In May and June 2012, Biogen conducted a similar set of regional consultants meetings in connection with its efforts to publicize the positive results of the CONFIRM clinical studies. Although the results of CONFIRM were comparable to the DEFINE results, Biogen claimed that it required the insight of another 96 "consultants" on the same issues that were the focus of the DEFINE consulting meetings. As with the DEFINE Regional Consultants Meeting, Biogen once again sought input from physicians about how they would utilize a drug with which they had no experience and about which they were wholly dependent on information provided by Biogen.

91. Instead of making use of experienced "consultants" whose opinions Biogen coveted four months earlier, Biogen deliberately selected a new set of "consultants" for the CONFIRM meetings. Thus, an additional 96 practitioners across the country were flown to luxury destinations across the country and paid thousands of dollars to hear Biogen speakers publicize a drug they could not legally promote. The CONFIRM regional consulting meetings were held in Charlotte, Chicago, Dallas, New York City, Orlando and San Francisco. And, as with the DEFINE meetings, the

information the consultants provided did not effect, and could not effect, the marketing programs Biogen has already designed for the anticipated launch of BG-12.

92. The doctors invited to the DEFINE and CONFIRM regional consultants meetings had no special expertise in marketing or the technical topics that were allegedly the subject of the consulting meetings. Instead, the selected physicians were identified by regional sales personnel based upon their ability to either prescribe large quantities of BG-12 or to influence their colleagues and other physicians to prescribe BG-12.

93. In addition to paying for all travel expenses, each "consultant" was paid a substantial stipend to attend the meetings. Not all of the consultants were paid the same amount. Biogen classified physicians based upon criteria that measured their ability to influence the prescription of MS treatments. Doctors who were thought to have the greatest ability to influence MS prescribing were paid the most, with lesser amounts paid to physicians who were deemed to have a lesser capability to drive prescriptions. The Relator has the names of the physicians who attended the DEFINE and CONFIRM regional consultants meetings and who received significant stipends.

94. The purpose of the meetings and the reason so much was spent on each consultant was to predispose each consultant to place as many patients on BG-12 as possible when the drug was ultimately approved by the FDA. In other words, the payments were kickbacks designed to influence each of the consultants to prescribe BG-12 as soon as it was available. Each of the consultants participated in the Medicare program, and on information and belief, each of the consultants prescribed BG-12 to at

least one Medicare patient within the first three months of Tecfidera being approved for use in the United States.

## **2. Biogen's Use of Sham Speaking Payments**

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95. The second mechanism Biogen employed to get payments to important prescribers was to pay physicians for speaking on behalf of the company and for receiving training to become a speaker. Recognizing the value of peer-to-peer selling, drug companies have traditionally employed physicians to give presentations regarding their products at dinner meetings and other gatherings. The physician attendees receive a good meal at a high end restaurant and the speaker receives payment for his time. In order to qualify to speak at such engagements, the physician must receive speaker training from the company. The speaker attends a weekend presentation at a major metropolitan center and is provided with first class meals and accommodations. The speaker is also paid for attending the training class.

96. Like consulting payments, speaking payments are permitted only if they are reasonable and do not further a kickback motive. But Biogen knew that even if the FDA or other authorities detected an increase in the number of Biogen's speakers, the regulators would be unable to discern whether the number was unreasonable. Training speakers and sponsoring promotional speaking events were routine activities for pharmaceutical companies and hardly subject to any oversight.

97. By 2008, however, Avonex had been on the market for twelve years and all MS practitioners were well acquainted with it. Although Tysabri was newer, it too was a mature drug that had been on the market for several years and was well known



to the industry. To the extent neurologists still had an interest in learning about the uses and administration of either drug, Biogen had trained hundreds of speakers and could easily handle the demand for any events with their available resources.

98. Yet despite the fact that there was little demand among neurologists for more promotional meetings and that Biogen already had more trained speakers than it could possibly employ, Biogen trained hundreds of new speakers on Avonex and Tysabri in 2009 and 2010. This initiative was consistent with Biogen's goal of increasing consulting opportunities for physicians in order to blunt the market entry of Gilenya.

99. Biogen could not just pay the physicians thousands of dollars to attend an all-expenses-paid weekend at a first class hotel in a major metropolitan area for nothing; but it did the next best thing. Notwithstanding that the cost to train each speaker was several thousand dollars, it only required speakers to appear twice on Biogen's behalf. And many speakers only had to speak once if the local sales force was unable to arrange a second engagement. (Speakers were also paid in full if no one attended their event or if the engagement was cancelled within three days of the scheduled date, as was often the case). Examples of such minimally utilized speakers include David Ewing (two talks in 2009), Richard LaFrance (one talk in 2009, one in 2010), Tommasina Papa-Rugino (one talk in 2009), Kathryn Chenault (one talk in 2009, two in 2010), and Kenneth Pugar (two talks in 2010).

100. Nor did Biogen get much impact for the one or two events at which the speaker actually presented. Given the large number of speakers who had to present at least once, and the small demand for the promotional programs, most speakers spoke to

miniscule audiences: frequently just one other physician. And often times, this audience member was someone the speaker knew quite well, such as a junior colleague from his or her own office. Biogen would pay several thousand dollars to wine and dine two doctors and to have one doctor conduct a chat that could have just as easily been held in the physicians' lunchroom. The value of such expenditures, however, was not from the information communicated to the audience member; it was the brand loyalty the speaker would exhibit after being paid to deliver Biogen's promotional message.

101. Biogen also held an excessive number of dinner meetings. In 2010, Biogen paid for 832 dinner meetings. It paid 367 doctors to attend, meaning that the average doctor was treated to between two and three dinners in 2010. Not counting the cost of the meal, which was always at an upscale restaurant, the average fee to "speak" at one of these dinners was \$2,500. Biogen paid out \$2.3 million in such speaker fees in 914 separate payments.

102. A different gambit eliminated the physician attendee altogether. Biogen also sponsored Patient Education Programs (PEP), where it paid doctors to speak to a room full of MS patients at a local hotel or community center. Biogen placed physicians into the PEP program who it believed did not have sufficient experience or expertise to educate fellow physicians. Conducting a short program before patients was much less rigorous than speaking before peers. In many ways, these PEP sessions were marketing programs for the inexperienced physicians, giving them a higher profile in the community and possibly attracting new patients.

103. The PEP meetings served no purpose for Biogen that was legitimate. If Biogen had wanted to fund patient outreach or education, it could have done so through any number of public and private organizations devoted to the cause. Biogen, however, knew that by assisting inexperienced physicians with marketing within their own communities, the neurologists would reward Biogen by prescribing its medications.

104. Biogen hosted 557 PEPs in 2010. It paid 456 physicians to speak at these events, paying \$1.3 million in 748 separate payments. On average, PEP speakers presented at one or two PEP programs a year.

105. Biogen had separate training programs for Tysabri and Avonex, although most of the training overlapped. Thus, if a physician wanted to talk about both drugs in a presentation, he would receive two all-expenses-paid weekends and double the training fee. Biogen's Compliance Department noted the duplication of content in the two training programs and questioned whether it was necessary for physicians who were speakers for both products to attend both trainings. But like most warnings from Compliance, this caveat was ignored.

106. After receiving Speaker Training, a physician was considered qualified to speak for a year. If the physician wished to continue to speak for Biogen, he either had to attend another all-expenses-paid conference at a first class hotel in a major metropolitan area or watch a 15 minute video that provided an annual update and reminded the physician of FDA regulations regarding speaking engagements. Speakers were paid several thousand dollars to repeat the Speaker Training program (which did

not vary much from year to year). They were not paid to watch the video. Most physicians who signed up for additional terms elected to be paid to take the training. Had Biogen wanted trained speakers, instead of wanting to pay physicians for future prescriptions, it would have required returning physicians to watch the video on their own time. The fact that Biogen happily paid numerous physicians thousands of dollars to attend a program they had already experienced is further evidence that the purpose of the program was to disguise kicking cash back to doctors.

107. A particularly lucrative speaking opportunity usually reserved for the highest volume prescribers was presenting at a consultants meeting or speaker training. Practicing physicians familiar with Avonex and Tysabri were the lecturers who instructed at these programs. These doctors also received all-expenses-paid weekends and substantial honoraria, but they only had to appear for their portion of the training. Making a presentation at these meetings was highly coveted. In theory, it was in Biogen's interest to have new speakers or consultants trained by the best qualified physicians, but this opportunity was used by sales and marketing executives to extend kickbacks to unqualified physicians who agreed to prescribe Biogen's products.

108. In connection with a consultant program held in 2010, Bill Ames and Mike Jones, who was the National Sales Director for the western half of the United States, required Jeff Ferrari to use an unqualified doctor as a key presenter. Jeff Ferrari was an RSMM whose territory included Los Angeles. The doctor was Darin Okuda, a Los Angeles doctor who prescribed Biogen products infrequently. Because of Okuda's unfamiliarity with Biogen's products, Jeff Ferrari was concerned that he would give a

poor lecture. However, Ames and Jones considered Okuda to be a priority given that even his small rate of Avonex prescriptions was deemed to be "at risk" given the impending launch of Gilenya. Ames and Jones believed they could preserve and even increase the quantity of Okuda's prescriptions if they provided him with lucrative speaking opportunities. Moreover, the sales force knew that Okuda was shopping for a Ferrari sports car (most new models start at \$200,000) and would appreciate the opportunity to receive income that would help him purchase it.

109. Over Jeff Ferrari's strong objections, Biogen gave Dr. Okuda the engagement and paid a substantial honorarium. The results worked out as Biogen predicted. After the speaking engagement, Okuda placed a greater percentage of his patients on Biogen's products. And not surprisingly, Biogen kept the lucrative payments coming. In fact, in just the first three months of 2012, Dr. Okuda has already earned \$34,000. Thanks to the increased generosity of Biogen, he was able to purchase his new Ferrari.

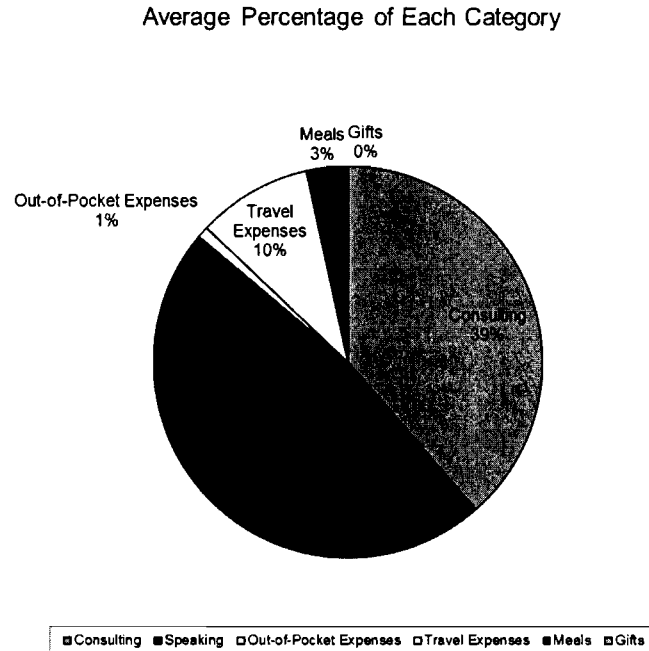
#### **F. Analysis of Biogen's Kickbacks**

110. The amount of money Biogen paid directly to doctors in 2009 exceeded \$8 million. That year it paid 820 physicians a total of \$8.8 million in consulting and speaking fees. The mean payout was \$10,600 per physician, and the median payout was \$3,300 per physician.

111. In 2010, it expanded the breadth of its program, reaching even more physicians. Biogen paid 1,200 physicians: 20% of the potential market for its product, and 40% of the group that controlled 60% of the market share. It spent a total of \$9.1



million in consulting and speaking fees. The following chart shows the breakdown between consulting payments and speaker payments in 2010:



112. In 2010, the mean payout was \$7,500 per physician, and the median payout was \$2,800 per physician. Average payouts to physicians, however, do not truly represent what Biogen intended. As noted above, Biogen stratified neurologists into four groups based on their prescription volume: key accounts, high prescribers, medium prescribers and low prescribers. It also categorized the 6,000 physicians into four loyalty groups. Those already loyal to Biogen were “Avonex advocates,” while those trending towards Biogen were “Avonex opportunity.” Those loyal to a competitor were labeled “competitor advocates,” and those trending away from Biogen were labeled “Avonex risk.”

113. Thus, each prescriber within the top 6,000 was classified in accordance with their prescription volume and their loyalty to Biogen. Examining how Biogen paid neurologists in the different categories is enlightening.

Value to  
Biogen

High ← Low

|                  | <u>Avonex<br/>advocate</u>                    | <u>Avonex<br/>Risk</u>                       | <u>Avonex<br/>Opportunity</u>               | <u>Competitor<br/>advocate</u>             |
|------------------|---|--|---|--|
| Key<br>account   | \$96,363<br>n=36 p=28<br>(78%)<br>\$2.68 m    | \$42,329<br>n=111 p=79<br>(71%)<br>\$3.34 m  | \$28,745<br>n=84 p=56<br>(67%)<br>\$1.61 m  | \$22,706<br>n=32 p=21<br>(66%)<br>\$0.48 m |
| High<br>volume   | \$21,536<br>n=74 p=30<br>(41%)<br>\$0.65 m    | \$14,503<br>n=427 p=157<br>(37%)<br>\$2.28 m | \$9,540<br>n=345 p=125<br>(36%)<br>\$0.53 m | \$9,686<br>n=88 p=27<br>(31%)<br>\$0.26 m  |
| Medium<br>volume | \$10,504<br>n=224 p=22<br>(10%)<br>\$0.23 m   | \$8,631<br>n=948 p=110<br>(11%)<br>\$0.95 m  | \$5,966<br>n=944 p=89<br>(9%)<br>\$0.53 m   | \$6,014<br>n=295 p=31<br>(11%)<br>\$0.19 m |
| Low<br>Volume    | \$3,848<br>n=250 p=14<br>(6%)<br>\$0.05 m     | \$5,729<br>n=551 p=27<br>(5%)<br>\$0.15 m    | \$4,204<br>n=737 p=24<br>(3%)<br>\$0.10 m   | \$5,575<br>n=370 p=8<br>(2%)<br>\$0.04 m   |
| All<br>Others    | \$10,392<br>n=16,580 p=44<br>(0%)<br>\$0.46 m |  |   |  |

In addition to depicting the average amount Biogen paid the sixteen categories of neurologists, the chart provides the total number of neurologists in each category, the

percentage of neurologists within each category who received payment from Biogen and gross amount paid within the category. (In the chart “n” is the total number of neurologists in the category and “p” is the number of neurologists in the category that Biogen paid).

114. The chart demonstrates that instead of seeking the most qualified consultants or speakers, Biogen deliberately paid the highest prescribers in proportion to their value to the company. For example, roughly 70% of all “key accounts” received consulting or speaker payments, regardless of qualification, professional affiliation, speaking ability, or academic pedigree. In contrast, only about 40% of the “high volume” prescriber received money.

115. Although not as important as ability to deliver a high number of prescriptions, brand loyalty was also important to Biogen’s payment programs as well. Biogen was most likely to either reward established customers (and thus ensure they would continue to favor Biogen with their prescribing) or to pay those neurologists who the company believed were likely to reduce their current level of prescribing. Both types of payments were made to maintain Biogen’s dominant market share. Biogen’s payment distribution is further evidence that the purpose of the payments was to induce prescriptions, not obtain services from the payees.

116. In 2010, in connection with Gilenya’s market entry, Biogen created yet another segmentation of physicians, based on certain attributes that were correlated to the likelihood the physician would adopt Gilenya. Biogen assigned all 16,000 prescribers of MS drugs in its database into one of four “risk” groups based on the

likelihood of adoption of Gilenya. Physicians most likely to adopt Gilenya were deemed "high risk," and those least likely to adopt it considered "low risk":

| <u>Segment No.</u> | <u>Segment Name</u>    | <u>Risk Level</u> | <u>No. of Physicians</u> | <u>No. in "Top 6,000"</u> |
|--------------------|------------------------|-------------------|--------------------------|---------------------------|
| 1                  | Progressive Drivers    | High              | 1,026                    | 985                       |
| 2                  | Independence Guardians | High              | 3,889                    | 1,323                     |
| 3                  | Non-committal Doers    | Medium            | 2,102                    | 784                       |
| 4                  | Cautious Minimalists   | Low               | 8,977                    | 2,247                     |

117. Nearly 1,000 of the top 6,000 neurologists were at high risk of switching to Gilenya because they were "progressive drivers," i.e. early adopters who would be likely to embrace Gilenya rapidly. Another 1,300 physicians were also high risk because they were "independence guardians" who focused on patient convenience. These physicians were thought to be at high risk of switching because an oral medication is more convenient than injections or infusion. The remaining 3,000 physicians were deemed a much lower risk for switching.

118. Once again, analysis of the payments to the neurologists within each classification shows that Biogen directed its payments in the manner most likely to preserve its market share. Biogen's average payments to each "progressive driver" was \$11,000 in 2009 and 2010. By comparison, Biogen's average payments to physicians in the bottom two risk categories, the "non-committal doers" and the "cautious minimalists," were \$562 and \$92, respectively. Biogen specifically targeted payments to physicians it deemed likely to use a competitor's product, and spread its money in a manner likely to keep those physicians prescribing Biogen's products.

**1. Biogen Violates its Own Rules to Pay Large Kickbacks to High Volume Prescribers**

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119. Given the value of high prescribers, Biogen made sure they were lavishly rewarded. The following table shows the highest paid doctors in 2008 and 2009:

| <u>Physician</u>      | <u>2008</u>  | <u>2009</u>  | <u>Total</u> |
|-----------------------|--------------|--------------|--------------|
| Munschauer, Rick      | \$267,219.00 | \$295,303.00 | \$562,522.00 |
| Tornatore, Carlo      | \$320,411.00 | \$196,790.00 | \$517,201.00 |
| Brandes, David        | \$220,180.00 | \$257,615.00 | \$477,795.00 |
| Frohman, Elliot       | \$235,447.00 | \$229,457.00 | \$464,904.00 |
| Vartanian, Tim        | \$272,200.00 | \$148,929.00 | \$421,129.00 |
| Zivadinov, Robert     | \$169,000.00 | \$194,760.00 | \$363,487.00 |
| Crayton, Heidi        | \$169,568.00 | \$123,553.00 | \$293,121.00 |
| Khatri, Bhupendra     | \$142,244.00 | \$124,438.00 | \$266,682.00 |
| Phillips, J. Ted      | \$ 56,998.00 | \$203,949.00 | \$260,947.00 |
| Scott, Thomas         | \$ 88,839.00 | \$171,022.00 | \$259,861.00 |
| Weinstock-Guttman, B. | \$174,447.00 | \$ 82,900.64 | \$257,347.64 |
| Jeffery, Douglas      | \$ 90,862.00 | \$142,500.00 | \$233,362.00 |
| Fox, Edward           | \$ 79,230.00 | \$148,602.00 | \$227,832.00 |

Three of the physicians listed above (Drs. Munschauer, Zivadinov, and Weinstock-Guttman) were affiliated with the Jacobs Neurological Institute in Buffalo, NY, one of the largest MS treatment centers in the country. The Jacobs Institute generated an enormous number of prescriptions for Avonex and Tysabri – the most in the Upstate NY region – and Biogen paid the physicians affiliated with the Institute in order to reward its personnel for the prescription volume and to maintain their beneficial relationship. Thus, it did not matter that Dr. Zivadinov was a radiologist affiliated with the Jacobs Neurological Institute and did not prescribe drugs himself, because the payments to him and the other members of the Institute’s MS practice area guaranteed favorable placement of Biogen’s products.



120. Not surprisingly, each of the physicians on the highest paid list (with the exception of Dr. Zivadinov), was a “key account” or a “high” volume prescriber. Most of these doctors were also considered at high risk for adopting Gilenya. Thus, payments were necessary to protect Biogen’s market share with these critical prescribers. Biogen had an internal rule that capped the amount that it paid to doctors at \$150,000 per year. This rule was supposed to prevent Biogen from making unjustifiable payments to doctors that would be immediately flagged as kickbacks. But Biogen allowed itself to selectively designate “exceptions” to the cap. In 2008, there were eight physicians who exceeded the cap. In 2009, however, Biogen doubled the number of exempted physicians, requesting exceptions for the following physicians:

David Brandes  
Robert Zivadinov  
Elliot Frohman  
Ted Phillips  
Doug Jeffery  
Rick Munschauer  
Tim Vartanian  
Dave Hojnacki  
Vincent Macaluso  
Stan Cohan  
Heidi Crayton  
Carlo Tornatore  
Dusan Stefoski  
Tom Scott  
Bhupendra Khatri  
Pat Coyle  
John Foley

121. In 2010, Biogen once again increased the list of exempted physicians, adding four additional names:

Andrew Pachner  
 Chris LaGanke  
 Peter Wade  
 Ed Fox

122. The amounts that Biogen paid between 2008 and 2010 were staggering. Five prescribers received more than half a million dollars each. Many others received more than a quarter of a million dollars each:

| <u>Physician</u>  | <u>2008</u>  | <u>2009</u>  | <u>2010</u>  | <u>Total</u> |
|-------------------|--------------|--------------|--------------|--------------|
| Tornatore, Carlo  | \$320,411.00 | \$196,790.50 | \$102,550.00 | \$619,751.50 |
| Brandes, David    | \$220,180.00 | \$257,615.43 | \$141,750.00 | \$619,545.43 |
| Frohman, Elliot   | \$235,447.00 | \$229,457.44 | \$115,250.00 | \$580,154.44 |
| Munschauer, Rick  | \$267,219.00 | \$295,303.60 | –            | \$562,522.60 |
| Vartanian, Tim    | \$272,200.00 | \$148,929.51 | \$101,675.00 | \$522,804.51 |
| Phillips, J. Ted  | \$56,998.00  | \$203,949.71 | \$122,500.00 | \$383,447.71 |
| Khatri, Bhupendra | \$142,244.00 | \$124,438.60 | \$111,275.00 | \$377,957.60 |
| Scott, Thomas     | \$88,839.00  | \$171,022.70 | \$108,375.00 | \$368,236.70 |
| Fox, Edward       | \$79,230.00  | \$148,602.23 | \$103,850.00 | \$331,682.23 |
| Foley, John       | \$80,610.00  | \$119,448.07 | \$113,400.00 | \$313,458.07 |

**2. Biogen Violates Its Own Rules Limiting the Fair Market Value of Individual Payments to Physicians**

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123. Biogen also violated its own rules in terms of the fair market value limits it placed on physician payments. For promotional speaking events, Biogen had a tier system, which limited payments a physician could earn according to the tier that the payment was deemed to fall within:

**2009 FAIR MARKET VALUE RATES**

| <b>Neurology Promotional Rates - MDs</b> | <b>Fees Include Travel</b> |
|--|----------------------------|
| Tier 1                                   | \$2100 - \$5600            |
| Tier 2                                   | \$1800 - \$4800            |
| Tier 3                                   | \$1500 - \$4000            |
| Tier 4                                   | \$1200 - \$3200            |

| <b>Neurology Promotional Rates - AHPs</b> | <b>Fees Include Travel</b> |
|---|----------------------------|
| Tier 1                                    | \$900 - \$2400             |
| Tier 2                                    | \$720 - \$1920             |
| Tier 3                                    | \$600 - \$1600             |
| Tier 4                                    | \$540 - \$1260             |

**Key Points:**

\*\* Consult with your RMP or an SBA (for Neuron speakers) **prior to quoting any program rates**

\*\* There will be an annual speaking cap in place for promotional events, please contact your RSMM or the SBA team if you have questions

Biogen routinely disregarded this tier system, and paid physicians according to the highest possible tier, even if the payment exceeded the tier that was truly appropriate.

124. Worse, Biogen also blatantly disregarded the upper limit for fair market value. The absolute maximum fee that Biogen could pay for promotion was \$5,600 per event. However, the following is a list of more than 100 payments – totaling nearly \$1 million – that exceeded Biogen’s maximum allowable payment:

| <u>Last Name</u> | <u>Amount</u> | <u>Event Date</u> | <u>Reason For Request</u>     |
|------------------|---------------|-------------------|-------------------------------|
| Munschauer       | \$8,820.00    | 1/21/2009         | HCP Speaker Fee-International |
| Tornatore        | \$5,950.00    | 2/4/2009          | HCP Speaker Fee               |
| Herndon          | \$5,950.00    | 2/10/2009         | HCP Speaker Fee               |
| Cohan            | \$7,350.00    | 2/25/2009         | HCP Speaker Fee               |
| Bakshi           | \$7,350.00    | 2/26/2009         | HCP Speaker Fee               |
| Brandes          | \$5,950.00    | 3/10/2009         | HCP Speaker Fee               |
| Coyle            | \$5,950.00    | 3/11/2009         | HCP Speaker Fee               |
| Brandes          | \$5,950.00    | 3/24/2009         | HCP Speaker Fee               |
| Kinkel           | \$5,950.00    | 3/25/2009         | HCP Speaker Fee               |
| Lathi            | \$6,300.00    | 3/25/2009         | HCP Speaker Fee               |
| Levin            | \$5,950.00    | 3/25/2009         | HCP Speaker Fee               |

| <u>Last Name</u> | <u>Amount</u> | <u>Event Date</u> | <u>Reason For Request</u>     |
|------------------|---------------|-------------------|-------------------------------|
| Skeen            | \$7,350.00    | 3/26/2009         | HCP Speaker Fee               |
| Tornatore        | \$7,350.00    | 4/1/2009          | HCP Speaker Fee               |
| Vartanian        | \$7,350.00    | 4/8/2009          | HCP Speaker Fee               |
| Brandes          | \$5,950.00    | 4/14/2009         | HCP Speaker Fee               |
| Munschauer       | \$7,350.00    | 4/14/2009         | HCP Speaker Fee               |
| Lathi            | \$11,100.00   | 4/15/2009         | HCP Speaker Fee               |
| Frohman          | \$7,350.00    | 4/16/2009         | HCP Speaker Fee               |
| Phillips         | \$7,350.00    | 4/16/2009         | HCP Speaker Fee               |
| Munschauer       | \$5,950.00    | 4/18/2009         | HCP Speaker Fee               |
| Levin            | \$5,950.00    | 4/21/2009         | HCP Speaker Fee               |
| Tornatore        | \$7,350.00    | 4/29/2009         | HCP Speaker Fee               |
| Vartanian        | \$7,350.00    | 5/5/2009          | HCP Speaker Fee               |
| Frohman          | \$5,950.00    | 5/7/2009          | HCP Speaker Fee               |
| Jeffery          | \$5,750.00    | 5/9/2009          | HCP Speaker Fee               |
| Brandes          | \$7,350.00    | 5/11/2009         | HCP Speaker Fee               |
| Moses            | \$6,300.00    | 5/11/2009         | HCP Speaker Fee               |
| Phillips         | \$5,950.00    | 5/13/2009         | HCP Speaker Fee               |
| Coyle            | \$5,950.00    | 5/14/2009         | HCP Speaker Fee               |
| Cree             | \$5,950.00    | 5/21/2009         | HCP Speaker Fee               |
| Fox              | \$6,300.00    | 5/22/2009         | HCP Speaker Fee               |
| Levin            | \$7,350.00    | 5/27/2009         | HCP Speaker Fee               |
| Cree             | \$5,950.00    | 6/4/2009          | HCP Speaker Fee               |
| Brandes          | \$5,950.00    | 6/8/2009          | HCP Speaker Fee               |
| Zivadinov        | \$5,950.00    | 6/9/2009          | HCP Speaker Fee               |
| Coyle            | \$5,950.00    | 6/11/2009         | HCP Speaker Fee               |
| Crayton          | \$6,300.00    | 6/11/2009         | HCP Speaker Fee               |
| Jeffery          | \$5,950.00    | 6/11/2009         | HCP Speaker Fee               |
| Kerr             | \$7,350.00    | 6/19/2009         | HCP Speaker Fee               |
| Crayton          | \$6,300.00    | 6/23/2009         | HCP Speaker Fee               |
| Fox              | \$7,350.00    | 6/25/2009         | HCP Speaker Fee               |
| Munschauer       | \$5,950.00    | 6/25/2009         | HCP Speaker Fee               |
| Brandes          | \$7,350.00    | 6/30/2009         | HCP Speaker Fee               |
| Benedict         | \$7,350.00    | 7/2/2009          | HCP Speaker Fee-International |
| Phillips         | \$5,950.00    | 7/9/2009          | HCP Speaker Fee               |
| Skeen            | \$7,350.00    | 7/15/2009         | HCP Speaker Fee               |
| Fox              | \$6,300.00    | 7/23/2009         | HCP Speaker Fee               |
| Cohan            | \$5,950.00    | 7/29/2009         | HCP Speaker Fee               |
| Zivadinov        | \$7,350.00    | 8/4/2009          | HCP Speaker Fee               |
| Zivadinov        | \$7,350.00    | 8/10/2009         | HCP Speaker Fee               |
| Lucas            | \$7,350.00    | 8/18/2009         | HCP Speaker Fee               |
| Phillips         | \$7,350.00    | 8/27/2009         | HCP Speaker Fee               |
| Tornatore        | \$7,350.00    | 8/27/2009         | HCP Speaker Fee               |

| <u>Last Name</u>  | <u>Amount</u> | <u>Event Date</u> | <u>Reason For Request</u>     |
|-------------------|---------------|-------------------|-------------------------------|
| Weinstock-Guttman | \$5,950.00    | 8/27/2009         | HCP Speaker Fee               |
| Cohan             | \$7,350.00    | 8/28/2009         | HCP Speaker Fee               |
| Coyle             | \$5,950.00    | 9/3/2009          | HCP Speaker Fee               |
| Tornatore         | \$5,950.00    | 9/17/2009         | HCP Speaker Fee               |
| Munschauer        | \$5,950.00    | 9/23/2009         | HCP Speaker Fee               |
| Phillips          | \$5,950.00    | 9/24/2009         | HCP Speaker Fee               |
| Coyle             | \$5,950.00    | 9/30/2009         | HCP Speaker Fee               |
| Khatri            | \$5,950.00    | 10/1/2009         | HCP Speaker Fee               |
| Vartanian         | \$7,350.00    | 10/1/2009         | HCP Speaker Fee               |
| Munschauer        | \$7,350.00    | 10/7/2009         | HCP Speaker Fee               |
| Fox               | \$6,300.00    | 10/8/2009         | HCP Speaker Fee               |
| Zamvil            | \$5,950.00    | 10/8/2009         | HCP Speaker Fee               |
| Stefoski          | \$5,950.00    | 10/9/2009         | HCP Speaker Fee               |
| Jeffery           | \$7,350.00    | 10/15/2009        | HCP Speaker Fee               |
| Coyle             | \$5,950.00    | 10/16/2009        | HCP Speaker Fee               |
| Katsamakias       | \$5,950.00    | 10/24/2009        | HCP Speaker Fee               |
| Coyle             | \$5,950.00    | 10/29/2009        | HCP Speaker Fee               |
| Jeffery           | \$7,350.00    | 11/5/2009         | HCP Speaker Fee               |
| Brandes           | \$5,950.00    | 11/9/2009         | HCP Speaker Fee               |
| Foley             | \$6,300.00    | 11/12/2009        | HCP Speaker Fee               |
| Fox               | \$5,950.00    | 11/12/2009        | HCP Speaker Fee               |
| Jeffery           | \$7,350.00    | 11/12/2009        | HCP Speaker Fee               |
| Scott             | \$5,950.00    | 11/20/2009        | HCP Speaker Fee               |
| Brandes           | \$7,350.00    | 11/23/2009        | HCP Speaker Fee               |
| Frohman           | \$7,350.00    | 12/9/2009         | HCP Speaker Fee               |
| Munschauer        | \$5,950.00    | 12/11/2009        | HCP Speaker Fee               |
| Cohan             | \$5,950.00    | 1/21/2010         | HCP Speaker Fee               |
| Pelletier         | \$5,950.00    | 2/3/2010          | HCP Speaker Fee               |
| Lucas             | \$5,950.00    | 2/5/2010          | HCP Speaker Fee               |
| Hojnacki          | \$6,300.00    | 2/15/2010         | HCP Speaker Fee               |
| Brandes           | \$5,950.00    | 2/16/2010         | HCP Speaker Fee               |
| Foley             | \$6,300.00    | 2/18/2010         | HCP Speaker Fee               |
| Brandes           | \$5,950.00    | 2/23/2010         | HCP Speaker Fee               |
| Pachner           | \$5,950.00    | 3/10/2010         | HCP Speaker Fee               |
| Lucas             | \$5,950.00    | 3/10/2010         | HCP Speaker Fee               |
| Brandes           | \$5,950.00    | 3/11/2010         | HCP Speaker Fee               |
| Frohman           | \$7,350.00    | 3/11/2010         | HCP Speaker Fee               |
| Fox               | \$7,350.00    | 3/16/2010         | HCP Speaker Fee               |
| Stefoski          | \$8,820.00    | 3/22/2010         | HCP Speaker Fee-International |
| Phillips          | \$5,950.00    | 3/30/2010         | HCP Speaker Fee               |
| Fox               | \$5,950.00    | 3/30/2010         | HCP Speaker Fee               |
| Frohman           | \$7,350.00    | 4/1/2010          | HCP Speaker Fee               |



| <u>Last Name</u> | <u>Amount</u> | <u>Event Date</u> | <u>Reason For Request</u> |
|------------------|---------------|-------------------|---------------------------|
| Vartanian        | \$5,950.00    | 4/5/2010          | HCP Speaker Fee           |
| Coyle            | \$5,950.00    | 4/7/2010          | HCP Speaker Fee           |
| Brandes          | \$7,350.00    | 4/19/2010         | HCP Speaker Fee           |
| Pachner          | \$7,350.00    | 4/20/2010         | HCP Speaker Fee           |
| Hojnacki         | \$6,300.00    | 4/21/2010         | HCP Speaker Fee           |
| Foley            | \$6,300.00    | 4/22/2010         | HCP Speaker Fee           |
| Brandes          | \$7,350.00    | 4/27/2010         | HCP Speaker Fee           |
| Hendin           | \$6,300.00    | 4/28/2010         | HCP Speaker Fee           |
| Brandes          | \$7,350.00    | 5/3/2010          | HCP Speaker Fee           |
| Coyle            | \$7,350.00    | 5/5/2010          | HCP Speaker Fee           |
| Frohman          | \$7,350.00    | 5/6/2010          | HCP Speaker Fee           |
| Galetta          | \$5,950.00    | 5/11/2010         | HCP Speaker Fee           |
| Cohan            | \$7,350.00    | 5/18/2010         | HCP Speaker Fee           |
| Hojnacki         | \$6,300.00    | 5/20/2010         | HCP Speaker Fee           |
| Frishberg        | \$5,950.00    | 5/25/2010         | HCP Speaker Fee           |
| Foley            | \$6,300.00    | 6/3/2010          | HCP Speaker Fee           |
| Laganke          | \$6,300.00    | 6/10/2010         | HCP Speaker Fee           |
| Vartanian        | \$5,950.00    | 6/14/2010         | HCP Speaker Fee           |
| Frohman          | \$7,350.00    | 7/15/2010         | HCP Speaker Fee           |
| Hendin           | \$6,300.00    | 7/21/2010         | HCP Speaker Fee           |
| Levin            | \$5,950.00    | 7/28/2010         | HCP Speaker Fee           |
| Selhorst         | \$5,950.00    | 8/20/2010         | HCP Speaker Fee           |
| Laganke          | \$6,300.00    | 8/24/2010         | HCP Speaker Fee           |
| Herndon          | \$5,950.00    | 8/26/2010         | HCP Speaker Fee           |
| Zamvil           | \$5,950.00    | 8/31/2010         | HCP Speaker Fee           |
| Lucas            | \$5,950.00    | 9/8/2010          | HCP Speaker Fee           |
| Jeffery          | \$7,350.00    | 9/9/2010          | HCP Speaker Fee           |
| Fox              | \$7,350.00    | 9/14/2010         | HCP Speaker Fee           |
| Cohan            | \$5,950.00    | 9/14/2010         | HCP Speaker Fee           |
| Zamvil           | \$7,350.00    | 9/15/2010         | HCP Speaker Fee           |
| Vartanian        | \$5,950.00    | 9/20/2010         | HCP Speaker Fee           |
| Fox              | \$7,350.00    | 9/21/2010         | HCP Speaker Fee           |
| Khatri           | \$5,950.00    | 9/22/2010         | HCP Speaker Fee           |
| Kita             | \$7,350.00    | 9/29/2010         | HCP Speaker Fee           |
| Foley            | \$6,300.00    | 9/30/2010         | HCP Speaker Fee           |
| Hojnacki         | \$6,300.00    | 9/30/2010         | HCP Speaker Fee           |
| Hojnacki         | \$6,300.00    | 10/13/2010        | HCP Speaker Fee           |
| Okuda            | \$7,350.00    | 10/21/2010        | HCP Speaker Fee           |
| Frohman          | \$5,950.00    | 10/21/2010        | HCP Speaker Fee           |
| Bandari          | \$5,950.00    | 10/26/2010        | HCP Speaker Fee           |
| Boster           | \$5,950.00    | 10/29/2010        | HCP Speaker Fee           |
| Foley            | \$6,300.00    | 11/11/2010        | HCP Speaker Fee           |

| <u>Last Name</u> | <u>Amount</u> | <u>Event Date</u> | <u>Reason For Request</u> |
|------------------|---------------|-------------------|---------------------------|
| Jeffery          | \$7,350.00    | 11/18/2010        | HCP Speaker Fee           |
| Zamvil           | \$5,950.00    | 11/18/2010        | HCP Speaker Fee           |
| Brandes          | \$7,350.00    | 12/6/2010         | HCP Speaker Fee           |
| Pelletier        | \$7,350.00    | 12/7/2010         | HCP Speaker Fee           |
| Lucas            | \$5,950.00    | 12/8/2010         | HCP Speaker Fee           |

**3. Biogen Rewards One of Its Highest Prescribers with the Ultimate Kickback, a Lucrative Job**

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125. In 2008 and 2009, no physician received more money from Biogen than Dr. Frederick Munschauer. He received \$562,522 in payments during those years, or about \$770 per day. A close look at his 2009 payments shows how this was achieved:

| <u>Date</u> | <u>Payment</u> | <u>Reason</u>                 |
|-------------|----------------|-------------------------------|
| 1/6/2009    | \$2,800.00     | HCP Speaker Fee               |
| 1/21/2009   | \$8,820.00     | HCP Speaker Fee-International |
| 1/26/2009   | \$7,350.00     | Consult Fee                   |
| 2/6/2009    | \$8,050.00     | Consult Fee                   |
| 2/6/2009    | \$4,550.00     | Consult Fee                   |
| 2/20/2009   | \$9,100.00     | Consult Fee                   |
| 2/25/2009   | \$3,675.00     | HCP Speaker Fee               |
| 2/26/2009   | \$3,675.00     | HCP Speaker Fee               |
| 3/4/2009    | \$3,675.00     | HCP Speaker Fee               |
| 3/5/2009    | \$3,675.00     | HCP Speaker Fee               |
| 3/13/2009   | \$1,250.00     | HCP Speaker Fee               |
| 3/20/2009   | \$9,100.00     | Consult Fee                   |
| 3/25/2009   | \$1,250.00     | HCP Speaker Fee               |
| 3/26/2009   | \$1,000.00     | HCP Speaker Fee               |
| 3/30/2009   | \$1,250.00     | HCP Speaker Fee               |
| 4/3/2009    | \$8,150.00     | Consult Fee                   |
| 4/14/2009   | \$7,350.00     | HCP Speaker Fee               |
| 4/18/2009   | \$5,950.00     | HCP Speaker Fee               |
| 4/28/2009   | \$2,800.00     | HCP Speaker Fee               |
| 5/2/2009    | \$4,550.00     | Consult Fee                   |
| 5/5/2009    | \$4,550.00     | HCP Speaker Fee               |
| 5/7/2009    | \$2,800.00     | HCP Speaker Fee               |
| 5/30/2009   | \$7,350.00     | Consult Fee                   |
| 6/3/2009    | \$4,375.00     | HCP Speaker Fee               |
| 6/4/2009    | \$4,375.00     | HCP Speaker Fee               |
| 6/11/2009   | \$1,400.00     | HCP Speaker Fee               |

| <u>Date</u> | <u>Payment</u> | <u>Reason</u>   |
|-------------|----------------|-----------------|
| 6/15/2009   | \$7,350.00     | Consult Fee     |
| 6/25/2009   | \$5,950.00     | HCP Speaker Fee |
| 7/7/2009    | \$4,050.00     | Consult Fee     |
| 7/9/2009    | \$1,250.00     | HCP Speaker Fee |
| 7/10/2009   | \$6,300.00     | Consult Fee     |
| 7/14/2009   | \$1,400.00     | HCP Speaker Fee |
| 7/22/2009   | \$4,550.00     | HCP Speaker Fee |
| 8/5/2009    | \$1,400.00     | HCP Speaker Fee |
| 8/13/2009   | \$4,550.00     | HCP Speaker Fee |
| 8/19/2009   | \$6,860.00     | HCP Speaker Fee |
| 9/10/2009   | \$8,330.00     | HCP Speaker Fee |
| 9/12/2009   | \$6,300.00     | Consult Fee     |
| 9/23/2009   | \$5,950.00     | HCP Speaker Fee |
| 10/2/2009   | \$9,100.00     | Consult Fee     |
| 10/7/2009   | \$7,350.00     | HCP Speaker Fee |
| 10/16/2009  | \$6,300.00     | Consult Fee     |
| 10/28/2009  | \$2,100.00     | Consult Fee     |
| 11/2/2009   | \$1,250.00     | HCP Speaker Fee |
| 11/6/2009   | \$5,600.00     | HCP Speaker Fee |
| 11/11/2009  | \$2,275.00     | HCP Speaker Fee |
| 11/13/2009  | \$7,350.00     | Consult Fee     |
| 11/18/2009  | \$4,550.00     | HCP Speaker Fee |
| 12/8/2009   | \$1,250.00     | HCP Speaker Fee |
| 12/9/2009   | \$4,550.00     | HCP Speaker Fee |
| 12/11/2009  | \$5,950.00     | HCP Speaker Fee |

Biogen paid Dr. Munschauer about once a week, sometimes more than once on the same day. He consulted 16 separate times, sometimes on the same day or just a few days apart. He earned \$7,000 for an average consulting event. He spoke 35 separate times in 2009, earning on average \$4,000 per speaking event. In 2009 alone, Biogen paid Dr. Munschauer seven payments that were above fair market value. And in each year, Biogen had to exempt Dr. Munschauer from the annual payment cap.

126. Like many physicians, Dr. Munschauer had figured out that he could ingratiate himself to a drug company like Biogen through prescriptions. Dr.

Munschauer was interviewed for a Consortium of Multiple Sclerosis (CMSC) podcast titled "How to Manage an MS Center and Make it Work." In that interview, Dr. Munschauer candidly admitted that "it is possible to have an MS center and not go broke...You have to be a little creative, but it is." What Dr. Munschauer was referring to was the lucrative kickback relationship that he and Biogen had "creatively" forged. In that same interview, Dr. Munschauer also admitted that he used a large amount of Tysabri in his practice, which was also "a revenue generating process for us."

127. Dr. Munschauer has also instructed neurologists visiting the CMSC website that kickbacks are there for the taking. Dr. Munschauer has specifically urged prescribers to "solicit industry support," and to "form strategic alliances" that allow them to "barter for support":

The screenshot shows a video player interface. On the left, a slide titled "Increasing Revenues: Non - Patient Sources" contains three bullet points:

- **Establish a "Center of Excellence" that will allow you to solicit industry, government, philanthropic support.**
- **Negotiate with all external and internal connections for what you need based on your known economic impact.**
- **Form strategic alliances. Barter for support.**

On the right side of the video player, there is a table of contents for the presentation:

| Outline                   | Search |
|---------------------------|--------|
| 22. Clinical Revenues ... | 00:10  |
| 23. Practice Managem...   | 00:10  |
| 24. Benchmarking: Pa...   | 00:10  |
| 25. The Volume Game       | 00:10  |
| 26. Principal # 5 You...  | 00:10  |
| 27. MS Centers: Proc...   | 00:10  |
| 28. MS Centers: Servi...  | 00:10  |
| 29. Creating an Oper...   | 00:10  |
| 30. Examples of Servi...  | 00:10  |
| 31. Requirements for ...  | 00:10  |
| 32. Your Practice: Thi... | 00:10  |
| 33. Non FinancialThi...   | 00:10  |
| 34. Principal # 6         | 00:10  |
| 35. Slide 75              | 00:10  |
| 36. Successful MS Ce...   | 00:10  |
| 37. Principal # 7         | 00:10  |
| 38. Slide 36              | 00:10  |
| 39. Principal # 8         | 00:10  |
| 40. Increasing Reven...   | 00:10  |
| 41. Sources of Extern...  | 00:10  |

At the bottom right of the video player, it says "1 Minutes 6 Seconds Remaining".

Munschauer was speaking from experience. As Chief of the Jacobs Neurological Institute, he had formed precisely the form of “strategic alliance” and “bartering” that he advocated. In exchange for writing the most prescriptions in the Upstate New York region, doctors affiliated with the Jacobs Neurological Institute received the most money – well over a \$1 million combined for Munschauer and Institute’s doctors and prescribing nurses from 2008 through 2010. Mindful of the revenue that the Institute created, Biogen targeted each person capable of influencing prescriptions with lavish payments. Biogen used “strategic P2P’s and PEP’s,” as well as lunches and dinners, to push for an even higher market share from the Institute.

For example, in late 2009, Biogen provided Munschauer with back-to-back payments for a PEP program and a P2P program, with the goal of increasing his market share from 73% to 75%. See Exhibit V. Biogen provided his colleague Weinstock-Guttman with a P2P speaking fee to speak to four of the Institute’s other prescribers (Hojnacki, Umhauer, Miller, and Ramanathan) with the goal of increasing her market share from 61% to 63%. *Id.* Biogen then targeted Hojnacki with a dinner, with the goal of increasing his market share from 45% to 50%. Biogen took nurses Miller and Umhauer to lunch, and took Miller to a dinner a few weeks later, with the goal of increasing their market shares by two percentage points (to 63% for Miller and 67% for Umhauer). Biogen gave additional payments to these doctors and nurses in form of additional PEP and P2P speaking fees with the goal of having 10 new patients put on Tysabri in the 4th quarter of 2009. *Id.*



128. Sometime in either 2008 or 2009, Biogen discussed rewarding Dr. Munschauer with the ultimate prize, a cushy job as VP of Medical Affairs. Biogen was not concerned that it would lose Dr. Munschauer's prescriptions. Dr. Weinstock-Guttman was still Director of the MS practice at the Institute, and Biogen was paying her and her colleagues, most notably Dr. Hojnacki, hundreds of thousands of dollars to maintain Biogen's overall share of the Institute's prescriptions. Biogen continues to give money directly to the Jacobs Institute through educational and research grants.

129. Biogen hired Dr. Munschauer, and he began working as a Biogen employee in January 2010. This position is far less demanding than a medical practice, and commands a higher salary, estimated to be \$300,000 or more. Dr. Munschauer also has received stock options and other emoluments and benefits that make this position valuable.

130. Not only are all of Dr. Munschauer's Avonex and Tysabri prescriptions tainted by the kickbacks he received, but every prescription he wrote after he knew that he was being considered for employment at Biogen and before his first day of work there was done with a clear conflict of interest. Accordingly, these prescriptions also violated his agreement to participate in federal programs and were thus ineligible for reimbursement.

#### **4. Biogen Broadly Distributes Its Kickbacks**

131. In addition to the massive sums directed to the highest prescribers, Biogen proportionally delivered sizeable yet smaller sums of cash to physicians who wrote

sizeable yet smaller quantities of prescriptions. The following two doctors illustrate this practice.

132. Dr. Donald Negroski is a neurologist in Florida. He typically wrote about 360 prescriptions for Avonex per year, earning Biogen roughly \$1 million. Biogen considered him a "Key Account," and because his market share was trending towards Biogen, he was labeled an "Avonex Opportunity." He was also considered high risk for "oral uptake."

133. To ensure that Dr. Negroski maintained his patients on Biogen's MS products, Biogen paid him almost exactly \$30,000 per year, a tiny fraction of the revenue he generated for the company. In 2009, Biogen paid him \$30,500; in 2010, it paid him \$30,550. As his 2010 payments reveal, this was done with a mix of consultant meetings, speaking dinners, and a PEP program:

| <u>Date</u> | <u>Amount</u> | <u>Type</u> | <u>Program</u>         |
|-------------|---------------|-------------|------------------------|
| 1/29/2010   | \$5,000.00    | Consult Fee | Consultant Meeting     |
| 2/18/2010   | \$2,000.00    | Speaker Fee | Promo Physician Dinner |
| 3/2/2010    | \$2,000.00    | Speaker Fee | PEP Program            |
| 4/21/2010   | \$2,000.00    | Speaker Fee | Promo Physician Dinner |
| 5/20/2010   | \$5,250.00    | Speaker Fee | Promo Physician Dinner |
| 8/6/2010    | \$5,400.00    | Consult Fee | Speaker Training       |
| 9/2/2010    | \$2,000.00    | Speaker Fee | Promo Physician Dinner |
| 10/23/2010  | \$4,500.00    | Consult Fee | Consultant Meeting     |
| 11/3/2010   | \$2,400.00    | Speaker Fee | Promo Physician Dinner |

No valuable feedback was ever obtained from Dr. Negroski, nor was it necessary for him to consult on so many occasions in such a short period of time. Moreover, his regular use as a speaker was not a reflection of his speaking abilities; it was to provide him with a regular source of payments. In fact, Dr. Negroski attended speaker training

in August 2010, despite the fact that Biogen had already used him as a speaker four times that year alone.

A similar example is Dr. Lilyana Amezcua, a neurologist in Los Angeles. She typically wrote about 120 prescriptions for Avonex per year, earning Biogen roughly \$300,000. Biogen considered her to be a “Medium” volume prescriber, and because her market share was trending away from Biogen, she was labeled an “Avonex Risk.” She was also considered high risk for “oral uptake.”

To increase Dr. Amezcua’s prescribing of Biogen’s biologicals, and to prevent her from diverting prescriptions to Novartis’s new oral tablet, Biogen paid her roughly \$20,000 per year, a tiny fraction of the revenue she generated for the company. In 2009, Biogen paid her \$15,100; in 2010, as the launch of Gilenya neared, it paid her \$24,500. Her 2010 payments reveal the same pattern of payments as Dr. Negroski:

| <u>Date</u> | <u>Amount</u> | <u>Type</u> | <u>Program</u>         |
|-------------|---------------|-------------|------------------------|
| 1/29/2010   | \$5,750.00    | Consult Fee | Consultant Meeting     |
| 2/24/2010   | \$2,000.00    | Speaker Fee | Promo Physician Dinner |
| 5/14/2010   | \$4,500.00    | Consult Fee | Consultant Meeting     |
| 7/28/2010   | \$2,000.00    | Speaker Fee | PEP Program            |
| 8/10/2010   | \$3,750.00    | Consult Fee | Speaker Training       |
| 10/21/2010  | \$2,000.00    | Speaker Fee | Promo Physician Dinner |
| 12/8/2010   | \$4,500.00    | Consult Fee | Consultant Meeting     |

134. As with Dr. Negroski, Biogen did not obtain any feedback of value from Dr. Amezcua, nor was it necessary for her to consult every quarter. Biogen regularly paid her to speak at events to provide her with payments, not to further its business objectives. And like Dr. Negroski, paying Dr. Amezcua to attend speaker training was

superfluous because Biogen had already paid her to speak on two occasions earlier in the year.

**G. Biogen Caused the Presentation of False Claims to the United States**

**1. Federal Reimbursement for Avonex & Tysabri**

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135. Through Medicare and Medicaid, the United States Government and the individual states reimburse a large percentage of all Avonex, Tysabri and Tecfidera prescriptions. Medicare not only covers individuals over age 65, but it also provides medical coverage for many individuals who are permanently disabled under the Social Security Act, as is the case for many MS patients. When medically necessary, Tysabri infusions are covered under Medicare Part B and are paid for by the federal government. Avonex injections may be covered under Medicare Part B or Medicare Part D, depending on the patient's circumstances. Tecfidera is reimbursed under Medicare Part D. It is estimated that 30% of all MS patients in the United States are covered by Medicare. Multiple sclerosis therapies represent Medicare's second largest drug expenditure outside of cancer treatment.

136. Medicaid, a joint program between the states and the federal government, also routinely pays for Avonex, Tysabri and Tecfidera prescriptions. Medicaid provides health coverage to millions of non-elderly low-income non-disabled adults, particularly those with families. Medicaid also provides coverage to several million low-income seniors and non-elderly people with disabilities. Given the substantial annual cost of IMA therapy, many uninsured MS sufferers turn to Medicaid to pay for their treatments. A 2007 study found that 10.5% of all MS sufferers were covered for MS

therapy through Medicaid. The federal government pays more than half of the funding for the Medicaid program.

137. The United States also pays for Avonex, Tysabri and Tecfidera through the Veteran's Administration, through the Federal Employees Health Benefits (FEHB) Program, and through TRICARE, its insurance program for Department of Defense personnel and their families.

138. The amount that the federal government and the states have spent on Avonex and Tysabri is substantial. The Relator estimates that since 2006, these government entities have spent roughly \$900 million on Avonex, and roughly \$200 million on Tysabri.

139. Every time a neurologist seeks reimbursement from Medicare, Medicaid or some other federal health care program for the administration of Tysabri or Avonex, a claim is presented for payment for the purposes of the False Claims Act. Similarly, every time a Medicare or Medicaid patient obtains Avonex or Tedfidera from a pharmacy, the pharmacy presents a claim for payment. As noted above, all of these claims are conditioned upon compliance with the Anti-Kickback Statute. Were the applicable federal program aware that the presented claim had been induced by a kickback, it would not be permitted to pay it.

**2. Biogen's Kickbacks Induced Medicare, Medicaid and the Federal Programs to Pay For Thousands of Prescriptions**

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140. Attached as Exhibits 1-4 are spreadsheets that list every payment known to the Relator that Biogen made to physicians pursuant to the sham consulting and



sham speaking programs described above. Although this list is extensive, it is not exhaustive; other payments have been made for which the Relator does not presently have documentation. These programs were initiated before the Relator became the Director for Regional Marketing, and there were numerous payments made in 2007 and 2008 which are not listed. Payments are still being made pursuant to these abusive programs at the time this Amended Complaint was filed.

141. For the reasons set forth above, none of these payments was made to obtain the services which were purportedly provided in exchange for Biogen's remuneration. In reality, each and every one of these payments was to induce the recipient to write prescriptions for Avonex or Tysabri in the future. The payments were made to either gain prescriptions from the neurologists or to maintain the prescriber's current level of support. Any payment listed in Exhibits 1-4 (and any payment made pursuant to the consulting and speaking programs that are not listed on Exhibits 1-4) constitutes a kickback.

142. Exhibits 1-4 list 6,682 kickbacks paid to 1,492 physicians in 2009 and 2010, totaling \$19,920,970. Every physician listed on Exhibits 1-4 who had more than two patients on Avonex or Tysabri likely submitted, or caused to be submitted, a federal claim for reimbursement because more than 40.5% of all MS patients have their MS medications paid for by Medicare, Medicaid or another federal health care program. Medicare and Medicaid pay approximately \$30,000 a year for each MS patient who is prescribed Avonex or Tysabri for their condition.

143. The physicians listed on Exhibits 1–4 who received kickbacks maintained between 31,000 to 47,000 patients on Avonex or Tysabri during the time they received kickbacks. If only 40% of these patients were covered by federal health care programs, then the United States spent between \$270,000,000 and \$435,000,000 annually on claims that were induced by kickbacks. For the years 2009 through 2011, this amount exceeds \$815 million and may be as high as \$1.3 billion.

144. Tecfidera therapy is even more expensive than Avonex or Tysabri. The current wholesale acquisition cost for annual treatment of Tecfidera is \$54,900. While it is too early to know how much Tecfidera was prescribed by the “consultants” who attended the regional DEFINE and CONFIRM consultants meeting, if each consultant only placed one Medicare or Medicaid patient on Tecfidera, the programs would have paid more than \$10,000,000 for the first year of treatment alone as a result of the kickbacks paid at those meetings. In all likelihood, the amount paid as a result of the DEFINE and CONFIRM kickbacks is probably much higher.

145. Each and every one of these claims would not have been paid had the United States known that the physician who submitted the claim (or who wrote the prescription that was the basis of the claim) had received a kickback from Biogen. As the person who knowingly paid the kickback to each and every one of the physicians, Biogen has caused the false claims which were submitted by the physicians and the pharmacies. Pursuant to the False Claims Act, Biogen is liable for the amount the United States paid on account of the false claims and a monetary penalty for each false claim submitted.

**FIRST CAUSE OF ACTION: UNITED STATES FALSE CLAIMS ACT**

31 U.S.C. §3729(a)(1)(A)

146. The Relator repeats and realleges the allegations set forth in Paragraph 1 through 145 as if fully set forth herein.

147. As described in detail above, Biogen has caused the presentation of numerous false claims to the United States through the Medicare and Medicaid programs and other federal health insurance programs for medically unnecessary, excessive and abusive claims for Avonex, Tysabri and Tecfidera. Biogen improperly paid kickbacks to induce health care providers to prescribe a Biogen product over a more appropriate competitor product. Indeed, Biogen encourages such prescribing by rewarding doctors and prescribing nurses with more and more payments based on their prescription levels. At all times, Biogen knew its kickback scheme would cause Medicare and Medicaid to pay for unnecessary, excessive or abusive claims for Avonex, Tysabri and Tecfidera; that was the entire purpose of the scheme.

148. The kickbacks described above resulted in the presentation of claims to the Medicare and Medicaid programs and other programs paid for by the United States. These claims were false claims because the United States and/or Medicaid officials are prohibited from paying any claims that were induced through the payment of a kickback. Had the program administrators known that the claims for Avonex or Tysabri were the product of the payment of kickbacks the claims would have been denied.

149. By paying kickbacks, Biogen also knowingly caused its customers, the physicians and prescribing nurses that wrote the Avonex, Tysabri and Tecfidera prescriptions, to violate their participation agreements with Medicare, Medicaid and other federal payment programs. These prescribers all certified that they were in compliance with the Anti-Kickback Statute, and compliance was a precondition for payment. Biogen knew that its conduct caused prescribers to violate their provider agreements, and to invalidate the precondition for payment. These false certifications and lack of compliance caused by the kickbacks were material to false or fraudulent claims being paid. Had Biogen or the physicians informed Medicare, Medicaid and the federal insurance programs about the kickback relationships, these physicians would have been excluded from further participation in the federal programs, and their claims would have been ineligible for reimbursement.

150. As a result of the kickbacks, millions of dollars were spent by Medicare, Medicaid, and the other federal programs for medically unnecessary, excessive, abusive, and tainted claims for Avonex, Tysabri and Tecfidera that should never have been reimbursed. Additionally, if a provider receives kickbacks, all of his or her claims, whether for Biogen products or other goods and services, are ineligible for reimbursement. Accordingly, Biogen is liable for all claims submitted by or as result of a physician that would have been ineligible because of its kickbacks.

WHEREFORE, Relator, on behalf of the United States of America, requests that this Court:

- (a) Enter judgment holding Biogen liable for a civil penalty of \$11,000 for each violation of the False Claims Act committed by it;
- (b) Enter a judgment against Biogen for three times the amount of damages sustained by the United States because of the its acts;
- (c) Award the Relator a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730;
- (d) Award the Relator his costs and reasonable attorneys' fees for prosecuting this action; and
- (e) Enter such other relief which the Court finds just and equitable.

**SECOND CAUSE OF ACTION: DISTRICT OF COLUMBIA FALSE CLAIMS ACT**

D.C. Code §§ 2-308.03 *et seq.*

151. The Relator repeats and realleges all of the allegations set forth in paragraphs 1 through 150 as if fully set forth herein.

152. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee of the District of Columbia a false claim for payment or approval, in violation of D.C. Code § 2-308.14(a)(1).

153. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false claim paid or approved by the District of Columbia, in violation of D.C. Code § 2-308.14(a)(2).

154. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen,



paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

155. By reason of Biogen's acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

156. Pursuant to D.C. Code § 2-308.14(a), the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**THIRD CAUSE OF ACTION: CALIFORNIA FALSE CLAIMS ACT**

Cal. Gov't. Code §§ 12650 *et seq.*

157. Relator repeats and realleges the allegations set forth in paragraphs 1 through 156 as if fully set forth herein.

158. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of the State of California or of any political subdivision thereof, a false claim for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

159. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false claim paid or approved by the State of California or by any political subdivision, in violation of Cal. Gov't Code § 12651 (a)(2).

160. California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and

continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

161. By reason of Biogen's acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

162. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**FOURTH CAUSE OF ACTION: COLORADO MEDICAID FALSE CLAIMS ACT**  
CRS §§ 25.5-4-304 *et seq.*

163. Relator repeats and realleges the allegations set forth in paragraphs 1 through 162 as if fully set forth herein.

164. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Colorado agency a false claim for payment or approval, in violation of CRS §25.5-4-305(a).

165. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Colorado agency, in violation of CRS §25.5-4-305(b).

166. Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

167. By reason of Biogen's acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

168. Pursuant to CRS §25.5-4-305(a), the State of Colorado is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**FIFTH CAUSE OF ACTION: CONNECTICUT FALSE CLAIMS ACT**  
Connecticut General Statutes, §17b-301a *et seq.*

169. Relator repeats and realleges the allegations set forth in paragraphs 1 through 168 as if fully set forth herein.

170. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Connecticut agency a false claim for payment or approval, in violation of Conn. Gen. Stat. § 17b-301b(a)(1).

171. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Connecticut agency, in violation of Conn. Gen. Stat. § 17b-301b(a)(2).

172. Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

173. By reason of Biogen's acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

174. Pursuant to Conn. Gen. Stat. § 17b-301b(a), the State of Connecticut is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**SIXTH CAUSE OF ACTION: DELAWARE FALSE CLAIMS AND REPORTING ACT**

6 Del C. §§ 1201 *et seq.*

175. Relator repeats and realleges the allegations set forth in paragraphs 1 through 174 as if fully set forth herein.

176. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, directly or indirectly, to an officer or employee of Delaware a false or fraudulent claim for payment or approval, in violation of 6 Del. C. § 1201(a)(1).

177. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved by Delaware in violation of 6 Del. C. § 1201(a)(2).

178. Delaware, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not have been paid but for the acts and/or conduct of Biogen as alleged herein.

179. By reason of Biogen's acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

180. Pursuant to 6 Del. C. § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of \$11 ,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**SEVENTH CAUSE OF ACTION: FLORIDA FALSE CLAIMS ACT**

Fla. Stat. §§ 68.081 *et seq.*

181. Relator repeats and realleges the allegations set forth in paragraphs 1 through 180 as if fully set forth herein.

182. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Florida agency a false claim for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

183. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Florida agency, in violation of Fla. Stat. § 68.082(2)(b).

184. Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

185. By reason of Biogen's acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.



186. Pursuant to Fla. Stat. § 68.082(2)(g), the State of Florida is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**EIGHTH CAUSE OF ACTION: GEORGIA STATE FALSE MEDICAID CLAIMS**

**ACT**

O.C.G.A. § 49-4-168

187. Relator repeats and realleges the allegations set forth in paragraphs 1 through 186 as if fully set forth herein.

188. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer, employee, fiscal intermediary grantee or contractor of the Georgia Medicaid Program a false claim for payment or approval, in violation of O.G.C.A. § 49-4-168.1(a)(1).

189. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program, in violation of O.G.C.A. § 49-4-168.1(2)(b).

190. The Georgia Medicaid program, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

191. By reason of Biogen's acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

192. Pursuant to O.G.C.A. § 49-4-168.1(a), the State of Georgia is entitled to three times actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used or caused to be made or used by Biogen.

**NINTH CAUSE OF ACTION: HAWAII FALSE CLAIMS ACT**

Haw. Rev. Stat. §§ 661-21 *et seq.*

193. Relator repeats and realleges the allegations set forth in paragraphs 1 through 192 as if fully set forth herein.

194. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(1).

195. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii, in violation of Haw. Rev. Stat. § 661-21(a)(2).

196. The State of Hawaii, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

197. By reason of Biogen's acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

198. Pursuant to Haw. Rev. Stat. § 661-21(a)(8) the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for

each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TENTH CAUSE OF ACTION: ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT**

740 Ill. Comp. Stat. §§ 175/1 *et seq.*

199. Relator repeats and realleges the allegations set forth in paragraphs 1 through 198 as if fully set forth herein.

200. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

201. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 Ill. Comp. Stat. § 175/3(a)(2).

202. Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

203. By reason of Biogen's acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

204. Pursuant to 740 Ill. Comp. Stat. § 175/3(a)(7), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of

\$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**ELEVENTH CAUSE OF ACTION: INDIANA FALSE CLAIMS AND  
WHISTLEBLOWER PROTECTION ACT**

Ind. Code. §§ 5-11-5.5 *et seq.*

205. Relator repeats and realleges the allegations set forth in paragraphs 1 through 204 as if fully set forth herein.

206. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee of the State of Indiana a false or fraudulent claim for payment or approval in violation of Ind. Code §§ 5-11-5.5-2(b)(1) and (8).

207. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana, in violation of §§ 5-11-5.5-2(b)(2) and (8).

208. Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

209. By reason of Biogen's acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

210. Pursuant to § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWELFTH CAUSE OF ACTION: IOWA MEDICAID FALSE CLAIMS ACT**

Iowa Code §685 *et seq.*

211. Relator repeats and realleges the allegations set forth in paragraphs 1 through 210 as if fully set forth herein.

212. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Iowa agency a false claim for payment or approval, in violation of Iowa Code §685.2.1.a.

213. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Iowa agency, in violation of Iowa Code §685.2.1.b.

214. Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

215. By reason of Biogen's acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

216. Pursuant to Iowa Code 685.2.1, the State of Iowa is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.



**THIRTEENTH CAUSE OF ACTION: LOUISIANA FALSE CLAIMS ACT/MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW**

46 La. Rev. Stat. Ch. 3 §§ 437.1 *et seq.*

217. Relator repeats and realleges the allegations set forth in paragraphs 1 through 216 as if fully set forth herein.

218. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to Louisiana false or fraudulent claims, in violation of 46 La. Rev. Stat. Ch. 3 §438.3(A).

219. By virtue of the acts described above, Biogen knowingly engaged in misrepresentation to obtain, or attempt to obtain, payment from Louisiana medical assistance programs funds, in violation of 46 La. Rev. Stat. Ch. 3 § 438.3(B).

220. Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen alleged herein.

221. By reason of Biogen's acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

222. Pursuant to 46 La. Rev. Stat. Ch. 3 § 438.5 and § 438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**FOURTEENTH CAUSE OF ACTION: MARYLAND FALSE HEALTH CLAIMS ACT**  
Md. Code Ann., Health-Gen §2-601 *et seq.*

223. Relator repeats and realleges the allegations set forth in paragraphs 1 through 222 as if fully set forth herein.

224. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Maryland agency a false claim for payment or approval, in violation of Md. Code Ann., Health-Gen §2-602(a)(1).

225. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Maryland agency, in violation of Md. Code Ann., Health-Gen §2-602(a)(2).

226. Maryland, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

227. By reason of Biogen's acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

228. Pursuant to Md. Code Ann., Health-Gen §2-602(b), the State of Maryland is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**FIFTEENTH CAUSE OF ACTION: MASSACHUSETTS FALSE CLAIMS LAW**  
M.G.L. c. 12 §§ 5A *et seq.*

229. Relator repeats and realleges the allegations set forth in paragraphs 1 through 228 as if fully set forth herein.

230. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented to the Commonwealth of Massachusetts, a false or fraudulent claim for payment or approval, in violation of M.G.L. c. 12 § 5B(1).

231. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to obtain payment or approval of a claim by the Commonwealth of Massachusetts or any political subdivision thereof, in violation of M.G.L. c. 12 § 5B(2).

232. Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

233. By reason of Biogen's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

234. Pursuant to M.G.L. c. 12 § 5B(9), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**SIXTEENTH CAUSE OF ACTION: MICHIGAN MEDICAID FALSE CLAIM ACT**

M.C.L. §§ 400.601 *et seq.*

235. Relator repeats and realleges the allegations set forth in paragraphs 1 through 234 as if fully set forth herein.

236. By virtue of the acts described above, Biogen knowingly caused to be presented to Michigan, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of M.C.L. § 400.603(1).

237. By virtue of the acts described above, Biogen knowingly caused to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit under the Michigan Medicaid program, in violation of M.C.L. 400.603(2).

238. Michigan, unaware of the falsity of the statements and claims caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

239. By reason of Biogen's acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

240. Pursuant to M.C.L. § 400.612, the State of Michigan is entitled to three times the amount of actual damages, forfeiture of all amounts received by Biogen and the maximum penalty of \$10,000 for each and every false or fraudulent claim made, used, presented or caused to be made, used or presented by Biogen.

**SEVENTEENTH CAUSE OF ACTION: MINNESOTA FALSE CLAIMS ACT**  
M.S.A. §15C.01 *et seq.*

241. Relator repeats and realleges the allegations set forth in paragraphs 1 through 240 as if fully set forth herein.

242. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a Minnesota agency a false claim for payment or approval, in violation of M.S.A. §15C.02(a)(1).

243. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a Minnesota agency, in violation of M.S.A. §15C.02(a)(2).

244. Minnesota, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

245. By reason of Biogen's acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

246. Pursuant to M.S.A. §15C.02(a), the State of Minnesota is entitled to three times actual damages plus the maximum penalty of \$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**EIGHTEENTH CAUSE OF ACTION: MONTANA FALSE CLAIMS ACT**

Mont. Code Ann. §§17-8-401 *et. seq.*

247. Relator repeats and realleges the allegations set forth in paragraphs 1 through 246 as if fully set forth herein.

248. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented to an officer or employee of a Montana governmental entity, a false or fraudulent claim for payment or approval, in violation of Mont. Code Ann. § 17-8-403(l)(a).

249. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to obtain payment or approval of a claim by governmental entities of Montana, in violation of Mont. Code Ann. § 17-8-403(l) (b).

250. Montana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

251. By reason of Biogen's acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

252. Pursuant to Mont. Code Ann. § 17-8-403(2), the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.



**NINETEENTH CAUSE OF ACTION: NEVADA FALSE CLAIMS ACT**

Nev. Rev. Stat. §§ 357.010 *et seq.*

253. Relator repeats and realleges the allegations set forth in paragraphs 1 through 252 as if fully set forth herein.

254. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to Nevada a false claim for payment or approval, in violation of Nev. Rev. Stat. §357.040(1)(a).

255. By virtue of the acts described above, Biogen knowingly made or used, or caused to be made or used, a false record or statement to obtain payment or approval by Nevada of a false claim, in violation of Nev. Rev. Stat. § 357.040(1)(b).

256. Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

257. By reason of Biogen's acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

258. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTIETH CAUSE OF ACTION: NEW JERSEY FALSE CLAIMS ACT**

N.J. Stat. Ann. §§2A:32C-1 *et seq.*

259. Relator repeats and realleges the allegations set forth in paragraphs 1 through 258 as if fully set forth herein.

260. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented to an employee, officer or agent of New Jersey or any contractor, grantee or recipient of New Jersey state funds, a false or fraudulent claim for payment or approval, in violation of N.J. Stat. Ann. 2A:32-C3a.

261. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid by New Jersey, in violation of N.J. Stat. Ann. 2A:32-C3b.

262. New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

263. By reason of Biogen's acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

264. Pursuant to N.J. Stat. Ann. 2A:32-C3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-FIRST CAUSE OF ACTION: NEW MEXICO FALSE CLAIMS ACT**

N.M.S.A §§ 27-14-1 *et seq.*

265. Relator repeats and realleges the allegations set forth in paragraphs 1 through 264 as if fully set forth herein.

266. By virtue of the acts described above, Biogen presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent, in violation of N.M.S.A. § 27-14-4(A).

267. By virtue of the acts described above, Biogen made, used or caused to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false, in violation of N.M.S.A. § 27-14-4(C).

268. New Mexico, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

269. By reason of Biogen's acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

270. Pursuant to N.M.S.A. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty which may be applicable for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-SECOND CAUSE OF ACTION: NEW YORK FALSE CLAIMS ACT**

N.Y. Fin. Law §§ 187 *et seq.*

271. Relator repeats and realleges the allegations set forth in paragraphs 1 through 270 as if fully set forth herein.

272. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to employees, officers or agents of New York or New York local governments, false or fraudulent claims for payment or approval, in violation of N.Y. Fin. Law § 189.1(a).

273. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by New York or a New York local government, in violation of N.Y. Fin. Law § 189.1 (b).

274. New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

275. By reason of Biogen's acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

276. Pursuant to N.Y. Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of \$12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-THIRD CAUSE OF ACTION: NORTH CAROLINA FALSE CLAIMS ACT**  
N.C.G.S. §1-605 *et seq.*

277. Relator repeats and realleges the allegations set forth in paragraphs 1 through 276 as if fully set forth herein.

278. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to an officer or employee of a North Carolina agency a false claim for payment or approval, in violation of N.C.G.S. § 1-607(a)(1).

279. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used a false record or statement to get a false or fraudulent claim paid or approved by a North Carolina agency, in violation of N.C.G.S. § 1-607(a) (2).

280. North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

281. By reason of Biogen's acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

282. Pursuant to N.C.G.S. § 1-607(a), the State of North Carolina is entitled to three times actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-FOURTH CAUSE OF ACTION: OKLAHOMA MEDICAID FALSE  
CLAIMS ACT**

Okla. Stat. §63-5053 *et seq.*

283. Relator repeats and realleges the allegations set forth in paragraphs 1 through 282 as if fully set forth herein.

284. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to Officers or employees of the State of Oklahoma a false claim for payment or approval, in violation of Okla. Stat. §63-5053.1B1.

285. By virtue of the acts described above, Biogen knowingly made or used, or caused to be made or used, a false record or statement to obtain payment or approval by Oklahoma of a false claim, in violation of Okla. Stat. §63-5053.1B2.

286. Oklahoma, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

287. By reason of Biogen's acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

288. Pursuant to Okla. Stat. §63-5053.1B, the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.



**TWENTY-FIFTH CAUSE OF ACTION: RHODE ISLAND FALSE CLAIMS ACT**

R.I. Gen. Laws §§ 9-1.1 *et seq.*

289. Relator repeats and realleges the allegations set forth in paragraphs 1 through 288 as if fully set forth herein.

290. By virtue of the acts described above, Biogen knowingly presented or caused to be presented to officers or employees of Rhode Island false claims for payment or approval, in violation of R.I. Gen. Laws §§ 9-1.1-3(a)(1).

291. By virtue of the acts described above, Biogen knowingly made or used, or caused to be made or used, false records or statements to obtain payment or approval by Rhode Island of false claims, in violation of R.I. Gen. Laws §§ 9-1.1-3(a)(2).

292. Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

293. By reason of Biogen's acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

294. Pursuant to R.I. Gen. Laws §§ 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-SIXTH CAUSE OF ACTION: TENNESSEE MEDICAID FALSE CLAIMS  
ACT**

Tenn. Code §§ 71-5-181 *et seq.*

295. Relator repeats and realleges the allegations set forth in paragraphs 1 through 294 as if fully set forth herein.

296. By virtue of the acts described above, Biogen presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent, in violation of Tenn. Code § 71-5-182(a)(1)(A).

297. By virtue of the acts described above, Biogen made, used, or caused to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false, in violation of Tenn. Code § 71-5-182(a)(1)(B).

298. Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

299. By reason of Biogen's acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

300. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-SEVENTH CAUSE OF ACTION: TEXAS MEDICAID FRAUD  
PREVENTION LAW**

Tex. Hum. Res. Code §§ 36.001 *et seq.*

301. Relator repeats and realleges the allegations set forth in paragraphs 1 through 300 as if fully set forth herein.

302. By virtue of the acts described above, Biogen knowingly presented or caused to be presented false or fraudulent claims to the State of Texas for payment or approval, in violation of Tex. Hum. Res. Code § 36.002.

303. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce Texas to approve and pay such false and fraudulent claims, in violation of Tex. Hum. Res. Code § 36.002.

304. Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

305. By reason of Biogen's acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

306. Pursuant to, in violation of Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of \$15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-EIGHTH CAUSE OF ACTION: VIRGINIA FRAUD AGAINST  
TAXPAYERS ACT**

Va. Code §§ 8.01-216.1 *et seq.*

307. Relator repeats and realleges the allegations set forth in paragraphs 1 through 306 as if fully set forth herein.

308. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee of the Commonwealth of Virginia a false or fraudulent claim for payment or approval," in violation of Va. Code § 8.01-216.3(A)(1).

309. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia in violation of Va. Code § 8.01-216.3(A)(2).

310. Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

311. By reason of Biogen's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

312. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of

\$10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**TWENTY-NINTH CAUSE OF ACTION: WASHINGTON MEDICAID FRAUD  
FALSE CLAIMS ACT**

Revised Code of Washington §§ 74.66.005 *et seq.*

313. Relator repeats and realleges the allegations set forth in paragraphs 1 through 312 as if fully set forth herein.

314. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee or agent of Washington a false claim for medical assistance in violation of Wash. Rev. Code § 74.66.020(1)(a).

315. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance by the State of Washington in violation of Wash. Rev. Code § 74.66.020(1)(b).

316. Washington, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

317. By reason of Biogen's acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

318. Pursuant to Wash. Rev. Code § 74.66.020(2), the State of Washington is entitled to three times the amount of actual damages plus the maximum penalty of

\$11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**THIRTIETH CAUSE OF ACTION: WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE LAW**

Wis. Stat. §§ 20.931 *et seq.*

319. Relator repeats and realleges the allegations set forth in paragraphs 1 through 312 as if fully set forth herein.

320. By virtue of the acts described above, Biogen knowingly presented, or caused to be presented, to an officer or employee or agent of Wisconsin a false claim for medical assistance in violation of Wis. Stat. § 20.931(2)(a).

321. By virtue of the acts described above, Biogen knowingly made, used, or caused to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance by the State of Wisconsin in violation of Wis. Stat. § 20.931(2)(b).

322. Wisconsin, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Biogen, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Biogen as alleged herein.

323. By reason of Biogen's acts, the State of Wisconsin has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

324. Pursuant to Wis. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of \$10,000 for



each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Biogen.

**CONCLUSION**

**WHEREFORE**, the Relator, on behalf of the United States and the States hereby prays that after a trial, this Court:

1. Enter judgment holding Biogen liable for a civil penalty of \$11,000 for each violation of the False Claims Act committed by Biogen;
2. Enter a judgment against Biogen for three times the amount of damages sustained by the United States because of the acts of Biogen;
3. Enter judgment holding Biogen liable for the maximum civil penalties permitted for each violation of the state false claims acts pled herein;
4. Enter judgment against Biogen for the damages sustained by the States and the District because of the acts of Biogen described herein, multiplied, as permitted under the state statutes identified herein;
5. Award the Relator a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730;
6. Award the Relator a percentage of the proceeds of recoveries under the state statutes identified herein as permitted under each state's statute;
7. Award the Relator his costs and reasonable attorneys' fees for prosecuting this action; and
8. Enter such other relief which the Court finds just and equitable.

**PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS**

Respectfully submitted,

**Relator Michael Bawduniak, on behalf of the United States of America; State of California; State of Colorado; State of Connecticut; State of Delaware; District of Columbia; State of Florida; State of Georgia; State of Hawaii; State of Illinois; State of Indiana; State of Iowa; State of Louisiana; State of Maryland; State of Michigan; State of Minnesota; State of Montana; Commonwealth of Massachusetts; State of Nevada; State of New Jersey; State of New Mexico; State of New York; State of North Carolina; State of Oklahoma; State of Rhode Island; State of Tennessee; State of Texas; Commonwealth of Virginia; State of Washington and State of Wisconsin**

By his attorneys,



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Dated: July 10, 2013

*-and-*

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(781) 255-5573

**CERTIFICATE OF SERVICE**

I, Thomas M. Greene, certify that a true copy of the above Second Amended Complaint was sent by hand delivery on July 10, 2013, to the United States Attorney's Office at the following address:

Carmen M. Ortiz, Esq.  
United States Attorney  
One Courthouse Way, Suite 9200  
Boston, MA 02210

I, Thomas M. Greene, further certify that a true copy of the above Second Amended Complaint was sent by e-mail on July 10, 2013 to the United States at the following addresses:

Patrick Callahan, Esq.  
Assistant United States Attorney  
One Courthouse Way, Suite 9200  
Boston, MA 02210  
Patrick.Callahan@usdoj.gov

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Thomas M. Greene