UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

UNITED STATES of AMERICA, *et al.*, *ex rel.* MICHAEL BAWDUNIAK, Plaintiff-Relator, vs. BIOGEN IDEC INC., Defendant	Civil Action No. 12-10601-IT

RELATOR'S TRIAL BRIEF

Table of Contents

Introduction

Pursuant to Local Rule 16(f), the Court's April 20, 2022 procedural order, *see* Doc. No. 548, and the parties' joint pretrial memorandum, *see* Doc. No. 598, Relator Michael Bawduniak (the "Relator") respectfully submits the following trial memorandum.

I. Concise Summary of the Evidence

The Relator will prove at trial that defendant Biogen Inc. ("Biogen") violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), by directing millions of dollars of kickbacks to Healthcare Providers ("HCPs") in the form of speaker and consultant honoraria, lavish dinners, and entertainment, for the purpose of inducing those HCPs to prescribe or recommend prescribing Biogen's Multiple Sclerosis ("MS") medications: Avonex, Tysabri, and Tecfidera (together the "MS Drugs"). From January 1, 2009 through March 18, 2014 (the "Relevant Period"), Biogen's kickback schemes caused the submission of hundreds of millions of dollars in false reimbursement claims for Biogen's MS Drugs to Government healthcare programs, including Medicare and Medicaid (together "Government Healthcare Programs"), in violation of the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA") and eleven States' false claims acts.[1]

This multimillion-dollar kickback scheme capitalized on the unique nature of the market for MS medications. MS is an incurable disease which can lead to complete debilitation. A small group of products, known as immunomodulating agents ("IMAs"), are approved to treat MS. They are expensive. But for drug companies, these products are extremely lucrative. Once

[1] The states false claims act include California (Cal. Gov't Code §§ 12650 et seq.), Connecticut (Conn. Gen. Stat. Ann. §§ 4-275 et seq.); Georgia (Ga. Code Ann. §§ 49-4-168 et seq.), Illinois (740 Ill. Comp. Stat. Ann. 175/1 et seq.), Massachusetts (M.G.L. c. 12 §§ 5A et seq.) New Jersey (N.J. Stat. Ann. §§2A:32C-1 et seq.), New York (N.Y. Fin. Law §§ 187 et seq), North Carolina (N.C.G.S. §1-605 et seq.), Tennessee (Tenn. Code §§ 71-5-181 et seq,), Texas (Tex. Hum. Res. Code §§ 36.001 et seq.), and Wisconsin (Wis. Stat. §§ 20.931 et seq.).

patients begin IMAs, often as relatively young or middle-aged adults, they frequently use those medications for the rest of their lives. When a prescriber places a patient on a Biogen MS product, the decision can result in thousands of dollars of profits annually for Biogen. Further, a relatively small number of HCPs treat MS. Six thousand doctors write over 90% of the prescriptions for MS drugs, and just 1,200 doctors wrote 60% of IMA prescriptions during the Relevant Period. These prescribers dominate the MS market and they were the targets of Biogen's kickback scheme.

The goals of Biogen's scheme were threefold: to preserve the eroding market share of Biogen's oldest biological product, Avonex; to increase the market share of its biological product Tysabri, which had been temporarily pulled from the market over safety concerns prior to the Relevant Period; and to ensure that its new oral MS drug, Tecfidera, once approved, would be prescribed at a high rate. Biogen's scheme was a resounding success. Biogen was able to halt the decline of Avonex's market share and hold its sales constant. Despite the FDA's approval of several new MS medications during the Relevant Period, U.S. sales of Avonex grew to $1.5 billion annually. Tysabri sales also continued to grow, despite a black box warning on its label warning of deadly side effects. And when Biogen introduced Tecfidera to the market in 2013, it quickly became a blockbuster drug, far surpassing its forecasted revenue total.

The Relator will prove at trial that Biogen's kickbacks to HCPs took four forms:

A. Consultant Meeting Fraud

Pharmaceutical companies occasionally retain a small number of highly qualified physicians to provide expert insight to support a company's medical or marketing operations. Since at least 2003, however, the federal government and the pharmaceutical industry have recognized that a drug company's retention of its customers to consult on sales and marketing matters entails a high risk of the drug company violating the AKS. Consequently, the industry

has recognized that customers should only be retained as customers where there is a legitimate business need for information that the company intends to use, and which it cannot obtain from other sources. In the Relevant Period, industry standards dictated that consultant meetings only be held to obtain information that the company did not know, and that they focus on eliciting information from the attendant prescribers, as opposed to providing marketing messages or data to the attendees. Further, the industry, and Biogen itself, recognized that companies should retain only the minimum number of consultants necessary to provide the needed information.

While Biogen paid lip service to these principles, its actual practices blatantly violated the prohibitions against using consulting payments to influence HCP prescribing. Biogen held hundreds of unnecessary consultant meetings throughout the Relevant Period, repeatedly paying its highest prescribing customers to attend meetings that it did not need, to obtain feedback that it never intended to utilize. Far exceeding industry norms, Biogen held more than 100 consultant meetings annually during the Relevant Period, and each year invited as many as 200 HCPs to a single meeting.

At trial, Relator will prove that no fewer than 74 of Biogen's consultant programs, comprising a total of 255 individual meetings, were not legitimate and were held in a manner inconsistent with industry practices. Relator will present the following evidence and testimony:

1. From senior executives down to the Biogen representatives in the field, Biogen employees viewed the invitation of key prescribers to consultant meetings as a marketing tactic to be used to influence prescribing and increase sales. For example:

   A. Tony Kingsley, the Vice-President of Biogen's U.S. Commercial Operations, identified consultant meetings as part of Biogen's "promotional spend" and advocated using them to advance sales "opportunities." To increase Avonex's market share he urged that consultant meetings be offered strategically, not

just to HCPs who already favored Biogen's products. In particular, Kingsley directed that consultant opportunities should be offered to local physicians who generally would not have the specialized expertise necessary to educate a company like Biogen, that already had ready access to top MS experts. Kingsley advocated for using community doctors outside of MS centers who had "large potential." He also sought to direct consulting opportunities to "potential up and comers" who were working "within large practices." It will be clear that these physicians appealed to Kingsley not because of their qualifications, but precisely because their practices comprised large numbers of MS patients who could be placed on Biogen's MS drugs. Trial Ex. 271.

B. Sales representative and other representatives in the field frequently expressed the need to have their customers participate in consultant meetings so as to reward high-prescribing HCPs or to encourage them to write more scripts for Biogen's drugs. *See,* e.g. Ex. 101, 112.

2. Kingsley personally instructed the Relator to organize as many consultant meetings as possible for the purposes of inducing the HCPs who were invited to the meetings to prescribe more Avonex and Tysabri to their patients. When the Relator informed Kingsley that no more weekends were available to schedule consulting events, Kingsley was pleased to learn that the Relator and his colleagues had turned to regional dinner consulting meetings, shorter dinner meetings held across the country that allowed many more HCPs to be paid as consultants.

3. The tone Kingsley set at the top of the organization was reflected in the words and deeds of lower-level Biogen executives who also viewed consultant meetings as opportunities to influence the prescribing behavior of the HCPs who were paid to "consult" for Biogen. Representative examples include:

A. The Director of Biogen's Thought Leader Liaisons (a team of regional marketers who worked directly with influential HCPs known as Key Opinion Leaders or "KOLs") sought to have Biogen retain, as consultants, HCPs who had attended meetings with Biogen's top competitor. Members of this team perceived that these HCPs should receive consulting opportunities from Biogen in order to ensure that they would continue to write scripts for Biogen's products and to counteract the influence that Biogen believed arose when those HCPs received payments from Biogen's competitor;

B. Bill Ames, a National Sales Director, arranged for large programs comprising multiple regional consultant programs, not only because such programs allowed more HCPs to be paid, but also because regional meetings allowed Biogen to disburse payments to important customers in all of its sales territories;

C. Chris Turchi, the Regional Director for Biogen's New York's sales division, was informed by one of the sales representatives on his team that the representative's best customers had to be "paid off" via invitations to consultant meetings. In response, Turchi directed the representative to write the customers' names on a bar napkin so there would be no paper trail within Biogen's documents and communications.

D. There were multiple brainstorming sessions among marketers and regional marketers to improvise potential topics for consulting meetings, not because Biogen needed input on these topics (or intended to use consultant feedback on these topics), but simply because Biogen's brands had budgeted money for

such programs as part of annual plans and Biogen would not forgo any opportunity to pay their customers.

4. As the above examples make clear, consultant selection was frequently influenced by sales considerations. Not only were many consultants selected based on their prescribing volume, but spreadsheets demonstrate that Biogen decided which potential consultants would receive invitations to meetings based on their prescribing rank. *See, e.g.,* Trial Exhibits 148, 153, 172, 231, 330, 331.

5. Biogen utilized Needs Assessment Forms ("NAFs") to document the supposed business need for each consultant meeting. These forms were reviewed by Compliance personnel who had insufficient training or background in marketing or pharmaceutical compliance to evaluate whether a legitimate need for the information actually existed. Nor did they have authority to prevent a meeting from going forward, even when they doubted one was necessary. All Compliance could do was identify potential issues, which could be – and in practice always were -- overridden by the department requesting the meeting. Handwritten comments from the Compliance reviewers repeatedly raised questions as to whether the number of meetings requested and/or the number of consultants requested were actually needed. *See, e.g.,* Trial Exhibits 28, 30, 31, 34, 35, 37, 41, 42, 43, 44. Although the comments asked the requesters to "consider" whether programs could go forward with fewer consultants or meetings, such reconsideration never occurred. Indeed, notwithstanding the Compliance department's explicit warnings, throughout the entire Relevant Period Biogen executives never cancelled or refused a single consultant program requested by marketers.

6. Biogen's regional consultant programs routinely resulted in more meetings being held and more consultants being retained than were reasonably necessary to fulfill any legitimate need for advice that may have existed. These regional programs were comprised of many small

meetings, often held over dinner, in multiple cities. Biogen held as many as 23 such meetings as part of a single such program. In each city, a different set of consultants viewed the same presentation and provided answers to the same discussion questions. Biogen's excuse for presenting the same content multiple times over was its alleged need to understand "regional" differences in MS treatment. The summaries of these meetings, however, generally did not discuss or analyze the possibility of such differences. *See, e.g.,* Trial Exhibits 48-52, 106, 169. Further, Biogen had no objective basis for its supposed belief that there might be such regional differences. The parties' MS experts will testify that there is no evidence, from any source, including Biogen internal documents or peer-reviewed medical journals, that there are regional differences in MS treatment. Unsurprisingly, Biogen never used the "regional" consultant advice it gathered, or implemented it into any "regional" promotional programs. *See, e.g.,* Trial Exhibits 228, 229, 232, 307.

7. Biogen also held annual National Consultant Meetings to which it invited many more "consultants" than could be reasonably necessary to fulfill any legitimate advisory need. For many years prior to the Relevant Period, Biogen held national "faculty meetings," high-science educational conferences involving cutting-edge scientific presentations. The influential physicians and scientists who attended would gladly have paid to attend such a conference. Instead, Biogen paid each of the attendees thousands of dollars to attend and covered all of their travel and meal expenses. When Biogen was informed that it could not pay doctors to attend a high-science conference of this type, it renamed the conference as a consultant meeting. As many as 200 "consultants" not only received the sizeable honoraria but enjoyed an expenses-paid weekend at a warm weather location. Compliance officials repeatedly warned Biogen's management that the size of the event made it impossible to collect actionable feedback, even if that were the purpose. *See, e.g.,* Trial Exhibit 57, 98, 149-152, 166, 167, 273. Tony Kingsley,

however pressed to keep the event, notwithstanding the Compliance department's objections, because of how it favorably influenced some of the most important MS practitioners in the country to prescribe and recommend Biogen's products.

8. Another set of consultant programs held to influence the attendees' prescribing took place prior to the launch of Biogen's oral medication, Tecfidera. Even though Biogen had already received ample feedback on the results of clinical trials of Tecfidera from recognized experts in MS, Biogen chose to present the results repeatedly to multiple sets of regional consultants, many months before it could legally promote them. The admitted purpose of these meeting was to "prime the market" for Tecfidera's launch. *See, e.g.,* Trial Exhibits 19, 20. Biogen tracked the HCPs it had invited to these meetings in order to generate new prescriptions of the product. *See, e.g.,* Trial Exhibit 204, 205, 206. After the launch of Tecfidera, Biogen held further Tecfidera consultant programs to provide information to high prescribers to assuage concerns about unanticipated side effects, another improper purpose for paying customers.

9. Biogen also held numerous improper "Sales Consultant Meetings." Despite the fact that Biogen's Business Ethics Policies prohibited sales employees from attending or participating in consultant meetings, Biogen's regional sales directors identified their most important customers and paid them to have dinner with the sales force at upscale restaurants for the supposed purpose of training the field force. Biogen failed to collect feedback from such events. *See, e.g.,* Trial Exhibit 38, 40, 76, 157-159, 245.

A. Email correspondence between Tony Kingsley and a regional director for the Southwest illustrates the true purpose of these meetings. (It is also further evidence of the tone at the top set by Kingsley at Biogen.) In an email, the Regional Director, Ethan Stein, described his concerns about an important KOL and high prescriber, Dr. Elliot Frohman, who had complained that he

was "not feeling the Biogen love" as much as he had previously. Biogen's competitors had raced into the gap to offer Dr. Frohman positions on their clinical trials and other opportunities. Stein informed Kingsley that it is a "minor miracle that we have not lost his business," and to keep the situation from getting worse, Stein had sought approval from Compliance (which he ultimately received) to retain Dr. Frohman for four consultant meetings, supposedly to educate Stein's sales team about MS. After receiving this information, Kingsley did not report Stein to Compliance, as Biogen's ethics policies required him to do, but instead provided support for Stein's initiatives to solicit more business from Dr. Frohman. Trial Exhibits 157 -159.

10. The content of Biogen's consultant programs provides additional evidence for Biogen's improper purpose to influence HCP prescribing. Much of the program content was promotional, consisting of marketing messages designed to cast a favorable light on Biogen's products. Some of the programs were essentially product details in which HCPs in attendance were quizzed directly about their prescribing intentions. Other programs, purportedly intended to solicit useful and unbiased feedback, presented the consultants with biased, skewed, and misleading data about Biogen's products or those of its competitors. If these programs were actually designed to obtain objective input from recognized experts, Biogen would have directed far more effort into ensuring that it presented the data relating to its products' safety and efficacy accurately.

11. Both parties' experts will agree that legitimate consulting events are supposed to be held to obtain and utilize the advisor's expert views. The facts that Biogen failed to utilize the feedback that it gathered at these meetings, and in some cases failed to even document what the feedback was, provides yet more evidence that the meetings were not held for their stated

purpose. Biogen's Compliance and Audit departments, to no avail, repeatedly raised concerns over the lack of records relating to what Biogen supposedly learned from the meetings and the lack of documentation that the advice was ever used. See *e.g.*, Trial Exhibits 69, 73, 166, 167, 182-185, 187, 227.

12. While Biogen's documents provide unpersuasive evidence of feedback utilization, its payment and program data record millions of dollars in honoraria to HCP consultants. Hundreds of these meetings occurred at lavish restaurants where consultants drank wine, liquor and cocktails; circumstances hardly conducive to serious business consultation. *See e.g.*, Trial Exhibits 54, 55, 61, 248, 343.

In summary, from 2009 to 2013, Biogen hired approximately 8.5% of its customers to provide advice about its marketing efforts, *every year*. No one who will testify in this litigation will be able to point to any other industry, or any other company, which paid such a high percentage of customers to provide consulting advice. When one examines the most prolific prescribers, those who wrote over 1,000 prescriptions a year for MS medications, almost 50% of those prescribers received consulting payments from Biogen.

When viewed in totality, the evidence and testimony will show that the purpose, content, execution and quantity of Biogen's Consultant programs during the Relevant Period did not meet industry standards, the requirements of Biogen's own policies, OIG guidance or PhRMA standards for commercial reasonableness or propriety. The Relator will prove that Biogen focused its efforts on influencing or interfering with the prescribing of its HCP consultants instead of the legitimate purposes of obtaining their strategic advice or feedback.

B. Speaker Programs

It is standard practice in the pharmaceutical industry for companies to recruit as speakers a number of expert doctors who can provide educational on-label presentations about FDA

approved products to less expert peers. Under the guise of holding such educational speaker programs, Biogen systematically provided HCPs with sizable honoraria, lavish dinners, alcohol, and other entertainment. Biogen knowingly and willfully used this remuneration to influence the prescribing of the HCPs who spoke and attended these events.

At trial, Relator will prove that Biogen held thousands of speaker programs with the intent to induce HCP attendees to recommend and prescribe its MS Drugs. Relator will present the following evidence and testimony:

1. For most of the Relevant Period, speakers were not chosen based on their expertise or their ability to communicate to an audience. Indeed, speakers were not evaluated prior to selection to ensure they had sufficient knowledge and ability to present effectively. Contrary to contemporary industry standards, speaker selection during most of the period was entirely driven by Biogen's sales force. The business plans of Biogen's sales representatives explicitly stated that HCPs would be invited to speak as tactics to drive their prescribing and to meet sales goals. Only after Biogen learned its sales and marketing practices were being investigated by the United States did Biogen take steps to vet the speaker selections of its sales representatives, and to ensure that its speakers were qualified to speak and had sufficient skills to communicate effectively. *See e.g.,* Trial Exhibits 77, 78, 80, 84, 129.

2. Sales documents also demonstrate that employees explicitly used speaker honoraria to reward their most important HCP customers and to increase HCP prescribing of Biogen's MS Drugs. In exhibits submitted in support of Relator's motion for partial summary judgment, the Court has already seen how Biogen deliberately rewarded favored prescribers by paying them to give PEP programs and driving MS patients to their practices to reward them economically. This conduct was widespread despite regional sales managers knowing full well that this conduct violated Biogen's ethics policies. *See e.g.,* Trial Exhibits 85-96, 116.

3. The recordings the Relator made for the FBI demonstrate how and why Biogen employees solicited speaking engagements for their HCP customers. *See e.g.,* Trial Exhibits 109, 199, 291, 297, 293, 299, 212. The recordings depict:

A. a Biogen employee admitting that it was necessary and appropriate to "pay your enemies and make them your friends";

B. Biogen employees' knowledge that certain HCPs wanted to be paid by Biogen and had to receive speaker opportunities to prevent them from working for Biogen's competitors;

C. employees basing decisions regarding which physicians should be paid to attend speaker training events based on which physicians were the most important customers;

D. Biogen's practice of inviting only physicians who prescribed enough product to paid speaker training events, as well as Biogen employees' desire to show their customers "some love;" by inviting them to such events; and,

E. one employee's view that an HCP should receive paid speak training because that HCP "saw a shit load of patients."

4. The paid speaker training opportunities described above were lucrative weekend junkets in resorts and other warm weather venues. As the tapes make clear, these opportunities were reserved for Biogen's most important customers. *See e.g.,* Trial Exhibits 470, 478, 539. HCPs were selected to attend the paid trainings based on their prescribing volume and their prescribing potential. *See e.g.,* Trial Exhibits 661, 771. In connection with Tecfidera speaker training programs, for example, HCPs were served their meals directly on a Fort Lauderdale beach. And, in connection with a speaker training program in Scottsdale Arizona, the event was

held at a resort abutting a PGA championship golf course so that HCPs could play rounds of golf on a championship quality course.

5. After spending millions of dollars to train speakers at such events, Biogen routinely failed to utilize them for actual speaking engagements. Biogen ostensibly required HCPs who attended paid speaker training events to speak twice within the 12 months following the events. Over 320 HCPs speakers – 37% of Biogen's entire HCP speaker force – failed to meet this requirement. And, after attending an all-expenses paid weekend training event, nearly 200 of these speakers failed to speak even once. *See e.g.,* Trial Exhibits 53, 54, 80, 82, 117, 210, 213, 226, 1259, 1260.

6. The majority of underutilized speakers were trained on Biogen's older drugs, Avonex and Tysabri. Several witnesses will testify that there was not much demand for HCPs to attend educational programs on these drugs, which had been on the market for years and which were well-understood by most MS practitioners. Indeed, Biogen's speaker events were habitually under attended. More than 1,000 speaker programs took place with zero or only one HCP in attendance. *See e.g.,* Trial Exhibit 74, 343, 730, 892, 953.

7. The audience of other events was artificially inflated by means of indiscriminate invitations. Biogen filled programs with non-HCPs—such as speakers' family members, secretaries, and office assistants—inappropriate attendees who had no legitimate business need to attend. *See, e.g.,* Trial Exhibits 1186-1188. Biogen also paid HCPs to speak to their own colleagues—education the speaker could have provided without payment from Biogen (and without Biogen providing an expensive dinner to speaker and attendees alike). *See, e.g.,* Trial Exhibit 343. In contrast to the rest of the industry, Biogen failed to institute audience controls at its speaker programs until close to the end of the Relevant Period.

8. Repeat attendance was rampant. Speaker programs are designed to provide all an attendee needs to know in a single session. However, thousands of Biogen's attendees went to multiple programs on identical subjects and slide decks. Other than to create an audience that justified paying an important customer to speak, no business or educational purpose was fulfilled by repeatedly inviting HCPs to eat and drink at Biogen's expense while viewing presentations they had already seen. In addition, Biogen permitted hundreds of speakers–purportedly experts in their field – to attend speaker programs on the subjects on which they had been trained and presented. *See, e.g.,* Trial Exhibits 18, 54, 74, 85-96, 122, 139, 146-147, 168, 205, 343.

9. Industry guidelines stipulated that meals provided to HCPs should be occasional and modest. Yet Biogen's speaker programs were held at upscale venues that served lavish dinners and alcohol. Venues included resorts, casinos, expensive steakhouses, award winning restaurants, country clubs, and video game arcades. *See, e.g.,* Trial Exhibits 66, 74, 241, 243, 246, 247, 277, 1205. Meals at over 1,500 programs cost in excess of $106.50 per person, an amount that the jury is unlikely to consider modest.

10. Many Biogen speaker events were primarily social gatherings. Over 1,000 speaker programs were held without any slide presentation on a Biogen MS Drug. *See, e.g.,* Trial Exhibit 80, 198, 343.

11. Relator's experts will opine that even when Biogen's speakers did use slide decks at dinner meetings, the material that Biogen provided them with was rudimentary, biased, misleading, and lacking in any significant educational value to the average HCP. The slide decks are also repetitive on their face. Many decks reused slides from earlier presentations or covered ground that was nearly identical to earlier programs. The level of repetition was to be expected given the age of Avonex and Tysabri, and the limited amount of new information available regarding these products. *See, e.g.,* Trial Exhibits 21,196, 228, 229, 232. The

mediocre quality of the slide decks, when compared with the standards of the venues, establishes that Biogen placed far more emphasis on providing an enjoyable experience to HCPs than on their education.

12. Biogen also tracked the prescribing of its highest paid HCP speakers and provided tools to its sales force to track effects of its speaker programs on prescribing. *See, e.g.,* Trial Exhibits 56, 97.

The number and scope of the payments Biogen made in connection with its speaker programs is also extraordinary. Every year Biogen paid almost 10% of its target market—those physicians who wrote 100 of more MS prescriptions annually—to speak. This is an exceptionally high number of speakers, particularly in the years prior to the Tecfidera launch when the only products being promoted by Biogen had been on the market for years and were familiar to most of the potential audience for such programs.

The totality of the evidence regarding the manner Biogen conducted its speaker programs leaves little doubt that the programs were created to provide an opportunity to direct payments to important customers who spoke at them, and to provide valuable benefits like meals and social experiences to the attendees. Remuneration, not education, was at least one purpose of these programs. Biogen paid the HCPs with the expectation that such treatment would result in the recipients' maintaining, if not increasing, their prescribing of Biogen products.

C. Blunting Gilenya's Entry

In late 2009, Biogen prepared for the entry of the first oral MS medication, Gilenya, introduced to the market by Novartis. While patients were required to inject Avonex and to attend a clinic to be infused with Tysabri, Gilenya could be conveniently administered by mouth. To protect its sales, Biogen therefore devised tactics to pay its key HCP customers to dissuade them from switching patients to Novartis's product and to continue prescribing Biogen's

medications. Biogen's tactics included Lunch and Learns, VIP meetings with key Biogen executives, and as relevant to this suit, speaker and consultant engagements.

At trial, Relator will prove that Biogen held speaker and consultant programs during the launch of Gilenya as a tactic that would prevent HCPs from attending Gilenya events. These tactics were implemented with the purpose of inducing the targeted HCPs to maintain their prescribing of Avonex and Tysabri, as opposed to switching their patients to Gilenya. Relator will present the following evidence and testimony:

1. Several months prior to Gilenya's launch, a global initiative at Biogen produced a "Break the Glass" Plan to blunt the market entry of new medications sponsored by Biogen's competitors. Part of the plan called for Biogen to increase its "share of voice" by holding multiple consultant meetings. Holding consultant meetings to amplify promotional messages during a competitor's product launch is abusive, because consultant meetings are not supposed to be used to communicate messaging to customers, but rather to solicit their expert advice. However, Biogen's plans called for the company to "[e]stablish meetings etc now, so that at the time of the new product launches physicians are engaged in us elsewhere." Trial Exhibit 15. Even Biogen employees admit that paying HCPs to attend Biogen consultant meetings to prevent doctors from attending a competitors' event is improper. But that is precisely what Tony Kingsley instructed the Relator and other Biogen employees to do as part of the company's plan to blunt Gilenya's market entry.

2. Another blunting tactic was the creation of a "Top 50 At Risk" list, which identified 50 influential HCPs believed to be at risk of adopting Gilenya. Biogen employees then drew up "blunting" tactics for each of those HCPs to keep them from prescribing Gilenya.

3. Biogen sales representatives were sent the Top 50 At Risk list and were directed to remunerate these targets, by providing the targets with lunches, dinners and other business

courtesies, awarding them grants and research opportunities, and inviting them to participate in speaker and consultant programs. *See, e.g.,* Trial Exhibits 131, 132, 146, 147. Written reports identified which persons on the Top 50 List were offered consulting or speaking engagements as tactics to dissuade them from switching their patients to Gilenya.

4. During the Gilenya launch period, Biogen marketing and sales employees were instructed to report "all the activity we have against these HCPs," including which HCPs had attended local consultant meetings, and which doctors were slated to receive speaker training in the next 60 days. When concerns were raised to senior management and the Compliance Department about the propriety of these "blunting" tactics—particularly with regard to paying customers for the purpose of preventing those HCPs from engaging with a competitor-- they were summarily ignored. When the Compliance department became aware that the commercial side of the company was engaged in inappropriate "blunting" activities, it simply advised that the word "blunting" not be used in connection with the tactics, which went forward as conceived. *See, e.g.,* Trial Exhibit 129.

5. Biogen also tracked the prescribing of HCPs on the Top 50 At Risk list, despite its knowledge that such tracking violated its ethics policies. *See, e.g.,* Trial Exhibits 10, 723, 724.

Biogen's blunting campaign proved successful. Novartis did not have a successful launch for Gilenya. The new drug barely affected the market share for Biogen's products despite its more convenient mode of administration. Most of the Top 50 at Risk identified by Biogen did not adopt Gilenya or only did so for a limited number of patients.

D. Compensation Exceeding Fair Market Value

During the Relevant Period Biogen, like most of its peers, retained third party vendors to help it determine whether the compensation it paid to its HCP speakers and consultants was consistent with Fair Market Value ("FMV"). To keep the costs of these services manageable,

Biogen should have worked with its FMV consultants to come up with fair rates that would have protected Biogen from overpaying physicians who it retained as speakers or consultants. Instead, Biogen used its FMV advisors to determine the maximum Biogen could get away with paying the HCP customers it intended to hire as consultants and speakers.

At trial, Relator will show that Biogen overpaid hundreds of HCP consultant and speakers with the purpose of influence their prescribing of Biogen's MS Drugs. Relator will present the following evidence and testimony:

1. Biogen repeatedly rejected its FMV advisors' rate proposals because the rates were too low. Instead, Biogen sought to maximize rates paid to HCPs, tripling the hourly rates paid its most prestigious neurologists, from $150 per hour, which it paid just before the Relevant Period, to $475 per hour, which it paid in 2014.

2. Biogen added a minimum of three hours of "local travel" time to all of its speakers and consultants' payments, even if an event was held within walking distance of the HCP's office. Biogen significantly and knowingly overpaid HCP speakers and consultants who traveled short distances to present a program, paying at least $1,050 in travel compensation to preeminent neurologists for every engagement, regardless of the actual travel time incurred.

3. Between 2012 and 2014 Biogen pushed its FMV consultants to approve inappropriately high rates for neurologists who spoke or consulted for Biogen. Biogen compensated these physicians as if they were ophthalmologists, an unrelated surgical specialty with significantly higher compensation, instead of neurologists. By compensating these speakers and consultants at a blended ophthalmology and neurology rate, Biogen paid these physicians at a level beyond that paid to any neurologist, even the most highly specialized and most highly compensated.

4. Beginning in 2014, Biogen adopted a compensation rate that illegally overpaid its most prestigious HCP speakers and consultants. Biogen paid approximately 300 at the implied 100th percentile—the compensation level that no neurologist exceeded. Biogen then tacked on a 15% premium above this 100th percentile rate. Paying HCPs 15% more than the highest paid neurologists in the country was well above fair market value.

The only reason for Biogen to overpay its speakers and consultants was to affect their prescribing. There is no other rational basis for overpaying Biogen's most important customers.

II. Concise Summary of Damages

Relator seeks damages based on the full amount the Government Healthcare Programs reimbursed for prescriptions written by HCPs who received kickbacks within a year or six months of their receipt of remuneration from Biogen.[2] Relator's damages expert, Dr. Meredith Rosenthal, has broken down the kickbacks into five categories: those derived from improper consultant meetings; those that were paid as a result of Biogen's abusive speaker program practices; those that derive from HCPs being improperly paid for attending speaker training; those that were paid in connection with Biogen's improper efforts to blunt the entry of Gilenya; and those neurologists who received inflated compensation rates due to improper rate blending or specialization premium.

Single Damages owed to the United States and the various States equals $1,036,900,151 using a 12 month taint period, or $702,367,584 using a six month taint period. Damages owed to the Government are reflected in the below tables. These amounts were calculated by summing the number of MS Drugs prescriptions written within a year after each HCP received a kickback

[2] Based on the testimony of Dr. Ross, Relator will also present an alternative damages calculation in the event that the jury finds that prescriptions written by kickback recipients were only tainted for six months.

from Biogen. The identity of the HCPs and events where Biogen provided these kickbacks are listed in Exhibits B. *See* HCP List with Biogen Contact ID Ex. B, Doc. No. 604-2.

TWELVE (12) MONTH TAINT PERIOD DAMAGES BY CATEGORY

Damage Subgroup	Medicare Claims	Medicare Paid Amount	Medicaid Claims	Medicaid Paid Amount	Low Penalty	High Penalty
Speaker Program	222,546	$767,120,470	33,432	$109,565,147	$1,407,879,000	$2,815,758,000
Speaker Training Program	44,743	$163,617,811	5,612	$17,278,566	$293,452,500	$586,905,000
Consultant Program	129,884	$403,084,243	19,304	$57,121,605	$820,534,000	$1,641,068,000
Blunting	6,622	$17,293,660	1,202	$2,839,044	$43,032,000	$86,064,000
Fair Market Value	78,180	$316,860,034	10,086	$40,065,868	$485,463,000	$970,926,000

TWELVE (12) MONTH TAINT PERIOD TOTAL DAMAGES

Total Claims	Single Damages	Double Damages	Treble Damages	Low Penalty	High Penalty
302,928	$1,036,900,151	$2,073,800,302	$3,110,700,453	$1,666,104,000	$3,332,208,000

SIX (6) MONTH TAINT PERIOD DAMAGES BY CATEGORY

Damage Subgroup	Medicare Claims	Medicare Paid Amount	Medicaid Claims	Medicaid Paid Amount	Low Penalty	High Penalty
Speaker Program	150,604	$490,321,419	23,100	$71,535,132	$955,372,000	$1,910,744,000
Speaker Training Program	23,912	$81,229,263	2,757	$7,937,070	$146,679,500	$293,359,000
Consultant Program	80,543	$234,665,458	12,392	$34,009,534	$511,142,500	$1,022,285,000
Blunting	3,877	$9,637,128	773	$1,744,067	$25,575,000	$51,150,000
Fair Market Value	56,894	$216,257,530	7,130	$26,993,954	$351,983,500	$703,967,000

SIX (6) MONTH TAINT PERIOD TOTAL DAMAGES

Total Claims	Single Damages	Double Damages	Treble Damages	Low Penalty	High Penalty
216,975	$702,367,584	$1,404,735,168	$2,107,102,752	$1,193,362,500	$2,386,725,000

III. The Facts Established by Pleadings, Stipulations or Admissions of Counsel

In addition to the below facts, the Relator incorporates by reference the stipulations previously filed with this court. *See* Doc. Nos. 483, 559, 565, and 597.

1. During the relevant period, January 1, 2009 through March 18, 2014 (the "Relevant Period") Biogen marketed and sold three MS drugs: Avonex, Tysabri, and Tecfidera (together the "MS Drugs"). *See* Biogen's Answer, Doc. No. 188 at ¶ 40; *see also* Joint Stipulated Facts, Doc. No. 597 at ¶¶ 5, 12, 15, and 19.

2. Avonex was approved in early 1996, and is injected once per week. Doc. No. 597 at ¶ 12.

3. Biogen introduced Tysabri (natalizumab) in 2004, and is given monthly by intravenous infusion. Doc. No. 597 at ¶ 15

4. Biogen voluntarily suspended the marketing and commercial distribution of Tysabri in 2005 to study the risk of Progressive Multifocal Leukoencephalopathy ("PML") and reintroduced Tysabri in 2006. *See* Doc. No. 188 at ¶ 45.

5. Tecfidera (dimethyl fumarate), was introduced to the United States market in 2013, and is a pill taken twice daily. Doc. No. 597 at ¶ 19.

6. During the Relevant Period, Government healthcare programs, including Medicare and Medicaid (together "Government Healthcare Programs"), reimbursed claims for Biogen's MS Drugs. *See* Doc. No. 188 at ¶¶ 168-70.

7. During the Relevant Period, Biogen convened speaker programs and consultant programs. Physicians and other Healthcare Providers ("HCPs") attended Biogen's speaker and consultant programs. Doc. No. 597 at ¶¶ 24, 27-28.

8. Biogen generally conducted two types of Speaker Programs: Peer to Peer programs ("P2Ps") and Patient Empowerment Programs ("PEPs") (together "Speaker Programs"). Doc. No. 597 at ¶ 30.

9. Biogen's U.S. Business Ethics Policies during the Relevant Period defined "Promotional Speaker Program", also known as a "P2P", as "a Biogen Idec sponsored event in which a Customer is engaged to educate Customers about an approved product." Biogen's U.S. Business Ethics Policies stated that the purpose of P2Ps was "to educate and inform Customers about 1) the benefits, risks and appropriate uses of a Biogen Idec approved product consistent with the package insert or 2) scientific and educational information as it relates to a therapeutic area that a Biogen Idec product is indicated to treat." Doc. No. 597 at ¶ 31.

10. According to Biogen's U.S. Business Ethics Policies during the Relevant Period, PEPs were one type of Program for Patients and Caregivers. Biogen's U.S. Business Ethics Policies during the Relevant Period defined "Program for Patients and Caregivers" as "an event organized, hosted and/or funded by Biogen Idec at which a Speaker is engaged to educate Patients and/or Caregivers about an approved product, condition or disease relevant to Biogen Idec. The purpose of a Program for Patients and Caregivers is to educate and inform Patients and/or Caregivers 1) about the benefits, risks and appropriate uses of a Biogen Idec approved product consistent with the package insert; or 2) about scientific and educational information related to a therapeutic area that a Biogen Idec product is indicated to treat or which is otherwise relevant to Biogen Idec." Doc. No. 597 at ¶ 32.

11. From January 1, 2009 through May 14, 2009, according to Biogen's U.S. Business Ethics Policies, HCPs who attended paid speaker training meetings were required to speak two times during the calendar year following the execution of their speaker agreement. From May 15, 2009 through the end of the Relevant Period, according to Biogen's U.S. Business Ethics Policies, HCPs who attended paid speaker training meetings were required to speak two times during the twelve months following the execution of their speaker agreement. Biogen's Responses to Request For Admission, Ex. A, Doc. No. 604-1 at 4-5.[3]

12. Prior to 2013, Biogen permitted its sales employees to nominate HCPs to become speakers. Doc. No. 604-1 at 7. In addition, prior to 2013 Biogen permitted its sales employees to train HCP speakers on the content of its speaker program slide decks. Doc. No. 604-1 at 6-7.

13. Biogen did not create speaker program slide decks that were tailored to a specific geographic region, territory, or city. Doc. No. 604-1 at 11-12.

14. From January 1, 2009 through April 12, 2013, Biogen Business Ethics Policies did not mandate that HCP speaker present slide decks at speaker program. Doc. No. 604-1 at 5-6.

15. Biogen conducted 1,229 speaker programs where no slide deck was presented. *See* Declaration of Meredith Rosenthal, Ph.D., in Support of Relator's Daubert Opposition Motions, Doc. No. 534 at 3.

16. Biogen's U.S. Business Ethics Policies during the Relevant Period defined "Consultant Meeting" as "a forum to receive advice, guidance, feedback, information or other services from consultants. Consultant Programs include, but are not limited to, advisory boards, focus group meetings and consulting engagements with individual Customers." Doc. No. 597 at ¶ 29.

[3] Biogen's Responses and Objections to Relator's Request for Admissions are attached in their entirety at Exhibit A.

17. Biogen was unable to locate consultant feedback for the regional consultant program "CHAMPIONS X – Evolving Messaging - Impact of Nabs on Long Term Efficacy Regional Consultant Meetings (CM63-10)" meeting held in New York, NY, Princeton, NJ, Boston, MA, and Long Island, NY. *See* Doc. No. 604-1 at 10.

18. During the regional consultant "Commercial BG12 Consultant Meeting (CM25-12)," held prior to the launch and approval of Tecfidera, Biogen sought feedback from HCPs about whether they intended to prescribe Tecfidera within three months following FDA approval of the drug. *See* Doc. No. 604-1 at 15

19. During the Relevant Period Biogen did not conduct any market research for the purpose of demonstrating the existence of regional differences in the treatment of MS. *See* Doc. No. 604-1 at 13-14.

20. During the Relevant Period, Biogen executives charged with approving NAFs, never rejected a consultant program. *See* Doc. No. 604-1 at 9.

21. During the Relevant Period, Biogen utilized two databases, AXIS and Physician's World, to aggregate certain information concerning its speaker programs and consultant programs. Doc. No. 597 at ¶ 33.

22. Biogen employees used AXIS to track speaker program event information from January 2009 through June 2013 and to track consultant program event information from January 2009 through March 2014. Doc. No. 597 at ¶ 34.

23. Physician's World replaced AXIS as the database where Biogen employees tracked speaker program event information in July 2013. Biogen employees used Physicians World to track speaker program event information from July 2013 through March 2014. Doc. No. 597 at ¶ 35.

24. Biogen does not intend to assert its eleventh affirmative defense at trial, and will not argue that its payments to HCP speakers or consultants fall within the personal services safe harbor. *See* Stipulation and Order regarding Relator's Summary Judgment-Related Argument Doc No. 483 at 2; Stipulation and Order Regarding Relator's Partial Summary Judgment Motion and the Court's Pretrial Order, Doc. No. 559 at 2; More complete statement of Biogen's objections to Relator's proposed jury instructions, Doc. No. 593-2 at 46-47.

25. Biogen does not intend to assert its seventh affirmative defense at trial and will not argue that, as a matter of law, Biogen cannot be liable under the FCA because it did not itself directly submit claims to the Government. Doc. No. 483 at 2.

IV. Contested Issues of Fact

1. Whether Biogen offered, paid, or provided any remuneration or other items of value to HCPs who attended its speaker and consultant programs.

2. Whether at least one of Biogen's purposes in offering or providing remuneration to HCPs was to induce them to prescribe or recommend prescribing Biogen's MS drugs.

3. Whether Biogen "knowingly and willfully," as those terms are defined by the AKS, paid remuneration to HCPs to induce them to prescribe or recommend prescribing Biogen's MS Drugs.

4. If Biogen violated the AKS, how many false claims for Biogen's MS Drugs were presented to Government Healthcare Programs for reimbursement as a result of Biogen's conduct.

5. If Biogen violated the FCA, the amounts of damages and penalties the Relator is entitled to recover on behalf of the United States and the States under the FCA and various States' False Claims Acts.

V. Contested Issues of Law

The Relator anticipates that the Court will need to address a number of key legal issues before or during the trial. All of these issues have been previously briefed for the Court in Relator's Partial Summary Judgment Motion, *see* Doc. No. 477, Relator's Daubert motions to exclude Biogen's expert witnesses, *see* Doc. Nos. 497-501, evidentiary questions raised in Relator's motions *in limine*, *see* Doc. Nos 566 and 568, evidentiary issues raised in the parties joint exhibit list, *see* Doc. No. 564-1, evidentiary issues raised by the parties deposition designations, Doc. No. 603, and questions raised by the parties dueling proposed jury instructions and verdict forms, *see* Doc. Nos 571-3, 571-4, 581, and 582. Below are short summaries of some of the key legal issues presently before the Court.

A. Issues Raised by Relator's Partial Summary Judgment Motion

There are three outstanding issues briefed in Relator's Partial Summary judgment motion.[4]

1. Relator moved for partial summary judgment on the issue of materiality. As set forth in Relator's memorandum in support of his partial summary judgment motion, AKS violations were *per se* material throughout the entire Relevant Period and there is no genuine issue of material fact that Biogen's alleged AKS violations were material to Government Healthcare Programs and that kickback tainted claims were ineligible for reimbursement. *See* Doc. No. 480 at 34-35; *See also* The United States Statement of Interest in Support, Doc. No. 496; State of Texas's Statement of Interest, Doc. Nos. 530 and 557; *see also Guilfoile v. Shields,* 913 F.3d 178 (1st Cir. 2019).

[4] After the parties briefed the issue of whether Biogen's HCP speaker payment fell within the Personal Services Safe Harbor protection, Biogen stipulated that it does not intend to assert this defense at trial. *See* Doc. No. 559 at 2.

2. Relator moved for summary judgment on Biogen's payments to 13 HCP speakers, arguing that there was no question of material fact that these payments violated the AKS. Sales documents and business plans produced by Biogen unequivocally show that Biogen awarded these speaker engagements for the express purpose of inducing prescriptions and driving patients to the HCP speakers. *See* Doc. No. 480 at 14-23. Biogen willfully engaged in this conduct in the face of its own policies prohibiting kickbacks. *Id.*

3. Relator moved for summary judgment on Biogen's overpayments to 54 HCPs, arguing that there was no question of material fact that between January 1, 2014 and March 18, 2014, Biogen excessively compensated these HCPs in order to induce these HCPs to prescribe Biogen's MS Drugs. *See* Doc. No. 480 at 23-33. During this three month period, Biogen paid well above fair market rates to these HCPs— a 15% premium above the implied 100th percentile—in clear violation of the AKS. *Id.*

B. The Correct Standard of Causation

Biogen asserts in its proposed jury instructions that to establish liability Relator must prove that 1) the kickbacks Biogen provided to HCPs caused those HCPs to prescribe more MS Drugs than they otherwise would have absent the kickbacks, and 2) HCPs entered into a *quid pro quo* agreement with Biogen to prescribe its drugs. *See* Doc. No. 581 at 54, 66-67.[5], a. Biogen's proposed standard of liability flies in the face of established precedent, including this Court's prior ruling in this action.

As set forth in Relator's Memoranda in support of his Daubert Motion to exclude portions of the expert report and testimony of Dr. Eric Gaier, and Memorandum in support of his Omnibus Motions *in Limine*, *see* Doc. Nos. 497, 555, and 567, to establish liability, the Relator

[5] These arguments were also advanced by Biogen's economics expert, Dr. Eric Gaier. *See* Gaier Rep. Ex. A1, Doc. No. 502-1. Relator addressed these arguments in his memorandum to exclude the testimony of Dr. Gaier. *See* Doc. Nos. 504 and 555.

need only show that 1) Biogen paid kickbacks to HCPs to induce them to prescribe or recommend Biogen's MS Drugs, 2) the HCPs thereafter prescribed those drugs, and (3) claims for payment for those prescriptions were submitted to a Government Healthcare Programs. *U.S. ex rel. Bawduniak v. Biogen Idec, Inc.*, No. 12-cv-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) ("It is sufficient to show that Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback."); *see U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96-100 (3d Cir. 2018) (Government need only show a link—not "but for" causation—between the individual or entity receiving a kickback and the submission of a claim for reimbursement to a federal health care program); *see generally U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) ("In order to avoid FCA liability . . . [,] a participant in a federal health care program [must] refrain from offering or entering into payment arrangements which violate the AKS, while making claims for payment to the Government under that program.").

It is well settled that when establishing liability under the AKS, the plaintiff is not required to show that a kickback actually affected the recipient's prescribing decisions. AKS liability can be established "regardless of whether the claim was the result of a quid-pro-quo exchange or would have been submitted even absent the kickback. *Bawduniak,* 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) (Relator "need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks."); *see also United States v. Teva Pharms. USA, Inc.*, 2019 WL 1245656, at *24 (S.D.N.Y. Feb. 27, 2019) (adopting *Bawduniak*; no FCA requirement "that physicians would not have prescribed Defendant's medication but for the kickbacks."); *U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, 2021 WL 101193, at *12 (D. Minn. Jan. 12, 2021) (resulting sale is

not an element of an AKS violation).[6] As this Court recognized in its decision denying Biogen's motion to dismiss, the claims at issue are false because each claim "seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute." *Bawduniak,* 2018 WL 1996829, at *3.

Thus, once it has been established that a claim tainted by a kickback has been submitted to the government, it is irrelevant to the liability analysis whether the doctor who received the kickback had entered into a quid pro quo arrangement with the kickback provider or whether the doctor would have written the same prescriptions absent the kickback. *See Greenfield*, 880 F.3d at 96-100 (plaintiff need not "prove a kickback actually influenced a patient's or medical professional's judgment"); *Fesenmaier*, 2021 WL 101193, at *14-16 (excluding expert opinions arising from regression analysis in an AKS action because an "increase in the purchase or utilization of Defendants' products after a kickback was paid is not relevant to causation"). While the Relator must identify a link between Biogen's alleged kickbacks and the false claims, the requisite link is established by showing that a HCP who received a kickback thereafter wrote prescriptions for the relevant drugs for which a claim was submitted to a Government Healthcare Program, *see Greenfield*, 880 F.3d at 99-100.

C. The Correct Measure of Damages

Based on Biogen's proposed jury instructions and the expected testimony of its expert testimony of Dr. Eric Gaier, Biogen will argue at trial that damages should be broadly reduced.

---

[6] *United States v. Teva Pharms USA, Inc.* No. 20-CV-11548-NMG, (D. Mass. Jun. 7, 2022), Ex. C, Doc. No. 604-3 (Adopting *Bawduniak* and holding that the "government need not show actual inducement to prove an FCA claim predicated on violations of the AKS."); *Greenfield,* 880 F. 3d at 96-97 (holding that plaintiffs need not show that kickback actually influenced prescribing decision); *U.S. ex rel. Gohil v. Sanofi U.S. Servs. Inc.*, 500 F. Supp. 3d 345, 366-67 (E.D. Pa 2020) (adopting *Greenfield* and holding that Relator does not need to prove a kickback "actually influenced a patient's or medical professional's judgment.); *United States v. Regeneron Pharms., Inc.*, , 2020 WL 7130004, at *11 (D. Mass. Dec. 4, 2020) (collecting cases); *see also* 155 Cong. Rec. at S10853.

See Doc. No. 581 at 84; *See* Doc. No. 502-1. Biogen suggests that "the measure of damages is the amount that the Government Health Insurance Program paid for Biogen's medications above what it would have paid for other available medications in the absence of the AKS violation," and proposes four far-reaching theories to reduce its liability. First, Biogen argues that damages should be limited to the maximum cumulative gross impact associated with "challenged" events—a reduction of damages by over 85%. Next, it contends that damages owed to the government should be reduced if a patient would have likely continued on the Biogen therapy regardless of whether his prescribing HCPs received a kickback. Third, Biogen argues that damages owed to the government should be reduced by the prescription costs the government would have otherwise paid for Biogen's competitor MS therapies. Finally, Biogen argues that the government is not entitled to AKS damages for claims reimbursed by its Medicare Pard D contractors and managed care organizations. None of Biogen's proposed damage reduction categories have any basis in established law.

As argued in Relator's memorandum in support of his motion to exclude the expert testimony of Dr. Gaier and Memorandum in support of his Omnibus Motions *in Limine*, *see* Doc. Nos. 504 and 567, the law is clear on damages in an FCA case premised on AKS violations: where claims submitted to the United States are made false because of AKS violations *damages are the full amount of each claim tainted by the kickbacks. See, e.g.*, *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008); *United States v. Teva Pharms USA, Inc.* No. 20-CV-11548-NMG, (D. Mass. Jun. 7, 2022) ("As a matter of law, however, damages for violations of the FCA predicated on violations of the AKS are measured as the entirety of the government's payments for claims tainted by those illegal kickbacks."), Ex. C, Doc. No. 604-3.[7] Because the government

[7] *See also U.S. ex rel. Freedman v. Suarez-Hojos*, 2012 WL 4344199, at *4 (M.D. Fla. Sept. 21, 2012) ("[T]he amount of the Government's damages resulting from the payment of false claims tainted by a kickback arrangement equals the full amount that Medicare paid on such claims.");

does not get what it bargained for when a payment is made for services resulting from a kickback, all resulting claims are false and the government is entitled to recover the full amount that is paid for the tainted prescriptions. *See Greenfield*, 880 F.3d at 97-98. *See also* Doc. No. 504.

D. Liability Of Biogen For Conduct Of Its Employees

Biogen contends that it cannot be held liable unless the Relator can prove that an employee with "sufficient authority" knowingly and willfully violated the AKS. *See* Doc. No. 588 at 75. Biogen is wrong. It is well established that employers may be held liable under the FCA for the conduct of their employees within the scope of their employment. *See U.S. ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72, 82 n.18 (1st Cir. 2012) ("We have long held that corporate defendants may be subject to FCA liability when the alleged misrepresentations are made while the employee is acting within the scope of his or her employment."); *United States v. Bank of New England, N.A.*, 821 F.2d 844, 856 (1st Cir. 1987) (same). Courts impute to corporate employers the knowledge of fraud by their employees because the employees gained such knowledge in the scope of employment. *See U.S. v. Anchor Mortg. Corp*., 711 F.3d 745, 747-48 (7th Cir. 2013) ("Corporations . . . 'know' what their employees know, when the employees acquire knowledge within the scope of their employment and are in a position to do something about that knowledge."). Fraud committed by employees acting within the scope of

---

U.S. ex rel. Longhi v. Lithium Power Tech., Inc., 575 F.3d 458, 473 (5th Cir. 2009) (affirming summary judgment that FCA damages were full amount paid out by Government); *U.S. ex rel. Emanuele v. Medicor Assocs.*, 2017 WL 4867614, at *10 (W.D. Pa. Oct. 26, 2017) (ruling that the proper measure of damages was the full amount of the government payments for services that it was legally prohibited from paying due to illegal referrals or kickbacks); *U.S. ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, 2013 WL 5340910, at *1 (E.D. Mo. Sept. 23, 2013) ("adopt[ing] the reasoning of *Rogan*, . . . and conclud[ing] that the proper measure of damages is the full amount of each [kickback] tainted claim"); *United States v. Novak*, 2018 WL 4205540, at *5 (N.D. Ill. Sept. 4, 2018) ("a fraud that conceals an individual's ineligibility to receive government spending intended for the benefit of third parties entitles the government to the full amount of the falsely-obtained payments.").

their employment will be imputed to the corporate employer regardless of whether a manager directed or was even was aware of the employee's conduct. *See United States v. Associates in Eye Care, P.S.C.*, No. 13-27-GFVT, 2014 WL 414231, at *8 (E.D. Ky. Feb. 4, 2014) ("courts have found employers vicariously liable under the FCA for acts of employees when the employees acted within the scope of their employment" and "the government does not necessarily need to allege that [the corporate employer] endorsed or directed [the employee's] behavior for vicarious liability to attach"). In this action the Relator will present evidence that Biogen employees acting within the scope of their employment knowingly and willfully provided kickbacks to HCPs and thereby knowingly caused false claims to be submitted to Government Healthcare Programs for MS Drugs. Accordingly, there is no need to instruct the jury on collective knowledge.

E. The Purpose of Biogen's Remuneration

Biogen asserts in its proposed jury instructions that Relator must prove by a preponderance of evidence Biogen provided to a healthcare provider was for the purpose of inducing the healthcare provider to write a prescription for one of the medications at issue in this case. *See* Doc. No. 581 at 51, 56. Biogen, however, misleadingly omits that to meet his burden, Relator need only prove that at least one purpose of the payment could be to induce or reward the referral or recommendation of business payable in whole or in part by a [f]ederal health care program." *Guilfoile*, 913 F.3d at 189; *See also United States v. Regeneron Pharms., Inc.*, 2020 WL 7130004, at *8 (D. Mass. Dec. 4, 2020) (violation of AKS can occur "so long as one purpose of the offer or payment is to induce Medicare or Medicaid [prescriptions]"; *see United States v. Teva Pharms. USA, Inc.*, 2019 WL 1245656, at *9 (S.D.N.Y. Feb. 27, 2019) ("Inducing referrals need not be the primary purpose for the kickback," and a "party need only prove that 'one purpose' of the defendant's bribe is to induce referrals.").

F. Expert Opinions

The Relator and Biogen each moved to exclude many of the opinions of their respective experts. *See* Doc Nos. 497-501, 509-515. Rather than recount the entirety of the parties' arguments for excluding this proposed expert testimony, below are some of the legal issues presently before the Court.

1. Expert opinion on intent.

Biogen has sought to exclude opinions of Relator's expert witnesses that it characterizes as "intent opinions." *See* Doc Nos. 509, 510, 512, 513, 514. As discussed in Relator's opposition memoranda, Relator's experts will not directly opine on what Biogen thought or intended, but they are permitted to opine on facts "from which a jury might infer intent." *See United States v. Valle*, 72 F.3d 210, 216 (1st Cir. 1995); *see also U.S. ex rel. Fesenmaier v. Cameron-Ehlen Grp., Inc.*, 2021 WL 101193, at *15 (D. Minn. Jan. 12, 2021) ("An expert may . . . testify about observable underlying facts that could be relevant to determining an individual or entity's intent.").

During oral argument on the parties Daubert motions, Biogen argued that Relator's experts may not opine about whether Biogen's speaker and consultant programs were legitimately educational or served a legitimate business because these are issues that a jury must decide. Biogen is wrong. The issue the jury will need to decide in this action is whether Biogen acted with an intent to unlawfully induce prescribing of its MS Drugs in contravention of AKS even if that was not Biogen's sole intent. *U.S. v. Bay State Ambulance & Hosp. Rental Service, Inc.*, 874 F.2d 20, 29-30 (1st Cir. 1989) (holding that "the gravamen of Medicare Fraud is inducement" and therefore that so long as one purpose was unlawful inducement the AKS has been violated). One of the ways that the Relator will seek to prove intent is by debunking Biogen's stated rationale for holding these programs as pretextual. If Biogen falsely claimed that

it held these events for the purpose of educating or receiving feedback from HCPs, then a jury could draw the inference, along with other evidence in the record bearing on intent, that in fact Biogen provided remuneration to HCPs for the purpose of inducing them to prescribe or recommend prescribing Biogen's MS Drugs. As in negligence actions where experts routinely opine regarding the standard of care and breach of those standards, *see, e.g., Montany v. Univ. of New England*, 858 F.3d 34, 37-40 (1st Cir. 2017), Relator's experts should be permitted to testify that Biogen's speaker programs bore none of the hallmarks of an educational program and that Biogen's programs deviated widely from accepted industry standards.

2. **Expert opinions identifying speaker program practices that are non-educational or that are commercially unreasonable.**

To rebut Biogen's purported justification for holding educational speaker programs, Relator intends to offer the expert testimony of Drs. Samuel Pleasure, Richard Schwartzstein, and Ms. Margie Kuo. Based on these experts' decades of experience treating MS, educating medical students, designing educational programs, and pharmaceutical marketing, these experts identified Biogen conduct that was commercially unreasonable and described specific Biogen speaker program practices that could not be understood to be educational or failed to align with accepted industry standards. *See* Kuo Rep., Schwartzstein Rep., Pleasure Rep., Doc. Nos. 502,-8, 502-9, 502-36. Biogen has sought to broadly exclude these expert opinions. As described in Relator's memoranda opposing Biogen's Daubert Motions, the identification of indicia of improper speaker program practices is admissible. *See* Doc. Nos. 535, 536, 538.

Conclusion

For the foregoing reasons, the Relator respectfully submits that he will prove his case at trial, and he is confident that the jury will find Biogen liable for False Claims Act violations resulting from its company-wide kickback schemes.

Respectfully submitted,

Relator MICHAEL BAWDUNIAK, on behalf of the UNITED STATES OF AMERICA and the States of CALIFORNIA, CONNECTICUT, GEORGIA, ILLINOIS, NEW JERSEY, NEW YORK, NORTH CAROLINA, TENNESSEE, TEXAS, WISCONSIN, and the Commonwealth of MASSACHUSETTS

By his attorneys,

Dated: June 28, 2022

/s/ Thomas M. Greene
Thomas M. Greene (BBO #210020)
tgreene@greenellp.com
Michael Tabb (BBO #491310)
matabb@greenellp.com
GREENE LLP
One Liberty Square, Suite 1200
Boston, MA 02109
(617) 261-0040

CERTIFICATE OF SERVICE

I hereby certify that, on June 28, 2022, this document (filed through the ECF system) was sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants.

Dated: June 28, 2022

/s/ Thomas M. Greene
Thomas M. Greene