UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.*, Plaintiffs and Relator, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	ECF CASE 11 CIV. 0071 (PGG)
UNITED STATES OF AMERICA, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	

MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THE UNITED STATES OF AMERICA'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

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Statutes

The United States of America respectfully submits this memorandum of law in opposition to Novartis Pharmaceuticals Corporation's ("Novartis"/"NPC") motion for summary judgment, and in support of the Government's cross-motion for partial summary judgment.[1]

In the Amended Complaint, the government alleged that Novartis systematically and deliberately channeled hundreds of millions of dollars of kickbacks to health care providers in the form of speaker honoraria, lavish dinners, and entertainment, for the purpose of inducing those doctors to prescribe Novartis drugs. The government further alleged that these rampant violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), caused the submission of hundreds of millions of dollars in false claims to federal health care programs, in violation of the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA").

Discovery has fully borne out these allegations. The government has (1) elicited testimony from dozens of former NPC employees and doctors, from approximately 20 states, proving that Novartis knowingly and willfully engaged in a nationwide scheme to pay off doctors for prescriptions through its speaker programs and roundtables; (2) uncovered dozens of internal Novartis documents confirming the existence and breadth of the scheme; (3) mined Novartis's own voluminous event data, exposing the exorbitant amounts NPC spent on swank dinners, the massive speaker fees showered on its top prescribers, and the inappropriate and, in some cases, entertainment-oriented venues NPC used to host its events; and (4) the patterns of serial event attendance by doctors on the take. All of this evidence has laid bare NPC's fraudulent business model of paying doctors to prescribe its drugs. Expert discovery has only served to underscore the vast and brazen nature of NPC's kickback scheme. The government's expert witnesses have opined, among other things, that many of NPC's events were bereft of

[1] The State of New York and the relator join in this opposition and cross-motion.

educational value; that NPC's bribes caused doctors to prescribe more NPC drugs; and that an effective compliance program, which NPC deliberately failed to implement, could have prevented its abusive practices. In short, the government has more than established disputed issues of fact that preclude summary judgment.

The government also cross-moves for summary judgment as to the proper interpretation of the release language of the 2010 settlement agreement. The settlement agreement by its terms plainly releases NPC from kickback-related liability for all claims submitted to federal health care programs for the drugs Diovan, Exforge, and Tekturna for the time period covered by that agreement. It does not, however, release causes of action arising from claims submitted to federal health care programs for drugs nowhere mentioned in that agreement.

STATEMENT OF FACTS

I. NPC's Nationwide Kickback Scheme to Induce Doctors to Prescribe Its Drugs

From January 2002 through November 2011, NPC engaged in a nationwide kickback scheme to induce physicians to increase the number of prescriptions they wrote for nine of its cardiovascular ("CV") drugs, Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, and Tekamlo, as well as Starlix, a drug used to treat Type 2 diabetes. Specifically, under the guise of compensating physicians for their participation in purportedly educational speaker programs and roundtables regarding its drugs, Novartis systematically provided doctors with remuneration in the form of substantial honoraria, lavish dinners costing hundreds of dollars per person, and other entertainment in order to unlawfully influence doctors' prescribing habits. United States of America's Response to Def.'s Statement of Undisputed Material Facts & Counterstatement of Additional Facts, Pursuant to Local Rule 56.1 ("CAF") ¶ 97. In total, at least 525,000 NPC events were implicated in this scheme, in all 50 states, through which NPC provided kickbacks to more than 95,000 health care providers. *Id.* ¶ 341.

The ostensible purpose of speaker programs and roundtables was to educate doctors about Novartis's products. *Id.* ¶ 117. Speaker programs were supposed to be events at which Novartis paid a doctor who had received specialized training to educate a group of other doctors about one or more Novartis drugs by presenting a Novartis slide deck and lecture, usually over dinner at a restaurant. *Id.* ¶ 118. Novartis generally paid speakers an honorarium of between $500 and $2,000 per event. *Id.* ¶ 120. Roundtables, in contrast, were supposed to be less formal events during which one or more doctors participated in a medical discussion led by a sales representative over a meal. *Id.* ¶ 121. These events could take place at a restaurant or in a doctor's office. *Id.* ¶ 123.

As numerous sales representatives admitted, however, in reality these promotional events were intended to be a means of allowing Novartis to systematically bribe doctors to write prescriptions for Novartis drugs. *Id.* ¶¶ 281-88, 291-309. One sales representative confessed that the "primary purpose of speaker programs and roundtables was to keep the doctors happy—by paying them honoraria and treating them to meals, often at high-end restaurants—so they would write prescriptions for Novartis drugs." *Id.* ¶ 282. Other sales representatives candidly called the practice "buying scripts," *id.* ¶ 283, "greas[ing] the[] physicians' palms," *id.* ¶ 281, and paying "bribes," *id.* ¶ 284. Another sales representative admitted that she "absolutely believe[s]" that doctors were paid to prescribe Novartis products, *id.* ¶ 281, and still another confirmed that these events "were merely a way for Novartis to line the pockets of . . . doctors . . . to get them to prescribe more Novartis product," *id.* Moreover, sales representatives would, as one put it, "lean on" the event participants "to achieve an increase in script writing." *Id.* ¶ 291.

That these events were really intended to serve as a means of funneling money and gifts to doctors in return for an increase in prescription writing, rather than their nominal educational

purpose, is confirmed by the way in which these events were designed and carried out. A description of some of the most common indicia of Novartis's unlawful intent follows.

A. Events Were Primarily Social Gatherings With Little or No Educational Content

First, many events featured little or no discussion of the drugs that were supposed to be the subject of the events, and were simply a reward to doctors in the form of a social evening paid for by Novartis. *Id.* ¶¶ 125-26, 129-44; *see also id.* ¶¶ 146-56. While the events typically lasted two to three hours, many had only 15 minutes or less of actual medical discussion, *id.* ¶¶ 124, 129, and many had even less than that, *id.* ¶¶ 132-41. In fact, there were numerous events where the medical discussion lasted five minutes or less, *id.* ¶¶ 134-42, including events with no medical discussion or only a passing reference to the drug that was supposed to be the subject of the event, *id.* ¶ 139.

For example, according to one sales representative, it was common for there to be just a few minutes of discussion focused on Novartis's desire for doctors to write more Novartis prescriptions: "There were numerous Lotrel events where [the speaker] would say, in substance—Thank you for coming, and remember to prescribe Lotrel—and the remainder of the event would consist of [the speaker] and the other attendees socializing with one another and discussing whatever they wanted." *Id.* ¶ 135. Another sales representative testified that at "80 percent" of the speaker programs she organized, the speaker was the only attendee and the event was entirely social, *id.* ¶ 140, while another said that "more often than not," speaker presentations on Lotrel were "five or ten minutes" after which the doctors socialized, *id.* ¶ 133, and still another said that "eight out of ten" speaker programs were entirely social, and at roundtables, "the relevant Novartis drug or disease state was often not discussed at all," *id.* ¶¶ 136-37.

Many events, particularly those that representatives characterized as "roundtables," were nothing more than a sales representative taking one or more doctors (typically high-prescribers) out for dinner. *Id.* ¶ 125. For example, one sales representative described a standing Novartis dinner with one doctor every Tuesday evening that "was basically a . . . social hour." *Id.* ¶ 126. Similarly, another sales representative admitted that she regularly invited her highest Lotrel prescriber and his wife to dinner, explaining "if you took a doctor out to dinner, you coded it as a roundtable." *Id.* ¶ 127.

Novartis also paid for holiday parties or happy hours for doctors and their staff, *id.* ¶ 142, and in some instances, sales representatives paid their high prescribing doctors to "speak" at phantom events that did not take place, *id.* ¶¶ 329-40.

This practice of hosting sham events for doctors was not confined to a specific time period or region. Rather, many former NPC employees and doctors, from approximately 20 states, confirmed that it was a regular practice to hold events with little to no medical discussion. *See id.* ¶¶ 125, 129-31.

B. Repeat Attendance Was Rampant at Novartis Events

NPC routinely invited the same doctors to the same or similar events over and over again within a short period of time. *Id.* ¶¶ 212-24, 226-27. The sales representatives recognized that repeat attendance served no educational need, *id.* ¶¶ 235-38, but nonetheless continued to invite their highest prescribing doctors as an inducement so they would continue to write prescriptions for the Novartis drugs, *id.* ¶¶ 232-33. According to Novartis's data, more than 65,000 doctors attended five or more NPC promotional events about the same drug in a single year, and more than 45,000 doctors attended five or more events about the same drug within six months. *Id.* ¶¶ 215, 221.

A doctor's repeat attendance at the same or similar event is a red flag that the purported event was merely a social occasion with little to no medical discussion. *Id.* ¶ 234; *see id.* ¶ 240. Indeed, numerous sales representatives and doctors have confirmed that, at many of the events with repeat attendees, there was little or no discussion of the Novartis drug that was supposed to be the subject of the events, and the events were primarily or exclusively social in nature. *Id.* ¶ 234

The high numbers of repeat attendees also reflects that sales representatives organized regular social outings around a cluster of doctors who were friends or members of the same medical practice, and then recorded those social dinners as educational events. *Id.* ¶¶ 242-58. Novartis's event data illustrates this trend: between 2004 and 2011, at least 6,600 groups of between three and nine doctors attended 30 or more events together. *Id.* ¶ 243. That is roughly 1,700 doctors in 350 clusters attending roughly 15,000 Novartis events together across 40 states. *Id.* ¶ 244.

Sometimes, the doctors in these cluster groups would take turns being the "speaker." *Id.* ¶¶ 259-60, 245-48. Doctors also routinely attended events on a drug for which they had previously spoken. *Id.* ¶¶ 266-67. Novartis's event data shows that roughly 12,000 doctors across all 50 states were trained speakers who subsequently attended at least one program on the same drug on which that doctor had previously presented. *Id.* ¶ 267. Of course, there was no legitimate educational benefit for a doctor to attend a program about a drug she was trained to speak about. *Id.* ¶¶ 261-65, 268.

By way of example, one cluster of five doctors in Harrisburg, Pennsylvania went to more than 100 Novartis events together over the course of five years. *Id.* ¶ 245. In 2007 alone, members of this cluster went to 34 events together—with no other doctors in attendance—

sometimes as often as five times a month. *Id.* ¶ 246. The doctors took turns "speaking" to one another on many of the same event topics, each receiving honoraria when it was their turn. *Id.* ¶ 247. As one of these doctors acknowledged, the events primarily involved him and the other participants "eating dinner, socializing and discussing whatever we wanted." *Id.* ¶ 248.

Another cluster of ten doctors in Rockford, Illinois went to 124 Novartis events together over the course of eight years. *Id.* ¶ 249. In this cluster, one of the doctors "spoke" at nearly every event, but the only doctors in attendance were some combination of the ten doctors in the cluster. *Id.* ¶ 250. Between 2006 and 2007, the Rockford cluster attended the speaker program titled "Aggressive Strategies for Lowering BP in At-Risk Patients" 33 times. *Id.* ¶ 251. At 31 of the 33 programs, the same doctor was designated "speaker" and received between $750 and $1,000 in honoraria. *Id.* ¶ 252. One of the attendees in this group reported that he received $100 from the speaker every time he attended one of the speaker's events, and acknowledged that his "primary reasons for going to the events were to interact socially with the other attendees, to receive a free meal, and to receive the $100 payment from [the speaker]." *Id.* ¶ 253.

Doctors have confirmed that they attended the same events repeatedly not for an educational purpose, but to socialize or as a favor to the Novartis sales representative. *Id.* ¶ 239-40. This is because the drugs had been on the market for a long time; were commonly prescribed for hypertension; their clinical attributes were well understood; the information conveyed at speaker programs and roundtables tended to be simplistic and straightforward, and the slide deck presentations purportedly shown at speaker programs were substantively similar and redundant. *Id.* ¶¶ 98-112, 149-56, 208-11. Sales representatives therefore recognized that it would be unreasonable to expect doctors to repeatedly attend their events if they were forced to listen to the same rudimentary information again and again. *Id.* ¶¶ 235-38. As one sales representative

explained with respect to Lotrel, presentations were abbreviated because if a presenter went "on and on and on about the drug, I would guess that doctors would get up and walk out." *Id.* ¶ 150.

Yet even in those instances when an event included a full medical discussion or a presentation of the relevant slidedeck, there would be no reason from an educational standpoint for a doctor to attend an event on the same drug multiple times within a short timeframe. The testimony of the government's medical education expert, Dr. Graham McMahon, and its expert cardiologist, Dr. Stanley Schneller, lays bare the pretextual nature of Novartis's stated justification for these events. Even assuming that a medical discussion of some sort had taken place, these experts explain that it would be so unlikely that clinicians would learn anything of value through excessive repeat attendance that these programs cannot have been constructed with an intent to educate. *See* McMahon Rep., Harwood Decl. GX 105, ¶¶ 15-16, 22-74; Schneller Rep., Harwood Decl. GX 104, pgs. 2, 22-30. Sales representatives and doctors echoed these opinions. CAF ¶¶ 235-40. But as education was never the aim of these programs, that did not deter the sales force from continuing to repeatedly extend invitations to the same doctors.

C. Novartis Rewarded Doctors with Lavish Meals at High End Restaurants

Many Novartis events were held at high-end restaurants, with exorbitant meal spending. *Id.* ¶¶ 158-65, 177-85. These lavish meals were designed to induce doctors to prescribe Novartis products. *See id.* ¶¶ 162, 194-95. Events were held at some of the most expensive restaurants in their regions, including the Four Seasons in Illinois, the Ritz Carlton and Gary Danko in California, Le Bernardin and Peter Luger in New York, Bohanan's in Texas, Grill 225 in South Carolina, Erling Jensen's in Tennessee, and Commander's Palace in Louisiana. *Id.* ¶ 467. Novartis frequently spent hundreds of dollars per doctor at these events. *Id.* ¶¶ 178-80.

According to Novartis's event data, of the events at issue, Novartis organized more than 40,000 events across all 50 states at which it paid more than $125 for *each* doctor's meal and

12,000 events at which it paid more than $200 per doctor. *Id.* ¶¶ 178-79. The same data shows that Novartis held more than 6,500 events across all 50 states at which it paid more than $250 per doctor. *Id.* ¶ 180. As egregious as these numbers are, however, the per person costs of many events was likely even higher than is reflected in Novartis's records, as sales representatives often doctored the paperwork associated with these events to reduce the average per person cost reflected in the data. *Id.* ¶ 181.

Representatives also allowed doctors to make extravagant alcohol orders to encourage their prescribing of Novartis drugs. *Id.* ¶¶ 189-95. And at many Novartis programs, alcohol was consumed in quantities that made clear that medical education was not the intended purpose of the event. *Id.* One doctor would regularly call a Novartis representative to ask him to come to a bar where that doctor and his friends were drinking so that Novartis could pick up the tab. *Id.* ¶ 190.

In addition, Novartis sponsored many events at venues where it was clear that the primary purpose was entertainment, not education. *Id.* ¶¶ 166-70. For instance, Novartis held events at wineries, golf clubs, and other sports venues. *Id.* Indeed, Novartis even held 75 events at Hooters. *Id.* ¶ 167.

NPC representatives also regularly invited or permitted spouses or guests of doctors to attend events, even when the guests were not themselves HCPs and thus had no reason to be there if the event were truly meant to be educational. *Id.* ¶¶ 198-99. They did so in order to keep the doctor prescribing for Novartis. *Id.* ¶ 200.

D. Novartis Paid Doctors to Speak to Induce Them to Prescribe More Novartis Drugs

Sales representatives used speaking engagements and the high honoraria associated with them to induce doctors to continue to write or to write more prescriptions for Novartis drugs. *Id.*

¶¶ 278-88, 291-97. For example, Novartis paid more than 2,000 speakers honoraria of at least $10,000 in a single calendar year, *id.* ¶ 271; Novartis paid nearly 700 speakers at least $25,000 in a year, *id.* ¶ 272; and Novartis paid more than 230 doctors at least $50,000 in a year, *id.* ¶ 273. All told, Novartis paid nearly 14,800 doctors across all 50 states a total of $204 million to speak at events regarding the drugs at issue between 2002 and 2011. *Id.* ¶ 274.

Sales representatives chose speakers based on their prescribing habits, i*d.* ¶¶ 278-80, 285, even where the doctor was not a good speaker or did not have a good reputation in the community, *id.* ¶¶ 313-25. And with that invitation came the expectation of continued and increased prescriptions of Novartis drugs. *Id.* ¶¶ 291-97. If, however, doctors did not prescribe high volumes of Novartis drugs, they were often dropped as speakers. *Id.* ¶¶ 326-28.

Some doctors were explicit that they would write Novartis prescriptions in exchange for speaking engagements. *Id.* ¶¶ 298-309. For example, one doctor "point blank" told a Novartis sales representative covering Northern, Illinois, and her supervisor, "You take care of me, and I'm going to take care of you." *Id.* ¶ 300. Thereafter, the sales representative, her manager, and a colleague "discussed it as a group" and decided to set up regular speaker programs for the doctor. *Id.* ¶¶ 301-02. Similarly, a doctor told a sales representative covering portions of New Mexico and Texas that a drop in his Diovan prescribing was attributable to the fact that he had not "had the opportunity to [do a] speaker program" for Novartis recently. *Id.* ¶ 303. In response, the sales representative scheduled more speaker programs for that doctor, and his prescriptions of Diovan went back up. *Id.* ¶¶ 304-05.

E. Novartis Sales Managers Condoned and Directed These Sham Practices

Many Novartis sales representatives delivered these kickbacks with the full knowledge of their managers, who not only condoned but directed many of these practices. *Id.* ¶¶ 404-11. Managers routinely advised their sales representatives to wine and dine their high-prescribers

and signed off on expense reports showing excessive spending. *Id.* ¶ 405. Managers also instructed their sales representatives to nominate high-prescribers to serve as speakers and schedule events with those doctors in order to encourage them to write more Novartis prescriptions, and to pull the funds if a doctor failed to do so. *Id.* ¶¶ 407-09. Managers even told sales representatives to pressure speaker to write more Novartis prescriptions. *Id.* ¶ 410.

II. Novartis Directed Its Sales Representatives to Funnel Honoraria and Meals to High-Prescribers and Threatened Them If They Failed To Do So

That Novartis's kickback scheme was so prevalent all across the country was not an accident. Rather, it was a direct outgrowth and the intended outcome of how Novartis structured its event programming. To become "the 800-pound gorilla" in the cardiovascular space, Novartis spent an astounding $475 million on honoraria and free meals for doctors on the Covered Drugs during the relevant period, delivered through more than 1 million speaker programs and roundtables. *Id.* ¶¶ 383-89. In 2004, for instance, Novartis executives planned to outspend all of Novartis's CV competitors *combined*. *Id.* ¶ 385. In order to deliver these inducements to doctors, Novartis executives set "extremely aggressive" event quotas for their sales force. *Id.* ¶ 390. When one sales force executive objected that Novartis's event quotas were unrealistic and pointed out, with some simple arithmetic, that they were unachievable without "excessive" attendance by doctors, she was overruled. *Id.* ¶ 391.

And Novartis made clear to its sales force that they were to spend every dollar of their event budgets. *Id.* ¶ 392. Sales representatives who failed to spend their money quickly enough would receive shaming emails sent to the whole team that singled out those representatives. *Id.* ¶ 394. Representatives who failed to spend their bloated budgets received negative evaluations, were put on probation, or threatened with termination. *Id.* ¶¶ 395-97.

Novartis paired carrots with those sticks. Sales representatives who spent their full budgets and then asked for additional funds were praised and promoted. *Id.* ¶ 398. And Novartis created an incentive structure that provided hefty bonuses (with no cap) and other perks, such as all-expense paid vacations to places like the Bahamas, if sales representatives hit prescription growth targets. *Id.* ¶¶ 399-402.

These measures were necessary because, with event budgets that big, sales representatives had great difficulty spending all that money. *Id.* ¶¶ 390-91. There was no way to do so legitimately, as Novartis's Vice President of Sales recognized. *Id.* ¶ 391. So, with the blessing of their sales managers, representatives identified high-prescribers interested in—and willing to respond to—honoraria and meals. *Id.* ¶¶ 277-78, 281-87, 291-93, 326-328, 404-11. By bribing these doctors, Novartis's sales force translated hundreds of millions of dollars of repetitive programming into 1.3 million new Novartis prescriptions. *Id.* ¶¶ 378-79.

III. Novartis Created a Toothless Compliance Program So As Not to Obstruct the Flow of Inducements

Having directed its sales force to deliver as many honoraria payments and free meals to doctors as it could, Novartis ensured that its compliance department would not get in the way. Until 2003, Novartis's compliance program consisted of only one person: Martins Putenis, an 18-year veteran of Novartis's marketing department. *Id.* ¶ 412. Putenis was known to "try to satisfy marketing colleagues rather than take the tough but 'correct' stand," and to "underplay [compliance] risks." *Id.* ¶¶ 413-14, 416. It was Putenis who authored Novartis's written compliance policies, which left ample room for kickbacks within vague and ambiguous standards. *Id.* ¶¶ 421-23. Indeed, Putenis himself approved speaker programs that took place at an NBA basketball game and on a fishing trip. *Id.* ¶ 420. Putenis's two successors, the first of whom was in the role until 2010 and saw no compliance issues with doctors repeatedly attending

the same event together, with speaker presentations lasting only 10 to 15 minutes, or with speaker programs being held in the middle of a restaurant, were no better. *See id.* ¶¶ 429-34.

Thus it is unsurprising that Novartis's so-called compliance department was content to allow the sales force to police itself, assigning primary responsibility for compliance oversight to the very sales managers who were tasked with ensuring that their sales representatives did whatever it took to spend their massive budgets and hit their growth targets. *Id.* ¶ 435. Novartis knew this was no way to enforce compliance, admitting in an internal document that "[d]istrict managers have . . . no real incentive to monitor" for compliance; in fact, given the overwhelming pressure on managers to ensure their representatives' event budgets were spent, and the fact that their bonuses were tied to prescriptions, managers' incentives ran the other way. *Id.* ¶¶ 436-37.

Having tasked the sales force with monitoring itself, Novartis's compliance department did little to identify compliance issues. *See id.* ¶¶ 424-28, 458-61. It declined to conduct any meaningful audits until late 2008, *id.* ¶ 452; and when the report from that 2008 audit warned that Novartis "may be subject to fines and penalties" for "holding sham speaker programs," the budget for audits was slashed, leaving "[i]nsufficient resources" to do the job. *Id.* ¶¶ 453-57.

Novartis's compliance program also buried affirmative complaints. A 2005 internal report describes Novartis's process for handling compliance complaints as "chaos and confusion." *Id.* ¶¶ 461-62. When Novartis finally created an investigation process for misconduct allegations in 2005, it was starved: until 2008, Novartis tasked a single employee with investigating essentially all allegations related to promotional events, creating a huge backlog. *Id.* ¶¶ 463-64.

It is telling that when Novartis's marketing executives found in 2006 that 25% of meals violated Novartis's already-generous spending caps, Novartis saw it as a cost issue. *Id.* ¶¶ 469-

70. Upon learning that, despite its "modest meal" policy, Ruth's Chris and Nobu were among the top restaurants (by spending) used for out-of-office programs, the response was not to crack down on noncompliance, but to consider negotiating lower rates with the restaurants. *Id.* ¶ 470.

As one former sales representative explained, Novartis's policy directing sales representatives not to pay kickbacks to doctors was just "CYA" that bore no relation to what the sales force was asked to do. *Id.* ¶ 419. Similarly, Novartis's toothless compliance program, which deferred to sales and did little to identify noncompliance, *id.* ¶¶ 449-52, 458-65, was simply a means of checking a box while ensuring that money continued to flow to doctors.

IV. Novartis Spent Hundreds of Millions on Inducements Because They Worked

Year after year, Novartis spent tens of millions of dollars on sham programs because these inducements were effective. *Id.* ¶¶ 341-82. Sales representatives from across the country have freely admitted that—using monthly data they received from Novartis corporate headquarters on doctors' prescription writing—they ensured that honoraria payments and event invitations were directed at those doctors who responded by writing more Novartis scripts. *Id.* ¶¶ 277-78, 281-87, 291-93, 326-328. If doctors failed to respond, sales representatives would stop the flow of honoraria, dinner invitations, and catered lunches. *Id.* ¶ 345. Numerous doctors have admitted that they wrote Novartis scripts over those of Novartis's competitors because they received honoraria and meals. *Id.* ¶ 346. And if a responsive doctor's numbers flagged, sales representatives would "lean on" that doctor by alluding to Novartis's past "support" of the doctor and asking for additional scripts in the future. *Id.* ¶¶ 347-48.

Novartis's return-on-investment analyses confirmed what sales representatives saw first-hand: doctors who were continually given honoraria or repeatedly invited to events increased their prescription writing in response. *Id.* ¶¶ 349-68. For example, in 2005, Lotrel roundtables provided Novartis with a stunning 460% return on investment. *Id.* ¶ 352. Throwing money at

speakers was also effective. Of Novartis's approximately 14,750 speakers, 75% of them wrote more new Novartis scripts in the months following receipt of honoraria than they did in other months. *Id.* ¶ 356. Novartis's marketing science group ran the numbers and recommended to the brand teams—who then set corresponding event quotas and budgets for the sales force—that high-prescribing doctors should be attending a dozen or so events *on each drug* per year in order to maximize Novartis's profit. *Id.* ¶¶ 363-67. Lavishing doctors with honoraria, fancy meals, and catered lunches paid off.

The government's expert economist, Professor Daniel McFadden, built a sophisticated model of doctors' prescribing behavior which confirms this. *Id.* ¶¶ 369-79. The results of that modeling show that, after controlling for national trends and doctors' baseline prescribing and making a number of conservative assumptions, attending sham events caused the more than 75,000 doctors who received illegal inducements from Novartis, considered in the aggregate, to increase their prescribing of Novartis drugs[2] for the following twelve months. *Id.* ¶¶ 374-75. Professor McFadden also found that Novartis's kickbacks caused each of more than 70,000 doctors to write Novartis prescriptions—together, more than 1.3 million scripts—they would not have written but for those kickbacks. *Id.* ¶¶ 377-79. Indeed, even the competing model put forward by Novartis's expert economist, Dr. Eric Gaier, shows that the inducements identified by the Government caused more than 41,000 doctors to write more Novartis prescriptions. *Id.* ¶ 380. This expert testimony proves the obvious: that Novartis spent nearly $325 million on sham events over nine years because they were a good investment, inducing doctors to write more prescriptions. *Id.* ¶ 341.

[2] There are two exceptions: Lotrel after a generic competitor entered the market, and Tekamlo. These were excluded from the Government's damages calculations.

ARGUMENT

I. THE GOVERNMENT HAS ADDUCED SUFFICIENT EVIDENCE TO CREATE A TRIABLE ISSUE OF FACT AS TO THE EXISTENCE OF A NATIONWIDE KICKBACK SCHEME TO INDUCE PRESCRIPTION WRITING

Throughout this litigation, the government has pursued a consistent theory of this case: that Novartis has used its promotional events as a means of channeling hundreds of millions of dollars to doctors, with the intent of buying prescriptions. The government has also consistently alleged that Novartis's unlawful intent manifested itself in a number of ways, including in the lavish nature of the dinners provided to doctors, the entertainment venues selected for these programs, the lack of educational value associated with these purportedly informational programs, and the payment of honoraria to speakers for events that either never took place at all or that were primarily social outings. Faced with the extensive evidence of the kickback scheme, Novartis now attempts to distort the evidentiary record by attacking discrete portions of the government's case, ignoring the majority of the evidence of fraudulent intent, and asking the Court to view the evidence in isolation. When viewed in its totality, however, the evidence of Novartis's intent to induce doctors to prescribe Novartis drugs is overwhelming.

A. The Government Has Adduced Evidence More Than Sufficient to Establish Novartis's Intent to Induce Prescription-Writing

Although Novartis sweepingly argues that the government's case must be dismissed in its entirety because of a purported lack of "particularized evidence of the alleged nationwide scheme," Mem. of Law in Support of Def. Novartis Pharm. Corp.'s Mot. for Summ. J. ("Br.") 9, Novartis is unable to identify a single element of the government's cause of action under the FCA (or the AKS as the predicate statute) as to which its proof is purportedly lacking. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Nor can it. The government's evidence that NPC engaged in a nationwide kickback scheme with the intent to induce prescription-writing is

wide-ranging and comprehensive, and more than sufficient to defeat Novartis's summary judgment motion.

The AKS makes it illegal for individuals or entities to "knowingly and willfully offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). It is undisputed that cash payments, lavish dinners, and entertainment constitute remuneration with the meaning of the AKS. *See, e.g.*, *U.S. ex rel. Gale v. Omnicare, Inc.*, No. 10-127, 2013 WL 3822152, at *6 n.67 (N.D. Ohio July 23, 2013) (remuneration includes "anything of value in any form whatsoever").

Thus, the critical inquiry here is whether the government has adduced evidence sufficient to create a triable issue of fact that one of the intended purposes of this remuneration was to induce health care providers to prescribe Novartis drugs. *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); *U.S. v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985) ("The statute is aimed at the inducement factor"). Because issues of intent and motive should not typically be resolved at summary judgment, particularly in cases involving allegations of kickbacks, the government need only adduce facts from which such intent can be inferred to defeat summary judgment. *U.S. ex rel. Emanuele v. Medicor Assocs*., 242 F. Supp. 3d 409, 430 (W.D. Pa. 2017); *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014); *see also Wechsler v. Steinberg*, 733 F.2d 1054, 1058 (2d Cir. 1984). The government has more than met this minimal burden.

Novartis disingenuously claims that, from the outset, the government's case was based solely on events at which there was little to no medical discussion, and that following discovery, the only evidence on this issue came from "a small group of witnesses" that reflected only "sporadic" wrongdoing. Br. 1. Novartis is wrong on both counts. The government's evidence of intent has never been limited to events at which there was limited medical discussion, although such events were widespread and are one part of the government's case, *see supra* Statement of Facts ("SOF") Part I.A. And as outlined in detail *supra* SOF Part I, the government has offered extensive direct and circumstantial evidence that one of the intended purposes of Novartis's promotional programs was to improperly induce prescribing.

As direct evidence, the government has pointed to the testimony of approximately 20 NPC sales representatives, who have admitted that they were, in the words of one witness, "buying prescriptions" by providing doctors with paid speaking opportunities, lavish meals, alcohol, and other benefits to induce them to write NPC prescriptions. CAF ¶¶ 281-87, 291-309, 403. Doctors in turn have confirmed that they understood that they had been invited to Novartis events because NPC wanted to induce them to write prescriptions, *id.* ¶ 196, and that they were in fact induced, *id.* ¶¶ 311, 346. Many contemporaneous documents, including emails between sales representatives and their managers, confirm that Novartis used its events to induce prescription writing. *See, e.g.*, *id.* ¶¶ 284, 286-87, 291-95. For example, in one email, a district manager informed her supervisor that her team was "[d]emanding that our trained Tekturna speakers prescribe Tekturna, *i.e.*, at least a dozen prescriptions, if they are going to speak for us." *Id.* ¶ 292.

Novartis's attempt to characterize this evidence as "isolated" or "anecdotal," Br. 11, from "sales representatives who covered narrow geographic regions," Br. 1, is absurd, given that the

witnesses and documents that speak directly to Novartis's unlawful intent span approximately 20 states and many of the most populous cities and regions across America, including Los Angeles, Las Vegas, Austin, Fort Worth, Chicago, Atlanta, Philadelphia, Baltimore, Tallahassee, Gainesville, Palm Beach, Alexandria, El Paso, Topeka, and Long Island. *See* CAF ¶¶ 129-31, 281-87. This direct evidence is sufficient standing alone to defeat Novartis's summary judgment motion. *See U.S. ex rel. Bibby v. Wells Fargo Bank, N.A.*, 165 F. Supp. 3d 1340, 1348 (N.D. Ga. 2015) ("The reasonable inference to draw here is that if the alleged violations of a national VA fee ban were occurring in seven states . . . such conduct is likely to have occurred nationwide."); *U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 177–78 (E.D. Pa. 2012) ("[T]he sheer number of claims identified by Plaintiff in at least three states and Puerto Rico suggests, without need for speculation, that Defendants' reporting practices likely occurred . . . . throughout the country.").

Yet there is also extensive circumstantial evidence from which a jury could infer Novartis's unlawful intent. Although the nominal justification offered by Novartis was that this remuneration was incidental to providing medical education regarding its products, CAF ¶ 117, a jury could easily conclude that the remuneration provided had such an attenuated connection with any ostensible educational purpose that this stated justification was entirely pretextual. A jury could reasonably draw such an inference, for example, from the nature of the venues; from the frequent exorbitant spend on meals and alcohol; from Novartis's regular inclusion of spouses and other guests at these events; from the number of events at which little to no medical discussion took place; and from the sheer number of times sales representatives invited doctors to attend the same or similar events over and over again. *See supra* SOF Part I. The evidence

that Novartis's stated justification for these programs is suspect is probative of its fraudulent intent.

Novartis's intent can also be gleaned from the pressure it placed on its sales force to hold more events than could be justified from any legitimate educational standpoint. *See supra* SOF Part II. Combining this with Novartis's practice of evaluating its sales force based on whether they spent their budgets, tying their bonuses and other rewards directly to the number of prescriptions written by doctors, and insisting that they focus their events on high prescribers, a jury could reasonably conclude that Novartis used its compensation structure to incentivize sales representatives to use their event budgets to purchase prescriptions. *See id.* & SOF Part I.E. The inference to be drawn from this evidence is strengthened by Novartis's lack of a meaningful compliance program. At the same time that Novartis was transferring millions of dollars in speaker fees and free meals to the very physicians that it was courting to increase its prescription writing—an activity that HHS-OIG had identified in 2003 as a key AKS risk area, CAF ¶ 448—Novartis deliberately elected to forego putting into place an auditing and monitoring program during most of the relevant period, thus permitting the sales force to freely ignore Novartis's written policies without consequence. *See supra* SOF Part III.

Given the breadth and scope of the evidence regarding Novartis's nationwide kickback scheme, Novartis's reliance upon cases in which evidence of a handful of potential false claims in a single location was found to be insufficient to demonstrate the existence of a nationwide scheme is particularly misplaced. For example, *U.S. v. Pfizer, Inc.*, 188 F. Supp. 3d 122 (D. Mass. 2016), is readily distinguishable; in that case a court found that the testimony of a single sales representative about his personal practices in nominating speakers, which was not supported by "documentary evidence, data, or testimony from doctors themselves," was

insufficient to establish that an entire speaker program series was a vehicle for providing kickbacks. *Id.* at 135. Similarly unavailing is *U.S. ex rel. King v. Solvay S.A.*, Civ. H-06-2662, 2016 WL 1258401, at *10-11 (S.D. Tex. 2016), *aff'd* 871 F.3d 318 (5th Cir. 2017), where the relator could only point to evidence of sales calls made to three doctors in a single state as evidence of a purported nationwide off-label marketing scheme.

In any event, the premise of Novartis's motion is flawed, as demonstrating the existence of a nationwide scheme is not a required element of either an AKS or FCA violation. Novartis can be held liable under the FCA even if its employees only "sporadically" violated the AKS. *See, e.g.*, *U.S. v. Incorporated Village of Island Park*, 888 F. Supp. 419, 437-39 (E.D.N.Y. 1995) ("Respondeat superior applies to violations of the False Claims Act committed by an employee of a corporation who is acting within the scope of his authority and, at least in part, for the employer's benefit."); *see generally U.S. v. Gen. Dynamics Nat'l Steel & Shipbuilding*, No. 07-982, 2010 WL 3463675, at *3 (S.D. Cal. Aug. 31, 2010).[3] Accordingly, while the government intends to prove at trial the existence of a nationwide scheme, as it will be probative of, *inter alia*, the scope of damages, it is not required to do so in order to establish liability.

B. The Jury Can Reasonably Infer Novartis' Intent to Induce Prescription-Writing From the Facts and Circumstances Surrounding the Events

In moving for summary judgment, Novartis ignores the vast bulk of the evidence of intent. Novartis argues instead that the jury should not be permitted to draw an inference of intent from event data demonstrating the circumstances in which a particular event occurred (such as the venue, the spend amount, or repeat attendance by the same doctors), calling such an inference "speculative and unsupported by the record." Br. 17-19. Novartis further contends

[3] *See also U.S. v. Dolphin Mortg. Corp.*, No. 06-499, 2009 WL 153190, at *12-15 (N.D. Ill. Jan. 22, 2009); *U.S. v. Straub Clinic & Hosp., Inc.*, 140 F. Supp. 2d 1062, 1070 n.7 (D. Hawaii 2001).

that without this inference the government's case cannot survive summary judgment. *Id*. This argument is clearly meritless.

First, as demonstrated by the discussion *supra*, the government's case hardly rests entirely, or even predominantly, on inferences drawn from the circumstances surrounding the events. Equally important is the direct evidence of intent from sales representatives and doctors, the immense pressure Novartis imposed on the sales force to spend money on doctors through their event budgets, the incentives provided to the sales force to increase prescription writing, and the deliberate failure by Novartis to take any steps to ensure compliance with the AKS.

Second, there is nothing unreasonable in inferring intent from the context in which events were held. What NPC refers to as "markers" are merely the same indicia of fraudulent intent that this Court has already determined are probative of whether an AKS violation occurred. Specifically, this Court has previously held that the existence of kickbacks could be "evidenced by the fact that (1) NPC sales representatives repeatedly invited the same participants and 'speakers' to attend events concerning the same drug or topic in a short span of time; [and] (2) NPC spent exorbitant amounts of money on these events, both at the macro level and at the individual event level . . . ." *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 515 (S.D.N.Y. 2014); *see also id.* at 516 (citing allegations that doctors "repeatedly attended Novartis events on the same topic within a short period of time," "exchanged roles as attendees and speakers at these events," and attended "events at high-end restaurants that resulted in exorbitant bills" as sufficient to describe a kickback scheme).

Indeed, discovery has only borne out that the inference of intent that the government would ask the jury to draw from evidence of repeat attendance, far from being speculative or conjectural, is supported by a substantial factual record. Drs. McMahon and Schneller's expert

testimony confirmed what this Court understood as a matter of common sense, that doctors would not be expected to derive educational value from repeatedly attending events regarding the same well-known drugs in a condensed amount of time. *See* McMahon Rep., ¶¶ 15-16, 22-74; Schneller Rep., pgs. 2, 22-30. And the witness testimony similarly established that it was well understood by sales representatives that repeat attendance served no educational purpose for doctors. *See supra* SOF Part I.B.

Novartis ignores entirely the Court's holding on this issue, most likely because it is inconsistent with NPC's repeated and false exhortations that the government's allegations regarding repeat attendance, inappropriate venues, and exorbitant event spending constitute a "new theory" of the case. Br. 1, 3, 12. But there is no reason for the Court to depart from its prior decision. Indeed, it is the inference that Novartis would have the Court draw from this evidence—that NPC reasonably expected that doctors experienced in the treatment of hypertension, many of whom were high prescribers of the Novartis CV drugs, would derive educational value from repeatedly attending programs about medications that had been on the market for many years over the span of a few months—that is implausible and unreasonable.

Moreover, the Court's ruling is entirely consistent with the numerous cases that have held that fraudulent intent can be inferred from surrounding circumstances, including cases involving "badges of fraud." *See, e.g.*, *In re Sharp Int'l Corp.*, 403 F.3d 43, 56 (2d Cir. 2005). Indeed, Judge McMahon recently agreed that an inference can reasonably be drawn that speaker programs constituted kickbacks where the same doctors attended events repeatedly. *U.S. ex rel. Arnstein v. Teva Pharm. USA, Inc.*, 2016 WL 750720, at *16-17 (S.D.N.Y. Feb. 22, 2016).

Novartis attempts to distinguish this caselaw, arguing that "badges of fraud" is a specific term of art that is confined to the context of fraudulent transfer. Br. 25. But courts routinely

allow fraudulent intent to be inferred from the surrounding facts and circumstances because such intent is rarely susceptible to direct proof, and this principle is not limited to fraudulent transfer cases. *See, e.g.*, *U.S. v. Gaspard*, 744 F.2d 438 (5th Cir. 1984) (mail fraud); *U.S. v. Gilbertson*, 588 F.2d 584, 587 (8th Cir. 1978) (mail fraud); *Hitachi Med. Sys. Am., Inc. v. Horizon Med. Grp.*, No. 5:07CV02035, 2008 WL 11380232, at *8 (N.D. Ohio Oct. 29, 2008) (common law fraud claim); *U.S. ex rel. Longhi v. Lithium Power Tech. Inc.*, 513 F. Supp. 2d 866 (S.D. Tex. 2007) ("[I]n most instances involving fraud, the 'jury may infer intent to defraud from all the facts and circumstances surrounding the transaction in question.'" (quoting *U.S. v. Rabe*, 250 F.3d 743 (5th Cir. 2001) (per curiam) (bank fraud case))).

Novartis next argues that the event data is insufficient to establish whether a particular event is a kickback because the data does not establish what medical information was conveyed at the event and how much each attendee benefited from the program. Br. 18-19, 21. Yet the government does not need to demonstrate that an event was a sham as to each attendee. Nor does the government need to prove that a doctor did not learn anything at an event to establish that an event was a kickback as to that doctor. Rather, the government need only prove that one of the reasons that Novartis provided the remuneration to that doctor was to induce prescribing. *See, e.g.*, *U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) (compensation for services actually rendered could nonetheless constitute a kickback if one purpose of the payment was to induce patient referrals); *Bay State Ambulance*, 874 F.2d at 29-30 ("the issue of sole versus primary reason for payments is irrelevant since any amount of inducement is illegal"); *U.S. v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985) (finding that payment to physicians violated AKS if, in addition to compensating them for legitimate duties, it was also intended to induce referrals).

Whether a doctor incidentally derived some educational benefit from the program is therefore irrelevant to this inquiry.

Finally, Novartis contends that drawing an inference of unlawful intent from the circumstances of an event is unreasonable because there could also be legitimate business reasons for the events to be held, including the promotional value of such events. Br. 19. As an initial matter, the government's marketing expert, Dr. Roberta Clarke, will dispute that excessive repeat attendance at these types of events served a legitimate promotional purpose, thus creating a disputed issue of fact, which alone precludes summary judgment on this point. *See* Clarke Expert Report, Harwood Decl. GX 112, ¶¶ 9, 31-48. But this argument suffers from a more fundamental defect. A plaintiff in an AKS case need not "negat[e] plausible alternative motives" for the remunerative arrangement, as AKS liability can be found even where there is also a potential business purpose for the transaction. *U.S. v. Millennium Radiology, Inc*., No. 1:11CV825, 2014 WL 4908275, at *7 (S.D. Ohio Sept. 30, 2014). Here, there is more than sufficient evidence for a jury to conclude that one purpose of the events was to pay unlawful remuneration to doctors, particularly where HHS-OIG had identified promotional events as a high risk area for AKS liability and Novartis failed to implement even minimally sufficient compliance procedures to protect against AKS violations.[4]

Next, Novartis cobbles together language from various parts of the Supreme Court's decision in *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016), to suggest that that decision imposed a "fair notice" requirement with respect to compliance

[4] To the extent that NPC contends that competing inferences could be drawn from this evidence, such an argument is inappropriate on summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986) (on summary judgment, all reasonable inferences must be drawn against the moving party). The decision as to "which of competing inferences to draw are to be made by the jury after trial." *Rule v. Brine, Inc*., 85 F.3d 1002, 1014 (2d Cir. 1996).

obligations. Br. 22. The quoted language, however, does not come from the Court's holding, but from the Court's rejection of the petitioner's argument. *Id.* at 2000. Nothing in *Escobar*, which addresses the different ways in which the fact-specific materiality element of an FCA claim can be satisfied—an element that courts routinely recognize is easily satisfied in the kickback context[5]—suggests that the government must provide "notice" that specific behavior could constitute an FCA violation. Br. 22.

In any event, Novartis can hardly claim that it had lacked notice that the AKS prohibits providing remuneration to doctors in order to induce prescription writing. And there is no support for the proposition that the government must, through the promulgation of regulations, guidelines, or administrative opinions, specifically inform pharmaceutical companies of every possible activity that could constitute an unlawful kickback. "Because the structure of a proscribed exchange may vary, the statute, at its core, 'is aimed at the inducement factor.'" *Cooper v. Pottstown Hosp. Co., LLC*, No. CIV.A. 13-01137, 2015 WL 1137664, at *3 (E.D. Pa. Mar. 13, 2015), *aff'd sub nom. Cooper v. Pottstown Hosp. Co LLC*, 651 F. App'x 114 (3d Cir. 2016) (quoting *Greber*, 760 F.2d at 71). Thus, it is "the extent to which conduct is motivated by inducing," rather than the form or structure of the kickbacks, that will "determine liability under the statute." Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952-01 (1991).

Novartis's notice argument rings hollow here, where the evidence shows that it routinely plied the same high-prescribing doctors with honoraria and free meals, often at high-end

[5] *See, e.g.*, *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) ("[T]he Court has no trouble concluding that compliance with the AKS is a 'material' condition of payment."); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp. 3d 323, 330 (S.D.N.Y. 2014) (observing that "[c]ourts have long held" that "compliance with the AKS is a precondition to the payment of Medicare and Medicaid claims").

restaurants with excessive per-person costs, in the guise of educational events on the same drug that could not reasonably be expected to deliver educational value. Novartis's argument that the government was required to spell out to it in a formal notice that this conduct could result in an enforcement action is frivolous. Regardless, the evidence shows that NPC was aware of widespread excessive spend and repeat attendance, *see* CAF ¶¶ 357-68, 391, 404-11, 467-71, and the PhRMA Code, of which NPC was a signatory, makes clear that meals should be "occasional," "modest," and "occur in a venue and manner conducive to informational communication and provide scientific or educational value," Gruenstein Decl. Ex. 54 at 6752053.

Novartis also posits a particularly specious due process argument. Relying upon cases arising in the criminal context, Br. 26, Novartis claims that the government has violated its due process rights by "demanding an inference" or a "presumption" that certain events constitute kickbacks. Br. 25-26. But cases regarding the due process rights of criminal defendants have no applicability to this civil case. *See, e.g.*, *Lavine v. Milne*, 424 U.S. 577, 585 (1976); *U.S. v. One Parcel of Property Located at 194 Quaker Farms Road, Oxford, Conn.*, 85 F.3d 985, 990 (2d Cir. 1996). More fundamentally, the government has nowhere "demanded" that any factfinder be required to make a particular inference or presumption, nor has it requested that the burden of proof be shifted from the government to the defendant. The government is simply seeking to put forward evidence in support of its burden of proof.

The thrust of Novartis's argument appears to be that the strength of the government's proof would effectively shift the burden of proof to NPC, because NPC will be required to rebut the government's case by "present[ing] evidence about what actually happened at each of the speaker programs." Br. 26. Yet, as a legal matter, because the government maintains the burden

of proof in this case, Novartis is not required to make any evidentiary showing whatsoever. As a practical matter, Novartis is free to make its own strategic calculations as to whether and how to respond to the government's case. Novartis can attack the government's evidence and experts in any number of ways, including by trying to demonstrate flaws in the experts' opinions or by introducing testimony from their own fact or expert witnesses. If Novartis opts to call witnesses or present evidence about specific events, that is not a due process violation.[6]

C. NPC's Attack on the Government's Medical Education Expert Is Meritless

Although Novartis claims that it reserves its arguments regarding the admissibility of Dr. McMahon's testimony for its *Daubert* motion, it then proceeds to make a number of challenges to the weight to be given to his testimony. Br. 12-13. Novartis's criticisms of Dr. McMahon are irrelevant to this summary judgment motion and, in any event, wholly without merit.

Novartis first claims that it "can find no FCA case in which the Government or a relator sought to establish liability through a set of expert-created markers." Br. 13-14. This is unsurprising, since the term "markers" is a term made up by Novartis to distort the completely ordinary and unobjectionable nature of Dr. McMahon's testimony. The criteria that Dr. McMahon uses to identify activity that inherently lacks an educational purpose—*i.e.*, attending the same or similar event three times within six months, attending an event within six months of being the paid speaker for the same or similar event, and attending at least three events within 12

[6] Novartis's citation to *U.S. ex rel. Crews v. NCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 857 (7th Cir. 2006), only serves to underscore this point. In *Crews*, the Seventh Circuit rejected the relator's argument that she was not required to come forward with any evidence of a false claim, and that the defendant instead bore the burden of proving the legality of its actions. *Id.* Here, in stark contrast, the government is attempting to present evidence of fraud to the jury in support of its burden of proof, while Novartis is attempting to prevent the government from doing so. Nothing in *Crews* supports the perverse argument that introducing admissible and probative evidence in support of a party's burden of proof amounts to a due process violation.

months with a per-person meal spend of at least $125, McMahon Rep. ¶ 54—are common-sense metrics that, with or without Dr. McMahon's testimony, a jury could conclude are evidence of kickbacks. Indeed, they are refined versions of the same metrics that this Court has already accepted as indicia of kickbacks, as discussed above. And there is nothing objectionable about the government presenting this criteria through Dr. McMahon, a qualified expert on medical education, as part of its proof on liability and damages.

Novartis next erroneously claims that Dr. McMahon's opinions are based upon his assumption that "each and every program about a drug was identical to all previous programs" and that "every speaker program or roundtable for the same drug consisted of a rote recitation of a single slide presentation that never varied or that never included unique medical discussion." Br. 15. Yet Dr. McMahon's report makes clear that his opinions were not based upon an assumption that the information presented at each program was "identical," McMahon Rep. ¶ 59, or that there was no opportunity for unique or unstructured medical discussion, *id.* ¶¶ 52, 64. Novartis's mischaracterization of Dr. McMahon's opinions should be rejected.

The only assumption that Dr. McMahon made in rendering his opinion was to give Novartis the benefit of the doubt that the events at issue took place in accordance with Novartis's own written guidelines and included some level of medical discussion or slideshow presentation. McMahon Dep., Harwood Decl. GX 219, 31:19-32:6; *id.* 86:15-22; McMahon Rep. ¶¶ 52-54. Novartis astonishingly calls this assumption "unfounded." Br. 3; *see also* Br. 14-15. Although it is certainly strange that Novartis challenges Dr. McMahon for assuming that a presentation or other discussion of the drug in question actually took place at Novartis events, the government does agree with Novartis that the evidence certainly shows that in many instances, this assumption is unfounded because in fact little to no medical discussion occurred. But this hardly

helps Novartis. *See, e.g.*, *Ramos v. SimplexGrinnell LP*, 796 F. Supp. 2d 346, 369 (E.D.N.Y. 2011) (conservative assumption that inures to the benefit of the defendant is not grounds for striking the opinion of an expert witness), *vacated in part on other grounds*, 773 F.3d 394 (2d Cir. 2014); *see also Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (contention that "assumptions are unfounded 'go to the weight, not the admissibility, of the testimony,' unless the assumption is "'so unrealistic and contradictory as to suggest bad faith'" (citation omitted)).

Finally, Novartis contends that Dr. McMahon improperly used the standards applicable to Continuing Medical Education ("CME") programs in evaluating the educational nature of its speaker programs and roundtables. Br. 16. Again, that is not the case. Dr. McMahon, who is an expert in the field of adult education generally, and medical education specifically, has made clear that, in rendering his opinion, he was applying general "principles of adult learning, which are broadly applicable" outside the CME context. McMahon Rep. ¶ 5; McMahon Dep. 21:3-18; *id.* 25:16-26:7.

II. THE 2010 SETTLEMENT RELEASED NPC FROM LIABILITY FOR CLAIMS RELATED TO DIOVAN, EXFORGE AND TEKTURNA, NOT EVENTS RELATING TO THOSE DRUGS

In an effort to limit its liability, NPC seeks to recast the 2010 settlement as broadly "releasing [it] from [liability for] any claims *related to its DET [Diovan, Exforge and Tekturna] events* from January 1, 2002 through December 31, 2009" (the "Settlement Period"). Br. 28 (emphasis added). But as shown below, the 2010 settlement released NPC from liability for causing the submission of false claims for kickback-tainted prescriptions of DET, not from all liability relating in any way to any DET event.

The 2010 settlement arose from *qui tam* complaints alleging, in relevant part, that NPC "illegally induced physicians to write prescriptions" for DET "through a panoply of kickback schemes," including speaker programs and roundtables. *See, e.g.*, First Am. False Claims Act Compl. at ¶¶ 5, 31-35, *U.S. et al. ex rel. Garrity v. Novartis Pharm. Corp.*, No. 08-2588 (E.D. Pa. Aug. 13, 2010), Dkt. No. 17. As with any FCA case against a drug manufacturer predicated on violations of the AKS, the theory was that NPC's kickback activity rendered it liable for causing false claims to be submitted to various federal health care programs, including Medicare, Medicaid and Tricare, in connection with reimbursement requests for *the specific drugs identified in the complaints*, *i.e.*, DET and three other drugs not at issue in this case (the "Settlement Drugs"). *See id.* at ¶ 3.

Accordingly, in settling those claims, the government provided a release to NPC for engaging in kickback schemes that caused false claims for reimbursement for the Settlement Drugs to be submitted to federal health care programs. The release did not extend to drugs beyond the Settlement Drugs. Nor did it extend to the conduct underlying the kickback schemes—to the extent that such conduct also tainted claims for reimbursement for drugs beyond the Settlement Drugs or was unrelated to a specific claim. Rather, it is clear that the 2010 settlement provides a release for liability only insofar as liability is related to specific, identified claims. FCA liability is predicated on the existence of a false claim for payment, and therefore all FCA resolutions, whether through a court-ordered judgment or a negotiated settlement, are tied to false claims.

The agreement starts out by defining the Settlement Drugs as being limited to Diovan, Exforge, and Tekturna (as well as three other drugs not at issue here). CAF ¶ 498. It then highlights the significance of the submission of claims for payment for the Settlement Drugs to

the conduct that the parties were settling, stating that "[t]he United States and the Medicaid Participating States contend that NPC caused to be submitted claims for payment for the [Settlement] Drugs to the Medicaid Program[,] . . . the Medicare [P]rogram[,] . . . the TRICARE Program," and other federal health care programs. *Id.* ¶ 499. The agreement then defines the "Covered Conduct" by modifying the reference to NPC's payment of kickbacks "to induce . . . prescri[ptions]" of the Settlement Drugs with the "submi[ssion]" of corresponding "false or fraudulent claims" to federal health care programs. *Id.* ¶ 500. The agreement states:

> During the period January 1, 2002 to December 31, 2009, NPC provided illegal remuneration, through mechanisms such as speaker programs, advisory boards, and gifts, (including entertainment, travel and meals), to health care professionals *to induce them to promote and prescribe the drugs Diovan*, Zelnorm, Sandostatin, *Exforge, and Tekturna*, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). *As a result of the foregoing conduct, NPC caused false or fraudulent claims to be submitted to or caused purchases by Medicaid, Medicare and the other Federal Health Care Programs.*"

Id. (emphasis added). The agreement goes on to provide a release to NPC for any "monetary claim that the United States has or may have for the Covered Conduct." *Id.* at ¶ 501. This language unambiguously provides that the 2010 settlement released claims for the Settlement Drugs (DET, among others) that were tainted by kickbacks.

Prior to submitting its pending motion, NPC had argued that the 2010 settlement released claims for payment not just for DET, but also the HCT variants of those drugs. *See, e.g.*, Ltr. From E. Chesler at 4, Dkt. 214. NPC has now dropped that argument.[7] However, in an effort to narrow the government's damages case, NPC has replaced that flawed argument with another, equally flawed argument. The government's damages expert has shown that the kickbacks that NPC provided to doctors though promotional events for the drugs at issue in this case (including

[7] There is no basis to make such an argument. Among other things, to market and sell the HCT variants of DET, NPC had to submit new New Drug Applications ("NDAs") to the FDA and obtain separate approvals from the FDA. *See* CAF ¶¶ 503-04.

DET) caused doctors to write more prescriptions not only for the drug that was the subject of a given event, but for other drugs as well. CAF ¶ 376. Based on this evidence and seeking to avoid liability for its unlawful actions, NPC now argues that the 2010 settlement released NPC from claims *related to drugs beyond DET and the other Settlement Drugs*. Br. 28.

NPC's new argument is contrary to the language of the 2010 settlement agreement and would lead to absurd results. As an initial matter, by its terms, the 2010 agreement (1) relates only to DET and the other, specifically-identified Settlement Drugs; (2) concerns the submission of corresponding claims for payment; and (3) defines the "Covered Conduct" in two sentences that, together, address claims for the Settlement Drugs that were tainted by kickback activities involving those drugs. In arguing that the 2010 settlement released liability for events related to DET as opposed to claims for DET, NPC misleadingly quotes only the first sentence of the agreement's definition of "Covered Conduct," while omitting the next sentence, which makes the link to claims submitted for DET explicit. The settlement was clearly intended to release NPC from liability for false claims for DET that were tainted by NPC's kickback activities involving those drugs, not from any liability arising from any event involving DET.

Under NPC's argument, the government released kickback-tainted claims submitted to federal health care programs for Lotrel, Starlix, Valturna and Tekamlo, even though the 2010 settlement nowhere mentions those drugs, and those drugs were not at issue in the underlying lawsuit. Br. 28. It is contrary to experience and common sense to read a settlement of conduct relating to six specific drugs as releasing liability for claims for other drugs. That was not the intent of the parties as reflected in the language of the settlement agreement. Indeed, if the settlement had been intended to release NPC from liability for events involving the Settlement Drugs (as opposed to kickback-tainted claims for those drugs), there would have been no need

for the second sentence of the "Covered Conduct" definition. That language should not be treated as surplusage. *See, e.g.*, *Shelby County State Bank v. Van Diest Supply Co.*, 303 F.3d 832, 837 (7th Cir. 2002).

Moreover, by its terms, the "Covered Conduct" does not include all DET events, but only those DET events through which "NPC provided illegal remuneration . . . to health care professionals to induce them to promote and prescribe" the Settlement Drugs. CAF ¶ 500. This language does not include DET events for which there was no unlawful intent to induce prescribing of the Settlement Drugs, or events that were intended to induce prescribing of non-Settlement Drugs. Thus, for example, if NPC held a combined Lotrel/Diovan event with the intent of inducing prescription-writing for Lotrel, such an event would not fall within the definition of Covered Conduct. The fact that the 2010 settlement cannot be read to include a release of claims related to *all* DET events, as NPC suggests, Br. 28, further illustrates the illogic of NPC's position. The parties could not have intended that the scope of the release would be subject to a fact-specific inquiry regarding NPC's intent with respect to each event. That the parties did not specify which events were supposedly released further demonstrates that the government's reading of the agreement as releasing liability for claims for the Settlement Drugs is the only plausible construction.

Finally, adopting NPC's reading of the settlement agreement would mean that, in this case, the government could recover as damages the claims it paid for prescriptions of DET to the extent that such prescriptions were induced by kickback-tainted events involving one of the other drugs at issue in this case (*e.g.*, Lotrel). It is implausible that, in settling a kickback case alleging that NPC caused the submission of false claims for DET, NPC would leave itself open to liability

for future kickback claims involving those same drugs. Yet that would be the consequence of the interpretation of the 2010 settlement that NPC is now proposing.[8]

III. THE GOVERNMENT CAN ESTABLISH BOTH LIABILITY AND COMPENSATORY DAMAGES

To establish liability, the government need only show that (1) NPC paid kickbacks to doctors to induce them to prescribe the drugs at issue, (2) the doctors thereafter prescribed those drugs, and (3) claims for payment for those prescriptions were submitted to a federal health care program. *See U.S. ex rel. Greenfield v. Medco Health Solutions, Inc.*, 880 F.3d 89, 96 (3d Cir. 2018) (government need only show a link between the individual or entity receiving kickback and the submission of a claim for reimbursement to a federal health care program); *U.S. ex rel. Bawduniak v. Biogen Indec, Inc.*, 12-10601, 2018 WL 1996829, at *3, *6 (D. Mass. April 27, 2018) (finding sufficient allegations that "Defendant paid kickbacks to [specific] physicians . . . to induce those physicians to prescribe particular medications, and that the physicians then prescribed those medications, causing claims to be submitted to Medicare and Medicaid"). Here, the government can make each of the above showings, *see supra* SOF Parts I-IV; McFadden Reps., Harwood Decl. GX 108-101; CAF ¶¶ 369-82, thus establishing liability on the part of NPC. Novartis's arguments as to why the government cannot establish liability or compensatory damages lack merit for the reasons set forth below.

A. To Establish Liability, the Government Need Not Show that Any Doctor Entered Into a *Quid Pro Quo* Arrangement with NPC or Increased His or Her Prescription Writing in Response to NPC's Kickbacks

[8] Because the government has always viewed the 2010 settlement as releasing NPC from liability for claims for DET, the government's damages expert did not calculate NPC's liability for claims for DET that were induced by kickback-tainted events for drugs other than DET. If this Court were to hold that the 2010 settlement released NPC from liability for events involving DET (as opposed to claims for DET), the government would seek leave to serve a supplemental expert report on damages so it could revise its damages methodology accordingly.

The FCA imposes liability when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B).[9] The government contends that NPC is liable under the FCA for causing claims to be submitted that were "false" because they were tainted by the kickbacks it paid to doctors, in violation of the AKS.

The AKS ensures that doctors' decision-making is based solely on the medical needs of their patients, and is not potentially affected by financial considerations. *U.S. v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). By making the payment or receipt of kickbacks a felony, *see* 42 U.S.C. § 1320a-7b(b), the AKS ensures that the government pays only for conflict-free medical care provided in the best interests of patients. A kickback eliminates that assurance because it taints the kickback-recipient's medical decisions with financial interest. As a result, "'[t]he Government does not get what it bargained for'" when it pays for items or services "'tainted by a kickback,'" *Greenfield*, 880 F.3d at 97 (quoting *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011)), as "[k]ickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole," *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53-54 (D. Mass. 2011).

Accordingly, courts have uniformly concluded that claims for medical care that are tainted by a violation of the AKS are "false" under the FCA, and that the kickback provider

[9] This version of the FCA took effect on May 20, 2009. *See* Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621. Although previous versions of the FCA phrased these provisions differently, *see* 31 U.S.C. §§ 3729(a)(1), (2) (2006), the differences are not material to this case.

(here, Novartis) is liable for any such claims submitted for reimbursement to the government. *See, e.g.*, *Wilkins*, 659 F.3d at 313; *Hutcheson*, 647 F.3d at 392-93; *U.S. ex rel. McNutt v. Haleyville Med. Supplies*, 423 F.3d 1256, 1259-60 (11th Cir. 2005); *U.S. ex rel. Schmidt v. Trimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *see also Westmoreland*, 812 F. Supp. 2d at 54-55 (collecting cases). The claims are false because compliance with the AKS is a fundamental condition of payment; the government does not get what it bargained for when a doctor's independence is potentially compromised by a kickback. *See id.* 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 even 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"); *Bawduniak*, 2018 WL 1996829, at *3, *6 (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").[10]

Therefore, to establish liability for its FCA claims here, the Government need not show (as NPC asserts, *see* Br. 35-37 & n.68) that the doctors who received kickbacks from NPC entered into a *quid pro quo* arrangement with NPC to write prescriptions for the drugs at issue, or

[10] *See also U.S. ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13-3702, 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) ("[t]he AKS does not require a kickback scheme to succeed in generating new business (*i.e.*, new patient prescriptions) in order for a violation to have occurred." (quotation marks omitted)); *Kester*, 23 F. Supp. 3d at 263 (same). The only case NPC cites to support its contrary position, *U.S. ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d at 318, is distinguishable. In that case, unlike here, the plaintiffs failed to present evidence that the defendant drug company provided kickbacks to doctors through its "marketing programs" such that the doctors' subsequent prescribing decisions could be viewed as tainted. *See id.* at 331-32.

that those doctors changed their prescription-writing habits after receiving kickbacks. Instead, as set forth above, the Government need only show that NPC paid kickbacks to doctors, and those doctors thereafter wrote prescriptions for NPC drugs that were paid for by federal health care programs. *See Greenfield*, 880 F.3d at 96; *Bawduniak*, 2018 WL 1996829, at *3, *6.

NPC's arguments to the contrary lack merit. Citing the Patient Protection and Affordable Care Act's ("PPACA") 2010 amendment to the AKS[11] — and in particular its "resulting from" language — NPC argues that "there must be evidence of an actual *quid pro quo* exchange" for "an AKS violation to give rise to a false claim." Br. 36-37. In effect, NPC argues that, through the 2010 amendment, Congress substantially narrowed the universe of claims that could be subject to FCA liability (*i.e.*, to those associated with a *quid pro quo* exchange). Courts have uniformly rejected this argument, finding that "[t]he legislative history . . . leads to the opposite conclusion." *Bawduniak*, 2018 WL 1996829, at*5; *see Greenfield*, 880 F.3d at 96-97; *Kester*, 41 F. Supp. 3d at 332. If NPC's argument were accepted, it would produce the untenable result that a defendant could be convicted of criminal conduct under the AKS for paying kickbacks to doctors to induce prescriptions, but would be insulated from civil FCA liability for the exact same conduct, absent additional proof of a *quid pro quo* exchange.

NPC further argues that absent evidence "that a doctor knowingly and willfully entered into a *quid pro quo* arrangement with NPC, the government cannot prove that doctors violated the AKS and that the certifications in which the doctors claimed compliance with the AKS were 'false.'" Br. 35-36. This argument is meritless. The government has sued Novartis, not

[11] The AKS was amended to provide that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). "[T]he amendment 'clarif[ied], [but did] not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the [FCA].'" *Greenfield*, 880 F.3d at 95 (quoting *Amgen*, 812 F.Supp.2d at 52); *see Wilkins*, 659 F.3d at 312 n.19.

individual doctors; to establish liability on the part of NPC, the government need not show that any particular doctor violated the AKS. Notably, NPC focuses exclusively on subsection (b)(1) of the AKS, which addresses those (like the doctors here) who "solicit[] or receive[]" kickbacks, 42 U.S.C. § 1320-7b(b)(1), while ignoring subsection (b)(2), which addresses those (like NPC here) who "offer[] or pay[]" kickbacks, *id.* §1320-7b(b)(2). But NPC's payment of such kickbacks itself constituted a violation of the AKS under subsection (b)(2), regardless of whether the doctors' acceptance of the kickbacks constituted a separate violation the AKS under subsection (b)(1).[12] Moreover, the government is not required to prove that NPC entered into an explicit *quid pro quo* agreement with any doctor in order to prevail. *See, e.g.*, *Hanlester Network v. Shalala*, 51 F.3d 1390, 1397 (9th Cir. 1995) ("reject[ing] the proposition that proof of an agreement is necessary under [subsection (b)(1) or (b)(2) of the AKS]"); *U.S. ex rel. Pasqua v. Kan-Di-Ki LLC*, No. 10–965, 2012 WL 12895229, at *4 (C.D. Cal. June 18, 2012) ("Proof of an agreement to refer business is not necessary to establish an AKS violation.").[13]

Additionally, the government does not need to present evidence of a doctor's false certification of compliance with the AKS in order to establish liability on the part of NPC, as NPC seems to suggest. The Second Circuit has explicitly recognized that "a false claim *may take many forms, the most common being* a claim for goods or services not provided, or provided

[12] Although unnecessary, there is evidence here from which a reasonable jury could conclude that doctors knowingly and willfully solicited or received kickbacks from Novartis, including by repeatedly accepting honoraria and meals for plainly sham events, *e.g.*, CAF ¶¶ 125-43, 226, 229-30, 234, 239-40, 257-59, and telling sales representatives that they would write more scripts in exchange for invites to events, CAF ¶¶ 298-309.

[13] The authorities NPC cites, *U.S. v. Krikheli*, 461 Fed. Appx. 7, 11 (2d Cir. 2012); Substantive Jury Instructions at 5, *United States v. Reichel*, No. 15-10324 (D. Mass. June 17, 2016), ECF No. 244, are consistent with this position. They stand for the proposition that for one party to provide remuneration to another party in violation of the AKS, the party providing the remuneration must *intend* for it to induce a *quid pro quo* response by the other party. *See id.* The cases do not, however, require that there actually be a *quid pro quo* agreement. *See id.*

in violation of contract terms, specification, statute or regulation." *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001), *overruled on other grounds by Escobar*, 136 S. Ct. at 1989 (emphasis added) (quoting S. Rep. No. 99-345, at 9 (1986)); *see U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385-86 (1st Cir. 2011). While the latter of those two forms may implicate a false certification, nothing in the FCA requires a certification to establish falsity. *See Hutcheson*, 647 F.3d at 385. Indeed, a claim may also be "false" where it contains no certifications at all, if it is the product of unlawful conduct, such as the payment of a kickback. *See U.S. ex rel. Lutz v. Blue Eagle Farming, LLC*, 853 F.3d 131, 135 (4th Cir. 2017).[14]

The claims in this case were false under three separate theories. The claims were "*per se* false" because they were the product of "[a]n AKS violation that result[ed] in a federal health care payment." *Id.* The claims were also "factually false," because, as discussed above, the government did not receive what it paid for: conflict-free medical care. *See Greenfield*, 880 F.3d at 97. And the claims were "legally false" under an implied false certification theory, because "the act of submitting a claim for reimbursement itself implie[d] compliance" with a statute, regulation or contractual term. *Mikes*, 274 F.3d at 699. In the healthcare context, a claim for payment implies compliance with the AKS, *see generally Westmoreland*, 812 F. Supp. 2d at 53, thus rendering a claim for payment tainted by an AKS violation impliedly false, regardless of whether there is an underlying false certification. None of these theories requires the government to present evidence of a false certification.

[14] *Cf. U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 542 (1943) (collusive bid-rigging renders claims false under FCA); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 787-88 (4th Cir. 1999) (fraudulent inducement to enter contract renders subsequent claims false); *U.S. v. McLeod*, 721 F.2d 282, 284 (9th Cir. 1983) (defendant liable under the FCA where he cashed erroneously issued check); *Murray & Sorenson v. U.S.*, 207 F.2d 119, 123-24 (1st Cir. 1953) (inflating bid based upon insider tip deemed fraudulent).

Nevertheless, even if the government were required to make such a showing, it could do so. As a condition of participating in the Medicare, Medicaid and Tricare programs, doctors, pharmacies, and other participants in the programs—such Medicare Part D plan sponsors—must sign certifications in which they certify compliance with relevant federal and state laws, including the AKS. *See* CAF ¶¶ 489-96; *Wood*, 246 F. Supp. 3d at 817. NPC's payment of kickbacks to doctors rendered false the doctors' own individual certifications of compliance with the AKS, as well as the corresponding certifications of other participants in the federal health care programs, such as the pharmacies that filled the doctors' prescriptions and the Part D plan sponsors. *See, e.g.*, *Wood*, 246 F. Supp. 3d at 818-19; *Arnstein*, 2016 WL 750720, at *24.

Finally, citing certain statements that this Court made in its opinion and order denying NPC's motion to dismiss, NPC argues that its violation of the AKS by "offering [or paying] a kickback to a doctor" cannot "alone . . . result in the submission of a false claim." Br. 37-38. As the caselaw makes abundantly clear, however, offering a kickback to a doctor who then writes a prescription that is reimbursed by a federal health care program is sufficient to establish FCA liability. To the extent that dicta in this Court's prior decision could be read to suggest otherwise, the Government respectfully submits that such a reading would be incorrect and contrary to the weight of authority.

B. The Government Is Entitled to Damages Measured By the Amount It Paid for Prescriptions Tainted by Novartis's Kickbacks

In FCA cases where "the government has paid for goods or services that return a tangible benefit to the government," compensatory "damages are measured . . . using a 'benefit-of-the-bargain' calculation in which a determination is made of the difference between the value that the government received and the amount that it paid." *U.S. ex rel. Feldman v. van Gorp*, 697 F.3d 78, 87 (2d Cir. 2012). However, in FCA cases like this one, where the government (1)

makes payments for the benefit of third parties and receives nothing of tangible value in return, (2) attaches conditions to the payments it makes, and (3) the conditions are not met, compensatory damages consist of the full amount that the government paid out.[15] *Id.* at 88-90; *see also U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386-87 (4th Cir. 2015) ("Compliance with the Stark Law is a condition precedent to reimbursement of claims submitted to Medicare. When [defendant] failed to satisfy that condition, the government owed it nothing."); *Longhi*, 575 F.3d at 473 (holding that in a case "[w]here there [was] no tangible benefit to the government" and the government's "intangible benefit of providing an 'eligible deserving' business with grants was lost as a result of the Defendants' fraud," "it is appropriate to value damages in the amount the government actually paid to the Defendants"); *U.S. ex rel. Antidiscrimination Ctr. of Metro N.Y., Inc. v. Westchester County*, No. 06-2860, 2009 WL 1108517, at *3 (S.D.N.Y. Apr. 24, 2009) (because the defendant (1) received a federal grant with certain express conditions and (2) failed to comply with one of those conditions, the government did not get what it bargained for and damages were the full amount of the grant).

In *U.S. v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008), the Seventh Circuit directly addressed the proper measure of damages in a case like this where claims for medical services are tainted by kickbacks. The defendant in *Rogan* was "a principal manager and financial beneficiary" of Edgewater Medical Center, and participated in a kickback scheme pursuant to which Edgewater billed the government for services tainted by kickbacks. 517 F.3d at 451-52. In determining the proper measure of damages, the court stated:

> [It is not] important that most of the patients for which claims were submitted received some medical care — perhaps all the care reflected in the claim forms. . . . Edgewater did not furnish any medical service to the United States. *The government offers a subsidy*

[15] Under the FCA, the government is also entitled to recover penalties in addition to compensatory damages. *See* 31 U.S.C. § 3729(a)(1). NPC's motion does not address penalties.

> *(from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that Edgewater received on [the kickback-tainted claims] must be paid back.*

Id. at 453 (emphasis added). Other courts have followed *Rogan*'s approach in the kickback context. *See, e.g.*, *U.S. ex rel. Freedman v. Suarez-Hojos*, No. 04-933, 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."); *U.S. ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, No. 12-00848, 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").

Here, as in *Rogan* and the other cases cited above, the government did not receive a tangible benefit from the claims it paid in connection with the kickback-tainted prescriptions at issue. Rather, the benefit to the government was the assurance that the conditions it attached to its payments would be met, including that the doctors who wrote the prescriptions were conflict-free and making prescribing decisions based solely on medical needs and not financial considerations. NPC's payment of kickbacks negated this assurance and, consequently, the government was harmed because it "d[id] not get what it bargained for." *Greenfield*, 880 F.3d at 97; *Wilkins*, 659 F.3d at 314.

Accordingly, in this case, the government is entitled to recover the full amount that it paid for the prescriptions that were tainted by NPC's kickbacks (*i.e.*, those prescriptions that the doctors who received kickbacks wrote while they were tainted by the kickbacks). The government's expert calculated this amount by summing the amounts the government paid in reimbursements for the Novartis drugs at issue prescribed by doctors while they were tainted by

kickbacks, as well as refills of any such prescriptions. *See* CAF ¶¶ 369-82. To determine that taint period, Professor McFadden built a sophisticated model to determine how long after receipt of a kickback the average doctor wrote additional Novartis scripts as a result. *See id.* This was a conservative method of defining the period during which the Government did not receive the benefit of its bargain (conflict-free prescribing decisions), since it is the length of time the average doctor was under the influence of those kickbacks.

NPC failed to address *Rogan* and the other cases cited above, and instead focused its attention on the argument that proximate cause is the appropriate causation standard. Br. 30-32. Yet applying a proximate cause standard is entirely consistent with the approach for calculating damages applied by *Rogan*, *Feldman*, and the above cases. Under the proximate cause standard, the government must show that the damages it is seeking "arise because of the falsity of the claim," *i.e.*, [that the damages] . . . would not have come about if the [relevant] misrepresentations had been true." *U.S. ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995); *see U.S. v. Luce*, 873 F.3d 999, 1010 n.33 (7th Cir. 2017) ("a causal connection must be shown between loss and fraudulent conduct"); *U.S. v. Hibbs*, 568 F.2d 347, 351 (3d Cir. 1977) (requiring that there be a "relationship between the unlawful act and the injury ultimately sustained"). As discussed above, in a kickback case like this one, the government is damaged because it did not get what it bargained for: a taint-free determination by a medical provider that the prescribed drug was appropriate for the patient. Absent the kickback, the government would have received exactly what it bargained for. Thus, it is not the case (as NPC wrongly asserts) that "precisely the same loss would have been suffered by the Government had the certifications been accurate and truthful," Br. 32 (citation omitted); the opposite is true. Moreover, the damages the government is seeking — the amount it paid for prescriptions that

were tainted by NPC's kickbacks — arose because NPC caused the submission of false claims. Therefore, proximate cause is established, as there is a direct "relationship between the unlawful act[s, *i.e.*, NPC's payment of kickbacks to doctors,] and the injury ultimately sustained [*i.e.*, the loss of the assurance that the doctors' prescribing decisions were unaffected by kickbacks]." *Hibbs*, 568 F.2d at 351.

NPC asserts that by seeking to recover its costs associated with all kickback-tainted prescriptions, without regard to whether the same prescriptions would have been written absent the kickbacks, "the Government . . . go[es] far beyond simply remedying damages caused by [NPC's] FCA violation." Br. 33. But whether or not the kickbacks actually affected the doctors' prescribing behavior is irrelevant to government's harm. Either way, the government did not get the assurance that it bargained for and damages are therefore the full amount that it paid for the kickback-tainted scripts. *See RehabCare*, 2013 WL 5340910, at *1 ("[T]he proper measure of damages is the full amount of each tainted claim, rather than the amount the United States would have paid had Defendants not engaged in kickbacks."); *see also Rogan*, 517 F.3d at 453; *U.S. ex rel. Lutz v. BlueWave Healthcare Consultants*, No. 14-230, slip op. at 2-3.

C. Novartis's Kickbacks Induced Doctors to Write More Novartis Scripts

Although unnecessary to do so, the Government can show that NPC's kickbacks did in fact influence the recipients' prescribing decisions. The Government has extensive evidence that Novartis spent millions on these programs each year because they worked. *See supra* SOF Part IV. This evidence includes not only witness testimony, but Novartis's own return on investment analysis. *Id.* And Professor McFadden has proved causation conclusively, demonstrating that attending sham events caused the more than 75,000 doctors who received illegal inducements from Novartis, considered in the aggregate, to increase their prescribing of Novartis drugs in the

following months. CAF ¶¶ 369-74; *see also id.* ¶¶ 377-79.[16] In sum, there is overwhelming evidence that Novartis conducted sham events because they caused doctors to write more Novartis prescriptions.

IV. NOVARTIS CANNOT AVOID LIABILITY FOR ILLEGAL INDUCEMENTS PROVIDED THROUGH IN-OFFICE ROUNDTABLES

As the government alleged, and will prove at trial, Novartis used speaker programs and roundtables, in-office as well as out-of-office, as means to deliver meals and honoraria to doctors to attempt to induce them to write Novartis prescriptions. It is undisputed that roundtables are, together with speaker programs, at the core of this case. In a baseless attempt to knock out tens of thousands of roundtables simply because they occurred in a doctor's office, Novartis falsely asserts that, until expert discovery, "the Government's case did not implicate in-office meetings." Br. 39. As discussed below, however, the Amended Complaint includes allegations about nearly two dozen in-office meetings. And lunch and learns were the subject of extensive fact discovery. The government has gathered overwhelming evidence of the sham nature of many of Novartis's roundtables, which include in-office roundtables, and Novartis's unfounded claims of surprise and "prejudice," Br. 44, should be rejected.

A. In-Office Programs Have Always Been Part of the Government's Case

[16] Novartis misunderstands Professor McFadden's testimony when it asserts that his aggregate model "merely showed which doctors were 'at risk' of prescribing more as a result of the alleged kickbacks." Br. 33. The aggregate model leveraged the prescribing data for the tens of thousands of doctors who received kickbacks to confirm that Novartis's scheme did, in fact, cause doctors to increase their Novartis prescribing and, further, to determine how long the average doctor was influenced after receipt. As explained above, the government is entitled to damages for its reimbursements for Novartis scripts written during this empirically determined taint period. Professor McFadden referred to individual tainted doctors as "at risk" of bias during this period, *see, e.g.*, Gruenstein Decl. Ex. 75 (McFadden Dep.) 126:8-19, during which the average tainted doctor was writing more Novartis scripts than he or she otherwise would have as a result of the kickback.

Novartis's premise—that the Government's allegations and discovery concerned out-of-office, but not in-office, programs—is simply false. Novartis begins its argument by incorrectly asserting, "From the beginning, this case has been about out-of-office promotional programs." Br. 39. In fact, the Amended Complaint expressly identified *twenty-one* kickback events as in-office programs. (ECF No. 62 ¶¶ 129, 131, 139, 142, 143.)

Accordingly, the parties engaged in discovery specifically with respect to the in-office lunchtime roundtables that Novartis now seeks to exclude, which were labeled "roundtables" pre-2006 and "lunch and learns" thereafter. In each of its three sets of discovery requests, as well as its Rule 30(b)(6) notice, the government defined promotional activity to include all roundtables concerning a Covered Drug, without regard to venue. CAF ¶ 475. In response, Novartis produced responsive information regarding in-office lunchtime roundtables, including lunch and learns. After extensive negotiations, the parties agreed that NPC's searches for responsive ESI would include search terms that combined "lunch" and "roundtable." *Id.* ¶ 476.

Perhaps most telling is the fact that the government sought, and Novartis agreed to produce, event-specific data for lunch and learns. *Id.* ¶ 477. Novartis used event categories to generate the set of event data to produce. *Id.* ¶ 478. In-office lunchtime roundtables were categorized as "REF-Roundtable" from 2002 until 2006, when they were given their own subcategory, "REF-Lunch-n-Learn." *Id.* ¶ 479. The government requested, and Novartis produced, all event data for both the "REF-Roundtable" and the "REF-Lunch-n-Learn" categories. *Id.* ¶ 480.

And the government pursued lunch and learns in its third-party discovery, as well. NPC cites to a few depositions in which counsel focused on out-of-office events as evidence that the government "explicitly carved out lunch-n-learns during fact discovery." Br. 42. NPC ignores

other depositions at which the government expressly questioned witnesses, some at great length, regarding lunch and learns. *Id.* ¶ 481. NPC likewise makes no mention of the fact that the government produced a number of declarations from former sales representatives, former sales managers or directors, and doctors, who specifically described the sham nature of roundtables generally, and in-office roundtables specifically. *Id.* ¶ 483. And, despite Novartis's suggestion to the contrary, Br. 44, Novartis's counsel similarly included lunch and learns in their questioning of at least a dozen deponents, *id.* ¶ 482.

Given this background, it is difficult to see how Novartis can claim to be surprised by the fact that these in-office roundtables are part of the government's case, let alone assert that lunch and learns somehow amount to "a new theory of liability" that would result in "[e]xtreme [p]rejudice" to Novartis. Br. 44. The government's theory of liability is the same for all promotional events, including roundtables: that Novartis used its speaker programs and roundtables, whether in-office or out-of-office, as opportunities to provide doctors with remuneration and other benefits, like free meals, in an attempt to induce them to prescribe more Novartis drugs. Because the government is not seeking to add new claims or theories of liability, the cases cited by NPC, Br. 45, are inapposite. *See, e.g.*, *U.S. v. Quicken Loans, Inc.*, 16 Civ. 14050, 2018 WL 1870605, at *2 & Dkt. No. 75 at 10 (E.D. Mich. Apr. 19, 2018) (limiting government's case to the four types of fraudulent practices alleged in the complaint).[17]

B. The Government Has Overwhelming Evidence of Sham Roundtables, Including Lunch and Learns

[17] *See also Family Dollar Stores, Inc. v. United Fabrics Int'l, Inc.*, 896 F. Supp. 2d 223 (S.D.N.Y. 2012) (barring defendant from adding counterclaim as to a new copyright registration after the close of discovery); *Oracle USA, Inc. v. SAP AG*, 264 F.R.D. 541 (N.D. Cal. 2009) (precluding plaintiffs from introducing evidence regarding new theory of damages where it repeatedly and explicitly disclaimed reliance upon that theory during discovery); *Aldridge v. Forest River Inc.*, 635 F.3d 870 (7th Cir. 2011) (denying motion to amend complaint during trial in products liability suit where plaintiff sought to allege a different defect).

As described above, *see supra* SOF Part I, the Government has overwhelming proof that the roundtables at issue in this case were shams. All of the evidence regarding roundtables generally applies equally to lunch and learns, as they are indistinguishable from any other species of roundtables except for the venue in which they were held. CAF ¶¶ 484-88. This evidence includes admissions by sales representatives that they put on roundtables, including lunch and learns, to deliver meals to doctors as an inducement. *Id.* ¶ 125. It also includes extensive documentary and testimonial evidence from Novartis's sales force and sales executives concerning unrealistic event quotas—quotas that included lunch and learns—that all but required sham programs. *See id.* ¶¶ 390-92. In particular, sales representatives in many of the declarations and depositions cited above specifically admit to putting on sham lunch and learns at which they imparted no medically relevant information to the attending doctors. *Id.* ¶¶ 125.

For purposes of this motion, Novartis takes the position that lunch and learns are not roundtables, but rather sales calls with catering. Br. 41 ("[T]here is no distinction in content between the promotional message at an in-office lunch meeting and a regular call by a sales representative."). This is contrary to many of Novartis's internal documents; indeed, Novartis's counsel presented one such document to a sales representative deponent in an attempt to "refresh [her] recollection that lunch and learns were a type of roundtable." Gruenstein Decl. Ex. 44 at 3719890 (after reading from a Novartis document stating "Roundtables may include: Lunch and Learn"). And it is contrary to the testimony of Novartis's own sales representatives, many of whom testified that in-office roundtables were the same in content as any other roundtable. CAF ¶¶ 485, 487-88.

This position also contradicts the statements of Novartis's experts in this matter, who admitted in their reports that lunch and learns were roundtables or differed from them only in

venue. *Id.* ¶ 484. In an abundance of caution, the Government initially directed its data expert and summary witness Dr. Goldberg not to include lunch and learn events when applying Dr. McMahon's criteria, due to uncertainty about the format and content of lunch and learns. However, after Novartis's own experts acknowledged that lunch and learns, as a category, were simply in-office lunchtime roundtables, the Government responded by directing Dr. Goldberg to include lunch and learns with all other roundtables for purposes of his and Dr. McFadden's rebuttal reports.

In the end, despite Novartis's recent assertion to the contrary, there is no meaningful distinction between lunch and learns and other types of roundtables. Indeed, many of the sales representatives deposed in this case could not distinguish between speaker programs, roundtables, and lunch and learns, disagreed about the distinctions, or asserted that the distinctions were not meaningful. *Id.* ¶¶ 485-88. As one representative put it, the "technicalities of, well, was it a roundtable, was it a speaker program, was it a lunch and learn" didn't "make . . . any difference."[18] *Id.* ¶ 488.

CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment should be denied, and the Government's cross-motion for partial summary judgment should be granted.

Respectfully Submitted,

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[18] Despite Novartis's bare assertions to the contrary, Br. 43-44, there is no reason the government's event criteria are any less applicable to lunch and learns than any other roundtables. A doctor who attends (1) multiple speaker programs and roundtables on the same drug within six months, (2) roundtables on a drug after being paid to speak on the same drug, or (3) roundtables with a per-person spend of greater than $125 satisfies the criteria regardless of whether the roundtables were out-of-office or in-office.

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