UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, and WISCONSIN; the DISTRICT OF COLUMBIA, the CITY OF CHICAGO, and the CITY OF NEW YORK *ex rel.*, and OSWALD BILOTTA, Plaintiffs, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 Civ. 0071 (PGG)**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION'S MOTION FOR SUMMARY JUDGMENT

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Novartis Pharmaceuticals Corporation ("NPC" or the "Company") respectfully submits this memorandum of law in support of its Motion for Summary Judgment, pursuant to Rule 56 of the Federal Rules of Civil Procedure.[1]

PRELIMINARY STATEMENT

In its Amended Complaint, the Government claims that NPC "held thousands of speaker programs all over the country at which few or no slides were shown and the doctors who participated spent little or no time discussing the drugs at issue. Instead, NPC simply wined and dined the doctors at high-end restaurants with astronomical costs". (Am. Compl. ¶ 2, ECF No. 79-1.) The Government asserts that through this alleged scheme, NPC "systematically paid doctors" kickbacks in violation of the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA"). (Id. ¶ 1.) But after extensive discovery, including production of nearly 12 million pages of documents and 48 fact depositions, the Government cannot prove that the Company directed a decade-long, nationwide scheme to pay kickbacks to doctors through promotional events.

At best, the Government can point to testimony from a small group of witnesses (mostly sales representatives who covered narrow geographic regions) in support of its case. But that testimony only shows that on a sporadic basis, NPC sales representatives, contrary to NPC policies, invited doctors to speaker programs that provided limited—and in the rarest instances, no—medical information about the drugs that NPC promoted. These witnesses were unfamiliar with speaker programs other than the ones they hosted or attended, and thus did not provide testimony—even if aggregated together with their fellow witnesses—that establishes anything

[1] NPC seeks summary judgment as to the Amended Complaint filed by the United States Attorney's Office for the Southern District of New York ("SDNY") (ECF No. 79-1), New York State's Complaint (ECF No. 61) and Relator's Third Amended Complaint (ECF No. 50). These three parties are collectively referred to as the "Government" herein.

like a nationwide scheme. The 18 sales representatives who testified did not attend or have knowledge about even 1% of the speaker programs and roundtables held during the relevant period. (See infra Section I.A.)

Lacking actual evidence to support its allegation of a kickback scheme, the Government instead relies on expert testimony to "prove" that tens of thousands of doctors attended speaker programs that "lacked educational value" for them personally. Notably, the Government no longer seeks to prove what the Amended Complaint asserts—that these events were entirely devoid of content. Instead, the Government now has a new theory: that certain doctors in attendance (but not all) could not possibly have learned anything at these events. According to the Government, this "inherent" lack of "educational value" inexorably proves that meals some doctors consumed were "kickbacks", while the meals consumed by other doctors at the same event were not.

The Government's new kickback theory, and therefore its claim under the FCA, fails as a matter of law for at least the following reasons.

First, the Government's experts base their opinion that these events could not be educational for certain attendees on three criteria or "markers".[2] These markers have no basis in the record. Instead, the experts contrived them by making an assumption about the events.

[2] The three markers are: (1) attending three or more programs regarding the same drug within six months; (2) speaking at a program on a drug and subsequently attending an event regarding the same drug within six months; and (3) attending three or more programs in twelve months with per-person meal cost of $125 or more. (See McMahon Rep. ¶ 54.) The Government refers to an event that hits upon one of its markers as a "trigger event" as to a particular doctor. (See id. at ¶ 42(d)(iii).) For example, under the second marker, where a Healthcare Professional ("HCP") spoke at an event and then attended an event about the same drug, the event at which the HCP spoke (Event Y) is not considered a trigger event, but the event that the HCP subsequently attended (Event Z) is considered a trigger event as to that HCP. Event Z is not considered a trigger event for the other HCPs in attendance (unless those HCPs independently met one of the markers for that event).

Specifically, the experts assumed that each speaker program involved a recitation of a complete slide deck (a sharp turn from the Government's original allegation that these events contained little or no discussion of the subject drugs), such that repeated attendance would not provide the doctors with any additional product or other medical information. The experts point to nothing that supports that assumption, which is not surprising considering the record reflects exactly the opposite, namely that the content and discussions at promotional events varied, even when the events involved the same drugs and the same slide decks. Because these expert opinions by their own admission rely on an unfounded premise, the opinions are unsound.

Additionally, and more fundamentally, the Government's argument rests on an invalid inference: that because the events were not educational (for some HCPs in attendance), they must have been kickbacks. The Government wrongly ignores a third option, which is not subject to genuine dispute: that the events were promotional. The Government cannot dispute—indeed its experts now assume—that as a general matter, NPC's events included a discussion of NPC's products and relevant disease states, and that the speaker programs were accompanied by NPC-approved slide decks and led by speakers who received training by NPC on the drugs. In fact, taking as true the Government's assumption that slide decks were routinely presented in full, the events surely were promotional. Even the Government's marketing expert acknowledged that there can be value to repeated exposure to promotional messages. Thus, the Government's new theory amounts to an effort to equate promotion with kickbacks. That effort is not only without any legal basis, it is unfair given that NPC, and the pharmaceutical industry generally, was never on notice that if a doctor attended an event satisfying the Government's "markers"—created solely for the purpose of this litigation—the Government would consider such attendance to violate the AKS.

The Government cannot use assumptions, especially assumptions unsupported by the evidence, in lieu of actual proof that NPC violated each element of both the FCA and AKS. Allowing the Government to bypass its burden of proof, and shift the burden to NPC, would violate NPC's due process rights. (See infra Section I.B.)

Second, nearly all the conduct for which the Government seeks to recover in this case was already the subject of an FCA case against NPC that has been fully settled and released. In 2010, NPC settled four FCA cases. Under the settlement, the Government released NPC for all conduct related to Diovan, Exforge and Tekturna speaker programs and roundtables held from 2002 to 2009. Now, the Government seeks to hold NPC responsible for additional prescriptions that purportedly resulted from these very same programs, merely because those prescriptions were for different drugs. This is an improper reading of the 2010 settlement release, which released any claims (i.e., damages) flowing from the challenged speaker programs. (See infra Section II.)

Third, the Government cannot establish causation as a matter of law, which both precludes a finding of harm (and therefore damages) as well as a finding of liability. The FCA is intended to remediate harm to the public fisc; it is not an "all-purpose antifraud statute". Courts of appeals uniformly have recognized that the FCA requires a showing of financial harm to the government that was caused by the alleged false claim. The Government's expert who purports to show "causation" can prove only that exposure to NPC's promotional practices increased prescriptions—exactly what promotional practices, which are indisputably permissible, are designed to do. This expert concedes that he cannot show that any prescription actually resulted from the challenged speaker programs (as opposed to other non-challenged promotional practices) or that any prescription was improper. Moreover, the Government cannot prevail on

liability because it has failed to prove that NPC and tens of thousands of doctors violated the AKS as there is simply no evidence establishing that these doctors entered into, or were even aware of, a quid pro quo relationship with NPC. (See infra Section III.)

Fourth, the Government's attempt vastly to expand the scope of this case at the eleventh hour is improper. After proceeding through years of discovery on the basis of an Amended Complaint that relates to two types of promotional programs—speaker programs and roundtables—the Government asserted for the first time in rebuttal expert reports that a third type of program, "lunch-n-learns", is also at issue. Both parties have long recognized that lunch-n-learns are not part of this case, and there would be substantial prejudice to NPC were this new allegation of fraud to be asserted after discovery has concluded.

STATEMENT OF FACTS[3]

Relator Oswald Bilotta filed his qui tam Complaint under seal on January 5, 2011 (Compl., ECF No. 1), and a Third Amended Complaint on July 10, 2013 (Third Am. Compl., ECF No. 50). SDNY filed an Amended Complaint in Intervention on August 26, 2013, and New York State filed a Complaint in Intervention on the same day. (Am. Compl., ECF No. 79-1; Compl. in Intervention, ECF No. 61.) These complaints allege that NPC conducted sham promotional programs, which were effectively vehicles to pay "kickbacks" to doctors who participated in the events in order to induce them to write prescriptions for drugs in NPC's cardiovascular division that were later reimbursed by federal health care programs in violation of the AKS and the FCA. (Am. Compl. ¶¶ 175,185, 188, ECF No. 79-1.)

The drugs at issue are Lotrel®, Valturna®, Starlix®, Diovan®, Exforge®, Tekturna® and Tekamlo®, collectively, the "Covered Drugs". (Am. Compl. ¶ 66, ECF No. 79-

[3] Pertinent facts are further described in NPC's Local Rule 56.1 Statement.

1.) Three of the Covered Drugs come in "HCT" versions.[4] (Id.) The Government has defined the relevant date range ("Relevant Period") as January 1, 2002 through November 30, 2011 for Lotrel, Starlix, Valturna, Tekamlo, Diovan HCT, Exforge HCT and Tekturna HCT. (Id. ¶ 172, ECF No. 79-1.) The Relevant Period for Diovan, Exforge and Tekturna (collectively, "DET Drugs" or "DET") is January 1, 2010 through November 30, 2011. (Id.) The Relevant Period for the DET Drugs is shorter because the promotional programs involving those drugs were the subject of a settlement agreement between the Government and NPC, executed on September 27, 2010 (the "2010 Settlement"). (Id.; see also infra Section II.) As part of the 2010 Settlement, NPC entered into a Corporate Integrity Agreement ("CIA") that set out specific obligations for NPC with respect to its promotional programs.[5]

The Government's allegations relate to two types of promotional events: speaker programs and roundtables.[6] (Am. Compl. ¶¶ 1-2, 147, ECF No. 79-1.) NPC's policies define "speaker programs" as "[a] promotional program led by an approved speaker".[7] NPC's compliance policies required speakers to undergo training before speaking on behalf of NPC and speakers were provided with NPC-approved slide decks that described clinical trial results and

[4] An "HCT" variant is the main compound (e.g., Diovan) plus hydrochlorothiazide, which is a water pill. (Statement of Undisputed and Material Facts ("SUMF") ¶ 9.)

[5] Am. Compl. ¶ 64, ECF No. 79-1; SUMF ¶ 90, 92.

[6] The Government, in its rebuttal expert reports, revised its damages calculations by adding a third category of events: lunch-n-learns. (See generally McFadden Rebuttal Rep.; Goldberg Rebuttal Rep.) Lunch-n-learn programs are in-office programs with a meal cap of $25 per person, where a sales representative presents relevant information to the doctors and their approved staff. (SUMF ¶ 31.) NPC's policies prohibited honoraria payments to doctors in connection with lunch-n-learns. (Id. ¶ 53.)

[7] See, e.g., id. ¶ 18.

other relevant medical information.[8] Some of the speakers were key opinion leaders and nationally recognized experts in their fields.[9] NPC paid the speakers an honoraria.[10]

NPC's policies define "roundtables" as field-based promotional discussions held outside doctors' offices between one or more doctors and an NPC sales representative.[11] NPC's policies prohibited honoraria payments to doctors in connection with roundtables.[12]

At roundtables and speaker programs, NPC's compliance policies permitted a "modest" meal for attendees,[13] as was allowed for under the 2002 and 2009 PhRMA Codes.[14] Although the 2002 and 2009 PhRMA Codes did not contain a specific monetary cap on these meals, NPC itself implemented such caps.[15] As early as 2004, NPC implemented meal caps that varied by region.[16] As early as 2006, NPC implemented a monetary meal cap of $125 per attendee for all regions.[17]

Promotional programs are widely and regularly conducted in the pharmaceutical industry, and are, according to NPC's policies, conducted "to convey valuable informational content that supports [NPC] products and related therapeutic areas".[18] The Government's marketing expert agrees that it is legitimate for pharmaceutical companies to promote their drugs

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[8] Id. ¶ 21-22.
[9] Id. ¶ 24.
[10] See, e.g., id. ¶ 50.
[11] Id. ¶ 28.
[12] Id. ¶ 52.
[13] Id. ¶ 46.
[14] See generally, id. ¶¶ 63, 67.
[15] Id. ¶¶ 46-49.
[16] Id. ¶ 47.
[17] Id. ¶¶ 48-49.
[18] Id. ¶ 16.

to doctors.[19] The Government's marketing expert also agrees that it is appropriate for pharmaceutical companies to use programs to discuss the results of drug studies, for sales representatives to answer questions posed by doctors, and for pharmaceutical companies regularly to remind doctors of the benefits of the products they manufacture.[20]

LEGAL STANDARD

Summary judgment is appropriate where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law". Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). When the burden of proof at trial falls on the nonmoving party, "it ordinarily is sufficient for the movant to point to a lack of evidence to go to the trier of fact on an essential element of the nonmovant's claim". Simsbury-Avon Preservation Club, Inc. v. Metacon Gun Club, Inc., 575 F.3d 199, 204 (2d Cir. 2009) (citing Celotex, 477 U.S. at 322-23). When the moving party has met its burden, "the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment". Simsbury, 575 F.3d at 204. The nonmoving party "may not rely on mere conclusory allegations nor speculation, but instead must offer some hard evidence showing that its version of the events is not wholly fanciful". Golden Pac. Bancorp. v. F.D.I.C., 375 F.3d 196, 200 (2d Cir. 2004) (citing D'Amico v. City of New York, 132 F.3d 145, 149 (2d Cir. 1998)). Furthermore, "the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact". Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original).

[19] Clarke Dep. Tr. 39:14-19.

[20] Clarke Dep. Tr. 41:21-43:4.

ARGUMENT

The Government's case should be dismissed as a matter of law because: (1) the Government has failed to adduce particularized evidence of the alleged nationwide scheme and instead impermissibly attempts to rely upon expert-created markers; (2) the Government seeks to hold NPC liable for conduct that was released by the 2010 Settlement with the DOJ; (3) the Government has failed to prove the essential FCA element of causation with respect to both damages and liability; and (4) the Government, at the end of discovery and at great prejudice to NPC, is trying to add an entirely new category of allegedly fraudulent promotional programs to its case ("lunch-n-learns").

I. THE GOVERNMENT LACKS PARTICULARIZED EVIDENCE AND IS NOT PERMITTED TO PROVE ITS CASE USING EXPERT-CREATED MARKERS.

In order to prove that NPC's events were "shams", the Government relies upon two contradictory theories. The Government's first theory is that the events included no medical discussion and were therefore simply mechanisms to provide kickbacks. Its second theory is that the events actually included lengthy medical discussion, and therefore, if a doctor attended more than twice, there could be no educational value for repeat attendance; accordingly, the third event was simply a mechanism to provide kickbacks. The fact that the Government's two theories of liability are irreconcilable underscores the Government's inability to prove its case.

With respect to its first theory (that the speaker programs included no medical content), at the close of discovery, the Government has failed to develop particularized evidence to support its narrative. To the extent the Government contends that it can prove this theory through anecdotal testimony, this approach fails as a matter of law. (See infra Section I.A.)

Because the Government uncovered, at best, isolated instances of misconduct, its experts had insufficient evidence to author opinions in support of its first theory. Accordingly,

its experts based their opinions on the second theory (the "marker" theory). But that theory also fails as a matter of law.

First, the purported markers are based on assumptions that are unsupported by facts. Second, the markers create an unreasonable and speculative inference because (1) the Government lacks sufficient evidence to justify the inference; (2) the inference ignores the undisputed fact that the events had promotional value; (3) the government's many pronouncements about promotional programs never indicated to NPC (or the rest of the pharmaceutical industry) that one could infer a kickback based only on a doctor's attendance at an event that satisfies one of the three markers; and (4) the inference violates due process, as it would effectively shift the burden of proof to NPC. (See infra Section I.B.)

A. The Government Failed To Establish Particularized Evidence to Prove the Nationwide Kickback Scheme It Originally Alleged, Despite an Extensive Investigation and Years of Discovery.

The Government survived NPC's motion to dismiss by premising its case on its first theory of liability, promising the Court that it would present evidence "not merely . . . that these speaker events were shams because of a failure to show slides or because they were held at highly-rated restaurants . . . . [but also because] . . . doctors were paid thousands of dollars in honoraria for events that never took place, that they never attended, at which they did not speak, or at which there was little or no medical discussion".[21] (Mem. of Law in Opp'n to Def.'s Mot. to Dismiss ("Opp'n") at 6, ECF No. 90.) In denying NPC's motion, the Court found that the Government's wide-ranging allegations of "lavish" programs that had "no substantive presentation or discussion about Novartis drugs" and were used "to induce doctors to write more

[21] In its opposition to NPC's motion to dismiss, the Government claimed the evidence would show that NPC "held thousands of speaker events at which few or no slides were shown . . . and at which the attendees spent little or no time discussing the drugs that were allegedly the focus of the programs". (Mem. Op. and Order at 3, ECF No. 110.)

prescriptions" were pleaded with enough specificity to meet Rule 9(b). (Mem. Op. and Order at 26 ("Order"), ECF No. 110.) As recently as two months ago, in response to NPC's request for a pre-motion conference regarding this summary judgment motion, the Government similarly claimed that its "evidence that NPC engaged in a nationwide kickback scheme with the intent to induce prescription-writing is not limited to 'markers,' but is wide-ranging and comprehensive . . . . Both HCPs and sales representatives will testify that . . . many events included little to no educational content and were primarily social in nature". (Mar. 19, 2018 Ltr from J. Vargas at 2, "Ltr from J. Vargas", ECF No. 215 (emphasis added).)

The allegation of a "wide-ranging and comprehensive" scheme was not borne out during discovery which, at best, reflects isolated, anecdotal evidence that some sales representatives conducted speaker programs that violated NPC's internal policy guidelines.[22] The Government cannot establish a nationwide scheme based on isolated examples of alleged misconduct. Without evidence to support a finding that NPC's speaker programs "had a 'universal and improper purpose' of inducing" doctors to prescribe NPC's drugs, the Government cannot survive summary judgment. See United States ex rel. Booker v. Pfizer, Inc., 188 F. Supp. 3d 122, 134 (D. Mass. 2016); see also United States ex rel. King v. Solvay, No. CV H-06-2662, 2016 WL 1258401, at *11 (S.D. Tex. Mar. 31, 2016), aff'd sub nom. United States ex rel King v. Solvay Pharm., Inc., 871 F.3d 318 (5th Cir. 2017) ("Taking these examples, it

[22] NPC produced nearly 12 million pages of documents and numerous data files. Eighteen former sales representatives, three former sales managers, 21 current and former headquarters personnel and six doctors were deposed. The parties also produced declarations from former sales representatives, sales managers and doctors. Despite this record, the Government has come nowhere near supporting its contention that NPC wilfully implemented a nationwide scheme to bribe doctors in violation of the AKS. Instead, the record reflects that NPC's programs were largely regarded by all parties involved as being an entirely lawful promotional practice. Indeed, in the few instances where sales representatives, including the Relator, admitted to conducting inappropriate programs, they also testified that they sought to hide their actions from the Company. (See, e.g., SUMF ¶¶ 14-15, 75-84.)

becomes clear that even if there were no problems with the admissibility of the underlying claims data, which of course there are, a reasonable jury could not get from this incredibly small number of claims isolated to one state to a scheme in which sales representatives across the country presented off-label information to physicians and caused them to prescribe the Drugs at Issue for nonreimbursible uses, resulting in off-label prescriptions being filled by Medicaid patients all over the country."); see also Ashlock v. Slone, No. 10 Civ. 453, 2012 WL 3055775, at *10 (S.D.N.Y. July 26, 2012).

B. The Government Cannot Save Its Lack of Evidence Through Application of Markers.

Presumably because it lacks the evidence needed to establish the existence of a nationwide kickback scheme, the Government puts forward a new theory of liability, which it attempts to support only through expert testimony. In a radical shift, the Government assumes that NPC's programs actually involved speakers giving robust presentations with slide decks and attendees engaging in medical discussion, but, nevertheless, argues these programs could not have provided any educational value for particular attendees and were therefore kickbacks as to those attendees (but not as to others). The Government relies for this novel theory on its purported "medical education" expert, who, by conflating Continuing Medical Education ("CME") standards with the standards for promotional programs (two entirely different things), contends that he has identified three markers for when speaker programs and roundtables "inherently lack[] educational purpose" for a given doctor: (1) a doctor attended three or more events regarding the same drug in the span of six months or less ("repeat attendance"); (2) a doctor attended a program on a drug on which the doctor had served as a speaker within the last

six months ("speaker-then-attendee"); and (3) a doctor attended three or more programs with a per-person meal spend of $125 or more over the course of 12 months.[23]

The Government's markers have turned this case into precisely what the Government once claimed it was not. Five years ago, NPC explained in its Motion to Dismiss that no two speaker programs were identical—for example, speaker programs for the same drugs could have very different titles and topics, and the discussions at each varied depending on the speaker and his or her expertise, the audience and the questions that arose during and after the presentation. (Mot. to Dismiss at 20, ECF No. 80.) In response, the Government argued that NPC missed entirely the point of the allegations: "Novartis's attempt to characterize this suit as a dispute about how educational information should be conveyed at a speaker program is disingenuous, given the explicit allegations regarding the lack of educational information being conveyed at many of these purported speaker programs." (Opp'n at 7, ECF No. 90.)

Remarkably, the Government's case now turns on three "criteria" that are exactly that—purported rules about how educational information should be conveyed. But its markers do not provide the Government with evidence to prove the existence of a sweeping kickback scheme. Dr. McMahon's markers cannot, for example, demonstrate that a particular doctor who attended three programs on the same drug within six months received no useful product or medical information from the third program. The Government has the burden of proof, and it simply cannot prevail on marker evidence alone, especially where there is no legal or factual basis for the markers. Indeed, the method of proof the Government is attempting to use in this case is unprecedented; we can find no FCA case in which the Government or a relator sought to

[23] McMahon Rep. ¶ 54.

establish liability through a set of expert-created markers, let alone was permitted by a court to proceed to trial on that basis.

i. The Markers Are Unsupported by the Factual Record and Do Not Prove the Existence of Kickbacks.

The three markers were created for purposes of this case by the Government through its medical education expert, Dr. McMahon. NPC will move to disqualify him, pursuant to Daubert, on the grounds that he is unqualified to offer his purported expert opinions, that his opinions are not based on relevant facts or data and that his opinions are unreliable. However, even assuming that Dr. McMahon is a reliable expert and that his testimony is admissible, these markers still cannot be used as a basis to survive summary judgment.

The markers are based solely on expert opinion that assumes facts that are inconsistent with the record. For this reason alone, the Government's claims fail as a matter of law. See, e.g., Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."). Specifically, Dr. McMahon established his markers based on an assumption that "the slide presentations at speaker programs were delivered in full".[24] On that basis, he concluded that the programs would be "largely similar" in content, repeat attendance (or attendance by a qualified speaker) would be "redundant", and therefore the programs must have lacked educational value as to certain attendees.[25] Dr. McMahon does not

[24] McMahon Rep. ¶ 54.

[25] McMahon Rep. ¶ 59.

cite any factual support for this assumption, stating merely that the Government asked him to make it.[26]

This assumption contradicts the Government's original theory of the case—that NPC's "sham" events had no substantive discussion of NPC's products. More importantly, Dr. McMahon's assumption that every program for the same drug necessarily and invariably was substantively identical to previous programs contradicts the discovery record, which reflects that there was significant variation in the degree and content of medical discussion at NPC's events. Stated differently, unless the Government can prove the assumption its expert makes—that each and every program about a drug was identical to all previous programs—it cannot reasonably assert that an attendee received no medically beneficial information at the program. And the discovery record shows exactly the opposite to be the case. Nearly every witness testified that programs varied as to content, length and nature of the medical discussions, including the questions and answers among the doctors attending.[27] Not one witness offered testimony supporting Dr. McMahon's assumption, which is 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. It is for reasons such as this that experts cannot base their opinions on assumptions that are not consistent with the facts. Sparta Commercial Servs., Inc. v. DZ Bank, 680 F. App'x 17, 19 (2d Cir. 2017) ("'An expert's opinions that are without factual basis and are based on speculation or conjecture' should be excluded from consideration at summary judgment or trial.") (quoting Major League Baseball Props., Inc. v. Salvino, Inc., 542 F.3d 290, 311 (2d Cir. 2008)); Brooke Grp. Ltd., 509 U.S. at 242 ("Expert testimony is useful as a guide to interpreting . . . facts, but it is not a substitute for them.").

[26] McMahon Dep. Tr. 86:15-25.

[27] See, e.g., SUMF ¶¶ 77-79.

Furthermore, there is a fundamental disconnect between Dr. McMahon's opinion—whether the events were educational by CME standards—and whether they had educational or promotional value for attendees. Dr. McMahon's expert qualifications are focused on CME and what is required for a program to qualify as CME—something that has nothing to do with the challenged NPC speaker events and roundtables, which were not, and never purported to be, qualifying CME programs.[28] Dr. McMahon may be able to identify educational "best practices" for CMEs and to predict when events will not satisfy those best practices. That does not enable him to divine, without any data, what happened at a promotional program, the level of informational value received by a physician who attended the program, or why that particular physician attended. Dr. McMahon acknowledged that he has not attended a speaker program in nearly 20 years,[29] and his list of materials considered includes no depositions and only six documents produced in this litigation.[30]

Moreover, even if Dr. McMahon's markers were credited, they show at most that attendees at certain promotional programs may not have received the type of educational experience that Dr. McMahon would expect of a CME class. The mere fact that a doctor went to programs at which information about the same drug was discussed does not establish that he or she did not receive information of value about the medicine or underlying disease. Nor can it establish that he or she received a kickback. As discussed in Section I.B.2, it is undisputed that speaker programs are promotional tools; a promotional program does not need to satisfy the standards of a CME session. Inferring that there is no educational value, or even worse, a kickback, because a speaker program did not include Dr. McMahon's preferred CME teaching

[28] McMahon Rep. ¶¶ 1-11.

[29] McMahon Dep. Tr. 9:4-7.

[30] McMahon Rep. App'x C.

methods would require pure speculation—particularly when Dr. McMahon admits that an attendee could have believed they had received educational value from the program.[31]

ii. The Government's Markers also Require an Unreasonable Inference that Fails as a Matter of Law.

The Government's inference that all speaker programs that hit upon one of its criteria are kickbacks is unreasonable, and without this inference, the Government's case cannot survive summary judgment. At summary judgment, inferences can only be made in favor of the nonmoving party if they are "reasonable" and "legitimate". See Reeves v. Sanderson Plumbing Prod., Inc., 530 U.S. 133, 150 (2000).[32] Inferences are unreasonable if they are "conclusory", "based on speculation" or "conjectur[al]". See Major League Baseball Properties, Inc., 542 F.3d at 310 (2d Cir. 2008) (quoting Kulak v. City of New York, 88 F.3d 63, 71 (2d Cir. 1996)); Berk v. St. Vincent's Hosp. & Med. Ctr., 380 F. Supp. 2d 334, 342 (S.D.N.Y. 2005) ("In determining what may reasonably be inferred from [a witness's] testimony, [the non-moving party] is not entitled to the benefit of unreasonable inferences, or inferences at war with the undisputed facts.") (citations and quotations omitted); McPherson v. New York City Dep't of Educ., 457 F.3d 211, 215 n.4 (2d Cir. 2006) ("[S]peculation alone is insufficient to defeat a motion for summary judgment.").

The inference the Government draws from its markers is unreasonable on four grounds. First, it is speculative and unsupported by the record. Second, it ignores that the programs that satisfy its criteria could have legitimate purposes for both NPC and the doctors.

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[31] McMahon Dep. Tr. 55:19-59:7.

[32] See also Faust Harrison Pianos Corp. v. Allegro Pianos, LLC, No. 09 CIV. 6707 ER, 2013 WL 2292050, at *13 (S.D.N.Y. May 24, 2013) ("Unreasonable inferences are insufficient to defeat a motion for summary judgment."); Bloch v. Gerdis, No. 10 Civ. 5144, 2011 WL 6003928, at *2 (S.D.N.Y. Nov. 30, 2011) ("gossamer inferences" are insufficient to defeat summary judgment); cf. Brooke Grp. Ltd., 509 U.S. at 242 (affirming directed verdict where "the record evidence does not permit a reasonable inference").

Third, the government has never before indicated that it would consider a doctor's attendance at a program that satisfies its markers to violate the AKS or FCA; indeed this inference is especially unreasonable given that speaker programs were legal during the Relevant Period, remain legal today, and are undisputedly viewed as a lawful way to promote a pharmaceutical company's particular drugs. Fourth, and critically, accepting the inference created by the markers would impermissibly shift the burden of proof to NPC.

i. NPC's event data is insufficient to give rise to an inference that doctors who attended an event that satisfied one of the Government's markers received a kickback.

The Government's inference is not logical or supported by the discovery record. The Government admits that it does not have specific evidence related to most of the allegedly sham events, or from the allegedly implicated doctors, to establish a kickback arrangement. Rather, the Government claims that NPC's event data is "particularized evidence" of wrongdoing. (Ltr. from J. Vargas at 2-3, ECF No. 215.) But this argument is belied by the data itself. The event data only show limited information, such as who attended an event, the cost of meals and the title of the slide presentation; they provide no information regarding what occurred at each program, including what information was presented, what questions were asked and how much each attendee benefitted from that information. The data are simply not enough to create a reasonable inference about the reasons for NPC to invite the doctors, the reasons the doctors attended or whether doctors received helpful medical information—the core questions, under the Government's theory, as to whether there was a kickback. Based on Dr. McMahon's assumptions, the Government now claims that an event could simultaneously be wholly lawful and informational as to some attendees, but a kickback as to others. Such an inconsistent result is precisely why nonparticularized evidence is unreliable. See, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc., No. 3:07-cv-00604-M, 2016 WL 3449833, at *18 (N.D. Tex. June 20,

2016) ("Without any evidence about the nurses and doctors involved in treating or certifying the sampled patients for hospice, for Relator to prevail at trial, jurors would have to take an impermissible inferential leap to conclude that those patients' certifications were not based on the proper clinical judgment of physicians."); Berk, 380 F. Supp. 2d at 353 (granting summary judgment where "there is simply too great an analytical gap between the data and the [expert] opinion proffered") (citation and quotation omitted); S.E.C. v. Gonzalez de Castilla, 184 F. Supp. 2d 365, 376 (S.D.N.Y. 2002) (finding that summary judgment in favor of a defendant was appropriate in an insider trading case, where the SEC relied on circumstances, timing and nature of relationship rather than direct evidence to prove fraud).

ii. The Government's markers ignore the promotional value of speaker programs.

The inference the Government would seek to present to a jury also ignores the host of legitimate reasons for a doctor to have participated in a trigger event and the legitimate reasons for NPC to have invited the doctor to participate in that event. Dr. McMahon assumes that a complete informational presentation was included at every event, but that the presentations were insufficiently "educational" once one of the markers was satisfied. These assumptions ignore the promotional value of repeated brand messaging and of different doctors sharing their experiences with a product and reinforcing its benefits. The mere fact of repeat exposure to a message does not mean that the physician received no information valuable to the treatment of his or her patients, whether new information, or simply a reminder of the different benefits (and in some cases side effects) of a product.[33] The Government's marketing expert, Dr. Roberta Clarke, recognized that it is legitimate for pharmaceutical companies to promote to doctors,

[33] Clarke Dep. Tr. 105:19–107:7.

including by informing doctors about the benefits of drugs.[34] Dr. Clarke also opined that multiple promotional visits with doctors, such as detailing, are appropriate.[35] In fact, according to Dr. Clarke, a doctor could continually receive useful information from multiple visits with a sales representative over the course of a year.[36]

The discovery record similarly shows that there are numerous reasons that render a doctor's attendance at multiple programs—even about the same drug—perfectly legitimate. To enumerate a few examples:

- different programs covered different aspects of the same drug, making each program unique and valuable;[37]
- programs featured different speakers who had different specialties, different patient experiences and backgrounds, making each program unique and valuable;[38]
- some speaker programs were presented by a nationally recognized hypertension expert making it unique and valuable compared to other programs that did not feature such speakers.[39]

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[34] Clarke Dep. Tr. 39:14–40:25. Dr. Clarke claimed that speaker programs have promotional value only when they are also educational. In reaching her conclusions, however, she assumed that both Dr. McMahon's opinions and the Amended Complaint were true. (See Clarke Dep. Tr. 51:11–52:10; 73:16–74:4.) Because the Amended Complaint and Dr. McMahon's opinions are inconsistent with the factual record, Dr. Clarke's conclusions are unreliable.

[35] Clarke Dep. Tr. 84:8–85:16.

[36] Clarke Dep. Tr. 105:19–107:7.

[37] For example, the undisputed evidence shows that some Lotrel programs varied depending on the different patient population being discussed. (See, e.g., SUMF ¶ 23.)

[38] See, e.g., id. ¶¶ 81, 83 (Contreras Dep. Tr. 53:21-54:1 ("I'm sure some of them went to, basically, the same speaking event maybe once or twice. Maybe they had questions, maybe the first time it was given by a cardiologist and second time by a nephrologist, and they wanted a different point of view from a cardiologist to a nephrologist."); Bazemore Dep. Tr. 117:17-118:5 ("I would hear once in a while, they would discuss their clinical experience or if they—if you had an endocrinologist there and—or a cardiologist and a family practice guy there at a speaker event, then they would talk more in-depth about things, if the products—whether it be NPC products or something else, they—you'd have more clinical experience. I think they would benefit from having someone else who's a cardiologist or an endocrinologist there versus someone in their own specialty.")).

[39] See SUMF ¶¶ 24-26.

The Government's other two markers also are based on unreasonable inferences about doctor motivations for attending programs. The second marker, which bars speakers as attendees, renders doctors as kickback-takers even if, for example, the trained speaker contributed to a robust discussion with other doctors at the program or if he or she learned something when attending that program (about the drug itself or about how to conduct an effective presentation).[40] None of this matters to the Government's theory, as the marker deems any attendance by a speaker within six months after speaking at a program to be a kickback.[41]

Similarly, doctors are deemed bribed by the third marker even if, for example, the doctors are unaware of the per-person cost of that or any other program,[42] the programs concerned completely different drugs,[43] the programs featured robust medical discussion and detailed information about clinical studies,[44] the restaurants had unmet minimum guarantees,[45] or the program costs included a substantial charge for the use of a private room.[46] The Government cannot survive summary judgment here, where "countless reasons" could explain NPC's behavior and the Government's arguments are "founded solely on speculation". Castellanos v. Target Dep't Stores, Inc., No. 12 Civ. 2775, 2013 WL 4017166, at *6 (S.D.N.Y. Aug. 7, 2013).

[40] McMahon Dep Tr. 60:6-13; Townsend Dep. Tr. 307:2-308:2; SUMF ¶¶ 81-82.

[41] McMahon Rep. ¶¶ 72-74.

[42] There was no evidence during discovery that showed that any physicians were aware of the actual costs of programs that they attended, let alone the per-person cost.

[43] See McMahon Rep. ¶¶ 75-78.

[44] SUMF ¶ 78.

[45] Id. ¶ 44.

[46] Id.; McMahon Dep. Tr. 136:13-24, 141:5-8.

iii. The government has never indicated that a doctor's attendance at a program satisfying any of its criteria would violate the AKS or FCA.

The inference that "trigger events" hitting upon the Government's criteria were kickbacks is further unreasonable because the government's numerous statements about promotional events never suggested to NPC or doctors that meeting these arbitrary markers could be considered a violation of the AKS or the FCA. As set forth in Escobar, the Government is required to provide "fair notice" to defendants to allow them to "anticipate and prioritize compliance obligations". See Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016) ("[C]oncerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality . . . requirement[]"). In Escobar, the Supreme Court explained that "fair notice" requires a "rigorous" and "demanding" analysis of the Government's actual behavior, including a determination of whether the Government "consistently refuses to pay claims . . . based on noncompliance with [a] particular" requirement. Id. at 2001-03. Accordingly, though it need not provide "actual notice", the Government must provide some indication that the challenged behavior could subject potential defendants to FCA liability.

NPC has not identified—and the Government has not pointed to—a single regulation, Office of Inspector General of the Health and Human Services Administration ("OIG") guideline or administrative opinion in which the government suggested during the Relevant Period that participating in an event meeting Dr. McMahon's markers would constitute illegal remuneration in exchange for writing prescriptions, or would cause a false statement material to a false claim. Government statements about promotional programs by pharmaceutical companies have said nothing about repeat attendance or any other conduct implicated by Dr. McMahon's markers. For example, in May 2003, the OIG issued the

"Compliance Program Guidance for Pharmaceutical Manufacturers" as part of a "major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud".[47] The guidance set forth "key areas of potential risk" about pharmaceutical companies' business arrangements with healthcare providers, and it specifically acknowledged that "speaking" programs with doctors were "potentially beneficial".[48] Importantly, the OIG said nothing about a limit on attendance by physicians at multiple programs, a ban on speakers attending programs on a drug about which they were trained or a dollar cap on the per person cost of promotional programs.

Similarly, neither the 2002 PhRMA Code (referenced in the 2003 OIG) nor its 2009 revisions suggested any limit on how many promotional programs a doctor can attend on a given drug, a prohibition on trained speakers being attendees at promotional programs hosted by other speakers or any dollar cap on the amount spent on meals.[49] Likewise, even though the government investigated NPC's conduct regarding speaker programs through 2010 (see infra Section II), the 2010 Settlement documents do not reflect any concern that speaker programs were allegedly kickbacks because of doctors' repeat attendance at programs, speakers attending other speakers' programs or the number of programs over a per-person spending limit.[50]

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[47] SUMF ¶ 54.

[48] Id. ¶ 55, 58.

[49] See generally id. ¶¶ 61-70. Although the 2002 and 2009 PhRMA Codes called for "modest [meals] as judged by local standards" (id. ¶¶ 63, 67), they do not define "modest" or give a monetary cap on per-person spending at promotional events. Similarly, the Codes called for venues to be "conducive to informational communication" (id. at ¶¶ 63, 67, 71), but failed to explain what that language meant in practice.

[50] See generally id. ¶¶ 85-89.

More significantly, the government closely monitored NPC's marketing activities, including speaker programs, in the 2010 Corporate Integrity Agreement,[51] but it nonetheless never expressed concern about repeat attendees at promotional programs. In the CIA, the government set out detailed oversight and compliance requirements for NPC regarding many of its operations, including speaker programs. The CIA required that speakers be trained, agreements be in writing, that speakers only use NPC-approved materials and that speakers not promote off-label uses.[52] The government also required NPC to track attendees, track aggregate spend on speakers and require sales representatives to evaluate whether programs complied with NPC requirements.[53] The government raised no concern about NPC's allowing doctors to attend multiple events, to be speakers and then attendees or to spend more than a specific amount per-person. The CIA also required NPC to conduct audits of speaker programs and required NPC to "review slide materials . . . speaker statements made during the program and Novartis representative activities" to assess whether the programs were conducted in accordance with NPC's policies, but never suggested that the audits should check how many times an attendee had previously attended a program on that drug, or whether any attendee was a trained speaker on the subject drug.[54] The government had plenty of opportunities to give notice to NPC about the three markers it now claims are material to FCA reimbursement, and it failed to do so. Absent such fair notice, the Government here cannot reasonably establish that NPC's alleged noncompliance with the markers is material to the FCA or that NPC violated the law.

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[51] See generally id. ¶¶ 90-94.

[52] Id. ¶¶ 91-92.

[53] Id. ¶¶ 91, 93.

[54] Id. ¶¶ 91, 94.

iv. The Government's unreasonable inference violates due process.

By demanding an inference that anything that hits upon any of its markers is per se a kickback, the Government effectively is seeking to shift the burden to NPC to prove that each of thousands of its events was lawful. No case law supports the presumption of fraud the Government seeks to invoke.

The Government seems to argue that when it combines its three markers with the extremely limited testimony obtained by the Government that a small handful of NPC's promotional programs violated NPC's internal policies (even though this testimony does not relate to the validity of the markers) and the testimony that NPC intended its promotional programs to do just that (promote its products), this collective "evidence" transforms the markers into "badges of fraud". (See Ltr. from J. Vargas at 3, ECF No. 215.) The Government has cited no FCA or AKS case in which kickbacks were identified based on application of such markers, nor is NPC aware of any such case.

"Badges of fraud" cannot be anything the Government contrives; it is in fact a term of art primarily used in the context of fraudulent transfers to prove intent. They are "circumstances so commonly associated with fraudulent transfers that their presence gives rise to an inference of intent". See In re Sharp Int'l Corp., 403 F.3d 43, 56 (2d Cir. 2005) (quoting Wall St. Assocs v. Brodsky, 257 A.D.2d 526, 529 (1st Dep't 1999)). Unlike fraudulent transfer badges of fraud, which occur with enough frequency to have been codified in the Uniform Fraudulent Transfer Act (see UFTA § 4(b)), the Government's markers here are not tested or recognized indicators that events served as kickbacks. Rather, they are unsubstantiated rules devised by the Government in hindsight for purposes of this case, years after the speaker events occurred. In addition to the fact that the Government's markers plainly cannot be considered "badges of fraud", they are not being used merely to infer intent, as the Government claims.

Rather, the Government is using them to infer the factual predicate that the events had no educational or promotional value, and then that inference is being further used to infer intent.

The Government's attempted burden shifting is impermissible and violates NPC's due process rights. See U.S. ex rel. Crews v. NCS Healthcare of Ill., Inc., 460 F.3d 853, 857 (7th Cir. 2006) ("[The relator] does not point to one relevant case under the FCA that shifted the burden of actually identifying a false claim from the relator to the defendant. In effect, [the relator] is arguing that [the defendant] must prove that each and every claim it ever filed . . . was lawful, an argument that defies common sense and the plain language of the FCA."); see also Vargas v. Keane, 86 F.3d 1273, 1276 (2d Cir. 1996) ("shifting the burden of proof from the prosecution to the defendant . . . is constitutionally deficient"); In re Miller, 698 F. App'x 26, Summary Order (2d Cir. 2017) (the government "concede[d] that due process was in fact violated, specifically stating 'the court impermissibly shifted the burden of proof to [defendant]' . . . ."); Lopez v. Curry, 454 F. Supp. 1200, 1205 (S.D.N.Y. June 26, 1978), aff'd, 583 F.2d 1188 (2d Cir. 1978) (finding that the trial court "violated due process by shifting the burden of proof to the defendant").

Under the Government's theory of the case, after it presents expert testimony "establishing" the markers, the burden shifts to NPC to present evidence about specific speaker program events to show that the markers are not reliable. NPC would be forced to put on evidence from numerous doctors and sales representatives about thousands of speaker programs to undermine the Government's markers (which the Government would use as a surrogate for actual proof). This creates an untenable situation where the Government, which bears the burden of proof, can present its case through generalized markers, while NPC must present evidence about what actually happened at each of the speaker programs.

If the Government seeks to prove that NPC convinced thousands of doctors (many of whom are key opinion leaders or highly respected local specialists) to violate the law in exchange for free meals, then due process requires that it meet its burden of proof with respect to each allegedly sham encounter.[55] See Town of New Windsor v. Tesa Tuck, Inc., 935 F. Supp. 315, 317 (S.D.N.Y. 1996) (refusing to shift the burden of proof where the plaintiff had not established an element of liability); cf. Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 367 (2011) (rejecting plaintiffs' attempt to shift the burden of proof through "trial by formula"). The Government cannot avoid its burden of proving that each of the alleged events was a kickback. Wall, 2016 WL 3449833 at *11 ("Relator was not required to pursue all potential false claims submitted in fourteen states over nearly a decade, of which she did not have personal knowledge. These choices, made by Relator, do not reduce her burden to produce reliable evidence of liability.").

II. THE GOVERNMENT CANNOT PROSECUTE NPC FOR CONDUCT RELEASED BY THE 2010 SETTLEMENT AGREEMENT.

The Government is seeking impermissibly to hold NPC liable and recover damages for conduct that was released by the 2010 Settlement. The 2010 Settlement was the result of an investigation by the DOJ following four relator qui tam actions[56] concerning the alleged payment of kickbacks by NPC to doctors in the form of sham Diovan, Exforge and Tekturna promotional events. One of the qui tam actions, the "Garrity Complaint" was filed by

[55] The Government's attempt to shift the burden is especially egregious given that it must present a prima facie case that NPC violated the AKS, which is a criminal statute.

[56] The four civil actions are: United States et al. ex rel. Austin and Montgomery v. Novartis Pharmaceuticals Corp., Civil Action No. 8:03-CV-1551 (M.D. Fla.); United States et al. ex rel. McKee v. Novartis Pharmaceuticals Corp., Civil Action No. 04-CV-1664 (E.D. Pa.); United States et al. ex rel. Copeland v. Novartis Pharmaceuticals Corp., Civil Action No. 06-CV-1630 (E.D. Pa.); and United States et al. ex. rel. Garrity v. Novartis Pharmaceuticals Corp., Civil Action No. 08-CV-2588 (E.D. Pa.). (See also 2010 Settlement at 1-2.)

the same lawyers who represent Relator here, and alleged "that NPC induced physicians to write prescriptions" for DET Drugs by paying them kickbacks "through a panoply of kickback schemes", including through sham speaker events. (First Am. False Claims Act Compl. at ¶ 5, United States et al. ex rel. Garrity v. Novartis Pharm. Corp., Civil Action No. 08-CV-2588 (E.D. Pa. Aug. 13, 2010) ECF No. 17).

The 2010 Settlement—which resolved all claims related to the DOJ's investigation and the four qui tam actions—explicitly released NPC from any claims related to its DET events from January 1, 2002 through December 31, 2009 (the "Settlement Period").[57] As this conduct has been the subject of a settlement and full release, NPC is entitled to summary judgment on all the alleged false claims that the Government contends derived from DET promotional programs during the Settlement Period.

The "Covered Conduct" released in the 2010 Settlement is defined to include "illegal remuneration" provided "through mechanisms such as speaker programs . . . and meals" that induced doctors to prescribe Diovan, Exforge and Tekturna "in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)".[58] The 2010 Settlement specifically released NPC from "any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 . . . ."[59]

The Government now seeks to hold NPC liable, again, for the same programs. The Government argues that in the 2010 Settlement, the "Covered Conduct" only released DET prescriptions and not prescriptions for other drugs. Accordingly, it takes the position that it can use the exact same DET events that were the subject of the 2010 Settlement as a basis for

[57] SUMF ¶¶ 85-88.
[58] Id. ¶ 87
[59] Id. ¶ 88.

liability, claiming that those events induced doctors to write prescriptions for drugs other than DET. This argument ignores the fact that the plain language of the "Covered Conduct" defines the "mechanism" of the kickbacks as, inter alia, "speaker programs" and "meals". Put another way, the Government's assertion that these DET events increased prescribing of non-DET drugs does not pull the events outside the scope of the release. The release covers all claims that the Government may have for this conduct, and that includes all claims under the FCA for prescriptions that were allegedly tainted by virtue of attendance at those programs. The Government cannot narrowly construe "Covered Conduct" to mean it only relates to specific drugs (DET), without applying that same narrow interpretation to DET speaker programs, which are clearly included in the "Covered Conduct". If, as the Government claims, the "Covered Conduct" of holding DET speaker programs only released DET prescriptions, then the Government cannot now claim the reverse—that those same DET speaker programs induced prescriptions for other drugs. The Government's attempt to link DET speaker programs exclusively to DET prescriptions in the 2010 Settlement is irreconcilable with the position it is taking in this case, that "[t]he remuneration received in connection with a speaker program was an inducement not just to prescribe the CV drug that was the subject of the particular program, but other CV drugs as well". (Opp'n at 14, ECF No. 90.)

The Government's tactic of basing its claims in this case on released conduct, like its use of markers and its belated assertion of fraud claims based on lunch-n-learns, vastly expands this case beyond what the law allows. Over 83% of the "trigger events" in this case—which are the ones that the Government's expert identify as the kickbacks that induced increased

prescribing—were DET drug events that occurred during the Settlement Period.[60] The Government cannot hold NPC liable twice for the same conduct, and accordingly, NPC is entitled to summary judgment related to claims based on NPC's conduct for the events previously released in 2010.

III. THE GOVERNMENT FAILED TO PROVE CAUSATION WITH RESPECT TO BOTH DAMAGES AND LIABILITY.

The Government cannot show that it suffered damages "because of" NPC's alleged wrongdoing, nor can it show that any alleged false claim "result[ed] from" an AKS violation. Accordingly, summary judgment should be granted in favor of NPC as to both damages and liability for these reasons as well.

A. The Government Cannot Prove that NPC Caused the Government to Suffer Actual Damages.

NPC is entitled to summary judgment with respect to compensatory damages because the Government cannot prove that NPC's alleged misconduct caused the Government actual harm. Under the FCA, a person who knowingly presents, or causes to be presented, a false claim for payment "is liable to the United States Government for . . . the amount of damages which the Government sustains because of the act of that person". 31 U.S.C. § 3729(a)(1) (emphasis added). The purpose of the FCA is to "recover a remedy for a harm done to the Government". United States ex rel. Feldman v. van Gorp, 697 F.3d 78, 84 n.3 (2d Cir. 2012). Accordingly, in order to recover damages, the Government must prove actual harm—in other words, "a causal connection must be shown between loss and fraudulent conduct". United

[60] With respect to the DET trigger events held during the Settlement Period, nearly 90% were exclusively for DET medications and the remaining 10% were dual programs for DET and another medication (either an HCT variant of DET or Lotrel).

States v. Luce, 873 F.3d 999, 1010 n.33 (7th Cir. 2017) (quoting United States v. Hibbs, 568 F.2d 347, 349 (3d Cir. 1977)).

In Luce, the Seventh Circuit squarely addressed the question of how the Government should prove causation in order to recover damages under the FCA and explained that "[t]he statutory limitation, 'by reason of' the commission of the unlawful act, compels consideration of the element of causation".[61] Id. at 1010-14 (footnote omitted).

In Luce, the defendant submitted false certifications to the Government in support of mortgage insurance applications. Id. at 1001-02. Specifically, the defendant certified that he had no criminal history, when in fact, he had recently been indicted for wire fraud, mail fraud and a number of other crimes. Id. The Government, unaware of the misrepresentations, insured mortgages on the homes and was required to pay the mortgages when defaults occurred. Id. at 1002-03. The Government argued that because it would not have insured the mortgages had it not been for the submission of the defendant's false certifications, it was entitled to three times the Government's net loss on the defaulted loans (for damages totaling over $110 million). Id. at 1004. Recognizing that these losses were sustained as a result of events—the mortgagors' defaults—that were not caused by the false certifications, the Seventh Circuit rejected the Government's "but for" basis to determine damages and, overruling its own 25-year precedent, "adopt[ed] the proximate cause standard for FCA cases". Id. at 1014. In doing so, the court noted that "the clear weight of authority among our sister circuits supports the view that 'but for' does not fulfill adequately the causation requirement of the statute". Id. at 1013.

[61] As noted in Luce, the FCA was amended in 1982 and the words "by reason of the doing or committing" were replaced with "because". 873 F.3d at 1010 n.34. However, as with other courts, Luce held that this change in language did not give "any substantive effect" and presumed "that the Act's meaning as to the causation requirement was unchanged by the 1982 amendment". Id.

Every circuit to consider the question of FCA damages has adopted this same proximate cause standard. See, e.g., United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah, 472 F.3d 702, 715 n.17 (10th Cir. 2006); United States ex rel. Schwedt v. Planning Research Corp., 59 F.3d 196, 200 (D.C. Cir. 1995); United States v. Miller, 645 F.2d 473, 475–76 (5th Cir. 1981); Hibbs, 568 F.2d at 347; see also United States v. Rapoport, 514 F. Supp. 519, 525 (S.D.N.Y. 1981) ("The proper inquiry is whether the Government incurred damage 'by reason of' [defendant's] causing false information to be stated on the loan application. To inquire merely whether the Government incurred damage because it honored its loan guarantee strips the statutory 'by reason of' restriction of any real significance.").[62]

The Government is unable to establish the necessary causal link between the claims for NPC medications at issue and any actual harm to support damages. Without showing causation, the Government could recover damages even though "precisely the same loss would have been suffered by the Government had the certifications been accurate and truthful"; such recovery has been rejected by the courts. Luce, 873 F.3d 999, 1010 n.33 (quoting Hibbs, 568 F.2d at 349). This is consistent with the principle "that the purpose of damages . . . under the [False Claims] Act is to make the Government 'completely whole' for money taken from it by fraud". See Feldman, 697 F.3d at 87.

[62] While the Second Circuit has not explicitly addressed this question, it has suggested that the proximate cause standard is applicable in determining damages under the FCA. See Feldman, 697 F.3d at 90. Relatedly, the Government has previously relied upon United States ex rel. Kester v. Novartis Pharm. Corp., 41 F. Supp. 3d 323, 340 (S.D.N.Y. 2014), a motion to dismiss decision, and United States ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89, 98–100 (3d Cir. 2018), a Third Circuit case that determined that a violation of the AKS can result in FCA liability (albeit also requiring that the Government establish some link between the AKS violation and the false claim). But, importantly, Luce, Kester and Greenfield do not address what the Government must prove in order to recover damages under an FCA claim—rather, they address what the Government must prove to establish liability.

In seeking reimbursement for nearly all prescriptions written by doctors who attended events that satisfy one of the Government's markers, without regard to whether those prescriptions were induced by the alleged kickbacks, the Government would go far beyond simply remedying damages caused by an FCA violation. In fact, the Government is using the FCA simply as an enforcement statute for the AKS, which it was never intended to be: "[t]he False Claims Act is not 'an all-purpose antifraud statute'". Escobar, 136 S. Ct. at 2003 (quoting Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 672 (2008)).

While the Government now argues that "[it] need not prove that HCPs prescribed more as a result of kickbacks," (Ltr. from J. Vargas at 4, ECF No. 215), it has spent much time and effort trying to do so—without success. The Government retained Professor Daniel McFadden, an econometrician, to run regression models showing, in the Government's words, "that NPC's kickbacks caused HCPs to write more NPC prescriptions than they would have absent those kickbacks". (Id.) Prof. McFadden, however, conceded that his models do not do that. Instead, his models only establish that promotional practices generally—including unchallenged speaker programs, drug sampling and physician detailing—caused higher rates of NPC prescriptions.[63] Indeed, one of Prof. McFadden's models, the "pooled" model, merely showed which doctors were "at risk" of prescribing more as a result of the alleged kickbacks rather than which doctors actually were influenced by those alleged kickbacks.[64] When NPC's expert challenged this methodology (in part because the model only analyzed doctors on an aggregate level as opposed to identifying which individuals were actually influenced by kickbacks), Prof. McFadden attempted to create a second model to demonstrate "actual

[63] McFadden Dep. Tr. 153:19-154:14.

[64] Id. at 107:8-108:17; 126:20-127:25; 132:21-133:19.

influence" on individual doctors.[65] However, as Prof. McFadden admitted, this model could not discern between the effect of allegedly illegal promotional activities and of the legal promotional activities that are unchallenged in this case.[66]

Prof. McFadden's models only demonstrate what NPC already agrees is undisputed: that its promotional practices led doctors to write more prescriptions. That is why all drug companies promote their drugs. The Government has failed, however, to produce any evidence from which a reasonable jury could conclude that any increase in prescriptions resulted from an illegal activity as opposed to a legal one, let alone determine that the Government suffered actual damages due to a nationwide scheme to defraud Government entities. Therefore, NPC is entitled to summary judgment insofar as the Government is seeking to recover actual damages. Moreover, because the Government has failed to establish the existence of actual damages, NPC is also entitled to summary judgment insofar as the Government seeks treble damages. Without proof that the Government suffered actual damages under the FCA, there is nothing for the Court to treble. See United States v. Bornstein, 423 U.S. 303, 314 (1976); see also Luce, 873 F.3d at 1013 (quoting Miller, 645 F.2d at 475–76) ("The language of the statute clearly requires that before the United States may recover [treble] damages, it must demonstrate the element of causation between the false statements and the loss.").

B. The Government's Lack of Proof With Respect to Causation Renders It Unable To Establish Liability.

Failure to establish causation not only prevents the Government from obtaining compensatory damages, it also compels summary judgment on liability. In a case such as this where the defendant does not directly submit claims to the Government, causation is an essential

[65] McFadden Rebuttal Rep. ¶ 5.

[66] McFadden Dep. Tr. 107:8-108:17; 126:20-127:25; 132:21-133:19.

element of FCA liability, and it is separate and distinct from the element of "falsity". 31 U.S.C. § 3729(a)(1)(A) (creating liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval") (emphasis added).[67] An underlying AKS violation may render a claim "false" for purposes of the FCA, 42 U.S.C. § 1320a-7b(b), but that does not mean that the FCA's separate causation requirement is automatically satisfied. As the statutory text makes clear, that is a separate inquiry. Moreover, the AKS provision relating to "falsity" upon which the Government relies also has its own statutory causation requirement—AKS violations can only render claims "false" when the claims "result[] from" the AKS violation. Id. So, whether analyzed through the rubric of the FCA's causation element or the FCA's falsity element, in FCA cases premised on underlying AKS violations, the Government must show that the defendant's actions caused the submission of a false claim—in this case, that means that at the very least, the Government must show that NPC actually caused doctors to violate the AKS.[68] Without proof that a doctor knowingly and willfully entered into a quid pro quo arrangement with NPC, the Government cannot prove that

[67] See, e.g., United States ex rel. Polansky v. Pfizer, Inc., 822 F.3d 613, 619 (2d Cir. 2016).

[68] NPC further submits that in order to establish liability, the Government must prove that NPC's allegedly illegal actions caused doctors to actually write prescriptions that they would not have otherwise written, which the Government cannot show. Contrary to its allegation in the Amended Complaint, the Government has failed to present factual evidence that many thousands of doctors wrote prescriptions for patients as a result of the alleged kickbacks. See United States ex rel. King v. Solvay Pharm., Inc., 871 F.3d 318, 329 (5th Cir. 2017) (affirming summary judgment on speaker program claims because Relator had no evidence that the "incidental benefits" of those programs, such as meals, actually caused doctors to prescribe Solvay products, nor did Relator have evidence that attendance at Solvay speaker programs "was conditioned upon prescribing Solvay's drugs to Medicaid patients"); see also supra Section III.A (demonstrating that the Government's causation expert, Prof. McFadden, fails to establish a causal link between NPC's allegedly illegal conduct and prescriptions); but see Kester, 41 F. Supp. 3d 323; Greenfield, 880 F.3d 89. Regardless, this Court need not address this question, because the Government is required to prove that doctors violated the AKS, rendering their certifications false, which requires a showing of a quid pro quo relationship, which the Government cannot establish.

doctors violated the AKS and that the certifications in which the doctors claimed compliance with the AKS were "false". If doctors did not submit false certifications, there are no false claims. Because the Government cannot prove that NPC caused doctors to violate the AKS, NPC is entitled to judgment as a matter of law.

The Government alleges that NPC engaged in a kickback scheme in which it invited tens of thousands of doctors to speaker program dinners and roundtables to induce those doctors to write more NPC prescriptions. (Am. Compl. ¶¶ 1, 175, ECF No. 79-1.) The Government no longer alleges that all, or even many, of these programs were shams; rather, it contends that some doctors did not derive educational value, because their attendance met one of the three Government "markers". The Government does not have evidence to support any inference of a quid pro quo arrangement in which NPC offered a meal in exchange for prescriptions and a doctor followed through by prescribing because they received that meal. Nonetheless, the Government argues that the claims it paid for NPC medications were false because of alleged kickbacks—even though there is no evidence that either NPC or the doctors had any understanding that they were in a kickback relationship.

In order for an AKS violation to give rise to a false claim, there must be evidence of an actual quid pro quo exchange, including evidence that the doctor "knowingly and willfully . . . receiv[ed]" remuneration in exchange for writing prescriptions. See 42 U.S.C. § 1320a-7b(b). In the Patient Protection and Affordable Care Act, ("PPACA") Congress made clear that there is no loosening of the FCA's standard causation requirement simply because the FCA violation is premised on an underlying AKS violation, as opposed to some other type of underlying legal violation. The amended statute stated 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]." See 42 U.S.C. § 1320a-7b(b) (emphasis added).

While it is possible to violate the AKS by merely offering a kickback to a doctor, this action alone cannot result in the submission of a false claim. This Court recognized the necessity of such evidence in denying NPC's motion to dismiss. The Court held that the Complaint:

> "sufficiently alleged that all of the claims attached to the[] pleadings are false claims, because they were submitted by doctors at a time when the doctors were writing prescriptions for NPC cardiovascular division drugs in exchange for kickbacks, while certifying that they were in compliance with state and federal laws, including anti-kickback statutes. At the pleading stage, it is not necessary for the Government Entities to demonstrate with precision that every prescription written by every doctor was written in exchange for a kickback."

(Mem. Op. and Order at 39-40, ECF No. 110 (emphasis added).) See also United States v. Krikheli, 461 Fed. App'x 7, at *3 (2d Cir. Feb. 2, 2012) (requiring the prosecution in an AKS case to prove "that the remuneration was offered or paid as a quid pro quo in return for the referring of the patient"); Substantive Jury Instructions at 5, United States v. Reichel, Crim. No. 1:15-cr-10324 (D. Mass. June 17, 2016), ECF No. 244 ("In order to be a relevant inducement [under the AKS] the remuneration must involve an intent to execute a quid pro quo transaction. A defendant cannot be convicted of the Anti-Kickback Statute merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions. If the remuneration is only for a purpose other than seeking to effect a quid pro quo transaction of payments of remuneration for order or purchase of drugs, it is not within the scope of the Anti-Kickback Statute."). In order to survive summary judgment, the Government must have evidence that doctors were parties to a

quid pro quo arrangement, including that they knowingly and willfully entered into such an arrangement, and that claims for NPC's drugs resulted from the quid pro quo.

Contrary to its allegation in the Amended Complaint, the Government has failed to present evidence that tens of thousands of doctors knowingly and willfully accepted kickbacks in exchange for prescribing NPC's drugs. The Government merely argues that these doctors attended speaker programs in a manner that hits on one of three "markers", without any proof that these doctors were part of a quid pro quo arrangement, agreed to participate in such arrangement or even were aware that they had been invited to enter into such arrangement.[69] In its motion to dismiss opinion, this Court ruled that the Complaint was "sufficient to support a strong inference that the doctors knowingly and willfully violated the anti-kickback laws when they wrote prescriptions for NPC drugs in exchange for this remuneration". (Mem. Op. and Order at 34, ECF No. 110.) The Court based its ruling on "a strong inference that the doctors recognized that the NPC speaker events were shams", as "[t]he doctors allegedly attended and/or were paid to speak at lavish events at which there was no substantive presentation about or discussion of NPC drugs." (Id.) But the Government now contends that most of the challenged events involved substantive content, and that some doctors in attendance benefitted from it, while others did not, based solely on the satisfaction of one of the Government's three markers. The idea that these markers, which the Government came up with years after the events at issue, somehow reflect a quid pro quo arrangement between certain doctors and NPC is untenable.

[69] As explained supra in Section I.B., the Government does not even have sufficient evidence to infer the factual predicate—that NPC's speaker programs lacked educational value. The Government cannot use an unreliable inference about a factual predicate as a basis to also infer a quid pro quo relationship.

IV. NPC IS ENTITLED TO SUMMARY JUDGMENT ON CLAIMS BASED ON IN-OFFICE LUNCH PROGRAMS THAT WERE NEVER PART OF THIS CASE.

From the beginning, this case has been about out-of-office promotional programs: (1) speaker programs, which are programs held at restaurants where a speaker, who is a doctor, presents medical information about a specific drug and then conducts a question and answer session; and (2) roundtables, which are programs held at restaurants where several doctors engage in a group discussion about a specific drug and there is no speaker. Throughout fact and nearly all of expert discovery, the Government's case did not implicate in-office meetings, which occur when a sales representatives brings sandwiches or snacks to a doctor's office and "details"[70] a drug to the doctor and other personnel over lunch—also known as "lunch-n-learns". The Government's Amended Complaint does not reference in-office lunch-n-learns as potential kickbacks—not one was included among the events alleged to have been kickbacks in the Amended Complaint. At multiple depositions during fact discovery, Government counsel caveated their questions to clarify that "promotional events" at issue did not include "lunch-n-learns".[71] And, consistent with its treatment of the case for almost seven years, the Government's opening expert reports did not include lunch-n-learns in its damages calculations, as the Government initially instructed its experts to exclude lunch-n-learns from their marker analyses.[72]

Only when NPC's experts pointed out that thousands of lunch-n-learns remained in the Government's damages calculation did the Government abruptly change its position. Just a few months ago, the Government served rebuttal expert reports in which the Government

[70] Detailing is the practice by sales representatives of presenting the benefits and risks of a medicine to healthcare providers to convince a physician to prescribe it in appropriate cases. (See Gaier Rep. ¶ 52; SUMF ¶ 37.)

[71] See, e.g., SUMF ¶ 32.

[72] Goldberg Rep. at 9, n.12; Goldberg Dep. Tr. 216:7-18, 221:23-222:3, 225:6-226:16.

included in-office lunch-n-learns as sources of kickbacks to physicians.[73] By including lunch-n-learns, the rebuttal expert reports more than doubled the number of alleged trigger events and nearly doubled the Government's potential damages claim.

The Government justifies this radical shift by claiming that "[l]unch-n-learns were added to the rebuttal analyses once NPC confirmed that lunch-n-learns were a form of roundtables." (Ltr. from J. Vargas at 5 n.4, ECF No. 215.) As explained more fully below, this claim inaccurately characterizes NPC's representations and also ignores data that the Government has had since the early days of discovery.

In excluding lunch-n-learns for nearly all of discovery, the Government failed to elicit sufficient evidence to survive summary judgment. Indeed, its experts have performed no analysis of them, apart from calculating damages for them in their rebuttal reports. Nor could they, as their three markers cannot plausibly be applied to these in-office programs. Allowing the Government to add lunch-n-learns to the case at this last stage would be highly prejudicial to NPC; it deprives the Company of the opportunity to defend these programs during discovery and it significantly increases the number of allegedly sham events and damages. Accordingly, summary judgment should be granted with respect to these claims. See, e.g., Family Dollar Stores, Inc. v. United Fabrics Int'l, Inc., 896 F. Supp. 2d 223, 235 (S.D.N.Y. 2012); Aldridge v. Forest River, Inc., 635 F.3d 870, 875 (7th Cir. 2011); Oracle USA, Inc. v. SAP AG, 264 F.R.D. 541, 544 (N.D. Cal. 2009).

A. Factual Background

In-office lunch programs are promotional meetings at which a sales representative details doctors over inexpensive food (typically under $25 per person) brought into a physician's

[73] See generally Goldberg Rebuttal Rep.

office.[74] These in-office lunches do not involve any honoraria payments to physicians.[75] At these "events", the sales representative delivers a detailing message to doctors similar to the one he or she does on a regular sales call. As Dr. Rebecca Clarke, the Government's marketing expert, testified, there is no distinction in content between the promotional message at an in-office lunch meeting and a regular call by a sales representative.[76]

Data about lunch-n-learns were included in databases that NPC produced to the Government in 2012. Those databases included three main categories of "event type"—Speaker Programs, Roundtables (through 2008) and Lunch-n-Learns.[77] The separate lunch-n-learn category was added only in January 2006; prior to that time all in-office lunch-n-learns were included within the "Roundtable" category.[78] However, it is evident in the data that numerous pre-2006 roundtable programs were actually in-office lunch-n-learns, as the listed locations are clearly doctors' offices and the description of the food provided delineates a quick-service meal (e.g., Dunkin Donuts):[79]

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[74] SUMF ¶ 31.

[75] Id. ¶ 53.

[76] Clarke Dep. Tr. 70:11-71:4.

[77] SUMF ¶¶ 34-36. These event types are sometimes referred to in the data as "REF-Speaker Program", "REF-Roundtable", or "REF-Lunch-n-Learn". "REF" stood for "Reference", and reflected the source of funds for these programs.

[78] Id. at ¶¶ 35-36.

[79] NPC's expert opines that over 75,000 Roundtable events are actually in-office lunches based on the description of the location as a doctor's office or venue as one unlikely to host an event (such as Panera or Subway). (Gaier Rep. at ¶ 130, App'x F.)

Event ID (evt_id)	Event type (event type)	Event title (evt_titl)	Location (location)	Event date (evt_start_dt)
801-9EX	REF-ROUNDTABLE	HEALTHY BP	DUNKIN DONUTS/DR. ROOSEL'S OFFICE	4/7/2004
F8K-P18	REF-ROUNDTABLE	BP SUCCESS ZONE IN-SERVICE	ALBANOS OFFICE/PANERA	8/23/2005
I3F-JQD	REF-ROUNDTABLE	BP SUCCESS ZONE IN-SERVICE	DR. MOUSSLY'S OFFICE/ BOSTON MARKET	8/10/2005

All this was necessarily evident to the Government, which had NPC's event databases well before intervening in 2013, showing that lunch-n-learns were a distinct event type as of 2006 and that thousands of pre-2006 roundtables were in-office lunch presentations. Produced documents, including those marked as exhibits at depositions, further showed that the category "roundtables" included lunch-n-learns prior to 2006.[80] Other documents showed that that lunch-n-learns were separated from roundtables in January 2006.[81]

B. The Government Has Insufficient Evidence To Survive Summary Judgment for Lunch-n Learns.

The Government, which expressly excluded lunch-n-learns from discovery, uncovered insufficient evidence related to them to withstand summary judgment.

i. The Government excluded lunch-n-learns from fact discovery.

The Government lacks record evidence and testimony that lunch-n-learns served as kickbacks—indeed, it explicitly carved out lunch-n-learns during fact discovery. At multiple depositions, Government counsel directed witnesses that it was not including lunch-n-learns in its definition of promotional events in this case. (See, e.g., SUMF ¶ 32, Chen Dep. Tr. 19:1-15 ("Q. Okay. So from this point forward I'm going to use the term 'promotional events'—to refer

[80] See, e.g., SUMF ¶ 35.

[81] See, e.g., id. ¶ 36.

to speaker programs and Roundtables, but it's not going to refer to Lunch & Learns. A. Okay.") (emphasis added).)

ii. The Government initially excluded lunch-n-learns from expert discovery.

The Government similarly excluded lunch-n-learns from its initial expert reports. Those reports revealed that the Government instructed its experts to take two actions removing in-office lunch programs from the case. First, it instructed its experts not to include "REF-LUNCH & LEARN" as an event type in their damages calculations.[82] Second, it had its experts remove any Roundtable or Speaker Program event from their calculations that had both of the words "lunch" and "learn" in the event title, again so as to leave in-office lunches out of the case.[83]

Any suggestion the Government makes now to justify its late addition of hundreds of thousands of events and millions of prescriptions on the ground that it did not know that in-office lunches were "a form of roundtables" (as it has claimed in its March 19, 2018 letter to the Court) is not plausible. (See Ltr. from J. Vargas at 5 n.4, ECF No. 215.)

C. Lunch-n-Learns Do Not Fit Within the Government's Markers.

The Government's experts did not consider lunch-n-learns when they developed their three kickback "criteria", and it is nonsensical to apply the markers to these in-office programs.

[82] Goldberg Dep. Tr. 225:6-226:16; Goldberg Rep. at 13.

[83] Goldberg Rep. at 13. As NPC's expert Eric Gaier pointed out, the Government's experts did not go far enough to capture lunch-n-learns that were roundtables by searching only for the term "lunch" and "learn" in the event title. (Gaier Rep. ¶ 34.) Using additional searches such as "Dunkin Donuts" and "Panera" as well as searches such as "doctor" or "medicine" NPC's experts show that thousands of obvious lunch-n-learns remained in their analyses despite Goldberg's attempt to eliminate them from the analysis. (See Gaier Rep. App'x F.)

The Government claims its first marker—attending three or more programs on the same drug over six months—shows that there is no educational purpose for a doctor to go to a program in such circumstances, implying that he or she was only there because NPC offered a lavish meal as an inducement. While NPC vigorously disputes that characterization, in-office lunches involve none of the same considerations. A doctor does not go to the meeting; instead, a sales representative who regularly calls on the doctor comes to the doctor's office. At that meeting, the sales representative delivers a variation on his or her sales message—there are no slides, no medical presentations led by a physician, and no honoraria payments. There is no meal at a "high-end" restaurant as the Government alleged in its Amended Complaint—just sandwiches or take-out food served in a doctor's office.

Lunch-n-learns even more clearly do not fit into the other two Government markers. As there is no paid speaker at these events, the marker barring attendance at a program by a paid and trained speaker is wholly inapplicable. The final marker—attending three or more programs over $125 per person within 12 months—is also inapplicable. Lunch-n-learns were not "lavish" meals at high-end restaurants; rather, they were in-office presentations made by sales representatives involving lunches and snacks from coffee and sandwich shops.

D. The Court Should Dismiss Claims Regarding Lunch-n-Learns Given the Extreme Prejudice to NPC.

Allowing a new theory of liability based on lunch-n-learn programs at this late date—nearly five years after the Government intervened—will result in prejudice to NPC. Fact discovery focused on restaurant events and speaker programs and has long ago concluded. Were lunch-n-learns part of this case, NPC's counsel would have probed the reasons sales representatives and doctors participated in them, including the subjects discussed and even the nature of the meals provided—all to rebut the suggestion that lunch-n-learns were illegal

kickbacks. NPC's experts conducted their analyses without considering in-office lunches as potential kickback events (as the Government's expert which they rebutted did the same).

Courts have rejected similar attempts by plaintiffs to shift theories of liability and damages at the last minute. For example, the court in United States v. Quicken Loans, No. 16-CV-14050, 2018 WL 1870605, at *2 (E.D. Mich. Apr. 19, 2018), prohibited the Government from trying to add new theories of fraud to its FCA complaint. In Quicken Loans, the district court directed the government to list the loans supporting its FCA claim. Id. at *1. The government's response included loans that the government alleged as fraudulent for reasons that went beyond the four allegedly fraudulent practices in its complaint. Id. The court indicated the government would not be allowed to expand the case, stating that "[h]aving successfully pled four specific flavors of fraud, the government must now be restricted to those categories." Id. at *2. The court further indicated that the government would "face a stiff headwind" with its motion to amend given a "strong case of prejudice" to defendant even though fact discovery had not concluded. Id. at *2, n.1.[84] Here, the prejudice is much more palpable as fact and expert discovery have concluded and NPC has had no ability to develop facts or expert opinions to defend against this new "flavor" of fraud. Accordingly, the Court should dismiss any FCA claim the Government now asserts based on a lunch-n-learn program.

[84] See also Family Dollar Stores, Inc., 896 F. Supp. 2d at 235 (rejecting amendment of the complaint post-discovery to add a new theory of copyright infringement, finding that it was "a blatant attempt to change the theory of the case after the close of discovery"); Oracle USA, Inc., 264 F.R.D. at 544 (N.D. Cal. 2009) (granting a motion to preclude plaintiff from seeking categories of lost profit damages that differed from the categories it had described in multiple discovery responses and representations to the court); Aldridge, 635 F.3d at 873, 875 (affirming a district court's ruling barring a plaintiff from changing her theory "at the eleventh hour" as to what part of a recreational vehicle caused her injuries and holding that the ruling "was consistent with the nature of the litigation from the beginning of the case and it prevented surprise to the defendants regarding the nature of the case that they had been defending throughout the litigation").

CONCLUSION

For the foregoing reasons, NPC respectfully requests that the Court grant its Motion for Summary Judgment.

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Respectfully submitted,

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