U.S. Department of Justice

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March 19, 2018

BY ECF and FACSIMILE (212) 805-7986
Hon. Paul G. Gardephe
United States District Judge
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *United States v. Novartis Pharmaceutical Corp.*, No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

The United States of America submits this letter in response to Novartis Pharmaceutical Corporation's ("NPC") March 14, 2018, request for a pre-motion conference ("NPC Ltr."). As discussed in detail below, the grounds set forth as the bases for the proposed motion are meritless. Moreover, none of the arguments that NPC proposes to raise would dispose of this case; NPC's arguments go only to the scope of the Government's claims and damages. Thus, while the Government does not oppose NPC's request to set a briefing schedule for its proposed summary judgment motion, the ultimate resolution of this case of enormous public concern should not be unduly delayed by the filing of this meritless motion. Because a trial will need to be held on the Government's claims regardless of the outcome of NPC's motion, the Government respectfully requests that the Court set a trial date and other pretrial deadlines, including a briefing schedule for any *Daubert* motions, at the conference scheduled for April 19.

The Government has alleged—and discovery has borne out—that, from January 2002 through November 2011, NPC engaged in a nationwide kickback scheme to induce doctors and other health care practitioners ("HCPs") to increase the number of prescriptions they wrote for certain of its drugs. Specifically, the Government has alleged that NPC provided HCPs with remuneration in the form of honoraria, lavish meals, and other benefits, under the guise of hosting professional meetings for the ostensible purpose of educating doctors regarding its products. The Government alleges that this scheme violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), thus rendering any claims submitted to federal health care programs for the prescriptions written by doctors who received such kickbacks false and fraudulent within the meaning of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"). The grounds on which NPC now proposes to move for summary judgment are wholly without merit.

First, NPC claims that it is entitled to summary judgment as to claims for which the Government intends to rely solely upon so-called "markers" to show that NPC, in providing

HCPs with remuneration, did so with the requisite intent to violate the AKS, i.e., knowingly and willfully for the purpose of inducing doctors to prescribe NPC medications. NPC Ltr. at 2. This argument is flawed in numerous respects.

The Government's 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. For example, the Government intends to introduce the testimony of numerous NPC sales representatives from across the country, who will confirm that they were, in the words of one witness, "essentially buying scripts" by providing HCPs with paid speaking opportunities, lavish meals, alcohol and other benefits in exchange for promises to write NPC prescriptions. HCPs will in turn testify that, based upon their interactions with NPC sales representatives, they understood that they had been invited to attend speaker programs and roundtables because NPC wanted to induce them to write more NPC prescriptions. Both HCPs and sales representatives will testify that HCPs got paid as speakers for events that never took place, that HCPs took turns playing the part of paid speaker and attendee at events, and that many events included little to no educational content and were primarily social in nature. The Government will also introduce evidence regarding NPC's compensation scheme for its sales representatives, to demonstrate how NPC deliberately incentivized its sales force to organize promotional events that provided HCPs with perks. Additionally, the Government will show that NPC's compliance program was close to non-existent for most of the relevant time period, further evidence of the intentional nature of NPC's conduct.

Despite this wealth of evidence, NPC insists that the Government's proof of intent will not include "particularized evidence." NPC Ltr. at 2. NPC does not explain what it means by this term, and thus it is difficult to respond to this point. To the extent this term refers to evidence regarding specific events, the Government is prepared to offer a great deal of "particularized evidence" regarding each of the events at issue in this litigation. The Government intends to introduce, *inter alia*, NPC's own business records regarding its speaker programs and roundtables, including event-specific information from NPC's event databases and available back-up documentation such as slide presentations. These business records constitute "particularized evidence" of material facts regarding each specific event, such as the date of a particular event; which HCPs attended a particular event; the purported topic of each event; the venue where the event took place; how much NPC spent per person on meals at each event; which HCPs attended the same events repeatedly; which HCPs repeatedly enjoyed meals paid for by NPC with just one or two of their colleagues or family members; and the honoraria earned by HCPs at such events.

To the extent NPC's argument regarding "particularized evidence" is intended to suggest that the jury cannot infer that an HCP received a kickback in connection with an event based upon the circumstances in which that event occurred (such as the venue, the spend amount, or an HCP's repeated attendance), that argument is clearly meritless. What NPC refers to as "markers" are merely the same indicia of kickbacks that this Court has already determined are probative of whether an AKS violation occurred. Specifically, this Court has previously held that the existence of kickbacks could be "evidenced by the fact that (1) NPC sales representatives repeatedly invited the same participants and 'speakers' to attend events concerning the same drug or topic in a short span of time; [and] (2) NPC spent exorbitant amounts of money on these

events, both at the macro level and at the individual event level . . . ." Mem. Op. & Order dated Sept. 30, 2014 (Dkt. No. 110) at 26.[1] This holding is entirely consistent with the numerous cases that have held that fraudulent intent can be inferred from surrounding circumstances, including "badges of fraud." *See, e.g.*, *In re Sharp Int'l Corp.*, 403 F.3d 43, 56 (2d Cir. 2005).

For this reason, the Government's reliance upon an expert witness in medical education to identify activities that inherently serve no legitimate medical educational purpose is entirely appropriate. The Government's expert will explain, *inter alia*, that NPC could not have reasonably thought that its programs on a particular drug (which were simplistic and redundant in content) would be informational as to the HCPs who attended more than three events in a six-month period, as the repetitive presentation of simplistic concepts to a medical audience would be inherently lacking in educational value. Such evidence serves to demonstrate that NPC's stated justification for the remuneration provided at such events—that it was incidental to valid educational programs—is pretextual. A jury can permissibly infer from this evidence that those HCPs who fall within this category were recipients of illegal kickbacks.

Because the Government intends to introduce particularized evidence regarding each of the events at issue, NPC's reliance upon *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016), NPC Ltr. at 2, is entirely misplaced. *Wall*, which considered a motion to strike expert witness testimony, addresses whether it is appropriate to use statistical sampling and extrapolation to establish the number of potentially false hospice eligibility certifications. *Id*. at *11-*12. As the Government is not intending to rely upon statistical sampling or extrapolation as a method for establishing liability, cases regarding the admissibility of statistical sampling are inapposite.

Second, NPC's proposed argument regarding causation fails both legally and factually. To establish causation, the Government must demonstrate that NPC's payment of kickbacks to HCPs caused the submission of a claim for payment that was false or fraudulent. *See* 31 U.S.C. § 3729(a)(1). To carry this burden, it is sufficient for the Government to show that (1) NPC provided kickbacks to HCPs, (2) the HCPs then wrote prescriptions for the NPC drugs at issue and (3) the pharmacies that filled those (kickback-tainted) prescriptions submitted at least one claim for payment in connection the prescriptions.[2] *See U.S. ex. Rel. Greenfield v. Medco Health Sols.*, 880 F.3d 89, 98-99 (3d Cir. 2018). The Government is not required to show that the kickbacks caused the HCPs to write prescriptions that they otherwise would not have written. *See id.* at 98 (refusing to require an FCA plaintiff to show that the kickback was the "but for" cause of the claim); *accord U.S. ex rel. Arnstein v. Teva Pharm. USA, Inc.*, No. 13-3702, 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016); *U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F.

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[1] NPC argues that the Government has "fundamental[ally] shift[ed] [its] theory of the case." NPC Ltr. at 2. This is not true. NPC insists that, until recently, the Government's case was built upon nine so-called "markers" that it planned to use to identify kickbacks at trial. As the Government has repeatedly and exhaustively explained to NPC, however, including in the letter filed with the Court on March 22, 2017 (Dkt. No. 197), that is not and never was the methodology that the Government intended to rely upon to prove its case at trial. Accordingly, NPC's claim that the Government has now "abandoned" its theory of its case is disingenuous.

[2] At a minimum, such a kickback-tainted claim would be impliedly false.

Supp. 3d 323, 331-32 (S.D.N.Y. 2014). This is because "the focus of the AKS is not the success of the bribe, but the bribe itself," *Arnstein*, 2016 WL 750720, at *17, and "[t]he Government does not get what it bargained for when a [party] is paid by CMS for services tainted by a kickback," *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011).

In light of the above, NPC's causation argument—that "[t]he Government has not presented any admissible evidence of causation" because its damages expert has not reliably "identif[ied] the HCPs who were actually influenced by the alleged kickbacks," NPC Ltr. at 3-4 & n.2—fails as a matter of law. As the above cases make clear, whether an HCP was "actually influenced" by a kickback is irrelevant to liability. It is also irrelevant to damages, as damages in a kickback case like this are based on the cost to the Government of prescriptions that were tainted by the kickbacks, since, as set forth above, the Government does not get what it bargained for (*i.e.*, the certainty that HCPs will exercise independent medical judgment in making prescribing decisions) when a claim is paid for services tainted by a kickback. *See Wilkins*, 659 F.3d at 314.

NPC's causation argument is also factually incorrect, because although the Government need not prove that HCPs "prescrib[ed] more as a result of . . . kickbacks," NPC Ltr. 3-4, the Government is prepared to do so at trial. One of the Government's experts, a Nobel Prize-winning econometrician, has created two sophisticated regression models that show that NPC's kickbacks caused HCPs to write more NPC prescriptions than they would have absent those kickbacks. One model measures the effect of the kickbacks across the set of HCPs who received kickbacks and shows that, on average (*i.e.*, in the aggregate), those HCPs wrote more prescriptions of the at-issue drugs than they would have without the kickbacks. The other model looks at the effect of the kickbacks on each kickback-receiving HCP individually, and similarly shows that NPC's kickbacks caused tens of thousands of those HCPs to write more prescriptions than they would have but for the kickbacks. Even the model proposed by NPC's expert, which is biased against finding causation or damages, finds that the kickbacks at issue caused tens of thousands of HCPs to write more prescriptions than they would have absent the kickbacks.

Third, NPC's argument based on the release encompassed in the September 30, 2010 settlement (the "2010 Settlement") is unavailing. The 2010 Settlement released claims that the United States "has or may have for the Covered Conduct," which, as relevant here, was specifically limited to NPC's provision in 2002 through 2009 of "illegal remuneration, through mechanisms such as speaker programs . . . to health care professionals to induce them to promote and prescribe the drugs Diovan® . . , Exforge®, and Tekturna® in violation of the [AKS]." Dkt. No. 126-1 at 3-4, 6. The 2010 Settlement does not release, nor even mention, the HCT versions of these drugs. As the Court has done previously, Dkt. No. 130 at 6, it should reject NPC's attempt to expand the scope of the 2010 Settlement beyond its unambiguous language.

Fourth, with respect to materiality, courts have long recognized—including in decisions issued since *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016)—that violations of the AKS are material to the Government's decision to pay for kickback-tainted claims. *See, e.g.*, *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817-18 (S.D.N.Y. 2017) ("[T]he Court has no trouble concluding that compliance with the AKS is a 'material' condition of payment."); *Kester*, 41 F. Supp. 3d at 330 (observing that "[c]ourts have long held" that "compliance with the AKS is a precondition to the payment of Medicare and Medicaid

claims"). In an effort to avoid this precedent, NPC focuses on the mechanisms that the Government alleges were used to provide HCPs with kickbacks and argues that the Government has "failed to assemble any admissible evidence" that the relevant federal healthcare programs would have refused to pay claims associated with HCPs who received kickbacks in that specific manner.[3] NPC Ltr. at 4. This argument fails because it is based on a false premise: that only some kickbacks are material to the Government's payment decisions. As the above-referenced case law makes clear, all kickbacks are material, because "[t]he Government does not get what it bargained for when a [party] is paid by CMS for services tainted by a kickback." *Wilkins*, 659 F.3d at 314. In any event, the Government identified in its Rule 26 disclosures witnesses from the relevant federal healthcare programs who, if necessary, will testify as to the materiality of the particular kickbacks at issue in this case.

Fifth, NPC is not entitled to carve out of this case those kickbacks that it provided to HCPs in connection with "lunch-n-learn" events. NPC acknowledges that the lunch-n-learns were a type of "roundtable" event, *see* NPC Ltr. at 4 (describing lunch-n-learns as "in-office roundtable[s]"), and there is no dispute that roundtable events are part of this case. Ignoring this, NPC argues that lunch-n-learns were not the subject of fact discovery, and therefore the Government has no admissible evidence that lunch-n-learns were kickbacks. But, during discovery, NPC produced tens of thousands of documents relating to lunch-n-learns, as well as data reflecting, *inter alia*, the dates, locations, attendees, meal spends, and relevant drugs and topics for hundreds of thousands of lunch-n-learns (notably, notwithstanding the representation in NPC's letter that lunch-n-learns had a $25 per person cap, *id.* at 5, the data reflects that tens of thousands of the lunch-n-learns had a per-person cost that exceeded this $25 cap). Moreover, numerous witnesses discussed lunch-n-learns during their depositions. Using this information, the Government will be able to show that NPC used both out-of-office and in-office roundtables—the latter being lunch-n-learns—to pay kickbacks to doctors.[4]

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[3] NPC suggests that materiality requires a showing that the federal healthcare programs "would have refused to pay the claims" had they known about the kickbacks, but that is not the standard. "As *Escobar* made clear, the [challenged conduct] does not have to be so grievous that the government would have completely denied payment upon discovering the truth — it is enough that the [conduct] would have affected the government's payment decision." *U.S. ex rel. Hussain v. CDM Smith, Inc.*, No. 14-9107, 2017 WL 4326523, at *8 (S.D.N.Y. Sept. 27, 2017).

[4] NPC suggests that the Government only included lunch-n-learns in its rebuttal analyses because it had erroneously included some of those events in its initial expert analyses. NPC Ltr. at 5. That is simply not true. Lunch-n-learns were added to the rebuttal analyses once NPC confirmed that lunch-n-learns were a form of roundtables. In any event, why lunch-n-learns were excluded from the experts' initial analyses is irrelevant to whether they are properly part of this case. NPC has conceded that the only substantive difference between lunch-n-learns and roundtables is that the former took place in doctor's offices and the latter took place at outside venues. Both are roundtables, both involved NPC providing remuneration (in the form of meals) to HCPs, and thus both are properly part of this case.

Respectfully,

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