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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES, et al. ex rel.
OSWALD BILOTTA,

Plaintiffs and Relator,

-against-

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

ORDER

11 Civ. 0071 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

In this qui tam action, Relator Oswald Bilotta – a former Novartis sales representative – alleges that Defendant Novartis Pharmaceuticals Corporation violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B), and related state laws by (1) causing false claims for reimbursement for patient prescriptions – which were allegedly written by health care providers in exchange for kickbacks – in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and related state laws; and (2) promoting the drug Valturna for off-label use, thereby causing the submission of false claims to federal and state health care programs. The United States (the "Government") and the State of New York have intervened as to the Anti-Kickback claims.

Plaintiffs contend that speaker events were a primary vehicle for Defendant's allegedly improper transmission of money to health care providers. More than one million speaker events are implicated by the claims in this lawsuit. (See Dec. 6, 2016 Tr. (Dkt. No. 187) at 5-6) Discovery is ongoing, and the Government has moved to compel Novartis to produce back-up documentation concerning 79,236 speaker events. The requested documents fall into

five categories: (1) the Advance Health Media ("AHM") database[1]; (2) honoraria to speakers; (3) PowerPoint presentations used at speaker events; (4) internal Novartis reports of investigations and final dispositions concerning complaints regarding speaker programs; and (5) back-up documentation concerning speaker events located within the electronically stored information ("ESI") of 363 sales representatives ("sales reps"), in addition to the searches of the 150 sales reps whose ESI Novartis has already produced. (See Dec. 6, 2016 Tr. (Dkt. No. 187) at 10-16) The requested documents concern, inter alia, speaker event topics; the location of speaker events; attendees; materials distributed at speaker events; invoices associated with speaker events; and possible violations of company policy. (Dkt. No. 150; Dec. 6, 2016 Tr. (Dkt. No. 187) at 10-16)

Novartis argues that the Government's motion to compel should be denied because – during nine months of negotiations regarding discovery (see Apr. 7, 2016 Tr. (Dkt. No. 163) at 3, 24, 28) – the Government waived any right to request back-up documentation for speaker events beyond 6,600 events it had initially identified. (See Novartis Br. (Dkt. No. 155) at 9-10) The Government contends, however, that the documents sought in its motion to compel were never the subject of the nine-month negotiation.

Novartis contends that it would be enormously burdensome for it to produce back-up documentation for the 79,236 speaker events, because the requested documents are not stored in a centralized database, and Novartis would be required to "search[] the email files of more than 5,000 sales representatives." (Folch Decl. (Dkt. No. 154) ¶ 38; Novartis Br. (Dkt. No. 155) at 22) The Government maintains, however, that the "back-up documentation [is] stored in

[1] AHM is a third-party vendor employed by Novartis to store back-up documentation concerning post-2007 speaker programs. (See Novartis Br. (Dkt. No. 155) at 21; Dec. 6, 2016 Tr. (Dkt. No. 187) at 10, 42)

one or more central repositories within Novartis, and [is] therefore not difficult to access." (Folch Decl. (Dkt. No. 154) ¶ 9(c)) The Government further contends that the back-up documentation is necessary because event data previously produced by Novartis are incomplete. (See Dec. 6, 2016 Tr. (Dkt. No. 187) at 6)

This Court finds that the Government never agreed to forego production of back-up documentation for the 79,236 speaker events, and further finds that these events and the underlying documents are central to the Government's claims. Accordingly, Novartis will be ordered to produce the AHM database information and documents regarding honoraria to speakers, PowerPoint presentations used at speaker events, and reports of investigations. As to sales rep ESI, however, the Court finds that the Government entered into an agreement with Novartis in which it agreed to limit its ESI discovery requests to 150 sales reps. The Government's motion to compel Novartis to search the ESI of an additional 363 sales reps will therefore be denied.

BACKGROUND

I. NATURE OF DISPUTE

The Amended Complaint alleges that from January 2002 through at least November 2011, Novartis systematically bribed doctors to induce them to write prescriptions for Novartis cardiovascular drugs. (Am. Cmplt. (Dkt. No. 62) ¶¶ 1, 71, 75, 77) The drugs at issue include Lotrel, Diovan, Diovan HCT, Tekturna, Tekturna HCT, Exforge, Exforge HCT, Valturna, Tekamlo, and Starlix. (Id. ¶ 66) According to the Government, Novartis sold these drugs through sales representatives who met with health care providers throughout the United States. (Id. ¶ 67) Novartis induced doctors to prescribe these drugs primarily through the use of "sham" speaker events. (Id. ¶¶ 1-3) Although the speaker programs purported to educate doctors about

Novartis drugs, according to the Government, the events contained little or no educational content. (Id.) Instead, Novartis used these sham events to provide doctors with remuneration in the form of honoraria, dinners at high-end restaurants, and entertainment. (Id.)

The Government's first set of document requests and interrogatories was served on September 20, 2013. (Govt. First Doc. and Interrog. Req. (Dkt. No. 154-1)) Document Request 8 is a broad request for a wide range of documents concerning speaker events, and encompasses documents discussing or reflecting event topics; event locations; scheduling; materials used or distributed during the events; attendance and registration for speaker events; the recruitment or selection of doctors who spoke at or attended the events; remuneration or other benefits provided to speakers or attendees; expenses associated with speaker events; violations of company policy; procedures and practices for speaker events; and the effect of speaker events on sales and market share (collectively, the "back-up documents").[2] (Id. ¶ 8; Folch Decl. (Dkt. No. 154) ¶ 3a; Dec. 6, 2016 Tr. (Dkt. No. 187) at 9-10)

The Government's Document Requests 2-5 target Novartis sales representative communications and incentive programs relating to speaker events. These document requests concern, inter alia, communications of Novartis sales representatives and managers regarding speaker events; sales rep compensation structure, including bonus, commission, and other incentives associated with speaker events; budgets, targets, goals, or quotas for sales reps; and the training of sales reps in connection with speaker programs ("sales rep materials"). (Govt. First Doc. and Interrog. Req. (Dkt. No. 154-1) ¶¶ 2-5; Folch Decl. (Dkt. No. 154) ¶ 3b)

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[2] The Government served a second set of document requests and interrogatories on May 1, 2015. Document Request 1 in the Government's second set of document requests is nearly identical to Document Request 8 in the Government's first set of document requests. (Compare Govt. First Doc. And Interrog. Req. (Dkt. No. 154-1) ¶ 8 (Doc. Req. No. 8) with Novartis Resp. and Obj. to Govt. Second Doc. And Interrog. Req. (Dkt. No. 158-5) at 17-18 (Doc. Req. No. 1))

The instant discovery dispute stems from a disagreement about whether the parties' nine months of negotiations concerning discovery – which culminated in Novartis's proposed discovery "protocol" of June 16, 2015 – encompassed both the Government's request for back-up documentation (Document Request 8) and the requests regarding sales rep ESI (Document Requests 2-5), or only concerned sales rep ESI. Novartis contends that the parties' negotiations addressed both categories, while the Government contends that the parties' negotiations and Novartis's proposed discovery "protocol" only concerned sales rep ESI.

II. THE PARTIES' DISCOVERY NEGOTIATIONS

Because the quantity of documents potentially relevant to the Government's claims in this case is massive, the parties entered into negotiations regarding the appropriate scope of discovery soon after this lawsuit was filed. From the outset, the parties' correspondence reflects a distinction between back-up documents and sales rep materials. See, e.g., Mar. 6, 2015 Govt. email (Dkt. No. 154-3) at 2; (Dkt. No. 158-3) at 2; Mar. 18, 2015 Novartis email (Dkt. No. 154-4) at 2-4; (Dkt. No. 158-2) at 5))

Much of the negotiation – conducted through an exchange of email proposals and counterproposals and multiple "meet and confers" – was aimed at developing a protocol for conducting searches of the ESI of Novartis sales reps. With respect to searches of sales rep ESI, the parties agreed to limit such searches to a specific number of sales reps. The Government agreed to provide Novartis with "an initial list of events . . . from which the parties [would] identify a set number of sales representatives/manager custodians" (see July 27, 2015 Govt. email (Dkt. No. 158-4) at 2) until a maximum of 300 sales representatives had been identified. (June 16, 2015 Novartis email (Dkt. No. 158-4) at 14) The Government subsequently agreed to limit the maximum number of sales reps to 150. (Folch Decl. (Dkt. No. 154) ¶ 24; Dec. 29, 2015

Govt. email (Dkt. No. 158-9) at 5; Feb. 2, 2016 Govt. email (Dkt. No. 158-10) at 2) The Government also identified approximately 6,600 speaker events for which it sought event-specific documents from the ESI of the 150 sales rep custodians. (Apr. 7, 2016 Tr. (Dkt. No. 163) at 16)

In a nine-page, single-spaced email dated June 16, 2015, and in earlier emails referenced in the June 16, 2015 email, Novartis proposed a protocol for conducting electronic searches at Novartis's headquarters, including, inter alia, the selection of headquarters custodians, search terms, and sales rep custodians. (June 16, 2015 Novartis email (Dkt. No. 158-4) at 10-18) Novartis relies on this email to argue that the Government waived its right to seek back-up documents for speaker events beyond the 6,600 initially identified. (Novartis Br. (Dkt. No. 155) at 9-10) There is no evidence that the Government accepted Novartis's proposed "protocol" for these discovery materials, however. Indeed, within a month of Novartis's June 16, 2015 "protocol" email, the Government made clear that it had never agreed to limit its requests for back-up documents to the 6,600 speaker events initially identified:

> [I]n agreeing that the universe of [sales representative] custodians could be identified by reference to specific events, we did not thereby agree that the scope of discovery from such custodians would also be limited to those events. The discovery requests themselves are not event-specific, and our interest in these records goes beyond documents specifically concerning the limited number of events that we are using to identify a potential custodian group.

(July 15, 2015 Govt. email (Dkt. No. 158-4) at 9-10)

On July 29, 2015, in connection with the Government's first motion to compel (Dkt. No. 126), this Court ordered Novartis to produce information regarding "all ten drugs at issue in this case for the time period between January 1, 2002 and November 30, 2011." (July 29, 2015 Order (Dkt. No. 130) at 9) Novartis produced speaker event data responsive to the Court's July 29, 2015 Order on September 9, 2015. (Folch Decl. (Dkt. No. 154) ¶ 17) "Having

received eight years' worth of Speaker Program Data from Novartis in September [three months after the "protocol" email] . . . . [o]n November 27, 2015, the Government sent Novartis a list of 79,236 [speaker] events it alleged to be shams." (Id. ¶ 30; see Nov. 27, 2015 Govt. Ltr. (Dkt. No. 158-7) at 3) The Government took the position that now that it had "identified for [Novartis] the specific events upon which [the Government] is basing its claims," Novartis was obligated to produce "all documents responsive to Document Request No. 8 that are associated with those events." (Dec. 23, 2015 Govt. email (Dkt. No. 158-8) at 3; (Dkt. No. 154-8) at 3)

Novartis responded that it had "grave concerns about the scope and burden" of the Government's "request for 'back-up materials' for more than 79,000 events." (Jan. 11, 2016 Novartis email (Dkt. No. 158-9) at 3) Novartis claimed that "the whole purpose of [the] protocol was to define and govern the scope of discovery . . . including with respect to specific sales representatives and events – that would satisfy [Novartis's] obligations in response to the Government's discovery requests," and that in requesting back-up documents for 79,000 speaker events, the Government had breached the parties' agreement reflected in the "protocol." (Jan. 23, 2016 Novartis email (Dkt. No. 158-10) at 4; (Dkt. No. 154-9) at 2)

Novartis now asserts that the Government's "request for 'back-up materials' for more than 79,000 events . . . was never part of the parties' agreed-upon discovery protocol." (Novartis Br. (Dkt. No. 155) at 4) The Government contends, however, that "the parties agreed at the outset of discovery negotiations that Novartis would provide back-up documentation with respect to the specific events at issue in this litigation," and that "[t]his agreement was reached separate and apart from the negotiated protocols regarding e-discovery, which is to be obtained from an extremely limited subset of sales representatives and other custodians." (Feb. 2, 2016 Govt. email (Dkt. No. 158-10) at 1; Folch Decl. (Dkt. No. 154) ¶ 37)

The Government has now moved to compel Novartis to produce (1) the back-up documentation for post-2007 speaker program events stored in the AHM database; (2) documents reflecting honoraria to speakers; (3) PowerPoint presentations used at speaker events; (4) internal Novartis reports of investigations and final dispositions concerning complaints regarding speaker programs; and (5) back-up documentation concerning speaker events located within the ESI of 363 additional sales reps, beyond the 150 sales reps whose ESI Novartis has already produced. (See Govt. Br. (Dkt. No. 151) at 6; Dec. 6, 2016 Tr. (Dkt. No. 187) at 10-16) The Government further requests that "Novartis be precluded from using at trial any event-specific documents in its possession, custody, or control that it does not produce to the Government pursuant to an order to compel." (Id.) Novartis argues that it should not be precluded from offering additional event-specific material which it might elect to proffer in its own defense at trial. (Novartis Br. (Dkt. No. 155) at 22)

DISCUSSION

I. LEGAL STANDARD

Rule 26(b)(1) of the Federal Rules of Civil Procedure provides that

> [p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1).

"This obviously broad rule is liberally construed." Daval Steel Prods. v. M/V Fakredine, 951 F.2d 1357, 1367 (2d Cir. 1991). "Nevertheless, discovery is not boundless, and a court may place limits on discovery demands that are 'unreasonably cumulative or duplicative,'

or in cases 'where the burden or expense of the proposed discovery outweighs its likely benefit.'" Kingsway Fin. Servs., Inc. v. Pricewaterhouse-Coopers LLP, No. 3 Civ. 5560 (RMB) (HBP), 2008 WL 4452134, at *4 (S.D.N.Y. Oct. 2, 2008) (quoting Fed. R. Civ. P. 26(b)(2)(C)(i), (iii)).

Courts have "the authority to confine discovery to the claims and defenses asserted in the pleadings, and . . . the parties . . . have no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings." Fed. R. Civ. P. 26(b)(1) Advisory Committee Note – 2000 Amendments. "Accordingly, discovery 'may not be used as a fishing expedition to discover additional instances of wrongdoing beyond those already alleged.'" Barbara v. MarineMax, Inc., No. 12 Civ. 368 (ARR) (RER), 2013 WL 1952308, at *2 (E.D.N.Y. May 10, 2013) (quoting Wells Fargo Bank N.A. v. Konover, No. 5 Civ. 1924 (CFD) (WIG), 2009 WL 585430, at *5 (D. Conn. Mar. 4, 2009)); see also Tottenham v. Trans World Gaming Corp., No. 00 Civ. 7697 (WK), 2002 WL 1967023, at *2 (S.D.N.Y. June 21, 2002) ("Discovery, however, is not intended to be a fishing expedition, but rather is meant to allow parties to flesh out allegations for which they initially have at least a modicum of objective support." (quotation marks and citation omitted)).

II. ANALYSIS

A. Request for Back-Up Documents Concerning the AHM Database, Honoraria, PowerPoint Presentations, and Investigation Reports

The Government argues that it "proceeded in this case under a fundamental assumption: once the Government was in a position to provide Novartis with a list of sham events, the Government would obtain from Novartis the documentation relating to those events." (Govt. Br. (Dkt. No. 151) at 4) According to the Government, "Novartis agreed at the outset of discovery to provide such back-up documentation once the Government identified the specific

events at issue."[3] (Id.) The Government further contends that the "ESI protocol for searching the electronic files of sales representatives" was "designed to address Novartis's burden objections with regard to an entirely separate set of documents." (Id. at 5) The Government therefore argues that "the parties had never agreed to use this separate discovery protocol as the . . . mechanism for identifying back-up documentation." (Id.)

Novartis contends, however, that "[t]he parties [had] agreed that [Novartis] would satisfy its obligations by searching for back-up documents for particular events identified by the Government pursuant to [the] detailed [ESI] protocol," which Novartis "understood [to] set forth the exclusive and entire event-specific discovery to be provided by [Novartis]." (Novartis Br. (Dkt. No. 155) at 3-4)

The record indicates that in March 2015, the parties agreed that the Government would provide Novartis with a list of the speaker events for which Novartis would produce back-up documents. (Mar. 6, 2015 Govt. email (Dkt. No. 154-3) at 2; Mar. 18, 2015 Novartis email (Dkt. No. 154-4) at 4) Novartis suggested – with regard to identifying sales rep custodians for relevant ESI – that "because the U.S. is prepared to limit its request for backup data about speaker programs to certain specifically identified programs, we believe that discovery into the [Novartis] sales force should be similarly limited by reference to those same programs, or a subset thereof." (Mar. 18, 2015 Novartis email (Dkt. No. 158-2) at 5; see id. at 7 ("because the U.S. is going to identify specific events for back-up purposes, we think it makes sense to limit

[3] According to the Government, its production of a "list of sham events" was delayed, because it was "waiting on the speaker program data and some other document discovery from Novartis[,] . . . [which the Government did not receive until] August or September of 2015." (Apr. 7, 2016 Tr. (Dkt. No. 163) at 18) "[I]n November [2015, the Government] produced [its] final sham list to [Novartis] with the 79,000 [events]. That was the first time [the Government] had given [Novartis the] complete list of sham events." (Id.)

discovery from [Novartis's] sales force to the representatives who organized those events that the U.S. identifies.")) There is no indication in the extensive correspondence submitted to this Court, however, that the Government ever agreed to Novartis's proposal that Novartis's production of back-up documents and ESI from sales reps be co-extensive, or limited to the same set of speaker events. Accordingly, although the Government agreed to provide Novartis with "an initial list of events ... from which the parties [would] identify a set number of sales representatives/custodians" for the purposes of developing an ESI protocol (July 27, 2015 Govt. email (Dkt. No. 158-4) at 2), there is no evidence to suggest that the list of 6,600 speaker events initially identified by the Government was coextensive with the list of events for which the Government would seek back-up documents.

Moreover, during a December 6, 2016 court conference, Novartis was unable to point to any document – whether formalized "protocol" or informal email – in which the Government agreed to such a restriction:

> THE COURT: Where does it say, either in this letter or someplace else, that the [G]overnment waived any right to seek information beyond the 6600 events that it identified, according to it, in connection with 150 sales reps? Where do I look to find the agreement that you're talking about in which the [G]overnment said, we are only interested in 6600 speaker events even though there are, I guess, a million[.] [W]here do I look to for that?
>
> NOVARTIS: I don't think there is a piece of paper where they said, we are waiving anything, nor would I have expected –
>
> THE COURT: There is nothing magic about the word waiver. We agreed to limit our requests for documents to the 6600 events that are associated with 150 sales reps. Where do I look to find that concession or agreement, whatever you want to call it?
>
> NOVARTIS: I will undertake to do this. I will undertake to root through the e-mails and see if there is a piece of paper that captures that point.

(Dec. 6, 2016 Tr. (Dkt. No. 187) at 35-36) No such document has been produced to this Court.

The Government contends that, at the time it formulated its document requests, it understood that "many categories of responsive back-up documentation [were] housed in central locations other than the electronic files of sales representatives," and that "searching for these documents in sales representatives' files would yield haphazard and incomplete results." (Govt. Br. (Dkt. No. 151) at 5; Folch Decl. (Dkt. No. 154) ¶ 9(c)) Therefore, "none of the ESI searches for sales force custodians was designed to comprehensively capture back-up documentation." (Govt. Br. (Dkt. No. 151) at 11) The Government further contends that – given its understanding that most back-up documents were located outside the files of sales rep custodians – "the Government never conceived that the [ESI] protocol would have any bearing on its request for the production [of] back-up documentation for all identified sham events." (Id. at 23)

Novartis contends, however, that it

> was explicit that the [June 16, 2015 email] protocol 'will locate documents potentially responsive to [the Government's] First Set of Requests, Requests Nos. . . . 8(a)-(f) . . . [and that Novartis] did not undertake to conduct additional searches to locate other materials responsive to First Document Request No. 8 . . ., the requests related to event-specific back-up documents. And the Government never objected or suggested that [Novartis] must also conduct additional searches to locate other event-specific back-up materials.

(Novartis Br. (Dkt. No. 155) at 10 (quoting June 16, 2015 Novartis email (Dkt. No. 158-4) at 15))

As noted above, however, the Government did object, in an email sent to Novartis about a month after Novartis's June 16, 2015 "protocol" email. The Government responded that

> in agreeing that the universe of custodians could be identified by reference to specific events, [the Government] did not thereby agree that the scope of discovery from such custodians would also be limited to those events. The discovery requests themselves are not event-specific, and [the Government's] interest in these records goes beyond documents specifically concerning the limited number of events that [the Government is] using to identify a potential custodian group.

(July 15, 2015 Govt. email (Dkt. No. 158-4) at 9-10) The Government further stated that while its discovery requests "certainly encompassed event-specific documents," it also sought "information regarding Novartis's practices regarding speaker programs; the training provided to health care providers; the recruitment of speakers; complaints made in connection with speaker programs; performance expectations and critiques; return on investment analysis; and communications with sales representatives and sales managers regarding speaker programs generally." (July 23, 2015 Govt. email (Dkt. No. 158-4) at 5)

The Court concludes that Novartis has not shown that the Government ever waived its right to request back-up documents concerning speaker events. To the contrary, as to back-up documents, the parties merely agreed that the Government would provide a list of speaker events for which Novartis would produce back-up documentation. (See Mar. 6, 2015 Govt. email (Dkt. No. 154-3) at 2; Mar. 18, 2015 Novartis email (Dkt. No. 154-4) at 4) The Government's production of a list of suspected "sham" events was hampered by Novartis's aforementioned delay in producing data concerning speaker events, and by its production of incomplete event data. (See Dec. 6, 2016 Tr. (Dkt. No. 187) at 6; Dec. 1, 2016 Govt. Ltr. (Dkt. No. 184) at 1) Therefore, the Government is entitled to back-up documents concerning the 79,236 speaker events it has identified as "sham" events. Novartis will produce information from the AHM database related to these events, as well as documents reflecting honoraria and PowerPoint presentations related to these events. Novartis will also produce investigation reports addressing potential violations of law and/or Novartis policies associated with speaker events.

1. Burden

Novartis complains that the discovery discussed above presents a "significant burden" to Novartis. (Novartis Br. (Dkt. No. 155) at 22)

Under Federal Rule of Procedure 26,

> parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Fed. R. Civ. P. 26(b)(1).

Here, an analysis of these factors weighs in favor of permitting discovery of back-up documents, even acknowledging the significant burden this discovery will place on Novartis. As to relevance, there can be no dispute that the back-up documents sought by the Government relate to issues that are at the heart of this litigation. (See Apr. 7, 2016 Tr. (Dkt. No. 163) at 39) The requested documents – which include records of payments made to doctors for speaking at Novartis events, and internal investigation reports concerning possible violations of company policy that occurred in connection with speaker events – are likely to shed light on the core issue in this case: whether Novartis's speaker events educated doctors about Novartis drugs, or merely served as a vehicle to provide doctors with remuneration in the form of honoraria, dinners at expensive restaurants, and entertainment.

With respect to the "importance of the issues at stake in th[is] action," this "case has the potential for broad public impact," see Zubulake v. UBS Warburg LLC, 217 F.R.D. 309, 321 (S.D.N.Y. 2003), given the Government's allegations that (1) "Novartis caused many thousands of prescriptions to be written as a result of payments and/or other remuneration made in connection with speaker programs that were kickbacks to doctors," and (2) Novartis paid "tens

of thousands of doctors kickbacks," each of whom then "wrote many thousands of dollars' worth of prescriptions for [Novartis] drugs[, which were then] paid for by federal health care programs." (Am. Cmplt. (Dkt. No. 62) ¶ 175) Accordingly, "public policy weighs heavily in favor of permitting extensive discovery." Zubulake, 217 F.R.D. at 321.

As to the amount in controversy, the scope and magnitude of this case, and the potential damages that would be imposed in the event of a finding of liability, suggest that extensive discovery is appropriate.

As to the parties' "relevant access to information," there is no suggestion in the record that the requested information is available to the Government by other means. Moreover, as to the parties' resources, Novartis does not contend that it lacks the resources to locate and produce the documents at issue; it argues, instead, that doing so will be a lengthy and time-consuming exercise. (See Mar. 33, 2016 Novartis Ltr. (Dkt. No. 141) at 5; Novartis Br. (Dkt. No. 155) at 23-26)

As to the magnitude of the burden associated with producing the requested documents, the Government's understanding that the back-up documents are centrally located appears to be consistent with Novartis's representations concerning the location of these documents. (See Novartis Br. (Dkt. No. 155) at 23-26) While Novartis states that the AHM database may not be "bulk exported," and that the back-up documents will have to be individually pulled, it does not contest that the database is centrally located. (See id. at 23) Similarly, documents concerning honoraria and internal investigation reports are maintained in known repositories, and their production should not be unduly burdensome. (See id. at 23, 26)

Having considered the burden that will be imposed on Novartis if it is required to respond to these discovery requests, this Court cannot find that the "burden or expense of the

proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). Accordingly, the Government's motion to compel will be granted as to the back-up documents.

B. Request for Back-Up Documents in the ESI of Sales Reps

The Government also moves to compel Novartis to produce "any back-up documentation that can be located through limited searches of the ESI of 363 sales representatives, in addition to the searches of the 150 sales representative custodians whose ESI Novartis has already processed." (Govt. Br. (Dkt. No. 151) at 6)

The Government's first set of discovery requests includes a request for back-up documents from the ESI of thousands of sales reps, who were responsible for tens of thousands of speaker events.[4] Recognizing the burden associated with searching the hard drives of thousands of sales reps' laptop computers for documents concerning tens of thousands of speaker events, see Cameron Decl. (Dkt. No. 157) ¶ 6 (noting "the significant burdens involved with searching the files of . . . sales representatives – specifically, because [Novartis] must individually load and search the files of each sales representative"), the parties proceeded to negotiate a protocol for selecting a limited number of sales reps whose ESI would be searched using agreed-upon search terms.

Initially, the parties focused on sales reps connected to speaker events cited in the Government's Amended Complaint and New York State's Complaint. In an April 9, 2015 email

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[4] As discussed above, the Government's Document Requests 2-5 – which the Government contends were the subject of the nine month negotiation process – concern, inter alia, communications of Novartis sales representatives and managers regarding speaker events; sales rep compensation structure, including bonus, commission, and other incentives associated with speaker events; budgets, targets, goals, or quotas for sales reps; and the training of sales reps in connection with speaker programs. (Govt. First Doc. and Interrog. Req. (Dkt. No. 154-1) ¶¶ 2-5; Folch Decl. (Dkt. No. 154) ¶ 3b)

to the Government, Novartis identifies 90 sales reps who organized 255 of the 267 speaker events cited in the two complaints. (See Apr. 9, 2015 Novartis email (Dkt. No. 158-2) at 2)

The Government acknowledged Novartis's list of 90 sales reps, but proposed that Novartis search the ESI of 300 sales reps:

> Thank you for identifying the number of custodians associated with 255 of the 267 events described in the [Amended] Complaint. As we have discussed, although it is not our preferred method of identifying sales representatives and sales managers custodians, in an effort to accommodate the burden arguments you have put forward regarding the use of health care providers as the method for identifying sales representative custodians, we will agree to instead designate as custodians those sales representatives associated with specific events, and the sales managers that supervised such sales representatives. In light of the low number of sales representatives identified using this approach, however, it appears that we need to expand the list beyond the programs listed in the [Amended] Complaint. We would propose that the parties agree to a total number of approximately 300 sales representative custodians, to be identified as follow[s]: 150 sales representative[s] associated with speaker programs for Lotrel, Starlix and Valturna; and the remaining 150 sales representatives associated with speaker programs for the remaining drugs. The sales managers who supervised such sales representatives should also be included as custodians.

(May 8, 2015 Govt. email (Dkt. No. 158-4) at 19-20) (emphasis added)

In the June 16, 2015 "protocol" email, Novartis agreed to provide sales rep ESI "on a rolling basis, until either (a) the maximum number of sales representatives proposed by the Government is reached – i.e., 300 in total . . . [or] (b) [Novartis] determines that the process has become unduly burdensome." (June 16, 2015 Novartis email (Dkt. No. 158-4) at 14) In sum, as of May-June 2015, the correspondence provided to the Court demonstrates that the parties had agreed that the ESI of no more than 300 sales reps would be searched.

In a November 10, 2015 joint letter to the Court, the parties reference their agreement concerning sales rep ESI:

> Regarding discovery from [Novartis's] sales force, the parties have agreed on an overall framework for that discovery (including the manner in which specific events and sales representatives/managers are to be identified), and are now starting to finalize the

> specifics, including the final search terms to be applied by [Novartis]. The parties have already exchanged a proposed set of search terms.

(Nov. 10, 2015 Jt. Ltr. (Dkt. No. 134) at 3)

In a December 29, 2015 email to Novartis, however, the Government agreed to reduce the maximum number of sales reps to 150:

> In the interests of resolving this matter quickly, however, so that document discovery can be completed forthwith, we will agree to reduce the number of previously agreed-upon sales representative custodians from 250 to 150. This is a drastic reduction, revising a prior agreement between the parties and almost cutting in half the number of documents we can now expect to receive from these key custodians.

(Dec. 29, 2015 Govt. email (Dkt. No. 158-9) at 5)[5]

In its motion to compel, however, the Government now seeks an order requiring Novartis to search the ESI of an additional 363 sales representatives, beyond the 150 sales reps to which the Government refers in its December 29, 2015 email. (See Govt. Br. (Dkt. No. 151) at 16) While the Government argues that "the burden of conducting limited and targeted searches of 363 additional sales representatives['] [ESI]" is not substantial (see id. at 19-20), the Government does not address a more fundamental issue – how its current motion can be reconciled with its representation on December 29, 2015, that it was only seeking the ESI of 150 sales reps. See Dec. 29, 2015 Govt. email (Dkt. No. 158-9) at 5.

Novartis argues that "[t]here is no clearer indication that the Government is attempting to rewrite the parties' negotiated protocol than its request for ESI searches for more than 363 additional sales representatives – for a total of 513 sales representatives. . . . [Novartis] should not be required to triple" its sales rep ESI production. (Novartis Br. (Dkt. No. 155) at 24)

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[5] Although this email indicates that – at some point after June 2015 – the Government had reduced its demand from 300 sales reps to 250 sales reps, the materials submitted to the Court do not address the reduction from 300 to 250.

In their November 10, 2015 joint letter, the parties stated that the agreed-upon protocol for obtaining relevant ESI from the electronic files of sales reps was developed through "a lengthy process" involving "extensive discussions . . . ; exchanges of substantive information . . . ; and the creation, testing and analysis of numerous potential search strings for electronic data. . . ." (Nov. 10, 2015 Jt. Ltr. (Dkt. No. 134) at 3) These negotiations were driven in part by the parties' understanding that retrieving documents from the ESI of sales reps would be particularly burdensome for Novartis. (See, e.g., Folch Decl. (Dkt. No. 154) ¶ 7(c); July 15, 2015 Govt. email (Dkt. No. 158-4) at 9; June 16, 2015 Novartis email (Dkt. No. 158-4) at 14) The parties' negotiated ESI protocol explicitly covers documents stored in sales reps' electronic files related to specific speaker events. (See Aug. 10, 2015 Govt. email (Dkt. No. 158-6) at 3)

Based on the materials submitted, the Court concludes that the Government entered into an agreement with Novartis in which Novartis would be required to search the ESI of no more than 150 sales reps. The Government has not presented any explanation or justification for why that agreement should be ignored now. Accordingly, the Government's request for an order directing Novartis to search the ESI of an additional 363 sales reps is denied.

C. The Government's Motion to Preclude Novartis From Using at Trial Documents not Produced During Discovery

The Government requests that "Novartis be precluded from using at trial any event-specific documents in its possession, custody, or control that it does not produce to the Government pursuant to an order to compel." (Govt. Br. (Dkt. No. 151) at 6) Novartis argues that this request is, in effect, a premature in limine motion. (Novartis Br. (Dkt. No. 155) at 27) Novartis further notes that the Government has a pending document request seeking the production of "all documents that Defendant intends to rely upon to dispute the facts alleged by the Government in its [] Amended Complaint or to support the defenses propounded by

Defendant in its Answer," and that Novartis will reveal its trial exhibits as part of the standard pre-trial process. (Id. (citing Kennedy Decl. (Dkt. No. 158-5) Ex. E, Doc. Req. 13, at 34))

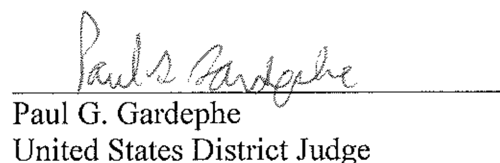
The Government's application appears designed to prevent unfair surprise at trial. The Government's pending document request addresses this same issue, however. Accordingly, the Government's motion is denied without prejudice. If the Government believes that Novartis's response to the pending document request is not adequate to address this concern, it may raise the issue with the Court.

CONCLUSION

The Government's motion to compel is granted in part and denied in part as set forth above. The parties are directed to confer as to the production of additional material required by this Order, and to update the Court by letter within two weeks' time as to the status of discovery. The Clerk of the Court is directed to terminate the motion (Dkt. No. 150).

Dated: New York, New York
March 28, 2017

SO ORDERED.



Paul G. Gardephe
United States District Judge