

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA et al.
ex rel. JULIE LONG,
Plaintiffs,

v.

CIVIL ACTION NO. 16-12182-FDS

JANSSEN BIOTECH, INC.,
Defendant.

**MEMORANDUM AND ORDER ON DEFENDANT'S
MOTION TO COMPEL AND FOR A PROTECTIVE ORDER (#328);
DEFENDANT'S MOTION FOR A PROTECTIVE ORDER VACATING
RELATOR'S FED. R. CIV. P. 30(b)(6) DEPOSITION NOTICE (#333);
AND RELATOR'S MOTION TO COMPEL COMPLIANCE WITH
THE COURT'S ORDERS AND TO COMPEL DISCOVERY (#345).**

KELLEY, U.S.M.J.

I. Introduction.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free business advisory services to physicians who prescribed its medications, in violation of the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a). Relator Julie Long alleges that Janssen Biotech, a company that manufactures and sells two infusible drugs, Remicade and Simponi ARIA, improperly employed teams of practice advisors, including relator, and hired outside consultants to provide services such as presentations, advice, and

customized analyses to doctors to assist them in running profitable infusion businesses (“in-office infusion suites,” or “IOIs.”).¹

This court held an oral argument on the three motions at issue here on January 23, 2023. (#364; #367 (transcript of hearing).) Five days after the argument, on January 27, 2023, Janssen filed a notice stating that it withdrew that part of its motion to compel (#328) that asked the court to order relator immediately to select 12 additional custodians. (#369.) In addition, Janssen made other proposals that it contended resolved many of the discovery disputes. *Id.* On the same date, relator filed a letter stating that while she did not object to Janssen’s withdrawing part of its motion to compel, she objected to Janssen’s proposals regarding providing other discovery, noting that she had asked Janssen to confer regarding the proposals but Janssen had refused, and disputing that Janssen’s proposals resolved outstanding discovery disputes. (#370 at 1.) The court asked the parties to file brief memoranda setting out what disputes remain, which the parties did. (#373 (relator); #374 (defendant).)

II. Chief Judge Saylor’s Order.

Since several of the disputes involve the interpretation of a previous order issued by Chief Judge Saylor, the court will set out the ruling here. On September 9, 2022, Chief Judge Saylor issued an order concerning appeals of three of this court’s discovery orders (##282, 283, 284), in which he generally affirmed the orders, but reversed on one point. (#320 at 3.) In one of the orders this court had expanded the date range for discovery, ordering Janssen to update its prior document productions and interrogatory responses about the IOI services at issue in this case from February

¹ Familiarity with the facts of the case and the history of the discovery disputes is presumed. The facts and a detailed analysis of the claims in the Second Amended Complaint (#55) are set out in Chief Judge Saylor’s Order and Memorandum on Defendant’s Motion to Dismiss. (#75.) This court outlined some of the history of the discovery disputes in a previous order. (#282.)

2016, the prior cutoff date, to February 2020. (#282 at 12-14.) Chief Judge Saylor found that to the extent that this court’s order “generally expanded the range of dates of documents that must be searched and produced from February 2016 (the date when relator’s employment ended) to February 2020, that order exceeded the reasonable requirements of the first phase of discovery” because the first phase was limited to the IOI services with which relator had experience, and “[i]f relator was not at the company, she cannot have been a witness to practices during that time.” (#320 at 3.) He ordered that “requests for production of documents during the first phase of discovery shall be generally limited to documents created through February 2016,” with two exceptions. *Id.* One is for “documents created between February 2016 and February 2020, other than routine personnel, payroll or tax documents, that mention relator Julie Long or her specific allegations or claims.” *Id.* at 3-4. The other is for “documents created between February 2016 and February 2020 that concern the termination or phase-out of any of the specific practices or programs that relator Julie Long participated in, or personally observed, while employed by Janssen, or the potential legality or illegality of any such practice or program.” *Id.* at 4.

III. Legal Standard.

“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” Fed. R. Civ. P. 26(b)(1). The party seeking to compel information in discovery has the burden of showing its relevance. *Johansen v. Liberty Mut. Grp., Inc.*, No. 15-cv-12920-ADB, 2017 WL 6045419, at *1 (D. Mass. Dec. 6, 2017) (citing *TG Plastics Trading, Co. v. Toray Plastics*, No. 09-cv-336S, 2010 WL 936221, at *2 (D.R.I. Mar. 12, 2010)). Once the moving party makes a showing of relevance, the opposing party bears the burden of showing that the requested discovery is

improper. *See Aronstein v. Mass. Mut. Life Ins. Co.*, No. 15-cv-12864-MGM, 2017 WL 2818993, at *2 (D. Mass. June 29, 2017).

“District courts exercise broad discretion to manage discovery matters” and “to tailor discovery narrowly.” *Heidelberg Americas, Inc. v. Tokyo Kikai Seisakusho, Ltd.*, 333 F.3d 38, 41 (1st Cir. 2003); *Primarque Prod. Co. v. Williams W. & Witt’s Prod. Co.*, No. 15-cv-30067-TSH, 2016 WL 6090715, at *2 (D. Mass. Oct. 18, 2016). Proportionality is determined 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).

Federal Rule of Civil Procedure 26(c) allows a party to seek and obtain a protective order based on a showing of good cause. Fed. R. Civ. P. 26(c). The court may “issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . forbidding the inquiry into certain matters, or limiting the scope of or disclosure or discovery to certain matters.” *Id.* Moreover, the court should limit discovery where it is “unreasonably cumulative or duplicative, or is obtainable from some other source that is more convenient, less burdensome, or less expensive.” Fed. R. Civ. P. 26(b)(2); *see IDS Prop. Cas. Ins. Co. v. Gov’t Emp. Ins. Co., Inc.*, 985 F.3d 41, 50 (1st Cir. 2021) (district courts possess “broad discretion” in “design[ing] protective orders”); *see, e.g., Braga v. Hodgson*, 605 F.3d 58, 59-60 (1st Cir. 2010) (affirming protective order precluding deposition and recognizing district court’s “broad discretion in ruling on pre-trial management matters” and First Circuit’s review of “district court’s denial of discovery for abuse of its considerable discretion”).

IV. The Present Motions.

A. The Parties' Positions After Janssen's Proposal Regarding Resolving Certain Issues.

In Janssen's memorandum setting out its view of the remaining discovery disputes, Janssen proposed:

to (i) produce ESI from all the non-legal personnel Janssen has identified as having significant involvement, (ii) identify and produce non-privileged ESI from non-legal personnel that had significant involvement from 2016 to 2020 in the termination of any of the programs or the assessment of the legality of the programs, (iii) allow Relator to review all of those documents and then select (without court intervention) two additional custodians (if there are any) that she believes had significant involvement who were not identified by Janssen, and (iv) if, after all that, Relator identifies additional people whose documents she believes should be produced, Janssen will meet and confer with Relator in good faith at that time.

(#374 at 2.)

Janssen concludes that its proposals resolve all but three issues raised in the parties' discovery motions. *Id.* at 3. Those remaining issues are: (1) Janssen's request for a protective order related to collecting and producing documents stored at outside counsel's offices (#329); (2) its request for a protective order related to the production of government communications, *id.*; and (3) relator's motion to compel production of additional Xcenda documents (#346). (#374 at 3-5.)

Relator sees things differently. First, relator objected to Janssen's proposals for resolving discovery disputes because Janssen still does not agree to disclose the persons on whom Janssen may rely to support its affirmative defenses, nor has Janssen unequivocally identified "the persons who had significant involvement in the relevant facets of the alleged kickback scheme." (#370 at 1.) Further, Janssen has never "provided sworn, complete, responsive, and clear answers to Plaintiff's interrogatories seeking identification of important fact witnesses." *Id.* at 2. Finally, Janssen is jumping the gun by announcing that it will make "a more limited production" of documents of non-ESI custodians, where the parties have never conferred about an appropriate

process for searching and producing documents “from the current and former employees who had significant involvement and are not selected as one of the permitted twelve custodians,” which this court previously ordered Janssen to do. *Id.* at 2; (#282 at 15.) In short, relator asks that the parties “complete the witness disclosure process – a process that Janssen is clearly continuing to attempt to evade,” before Janssen unilaterally, without conferring with relator, dictates the resolution of the outstanding motions. (#370 at 2.)

Relator argues at length concerning what she perceives to be the outstanding issues, *see* #373. The court addresses these issues below.

B. Janssen’s Motion to Compel (#328).

In its motion, Janssen asked the court to enter:

(1) an order compelling Relator to identify the remaining 12 custodians in compliance with this Court’s order; and (2) an order protecting Janssen from Relator’s unreasonable demands to (a) identify how its employees documents are stored, (b) identify “current and former employees with significant involvement in the development, review, approval, monitoring, and/or delivery of the support services at issue in this case” after February 19, 2016, (c) collect and identify on a privilege log or produce documents located in the offices or data systems of any outside counsel that provided Janssen advice regarding the programs at issue spanning over 25 years, (d) identify the roles of the over 700 non-legal individuals listed on Janssen’s privilege log, spanning a nearly 20-year period, and (e) produce communications with DOJ, HHS-OIG, and CMS concerning this action, including communications earlier this year.

(#328 at 1.)

1. Relator’s Selection of Additional Custodians.

As noted above, Janssen has withdrawn its request that the court order relator immediately to choose 12 custodians; instead Janssen agreed to produce ESI from all 29 individuals whom it had listed as possible custodians. (#374 at 2.). Some background about this issue is warranted. Over a year ago, on February 17, 2022, this court ordered Janssen to produce documents from 12 additional custodians and 3 legal custodians, to be selected by relator. (#282 at 10-12.) In addition,

in a separate part of the court's order addressing relator's complaint that Janssen was not searching for or producing responsive documents from any employees' files other than the ESI custodians', this court ordered Janssen to conduct a reasonable inquiry and produce documents from "all sources":

... [A]s in every case governed by the Federal Rules, Janssen must make a reasonable inquiry and undertake a reasonable effort to produce requested documents possessed by current and former employees who had significant involvement in the development, review, approval, monitoring, and/or delivery of the support services at issue in this case, whether or not relator happened to name such employees as ESI custodians. The court orders the parties to confer regarding this Order, and to devise a strategy for sampling or conducting reasonable searches for relevant documents that, after a good-faith effort, Janssen knows exist in certain employees' files.

Id. at 15.

Other than producing the names (along with job function, job titles and dates of employment) of the 29 potential ESI custodians (#329 at 5), Janssen apparently has never complied with the court's order quoted above. After appealing this court's order concerning additional custodians to Chief Judge Saylor to no avail, *see* #320, Janssen, the day after Chief Judge Saylor's order issued, provided relator with the list of 29 individuals, whom Janssen said "*may have had* such 'significant involvement,'" and asked relator immediately to choose 12 of them. (#329 at 8.) (emphasis added.) Relator chose 3 custodians from the list but declined to choose more until she received discovery concerning potential witnesses in this case. She now insists that Janssen comply with its obligations to disclose the employees who possess relevant documents and information concerning the alleged kickback violations and disclose the employees who possess documents and information that it may use to support its affirmative defenses. (#332 at 4.) In short, argues relator, "Janssen must be required to meet its obligations by fully and properly disclosing the key witnesses before relator should be ordered to select all custodians." *Id.*

Rather than addressing realtor's concerns about deficiencies in its identification of witnesses, Janssen unilaterally decided, shortly after the oral argument on this motion, to provide ESI production for the 29 individuals on the list of potential custodians. (#374.) While this is certainly an encouraging development, Realtor asserts that this, along with Janssen's other proposals, does not satisfactorily resolve all the present discovery disputes, and the court agrees. First, relator is entitled to the requested discovery concerning who the key witnesses in the case are before selecting custodians; Janssen may well decide to select individuals who are not presently on the list. Second, the documents of the 29 persons, listed by Janssen as custodians, whom Janssen avers "may have had" significant involvement, are clearly encompassed by the court's order, quoted above. Janssen should have already produced requested documents concerning these persons. As this court has unequivocally ordered, and as Chief Judge Saylor affirmed: Janssen's discovery obligations are not limited to named custodians.

To the extent Janssen has not already done so, the Court orders Janssen to provide complete responses to realtor's interrogatories, including explicitly stating that certain witnesses and documents support a particular defense, in accordance with the Local Rules, Federal Rules, and the court's previous orders, including but not limited to #322 at 10-13 (ordering Janssen to supplement its responses to contention interrogatories 15, 20 and 22, including naming witnesses). Further, Janssen shall supplement its Rule 26(a) initial disclosure information, including fully and unambiguously disclosing the individuals likely to have discoverable information it may use to support its defenses and the documents it may use to support those defenses. To the extent Janssen points relator to documents in which the names of witnesses may be found, the documents must be in such a form and must be specific enough to be the functional equivalent of a supplemental discovery response. And, Janssen shall highlight the names of the witnesses on any such

documents. Failure to include witnesses and documents in this disclosure, in the absence of good cause, shall constitute waiver of Janssen's ability to use them to support its defenses. This information shall be provided within two weeks of this order.

Janssen shall also inform relator how potential ESI custodians' documents are stored (i.e. paper format, electronically, or other formats), and confer with relator about this matter, so that relator will be able to gauge the time and effort required to retrieve the documents. (#332 at 7.) Contrary to Janssen's argument, this information is not forbidden "discovery on discovery" (#329 at 5), rather, in a large document case such as this one, it is essential information for relator to have when deciding whom to choose as custodians.

Only after Janssen has provided relator with the above information shall relator be obligated to choose its additional custodians. Further, the court reiterates its order that Janssen must confer with relator concerning devising a strategy for sampling or conducting reasonable searches for relevant documents that, after a good-faith effort, Janssen knows exist in certain employees' files.

2. Must Janssen Identify Employees with Significant Involvement in the Programs after February 2016?

As explained above, Chief Judge Saylor ordered that the general cutoff date for discovery concerning the IOI programs at issue is February 2016, the date when relator's employment ended, other than documents specifically mentioning relator and her claims, or documents concerning the termination or phase-out of any specific programs or practices that relator participated in or personally observed while employed, or the potential legality of such programs, for which the cutoff date is February 2020. (#320 at 3-4.) The parties appear to dispute whether Chief Judge Saylor's exceptions included only documents, or also include the identification of persons with significant involvement in the programs at issue, and if persons are included, whether the only

persons Janssen need identify for the time period of 2016 to 2020 are those who are included in Chief Judge Saylor's specified exceptions. *See, e.g.,* #332 at 12-16.

Janssen eventually conceded that it will provide relator with the names of persons who were involved in the phase-out of the programs or in assessing the potential legality of them from February 2016 to February 2020, including their roles and the dates that they held their roles. (#369 at 2-3.) Relator lists seven categories of activities that fall within the parameters of Chief Judge Saylor's exceptions and requests the identities of current and former employees who had significant involvement in these activities, including between February 2016 and February 2020.

Those activities are:

- Reviewing, assessing, and/or advising Janssen regarding the legality or illegality of providing any or all of the services and related programs;
- Analyzing, reviewing, and/or advising Janssen whether it should or should not seek an advisory opinion from OIG concerning any of the services or related programs;
- Reviewing, assessing, and/or advising Janssen whether providing any or all of the services and related programs complied with the company's compliance policies;
- Creating or revising the company's compliance policies concerning the provision of free services, consulting, education, and support to customers;
- Reviewing, assessing, and/or advising Janssen whether providing any or all of the services and related programs complied with industry standards;
- Decisions to terminate or phase-out the services and related programs that Janssen ceased providing during the period ... and
- Performing the analyses or reviews and/or providing the opinions or advice that Janssen adopted or relied upon in reaching the alleged good faith belief that it was acting lawfully in providing the services during the period.

(#332 at 14.)

The court agrees with relator that the activities listed above fall into the exceptions set out in Chief Judge Saylor's order and that Janssen should provide to relator the names of current and

former employees with significant involvement in these activities, including their roles and the dates they held the roles, from February 2016 to February 2020. To the extent that the above list can be read to include “all programs” that Janssen provided, it is narrowed to the “specific practices or programs that relator Julie Long participated in, or personally observed, while employed by Janssen.” (#320 at 4.) In addition, Janssen should provide the names, roles, and dates of roles for persons who had significant involvement from February 2016 to February 2020 in the review of or response to relator’s “specific allegations or claims,” subject to the court’s holding below in part 3 concerning privileged communications from counsel. *Id.* If Janssen has not already agreed to provide relator with this information, the court now orders it to, within two weeks of this order. If relator is asking the court to order Janssen to provide information about persons who had significant involvement in the programs at issue in this case beyond February 2016, without regard to Chief Judge Saylor’s exceptions, the motion is denied.

3. Documents Possessed by Outside Counsel.

Early in discovery, this court ordered Janssen to provide discovery concerning its knowledge of the legality of providing IOI support for the programs at issue in this phase of the case, including all relevant non-privileged legal advice it received, and to produce a privilege log concerning the relevant but privileged information. (#237.) The court noted that this information is critical to proving relator’s claim that Janssen acted knowingly and willfully in violating the AKS, *see, e.g.*, #282 at 8, and to challenging Janssen’s affirmative defense that it had a good faith belief that providing IOI support was lawful. *Id.*

The court eventually reconsidered its order, and in an effort to streamline discovery and relieve Janssen of the burden of combing through the documents of multiple attorneys over a period of many years for the “sole purpose of creating a privilege log,” the court ordered that

Janssen need only review and log privileged documents from the files of three legal custodians, to be selected by relator, who provided legal advice, reviews, or analyses for the relevant programs. *Id.* at 16. Relator, arguing now that the court’s previous order limiting it to three legal custodians only pertained to “individual in-house attorneys,” complains that Janssen has not retrieved documents that are possessed by its outside counsel, nor created privilege logs, responsive to relator’s requests. (#332 at 9-12).

Relator argues, as she did before, that she is entitled to information “about the reviews and advice Janssen received concerning the legality or illegality of the services, which is highly relevant both to relator’s claims and Janssen’s affirmative defenses.” *Id.* at 11. Relator correctly points out that “documents held by a party’s outside counsel are in the party’s control for purposes of requests for production under Rule 34.” *Id.* at 10. She continues, “[e]ven if Janssen claims [the information sought] is privileged, relator is nevertheless entitled, under Rule 26(b)(5), to information that will enable her to assess the privilege claim and to know that Janssen sought relevant legal advice, the subject matter of the advice, when it received the advice, who provided the advice, and who received the advice.” *Id.* at 11. When the court ordered Janssen to produce discovery from “all sources,” not just from ESI custodians, relator argues, the term “all sources” included outside counsel. *Id.* Relator raises the specter that if this court does not require Janssen to search outside counsel’s files for responsive documents, the court will “create a safe haven where Janssen could conceal any other documents it does not want used in this action.” *Id.* at 11.

Relator, in a separate motion that was decided by Chief Judge Saylor, previously moved to compel the disclosure of legal opinions related to the lawfulness of defendant’s services to physicians, asserting that Janssen had waived any privilege with regard to the materials by placing them at issue through its assertion of affirmative defenses and its reliance on legal advice that put

into issue its actual knowledge and beliefs regarding the lawfulness of the programs at issue in this case. (#263 at 1.) Janssen has made clear that it is not invoking an advice of counsel defense. (#264-8.) Chief Judge Saylor denied realtor's motion to compel legal opinions, finding that Janssen's "assertion that it acted in good faith by adhering to internal-compliance protocols, which included a legal review, does not necessarily implicate privileged communication to such a degree" that Janssen had waived privilege over the requested documents. (#303 at 4.) "Put another way, the mere assertion of good faith as a defense, and the mere production of [legal review] materials, is not sufficient to trigger a finding of implied waiver." *Id.*

Relator argues that her demand for discovery here is different from the one that Chief Judge Saylor resolved in his order, quoted above. In sum, relator states:

[T]he issue of whether Janssen has waived the attorney-client privilege is *not before the Court* because Relator is not currently asking for a ruling that Janssen has waived the privilege by asserting the affirmative defense that Relator cannot establish the AKS's willfulness element because the company had a good faith belief that its conduct was lawful. At this time, Relator is merely trying to obtain the identities of the attorneys (in-house and outside counsel) who are among the most important fact witnesses in this case because they reviewed the legality of the services and/or advised the company regarding whether the services were lawful. Whether Janssen is ultimately able to assert the good faith belief defense without allowing Relator to discover the substance of the legal reviews and advice it received in order to examine the veracity of Janssen's purported belief that providing the alleged kickbacks was lawful is a question for another day. Relator will likely raise this issue once Janssen complies with the Court's order by fully and clearly describing the bases for its affirmative defenses.

(#349 at 14.) (emphasis in original.)

The court finds that at this time, because Janssen has declined to assert an advice of counsel defense, because Chief Judge Saylor has ruled with regard to a related motion that Janssen has not waived any privilege by asserting its defenses, and because the court has allowed relator three legal ESI custodians, Janssen does not have to disclose to relator the requested discovery, even if realtor is not seeking legal advice itself but merely the identities of the attorneys who provided it, and "the

nature of the communications, and when it was provided.” (#339 at 23.) The court makes this ruling in the interests of keeping discovery within manageable limits at this stage of the case.

The court takes seriously relator’s concern that there may be unprivileged, relevant documents in the custody of outside counsel that Janssen now will not have to produce. The court orders Janssen to make a good faith effort to locate any such documents and turn them over to relator. Further, this order does not in any way limit relator’s ability to bring this issue up again, as relator states she likely will, if relator has reason to argue again that Janssen has waived its privilege or that there are responsive, unprivileged documents in the custody of outside counsel.

4. The Privilege Log Dispute.

This court previously ordered Janssen to provide an updated privilege log including a description of “who the parties are in each communication and what their roles were in the company.” (#284 at 3-4.) The privilege log that Janssen produced listed the roles of “50 individuals associated with legal functions” but did not identify the names or roles of over 700 “non-legal personnel” on the log. (#329 at 13.) Janssen argues that it is unduly burdensome for it to be required to search through nearly 20-year-old records to determine the role of every person on the log. *Id.* at 14. Janssen insists that relator “has articulated no legitimate basis for needing to know the roles of every individual on every privileged communication,” *id.*, but that clearly is wrong: relator is correct that “the ordered information is necessary for relator to assess the appropriateness of Janssen’s privilege claims.” (#332 at 17.) In fact, the identity of the lawyers on the communications is only one part of the information that must be included on a privilege log, where one of the questions relator must answer is whether a third party, typically a non-lawyer, was privy to a communication and destroyed the privilege. *See, e.g., Cavallaro v. United States*, 284 F.3d 236, 245, 247 (1st Cir. 2002) (holding that communications must have been intended to be confidential

and made for the purpose of giving or obtaining legal advice to qualify as privileged and disclosing attorney-client communications to a third party undermines the privilege); *Crane Sec. Tech., Inc. v. Rolling Optics, AB*, 230 F. Supp. 3d 10, 15-16 (D. Mass. 2017) (same). Realtor demands that Janssen be ordered to amend the log to include every person's name and their role. (#332 at 17.)

While it is important for relator to know who the parties were to a particular communication to assess the validity of the claim of privilege, the court acknowledges that it may be difficult for Janssen to identify every person and their role on the log. At the hearing on the motion, realtor said it would be helpful to have the email addresses associated with each entry and Janssen agreed to provide them, (#367 at 42 (transcript of hearing)), which the court expects will assist the parties in identifying persons and their roles. If the parties are not able to reach agreement on how to resolve this dispute after relator receives this information and further confers with Janssen concerning specific entries about which relator has questions, the court will entertain a further motion on this subject.

5. Whether Janssen Must Produce Communications with DOJ, HHS-OIG, and CMS Concerning This Action and Up to the Present Time.

This court previously allowed realtor's request for whatever information Janssen disclosed to the U.S. Department of Justice ("DOJ") regarding this action; whether Janssen ever sought guidance or an advisory opinion from the Health and Human Services Office of the Inspector General ("HHS-OIG"); and "any communications [Janssen] had with Medicare concerning its provision of the IOI Support to physician practices." (#284 at 7.) Relator recently requested that Janssen produce all communications Janssen has had with the DOJ, HHS-OIG, and the Centers for Medicare and Medicaid Services ("CMS") "concerning this action." (#329-2 at 5.) Janssen responds that it is not aware of any communications with Medicare regarding the programs at issue in this case, but will produce them if they are identified. (#329 at 14.) Janssen states that it has

produced subpoenas it served on DOJ, HHS-OIG, and CMS in this action, and “it has produced and will continue to produce any discovery actually received from U.S. Government agencies” to relator. *Id.* at 14-15. Janssen objects, however, to producing “communications with HHS-OIG and CMS concerning Janssen’s efforts to obtain discovery from these agencies in this action.” *Id.* at 15. In addition, Janssen disputes that relator is entitled to receive communications with the U.S. Government concerning this action “to the present”; Janssen argues that Chief Judge Saylor’s cutoff date of February 2020 should apply to these materials. *Id.*

With regard to Janssen’s communications with the DOJ, relator correctly states that she is entitled to the *ex parte* communications that Janssen has had with the United States, in which Janssen has provided the United States with information and documents that are relevant to relator’s claims and Janssen’s defenses. (#332 at 18.) Relator describes these communications as follows:

As defendants in *qui tam* actions routinely do, Janssen has provided its assessments of Relator’s claims, the company’s defenses, and the evidence in an *ex parte* effort to cause the United States to move for dismissal of the action under 31 U.S.C. § 3730(c)(2)(a). Janssen has also had *ex parte* communications with the United States concerning discovery that Janssen requested through document subpoenas directed to the Department of Justice (“DOJ”), Office of Inspector General for the Department of Health and Human Services (“OIG”), and the Centers for Medicare and Medicaid Services (“CMS”). There likely have been other *ex parte* discussions concerning matters related to this litigation.

(#332 at 18.)

These communications are undeniably relevant and not privileged, as the court has already found. (#284 at 7.) The court rejects Janssen’s assertion that the February 2020 cutoff date established by Chief Judge Saylor for discovery concerning the programs at issue in this case applies to Janssen’s communications with the DOJ and other government agencies about this case. In its previous order, affirmed by Chief Judge Saylor, (#320 at 3), this court did not set any

temporal limitation on this discovery, and there should be none. As relator points out, applying a cutoff date of February 2020 makes no sense with regard to these particular documents, because the case is in active litigation and the communications are ongoing; because in February 2020 this action was “only ramping up and discovery had not even started”; and because Janssen has had communications since February 2020 that are important to the case. (#332 at 20.) Most tellingly, however, relator asserts that Janssen requested that relator provide her counsel’s communications with the DOJ concerning this action without a temporal limitation, and she has done so. *Id.* at 21. As relator comments, “It cannot be that only Relator is obligated to comply with the Rules of Civil Procedure.” *Id.*

Janssen also must provide relator with ex parte communications with HHS-OIG and CMS concerning this action. Relator points out that while Janssen provided relator with copies of subpoenas served on these agencies, “it has not produced the communications concerning the subpoena and discovery it is seeking.” *Id.* at 22. The court agrees with relator that these documents are relevant, not privileged, and not burdensome to produce. *Id.* They are discoverable for the same reasons that the DOJ communications are.

Janssen shall produce its ex parte communications with the DOJ, HHS-OIG and CMS regarding this action within two weeks of this order and shall produce such communications going forward.

C. Janssen’s Motion for a Protective Order Vacating Relator’s Rule 30(b)(6) Deposition notice (#333).

Relator noticed a deposition of a Rule 30(b)(6) witness from Janssen; the purpose of the deposition is to “obtain the identities of the key fact witnesses” in “eight pivotal areas.” (#339 at 11-12.) The court allows Janssen’s motion to vacate the notice of deposition (#333), because the court finds that the topics seek the identities of potential witnesses, which can be obtained more

conveniently and accurately through other means. Janssen shall provide written answers, attested under oath to be true, to the eight questions that relator has posed within two weeks of this order.²

The answers shall only be with regard to the services at issue in this case, not all services.

D. Relator's Motion to Require Compliance with the Court's Orders and to Compel Discovery (#345).

Most of the issues in this motion overlap with issues raised in the other two motions. (#346 at 3.) In its opposition, Janssen includes a chart in which it states that many of the issues have been resolved because it is presently providing the requested discovery to relator, (#355 at 6-8), and in its sur-reply, it updated this chart to demonstrate that more progress had been made in providing discovery to relator. (#362-1 at 3-6.) If some disputes between the parties now only concern the

² The questions to be answered are: 1. "The persons (excluding the PRC) that had significant involvement in the development and/or approval of the strategy or plan to provide and/or continue to provide any or all of the IOI Support Services"; 2. "The persons (excluding the PRC) that had significant involvement in the decision to stop providing any or all of the IOI Support Services"; 3. "The persons (excluding employees acting in the capacity of an Area Business Specialist or Regional Business Manager) that had significant involvement in assessing, evaluating, and/or analyzing customer demand for and the value customers derived from any or all of the IOI Support Services"; 4. "The persons (excluding the PRC) that had significant involvement in reviewing, assessing, and/or advising [Janssen] regarding the legality or illegality of providing any or all of the IOI Support Services"; 5. "The persons who analyzed, reviewed, and/or advised whether [Janssen] should or should not seek an advisory opinion from OIG concerning any of the IOI Support Services"; 6. "The persons (excluding the PRC) that had significant involvement in reviewing, assessing, and/or advising [Janssen] whether providing any or all of the IOI Support Services complied with [Janssen's] compliance policies"; 7. "The persons that performed the analyses or reviews and/or provided the opinions or advice concerning the HHS or OIG guidance, OIG advisory opinions, Anti-Kickback Statute, False Claims Act, federal regulations, and/or judicial decisions referenced in [Janssen's] responses to interrogatories 15 (amended) and 20-22 that [Janssen] considered, relied upon, and/or adopted in reaching the asserted belief at the time [Janssen was] providing the IOI Support Services that [Janssen was] acting lawfully"; and 8. "The persons that performed the analysis(es) or review(s) and/or provided the opinions or advice concerning the meaning, implication, or significance of the United States' investigation or inquiry referenced in [Janssen's] response to interrogatories 15 (amended) and 20-22 that [Janssen] considered, relied upon, and/or adopted in reaching the asserted belief at the time [Janssen was] providing the IOI Support Services that [Janssen was] acting lawfully" (#339-1 at 5-8 (Relator's Notice of 30(b)(6) Deposition).)

timing of Janssen's providing certain categories of discovery, and those disputes are not addressed by the court's deadlines above, the court orders the parties to confer about the dates of completion and if they cannot agree, to file a joint memorandum setting out their competing timetables, and the court will set dates. This joint memorandum shall be filed within three weeks of the date of this order.

One issue that is raised in this motion only concerns contracts Janssen entered into with outside consultants and law firms related to providing the IOI services at issue in this case. For example, relator asserts that contrary to what Janssen says, it has not provided relator with all relevant contracts from Xcenda, an outside healthcare consultant that provided services at issue in this case to physicians free of charge. (#359 at 14.) Janssen is ordered to provide any outstanding Xcenda contracts to relator within two weeks of this order.

In addition, Janssen contracted with a law firm, Akin Gump, to hold telephone seminars during which it provided certain physician practices—including accounts in Central Pennsylvania, where relator was working—free information concerning changes in Medicare payment rates. *Id.* at 14-15. Contracts with Aiken Gump, insofar as they reflect how much Janssen paid for the provision of these seminars during the relevant time period, are clearly relevant and not privileged, and should be produced. Janssen agreed to provide this information to relator at the oral argument on this motion, (#367 at 59), and to the extent that Janssen has not already turned this information over to relator, it is ordered to do so within two weeks of this order.

V. Conclusion.

For the above reasons, Janssen's motion to compel and for a protective order, (#328), is allowed in part and denied in part; Janssen's motion for a protective order vacating relator's Rule

30(b)(6) deposition (#333) is allowed; and relator's motion to compel compliance with the court's orders and to compel discovery (#345) is allowed in part and denied in part.

March 9, 2023

/s/ M. Page Kelley
M. Page Kelley
Chief United States Magistrate Judge