**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| UNITED STATES OF AMERICA; and THE STATE OF NEW YORK<br><br>*ex rel.* DR. ANTONI NARGOL and DR. DAVID LANGTON<br><br>Plaintiffs-Relators,<br><br>v.<br><br>DEPUY ORTHOPAEDICS, INC., DEPUY, INC., and JOHNSON & JOHNSON SERVICES, INC.,<br><br>Defendants. | Case No. 12-10896-MPK |

**MEMORANDUM IN SUPPORT OF DEPUY'S MOTION TO QUASH SUBPOENAS**

Antoni Nargol and David Langton (together, **Relators**) filed this *qui tam* action over eight years ago. Despite its "Biblical" duration (#351, at 57), Relators waited until the twice-extended deadline for the "completion of document production . . . including third party documents" (#357) had expired to demand a massive amount of data, which they claim is vital to their case but "not require[d]" (#404, at 11), from the Centers for Medicare and Medicaid Services (**CMS**) and the New York State Department of Health (**NYSDOH**). And when they did, they ignored clear and binding guidance from the United States Supreme Court, *see United States ex rel. Touhy v. Ragen*, 340 U.S. 462, at 468–70 (1951); the Department of Health and Human Services (**HHS**) and its Office of General Counsel (**OGC**), *see* 45 C.F.R. Part 2; the Federal Rules of Civil Procedure, *see* Rule 45(a)(4); and this Court (#357).

Having squandered years of discovery and blown the January 6, 2020 document production deadline, Relators should not be permitted to resurrect their untimely and procedurally improper subpoenas of CMS and NYSDOH by relying on an Order (# 414) that, in material part, redressed Relators' discovery failures. The Court should quash the subpoenas.

## BACKGROUND

In its Order of July 8, 2020 (#414), the Court detailed most of the background relevant to this motion. Accordingly, only a brief recap follows.

Relators filed this *qui tam* action in 2012. (#1.) They amended their complaint to add allegations about DePuy's manufacture of the Pinnacle 36mm metal-on-metal total hip replacement system (**Pinnacle**) in 2013. (#23 (filed under seal).) The United States declined to intervene in 2014 (#32), the Court (Saylor, J.) dismissed the case with prejudice in 2015 (##184; 185), and the First Circuit remanded a significantly narrowed set of allegations in 2017 (#204).

Since then, Relators have focused their attentions on other matters. (#341, at 2 ("counsel for Relators have been predominantly focused on attending to the finalization of the [DePuy] MDL settlements" and "within the last few months, it was decided that counsel for Relators . . . will be the lead plaintiffs' trial counsel in the first bellwether trial in the Opioid MDL")). Relators have made little effort to advance this action and, on at least two occasions, they have requested last-minute extensions of long-pending discovery deadlines. (##341; 354.)

First, in August 2019, Relators asked the Court to extend the deadline for "[c]ompletion of all document production" from September 30, 2019, to December 2, 2019. (#341, at 3.) The Court obliged (#343) but warned that any additional extension would require "really good cause." (#351, at 71.) Second, in December 2019, Relators asked the Court to extend the same

deadline, again, from December 2, 2019 to January 6, 2020. (#354, at 3.) The Court obliged but admonished:

> The court now makes clear that the new deadline for completion of document production, January 6, 2020, applies to all documents, ***including third-party documents***, not just those in the relators' possession, custody, and control. ***The court does not anticipate granting any further motions for extensions.***

(#357 (emphases added).)

Despite those unequivocal admonitions, Relators waited until the January 6, 2020 deadline had arrived to request, for the third time, "additional time to complete their collection" of documents including "Medicare and Medicaid claims data." (#361, at 7.) At that time, Relators reminded the Court that "obtaining such information from the Government 'involves two-year requests'" because of the "peculiarities of Medicare and Medicaid's reimbursement methodologies" for Pinnacle components but, Relators assured, they were trying to expedite the process. (#361, at 7–8 n.11 (quoting #351).)

Weeks later, having not received the "additional time" that they requested, Relators subpoenaed CMS and NYSDOH. The subpoenas, served January 17 and 27, 2020, respectively, are included herewith as **Exhibits A** and **B**. In explicit violation of Federal Rule of Civil Procedure 45(a)(4), Relators did not provide copies of the subpoenas to DePuy until January 27, 2020, after they had served them. *See* Email from R. Brooks to H. Bornstein dated Jan. 27, 2020, included herewith as **Exhibit C**.

The subpoenas demanded data reflecting Medicare and Medicaid payments for all Pinnacle component implantations and related services (i.e., "claims data"), but Relators failed to abide the *Touhy* regulations that govern discovery from the United States when it is a third party to civil litigation, such as when, as here, the government has declined to intervene in a *qui tam*

action. 31 U.S.C. § 3730(b)(4)(B); *cf*. 45 C.F.R. 2.1(d)(1) (noting that HHS *Touhy* regulations do not apply to civil proceedings in which the United States is a party). Generally, those regulations require the requesting party to explain why the subpoena promotes the objectives of HHS while assuring "strict impartiality with respect to private litigations" and "minimizing the disruption of official duties." 45 C.F.R. §§ 2.1, 2.3, 2.5.

Like the Court, CMS declined to countenance Relators' untimely and procedurally improper subpoenas. Through OGC, CMS advised Relators on January 29, 2020:

> Given the Court's Dec. 10 Order ("The court now makes clear that the new deadline for completion of document production, January 6, 2020, applies to all documents, including third-party documents, not just those in relators' possession, custody, or control.") and your pending motion to extend the time for third-party discovery, we see no need to object or otherwise respond to your subpoena until such time as the court orders an extension of the time for discovery.

(#404-6.)

Meanwhile, after a long hiatus, Relators hastily returned their attentions to this case. They moved for "clarification" of various discovery orders (#358), sought leave to share confidential documents with potential new co-counsel (#373), moved to compel certain information from DePuy (## 360; 399), and eventually moved to stay discovery (#403). Amid an unforeseeable pandemic and Relators' post-Eleventh Hour flurry of motions, the Court stayed discovery on March 20, 2020. (#405.)

On July 8, 2020, the Court largely denied Relators' discovery motions and largely granted DePuy's, reserving on "whether relators violated Judge Katz's confidentiality order, and, if so," whether striking allegations or dismissing the case was warranted. (#414, at 10–14.) Important here, the Court reiterated that its December 10, 2019 scheduling order "made clear that the new deadline for completion of document production, January 6, 2020, applie[d] to all

documents, including third-party documents, not just those in relators' possession, custody or control" and stated that "the court did not anticipate granting any further motions for extensions as it had previously granted several of relators' motions to modify the scheduling order." (*Id.* at 10 (citations and quotation marks omitted).)

Then, the Court denied Relators' motion to modify the December 10, 2019 scheduling order except as "clarified in this Memorandum." (*Id.* at 13.) Specifically, the Court ordered Relators to come into compliance with their pre-January 6, 2020 discovery obligations, including by producing materials that Relators had shared with QA Consulting and the protocols, steps, and processes that they used to measure Pinnacle components (*id*. at 13–14)—information that DePuy had first requested in its First Set of Requests for Documents in February 2018. The Court gave Relators two months to do so, holding that "[a]ll remaining document production, which applies to all documents, including third-party documents, not just those in relators' possession, custody, or control, shall be completed by August 31, 2020." (*Id*. at 14.) Critically, the Court's instructions did not address, let alone decide in Relators' favor, their motion for more time to collect Medicare and Medicaid claims data (#361).

Nevertheless, Relators contacted CMS immediately after the Court issued the July 8, 2020 Order to demand production in response to their subpoenas, advising that "the Court extended the discovery deadline to August 31, 2020." Letter from E. Heard to R. Brooks dated July 13, 2020, included herewith as **Exhibit D**. In response, CMS wrote:

> A party seeking third party discovery from the United States must comply with any applicable agency Touhy regulations. *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468–70 (1951) (upholding regulation prohibiting agency employees from releasing documents without consent of agency head); 45 C.F.R. Part 2 (outlining the appropriate procedures that must be followed when documents are requested from an agency).

*Id*. After lodging additional objections, CMS indicated that it would work with Relators to collect and produce responsive information but directed Relators to "agree with defendant as to the data you seek and the timeframes needed so that the data pull is done only once by CMS." *Id.*

Relators did not inform DePuy of their renewed efforts to enforce the CMS and NYSDOH subpoenas, let alone contact DePuy, as CMS instructed, to confer on their scope. *See* Declaration of A. Tarosky dated July 16, 2020 ¶ 7, included herewith. Instead, Relators waited until DePuy contacted them to advise of its intention to file motions to quash to suggest that the subpoenas might be narrowed. *Id.* As DePuy noted in response, however, the subpoenas are untimely, unfairly prejudicial, and procedurally improper. *Id*. No narrowing of their scope will remedy those deficiencies.

Meanwhile, on July 14, 2020, DePuy counsel spoke to CMS counsel, and CMS counsel advised that it may take six to eight weeks just to gather the claims data, and additional time to quality check and produce it to the parties. *Id.* ¶ 6.

## ARGUMENT

Although a party ordinarily does not have standing to move to quash a subpoena issued to a third party, *see Guarriello v. Family Endowment Partners, L.P.*, 2015 WL 13694425, at *3 (D. Mass. Oct. 30, 2015), courts have recognized exceptions, including when the subpoena implicates a right of a party and/or calls for irrelevant information. *Id*. Here, Relators' subpoenas implicate DePuy's right: (1) to a fair proceeding consistent with due process and the requirements of the Federal Rules of Civil Procedure; (2) to HHS's "strict impartiality" in adherence to *Touhy* regulations in litigation in which it is a third party, 45 C.F.R. § 2.3; and (3) to a timely resolution of Relators' allegations based on information that is relevant to Relators' remaining claims or DePuy's defenses. Fed. R. Civ. P 26(b)(1).

## I. Relators' Untimely and Procedurally Improper Subpoenas Unfairly Prejudice DePuy.

A court may quash a Rule 45 subpoena that unfairly prejudices a litigant or "'on ground of untimeliness.'" *Hearts with Haiti, Inc. v. Kendrick*, 2014 WL 12650626, at *2 (D. Me. Nov. 30, 2014) (quoting *Galloway v. Islands Mech. Contractor, Inc.*, 2013 WL 163985, at *4 (D.V.I. Jan. 14, 2013)). Unfair prejudice may arise when a party uses its "'failure to comply with the discovery schedule to [its] advantage,'" including by serving a subpoena after an applicable discovery deadline. *Hearts with Haiti*, 2014 WL 12650626, at *2 (quoting *Pegoraro v. Marrero*, 281 F.R.D. 122 (S.D.N.Y. Feb. 3, 2012)).

Here, Relators "post-discovery service," *Hearts with Haiti*, 2014 WL 12650626, at *2, of subpoenas on CMS and NYSDOH are both untimely and unfairly prejudicial. Since the First Circuit remanded this case, DePuy has taken significant written discovery of Relators, asked for dates for depositions of Relators and their consultant at QA, and diligently worked to narrow disputed issues and prepare the case for dispositive motions practice. Relators have participated, at best, in fits and starts. As they have admitted to the Court, since at least January 2019, their attentions have been on other matters. (#341, at 2.)

With the return of previous counsel in late 2019/early 2020 (*see* #354, at 3 ("Mr. Brooks is an experienced False Claims Act lawyer.")), and the Court's efforts to finally bring the long document discovery period to a close, Relators have scrambled to take the steps that they have failed to take for years. In particular, if Relators believed that they needed claims data, *see United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 41–42 (1st Cir. 2017), they should have requested it years ago and left ample time in the document discovery period for the collection, production, review, and assessment of that data. *See United States ex rel. Gohil v. Sanofi U.S. Services, Inc.*, 2020 WL 1888966, at *4 (E.D. Pa. Apr. 16, 2020) ("A district court is

well within its discretion when it denies untimely discovery requests that could have been made at an earlier date.").

Instead, they waited to request a massive amount of data which, as Relators acknowledge, is difficult to gather. (*See* #361, at 7–8 n.11; *see also* #219, at 24–29 (Relators' allegations about how Medicare and Medicaid pay for Pinnacle components and related implantation services)). As CMS advised on July 14, 2020, it will likely take between six and eight weeks just to gather the data. *See* Declaration of A. Tarosky dated July 16, 2020 ¶ 6. By then, of course, Relators will have blown yet another discovery deadline. (#414, at 14.)

Meanwhile, DePuy has been forced to spend significant sums to conduct discovery and otherwise defend itself. Moreover, if claims data is produced, DePuy will be forced to assess its adequacy and likely make its own requests for additional data. For example, as Relators have advised, their case is based on their attempts to estimate the as-manufactured dimensions of about 200 explanted Pinnacle components. (#351, at 31–32.) Those Pinnacle components were mostly, if not all, explanted from patients in the United Kingdom, not the United States. Therefore, it is unlikely that Medicare, Medicaid, or any other United States health care program would have paid for any of the explants that Relators actually examined. DePuy may be forced to seek information from CMS and NYSDOH to establish that important point.

In short, Relators' case has morphed through myriad amended complaints, changes of counsel and, now, last minute attempts to inject a massive amount of new information into a dying case. DePuy should not continue to have to shoot at a moving target.

## II. Relators Should Not Be Allowed to Circumvent Applicable *Touhy* Regulations.

Relators' subpoenas should also be quashed because Relators failed to follow HHS's *Touhy* procedures, which apply to all private litigants seeking discovery from the agency. 45

C.F.R. § 2.1. In particular, parties in a *qui tam* action that the United States has declined, like this one, must obtain documents and testimony from the government, if at all, through the relevant *Touhy* procedures, which must apply equally to plaintiff-relators and defendants. *See, e.g.*, *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Amer.*, 474 F. Supp. 2d 75, at 79–80 & n.5 (D.D.C. 2007). Such regulations assure that when the government is not a party to a lawsuit, public resources are not expended on private affairs until the head of the relevant agency (or his or her designee) has determined that the expenditure is in the government's interests. *See Touhy*, 340 U.S. at 468 ("When one considers the variety of information contained in the files of any government department and the possibilities of harm from unrestricted disclosure in court, the usefulness, indeed the necessity, of centralizing determination as to whether subpoenas duces tecum will be willingly obeyed or challenged is obvious.").

HHS's *Touhy* regulations provide that HHS will "maintain strict impartiality with respect to private litigants" and endeavor to "minimize the disruption of official duties." Moreover:

> No employee or former employee of [HHS] may provide testimony or produce documents in any proceeding to which this part applies concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department unless authorized by the Agency head pursuant to this part based on a determination by the Agency head, after consultation with [OGC], that compliance with the request would promote the objectives of the Department.

45 C.F.R. § 2.3. In addition to "Agency head" approval, OGC must assure that the subpoena is "legally sufficient" and "properly served." 45 C.F.R. § 2.5(a).

Relators have not followed those rules. There has been no request of, or determination by, the "Agency head" (*see* 45 C.F.R. § 2.2) that compliance with Relators' subpoenas "would promote the objectives of the Department," *see* Ex. D, and as explained in Parts I and III, the subpoenas are legally insufficient. Accordingly, the subpoenas should be quashed.

### III. Even if Timely and *Touhy*-Compliant, Which They Are Not, Relators' Subpoenas Call for Irrelevant Information.

Generally, "a party may obtain discovery," including from third parties, "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). A Rule 45 subpoena may be quashed if it subjects the recipient to "undue burden." Fed. R. Civ. P. 45(d)(3)(A)(iv).

Here, Relators have produced an Excel spreadsheet which, they claim, collects the results of their attempts to estimate the as-manufactured dimensions of about 200 Pinnacle components following explantation. (#351, at 31–32.) As discussed in Part I, *supra*, the vast majority of those components, if not all of them, were implanted into and subsequently explanted from patients in the United Kingdom, where Relators live and practice. Accordingly, it is highly unlikely that claims associated with any of the Pinnacle components that Relators actually analyzed were submitted to CMS, NYSDOH, or any other United States health care program. Accordingly, the claims data that Relators have requested is irrelevant. 31 U.S.C. § 3729(b)(2)(A)(i) (defining "claim" for purposes of the False Claims Act as "any request or demand" that is "presented to an officer, employee, or agent ***of the United States***") (emphasis added). And as CMS has indicated, it may also subject "HHS to an unreasonable burden." Ex. D.

## CONCLUSION

For the foregoing reasons, the Court should quash Relators' subpoenas to CMS and NYSDOH. Exs. A, B.

Dated: July 16, 2020

Respectfully submitted,

DEFENDANTS
DEPUY ORTHOPAEDICS, INC., DEPUY, INC.,
JOHNSON & JOHNSON SERVICES, INC.

By their attorneys,

*/s/ Mark D. Seltzer*

Mark D. Seltzer, Esq.
(BBO No. 556341)
Hannah R. Bornstein, Esq.
(BBO No. 670433)
Colin T. Missett, Esq.
(BBO No. 706248)
NIXON PEABODY LLP
53 State Street
Boston, Massachusetts 02109
Telephone: (617) 345-1000

Adam R. Tarosky
(admitted *pro hac vice*)
Nixon Peabody LLP
799 9th Street NW
Suite 500
Washington, DC 20001-5327
Telephone: (212) 940-3000

**CERTIFICATE OF SERVICE**

I hereby certify that on July 16, 2020 I electronically filed the foregoing document with the United States District Court for the District of Massachusetts by using the CM/ECF system. I certify that the parties or their counsel of record registered as ECF Filers will be served by the CM/ECF system:

*/s/ Colin T. Missett*