

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA and
THE STATE OF NEW YORK

CIVIL ACTION No. 12-10896-MPK¹

ex rel. DR. ANTONI NARGOL & DR. DAVID
LANGTON,
Relators,

v.

DEPUY ORTHOPAEDICS, INC., DEPUY, INC.,
and JOHNSON & JOHNSON SERVICES, INC.,
Defendants.

MEMORANDUM AND ORDER ON DEPUY'S
MOTION FOR RECONSIDERATION (#545).

KELLEY, U.S.M.J.

I. Introduction.

In May 2012, Dr. Antoni Nargol and Dr. David Langton brought this qui tam action against DePuy Orthopaedics, Inc., DePuy, Inc., and Johnson & Johnson Services, Inc. (collectively, DePuy) under the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, and the New York state false claims act. (##1; 219.)² At issue is the metal-on-metal (MoM) hip replacement device DePuy manufactured under its “Pinnacle” product line (the Pinnacle or the Pinnacle device). (#219 ¶ 6.) Relators allege that over a five-year period, DePuy illegally promoted and sold a significant

¹ With the parties’ consent, this case has been assigned to the undersigned for all purposes, including trial and the entry of judgment, pursuant to 28 U.S.C. § 636(c). (#318.)

² The Department of Justice (DOJ) declined to intervene on behalf of the United States. (#32.) Previous claims arising under the laws of other states have been dismissed. *See* #204 at 31.

number of Pinnacle devices that fell outside FDA-approved manufacturing specifications, causing false claims to be submitted to Medicare and Medicaid. *See id.* ¶¶ 88, 104, 179-181, 349.

A key issue in this action is that relators previously served as experts and consultants in multi-district litigation (MDL) involving the Pinnacle device and another MoM hip replacement device manufactured by DePuy, called “ASR.” In those roles, relators had access to confidential information subject to protective orders. (##103 at 18; 522-21.) Relators have been warned by multiple courts that they are required to comply with the protective and court orders that govern their use of that confidential information. *See, e.g.*, ##101; 103 at 18; 249; 414. In addition, they have been chastised repeatedly for failing to comply with those orders. *See, e.g.*, ##104 at 22, 27; 103 at 18; 414. DePuy moved to strike allegations and to dismiss the case, (#519), citing relators’ use of confidential information in their second amended complaint as a basis for dismissal. The court denied the motion (#542); DePuy moved for reconsideration (#545). For the reasons discussed below, DePuy’s motion (#545) is ALLOWED.

II. Factual Background.

A. Relators’ Claims.

DePuy is in the business of designing, manufacturing, and distributing MoM hip replacement devices used to treat medical conditions such as late-stage degenerative hip disease, hip joint damage, and osteoarthritis. (#219 ¶ 73.) Relators describe themselves as “two of the most prominent experts in MoM surgical technique and engineering technology.” *Id.* ¶ 23. Throughout the 2000s, relators used DePuy MoM devices such as the Pinnacle and ASR to treat hip conditions in many patients. *Id.* ¶ 24. These devices included a metal head, cup, and liner, which together mimic the cup and ball of a hip joint. *Id.* ¶¶ 6, 148, 154.

As Relator Langton began noticing problems with the Pinnacle, he gathered data on explanted devices. (#219 ¶ 70.)³ He examined over 250 explanted and unused Pinnacle devices and collected measurements of the explants in a database. *Id.* Relators hired QA Consulting (QA) to perform a statistical analysis of the explant data. *Id.* ¶¶ 344, 346. They allege that, “[b]ased upon QA’s statistical analysis, DePuy’s manufacturing process fails to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time.” *Id.* ¶ 349. Relying in large part on QA’s analysis, relators’ claims are premised on the allegation “that DePuy falsely palmed off devices that, due to latent manufacturing defects, materially deviated from the design specification of the FDA-approved Pinnacle MoM device.” (#204 at 6); *see also U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 32 (1st Cir. 2017).

B. Relators’ Confidentiality Obligations.

1. ASR MDL.

In 2010, in response to high failure rates for the ASR device, DePuy announced a recall. (#219 ¶ 55 & n.4.) At the same time, the company faced a rash of product liability lawsuits regarding the ASR device that were consolidated into an MDL. *Id.* ¶¶ 56-57; *see In re: DePuy Orthopaedics, Inc., ASR Hip Implant Prods. Liab. Litig.*, No. 10-md-2197 (N.D. Ohio). Prior to bringing this lawsuit, relators served as testifying experts or fact witnesses, or otherwise provided expert assistance, in many product liability and personal injury cases against DePuy, including the ASR MDL. *Id.* ¶¶ 68, 72. Beginning around May 2012, plaintiffs’ counsel in the ASR MDL provided relators with confidential DePuy documents to assist them in preparing for their expert

³ The Pinnacle device was made in multiple sizes; the product at issue in this case is the 36mm Pinnacle device. (#219 ¶ 359.)

testimony there. (#103 at 12.) These documents were subject to a protective order which bound both relators to certain confidentiality obligations. *Id.*

2. Pinnacle MDL.

Since 2011, “more than 5,000 personal injury actions have been filed by patients who have been injured by the Pinnacle device.” (#219 ¶ 58.) Like the ASR cases, these cases were consolidated into an MDL. *Id.*; see *In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, No. 11-md-2244 (N.D. Tex.). Langton consulted with plaintiffs’ counsel in support of the Pinnacle MDL but was not formally retained as an expert. (#529 at 19 n.25.) Although Langton was not formally retained, he consulted with plaintiffs’ counsel and experts, received remuneration for his time and efforts, and had access to materials that would not otherwise have been available to someone who was not associated with the litigation. See, e.g., #522-11 at 2 (email communications between Langton and plaintiffs’ counsel, discussing documents he wanted to review and whether he would be billing plaintiffs’ counsel for his time). On November 15, 2013, he signed a confidentiality agreement, indicating that he had read the Pinnacle MDL’s stipulated protective order, understood its terms, and “agree[d], upon threat of penalty of contempt, to be bound by such terms.” (#522-21 at 7.)

3. Relators’ Repeated Violations of Confidentiality Orders.

In July 2014, relators disclosed to this court that they had included in their complaint confidential information subject to protective orders in both MDLs. (##34; 37 at 3-4.) Judge Saylor, who was presiding over the case at that time, granted relators leave to amend the complaint so as to remove the offending material. (#101). The second amended complaint was required to be

accompanied by affidavits from relators sworn to under the pains of perjury that certify that the second amended complaint **does not violate any relevant court order, including the protective orders issued in the MDL proceedings** in the

Northern District of Ohio or the Northern District of Texas or the order issued by the court in Ohio on January 5, 2015.

Id. (emphasis added.) Relators filed their second amended complaint with the required accompanying affidavits on May 4, 2015. (##115-3; 115-4.)⁴

In 2015, relators asked the presiding judge of the ASR MDL, Judge Katz, to relieve them of their obligations under the protective order in that case. (#103 at 11.) They admitted that in contravention of the protective order, between May 2012 and June 2014, they had given confidential documents and information to the U.S. government and to several states in support of this case. *Id.* at 12; *see* #522-3 at 2 (letter from DOJ to counsel for relators, noting that relators had improperly disclosed materials subject to the ASR MDL protective order). Judge Katz refused to modify the protective order, and instead reminded relators that they “are *prohibited* from sharing or using the information they received in their capacities as experts [in that litigation] in [the present qui tam proceeding]. They are also *prohibited* from sharing their information with any third-party, including any government entities, foreign or domestic.” (#103 at 18.) He expressed particular concern regarding relators’ conduct, noting that

[a]llowing . . . modification of the Confidentiality Order rewards the [relators] for using confidential information they obtained in their roles as experts; information which would not have been available to them absent their special employment. . . . If the Court agreed with [relators’] request, these retained experts would be free to use the knowledge they obtain during this litigation for their own benefit. This result is unacceptable.

Id. at 15, 17.

⁴ Relators were later ordered to file a corrected version of the second amended complaint, removing “all claims and allegations no longer viable or relevant in light of the ruling of the United States Court of Appeals for the First Circuit.” (#216). *See generally DePuy*, 865 F.3d 29. That version of the second amended complaint, (#219), is now the operative complaint.

In December 2017, the parties entered into a stipulated protective order in this case, which the court approved in January 2018. (##247; 249.) The parties stipulated to the following: “nothing in this Protective Order alters the January 5, 2015 ruling issued by the Honorable David A. Katz in the matter *In re DePuy Orthopaedics, Inc., ASR Hip Implant Products*, Case No. 1:10-md-2197 (N.D. Ohio).” (#249 ¶ 17.)

In a briefing submitted to the court in March 2020, relators insisted that their record-keeping demonstrated that “there has been no ‘inadvertent’ use of confidential information in order to plead the QA Allegations.” (#386 at 9.) Nearly six months later, however, relators filed a motion to correct that briefing, noting that they had, in fact, provided QA with Pinnacle device history records they had obtained through the Pinnacle MDL. (#468 at 8.) Despite this, they averred that QA had not used the device history data and noted that, “[w]ith respect to the statistical allegations pleaded in the complaint, Relators confirmed with certainty that QA did not rely upon any MDL-derived information in preparing its Pinnacle Explant Analysis.” *Id.* at 6.

In July 2020, relators asked this court not to hold them to their obligations under the ASR MDL protective order or Judge Katz’s 2015 order. (##358, 359). The court denied their request and ordered relators to continue complying with their MDL confidentiality obligations as well as Judge Katz’s 2015 order. (#414 at 10-11.) For the avoidance of doubt, the court further clarified that “[relators] are prohibited from using any of the information they received in their capacities as experts in the MDL litigations to prosecute the present case.” *Id.* at 11.

C. Pinnacle Device Measurements.

Two sets of measurements have been the subject of recent motion practice in this case. The first are the nominal (as-designed) dimensions and tolerance levels (the accepted upper and lower deviation limits from a nominal dimension) of the Pinnacle Liner, and the second are the nominal

dimensions and tolerance levels of the Pinnacle Head. (##522 at 9 (defining nominal); 219 ¶ 160 (defining tolerance levels).) The parties have debated whether the measurements are public or confidential—in other words, whether relators violated a protective or court order by relying on the measurements in their second amended complaint.

Relators claim that “[e]ngineering drawings . . . are the most authoritative sources of a device’s precise dimensions.” (#594-2 at 3.) In September 2013, Langton began seeking out these drawings for the Pinnacle device. He first asked plaintiffs’ counsel in the Pinnacle MDL whether they had a “redacted 510K for [P]innacle liners . . . with engineering drawings.” (#522-5 at 2.)⁵ Counsel told him they had not found one but that it was on their “to do list.” *Id.* On October 3, 2013, Langton and an expert from the Pinnacle MDL, Dr. Gregory Sawyer, communicated via email about the Pinnacle device. (#522-7 at 2.) Langton asked Sawyer for drawings of the device, and Sawyer noted that the drawings he had were “essentially unreadable,” adding, “I completely understand your frustration.” *Id.* Langton went on to ask Sawyer to confirm the dimensions of the Liner and Head, but there is nothing on the record to indicate whether Sawyer responded. *Id.*

Several weeks later, on October 31, 2013, Langton again emailed plaintiffs’ counsel in the Pinnacle MDL, asking for “the engineering drawings of the original [P]innacle device.” (#522-12 at 6.) His request was forwarded to someone else at the same firm, who informed him that he would need to sign a protective order before they could provide him with “the CAD drawings and related files” he was requesting. *Id.* at 5.⁶ She also noted that the files “contain proprietary

⁵ “[U]nder the 510(k) process,” an applicant seeking FDA approval for a medical device “is required to demonstrate only that the device is substantially equivalent in terms of safety and effectiveness to an existing FDA-approved device.” (#219 ¶ 110 (citing 21 C.F.R. § 807.92(a)(3)).)

⁶ CAD is an acronym for computer-aided design.

information.” *Id.* A few days later, Langton emailed plaintiffs’ counsel and stated that while he had not yet signed the protective order, he agreed with its terms and wanted the files. *Id.* at 4. He was again told that he would receive the files as soon as he sent them a signed copy of the protective order. *Id.* at 3. He received the materials he was requesting on November 15, 2013, the same day that he signed the protective order. *Id.* at 3; *see* #522-21 at 7. The following day, Langton, who is based in the U.K., emailed one of plaintiffs’ counsel, who was in Sweden to take depositions in connection with the MDL. (#522-11 at 3-4.) Langton asked if counsel had “the [P]innacle 510K” with him and then booked a flight to Sweden so that he could review it in person. *Id.* In an email dated November 20, 2013, Langton wrote to plaintiffs’ counsel, noting that he “was given a flash disc which has made interesting reading.” (#522-12 at 2.)

Although there is no dispute that Langton received documents from plaintiffs’ counsel in the Pinnacle MDL, relators have refused to produce these documents to DePuy. (#537 at 13 (noting that “Relator Langton received a set of (unidentified and unproduced) documents from Pinnacle MDL plaintiffs’ counsel”); #541 at 11 n.20 (“Relators ought not to be required to reconstruct and reassemble a flash drive received more than seven years ago when discovery of its irrelevant contents would do no more than waste more of the Court’s time.”).)

1. Pinnacle Liner Measurements.

An engineering drawing of the Pinnacle Liner (one component of the Pinnacle device) was produced in the Pinnacle MDL in August 2013. (#522-4 at 2.) It was produced in its native format (a CAD file), therefore the document itself did not include a Bates stamp or confidentiality designation. *Id.* The file was emailed from DePuy’s counsel to plaintiffs’ counsel in a zip folder labeled “Design_Drawings_AttyEyesOnly.zip,” which contained native files with “AttyEyesOnly” in the filenames. *Id.* The Pinnacle Liner drawing, with the filename

“121887354_Rev_H_AttyEyesOnly.igs,” contained the Pinnacle Liner’s nominal radius and tolerance levels, measured in inches. *Id.* at 15.

On October 2, 2013—before Langton signed the Pinnacle MDL protective order—plaintiffs’ counsel in the Pinnacle MDL sent him two “DePuy Drawings” of the Pinnacle Liner. (#522-6.)^{7, 8} One of them was the drawing that contained the Liner’s nominal radius and tolerance levels. *Id.* at 3. Unlike the documents that DePuy produced, however, the drawing Langton received had the filename “121887354_Rev_H.pdf”; in other words, the “attorneys’ eyes only” designation had been removed. *Id.* at 2.⁹ On November 8, 2013, relators’ counsel forwarded the drawing to QA, noting: “These appear to be the Pinnacle drawing dimensions.” (#522-20 at 2.) That drawing also did not contain the “attorneys’ eyes only” designation in its filename. *Id.* at 2-4. At a hearing before this court in February 2021, relators’ counsel stated that “we’re not aware of whether or why or how any ‘Attorneys’ Eyes Only’ . . . may have been removed from this document. We simply have no idea why that would be the case.” (#502 (1/19/21 Hrg. Tr. at 35:25-36:4).) When, why, and by whom the designation was removed remains unresolved.

⁷ Relators repeatedly misstate that Langton received the Liner drawing from Dr. Sawyer. *See, e.g.*, #529 at 9 (“The Pinnacle Drawing Relators received from Dr. Sawyer on October 2, 2013 . . .”); *id.* at 20 (asserting that “Dr. Langton received the Pinnacle Drawing not from MDL counsel, but from Dr. Sawyer indirectly”); #594-2 at 4 n.6 (referencing “Dr. Sawyer’s liner drawing”). It is clear that Langton received the drawing directly from plaintiffs’ counsel. (#522-6.)

⁸ At a January 19, 2021 hearing, counsel for DePuy stated that the Pinnacle Liner and Head drawings were produced in both MDLs in August 2013. (#502 (1/19/21 Hrg. Tr. at 12:3-6).) DePuy has not asserted this in its briefings on the motions, but if this is true, Langton would have been subject to the ASR MDL protective order when he received the Pinnacle Liner drawing in October 2013.

⁹ DePuy submitted an affidavit from an expert who confirmed that, despite the slightly different filenames, the documents were identical. (#522-24.)

DePuy took the Pinnacle Liner off the market in August 2013. (#219 ¶ 156.) The Pinnacle Liner drawing (which was incorporated into the Liner’s 510(k)) was used as an exhibit at a Pinnacle MDL trial in 2014 and is now publicly available. (##522-15 at 19 (drawing in 510(k)); 529-5 at 16 n.5 (copy of DePuy’s motion to seal trial exhibits in the Pinnacle MDL, in which DePuy stated that it was not seeking to seal its Liner drawings).)¹⁰ Yet relators did not know that the Liner dimensions were public until January 2021, nearly six years after they filed their second amended complaint and affidavits certifying its compliance with court orders. (##504-4 at 3 (copy of January 30, 2021 email from relators’ counsel to counsel for DePuy, noting their discovery that the Liner drawing had been made public in 2014); 504 at 1 (discussing “[r]elators’ recent discovery”).)

2. Pinnacle Head Measurements.

A second component of the Pinnacle device was the Pinnacle Head. (#219 ¶ 154.) On November 17, 2013—days after Langton signed the protective order and received materials produced in the Pinnacle MDL—counsel for relators sent QA a spreadsheet containing data from Langton’s explant studies. (#522-8.) The spreadsheet also included nominal dimensions and tolerance levels for the Pinnacle Head and Liner, and provided those measurements in millimeters to five decimal places. *Id.* at 3. The following day, counsel for relators sent QA a second spreadsheet that also contained this information. (#522-9 at 2-3.) Specifically, the spreadsheets listed a nominal Head diameter of [REDACTED], a lower specification limit of [REDACTED], and an upper specification limit of [REDACTED]. (##522-8; 522-9.) This reflects a tolerance level of

¹⁰ The Pinnacle Liner 510(k) also contains a table that lists dimensions and tolerance levels for the Liner and Head. (#522-15 at 59.) As discussed *infra*, however, the Head dimensions provided in the table differ from those listed on Pinnacle Head engineering drawings.

██████████. See ##522-8 at 3; 594-2 at 3.¹¹ The explant data that Langton had gathered also reported measurements for the explanted Heads and Liners in millimeters. See ##522-8 at 3; 594-2 at 3. Using this information, QA was able to compare measurements from the explanted devices against the Pinnacle’s nominal (intended) measurements. (#219 ¶¶ 346-349.)

Relators have admitted that the measurements for the Pinnacle Head are not public. (#592 at 1 n.1 (“To date, [r]elators have not yet located the Pinnacle [] head’s engineering diagram in the public domain.”).) DePuy states that this is “because these precise specifications for the Pinnacle head—which is still on the market today—were, and have always remained, DePuy’s confidential (i.e., non-public) and proprietary commercial information.” (#565 at 6 (emphasis omitted).)¹²

To account for their use of this non-public information in their second amended complaint, relators first asserted that they were able to obtain it using the now-public Liner drawing. (#529 at

¹¹ Converted to inches, the nominal Head diameter is ██████████, with a tolerance level of ± ██████████.

¹² After stating in a September 30, 2021 supplemental filing (#592 at 1 n.1) that they had not identified a public version of the Pinnacle Head drawing, relators filed an affidavit nearly two weeks later that identified, for the first time, a website with an approximately 600-page DePuy document containing versions of the Pinnacle Head drawing with the measurements at issue. (##597-11 ¶ 15; 597-5). That website indicates that the document was not uploaded to the site until July 2018, three years after relators filed their second amended complaint with accompanying affidavits as to its conformance with court orders on confidentiality. See Industry Documents Library, *Summary Report for Protocol for the Transit Test of Pinnacle Insert Product Range*, <https://www.industrydocuments.ucsf.edu/docs/#id=yjxn0226> (last visited Nov. 9, 2021) (listing July 19, 2018 as the date the document was added to the database). The website identifies the document as an exhibit from a Pinnacle MDL trial. *Id.* Relators acknowledge that DePuy was given leave to redact the document after the trial due to the confidential nature of its contents, though it is not clear that the version of the document that is available on the website contains the full redactions authorized in the Pinnacle MDL. See *id.*; #597-11 ¶ 15; #529-6 at 9 (Pinnacle MDL order allowing redaction of the document). Where relators found this document at the eleventh hour—well after briefing on the relevant motions was due and years after their second amended complaint was filed—and where DePuy contests the disclosure of this document as being in contravention of the Pinnacle MDL’s order regarding its redaction, the court does not consider it to be evidence of public disclosure.

9-10 (“The Pinnacle Drawing [r]elators received . . . on October 2, 2013 disclosed all of the data needed to identify the precise nominals and tolerances that were incorporated into the SAC.”).) Relators stated that the key piece of information gleaned from the Liner drawing was the nominal radius of 0.7106 inches. *Id.* at 8. The drawing also provided the radius’ tolerance level (± 0.0002). (#529 at 9-10.) Relators claimed that they were able to use these dimensions to calculate the diameter of the Pinnacle Head and then convert it to millimeters. (#529 at 8.) In their initial briefing, they alleged that Langton took 36mm (the publicly disclosed diameter of the Pinnacle Head), then divided it by 25.4 to get the diameter in inches, which was 1.41732283. *Id.* He then rounded this to [REDACTED], purportedly because the number for the Pinnacle Liner radius (which relators took from the now-public Pinnacle Liner drawing) was 0.7106; i.e., that number was also rounded to four decimal places. *Id.*¹³ Converting [REDACTED] to millimeters again (multiplying by 25.4) results in [REDACTED] Head diameter that relators provided to QA. *Id.*

In a more recent filing, relators recite a different account of how Langton arrived at the Head measurements they provided to QA in November 2013. *See* #594-2. Now, they state that Langton took the 0.7106 value from the Liner drawing and multiplied it by two to determine that the Liner diameter was 1.4212 inches. *Id.* at 2. He then converted this to millimeters to obtain a Liner diameter of 36.09848mm. *Id.* Next, he subtracted 100 μ m (which relators state was a known figure) from the Liner diameter to obtain a Head diameter measurement of 35.99848mm. *Id.* But this is not the number that relators provided to QA. Instead, relators state that they took several additional steps to arrive at that number. Next, Langton converted 35.99848mm back to inches, resulting in a measurement of 1.41726 inches. *Id.* He again states that he rounded this measurement

¹³ Other dimensions in the Liner drawing are provided to three, four, five, and six decimal places. *See* #522-6.

to four decimal places because the Liner radius from the Pinnacle Liner drawing was provided to four decimal places. *Id.* He then converted this number, [REDACTED], *back* into millimeters, resulting in a Head diameter measurement of [REDACTED]. *Id.* This is the value that was provided to QA. (##522-8; 522-9.) To determine the upper and lower tolerance levels, Langton took the tolerance levels from the Liner radius (± 0.0002) and multiplied it by two to find the tolerance levels for the diameter: [REDACTED]. (#594-2 at 3.) He converted this number to millimeters to get [REDACTED], and then added that to [REDACTED] to get [REDACTED] for the upper tolerance limit and subtracted it from [REDACTED] to get [REDACTED] for the lower tolerance limit. *Id.* These figures were also provided to QA. (##522-8; 522-9.)

In an attempt to explain his rounding and conversion choices, in a late-filed affidavit Langton stated that “[t]he accuracy of the [Coordinate Measuring Machine (CMM)] used by DePuy in the later years of manufacture was approximately 1 micron. I know this because DePuy used . . . the same machine I routinely use.” (#597-11 ¶ 34.)¹⁴ He also stated, however, that the CMM’s accuracy is only 0.0001 when measured in inches (which is 2.54 microns, not 1), and that this therefore requires rounding to four decimal places. *Id.* ¶¶ 33-34. Yet converting 1 micron to inches yields 0.00003937 inches, which when rounded results in a number with five decimal places (0.00004). This is consistent with the measurements Langton provided to QA in 2013, which were not rounded to four decimal places, but to five. *See* #522-8 (providing explant measurements to five decimal places). Lastly, Langton also claimed that “[i]n inches, . . . the only viable way of reporting measurement results is to four decimal places” and that DePuy “typically” reports its dimensions to “three decimal places in millimeters.” (#597-11 ¶ 34.) But as noted earlier, DePuy’s

¹⁴ In a 2012 article published in *Bone & Joint Research* discussing the failure of DePuy’s ASR devices, Langton stated that the same CMM had “an accuracy of 0.8 μm .” (#601-1 at 3.)

engineering drawings for the Liner include dimensions in inches to three, four, five, and six decimal places.

In spite of the two different detailed versions of the steps Langton has described, in his affidavit he equivocates regarding his methods, stating, “I **appear** to have used a liner drawing to derive the nominal head diameter used in the [second amended complaint’s] Falsity Rate allegation.” (#597-11 ¶ 32(i) (emphasis added).) DePuy has a simpler explanation: relators must have had access to an engineering drawing of the Pinnacle Head, which would have provided them with all of the information they needed and avoided the back-and-forth conversions, rounding, and calculations described by relators. (#537 at 6, 12).¹⁵ In support of DePuy’s motion for reconsideration, the court asked it to provide sample drawings that contain these figures. (#581.) DePuy provided three drawings, two of which were produced in the Pinnacle MDL in March 2013. (##586-4 at 4; 586-2, 586-3.) These drawings provide the diameter for the Pinnacle Head as [REDACTED] inches, with a tolerance level of \pm [REDACTED]. *See, e.g.*, #586-2 at 2.¹⁶ DePuy notes that to obtain the numbers that relators provided to QA from the Head drawing would have required far fewer steps, conversions, and guesswork than Langton’s purported methods. *See* ##537 at 12; 586-4 at 5.¹⁷

¹⁵ Langton states in his affidavit, “I do not recall using an engineering drawing of the Pinnacle head to determine a [REDACTED] nominal head diameter, including any of the Pinnacle head drawings DePuy has presented to the Court in its September 30, 2021 filing.” (#597-11 ¶ 32(e).)

¹⁶ Similar to the Pinnacle Liner drawing, the Head drawing includes measurements listed to three, four, and six decimal places. *See* ##586-2; 586-3.

¹⁷ DePuy also notes that the Head dimensions listed in the Liner’s publicly disclosed 510(k) are inconsistent with the dimensions relators obtained and provided to QA. (#586-4 at 5); *see* #522-15 at 59 (table showing Head diameter measurement of 1.41728 inches and tolerance levels of \pm 0.00039 inches). Had relators used those dimensions, which were not rounded to four decimal places, it would have altered QA’s analysis and the related allegations in the second amended complaint. *See* #522 at 10; *DePuy*, 865 F.3d at 40 (discussing “minute but material manufacturing defects” alleged in relators’ second amended complaint).

3. QA Report.

QA wrote a report summarizing its analysis, which was addressed to relators' counsel and dated December 18, 2013. (#522-13 at 2.) The report contains a table listing the Pinnacle's design specifications for both the Liner and Head, and notes that the specifications were "provided to QA[]." *Id.* These numbers match those that relators provided to QA in spreadsheets in November 2013. (##522-8; 522-9.) The results of QA's analysis, which include nonconformity rates for the Pinnacle Head and Liner, are provided in the report and repeated in the second amended complaint. *Id.* at 3; *see, e.g.*, #219 ¶ 349 ("Based upon QA's statistical analysis, DePuy's manufacturing process fails to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time.").

As DePuy has noted, the First Circuit's opinion regarding DePuy's 2015 motion to dismiss quoted the second amended complaint's QA-derived statistics twice, and found that at least one of those statistics ("that more than half of those implants fell outside the specifications approved by the FDA") supported a finding that Relators had satisfied Rule 9(b). *DePuy*, 865 F.3d 29, 41 (1st Cir. 2017); *id.* at 33 ("According to the complaint, 'DePuy's manufacturing process fail[ed] to produce implant heads within specification 14.93% of the time and implant liners 50.41% of the time.'" (quoting #219 ¶ 349)); *id.* at 37 (noting allegation that DePuy "fail[ed] to produce explant heads within specification 14.93% of the time and 50.41% of the time for the explant liner." (quoting #219 ¶ 349)).

In his recent affidavit, Langton stated that "[i]t recently came to [his] attention" that information he provided to QA in 2013 "was used to support the nonconformance allegations of the [second amended complaint]." (#597-11 ¶ 23.) This is in spite of the representations he made in his 2015 affidavit that the second amended complaint did not contain confidential information,

the fact that the second amended complaint clearly references QA in the nonconformance allegation, and the First Circuit's reliance on that allegation in finding that relators had satisfied their Rule 9(b) burden. *See DePuy*, 865 F.3d 29, 41; (##115-3; 219 ¶ 349.)

III. Procedural Background.

On February 5, 2020, DePuy filed a motion to strike allegations and dismiss the second amended complaint. (##368.) DePuy argued that relators had violated the ASR MDL protective order and Judge Katz's order when they included confidential information from the ASR MDL in their complaint by means of allegations citing to QA's analysis. (##369 at 5-6.) The parties briefed the motion (##369; 386; 397; 409), and after a hearing, the court denied it without prejudice so that DePuy could add evidence the court ordered relators to produce to DePuy regarding their work with QA. (##414; 418.) DePuy renewed its motion on March 5, 2021, arguing that the second amended complaint, in relying on QA's analysis to support its allegations, violated protective orders in both MDLs, Judge Katz's order, and Judge Saylor's order. (##522 at 8; 519; 537.) Relators opposed the motion. (##529; 541.)

The court heard oral argument on the issues raised by DePuy at two separate hearings in January and February 2021. (##499; 502; 506; 509.) At the hearing in January, the court heard the parties regarding relators' continued failure to provide DePuy with documents they had been ordered to produce. (##499, 502.) The court informed relators that "if certain information cannot be produced, there needs to be a very good reason why not, or you risk, as I said, having an adverse inference taken against you." (#502 (1/19/21 Hrg. Tr. at 64:25-65:3).) At a hearing several weeks later, the court reiterated that if relators

can't demonstrate that QA only relied on public documents and DePuy is able to somehow show there's something you're not telling them or you're not giving them that enables you to prove that, then I will draw an adverse inference against you. . . .

So I'm going to leave it up to you . . . to decide how do I demonstrate that everything QA relied on in the second amended complaint was public.

(#509 (2/5/21 Hrg. Tr. at 18:9-18).)

On July 6, 2021, the court denied DePuy's motion, stating its finding "that DePuy has failed to establish that any information in the Second Amended Complaint (SAC) that previously may have been restricted was not in the public domain at the time of the filing of the SAC. DePuy thus has failed to demonstrate that relators violated any relevant court order in pleading allegations in the SAC." (#542).

IV. Motion for Reconsideration.

DePuy timely filed its motion for reconsideration of the court's denial of their motion to strike and dismiss, citing Federal Rules of Civil Procedure 59(e) and 60(b). (#545.) DePuy argued that the court committed an error of law by shifting the burden of proof onto DePuy, and that the evidence showed that relators were unable to point to a public source of information regarding the Pinnacle Head's measurements. (#546 at 1-2.) In addition, DePuy noted relators' decision to "selectively withhold documents to prevent DePuy from uncovering how Relators identified the DePuy proprietary information that was incorporated into the [second amended complaint]." *Id.* at 2. Relators opposed the motion, stating that they had successfully shown that the information in the second amended complaint—including "the dimensions and tolerances of the Pinnacle explants"—were not confidential when it was filed. (#555 at 2.) The parties submitted a reply and sur-reply. (##565; 579.)

On September 16, 2021, the court ordered the parties to submit supplemental briefs addressing two narrow issues. (#581.) Relators were ordered to explain "how they were able to determine the upper and lower tolerance levels for the Pinnacle Head to five decimal places." *Id.* DePuy was ordered to "provide the Court with the document(s) they allege to be proprietary and

which contain(s) the Pinnacle head dimensions and tolerance levels and/or means to calculate them to five decimal places exactly as set forth in the December 2013 report from QA.” *Id.* The parties responded (##586; 594-2) and, after additional briefing, were permitted to file a second set of supplemental materials. (##593; 597-11; 601-5.)

A. Legal Standard.

Although “the Federal Rules of Civil Procedure do not specifically provide for the filing of motions for reconsideration, such motions are typically evaluated pursuant to either Federal Rule of Civil Procedure 59(e) or Federal Rule of Civil Procedure 60(b).” *Wasson v. LogMein, Inc.*, No. 18-cv-12330, 2021 U.S. Dist. LEXIS 52070, at *10 (D. Mass. Mar. 18, 2021). “[A] motion ‘asking the court to modify its earlier disposition of the case because of an allegedly erroneous legal result is brought under Fed. R. Civ. P. 59(e).’” *United States v. \$23,000 in U.S. Currency*, 356 F.3d 157, 169 n.9 (1st Cir. 2004) (quoting *Appeal of Sun Pipe Line Co.*, 831 F.2d 22, 24 (1st Cir. 1987)).

A party “can succeed on a Rule 59(e) motion for reconsideration . . . only if they can show that ‘the original judgment evidenced a manifest error of law, if there is newly discovered evidence, or in certain other narrow situations.’” *Capron v. Office of the AG of Mass.*, 944 F.3d 9, 44 (1st Cir. 2019) (quoting *Biltcliffe v. CitiMortgage, Inc.*, 772 F.3d 925, 930 (1st Cir. 2014)). “Where the district court believes with good reason that it based its initial decision on an ‘error of law,’ or if its ruling ‘patently misunderstood a party’ or misapprehended the question before it,” it is within “the court’s discretion to allow a motion for reconsideration.” *IDS Prop. Cas. Ins. Co. v. Gov’t Emples. Ins. Co.*, 985 F.3d 41, 51 (1st Cir. 2021) (quoting *Ruiz Rivera v. Pfizer Pharms., LLC*, 521 F.3d 76, 82 (1st Cir. 2008)).

B. Analysis.

As DePuy notes, the court previously stated that given DePuy’s allegations of misconduct, relators’ repeated failures to comply with this court’s orders regarding the production of specified documents, and relators’ past disclosure of confidential material, it was relators’ burden to demonstrate that the information contained in their second amended complaint was public in order to defeat DePuy’s motion to strike and dismiss. *See* ##502 (1/19/21 Hrg. Tr. at 64:25-65:3); 509 (2/5/21 Hrg. Tr. at 18:9-18). This did not absolve DePuy of *any* burden as the moving party. Nevertheless, the court agrees that, on reconsideration, relators failed to carry the burden the court articulated as to the Pinnacle Head measurements such that an adverse inference is appropriate.

Relators have represented that “[e]ngineering drawings . . . are the most authoritative sources of a device’s precise dimensions.” (#594-2 at 3.) Consistent with this view, Langton sought out those drawings for months in late 2013, going so far as to fly to Sweden in order to review them. Relators admit using the Pinnacle Liner drawings that Langton received in October 2013 to calculate the Liner’s nominal and tolerance levels that they provided to QA in November 2013. (##529 at 4; 597-11 ¶ 32(h).) Although removal of the “AttyEyesOnly” designation from those Liner drawings remains a troubling mystery, DePuy essentially concedes that, when the second amended complaint was filed in 2015, the Liner drawings and dimensions were public. (##537 at 5-6; 546 at 9-10.)

The Pinnacle Head measurements are a different story. Because relators have provided limited details to fill out the narrative, the court must supply details on its own, including through the use of adverse inferences. Relators are unable to prove that the Head measurements are public. *See* #592 at 1 n.1. In addition, their attempts to back into the measurements through mathematical contortions—such as converting measurements from millimeters to inches and back again—and

the multiple differing accounts of how Langton arrived at the measurements, lack credibility, particularly given relators' contention that engineering drawings are "the most authoritative sources for a device's precise dimensions" (#594-2 at 3) and Langton's extraordinary efforts to obtain Pinnacle drawings. DePuy produced the Pinnacle Head drawing in the Pinnacle MDL in March 2013, therefore plaintiffs' counsel had access to it, yet relators refuse to disclose what documents Langton received from plaintiffs' counsel in November 2013. Days after receiving those documents, relators provided QA with precise measurements for the Pinnacle Head. The court thus accepts that the simplest explanation—that relators had access to the Pinnacle Head drawing—is the most likely.¹⁸ All the more so given relators' admission that they used dimensions from the Pinnacle Liner drawing, a document they did not know to be public when they filed their second amended complaint in 2015.

The court therefore draws the adverse inference that one of the materials Langton received from plaintiffs' counsel in the Pinnacle MDL in November 2013 was a Pinnacle Head drawing. In addition, the court draws the adverse inference that relators took the Head diameter and tolerance levels from this drawing to determine the Head diameter and tolerance levels in millimeters that they then provided to QA. This information was confidential and subject to a protective order that Langton had signed prior to receiving it, and that information remains confidential today. As a result, inclusion of allegations derived from that information in the second amended complaint was in violation of the Pinnacle MDL protective order, Judge Saylor's order, and this court's order. *See* ##522-21 at 7 (signed protective order); 101 (Judge Saylor's order, requiring relators to swear under the pains of perjury that the second amended complaint did not contain confidential

¹⁸ Again, Langton has stated that he does not "recall" using the Head drawing but has not affirmatively denied using it. (#597-11 ¶ 32(e).)

information); 414 at 11 (this court’s order, warning relators that they were prohibited from using information they received from the MDL litigations in this case).¹⁹ It was also contrary to relators’ sworn affidavits that the second amended complaint did not contain confidential information in violation of any relevant court order. (##101; 115-3 (Langton’s affidavit); 115-4 (Nargol’s affidavit.) In light of the adverse inferences drawn above, the court strikes allegations related to the Pinnacle Head from the second amended complaint.

C. Dismissal Under Rule 41(b).

In its original motion, DePuy asked the court to not only strike the QA-related allegations, but to dismiss the second amended complaint in its entirety under Federal Rule of Civil Procedure 41(b). (#519.)

1. Legal Standard.

Rule 41(b) provides that “[i]f the plaintiff fails . . . to comply with these rules or a court order, a defendant may move to dismiss the action or any claim against it.” In addition to authority under Rule 41(b), the First Circuit has held that “the rules of civil procedure do not completely describe and limit the power of district courts,” because district courts have inherent authority to dismiss an action. *John’s Insulation v. L. Addison & Assocs.*, 156 F.3d 101, 108 (1st Cir. 1998) (quoting *Brockton Sav. Bank v. Peat, Marwick, Mitchell & Co.*, 771 F.2d 5, 11 (1st Cir. 1985)). In particular, “[a] district court has broad authority to . . . dismiss a case for failure to obey . . . orders.” *Id.* (second and third alterations in original) (quoting *Robson v. Hallenbeck*, 81 F.3d 1, 2 (1st Cir. 1996)). Thus, “the Civil Rules reinforce and augment the inherent power of district courts to dismiss cases for disregard of judicial orders.” *Young v. Gordon*, 330 F.3d 76, 81 (1st Cir. 2003).

¹⁹ Despite the fact that Langton was not formally retained as an expert in the Pinnacle MDL, any attempt to suggest that his confidentiality obligations were diminished by the absence of the title “expert” would be disingenuous.

“When noncompliance occurs, the ordering court should consider the totality of events and then choose from the broad universe of available sanctions in an effort to fit the punishment to the severity and circumstances of the violation.” *Young*, 330 F.3d at 81. Before dismissing a case with prejudice, the court should consider “the severity of the violation, the legitimacy of the party’s excuse, repetition of violations, the deliberateness vel non of the misconduct, mitigating excuses, prejudice to the other side and to the operations of the court, and the adequacy of lesser sanctions. . . .” *Benitez-Garcia v. Gonzalez-Vega*, 468 F.3d 1, 5 (1st Cir. 2006) (quoting *Robson*, 81 F.3d at 2-3); see *Malot v. Dorado Beach Cottages Assocs. S. En C. Por A*, 478 F.3d 40, 44 (1st Cir. 2007) (noting that these factors are non-exclusive). “Courts should only impose this severe sanction where the plaintiff’s conduct is ‘extreme.’” *Humphrey v. Comoletti*, No. 15-cv-14170, 2018 U.S. Dist. LEXIS 94000, at *7 (D. Mass. June 5, 2018) (quoting *Chamorro v. Puerto Rican Cars, Inc.*, 304 F.3d 1, 4 (1st Cir. 2002)). In addition, “where a noncompliant litigant has manifested a disregard for orders of the court and been suitably forewarned of the consequences of continued intransigence, a trial judge need not first exhaust milder sanctions before resorting to dismissal.” *HMG Property Investors, Inc. v. Parque Indus. Rio Canas, Inc.*, 847 F.2d 908, 918 (1st Cir. 1988).

2. Analysis.

By including allegations which rely on confidential information in their second amended complaint, relators violated the protective order in the Pinnacle MDL and two court orders in this case. “Without a doubt, the disregard of court orders qualifies as extreme behavior” *Malot*, 478 F.3d at 44. Not only have relators violated those orders, but they have done so repeatedly over the course of this nearly decade-long litigation, evidencing a pattern of disregarding orders from this and other courts. Repeated attempts by this court and others to hold relators to their obligations

have proven futile, making dismissal the most appropriate sanction, particularly when the court cannot trust that the remaining allegations of the second amended complaint are untainted. *See Jackson v. Polaroid Corp.*, Nos. 98-1486, 98-1645, 1999 U.S. App. LEXIS 257, at *3 (1st Cir. Jan. 4, 1999) (affirming dismissal when, “after being specifically warned to file a complaint that complied with Rule 8, appellant filed another complaint that suffered from the identical problems”); *Robson*, 81 F.3d at 4 (“A succession of violations . . . indicating a general unwillingness to comply with a court-imposed . . . order, is for us enough to justify dismissal.”).

As for whether their conduct was deliberate: at best, their actions are the result of poor record-keeping and investigation into the source of their allegations, while at worst, their actions could be said to demonstrate an intentional and repeated disregard of court orders. *See* ##115-3 (Langton’s 2015 affidavit, in which he asserted that the second amended complaint did not violate any court orders); 597-11 ¶ 23 (Langton’s 2021 affidavit, in which he claimed that he did not know that QA’s analysis was used to support allegations in the second amended complaint, even though the allegations clearly reference QA); *id.* ¶ 32 (Langton’s 2021 affidavit, in which he admitted taking measurements from a Pinnacle Liner drawing). While the court understands that relators received documents through multiple roles in multiple cases, it was their obligation to keep track of the information they received and to know whether it was subject to a protective order. The fact that relators refuse to disclose what documents Langton received in 2013 also suggests that they are purposefully hiding documents that would hurt the position they have taken on DePuy’s motions.

DePuy has certainly been prejudiced by relators’ actions. Had relators complied with Judge Saylor’s 2015 order, they would have identified the confidential information relied upon in their second amended complaint. Instead, they swore—incorrectly—that the complaint did not contain

confidential information and proceeded to litigate this case for an additional six years. Although DePuy might have chosen to investigate whether confidential information was included in the second amended complaint soon after it was filed, it was ultimately relators' responsibility to affirm that the information was publicly available. Not only was it their responsibility, but they certified to the court that they had completed that task.

The court finds dismissal appropriate because lesser sanctions would prove inadequate. Relators have shown that they are unable to comply with orders from this and other courts and that their representations regarding their purported compliance are unreliable. *See, e.g.*, ##386 at 9 (claiming that "there has been no 'inadvertent' use of confidential information in order to plead the QA Allegations"); 468 at 6 (correcting statement in #386 and asserting that "[w]ith respect to the statistical allegations pleaded in the complaint, Relators **confirmed with certainty** that QA did not rely upon any MDL-derived information in preparing its Pinnacle Explant Analysis" (emphasis added)); 597-11 ¶ 32 (Langton's admission to using a Pinnacle Liner drawing to obtain measurements). Nor will relators be given an opportunity to amend. On February 2, 2016, Judge Saylor denied relators' request to file a third amended complaint, observing that "[t]he present case is nearly four years old, has had three iterations of the complaint, and has seen the desks of three judges in this district. The relators have had ample opportunity to file a complaint that complies with the requirements of Rule 9(b), and have failed to do so." (#184 at 4); *see DePuy*, 865 F.3d at 42-43 (affirming denial of leave to amend). As Judge Saylor observed nearly five years ago, relators have had ample time to amend their complaint and to comply with their confidentiality

obligations. Allowing them additional time would unfairly prejudice DePuy and reward relators for their accumulated missteps. *See* #184.²⁰

Lastly, relators have been on notice of their confidentiality obligations since signing protective orders in the MDLs and since the 2015 orders issued by Judge Saylor and Judge Katz. They also had an opportunity to be heard through two stages of motion practice on this most recent violation. Relators have had sufficient notice and time to appropriately address the allegations raised by DePuy and understood that dismissal was at stake given the nature of DePuy's motions and previous court orders. *See Malot*, 478 F.3d at 44 (discussing a "procedural dimension" that courts should consider when dismissing with prejudice under Rule 41(b)).

In summary, "dismissal is necessary and appropriate in this case because [relators'] misconduct has been willful, extreme, and extended, and because the court cannot discern an appropriate alternative sanction." *Sloane v. Thompson*, 128 F.R.D. 13, 15 (D. Mass. 1989).²¹

²⁰ Relators' counsel did not file their supplemental response to the motion for reconsideration under seal, even though it contained the confidential Pinnacle Head measurements at issue and Relators admitted that they had not found any public disclosure of these measurements. (##587; 592 at 1 n.1) That DePuy had to file an emergency motion to seal, which the court granted, further illustrates Relators' seeming inability to comprehend and comply with their confidentiality obligations. *See* ##588, 589.

²¹ Relators claim that the challenged allegations in the second amended complaint are not material to their case (such that striking the allegations without dismissing the case would be sufficient), while DePuy argues that the case cannot survive without them. *See* ##522 at 30; 529 at 16-17. Relators' frequent and flagrant refusal and/or inability to comply with multiple court orders warrants dismissal of the case *in toto*, regardless of the materiality of the challenged allegations.

V. Conclusion.

DePuy's motion for reconsideration (#545) is ALLOWED and the case is hereby dismissed with prejudice.

/s/ Page Kelley
PAGE KELLEY
Chief United States Magistrate Judge

November 10, 2021