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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081 **JOINT MEMORANDUM RE ISSUES TO BE ADDRESSED AT THE MAY 24, 2024 CASE MANAGEMENT CONFERENCE** (Applies to All Actions)

Pursuant to Case Management Order No. 22 ("CMO 22"), the Parties submit this Joint Memorandum in advance of the sixth Case Management Conference ("CMC") scheduled for May 24, 2024. *See* Doc. 724, at 1.

I. Common-Issue Discovery

A. Defendants' Collection, Review, and Production of Documents

1. Plaintiffs' Position

The Court set this hearing to follow up on the May 10th case management conference and to address any still-outstanding electronic discovery issues. Plaintiffs are pleased to report that, at present, there are no ESI discovery issues that require the Court's intervention to resolve.

Plaintiffs would stop this update there, except that Defendants have used the joint memo as an opportunity to set the stage for future discovery disputes (that may never come to fruition) and to attack the merits of Plaintiffs' case. Plaintiffs must therefore address both.

In mid-March, Defendants agreed to utilize Technology Assisted Review ("TAR"), which both Parties anticipated would speed review and reduce associated costs. At that time, Defendants had already begun to collect the entire Custodial File for the Custodians identified by the Parties.

Defendants chose to conduct a relevance review of each Custodian's file, rather than conduct a quick and easy privilege review and produce the documents subject to the protective order already agreed to by Plaintiffs. When Defendants complained that the burden of their relevance review was too great, rather than argue against the need for a relevance review, Plaintiffs very quickly agreed to allow Defendants to narrow the universe of information with search terms (although the approach is disfavored by data scientists for various reasons).

From the inception, Plaintiffs expressed willingness to help Defendants narrow even further the universe of information subject to their relevance review. To that end, Plaintiffs requested hit reports and other information that they could use to make data-informed decisions.

Defendants chose not to share any metrics with Plaintiffs until **April 30**, importantly, a day before the Parties' last joint memo to the Court was due to be

exchanged. That information came about a month and a half after the Parties agreed to the TAR review. Defendants chose to continue the review for those many weeks. Defendants cited unexplained, technical issues for the delay and the Court's tight discovery schedule for the need to continue the review.

Once Defendants finally did share review metrics with Plaintiffs, the Parties were able to quickly reach resolution on issues presented with the first 30 Custodians. Since May 10th, the Parties have been working diligently to conceive, test, and refine the most efficient search methodologies to apply to the first 30 Custodial sources.

To reach resolution, the Parties compromised, which required Plaintiffs to make dramatic and material concessions on search methodologies, concessions that increase the likelihood that important, responsive information will neither be identified nor produced. Plaintiffs embraced these material concessions to reduce discovery costs that may be experienced by the Defendants. Plaintiffs are confident that if the Parties work in good faith and share objective metrics concerning the measured performance of the search methodologies being employed, the Parties can complete the review of the second 30 Custodial sources in a similarly collaborative way.

For the first 30 Custodians, Plaintiffs agreed to the application of a series of more and more restrictive document culling criteria that sequentially reduced the collected Custodial data set from approximately 24 million documents to less than 1.38 million documents (exclusive of family members), ***all prior to the application of the TAR machine-learning review workflow, which does not require the review of all documents***.

As the Court is aware, the chief benefit of using a TAR machine-learning workflow is that it eliminates the need to review very large swaths of documents that are predicted to be non-responsive. The TAR machine-learning technology applies a score – from zero to one hundred – to each document in the dataset that

corresponds to the predicted likelihood of the document being evaluated as responsive. In that way, the reviewing party need only review the subset of *mostly* responsive documents and can avoid having to review an even larger subset of *mostly* non-responsive content. There are established protocols for evaluating when the point of diminishing return has been achieved with such a review workflow.

When balancing difficult choices between search methodologies and cost containment, Plaintiffs place great weight upon the ***probative value*** of the responsive evidence being produced as well as the probative value of the responsive evidence not being produced. This criteria is highly consistent with managing costs ***by both Parties*** and the avoidance of evidence management activities ***by both Parties*** that are unlikely to materially promote the development of responsive and highly probative evidence. The predictive ranking score provided by the TAR workflow technology ***tends*** to have a substantial correlation to probative value. This is why being able to see the overall graphical distribution of predictive ranking volumes is the best evidence to enable Plaintiffs to make informed compromises with the Defendants. In the absence of those objective metrics, Plaintiffs are forced to take positions that may be unnecessarily conservative, simply because the essential information is not being shared.

Plaintiffs continue to believe that the easiest way for Defendants to reduce costs is to share objective information with the Plaintiffs so that Plaintiffs can make informed and potentially more aggressive decisions to reduce the world of information that Defendants will have to review.

Again, for the present, there are no issues for the Court to resolve. Plaintiffs have the requisite experience and insight to collaboratively evaluate costs with the Defendants and to reduce costs in a way that is most likely to ensure that the most probative evidence critical to the needs of this case will be most efficiently identified and produced.

Regarding relief that Defendants signal they may seek from the Court in the future, cost shifting in particular, such relief is simply one more in a growing list of unnecessary and extreme positions that Defendants have taken in this case – for example, 1) arguing that Plaintiffs were not entitled to discovery on successor liability, 2) arguing that the Court should apply ERISA discovery restrictions that would require Plaintiffs to seek leave before serving written discovery, 3) refusing to provide a response to an interrogatory merely requesting the identities of individuals with relevant information until Plaintiffs threatened to call the Court, and 4) arguing that 20 Custodians is appropriate in an MDL where Defendants themselves identified more than 200 individuals with relevant information (and Plaintiffs identified still more). As the 2015 comments to Rule 26 make clear, cost shifting should not be an ordinary practice, and the responding party bears the burden of production.

The rule that cost shifting should be uncommon is especially prescient here, where Defendants' own choices have caused most of their expense. Should Defendants pursue such a remedy, Plaintiffs may request 1) that Defendants be required to forgo relevance review, 2) that Plaintiffs be allowed discovery into Defendants discovery practices and costs, and 3) all other appropriate remedies. Plaintiffs reserve full argument of those issues until such time as the Parties actually reach impasse, which Plaintiffs sincerely hope to avoid.

Turning briefly to defend the merits of the case, Defendants falsely stated in their position statement that this MDL is unlike any other in recent history in that no FDA recall or other such event triggered the lawsuit. One very easy counterexample is the talcum powder litigation, where Plaintiffs proved to a jury time and again that the powder contained cancer-causing asbestos; the most recent

meta-analysis agrees.[1] At the start of that lawsuit, there was no FDA recall or other such event to trigger the case, just injured people – but the FDA *did* eventually, during the litigation, find asbestos in baby powder, and the responsible company did eventually pull its product from the market.[2] So-called "lawyer advertising" in that case, as here, provided an important public service that the offending company did not. Defendants in this case are equally dismissive of their own responsibility, and their joint memo position proves that they do not take Plaintiffs' injuries seriously. First, Plaintiffs have died because of a defect in these devices that discovery is already proving Defendants were aware of and chose not to fix. Second, other Plaintiffs will remain on medical monitoring for the rest of their lives, on top of a battle with cancer, because they have fragments of the faulty device stuck in their heart. Third, even those Plaintiffs who were not permanently, physically injured were permanently affected in other ways; for example, it is difficult to imagine a Plaintiff, already battling cancer, whose treatment must be interrupted because of a port-related infection and who must be hospitalized to *fight for their lives* with their family watching, could walk away unscathed emotionally. And even those Plaintiffs who had the device removed and were lucky enough to recover suffered greatly and unnecessarily – especially those whose treatment necessitated that they have another faulty device implanted. In sum, without intending hyperbole, Defendants dismissiveness of Plaintiffs is not only wrong, it is insulting to human dignity.

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[1] Sean A Woolen, MD MSc, Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: a Systematic Review and Meta-analysis (Feb. 2, 2022), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9360263/.

[2] United States Food and Drug Administration, FDA Advises Consumers to Stop Using Certain Cosmetic Products: Product samples test positive for asbestos, available at https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products.

With respect to the number of cases, this Court has considered on multiple occasions Defendants' complaint that the number of cases is allegedly "low," and Defendants' argument has not improved in the interim. To the extent the number of cases bears on the proportionality concerns expressed by Defendants, Plaintiffs have only expressed willingness to negotiate. Plaintiffs have no desire for Defendants to spend $14 million on production. However, the Court should be made aware that Nelson Mullins well understands that around $3.5 million is a normal spend for discovery in a midsize lawsuit;[3] an MDL is *not* a midsize lawsuit. That said, Plaintiffs will obviously endeavor in good faith to keep Defendants' costs as low as Plaintiffs are reasonably able. Defendants cannot and do not claim Plaintiffs have indicated otherwise.

Again, for the present, there are no issues for the Court to resolve. Plaintiffs have the requisite experience and insight to collaboratively evaluate costs with the Defendants and to reduce costs in a way that is most likely to ensure that the most probative evidence critical to the needs of this case will be efficiently identified and produced.

2. Defendants' Position

As set forth in the last Joint Memorandum, Defendants have raised proportionality concerns about the volume of documents being returned by the parties' search terms and the general scope and cost of discovery. *See* Doc. 693, at 7-10. Defendants hereby provide the Court with an update on their production of documents to date, as well as the parties' agreed-upon solution to this critically important proportionality issue.

a. Update on Defendants' Productions

[3] John D. Martin (Nelson Mullins), Cost-shifting in E-discovery: Options and Opportunities (July 16, 2014), available at https://www.nelsonmullins.com/storage/08072d1bbd4540670f001b82b12faeb1.pdf.

Defendants continue to work diligently to identify, collect, and produce documents responsive to Plaintiffs' Requests for Production ("RFP"). This chart summarizes Defendants' productions to date:

PRODUCTION	DATE	DESCRIPTION	DOCS	PAGES
BARD_IPC_MDL_001	12/26/2023	*Cruz* Production	6,290	91,035
BARD_IPC_MDL_002a	1/5/2024	Prior Patent Litig. Production (I of IV)	211,955	993,418
BARD_IPC_MDL_003	1/5/2024	Prior Port Litig. Deposition Transcripts	48	1,794
BARD_IPC_MDL_002b	1/11/2024	Prior Patent Litig. Production (II of IV)	200,966	1,396,347
BARD_IPC_MDL_004	1/12/2024	CV of Information Infrastructure Rule 30(b)(6) Deponent & Related standard operating procedures ("SOPs")	18	241
BARD_IPC_MDL_005	1/17/2024	SOPs and corporate org document related to Information Infrastructure Deposition	4	50
BARD_IPC_MDL_006	1/19/2024	Information Infrastructure Document	1	9
BARD_IPC_MDL_002c	1/19/2024	Prior Patent Litig. Production (III of IV)	97,634	449,900
BARD_IPC_MDL_002d	1/24/2024	Prior Patent Litig. Production (IV of IV)	137,420	814,251
BARD_IPC_MDL_007	1/26/2024	510(k) submissions related to the Product Codes	19	4,599
BARD_IPC_MDL_008	2/2/2024	510(k) submissions and related docs for the Product Codes	498	15,508
BARD_IPC_MDL_009	2/9/2024	Corrective and Preventative Actions (CAPAs), Remedial Action Plans (RAPs), Situational Analyses (SAs), Health Hazard Evaluations (HHEs) / Health Risk Assessments (HRAs), and Failure Investigation reporting documentation associated with the Product Codes	293	8,583
BARD_IPC_MDL_010	2/16/2024	Marketing documents, SOPs, supplement of three 510(k)s	2,168	20,057
BARD_IPC_MDL_011	2/23/2024	Marketing team documents	4,316	24,239
BARD_IPC_MDL_012	2/29/2024	Design History Files, Instructions for Use, Patient Guides, and CAPAs	6,650	120,589
BARD_IPC_MDL_013	3/8/2024	Marketing shared drives, R&D shared drives, and Notes to File regarding various 510(k)'s	16,588	150,676

BARD_IPC_MDL_014	3/15/2024	Documents from Design History Files and SOPs collected from Master Control	394	3,471
BARD_IPC_MDL_015	3/15/2024	Marketing shared drives and R&D shared drives	16,030	114,792
BARD_IPC_MDL_016	3/22/2024	Marketing shared drives and R&D shared drives	11,907	238,458
BARD_IPC_MDL_017	3/30/2024	R&D, Regulatory, Clinical Affairs, and Marketing departmental shared drives	14,220	111,010
BARD_IPC_MDL_018	4/5/2024	Marketing, R&D, Regulatory, & Medical Affairs departmental shared drives	12,613	69,351
BARD_IPC_MDL_019	4/12/2024	Marketing & R&D departmental shared drives	14,982	60,484
BARD_IPC_MDL_020	4/20/2024	Documents from Master Control Archive	19,918	105,149
BARD_IPC_MDL_021	4/23/2024	R&D, Marketing, Regulatory, & Clinical Affairs departmental shared areas, and an export from WorkDay	6,927	64,542
BARD_IPC_MDL_022	4/26/2024	Documents from first 30 Custodial Files & Volume 1 of Defendants' Privilege Log	42,300	168,088
BARD_IPC_MDL_023	5/3/2024	Regulatory departmental shared drive documents	3,328	25,384
BARD_IPC_MDL_024	5/3/2024	Documents from Master Control Archive	26,254	125,322
BARD_IPC_MDL_025	5/10/2024	Documents from Master Control	18,336	373,712
BARD_IPC_MDL_026	5/10/2024	Documents from Custodial Files of first 30 Custodians	31,161	125,288
BARD_IPC_MDL_027	5/17/2024	Documents from Master Control Archive	7,719	31,555
BARD_IPC_MDL_028	5/17/2024	Documents from Custodial Files of first 30 Custodians	35,125	128,206
Total			**946,082**	**5,836,108**

b. The Parties' Conferrals over Proportionality

The original ESI protocol agreed upon by the parties has proven to be prohibitively costly. Utilizing Plaintiffs' originally proposed search terms, the cost to review and produce ESI for the 60 Custodial Files contemplated by the Court's CMO No. 18 (Doc. 525, at 3) has been projected to exceed $14,000,000. *See* Ex. A, Decl. of Eric Smith, at ¶10. Even after taking preliminary steps to try to streamline

the process, Defendants are currently spending $350,000 per week on document reviewers alone.

To their credit, Plaintiffs have acknowledged the disproportionate expense Defendants are incurring and have been very willing to meet and confer to help reduce Defendants' spend. As a result of those discussions and Defendants' disclosure of detailed objective metrics and sampling results, Plaintiffs recently agreed to use search terms proposed by Defendants to reduce the volume of irrelevant material that is put into the TAR workflow (from 6.1 million documents to 1.375 million documents), and also agreed Defendants could cease review of the documents in the TAR universe for the first 30 Custodians. However, the projected burden and expense to complete review of the first 30 Custodians alone is by itself a sizeable ***$3.2 million***. The extraordinary projected cost for this ESI has been driven in large part by the substantial volume of data (over 14 million documents prior to application of e-mail threading and other analytics) identified by Plaintiffs' original search terms and the considerable review, testing and analysis of terms that was required to reach this point. Moreover the $3.2 million figure does not take into consideration the substantial costs associated with Defendants' review and production of Non-Custodial Sources (which largely constitute "core" documents that will directly inform liability issues in this MDL), the production of documents from prior litigations (*e.g.*, the patent litigation and documents produced in the *Cruz* matter), outside counsel's work related to review and production activities, or other additional analysis or work performed by Defendants' ESI vendor.

On the other side of the proportionality equation, the number of filed cases in the MDL remains disproportionately low relative to the cost of this ESI discovery. Further, Defendants have analyzed the alleged injuries in the cases filed to date, and have reason to believe many of the claimed injuries are relatively minor, such as infections that do not involve permanent injury or permanent retention of a Port

device. Indeed, in several cases, Plaintiffs received the same or similar products after experiencing complications with the subject device.

While the Parties recently reached an agreement to use Defendants' proposed search terms, they also agree that it is premature to address three remaining issues, which may need to be revisited, once the Parties have more data:

(1) the appropriate cutoff to apply to the predictive coding rank or recall rate for the next Custodial set to ensure the expense of the discovery is proportionate;

(2) whether the Court should consider reducing the second set of Custodians (originally set at 30) for review;

(3) whether the Court should consider cost-sharing for the next set of Custodians.

Should Defendants determine that the burden and expense related to the second set of 30 Custodians or Non-Custodial discovery be disproportionate, and the parties unable to reach swift agreement to mitigate Defendants' expense, Defendants will request a conference to address the proportionality requirements of Rule Rule 26(b)(1).

i. The Port Litigation Generally

This MDL is unlike most other prescription device or drug MDLs in recent years. In the 5 years before Plaintiffs moved to form this MDL, Defendants were named in only 11 actions involving its vascular port products. There has been no significant precipitating event (other than attorney advertising) to explain the sudden proliferation of these cases. Unlike the circumstances giving rise to many other MDLs, there has been no action by the FDA related to these products—no public health notification, no FDA-issued recall, no Warning Letter, and no order requiring clinical studies. Moreover, there has been no landmark scientific studies questioning the safety or effectiveness of port products generally, much less of Defendants' products in particular. Rather, Defendants' vascular port products have been on the market for over 40 years. For decades, doctors have effectively used

these products to assist patients to receiving chemotherapy, IV medication, parenteral nutrition, and other life-sustaining treatment. And doctors continue to do so, as the use of vascular ports is the standard of care in many medical situations.

ii. Defendants' Productions

Although Defendants engaged in litigation in only a few port cases prior to the MDL, they did collect, review, and produce significant materials in the port patent litigation and *Cruz* matter, which they have in turn reproduced to Plaintiffs here. Additionally, Defendants have produced significant additional "core" documents from Non-Custodial Sources to Plaintiffs and have also been providing Plaintiffs with rolling productions of documents from the Custodial Files of the first 30 Custodians. To date, Defendants have produced over 946,000 documents consisting of more than 5.8 million pages, including "core" documents for numerous product codes at issue.

iii. Defendants' Assessment of Current MDL Claims

Defendants' proportionality concerns are not based solely on the increasingly substantial burden and expense imposed by ESI discovery, through that consideration alone certainly warrants a reevaluation of the discovery plan in this litigation. Rather, on the other side of the proportionality equation, the number of filed cases in the MDL remains disproportionately low relative to the cost of common discovery. Moreover, based on Defendants' analysis thus far of the alleged injuries of the MDL Plaintiffs, Defendants have reason to believe most of the claims involve relatively minor injuries.

While Defendants have somewhat limited information on Plaintiffs' claims and are still awaiting receipt of a number of PPFs,[4] Defendants believe that more than half of the claims (over 130) involve allegations of an ***infection*** allegedly

[4] The data changes on a weekly basis, and some Plaintiffs' allegations in their short form complaints differ from the allegations in their PPFs. Because these data are in flux, Defendants' representations regarding the nature of the MDL Plaintiffs' claims and the figures for each are necessarily less than exact.

caused by the port catheter. However, infection is a known and warned of complication with all implantable vascular access devices and is often the result of the methods used to access the port or the result of other comorbidities.[5] In the vast majority of these 130 claims, the port was removed following normal procedures, the infection was treated, and the patient recovered fully. In fact, many of these patients had another port implanted once the initial port was removed. Tellingly, several of the Plaintiffs alleging infection admit that they have no long-term or ongoing complications.

Approximately 64 of the 243 claims involve allegations that the catheter attached to the port ***fractured*** or separated from the port body. This too is a known and warned of complication that often relates to how the port and catheter were implanted. Some of the claimants allege a piece of the catheter migrated to their heart or lungs. However, based on Defendants' review of the records provided thus far, the vast majority of the ports and catheters were removed following normal procedures, and the catheter fragments were removed using a percutaneous approach through a vein (and not via a surgical procedure, such as open-heart surgery). Defendants are aware of less than 10 Plaintiffs who allege that a fragment has not or cannot be removed.

The remaining claims generally involve allegations of ***thrombosis***. Again, this is a known and warned of complication with all implantable vascular access devices and also a known risk with cancer patients (who make up a sizeable percentage of the patients utilizing ports). As with the other claims, the overwhelming majority of these Plaintiffs had their port and catheter removed following normal procedures, and they have fully recovered.

iv. Next Steps Regarding ESI

[5] The overwhelming majority of the cases filed involve patients diagnosed with some form of cancer. A weakened immune system and susceptibility to infection are known complications of cancer.

Given that Defendants are projected to spend over $3.2 million on review of the first 30 Custodians alone, and continue to spend $350,000 per week on document review, it would be unreasonable for Defendants to continue to spend similar amounts for the next 30 Custodians, nor would such an expense be proportionate to the needs of this litigation. While Plaintiffs have agreed to work with Defendants to curtail the expense for subsequent data sets, if compromise cannot be swiftly reached once information is available, Defendants will seek Court intervention.

Defendants' concerns about the overly burdensome number of Custodians has been borne out by the latest estimated costs of review. However, given that the updated search terms were only agreed to this weekend, Defendants are still in the process of collecting and culling the second 30 Custodial Files before sending the data to their discovery vendor in effort to mitigate the expense of hosting millions of irrelevant documents. Defendants therefore submit that issues regarding the appropriate predictive rank and/or recall rate cutoff, number of Custodians, and/or cost-shifting for the second set of 30 Custodial Files are not yet ripe, and respectfully reserve the right to raise these issues if it becomes apparent that this further discovery of Custodial Files or discovery as a whole is disproportionate to the needs of the case.

B. Non-Custodial Sources

Defendants are continuing to work on issues relating to collection of documents from DocuShare; and will be prepared to discuss at the CMC the issues impeding their ability to provide a substantial completion deadline at that time. *See* Doc. 724, at 1-2.

C. Conferrals over the Scope of Relevant Discovery

As set forth in the last Joint Memorandum, *see* Doc. 693, at 10-11, n.6, the parties have been negotiating over whether certain categories of documents fall

within the scope of relevant discovery. The parties have reached agreement on these issues, which are memorialized *infra*. The parties agree the scope of discovery of the categories below is limited to documents from the Custodial Files of general liability Custodians that are reviewed as part of the TAR workflow.

- **Non-IPC Devices**: Plaintiffs seek discovery of certain documents related to non-IPC devices, including peripherally inserted central catheters ("PICCs") and central venous catheters ("CVCs"). Defendants generally object to the expansion of discovery beyond the IPC devices that are the subject of this MDL, but recognize that certain technologies used in PICCs and CVCs may be relevant. After conferring about the relevancy of these other devices,[6] the parties agree on limiting discovery of documents reviewed as part of the Custodial TAR workflow to those documents that may implicate Plaintiffs' "Alleged Defect Theory." This includes, for example, documents related to antimicrobial or antithrombotic coatings, the smoothness/roughness of catheters, degradation of catheters, and the strength of the catheters insofar as those issues informed alternative catheter designs contemplated for use in the United States.
- **Ethanol Locks & 3CG Catheter Position Technology**: Plaintiffs seek discovery regarding (1) ethanol lock therapy, which is a potential mechanism to reduce catheter-related bloodstream infections discussed in scientific literature; and (2) Defendants' 3CG catheter position technology, which allows for confirmation of the catheter tip via ECG in lieu of fluoroscopy or x-ray. Defendants agree to produce documents discussing ethanol locks with respect to IPCs, but not other devices such

[6] Plaintiffs have agreed to exclude dialysis and hemodialysis catheters from the scope of relevant discovery. Plaintiffs have reserved their right to re-raise the issue if discovery shows the need.

PICCs. Defendants further agree to produce documents related to Plaintiffs' "Alleged Defect Theory" in catheters when used in conjunction with Defendants' 3CG catheter position technology.

- **Foreign Discovery**: Defendants agree to produce documents from the Custodial TAR workflow that relate to (a) regulatory communications with foreign regulatory bodies regarding ports in accordance with and as limited by CMO 15; (b) relevant adverse events for ports, such as internal discussion of fracture, infection or thrombosis;[7] (c) discussion of the US market or consideration of technologies for use in the US market regarding ports; and (d) with respect to Japan only, documents regarding Plaintiffs' "Alleged Defect Theory" (i) as it relates to ports or (ii) as it relates to the certain alternative designs identified by Plaintiffs.

II. Plaintiff Profile Forms

1. No Profile Form Served

The Court previously excluded the cases below from the Initial Plaintiff Pool for failure to serve a PPF. In CMO 22, the Court requested a status update on the five cases in which PPFs have not produced and ordered the production of outstanding medical records and information by May 23, 2024. *See* Doc. 724, at 2-4. The present status of the cases is as follows:

Plaintiff and Member Case Number	Date of Delinquent PPF Notice	Current Status
Wright, Diana 2:24-cv-00438	4/2/2024	DISMISSED

[7] Defendants will be producing to Plaintiffs Excel exports from Defendants' current and historic complaint databases, TrackWise and Easy Track. The production will include IPC adverse event reports unrestricted by date and not limited to the Product Codes or adverse events at issue. Accordingly, the parties are meeting and conferring to discuss limitations on Defendants' production of adverse event compilations located in Custodial Files or shared areas in effort to limit Defendants' expense of redacting protected patient and voluntary reporter information.

Bennett, Patricia 2:24-cv-00660	4/26/2024	PPF served
Garza, Amber 2:24-cv-00700	4/30/2024	PPF served
Graham, Janice 2:24-cv-00696	4/30/2024	PPF served
Palazzo, Susan (deceased) 2:24-cv-00701	4/30/2024	PPF served

Defendants do not seek any further relief regarding these cases.

2. Certain or all Medical Records Not Produced

In CMO 22 (Doc. 724), the Court ordered the following plaintiffs to produce the missing medical records identified in Defendants' deficiency notice; state that the disclosures are complete; or provide an explanation that the records have been requested, but not yet received:

Plaintiff and Member Case Number	Date of Deficiency Notice	Current Status
Hawkins, Vera 2:23-cv-02020-DGC	1/4/2024	**Plaintiff responded that she has produced all records received**
Eckert, Rebecca 2:24-cv-00139-DGC	3/26/2024* *LTR asking for supplementation based on review of medical records	**No response since CMO 22 was entered**
Shelby, Burgandy 2:24-cv-00359	4/1/2024	**Plaintiff responded that she has produced all records received**

Whitby, Latwon 2:24-cv-00482-DGC	4/12/2024	**No response since CMO 22 was entered**
Gay, Paisami 2:23-cv-1755-DGC	1/4/2024	**Plaintiff responded that he has produced all records received**
Kessler, Paul 2:23-cv-1696-DGC	1/4/2024	**Plaintiff responded that he has produced all records received**
Catanzaro, August 2:24-cv-00292-DGC	3/29/2024	**No response since CMO 22 was entered**

Because Plaintiffs' leadership has communicated that they expect these plaintiffs to comply with CMO 22, Defendants will update the Court on the status and address any relief sought during the case management conference.

3. Inconsistencies in Information, Unclear Claims or Incomplete Medical Records Produced

In CMO 22, the Court ordered the following plaintiffs to respond to Defendants' deficiency letter by May 23, 2024. The current status is below:

Plaintiff and Member Case Number	Date of Deficiency Notice	Current Status
Kessler, Paul 2:23-cv-1696-DGC	1/4/2024	**Plaintiff responded that he has produced all records received.**
Catanzaro, August 2:24-cv-00292-DGC	3/29/2024	**No response since CMO 22 was entered**

Dragon, Melissa 2:24-cv-00480	4/9/2024	**No response since CMO 22 was entered**
Gay, Paisami 2:23-cv-1755-DGC	1/4/2024	**Plaintiff responded that he has produced all records received.**
Amos, Larissa 2:24-cv-00290-DGC	3/22/2024	**Plaintiff responded that she has produced all records received.**
Nicosia, Danielle 2:23-cv-2122-DGC	1/23/2024	**No response since CMO 22 was entered**
Prescott, Jennifer 2:23-cv-2729-DGC	2/21/2024	**No response since CMO 22 was entered**

Because Plaintiffs' leadership has communicated that they expect these plaintiffs to comply with CMO 22, Defendants will update the Court on the status and address any relief sought during the case management conference.

4. PPFs in the 15 day Cure Period

The following cases were in the "15 day" cure period at the time of the last case management conference. In CMO 22, the Court ordered the plaintiffs below to serve complete PPFs including medical records on or before May 23, 2024:

Plaintiff and Member Case Number	Date of Deficiency Notice	Current Status
Edgell, Joshua 2:24-cv-00531-DGC	4/23/2024	**Complete PPF served**

McLaurin, Erin 2:24-cv-00487-DGC	4/23/2024	**Complete PPF served**
DeStefano, Christine (deceased) 2:24-cv-00588-DGC	4/23/2024	**Complete PPF served**
Galvan, Marisella 2:24-cv-00578-DGC	4/23/2024	**Complete PPF served**
Holzman, Karen 2:24-cv-00590	4/24/2024	**No response**
Jackson, Jeffrey 2:24-cv-00599	4/24/2024	**Complete PPF served**
Latham, Lindy 2:24-cv-00586	4/24/2024	**No response to deficiency letter**
Stack, Gary 2:24-cv-00619-DGC	4/26/2024	**Complete PPF served**
Toranzo, Giny 2:24-cv-00577-DGC	4/26/2024	**Complete PPF served**
Traylor, Donna 2:24-cv-00621-DGC	4/26/2024	**Complete PPF served**
Wilson, Piper 2:24-cv-00425	4/26/2024	**Complete PPF served**
Chapman, Tina 2:24-cv-00651	4/29/2024	**Complete PPF served**
Peterson, George 2:24-cv-00678	4/29/2024	**Complete PPF served**
Young, Gloria 2:24-cv-00679	4/29/2024	**Complete PPF served**
Mobley, Cynthia 2:24-cv-00677	4/29/2024	**Complete PPF served**

Farmer-Garmon 2:24-cv-00620	5/1/2024	**Complete PPF served**
Cunningham, Jeanette 2:24-cv-00664-DGC	5/1/2024	**Complete PPF served.**
Taylor, Sabrina 2:24-cv-00704	5/1/2024	**Complete PPF served**
Woods, Marilyn 2:24-cv-00615	5/1/2024	**Complete PPF served**
Terry, Misty 2:24-cv-00686	5/1/2024	**Complete PPF served**
Verdugo, Shirley 2:24-cv-00721	5/2/2024	**Plaintiff dismissed**
Johnson, Linda 2:24-cv-00687	5/2/2024	**PPF and Response Letter served**
Holcomb, Angela (deceased) 2:24-cv-00707	5/3/2024	**Complete PPF served**
Hall, Vicky 2:24-cv-00716	5/3/2023	**Complete PPF served**
LaPlante, Angel 2:24-cv-00418	5/6/2023	**PPF and Response Letter Served**

Plaintiffs' leadership is aware of the status of these cases and has informed Defendants that they are working with the plaintiffs. Defendants will update the Court on the status and address any relief sought during the case management conference.

4(a). PPFs with Medical Records in Electronic Health Information (EHI) Format

This is one final group of plaintiffs all represented by the same law firm whose PPFs were in the 15 day cure period, who served medical records

downloaded from the plaintiff's EHI data files rather than records sent directly from medical providers and/or a medical provider's copying service. They are in the chart below. Plaintiffs' Leadership is also aware of these issues and is in contact with the law firm. As with the issues above, Defendants will update the Court on the status and address any relief sought during the case management conference for these cases.

Plaintiff and Member Case Number	Date of Deficiency Notice
Gallaher, Kathy 2:24-cv-00723	5/2/2024
Fogle, A (minor) 2:24-cv-00720	5/2/2024
Holdridge, Donna 2:24-cv-00719	5/2/2024
Myers, Rebecca 2:24-cv-00718	5/2/2024
Miller, Linda 2:24-cv-00724	5/2/2024
Perry, Anetria 2:24-cv-00722	5/3/2024

5. Port Body Claims

Defendants' Position

The mechanism established in this MDL for plaintiffs to identify their individual claims based on the claims in the Master Complaint is the Short Form Complaint ("SFC") and the Plaintiff Profile Form ("PPF"). When the Master Complaint was amended to include port body claims, the Court entered CMO 15

(Doc. 465) addressing plaintiffs who served SFCs and PPFs before the port body claims were added and ruled that any revisions to PPFs submitted before March 15, 2024, to identify port body claims "shall be submitted to Defendants by May 1, 2024." The PPF is the mechanism for those plaintiffs to identify a port body claim. Some plaintiffs who served PPFs before March 15 amended their PPF to identify port body claims.

Similarly, the parties agreed that the PPF is the mechanism for plaintiffs who served their PPF after March 15 to identify whether they are asserting a port body claim. Amended CMO 8 (Doc. 477) was entered on March 11, 2024, and includes a section regarding port body allegations. Some plaintiffs who submitted PPFs after March 15 affirmatively stated whether they were or were not asserting a port body claim. However, as was discussed in the case management conference on May 10, 2024, some plaintiffs submitted the PPF with the port body section left blank. In CMO 22 (Doc. 724) entered on May 13, 2024, the Court ordered Plaintiffs who served a PPF on or after March 15 and who did not complete the portion of the PPF regarding port body claims to complete that portion by May 23, 2024. As of the time of the filing of this Joint Submission, there are 23 plaintiffs in the Initial Plaintiff Pool whose PPF was due on or after March 15 who left the port body page blank, have not complied with the Court's Order in CMO 22 and did not identify a port body claim in their Short Form Complaint.

If a Plaintiff who submitted a PPF before March 15, 2024, did not amend the PPF to assert a port body claim, Defendants request that they be precluded from asserting a port body claim. Likewise, for the plaintiffs in the Initial Plaintiff Pool who served PPFs after March 15 and who did not identify a port body claim in the SFC and who left the page of the PPF addressing port body claims blank, Defendants request that they also be precluded from asserting a port body claim. As Plaintiffs' counsel explained at the May 10, 2024, case management conference, plaintiffs alleging erosion caused by the port body bumps should know whether the

claim exists and be able to identify it in the PPF. Plaintiffs claim that whether the port body caused or contributed to their alleged injury is a causation issue. But, to the contrary, the claim that an injury was contributed to or caused by the port body is a design defect claim regarding the material composition of the port body (as Plaintiffs' counsel explained at the May 10, 2024, CMC). As part of the bellwether selection process and when identifying cases for the Initial Plaintiff Pool, it is imperative that Defendants know what claims are asserted. The plaintiffs have been ordered three times to provide the information regarding their claims. (See, Amended CMO 8, CMO 15 and CMO 22.). The plaintiffs in the Initial Plaintiff Pool who failed to comply with those orders and did not amend the PPF or left the port body section of the PPF blank should be precluded from asserting a port body claim as a sanction for failing to comply with the Court's orders. An underlying threshold premise of the Initial Plaintiff Pool, the PFS/DFS Group, Discovery Group, and ultimately Bellwether Group selection process is that all parties will be well- situated to select representative cases at each step of the process. (See CMO 10, Bellwether Selection, noting that the bellwether cases should be selected "in a manner consistent with achieving the goal of proportionate identification of representative cases.") Whether or not a particular plaintiff alleges an injury as a result of an alleged defect in the port body itself, as opposed to the catheter component, is a threshold question that Defendants view as critical to their ability to adequately assess the plaintiff pool and facilitate the selection of representative cases, with the aim toward achieving the ultimate goal of the bellwether process.

Plaintiffs' Position

Defendants' position and proposed remedies in connection with what they refer to as "port body claims" conflates the functions of pleadings with those of written discovery. Defendants indicate that it is imperative they know what claims are being asserted in the cases in this litigation, and Plaintiffs don't disagree.

However, the issue which Defendants raise and the rights which Defendants seek to curtail with their recommended remedies are addressed by Rule15(b) which permits the pleadings to be amended freely to conform to the evidence throughout the case. Fed. R. Civ. P. 15(b) It is important to note that all cases in this MDL have filed Short Form Complaints which incorporate by reference the Amended Master Complaint (AMC) and thus, the allegations regarding the causal relationship between the enumerated defects in the port reservoir component of the Bard IPC devices and the injuries set forth in the AMC.

The presence of the port reservoir allegations in the AMC provides Defendants with adequate notice that such claims and theories are at issue in the member cases, and Defendant suffers no prejudice if a plaintiff presents evidence at trial which sounds in those theories. Rather, it would only be plaintiffs who are prejudiced if they are foreclosed from offering evidence of injuries related to defects in the port reservoir, should the available evidence in such cases support those theories. This is especially relevant in light of the fact that injuries such as infection and thrombosis to which the alleged defects of the port body may materially contribute are often clinically detected in the catheter component of the device.

Plaintiffs agreed at the Case Management Conference that plaintiffs who have failed to respond to the questions in the PPF relating to port body injuries are properly the subject of deficiency notices contemplated in CMO No. 8 and that such deficiencies must be remedied. However, Defendants' proposed remedy for plaintiffs who have not affirmatively indicated injuries related to the port body in the PPF seeks to fashion an unprecedented and prejudicial claim preclusion mechanism in contravention of Rule 15(b). This proposed remedy would contravene the terms of CMO No. 8, which was jointly negotiated by the parties, and which already provides the Defendants with remedies in connection with plaintiffs' PPF disclosures. It is Plaintiffs' position that the terms and remedies

entered by the Court in CMO 8 should continue to govern issues regarding plaintiffs' PPF disclosures.

Dated: May 22, 2024

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard Implanted Port Catheter Products Liability Litigation	MDL No. 3081 **DECLARATION OF ERIC SMITH IN CONNECTION WITH DEFENDANTS' JOINT SUBMISSION CONCERNING REVIEW RELATED EXPENSE** (Applies to All Actions)

I, Eric Smith, declare as follows:

1. I am an Associate Director in the Document Review Services group at Epiq eDiscovery Solutions, Inc. ("Epiq"), which has been engaged as the primary eDiscovery vendor for Defendants in the above referenced matter.

2. Epiq provides the document review hosting and associated project management resources, along with associated technology solutions and document review platforms.

3. Epiq has also been engaged to perform the "eyes on" document review portion of this project, which includes traditional contract attorney document review teams, supplemented with Technology Assisted Review ("TAR") consultant(s) and other resources as deemed necessary to support the needs of the project.

4. In this capacity, I have been overseeing the management of the eye's on document review portion of the project in conjunction with our TAR consultant.

5. As of May 17, 2024, Epiq's document review contract attorney team for this project consists of 196 individuals.

6. Based on the needs of the project, Epiq anticipates adding at least an additional 112 reviewers to the current team.

7. The cost of document review since inception of this matter through May 17, 2024, is over $2,000,000.00. This includes expense associated with review of both Custodial and Non-Custodial documents to date.

8. The original search terms applied to cull the Custodial File collections of the first 30 Custodians that were available as of April 29, 2024, resulted in 6,125,815 being included in the TAR universe.

9. Epiq estimated, based on the information available as of April 29, 2024, that it would cost over $8,000,000 to complete review of the projected population for the first 30 Custodians, even using the efficiencies of the TAR workflow. This figure includes first level review, redactions, privilege and QC work of the Epiq team.

10. Expanding review to documents for the projected population from 60 Custodial Files, we estimated, based on the information available as of April 29, 2024, that review would cost over $14,000,000.

11. Applying the Defendants' proposed search terms reduced the volume of documents in the TAR workflow by over 77%, from 6,125,815 to 1,375,848.

12. At the request of counsel, and in conjunction with our TAR consultant, we estimate the total cost associated with Epiq's review of the first 30 Custodians in the TAR workflow will be **$3,253,765.00**. This is based on the following assumptions:

a. As of May 16, 2024, Epiq has reviewed approximately 795,291 documents as part TAR related activities. This includes documents reviewed in the 6.1 million universe before Defendants' search terms were applied.

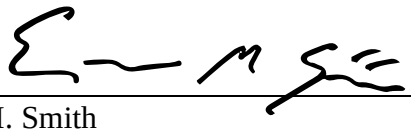
b. As of May 17, 2024, Epiq estimates having to review an estimated additional 169,000 documents that are part of responsive families or are documents excluded from the TAR workflow for technical reasons.

c. As of May 17, 2024, we estimate that the team will ultimately review an estimated total of 1,261,614 documents once the supplemental collection of Custodial File documents for the first 30 Custodians is added to the TAR workflow.

d. We estimate ~5% of this universe will require privilege or redaction review.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 21, 2024



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