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Co-Lead Counsel for Plaintiffs

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 NOVEMBER 16, 2023 CASE MANAGEMENT CONFERENCE**

Pursuant to Case Management Order No. 2 ("CMO 2"), the parties submit the following Joint Memorandum in advance of the upcoming Case Management Conference ("CMC") on November 16, 2023. *See* Doc. 42.

I. Motions to Dismiss and Motion to Strike

The parties' positions regarding motions to dismiss and motions to strike are set forth below.

A. Defendants' Position

To preserve Defendants' rights and defenses and to avoid any issue of potential waiver, Defendants have moved to strike the port body allegations and the Peritoneal Titanium Port from the Master Complaint and Short Form Complaint pursuant to Federal Rule of Civil Procedure Rule 12(f). The Motion submitted herewith incorporates by reference Defendants' Position Statement on this issue. Defendants do not anticipate any further motions to dismiss in response to the Master Complaint at this time.

B. Plaintiffs' Position

Pursuant to the Court's instruction at the first CMC, Plaintiffs disclosed their draft Master Long-Form Complaint ("Master Complaint") to Defendants well in advance of the filing deadline. *See* Doc. 53 (Sept. 18, 2023 Tr.) at 21:17-22:16. Reserving all rights and waiving none, Plaintiffs circulated their drafts on October 20 (one week before the deadline) and again on October 26 (one day before the deadline). On October 27, Plaintiffs filed their 96-page, 17-count Master Complaint "seek[ing] judgment against Defendants for personal injuries . . . sustained from Defendants' unreasonably dangerous implanted port catheter ('IPC') devices." Doc. 93-1 at 2.

After inspecting Plaintiffs' well-pleaded Master Complaint, Defendants confirmed they will not move to dismiss Plaintiffs' claims as preempted by federal law. Defendants also confirmed they will not move to dismiss the Master Complaint for failure to state a claim under Rule 8 or even Rule 9's heightened pleading standard. Finally, heeding the Court's guidance, Defendants confirmed they will not move to dismiss on statute-of-limitations, learned-intermediary, or any state-specific grounds. *See* Doc. 53 at 25:9-26:6. Nor should they. *See In re Bard IVC Filters Prods. Liab. Litig. ("IVC")*, MDL 2641, Doc. 1481 at 3-5 (D. Ariz. Apr. 20, 2016).

Unable to dismiss any of Plaintiffs' claims, Defendants have "unilaterally" filed

a motion to "strike the port body allegations and the Peritoneal Titanium Port from the Master Complaint and Short Form Complaint pursuant to . . . Rule 12(f)." *See supra* at 2; *cf. infra* at 6. Defendants' sudden U-turn is improper. Although CMO 2 requested the parties' positions on "motions to dismiss," the spirit of the order calls for position statements on "*any*" motions "Defendants *propose to file* in response to the master complaint." *See* Doc. 42 at 3 (emphasis added). The Court's comments at the first CMC leave zero doubt. *See* Doc. 53 at 29:5-30:7 (describing "joint memo that . . . sets out the [D]efendants' proposals on what motions, if any, you think should be filed with respect to the complaint"). Undeterred, Defendants defy their own request to "set forth their position more fully in the Joint Memorandum due on November 9th and be heard on this issue at the November 16th conference," not to mention the Court's final instruction to "address their concerns about the proposed master complaint in the joint memorandum." Defendants' Master Answer to Plaintiffs' Master Complaint is the only responsive pleading the Court blessed for filing. *See* Doc. 42 at 3.

If any filing should be stricken, then, it is Defendants' *ultra vires* motion to strike, not a few paragraphs in the Master Complaint. *See Revive You Media LLC v. Esquire Bank*, 2018 WL 2164379, at *9 (D. Ariz. May 10, 2018) (Campbell, J.) ("Motions to strike are generally disfavored and should not be granted unless it is clear that the matter to be stricken could have no possible bearing on the subject matter of the litigation.").

II. Master Complaint and Scope of the MDL

Pursuant to the Court's October 30, 2023 instruction, the parties' positions regarding the scope of the MDL are set forth below.

A. Defendants' Position

Defendants object to Plaintiffs' improper attempt to expand to the scope of the MDL to include port body allegations in the Master Complaint. *See* Compl. ¶¶ 267-93, 305-06, 326-331 355, 388, Doc. 93-1. The scope of this MDL, and thus by extension the scope of the Master Complaint, is limited to factual allegations and legal contentions related to whether Defendants' barium-sulfate-containing catheters are defective. The

Master Complaint's port body allegations, on the other hand, involve a different component part of Defendants' devices and different alleged defects. For the reasons set forth more fully below, this Court should reject the proposed Master Complaint and order Plaintiffs to strike the wholly unrelated port body allegations:

- ***First***, the MDL that the Judicial Panel on Multidistrict Litigation ("JPML" or "Panel") created relates to allegations of defects only in the catheter component of Defendants' implantable port devices, not the port body. Plaintiffs' novel allegations take issue with Defendants' alleged use of Delrin in manufacturing port body reservoirs, as well as the palpation bumps on the surface, or septum, of the port bodies—defects that they never asserted were within the scope of this MDL until the eve of their deadline to file the Master Complaint.
- ***Second***, an administrative Master Complaint cannot substantively expand the scope of an MDL to include factual allegations and legal contentions not presented to the JPML.
- ***Third***, the inclusion of allegations regarding an unrelated and previously undisclosed purported defect in a different component part will upend the Parties' ability to efficiently complete common issue discovery and engage in bellwether trials pursuant to the timeframe set by this Court.

In addition to Plaintiffs' improper attempt to expand the scope of the MDL to include port body allegations, Plaintiffs have also improperly listed a Peritoneal Titanium Port in Exhibit A to the Master Complaint and in the proposed Short Form Complaint as a relevant device. That device is implanted differently and has different indications for use than the devices that are the subject of the JPML's Order. The Peritoneal Titanium Port is indicated for patient therapy requiring repeated access to the peritoneal cavity, and the catheter is inserted into the peritoneal cavity in the abdomen. The devices that are the subject of this MDL are indicated for repeated access to the vascular system and contain a catheter that is inserted into a vein near the clavicle or

neck. Consequently, the Peritoneal Titanium Port falls outside the scope of the MDL, which is limited to "implantable vascular access devices." Mem. in Supp. of Pls.' Mot. to Transfer Actions, No. MDL 3081, ECF No. 1-1, at 1 (J.P.M.L. May 24, 2023). This Court should further order Plaintiffs to strike that device from the Master Complaint and Short Form Complaint.

1. This MDL Has Always Been About Alleged Defects in Defendants' Implantable Port Catheters

The proposed, and ultimately formed, MDL has always been about the catheter component of implantable port catheters. *See In re Bard Implanted Port Catheter Prod. Liab. Litig.*, No. MDL 3081, 2023 WL 5065100, at *1 (J.P.M.L. Aug. 8, 2023) ("All actions can be expected to share factual questions arising from allegations that defendants manufacture the *catheter component* of their port devices with a concentration of barium sulfate that is too high, which reduces the material integrity of the catheter, and can lead to injuries, including infection, fracture of the catheter, migration of the catheter, and thrombosis."); Mem. in Supp. of Pls.' Mot. to Transfer Actions, *In re Bard Implanted Port Catheter Prod. Liab. Litig.*, No. MDL 3081, ECF No. 1-1, at 7 (J.P.M.L. May 24, 2023) ("The Actions . . . allege that the design of the *catheter components* of Defendants' products are rendered unreasonably dangerous by a common design element, namely exposed barium sulfate on the catheter surface, and that said unreasonably dangerous condition caused Plaintiffs' injuries."). Neither the Movants before the JPML nor the Panel considered or addressed any allegations relating to the port body component of Defendants' devices.

Indeed, Plaintiffs made *no* representations about port body allegations as being within the scope of the MDL in their overview of the common issues in the Joint Memorandum submitted in advance of the Initial CMC. *See* Joint Mem., Doc. 23, at 3 ("All of the devices had the same indication for use and were defectively designed and/or manufactured in the same way: Defendants designed and manufactured the devices to include a polymer catheter that is impregnated with barium sulfate powder but which

fails to encapsulate, coat, or otherwise cover the barium-impregnated polymer surfaces of the catheter. . . ."). Nor did the issue come up at the Initial CMC.

The timing of Plaintiffs' inclusion of these allegations into the proposed Master Complaint also underscores the inappropriateness of the allegations. At the Initial CMC, the Court intimated to the Parties that the Master Complaint should be "exchang[ed] . . . along the way" so "that both sides understand what is being filed in this complaint." Sept. 18, 2023 Hr'g Tr. 21:23 to 22:2 (Doc 53). After initially taking the position that Defendants were not entitled to see a draft, Plaintiffs provided Defendants a draft that, consistent with the Parties' understanding, did not include port body allegations on October 20th. On October 22nd at 9:41 p.m. EST, Plaintiffs stated for the first time that they were "still evaluating whether to include allegations about port bodies in addition to catheter defects in the Master Complaint." On October 26th at 7:39 p.m.—the night before Plaintiffs' filing deadline—Plaintiffs first circulated a draft containing the disputed allegations.

In short, Plaintiffs cannot credibly argue that the port body allegations have always been part of this MDL. The record shows otherwise. Plaintiffs provide no explanation as to why they did not raise the port body allegations before the JPM, or before this Court in the initial Joint Memorandum or at the initial CMC.

2. Plaintiffs Cannot Expand the Scope of an MDL by Filing an Administrative Master Complaint

This Court should reject Plaintiffs' sweeping interpretation of CMO No. 2's provision that "the parties shall provide to the Court a master complaint drafted by Plaintiffs" provides them with unfettered discretion to expand the scope of this MDL to include claims regarding distinct alleged defects in a different component of a medical device. To the contrary, it is well-settled that "Plaintiffs may not unilaterally add to an MDL." *In re: Philips Recalled CPAP, Bi-Level Pap, and Ventilator Prods. Litig.*, No. 21-md-1230, 2023 WL 7019287, at *55 (W.D. Pa. Sept. 28, 2023) (dismissing claims related to device not "listed as a device at issue in this MDL"); *see also In re Jamster*

Mktg. Litig., No. 05-cv-819, 2008 WL 4482307, at *6 (S.D. Cal. Sept. 29, 2008) (stating that "[t]he primary purpose of MDL proceedings is to provide efficiencies in coordinated pretrial discovery and other pretrial matters—not to use the MDL proceedings as a means to expand the scope of the litigation beyond the core issues identified by JPML").

Defendants have consented to the adoption of a direct filing mechanism via a Master Complaint and Short Form Complaint to promote efficiencies in this MDL. *See* CMO No. 2, § V, Doc. 42. However, Plaintiffs cannot use the Master Complaint—which they intend to be an administrative summary of all the allegations and claims in this MDL—to expand the MDL's scope. The inclusion of the new allegations and claims in the Master Complaint improperly circumvents the JPML's role of vetting tag-along actions as having common questions of fact. As defined in the JPML's Rules of Procedures, a "'tag-along action' refers to a civil action pending in a district court which involves common questions of fact with . . . actions previously transferred to an existing MDL, and which the Panel would consider transferring under Section 1407." JPML Rule 1.1(h). Upon receipt of a notice of potential tag-along actions, the Clerk of the JPML may (A) enter a conditional transfer order ("CTO") "transferring that action to the previously designated transferee district for the reasons expressed in the Panel's previous opinions and order"; or (B) "determine[] that a potential tag-along action is not appropriate for inclusion in an MDL proceeding." JPML Rule 7.1(b). If the Clerk enters a CTO, any party opposing transfer may file a notice of opposition and motion in support of vacating the CTO. JPML Rule 7.1(c), (f).

Direct filing removes the requirement of going through the CTO process. *See Sykes v. Cook Inc.*, 72 F.4th 195, 202 (7th Cir. 2023). However, the direct-filing procedure must still ensure that all actions filed in the transferee court are "appropriate for inclusion in [the] MDL proceeding," which means that the allegations must fall within the purview of "the Panel's previous opinions and order." JPML Rule 7.1(b). As mentioned, the JPML's Transfer Order does not contemplate or include port body allegations, only those related to the use of barium sulfate in catheters. Allowing port

body allegations to be included in the Master Complaint would open the door to a plaintiff asserting ***solely*** port body allegations to be improperly included in the MDL. Such a case would lack common questions of fact with the cases in the MDL and—absent direct filing—would be the subject of a meritorious motion to vacate CTO, if not an initial determination by the Clerk that the action "is not appropriate for inclusion in an MDL proceeding." *Id.* If the Master Complaint contains allegations outside of the scope of this MDL, then there would be no mechanism to vet and exclude improper, direct-filed "tag-alongs." *See In re: Aqueous Film-Forming Foams Prod. Liab. Litig.*, No. 23-cv-2384, 2023 WL 6846676, at *4 (D.S.C. Oct. 17, 2023) ("[I]t is obvious that no party by unilateral fiat can include a civil action in an MDL without an opportunity for opposing parties to interpose objections, including whether the newly filed claim exceeds the scope of the transfer order of the JPML.").

None of Plaintiffs' cited decisions—most of which were issued by the JPML and not a transferee court—change the foregoing principles of MDL practice. First, Plaintiffs' reliance on *In re: Aqueous Film-Forming Foams Prod. Liab. Litig.*, MDL No. 2873, 2021 WL 755083, at *1 (J.P.M.L Feb. 4, 2021), is misplaced as that decision was issued by the JPML on a motion to vacate a CTO. Accordingly, it supports Defendants' position that the JPML, not the transferee court, resolves questions regarding whether particular facts or claims fall within the scope of a Transfer Order.

Plaintiffs then cite several decisions where the JPML created industry-wide, or near industry-wide, MDLs with multiple defendants and multiple products. *See In re: AndroGel Products Liab. Litig.*, 24 F. Supp. 3d 1378, 1379-80 (J.P.M.L. 2014); *In re Proton-Pump Inhibitor Products Liab. Litig. (No. II)*, 261 F. Supp. 3d 1351, 1354-55 (JPML 2017); *see also In re: Natl. Football League Players' Concussion Injury Litig.*, 842 F. Supp. 2d 1378, 1379 (JPML 2012) (including separate defendant in Transfer Order and stating that transferee court may remand those claims or actions if they are not sufficiently related). In all of those decisions, the Panel *included* the disputed actions, parties, claims, or products in its Transfer Order, and further held that the transferee

court had the discretion to *narrow* the MDL to exclude that did not in fact present common issues. *In re: AndroGel Products Liab. Litig.*, 24 F. Supp. 3d at 1380 (stating that "the transferee judge retains wide discretion as to how the MDL should be defined, and if, after close scrutiny, the transferee judge determines that remand of any claims or actions involving any particular product is appropriate, procedures are available whereby this may be accomplished with a minimum of delay").

Plaintiffs ask this Court to do the opposite. They ask this Court to *expand* the MDL to include new claims and allegations that were *not included* in the Panel's Transfer Order. Defendants respectfully submit that this Court lacks the authority to expand the MDL. Rather, this Court's authority and discretion is limited to "control[ling] the scope" of this MDL by severing, remanding, or striking improper cases, claims, or allegations. *In re Medtronic, Inc. Implantable Defibrillators*, No. 05-md-1726, 2007 WL 968436, at *1 (D. Minn. Mar. 7, 2007) (remanding cases involving claims related to devices not within scope of MDL and holding that "any unnecessary allegations concerning or references to any devices other than the [devices within the MDL's scope] shall be stricken from any complaint remaining in or that hereinafter becomes a part of [the MDL]").

Plaintiffs' reliance on *In re: Exactech Polyethylene Orthopedic Products Liability Litigation* and *IVC* is also misplaced. In *Exactech*, both parties in fact addressed the additional devices that were identified in the Master Complaint before the JPML. *See* Mem. in Supp. of Mot. to Transfer, MDL No. 3044, ECF No. 1-1, at 2 (J.P.M.L.); Resp. of Defs. to Mot. to Transfer, ECF No. 42, at 2, 5-6 (J.P.M.L.). Then, once the MDL was formed, the Parties agreed that "[w]hile each of these Devices is distinct, common among them is that they all incorporate Exactech's ultra-high molecular weight polyethylene ("UHMWPE") inserts or liner components," which Plaintiffs allege are "defective due to an alleged increased risk of accelerated wear and degradation, thereby necessitating early replacement of the components." *In re: Exactech Polyethylene Orthopedic Prod. Liab. Litig.*, Joint Statement of Case for Science Submission, No. 22-

md-3044, ECF No. 99-1, at 1 (E.D.N.Y.). Accordingly, there was a common alleged defect. Here, in contrast, Plaintiffs seek to expand the MDL to encompass entirely different alleged defects in a separate and distinct component of the devices at issue.

In *IVC*, this Court correctly ordered Defendants to "file a motion with the panel on multidistrict litigation to expand this MDL to include the [additional device] cases or to create a new MDL including [those] cases" before agreeing to oversee those cases. *In re: Bard IVC Filters Prod. Liab. Litig.*, No. 15-md-2641, CMO No. 38, ECF No. 12853 (D. Ariz.). Plaintiffs should follow that same procedure here if they intend to pursue their novel port body allegations and wish to include the Peritoneal Titanium Port in this MDL.

3. Plaintiffs' Port Body Allegations Are Not a Common Issue Suitable for Coordinated Proceedings in this MDL

Only the JPML, not Plaintiffs before the transferee court, can decide whether port body allegations belong in this MDL. *See In re: Philips Recalled CPAP, Bi-Level Pap, and Ventilator Prods. Litig.*, 2023 WL 7019287, at *55 (rejecting Plaintiffs' argument that the transferee court "has the authority to determine the scope of the MDL and include devices not originally included," and holding that "Plaintiffs are thus relegated to the accepted methodology to expand an MDL" by moving before the JPML). Plaintiffs' arguments regarding why these claims should be the subject of coordinated proceedings in a single MDL should be presented to the JPML in the first instance. That said, a comparison of the allegations concerning port bodies and catheters plainly shows that they are not amenable to common discovery.

Plaintiffs allege that Defendants' catheters are "comprised of a polymeric mixture containing barium sulfate." Compl. ¶ 230. According to Plaintiffs, "when barium sulfate dissociates [from the surface of the catheter], it causes injury, including but not limited to catheter fracture, infection, and thrombosis." *Id.* ¶ 266; *see also id.* ¶¶ 244-56. Plaintiffs (and presumably their intended experts) assert that Defendants could have employed alternative designs, which include using alternative radiopaque materials,

sheathing the catheters, or coating the catheters with a surface-modifying additive. *Id.* ¶¶ 257-59.

Plaintiffs' port body allegations are entirely different and have nothing to do with barium sulfate. Instead, Plaintiffs first target the utilization of "polyoxymethylene ("POM") [marketed as Delrin] in the construction of the port reservoir." *Id.* ¶ 267. According to Plaintiffs (and likely a different set of experts), Defendants' formulation of POM "is not compliant with the applicable specification standards for POM used in medical devices," and their "manufacturing process for the POM-containing [port bodies] lack adequate measures to stabilize the POM to prevent oxidative degradation." *Id.* ¶¶ 281-82. Plaintiffs assert that "[o]xidative degradation reduces the mechanical properties of the polymer," which in turn increases the risk of port body fractures, infections, and thrombosis. *Id.* ¶¶ 275, 283-84. Plaintiffs contend that Defendants could have used "more stable plastic materials." *Id.* ¶ 286.

Plaintiffs also allege a second, distinct issue with the port bodies. They claim that certain palpation bumps "cause undue compression stress on the tissue of the subcutaneous pocket in which the port is placed." *Id.* ¶¶ 287, 289. Plaintiffs allege that this "compression stress leads to ulceration and tissue necrosis, which causes erosion of the port through the patient's skin." *Id.* ¶ 291. Again, none of these port body allegations were presented to or considered by the JPML, nor are they part of the Panel's Transfer Order assigning MDL 3081 to this Court. Moreover, these allegations would require a separate track of fact discovery (limited to only a subset of Plaintiffs), as well as a whole set of new experts or, at the very least, distinct topics for expert discovery.

* * *

For the foregoing reasons, this Court should not enter the Master Complaint and should order Plaintiffs to strike the port body allegations from any amended pleading submitted for the Court's approval. Any plaintiff who alleges solely a port body injury should not be part of this MDL. To the extent that any plaintiff alleges an injury caused by the port body in addition to an injury caused by an implantable port catheter, that

plaintiff should set forth those allegations in her Short Form Complaint. Those issues will then be resolved on remand. In addition, this Court should further order Plaintiffs to strike the Peritoneal Titanium Port from the Master Complaint and Short Form Complaint.

B. Plaintiffs' Position[1]

Defendants contend that the Master Complaint's allegations regarding port-body defects and the Peritoneal Titanium Port fall outside the scope of this MDL. *See, e.g.*, Doc. 93-1 at 3, 29-30, 44-47. If Defendants had their way, this MDL would "always" be frozen in time as of the JPML's transfer order, forever pigeonholing Plaintiffs to the one defect they managed to uncover before discovery had even started. *See supra* at 5. That is not how it goes. This Court is empowered to define the MDL's scope, which properly includes catheter *and* port-body defects, as well as all 25 Bard IPC models in the Master Complaint. *See In re Aqueous Film-Forming Foams Prods. Liab. Litig.*, 2021 WL 755083, at *1 (J.P.M.L. Feb. 4, 2021) ("MDLs can naturally expand to encompass other claims involving the products at issue and presenting similar factual questions.").

Defendants' objection hinges on the false premise that the JPML alone decides the scope of an MDL. *See supra* at 7-8. Not so. The law is clear that the transferee court has "wide discretion as to how the MDL should be defined." *In re AndroGel Prods. Liab. Litig.*, 24 F.Supp.3d 1378, 1380 (J.P.M.L. 2014); *see, e.g.*, *In re Proton-Pump Inhibitor Prods. Liab. Litig.*, 261 F.Supp.3d 1351, 1354-55 (J.P.M.L. 2017) (noting MDL judge's "substantial discretion to refine the litigation's parameters"); *In re Medtronic, Inc. Implantable Defibrillators*, 2007 WL 968436, at *1 (D. Minn. Mar. 7, 2007) ("This Court has express authority from the JPML to exercise its discretion to

[1] The Court's October 26 email invited "*brief* position statement[s]" (emphasis in original), yet Defendants' statement is anything but "*brief*." Unfortunately for the Court, Defendants rebuked Plaintiffs' repeated efforts to stipulate to a word limit (e.g., 500 or 750 words per statement), objecting to any word limit as "arbitrary." Plaintiffs respectfully request that the Court institute a word limit moving forward. *See, e.g.*, *IVC*, Doc. 1471 at 2-10 (matrix setting forth defendants' sub-500-word position statements).

control the scope of [the] MDL."). This Court—not the JPML—is in the "best position" to define which "claims are sufficiently related . . . to remain in centralized proceedings." *In re Nat'l Football League Players' Concussion Inj. Litig.*, 842 F.Supp.2d 1378, 1379 (J.P.M.L. 2012); *see* David F. Herr, *Multidistrict Litigation Manual* § 5:44.[2]

Plaintiffs' Master Complaint is no different than in *IVC*. There, too, the Master Complaint enumerated six models as the "subject IVC filters," *see IVC*, Doc. 364 at 2, elaborating on the JPML's transfer order that had addressed only "retrievable inferior vena cava filters," *In re Bard IVC Filters Prods. Liab. Litig.*, 122 F.Supp.3d 1375, 1376 (J.P.M.L. 2015). Nonetheless, the MDL eventually expanded beyond the terms of the transfer order to include an additional model, the Simon Nitinol Filter ("SNF"), even though that filter was permanent not retrievable. *See In re Bard IVC Filters Prods. Liab. Litig.*, 2019 WL 3928657, at *4 n.3 (D. Ariz. Aug. 20, 2019).

Exactech is also instructive. There, the JPML's transfer order spoke only of "knee or hip replacement devices" and named just three models. *See In re Exactech Polyethylene Orthopedic Prods. Liab. Litig.*, 637 F.Supp.3d 1381, 1382 (J.P.M.L. 2022). The Master Complaint, however, identified four additional hip and knee devices; it also "unilaterally add[ed]," *cf. supra* at 6, an entirely new category for ankle devices, *see In re Exactech Polyethylene Orthopedic Prods. Liab. Litig.*, MDL 3044, Doc. 94 at 5 (E.D.N.Y. Jan. 26, 2023). Neither the MDL court nor the defendants blinked. *See id.*; *see also, e.g.*, *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*,

[2] To the extent the JPML has addressed the proper scope of an MDL, those cases usually involve the addition of an entirely new defendant or type of claim, unlike here. *See, e.g.*, *supra* at 8 (citing *In re Aqueous Film-Forming Foams Prods. Liab. Litig.*, 2023 WL 6846676, at *3-4 (D.S.C. Oct. 17, 2023) (holding "inclusion of insurance coverage disputes in an MDL involving underlying tort claims . . . has traditionally been, and should be, reserved to the JPML")). Defendants lean on an unpublished report and recommendation in *In re Philips*, but that was a unique case where the JPML had delimited the 19 recalled models included in the MDL. *See supra* at 10 (citing *In re Philips Recalled CPAP, Bi-Level PAP, & Ventilator Prods. Liab. Litig.*, 2023 WL 7019287, at *55 (W.D. Pa. Sept. 28, 2023)); *In re Philips Recalled CPAP, Bi-Level PAP, & Mech. Ventilator Prods. Liab. Litig.*, 568 F.Supp.3d 1408, 1410 n.4 (J.P.M.L. 2021).

787 F.Supp.2d 1358, 1360 (J.P.M.L. 2011) (deferring to "transferee judge . . . regarding the inclusion of metal-on-metal [devices] and other configurations").

Compared to *IVC* and *Exactech*, Plaintiffs' Master Complaint does not come close to "circumvent[ing] the JPML's role." *See supra* at 7. Consistent with the "common questions of fact" in the transfer order, the Master Complaint alleges that "[D]efendants manufacture the catheter component of their port devices with a concentration of barium sulfate that is too high." Doc. 1 at 1; *see, e.g.*, Doc. 93-1 at 48. That the Master Complaint alleges *another* common issue of fact regarding port-body defects—implicating the *same* devices and causing the *same* injuries—is of no moment. *See* Doc. 93-1 at 44-47 (identifying two IPCs utilizing plastic port bodies); *id.* at 22 (identifying 13 IPCs with palpation bumps). In fact, the JPML noted still other commonalities that transcend the catheter defect. *See* Doc. 1 at 1 ("All actions share common issues of fact regarding . . . whether [D]efendants adequately tested the devices, and whether [D]efendants adequately monitored and reported adverse events relating to product failures."). The Master Complaint therefore coheres with the transfer order. Defendants' attempt to read between the lines of that order does not, however. Nowhere did the JPML preclude Plaintiffs from raising an additional port-body defect, as Defendants represent. *Cf. supra* at 4 (claiming the transfer order "relates to allegations of defects *only* in the catheter component . . . *not* the port body") (emphasis added).

Stuck with the same products causing the same indivisible injuries, Defendants capitulate that MDL Plaintiffs may bring port-body claims "in addition to" catheter claims. *See supra* at 11-12. Still, Defendants strangely argue that differences in the injury mechanism warrant striking port-body allegations and severing those claims for resolution on remand. *See id.*But just as Defendants argued in *IVC*, there is no sense in "re-litigation of the same issues in different courts," which would "significantly impact the parties and the judiciary." *IVC*, Doc. 12700 at 7 (quoting *In re Bard IVC Filters*, 122 F.Supp.3d at 1376). Litigating both defects together in this MDL—rather than relegating port-body claims to parallel lawsuits outside this MDL—will "streamline pretrial

proceedings," "reduce duplicative discovery," "as well as prevent inconsistent rulings." Doc. 1 at 1; *see, e.g.*, *In re Stryker Orthopaedics LFIT V40 Femoral Head Prods. Liab. Litig.*, 249 F.Supp.3d 1353, 1355 (J.P.M.L. 2017) (concluding that "individualized factual issues" did not "negate the efficiencies to be gained by centralization"); *In re Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F.Supp.2d 1371, 1372-73 (J.P.M.L. 2007) (rejecting Bard's argument that cases involving "different models" and "various types of defects" should not be consolidated given availability of "discovery with respect to any non-common issues").

At bottom, all that is required here is a common product and a common injury. *See In re Valsartan Prods. Liab. Litig.*, 433 F.Supp.3d 1349, 1352 (J.P.M.L. 2019) ("A complete identity of factual issues . . . is not a prerequisite . . . where, as here, the actions arise from a common factual core."); *e.g.*, *In re Aqueous Film-Forming Foams*, 2021 WL 755083, at *1-2 (noting the MDL had already "naturally expand[ed]" to include multiple mechanisms of injury); *In re Stryker*, 249 F.Supp.3d at 1356 (consolidating "substantially similar" devices because plaintiffs "experience[d] similar problems"). And this Court has already confirmed that the common thread connecting all products and defect theories is that "Plaintiffs in these cases allege that Defendant[s] . . . are liable for *injuries caused by implantable port catheters*." Doc. 7 at 1 (emphasis added).

Though the Peritoneal Titanium Port is an "implantable port catheter," *see id.*, Defendants attempt to distinguish it from the other IPCs because it is not an implantable *vascular* access device. *See supra* at 5. But Defendants inexplicably ignore that the Peritoneal Titanium Port also contains a "radiopaque catheter" made of barium sulfate[3]—the very defect highlighted in the JPML's transfer order that Defendants hyperfixate on. *See* Doc. 93-1 at 39. To be sure, discovery may reveal still more commonalities, especially since the Peritoneal Titanium Port shares a model number with the BardPort Titanium Implantable Port. *See id.* at 94.

[3] *See* https://www.bd.com/en-us/products-and-solutions/products/product-page.0603000#overview.

The ultimate irony is Defendants' change of heart since *IVC*. There, Defendants recognized that even distinct categories of products (retrievable and permanent filters) "involve[d] overlapping discovery concerning many of the same scientific studies, common expert witness issues, and duplicative pretrial motions." *IVC*, Doc. 12700 at 3; *see also In re Bard IVC Filters Prods. Liab. Litig. ("IVC JPML")*, Doc. 483-1 (J.P.M.L. Nov. 1, 2018). In Defendants' words, "expand[ing]" the MDL to "include one additional [product]" and two related defects is "the *most convenient and efficient path forward*." *IVC JPML*, Doc. 483-1 at 6 (emphasis added).

Equally hypocritical is Defendants' criticism of the "timing" of Plaintiffs' allegations. *See supra* at 6.[4] In *IVC*, Defendants delayed until three years into the MDL to include the SNF. *See IVC*, Doc. 12700 at 4. Three months into this MDL, the time is now for the parties and the Court to "ma[ke] early efforts to define the scope of this litigation." *In re Bisphenol-A (BPA) Polycarbonate Plastic Prods. Liab. Litig.*, 2010 WL 2134275, at *1 (W.D. Mo. May 26, 2010). Plaintiffs expeditiously and carefully drafted their Master Complaint, cataloguing over two dozen models of IPCs after Defendants refused to define the universe of model names and numbers. *See* Doc. 93-1 at 3-4. Because "other devices may be added once . . . discovery proceeds," Doc. 23 at 3; Doc. 93-1 at 4 n.2, the Court should "not limit the scope of this MDL docket" at this embryonic stage, *see In re DePuy*, 787 F.Supp.2d at 1360.

For all these reasons, the Court should approve the Master Complaint, including its allegations involving port-body defects and the Peritoneal Titanium Port.

III. Successor Liability

The parties' positions regarding successor liability are set forth below.

[4] Heeding the Court's instruction, Plaintiffs disclosed several drafts of their Master Complaint to Defendants before the filing deadline. Defendants' attempt to use Plaintiffs' work product against them defies the Court's instruction. *See supra* at 6.

A. Plaintiffs' Position[5]

The Court directed Defendants to disclose whether "the potential liability of one or more Defendants is limited to a particular period of time, a particular product, or a particular category of successor liability, or is limited in some other way related to the concept of successor liability." Doc. 42 at 4. Defendants' answer is no less mysterious today than eight weeks ago. Suffice it to say, the parties are far from "reach[ing] agreement" on the potential liability of each Defendant in this MDL. *See* Doc. 53 at 46:2-4.

As Plaintiffs explained at the first CMC, successor liability is a "hot topic" in modern mass torts. *Id.* at 44:19-45:19. Historically, when MDL plaintiffs sued multiple corporate defendants, the defendants operated as—and were ultimately treated as—a monolithic entity. *See, e.g.*, *IVC*, Doc. 17567 at 2-4 (collapsing all defendants as "Bard" on the verdict form). Plaintiffs certainly "hope" it could be so straightforward here, but that is "more hope than likelihood" given the burgeoning trend. *Cf. infra* at 25 (quoting *In re Bard IVC Filters Prods. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016)).

In recent years, MDL defendants have attempted to capitalize on their individual identities, especially in conjunction with pre-litigation mergers or post-litigation bankruptcies. In the *Talcum Powder* MDL, defendants deployed the "Texas two-step" to limit their tort liability, seeking shelter in bankruptcy court instead of litigating the MDL's merits. *See In re LTL Mgmt., LLC*, 64 F.4th 84, 94-97 (3d Cir. 2023).[6] Similarly, in the *Earplugs* MDL, defendants "devised a scheme" involving a "funding and indemnity agreement" in which 3M's subsidiaries assumed all liabilities and declared bankruptcy, while 3M paradoxically funded the bankruptcy. *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2022 WL 17853203, at *3 (N.D. Fla. Dec. 22, 2022).

[5] Despite promising not to address the merits, Defendants spill their ink on four pages of irrelevant summary-judgment briefing on successor liability. *See infra* at 21-23.

[6] Notably, the debtor's counsel in that bankruptcy proceeding also represent Defendants here. *See In re LTL Mgmt., LLC*, Case No. 3:21-bk-30589, Doc. 414 (W.D.N.C. Bankr. Nov. 15, 2021) (application to employ McCarter & English).

Because defendants' bad-faith conduct "upend[ed]" that MDL and "derailed [plaintiffs'] efforts to litigate . . . on the merits," the MDL court wielded its inherent powers to prohibit 3M from shifting blame to its subsidiaries. *Id.* at *6-7. The MDL court nonetheless lamented 3M's abuse of the judiciary as it "would have organized th[e] litigation very differently" had it known successor liability was at issue. *Id.* at *6 (discussing missed opportunity for "common discovery on successor liability").

Against that disturbing backdrop, the parties' views on Defendants' potential liability radically diverge at the outset: Defendants believe CMO 2 requires them to address the liability of *only* Becton, Dickinson and Company ("BD") as the successor to C.R. Bard, Inc. ("C.R. Bard"); Bard Access Systems, Inc. ("BAS"); and Bard Peripheral Vascular, Inc. ("BPV"). Plaintiffs, on the other hand, rely on CMO 2 itself, which plainly requires Defendants to address whether "*one or more* Defendants" have liability limited in time, by product, or otherwise. *See* Doc. 42 at 4 (emphasis added).

Even as to BD alone, Defendants have barely scratched the surface of successor liability. Plaintiffs cannot hold BD liable for the conduct of C.R. Bard, BAS, or BPV, Defendants say, because "BD did not expressly or impliedly assume any of C.R. Bard's liabilities as part of the 2017 acquisition." *Infra* at 23. But this bare-bones statement tells Plaintiffs nothing more than what is already in the public domain.[7] Defendants go so far as to say that "BD cannot be held liable for any claims related to [Bard IPCs]," even post-merger. *Infra* at 21, 26. Apparently, Defendants believe BD is somehow immune for its own IPC-related conduct, even though BD touted that "Bard has joined BD" and the remaining Defendants' "product offerings were taken over by and integrated into BD's Interventional and Medical segments." *E.g.*, Doc. 93-1 at 8-13. When Plaintiffs pressed for an explanation as to BD's involvement in designing, manufacturing,

[7] *See, e.g.*, BD, Registration Statement (Form S-4) (May 23, 2017), https://www.sec.gov/Archives/edgar/data/10795/000156761917001094/s001711x1_s4.htm#tTMA; BD, Annual Report (Form 10-K) (Nov. 22, 2017), https://investors.bd.com/sec-filings/annual-reports##document-42-0000010795-17-000021-1.

labeling, and/or selling Bard IPCs, Defendants refused to engage and punted to their Master Answer.

After nearly two months of meeting and conferring, only one thing is clear: Defendants know much more than they let on. When commenting on the draft DPF, for example, Defendants assured Plaintiffs that they "doubt there will be much question [about liability] with regard to [BAS] or C.R. Bard in most cases." Plaintiffs pushed for clarification on what "most cases" meant, but Defendants refused to demarcate "a particular period of time, a particular product, or a particular category." *See* Doc. 42 at 4. Similarly perplexing, Defendants declared that they "will be unable to assess whether there is a potential for liability [with respect to BPV] until [they] have more detailed information about a case." Yet again, Defendants failed to explain what additional information they supposedly require to ascertain BPV's exposure in this MDL, despite their involvement in drafting the Short-Form Complaint and PPF.

Given BD's efforts to evade legal and financial responsibility[8] and the other Defendants' refusal to pin down who bears potential responsibility, Plaintiffs' Master Complaint pleaded successor liability. *See* Doc. 93-1 at 87-89. Plaintiffs also intend to explore this subject in general discovery. *See infra* at 40. But regardless of that discovery, the Court should order each Defendant to identify the parameters of its potential liability (*i.e.*, "particular period of time," "particular product," and "particular category" of conduct or claims for which it may be liable) and crystalize its position on the liability of the other Defendants. *See* Doc. 42 at 4. They should do so by the next CMC. After all, Defendants have already had two months to resolve these very issues.

Sidestepping CMO 2, Defendants relegate successor liability to the close of the case, claiming it is a post-judgment issue that only becomes ripe if Plaintiffs are unable "to collect a judgment against an entity found directly liable." *See infra* at 24-25. If

[8] After purporting to confer with Plaintiffs about successor liability for numerous weeks, Defendants disclosed for the first time in their draft position statement that BD engineered a "reverse triangular merger" to dodge successor liability. *See infra* at 23.

Defendants had their way, Plaintiffs would be "forced to litigate these issues on a piecemeal basis following remand to transferor courts, substantially increasing their costs and unfairly subjecting them to the risk of inconsistent rulings." *In re 3M*, 2022 WL 17853203, at *6. Those inefficiencies are entirely avoidable here "given the Court's mandate to resolve common questions," including both direct and successor liability, "in this consolidated proceeding." *Id.* (citing 28 U.S.C. § 1407). This Court should therefore "organize[] this litigation" to address successor liability through "common discovery." *Id.* Until Defendants clear the air on who is potentially liable and the solvency of those entities, "common-issue discovery" is essential for both direct and successor liability. *See infra* at 25.[9]

Plaintiffs will also seek case-specific discovery on successor liability, *see infra* at 34-36, culminating in "summary judgment and/or bellwether trials" to determine which Defendant(s) are legally and financially liable for Plaintiffs' injuries, *cf. In re 3M*, 2022 WL 17853203, at *6. Even then, Defendants could upend this MDL at the eleventh hour by restructuring, entering into indemnity agreements, or filing for bankruptcy. *See id.* at *3; *In re LTL*, 64 F.4th at 93-99; *In re Aearo Techs. LLC*, 2023 WL 3938436, at *2-6 (S.D. Ind. Bankr. June 9, 2023). Such strategies typically fail, but they still threaten to derail the Court's plan "to resolve this case in three years." Doc. 53 at 5:18-19.

B. Defendants' Position

Plaintiffs raised the issue of successor liability at the initial CMC to see whether BD would "agree[] that it is the successor in liability to C.R. Bard, [BAS], [and] [BPV] so there's no debate about if C.R. Bard was liable for something, whether [BD], the parent company now, would be liable for that same conduct." Sept. 18, 2023, Hr'g Tr. 45:12-19 (Doc 53). After meeting and conferring, Defendants advised Plaintiffs that the

[9] Knowing common discovery is appropriate (if not inevitable) on this seminal issue, Defendants ask the Court to shadow *Smith*. *See infra* at 26. But *Smith* is readily distinguishable, involving neither an MDL nor successor liability. *See Smith v. Unum Life Ins. Co. of Am.*, 2022 WL 1136639, at *1 (D. Ariz. Apr. 18, 2022). The Court ordered "limited discovery" because "discovery in ERISA cases is limited." *Id.* at *4.

answer is no: BD cannot agree to such a stipulation. For the reasons that follow, BD cannot be held liable for any claims related to any products identified in the Master Complaint under any theory of successor liability or veil-piercing. BD did not assume C.R. Bard, BAS, or BPV's liabilities as part of BD's acquisition of C.R. Bard in 2017, and Plaintiffs do not assert in the Master Complaint that C.R. Bard, BAS, and BPV are insolvent or at risk of being unable to satisfy any judgment.

Conducting or prioritizing discovery into successor liability and veil-piercing at the outset of this MDL would put the "cart before the horse" and distract the Parties from the core issues at stake: whether any alleged defect related to the concentration of barium sulfate in Defendants' catheters caused Plaintiffs' injuries, and whether any Defendant (BD, C.R. Bard, BAS, and/or BPV) can be held *directly* liable for those alleged injuries. For the reasons set forth herein, such discovery should be set on a separate schedule and limited to Court-approved requests and deposition topics in advance of a motion for a summary judgment.

With respect to *direct* liability, Plaintiffs may serve discovery related to questions such as which Defendants designed, manufactured, and distributed particular devices, and when. This Court should reject Plaintiffs' request that at the outset of this litigation this Court order "each Defendant to identify the parameters of its potential liability" in this MDL involving a Master Complaint that identifies dozens of devices implanted into Plaintiffs over an at-least fifteen-year period.

1. Plaintiffs Cannot Rely on Principles of Successor Liability or Veil Piercing to Hold BD Liable for its Subsidiaries' Conduct

Successor liability becomes a relevant issue in a product liability case when a plaintiff is injured by a product manufactured by a liable company that no longer exists due to a merger, acquisition, or other corporate transaction. *See Restatement (Third) of Torts: Prod. Liab.* § 12 (1998) ("Almost all of the reported decisions applying the bases of successor liability stated in this Section involve predecessors that transfer all of their assets to successors and then dissolve or otherwise cease operations."); *Stalwart Capital,*

LLC v. iCap P. N.W. Opportunity and Income Fund, LLC, 762 F. App'x 367, 369 (9th Cir. 2019) ("[B]ecause there was no liability to [plaintiff], there was no need to engage in an analysis of successor liability . . . ."). In that circumstance, the plaintiff may look to a successor company to obtain a recovery. However, "[t]he well-settled general rule, adopted in virtually every State, is that where one company sells or otherwise transfers all its assets to another company, the latter is not liable for the debts and liabilities of the transferor." *Ronnoco Coffee, LLC v. Westfeldt Bros., Inc.*, 939 F.3d 914, 920 (8th Cir. 2019) (internal quotation marks omitted).

Most states recognize only four exceptions to this general rule of non-liability. These exceptions may apply when the acquisition:

> (a) is accompanied by an agreement for the successor to assume such liability; or
>
> (b) results from a fraudulent conveyance to escape liability for the debts or liabilities of the predecessor; or
>
> (c) constitutes a consolidation or merger with the predecessor; or
>
> (d) results in the successor becoming a continuation of the predecessor.

Restatement (Third) of Torts: Prods. Liab. § 12 (1998). A minority of states recognize a fifth exception called the product-line exception. *See Ramirez v. Amsted Indus., Inc.*, 431 A.2d 811, 825 (N.J. 1981) (adopting exception in New Jersey); *Winsor v. Glasswerks PHX, L.L.C.*, 63 P.3d 1040, 1049-50 (Ariz. App. 2003) (rejecting exception in Arizona). None of these exceptions applies to BD's 2017 acquisition of C.R. Bard and its subsidiaries.

First, Plaintiffs cannot rely on any contractual assumption of liabilities. "When a company acquires another corporation and the target continues to operate as a separate entity, the purchasing corporation will not assume the liabilities of the acquired corporation unless it expressly agrees to do so." *Jurista v. Amerinox Processing, Inc.*, 492 B.R. 707, 766 (D.N.J. 2013). The Master Complaint contains no facts or non-conclusory allegations that reflect an express assumption of liabilities pursuant to the publicly available merger agreement. *See, e.g.*, Compl. ¶¶ 58, 62-63, 566-67; *see also In*

re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig., No. 13-md-2445, 2017 WL 4810801, at *7 (E.D. Pa. Oct. 25, 2017) (noting that "this exception requires an interpretation of the parties' agreement"); *Rice v. First Energy Corp.*, 339 F. Supp. 3d 523, 537 (W.D. Pa. 2018) ("A statement in SEC filings in which the parent consolidates by description its subsidiary's efforts and its own 'is not atypical, and certainly does not suggest that, via fraud or its equivalent, the parent corporation has become indistinguishable from the subsidiary.'" (quoting *Suboxone*, 2017 WL 4810801, at *11)). That is so because BD did not expressly or impliedly assume any of C.R. Bard's liabilities as part of the 2017 acquisition. To the contrary, BD acquired C.R. Bard through a reverse triangular merger, which is a transaction "specifically designed to preclude the imposition of successor liability." *Norfolk S. Ry. Co. v. Pittsburgh & W. Virginia R.R.*, 153 F. Supp. 3d 778, 808 (W.D. Pa. 2015), *aff'd*, 870 F.3d 244 (3d Cir. 2017). "In a reverse triangular merger, the acquiring corporation . . . forms a new subsidiary, which is merged into the target corporation . . . so that the target corporation is a surviving corporation that continues to own its assets." *N. Valley Mall, LLC v. Longs Drug Stores California, LLC*, 238 Cal. Rptr. 3d 368, 371 (Cal. App. 3d Dist. 2018).

Next, with respect to the merger and continuation exceptions, an "essential characteristic" of these exceptions "is that one corporation survives while another ceases to exist." *Pub. Serv. Elec. & Gas Co. v. Cooper Indus., LLC*, -- F. Supp. 3d --, 2023 WL 4173010, at *9 (D.N.J. June 26, 2023) (quoting *U.S. v. Gen. Battery Corp., Inc.*, 423 F.3d 294, 308 (3d Cir. 2005)). Plaintiffs cannot rely on these exceptions given that the C.R. Bard, BAS, and BPV still exist. Similarly, the product line exception is inapplicable because there remains a remedy against the original manufacturer. *See Oticon, Inc. v. Sebotek Hearing Sys., LLC*, 865 F. Supp. 2d 501, 510 (D.N.J. 2011) (holding that exception "does not apply where the claimant had a potential remedy against the original manufacturer but failed to exercise all available means to assert his or her claim"). Finally, the fraud exception is inapplicable as Plaintiffs assert in a conclusory fashion

that BD acquired these allegedly liable entities to escape its own liability. *See, e.g.*, Compl. ¶ 570.

Nor can Plaintiffs rely on the "conceptually distinct," equitable remedy of veil-piercing to impose liability on BD. 1 Fletcher Cyc. Corp. § 48; *see also Specialty Companies Group, LLC v. Meritage Homes of Arizona, Inc.*, 492 P.3d 308, 310 (Ariz. 2021) ("[A]n attempt to pierce the corporate veil is not itself a cause of action but is raised in the context of another cause of action"); *Hillman Power Co., LLC v. On-Site Equip. Maint., Inc.*, 632 F. Supp. 3d 736, 738 (E.D. Mich. 2022) (stating that veil piercing is a "post judgment remedy" under New Jersey law). Pursuant to the doctrine of veil-piercing, "a parent company [can be] held liable for the acts of its subsidiary, if (1) there is unity of control between parent and subsidiary such that one is the 'alter ego' of the other, and (2) observing the corporate form's privileges and protections would be unjust." *Specialty Companies Group, LLC*, 492 P.3d at 310. "Except in cases of fraud, injustice, or the like, courts will not pierce a corporate veil." *Richard A. Pulaski Const. Co., Inc. v. Air Frame Hangars, Inc.*, 950 A.2d 868, 877–78 (N.J. 2008) (quoting *Dept. of Envtl. Prot. v. Ventron Corp.*, 468 A.2d 150, 164 (N.J. 1983)). Plaintiffs fail to allege facts that establish the requisite showing of control or domination by BD of its subsidiaries in the Master Complaint. Plaintiffs also fail to plead facts that suggest that BD used its subsidiaries to perpetuate any type of fraud or injustice. Indeed, following BD's acquisition of C.R. Bard, C.R. Bard resolved prior cases asserting the same defects as alleged in this MDL without issue.

Accordingly, neither successor liability nor veil-piercing are meritorious or relevant theories of liability in this MDL.

2. Discovery into Issues Related to Successor Liability and Veil-Piercing Should be Narrowly Circumscribed and Should Proceed on a Separate Schedule

If this Court is inclined to allow any discovery on successor liability and veil-piercing to proceed in this MDL, the discovery should be staggered, and Plaintiffs should be required to propose to the Court the specific discovery requests they intend to serve

to ensure that discovery remains appropriately limited. *See Smith v. Unum Life Ins. Co. of Am.*, No. 21-cv-01858-PHX-DGC, 2022 WL 1136639, at *1 (D. Ariz. Apr. 18, 2022).

Prioritizing discovery into these issues at the outset of this MDL does not "promote the just and efficient conduct of such actions," 28 U.S.C. § 1407(a), or satisfy Rule 26(b)(1)'s relevance standard. Beyond the fact that discovery will uncover no evidence sufficient to overcome summary judgment on these issues, the entire exercise is academic in nature absent any risk that Plaintiffs are unable to recover against BD, C.R. Bard, BAS, or BPV on any theory of direct liability. Plaintiffs may seek discovery regarding each entity's direct liability in the ordinary course of common-issue discovery. On the other hand, the relevance of Plaintiffs' successor liability and veil-piercing discovery rests on conditions precedent that Plaintiffs have not satisfied: the inability to collect a judgment against an entity found directly liable. Accordingly, at this time, "the discovery appears to be only potentially relevant—more hope than likelihood." *In re Bard IVC Filters Products Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016).

Nor will Plaintiffs' proposed discovery be "proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1). These concepts rank low on importance relative to the other issues in this MDL—namely, direct liability. Furthermore, the burden of this discovery will far outweigh its benefit under the circumstances. During the parties' conferrals, Plaintiffs proposed to serve additional Interrogatories beyond Rule 33's limit of twenty-five on these issues. Accompanying these Interrogatories will be document requests and deposition notices, including, very likely, notices for apex depositions. The subject matter at issue will likely engender disputes over privilege and objections to certain depositions and topics for depositions, among others. Expanding the scope of discovery into such a tangential and contentious topic will risk delay of the fact discovery period, pose significant hardship to Defendants, and—in all likelihood—provide no return to Plaintiffs given that all named Defendants are in operation and actively participating in this litigation. Absent any need for this discovery, the discovery will be nothing more than a costly and harassing fishing expedition into Defendants' corporate structure.

In light of the foregoing, Defendants respectfully request this Court stagger this discovery until the parties have substantially completed discovery into direct liability issues. Requiring the parties to take discovery on direct liability first may obviate the need for successor liability discovery or, at the very least, may allow the parties to hone in on the key issues for discovery at the appropriate time. Should the parties agree that successor liability and/or veil-piercing remain an issue following additional conferrals, this Court should adopt a procedure similar to the one adopted in *Smith*. This procedure, modified from *Smith*, would provide:

> [T]he Court will review the actual interrogatories, requests for production, and requests for admission that Plaintiff[s] wish to serve rather than granting blanket permission for discovery to proceed on these topics. This procedure will help limit discovery, prevent additional discovery disputes from coming before the Court, and . . . promote [the] primary goal[s] of [this MDL in accordance with 28 U.S.C. § 1407 and Fed. R. Civ. P. 26(b)(1)].
>
> Plaintiff[s] shall file, [on a date to be determined at a future case management conference], the particular interrogatories, requests for production, and requests for admission that [they] wish[] to serve regarding [successor liability and veil-piercing]. [Plaintiffs] should also provide the Rule 30(b)(6) notice [they] intend[] to serve . . . . Defendants will submit any objections they have to Plaintiff's proposed discovery [three] week[s] after [Plaintiffs] files [their] proposal. Plaintiff[s] shall not file a reply unless requested by the Court.
>
> IT IS ORDERED that limited discovery regarding [successor liability and veil-piercing] will be permitted. The parties shall follow the procedures set forth above, and the Court will issue an order on the specific discovery that is allowed. The parties' filings shall not exceed 7 pages each.

Smith, 2022 WL 1136639, at *4 (alterations added).

3. Common-Issue Discovery will Address the Potential Liability of Defendants for Particular Devices and Time Periods

CMO No. 2 requires the Parties to "discuss and describe their views on th[e] issue[s] [of potential and successor liability] and a procedure for resolving disagreements." Defendants complied with that directive. Defendants advised Plaintiffs that BD cannot be held liable for any claims related to any products under any theory of successor liability; and that questions of direct and successor liability, including questions related to particular devices and time periods, will be the subject of common-

issue discovery.

This Court should not be distracted by Plaintiffs' lamentations that Defendants were unable to answer unduly broad and open-ended questions of potential liability that were untethered to any fact pattern via e-mail or telephone calls during their conferrals. This is a multi-defendant MDL involving a Master Complaint that identifies dozens of devices that, per the individual complaints that have been filed to date, have been implanted and explanted into plaintiffs for at least a fifteen-year period from 2008 to 2023. Formal discovery tools properly employed by the Parties should be used to answer such questions.

This Court should also reject Plaintiffs' demand that this Court "order each Defendant to identify the parameters of its potential liability (*i.e.*, 'particular period of time,' 'particular product,' and 'particular category' of conduct or claims for which it may be liable), and crystalize its position on the liability of the other Defendants . . . by the next CMC." Plaintiffs cite no authority for such a sweeping order. Nor do they endeavor to explain why exploration of these subjects in general discovery is insufficient, or warrants immediate attention. Plaintiffs are not entitled to what are, in essence, unbounded contention interrogatories prior to the service of any other discovery requests in this MDL. *Cf.* Fed. R. Civ. P. 33(a)(2) (prescribing that courts can defer answers to contention interrogatories "until designated discovery is complete, or until a pretrial conference or some other time"); *Fredrics v. City of Scottsdale*, No. -21-cv-001, 2022 WL 60546, at *1 (D. Ariz. Jan. 6, 2022) ("Contention interrogatories are generally considered overbroad and unduly burdensome because they call for an answering party 'to provide a narrative account of its case.'" (quoting *Gov't Benefits Analysts, Inc. v. Gradient Ins. Brokerage, Inc.*, 2012 WL 3238082, at *9 (D. Kan. Aug 7, 2012))).

This MDL is in its nascent stages. No discovery has been taken in any case. Yet, Plaintiffs effectively demand that Defendants provide them with immediate and complete narratives of the corporate and regulatory histories of each Defendant and device at issue in this MDL. In Defendants' view, those questions may be explored in

the ordinary course of discovery and may be the subject of appropriately phrased contention interrogatories served by a potential bellwether plaintiff. *See In re Dealer Mgt. Sys. Antitrust Litig.*, MDL No. 2817, No. 18-cv-864, 2019 WL 6498081, at *5–6 (N.D. Ill. Dec. 3, 2019) ("[C]ontention interrogatories often are most-appropriate toward the close of discovery, or even after the close of discovery, to eliminate the possibility that [the responding party] has not yet had time to gather the information to support its claim [or defense]."); *B. Braun Med. Inc. v. Abbott Laboratories*, 155 F.R.D. 525, 527 (E.D. Pa. 1994) (explaining that "[c]ontention interrogatories ask a party . . . to take a position, and explain or defend that position, with respect to how the law applies to facts" and that "courts may defer them until a later stage of discovery" because "if Defendants are forced to respond, they may have to articulate theories of their case not yet fully developed"). After discovery and in advance of trial, the Parties may revisit whether any agreement or stipulation as to potential liability of one or more Defendants is warranted.

IV. Bellwether Selection, Discovery, and Trial

Attached hereto as Exhibit A is a proposed Case Management Order regarding Bellwether Selection, Discovery, and Trial. The parties have agreed to the great majority of the CMO, but disputes remain as to some issues in Section V. The parties' positions regarding those disputes are set forth below.

A. Plaintiffs' Position

1. Consolidated Trials

The same common questions of fact that supported consolidated pretrial proceedings, *see* 28 U.S.C. § 1407(a), support consolidated bellwether trials, *see* Fed. R. Civ. P. 42(a)(1). Consistent with the purpose of this MDL, consolidated trials would "promote the just and efficient conduct of such actions." *See* 28 U.S.C. § 1407(a); *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 2010 WL 797273, at *3 (N.D. Ga. Mar. 3, 2010). Indeed, MDL courts are "urged to make good use of Rule 42(a) in order to expedite the trial and eliminate unnecessary repetition." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1314 (11th Cir. 2017). The "substantial savings of time and

money that consolidation offers" is a boon to "both plaintiffs and defendants," not to mention the judiciary and jury. *Campbell v. Bos. Sci. Corp.*, 882 F.3d 70, 76 (4th Cir. 2018). These efficiencies are particularly meaningful here given the Court's intention "to resolve this MDL within 3 years." Doc. 7 at 4; *see* David F. Herr, *Manual for Complex Litigation* § 22.93 (4th ed. 2023) (stating that "consolidated trials" can "achieve greater efficiency and expedition in resolving mass tort cases"). Even Defendants' caselaw recommends consolidating cases involving "the same medical device." *See, e.g.*, *McCoy v. Biomet Orthopedics, LLC*, 2019 WL 6324558, at *7-8 (D. Md. Nov. 25, 2019).

Defendants aver that "few MDLs" have consolidated cases for bellwether trials. *See infra* at 34. But not a single one of their unpublished cases—*Leeds*, *Coleman*, *Taylor*, *Johnson*, *McCoy*, *Barraza*,[10] or *Crabtree*—involved MDL bellwether trials. The only other "authority" that defense counsel cites—an unvetted pamphlet penned by their like-minded brethren, *infra* at 34—is unsurprisingly one-sided, omitting cases old and new that were consolidated for trial. *See, e.g.*, *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2021 WL 2783898, at *1-2 (N.D. Fla. July 2, 2021); *In re Syngenta AG MIR 162 Corn Litig.*, 2017 WL 2876767, at *4 (D. Kan. July 6, 2017); *In re Mentor Corp.*, 2010 WL 797273, at *4; *In re Air Crash Disaster on Nov. 15, 1987*, 720 F. Supp. 1455, 1461 (D. Colo. 1988). The inescapable truth is that consolidation is "frequently" ordered in MDLs and cases involving "a common product." *See, e.g.*, 9A Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 2384 (3d. ed. 1998) (collecting cases).

Defendants' "gloomy, 'the sky is falling' forecast" on consolidation, *In re Mentor Corp.*, 2010 WL 797273, at *4, ignores the reality that any potential prejudice and confusion can be remedied through jury instructions and verdict forms, *e.g.*, *Eghnayem*, 873 F.3d at 1315; *Campbell*, 882 F.3d at 74-75; *see also United States v. Stone*, 9 F.3d

[10] Defendants tout this Court's decision in *Barraza*, *see infra* at 33, but certification of a class action is "chalk and cheese" compared to consolidation of MDL cases for trial. *See Barraza v. C. R. Bard Inc.*, 322 F.R.D. 369, 373 (D. Ariz. 2017).

934, 938 (11th Cir. 1993) ("Few tenets are more fundamental to our jury trial system than the presumption that juries obey the court's instructions."). Defendants also surmise that different state laws preclude consolidation, but they misapprehend Rule 42's disjunctive language. *See* Fed. R. Civ. P. 42(a) (requiring "a common question of law *or* fact") (emphasis added).

If the Court harbors any doubts about ordering consolidation at this nascent stage, Plaintiffs request the opportunity to brief the issue during the bellwether process. When submitting their Bellwether Group 1 proposal on March 10, 2025, Plaintiffs could simultaneously move to consolidate some but not all cases depending on their commonalities. *See, e.g.*, *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, 2016 WL 10719395, at *1-2 (N.D. Tex. Jan. 8, 2016) (consolidating for trial five of "ten cases [that] were initially selected as bellwether cases"); *In re 3M Combat Arms Earplug Prods. Liab. Litig.*, 2021 WL 773018, at *2 (N.D. Fla. Jan. 5, 2021) (consolidating three of five cases for trial and trying remaining two individually).

2. Number of Bellwether Cases

Plaintiffs recommend a modest 10 bellwether cases. *Cf., e.g.*, *In re 3M*, 2022 WL 17853203, at *2 (19 bellwether cases). Adding a few cases beyond the six bellwethers in *IVC* adds another layer of insurance against attrition—a possibility that Defendants not only recognize, *see infra* at 31-32, but actually hope to achieve through statutes of limitation. Even assuming only two cases fall out of the pool, as in *IVC*, Defendants' proposal for seven cases would yield just five data points from five single-plaintiff trials. Plaintiffs' proposal for 10 cases, in contrast, could yield eight data points from the same number of trials (e.g., four single-plaintiff trials and one four-plaintiff trial; or three single-plaintiff trials, one two-plaintiff trial, and one three-plaintiff trial) or even fewer trials (e.g., two single-plaintiff trials and two three-plaintiff trials). By extending trial time by merely a few more days for each additional plaintiff, the parties and the Court could increase data by over 50% (from five to eight verdicts) to drive settlement.

Despite their team of "over 1,000 attorneys,"[11] Defendants bemoan the "undu[e] burden[]" of working up three more bellwethers, *see infra* at 32, even though much of the workup will occur in Discovery Group 1, *see IVC*, Doc. 4866 at 1-2. The added labor of taking a few additional case-specific depositions in three cases, *see IVC*, Doc. 5883 at 1-4, is offset by the substantial time and resources saved by multi-plaintiff trials, *see In re Joint E. & S. Dists. Asbestos Litig.*, 125 F.R.D. 60, 63 (E.D.N.Y. 1989) ("When six to eight claims are consolidated for trial, [common evidence] can be presented once rather than six to eight times in individual trials."). And more cases in the pool also permits more flexibility in selecting representative trials (single- or multi-plaintiff). Preserving that flexibility is critical as the parties and the Court cannot yet anticipate the docket's composition and which commonalities could be consolidated. *Cf. IVC*, Doc. 5770 at 1-2. Ultimately, more bellwether cases mean more verdicts, and more verdicts mean more information to "facilitate a global settlement." *See IVC*, Doc. 8871 at 1-2. Absent a global settlement, preparing three more cases for trial will simulate remand trials—some of which will surely be consolidated given the size of this MDL.

To the extent the Court is unsure about the appropriate number of bellwether cases, there is no need to decide on the number right now. When the parties submit their proposals on March 10, 2025, they can also address the appropriate number.

B. Defendants' Position

1. Number of Bellwether Cases

In the Bard IVC Filter MDL, the Court selected six bellwether cases. Here, Defendants proposed that the parties work toward developing a pool of seven bellwether cases. Defendants' reasoning is based on the fact that two cases eventually dropped out of the Filter MDL bellwether pool, one based on a summary judgment ruling and one based on a motion filed by Plaintiffs. In Defendants' view, adding one additional bellwether case to the group would provide some protection for the Court and the parties

[11] *E.g.*, https://www.nelsonmullins.com/culture.

in the event that one or more cases dropped out of the pool (for whatever reason) in this MDL. Plaintiffs' counsel do not take issue with that position, but advocate for the selection of ten bellwether cases. They appear to be doing so based on a desire to have sufficient bellwether cases for the consolidated trials they are requesting. Defendants, however, strongly oppose the notion of consolidated trials, and hence, do not believe that ten bellwether cases are needed. Even if the Court were to contemplate consolidation over Defendants' objection, Defendants still believe that ten bellwether cases (with the associated development of case-specific experts and the resulting motions practice) would be unduly burdensome for both the Court and the parties. Additionally, the work necessary to prepare that many cases would make it more difficult to complete all discovery and work on the cases within the time frame envisioned by the Court.

2. Consolidated Trials

Defendants strongly object to consolidated bellwether trials. This Court noted that it intended "to try four or five bellwether trials," and then "wrap up the MDL" by September 2026. Sept. 18, 2023 Hr'g Tr. 6:2-3; 8:24-25 (Doc. 53). The goal is not "'to try large numbers of bellwether trials' before the conclusion of this MDL," as Plaintiffs contend, but rather to produce "representative verdicts." Manual for Complex Litigation (Fourth) § 22.315. Specifically, "[t]he purpose of the bellwether trials is to give the parties insight into how their claims and defenses are received by juries, in the hope of helping facilitate a global settlement before the cases are remanded to their original jurisdictions." CMO 28 at 1-2, *In re Bard IVC Filter Prods. Liab. Litig.*, 2:15-md-2641, Doc. 8871 (D. Ariz. Nov. 21, 2017). "They enable courts and juries 'to give the major arguments of both parties due consideration without facing the daunting prospect of resolving every issue in every action.'" *Adams v. Deva Concepts, LLC*, No. 1:20-CV-9056-GHW, 2023 WL 6518771, at *2 (S.D.N.Y. Oct. 4, 2023) (citation omitted).

"Consolidation can tilt the playing field, undermining the goal of producing representative verdicts." Bolch Judicial Institute, Duke Law School, *Guidelines and Best*

Practices for Large and Mass-Tort MDLs (2d ed. 2018), available at https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1004&context=bolch. This is because "if the unique details of each case were consolidated during a single trial, 'the jury's verdict might not be based on the merits of the individual cases but could potentially be a product of cumulative confusion and prejudice,'" *Leeds v. Matrixx Initiatives, Inc.*, No. 2:10-CV-199DAK, 2012 U.S. Dist. LEXIS 47279, at *7-8 (D. Utah Apr. 2, 2012) (citation omitted), "created by the parade of [plaintiffs' witnesses] and the possibility of factual and legal confusion on the part of the jury." *Coleman v. Quaker Oats Co.,* 232 F.3d 1271, 1297 (9th Cir. 2000). This is especially true where the cases "involve the application of different, and likely distinct, state law, different [devices], different implanting and treating physicians, and a variety of alleged device failures," which will lead to untenable evidentiary problems. *Taylor v. C R Bard Inc.*, No. 5:19-CV-469-BR, 2020 WL 4805436, at *2 (E.D.N.C. Aug. 17, 2020). "A cumulative presentation of the evidence would risk that the jury would resolve the confusion by considering all the testimony to pertain to all the claims, despite any limiting instructions," and risk that the "jury would be unduly influenced by the facts of one case and respond in [all] cases accordingly." *Johnson v. Adv. Bionics, LLC*, No. 2:08-cv-02376-JPM, 2011 WL 1323883, at *5-6 (W.D. Tenn. April 4, 2011); *McCoy v. Biomet Orthopedics, LLC*, No. CV ELH-12-1436, 2019 WL 6324558, at *5–8 (D. Md. Nov. 25, 2019) ("[A] jury may be tempted to conclude that, in light of plaintiffs' similar complaints, [multiple] devices are defective. In other words, the jury may impute the flaws of one implant to the other, rending that device 'guilty by association.'").

Indeed, it was these very differences that persuaded this Court to decline to certify the *Barraza* class action where plaintiffs proposed to hold a single consolidated trial involving plaintiffs with different filters, implanted by different doctors, and from different states, implicating different state law. *See Barraza v. C. R. Bard Inc.*, 322 F.R.D. 369, 381 (D. Ariz. 2017) (acknowledging that "filter-by-filter inquiries into design and manufacturing defects will be required; at each step, the state of the art must

be examined; failures to disclose will vary from year to year and filter to filter; the knowledge possessed by each [plaintiffs'] physician must be established to resolve the learned intermediary defense; and each [plaintiffs'] knowledge of the risk and response to suggestions of removal … will be needed to resolve defenses of assumption of the risk and contributory or comparative negligence").

Further, "courts have recognized that where a group of cases is being ***tried for the first time***," as here, "the interests of efficiency would also be served by letting the cases proceed separately, as separate trials will help define the exact factual and legal contours of the claims and defenses and may allow the parties to better assess the value and strength of the remaining matters." *Crabtree v. Livanova, PLC*, No. CV 18-4588, 2022 WL 19517407, at *4 (E.D. La. Mar. 30, 2022) (cleaned up) (emphasis added). For that reason, few MDLs – including the Bard IVC Filter MDL – have consolidated cases for bellwether trials. *See* John Beisner, Jessica Miller & Nina Rose, et al., *Trials and Tribulations: Contending with Bellwether and Multi-Plaintiff Trials in MDL Proceedings*, U.S. Chamber Institute for Legal Reform, at 2 (Oct. 2019), available at https://instituteforlegalreform.com/wp-content/uploads/2020/10/Contending_with_Bellwether_and_Multi-Plaintiff_Trials_in_MDL_Proceedings.pdf (finding from review of the dockets of 135 MDL proceedings active between 2008 and 2019 that just 7 of 73 bellwether trials involved more than one plaintiff).

V. Affirmative Disclosures (Profile Forms)

Attached hereto as Exhibit B is a proposed Case Management Order regarding Profile Forms; Exhibit C is a proposed Plaintiff Profile Form ("PPF"), and Exhibit D is a proposed Defendants' Profile Form ("DPF"). The parties have agreed to the CMO and PPF, but a dispute remains as to Section V of the DPF. The parties' positions regarding that dispute are set forth below.

A. Plaintiffs' Position

The sole remaining dispute relates to Section V of Plaintiffs' proposed DPF (Exhibit D). That section relates to both direct and successor liability, asking Defendants

to identify which of its corporate entities have potential liability for Plaintiff's claims (given the product at issue, time of manufacture, etc.). Defendants' position is that it is simply too difficult a task to determine which corporate entities may be liable in a case based on the limited information provided in a PPF—conveniently ignoring that Defendants had a hand in drafting the PPF. Defendants also claim hardship due to the various entities' evolving roles in the production and distribution of the devices, but their argument is unconvincing for several reasons.

First, Defendants raise no objection to Section IV.3 of the DPF, which requires them to provide the date and location of manufacture of the device at issue in the particular case. At the time Defendants provide a response to this section of the DPF, they should—at a minimum—be able to disclose the entity that owned and operated the production facility and the entities that were party to a manufacturing contract with the production facility.

Second, Defendants raise no objection to the DPF's requirement to produce the Device History Record ("DHR") for the device at issue in the case. Pursuant to FDA regulations, the DHR must contain, *inter alia*, "[t]he acceptance records which demonstrate the device is manufactured in accordance with the [Device Master Record]." 21 C.F.R. § 820.184. In turn, the Device Master Record ("DMR"), that a manufacturer is required to maintain, must include:

> (a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;
>
> (b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;
>
> (c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;
>
> (d) Packaging and labeling specifications, including methods and processes used; and
>
> (e) Installation, maintenance, and servicing procedures and methods.

21 C.F.R. § 820.181. Defendants' production of the DHR will allow them to easily determine which entity was the holder of the DMR at the time of production and which

entities were responsible for maintaining the specifications and procedures in the DMR at the time of production.

Lastly, owners or operators of establishments involved in the production and distribution of medical devices intended for use in the United States are required to register such establishments annually with the FDA. *See* 21 C.F.R. § 807.3 *et seq.* For every IPC, then, Defendants were obligated to register any entity that, for example: "[i]nitiates or develops specifications for a device that is to be manufactured by a second party" or "[s]terilizes or otherwise makes a device for or on behalf of a specifications developer or any other person[.]" 21 C.F.R. § 807.20(a)(1)-(2). Assuming Defendants have complied with these requirements, they would simply have to consult the annual establishment registration submission for the year of manufacture of the device at issue.

In sum, identifying the entities that engaged in the various steps of designing, manufacturing, labeling, and distributing the IPCs—and who would have potential liability as a result—is far from the protean concept Defendants claim, and the investigation Defendants would have to undertake in order to provide the disclosures in Section V of Plaintiffs' proposed DPF is far from burdensome. Plaintiffs have also expressed a willingness to remove these questions from the DPF after Defendants have provided a satisfactory response to the successor-liability question. *See supra* at 19-20. Until they do, the Court should enter an Order adopting Plaintiffs' proposed DPF.

B. Defendants' Position

Defendants object to the three questions set forth in Section V of the draft profile form. The three questions seek to have Defendants provide definitive statements—at the outset of a case and with only skeletal knowledge about a claim—as to which corporate entities are properly named in the lawsuit, which have "potential liability," and which have "potential financial liability."

The fact that Defendants need additional information to be able to respond to such questions is not surprising, as Plaintiffs mistakenly claim. Both Plaintiffs and Defendants have a great deal of investigation to accomplish in order to understand the

respective roles of the various entities at a given point in time. The challenge is exacerbated by the fact that both Bard Access Systems and Bard Peripheral Vascular have had roles with these devices at various points in time, and those roles have changed and evolved. Additionally, various components of the devices are manufactured at different locations. The parties are going to have to explore those roles together during common issue discovery before any determinations can be made as to which entities are potentially liable in a given case. It is simply not possible to provide the sort of definitive statements that Plaintiffs are seeking at this premature juncture.

Finally, none of the technical FDA regulations cited by the Plaintiffs alter that fact. Identifying which entity (of obviously related entities) maintains a Device Master Record or which entity has registered an establishment may be factors that Plaintiffs will argue in determining which entities have potential tort liability in a given case, but those factors are by no means determinative. As previously noted, the involvement of these entities with implantable port catheters has evolved over time, and during some periods of time, may have even been overlapping. Common issue discovery will clarify those roles.

VI. Scope of Discovery and Common Fact and Expert Discovery

Attached hereto as Exhibit E is a proposed Case Management Order regarding Common Fact and Expert Discovery Schedule.

The parties have submitted an agreed-upon proposed CMO for bellwether selection, which includes the procedure for discovery in the Initial Plaintiff Pool, although the parties agree that procedures for case-specific discovery have not yet been fully negotiated.

The parties have also submitted an agreed-upon proposed CMO setting forth a schedule for common fact and expert discovery. The parties have agreed to negotiate a deadline by which Defendants shall substantially complete production of documents and ESI. To facilitate agreement on what the substantial-completion date should be, the parties will continue negotiations after Plaintiffs serve their initial written discovery

requests so that Defendants may more fully understand the scope of what Plaintiffs seek as well as what will be required of Defendants for compliance. If the parties cannot reach agreement, the parties agree to present the issue to the Court on December 22.

Regarding the parameters of general fact and expert discovery, broadly speaking, the parties have agreed that the Federal Rules shall apply, with limited exceptions as defined herein, as well as in other protocols negotiated by the parties and by this Court's orders. Some of those exceptions, as well as other miscellaneous discovery issues that have been discussed and agreed upon, include the following:

- **Initial Disclosures:** The parties have agreed to forego Rule 26(a) Initial Disclosures contingent on Defendants' production of relevant insurance information, if any, on or before the disclosure deadline.
- **Number of Interrogatories:** Plaintiffs expressed a concern that the Federal Rules may not provide enough interrogatories to complete common fact discovery unless Defendants would commit to answer each interrogatory with respect to each product design at issue to the extent that the interrogatory necessitates different answers for each product design. For example, Plaintiffs will undoubtedly seek information about which individuals were part of the team responsible for the design of IPCs. There are currently 25 IPC designs at issue in the Master Complaint. To the extent that different individuals were responsible for different product designs, Plaintiff will seek the identity of all of those individuals with information regarding the alleged defects. While Plaintiffs have not yet shared their interrogatories, Defendants agree in principle to respond to Plaintiffs' interrogatories for the products within scope of the litigation, which Defendants note is a seminal issue currently before the Court. Defendants do not waive their rights to assert objections to the interrogatories, and, to the extent Defendants believe an interrogatory is too burdensome, the parties will meet and confer regarding such burden. If resolution cannot be reached, Defendants shall request a call with the Court

for resolution as set forth in CMO 2.

- **Custodians & Search Terms:** The parties will meet and confer regarding Defendants' relevant Custodians and Non-Custodial Sources as well as the search methodologies that Defendants determine to apply to these Sources once Plaintiffs serve their document requests and the parties receive guidance from the Court on the Master Complaint and successor-liability issues.
- **Deposition Protocol:** The parties are negotiating a proposed deposition protocol that will increase the number of depositions permitted by the Federal Rules. Either an agreed, proposed protocol or remaining disputes regarding the proposed protocol will be submitted to the Court on November 22.
- **Available Production & Depositions:** Defendants have committed to meet and confer with Plaintiffs once discovery opens regarding Defendants' discovery in prior IPC product-liability litigation and the scope of what Defendants will reproduce in this MDL. Additionally, the parties will meet and confer regarding other cases concerning IPCs in which Defendants were parties, whether specific information in those cases is relevant to this MDL, and Defendants' ability to produce that information for use in this MDL. Finally, there are two broader issues that may affect the course of discovery. Those issues are 1) discovery related to port-body or peritoneal-port allegations in the Master Complaint, and 2) discovery related to successor liability and veil piercing.

With respect to port-body and peritoneal-port discovery, Defendants' position is that they will provide discovery relating to the allegations set forth in the JPML's transfer order; that is, discovery related to whether Defendants' implantable vascular access devices are defective based on the concentration of barium sulfate in the catheter component of the devices. To the extent Plaintiffs' discovery requests seek production of documents or information that relate to allegations involving a port body or a peritoneal port, Defendants will object to those requests until the issue is resolved by the

Court. Plaintiffs point out that, if common fact discovery moves forward while this Court or the JPML are deciding the issue, it may necessitate that some ESI and documents be re-collected and that some depositions be re-taken, limited to the port-body or peritoneal-port discovery.

With respect to successor liability and veil piercing, Defendants' position, as set forth in Section III, is that discovery on the issue should be staggered. Plaintiffs disagree. Relatedly, Plaintiffs may seek additional interrogatories beyond the twenty-five permitted under Rule 33(a) because of the need to investigate successor liability and veil piercing. Defendants *may* consent to an increase in the number of interrogatories upon receipt of (1) additional information from Plaintiffs regarding their proposed topics and handling of subparts, and (2) guidance from the Court on the Master Complaint and successor liability issues. The Parties have agreed to meet and confer regarding these issues pending the Court's decision on related matters. Plaintiffs reserve their right to seek leave to serve additional interrogatories.

VII. Common Document Depository

The parties have agreed to use MDL Centrality for the submission and processing of profile forms, fact sheets, and deficiency letters, as set forth in the proposed Case Management Orders.

Dated: November 9, 2023

Respectfully submitted,

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