BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

IN RE: BARD IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION	MDL No. 3081

DEFENDANTS BECTON, DICKINSON AND COMPANY, C.R. BARD, INC., BARD ACCESS SYSTEMS, INC., AND BARD PERIPHERAL VASCULAR, INC.'S MEMORANDUM IN SUPPORT OF THEIR MOTIONS TO VACATE CONDITIONAL TRANSFER ORDER NOS. 10 AND 11

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INTRODUCTION

Defendants Becton, Dickinson & Company, C.R. Bard, Inc., Bard Access System, Inc., and Bard Peripheral Vascular, Inc. respectfully submit this Memorandum in support of their Motions to Vacate Conditional Transfer Order ("CTO") Nos. 10 and 11.

These Motions follow on the heels of Plaintiffs' unsuccessful attempt to expand the scope of this MDL before the transferee court to include allegations related to novel defects in the port reservoir component of Defendants' implantable port devices—allegations that are strikingly different than the allegations identified in the Panel's initial Transfer Order. Plaintiffs conceded before the transferee court that these allegations were not raised in the Motion to Transfer Actions pursuant to 28 U.S.C. § 1407, and that these detailed allegations were not pleaded in any complaint currently in the MDL. *See* Fanning Cert., Ex. A: *In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, No. 23-md-3081, Case Management Order No. 6, at 2-5, ECF No. 111 (D. Ariz.).

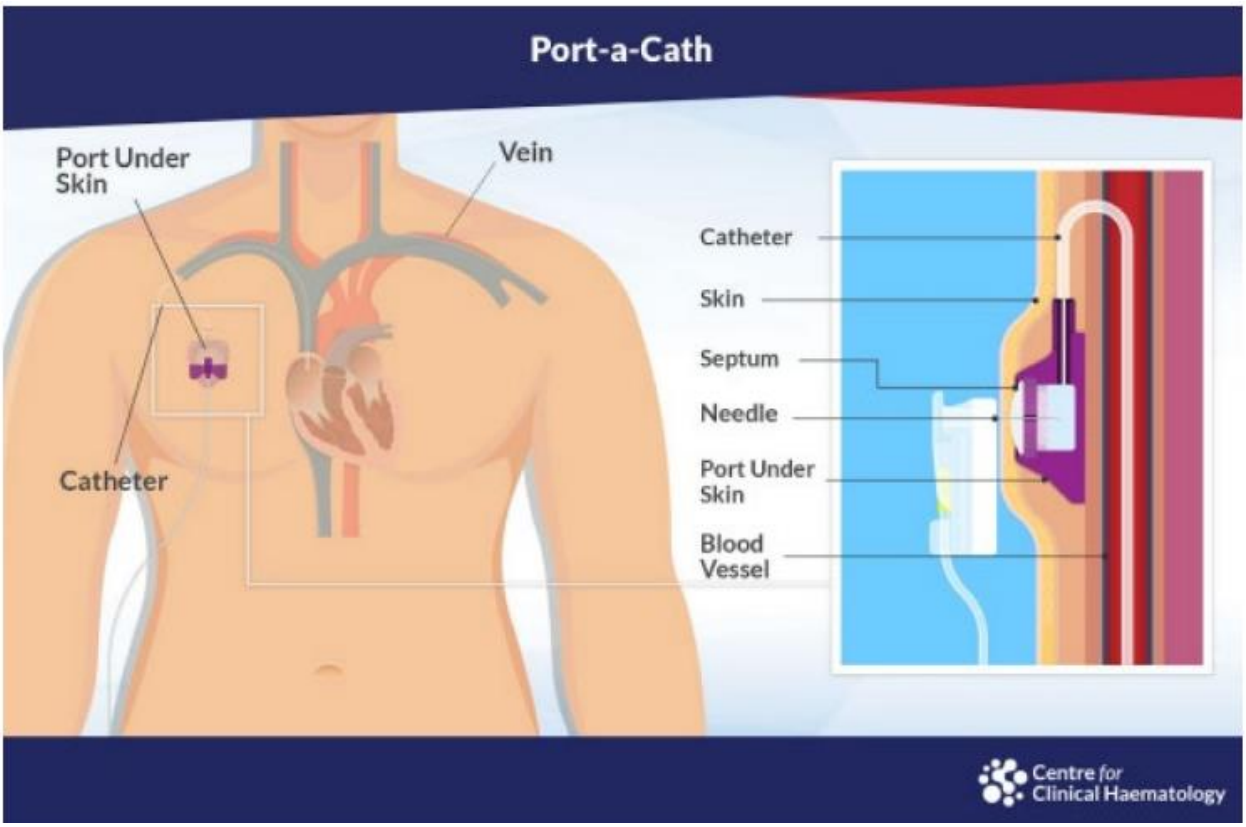
Plaintiffs have since filed the three complaints that are the subject of these Motions. Defendants respectfully request the Panel vacate the CTOs pertaining to these actions because they fall outside of the scope of the Transfer Order dated August 8, 2023. In the event that Plaintiffs request that the Panel expand the scope of the MDL to encompass these novel and unrelated allegations, Plaintiffs fail to satisfy 28 U.S.C. § 1407(a)'s standard for doing so. For these reasons and those that follow, these actions should not be transferred to the MDL at this time.

RELEVANT BACKGROUND

I. The New Complaints Allege Novel Defects Related to the Port Reservoir that are Distinct from the Alleged Catheter-Related Defects.

This MDL concerns an alleged defect in the catheter component of Defendants' implantable port catheter devices. These devices consist of two primary components: an injection port with a self-sealing silicone septum and a radiopaque catheter. The injection port is typically

implanted under the skin in the lateral region of the chest below the clavicle. A catheter connected to the injection port is tunneled under the skin to an insertion port in a vein. The tip of the catheter is advanced from its insertion point to the junction of the superior vena cava and the right atrium where the medication or fluids are introduced into the bloodstream.



See In re: Bard Implanted Port Catheter Prods. Liab. Litig., No. 23-md-3081, Master Compl. ¶ 161, ECF No. 119 (D. Ariz.).

Certain Defendants manufacture and distribute a number of different devices comprised of unique combinations of injection ports and catheters, including both power-injectable ports marketed under the tradename "PowerPorts," and non-power-injectable ports. Defendants' port reservoirs are made from plastic or titanium. PowerPorts have three "palpation bumps" on the septum to assist medical providers identify the port as a power-injectable device. Defendants' non-power injectable devices do not have these bumps.

See Fanning Cert., Ex. B, C: PowerPort and Non-Power Port Specification Sheets.

Defendants' catheters are made from polyurethane or silicone and contain barium sulfate, which is a radiopaque substance that allows the catheter to be seen on diagnostic imaging such as x-ray, CT or MRI. 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." *In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, No. 23-md-3081, Master Compl. ¶ 265, ECF No. 119 (D. Ariz.). Plaintiffs (and presumably their 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.* ¶¶ 256-58. In May 2023, plaintiffs moved to centralize actions that alleged catheter-related injuries and the foregoing barium sulfate theory, which the Panel ultimately granted.

Plaintiffs' two novel theories related to the port reservoir have nothing to do with barium sulfate or the catheters. Instead, these Plaintiffs first take aim at Defendants' alleged utilization of polyoxymethylene ("POM"), which is marketed as Delrin, in plastic port reservoirs. *See Meadors v. Becton, Dickinson and Co.*, No. 23-cv-22267 (D.N.J.), Compl. ¶ 20, ECF No. 1. Plaintiffs contend that "POM is a lower-cost material in comparison to titanium," and is "known to undergo oxidative degradation during processing, in vivo, and when exposed to radiography; leading to the reduction of the mechanical properties of the polymer and the release of toxic formaldehyde as a degradation product." *Id.* ¶¶ 21-22. According to the new Complaints, Defendants' formulation of POM provided by DuPont includes a "Medical Caution Statement which prohibits the use of Delrin 500 NC010 for applications involving permanent implantation in the human body as well as 'brief or temporary' implantation absent explicit permission from DuPont." *Id.* ¶ 24. Plaintiffs further allege that "Delrin 500 NC010 is not compliant with applicable specification standards adopted by the FDA for POM used in medical devices," and that "[t]he process for POM-containing ports lacks adequate measures to stabilize the material to prevent oxidative degradation." *Id.* ¶¶ 25-26. Plaintiffs assert that Defendants' use of POM leads to the formation of physical defects, which in turn "increases the risk of thrombosis and infection." *Id.* ¶¶ 27-28. Plaintiffs purport to identify a number of alternative designs for plastic port reservoirs. *Id.* ¶ 30.

Beyond POM, the new complaints raise a second novel defect limited to PowerPorts' palpation bumps. *See id.* ¶¶ 31-35. Plaintiffs assert that "[a]fter implantation, the raised bumps

cause undue compression stress on the tissue of the subcutaneous pocket into which the port is placed." *Id.* ¶ 33. "Such compression stress leads to ulceration and tissue necrosis which potentiates port and catheter infection as well as possible erosion of the port through the skin of the patient." *Id.*

As the foregoing allegations indicate, the novel port-related contentions have no overlap with Plaintiffs' contentions related to the concentration of barium sulfate in the catheters.

II. This MDL is Limited to the Alleged Defect Related to the Concentration of Barium Sulfate in Defendants' Catheters.

The proposed, and ultimately formed, MDL has always been about the catheter component of Defendants' devices. Neither the Movants before the JPML nor the Panel itself considered or addressed any allegations relating to the port reservoir in connection with the initial Motion to Transfer Actions. *See In re Bard Implanted Port Catheter Prod. Liab. Litig.*, MDL No. 3081, -- F. Supp. 3d --, 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 . . . ." (emphasis added)); 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." (emphasis added)).

Once the MDL was formed, Plaintiffs made ***no*** representations about port reservoir allegations being within the scope of the MDL in their initial overview of the common issues in advance of the initial case management conference. *See In re: Bard Implanted Port Catheter*

Prods. Liab. Litig., No. 23-md-3081, Joint Mem., at 3, ECF No. 23 (D. Ariz.) ("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 conference itself, at which time the parties agreed to a direct-filing mechanism and the filing of a proposed administrative master complaint.

Over one month later, on the night before Plaintiffs' deadline to file the master complaint, Plaintiffs circulated a draft containing the disputed port reservoir allegations for the first time. Defendants promptly objected to Plaintiffs' unilateral attempt to expand the scope the MDL. The parties then briefed the issue before the transferee court in a joint memorandum filed on November 9, 2023. Defendants argued that:

1) Plaintiffs could not credibly argue that the port reservoir allegations have always been part of this MDL and failed to provide any explanation as to why they did not raise the port reservoir allegations before the JPML;

2) the inclusion of the new allegations in the master complaint would improperly circumvent the JPML's role of vetting tag-along actions as having common questions of fact;

3) the transferee court's authority is limited to *controlling* the scope of an MDL by severing, remanding, or striking improper cases and claims—not *expanding* the scope of the MDL—and thus, the JPML must resolve the issue of whether port reservoir allegations are within the scope of the initial Transfer Order; and

4) Plaintiffs' port reservoir allegations are not suitable for coordinated proceedings in this MDL.

See Fanning Cert., Ex. D: *In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, No. 23-md-3081, Joint Memorandum, at 3-11, ECF No. 102 (D. Ariz.).

In response to Defendants' arguments regarding the proper procedure to follow, Plaintiffs' Co-Lead Counsel filed the first case containing the disputed port reservoir allegations the day after

the parties submitted the joint memorandum. *See Meadors v. Becton, Dickinson and Co.*, No. 23-cv-22267 (D.N.J. Nov. 10, 2023). On November 15, 2023, Plaintiffs' Co-Lead Counsel filed a Notice of Tag Along for *Meadors*. *See* ECF No. 106.

At the second case management conference held on November 16, 2023, the transferee court heard argument on the parties' positions related to the inclusion of the port reservoir allegations in the master complaint. With respect to the filings to date, Plaintiffs' Co-Lead Counsel conceded: "[t]here were references in those memoranda to the catheter defect with respect to barium sulfate. There was not a mention of the port reservoir issue . . . ." Fanning Cert., Ex. E: *In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, No. 23-md-3081, Nov. 16, 2023, Hearing Tr. at 17:14-19 (D. Ariz.). When asked about pending cases that contain the disputed port reservoir allegations, Plaintiffs' Co-Lead Counsel identified only *Meadors*. *See id.* at 18:6 to 19:14.

The transferee court thereafter correctly held that the port reservoir allegations are not part of the MDL. *See* Fanning Cert., Ex. A: Case Management Order No. 6, at 2-5. The transferee court found that (1) "Plaintiffs do not dispute that alleged port reservoir defects were not raised before the [Panel]"; (2) Plaintiffs do not "dispute that the Panel established this MDL to address claims alleging defects in the catheter component of Defendants' port devices due to high concentrations of barium sulfate"; (3) Plaintiffs' port reservoir "claims were not part of the MDL when the Panel issued its transfer order in August 2023"; and (4) "this MDL has not 'naturally expanded' to include port reservoir claims – Plaintiffs confirmed at the conference that no case currently pending in this MDL has alleged port defects based on the presence of POM." *Id.* at 2-4.

The transferee court then issued a number of critically important Case Management Orders that are premised on the exclusion of the port reservoir allegations. The transferee court ordered that it will conduct six bellwether trials drawn from an initial plaintiff pool that includes all cases

filed by April 1, 2024; that common-issue fact discovery shall be completed by January 31, 2025 with a to-be-determined date for the substantial completion of Defendants' document production; that all common-issue expert discovery shall be completed by June 30, 2025; and that the final list of cases for bellwether trials shall be set by March 10, 2025. *In re: Bard Implanted Port Catheter Prods. Liab. Litig.*, No. 23-md-3081, Case Management Order Nos. 9, 10, ECF Nos. 114, 115.

Following the second case management conference, two additional cases were filed that comprise the CTOs that are the subject of these Motions to Vacate. On November 16, 2023, a member of the Plaintiffs' Steering Committee filed a second action, *Franks v. Becton, Dickinson and Co.*, No. 23-cv-22267 (N.D. Tex. Nov. 16, 2023), which the district court *sua sponte* noticed as a potential tag along action. *See* ECF No. 108. Finally, Plaintiffs' Co-Lead Counsel filed a Notice of Tag Along on November 20, 2023, for a third action: *Hunter v. Becton, Dickinson and Co.*, No. 23-cv-3048 (D. Colo. Nov. 17, 2023). *See* ECF No. 112. *Meadors* and *Franks* are subject to CTO No. 10, and *Hunter* is subject to CTO No. 11. Defendants filed Notices of Oppositions to CTO Nos. 10 and 11. Defendants now respectfully submit this Memorandum in support of their Motions to Vacate these CTOs.

ARGUMENT

Section 1407 prescribes that "civil actions involving one or more common questions of fact . . . may be transferred to any district for coordinated or consolidated pretrial proceedings . . . upon [the Panel's] determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). 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, the Clerk may: (A) enter a 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). A CTO "can be and will be vacated upon the showing of good cause by any party." *In re Grain Shipments*, 319 F. Supp. 533, 534 (J.P.M.L. 1970). Critically, transfer is appropriate only if the action satisfies "the reasons expressed in the Panel's previous opinions and order." JPML Rule 7.1(b). In addition, if "inclusion of the [tag-along] action [] would not promote the just and efficient conduct of the litigation," a motion to vacate should be granted. *In re Checking Account Overdraft Litig.*, 818 F. Supp. 2d 1373, 1374 (J.P.M.L. 2011); *accord In re: Welding Fume Products Liab. Litig.*, 560 F. Supp. 2d 1356, 1357 (J.P.M.L. 2008).

Plaintiffs have not disputed—nor could they dispute—that the port reservoir allegations are not encompassed by "the Panel's previous opinions and order." JPML Rule 7.1(b). That should end the Panel's inquiry. But, to the extent that the Panel considers an expansion of the MDL to encompass these claims, the Panel should decline any invitation to do so.

I. The New Complaints Lack Sufficient Common Issues of Fact and Law with the Actions that are Part of the MDL.

In transferring the actions identified in the initial Transfer Order, the Panel rejected Defendants' argument that "individual factual issues will predominate with respect to the wide variety of alleged injuries [and] products" on the basis that "the plaintiffs in the cases now before the Panel allege a ***common mechanism*** for their various injuries." *In re Bard Implanted Port Catheter Prod. Liab. Litig.*, MDL No. 3081, -- F. Supp. 3d --, 2023 WL 5065100, at *1. Plaintiffs

now seek to introduce ***two additional mechanisms*** for their alleged injuries; mechanisms that (1) relate to a different component of the device (port reservoirs as opposed to catheters), (2) only impact a subset of devices (plastic port reservoirs and/or PowerPorts), and (3) give rise to unique port-related injuries. Plaintiffs therefore seek to change and expand the scope of this MDL. The Panel "do[es] not change the scope of an MDL lightly" however, *In re Google Play Store Simulated Casino-Style Games Litig.*, 544 F. Supp. 3d 1364, 1366 (J.P.M.L. 2021), and it should not do so here given that there is no longer a common mechanism for the various alleged injuries.

The common issues must predominate over the highly individualized issues specific to each plaintiff to render transfer or centralization appropriate. *See In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, 223 F. Supp. 3d 1351, 1352 (J.P.M.L. 2016) (denying motion for centralization because "the[] common factual questions [did not] predominate over the plaintiff-specific factual and legal questions presented in these actions"). These plaintiffs do not come close to meeting this standard with respect to their port reservoir allegations. Their new allegations concern a distinct component part of Defendants' implantable port catheter devices that has different design features, a different function, different materials, and different suppliers. As for the alleged mechanism of injury, there is no overlap in Plaintiffs' theories. Plaintiffs' POM and barium sulfate theories focus on different substances that comprise the respective component parts. Plaintiffs' palpation bump theory in turn focuses on a physical design feature—not a materials issue.

In short, there is no commonality at all between these actions' substantive allegations and the substantive allegations that are currently within the scope of this MDL. Although the allegations broadly concern subsets of devices that have been identified in the MDL and involve common defendants, that is where the commonality ends. Thus, "non-common issues far exceed the common issues." *In re: Google Digital Advertising Antitrust Litig.*, MDL No. 3010, Order

Vacating Conditional Transfer Order, ECF No. 194 at 2 (J.P.M.L. June 1, 2022); *see also In re: Navistar Maxxforce Engines Marketing, Sales Practices & Prods. Liab. Litig.*, MDL No. 2590, Order Vacating Conditional Transfer Order, ECF No. 208 at 2 (J.P.M.L. Feb. 4, 2018) ("unique factual and legal inquiries" "likely will overwhelm any commonalities that may exist").

II. Transfer of the New Complaints Will Not Promote the Just and Efficient Conduct of the Actions.

"Common factual questions . . . are not the sole prerequisite for centralization under Section 1407. Centralization also must promote the just and efficient conduct of the actions." *In re Cincinnati Ins. Co. COVID-19 Bus. Interruption Protec. Ins. Litig.*, 492 F. Supp. 3d 1347, 1349–50 (JPML 2020). Moreover, it is well settled that a minimal number of actions imposes a heavier burden on the party seeking transfer or centralization. *In re Stivax Mktg. and Sales Practices Litig.*, 645 F. Supp. 3d 1383, 1384 (J.P.M.L. 2022); *In re Covidien Hernia Mesh Prod. Liab. Litig.*, 481 F. Supp. 3d 1348, 1349 (J.P.M.L. 2020) (denying centralization of twelve actions pending in nine districts). Transfer of these cases will not result in their efficient management, or increase the efficiency of the MDL as defined.

If these cases are transferred to the MDL, the parties will be required to, among other things, expand the scope of discovery into an unrelated component part, seek third-party discovery from different material supplier, retain different specialized experts for the issuance of new expert reports, and devote one or more bellwether trials to the port reservoir allegations. Given that there are only three cases at issue, there is no need for such a dramatic expansion of the MDL. The parties and the transferee court should focus on the common issue discovery related to the approximately seventy pending catheter-related cases. Given the substantial amount of work to be done in the catheter cases, these cases will not receive the individualized attention that would

receive in their home districts. These three cases can be efficiently managed on their home districts given the overlap of counsel and low number of cases.

The Panel has also stated that "centralization under Section 1407 should be the *last solution* after considered review of all other options." *In re: Best Buy Co., Inc., Cal. Song-Beverly Credit Card Act Litig.*, 804 F. Supp. 2d 1376, 1378 (J.P.M.L. 2011) (emphasis added). Informal coordination is a "practicable" alternative that will minimize any inconveniences to the parties or witnesses (i.e., cross-noticing depositions) given the overlap in counsel. *In re Belviq (Lorcaserin HCI) Prod. Liab. Litig.*, 555 F. Supp. 3d 1369, 1370-71 (J.P.M.L. 2021); *see also In re: Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig.*, 959 F. Supp. 2d at 1376 (denying centralization where "many of the actions involve common plaintiffs' counsel"; and defendants agreed "to appropriately coordinate any common discovery or other pretrial matters across the cases"); *In re Linear Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, 341 F. Supp. 3d at 1382 ("[P]laintiffs in most actions are represented by a single law firm or firms that are working as co-counsel with that firm in other related actions. . . . Given the significant overlap in plaintiffs' counsel, alternatives to transfer exist that may minimize whatever possibilities there might be of duplicative discovery and/or inconsistent pretrial rulings."). Defendants remain willing to engage in informal coordination.

III. Vacating the CTOs Do Not Preclude Subsequent a Motion for Transfer Should the Circumstances Warrant.

"[B]ased upon the consideration of the pleadings, it must appear that transfer to the MDL will enhance efficiency and convenience of the litigation." *In re: Aqueous Film-Forming Foams Prods. Liab. Litig.*, MDL No. 2873, ECF No. 20 (J.P.M.L. Oct. 5, 2018). Plaintiffs have not met that standard with respect to the port reservoir allegations.

Defendants anticipate that Plaintiffs will argue that it is unclear whether their injuries were due to a catheter-related issue or a port-related issue, and therefore, transfer of these cases to the MDL is warranted. The Panel should reject that proposal. If individualized discovery in these actions indicates that the case does involve a catheter-related injury, then Plaintiffs may seek transfer at that time. *See id.* (noting that the Panel "do[es] not foreclose the possibility that discovery and pleading practice . . . may demonstrate that transfer of this action to the MDL is ultimately warranted"); *In re: Welding Fume Products Liab. Litig.*, 560 F. Supp. 2d at 1357 ("All parties remain free to move for transfer should future pretrial proceedings demonstrate that the action involves sufficient questions of fact common to the actions in MDL No. [3081] or circumstances otherwise dictate that transfer has become appropriate.").

CONCLUSION

For the foregoing reasons, Defendants respectfully request the Panel grant this Motion to Vacate the Conditional Transfer Orders Nos. 10 and 11.

Dated: December 12, 2023

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