**BEFORE THE UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION**

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| **IN RE: BECTON, DICKINSON AND COMPANY IMPLANTED PORT CATHETER PRODUCTS LIABILITY LITIGATION** | ) ) ) ) ) | **MDL DOCKET NO. _____** |

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO TRANSFER ACTIONS PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED OR CONSOLIDATED PRETRIAL PROCEEDINGS**

## I. INTRODUCTION

Pursuant to 28 U.S.C § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation ("the Panel"), Movants [redacted] and [redacted] respectfully submit this Memorandum in support of their Motion to Transfer Actions for coordination of pretrial proceedings. Movants seek transfer of all cases identified in the Schedule of Actions to a single District Court selected by this Panel, as well as any later filed cases involving similar facts or claims. The cases on the Schedule of Actions arise from injuries caused by the failure of implanted port products manufactured by the defendants enumerated herein. Also commonly referred to as Injection Ports, Port-a-Catheters or "Port-a-Caths," the implanted port products at issue in this Motion are implantable vascular access devices designed to help administer intravenous therapies including medication, fluids and parenteral nutrition without having to repeatedly access a peripheral vein. An implanted port product consists of an injection reservoir which is

implanted under the patient's skin and an attached catheter which acts as a conduit for the intravenous therapies injected into the reservoir. Implanted ports are commonly part of chemotherapy treatment for cancer patients or those with severe autoimmune disorders.

The actions identified in the Schedule of Actions ("the Actions") are brought by individuals (the "Plaintiffs") injured by the failure of an implanted port device. The Actions name as defendants three affiliated business entities involved in the design of implanted port devices, including C.R. Bard ("Bard") and Becton, Dickinson and Company ("BD") and Bard Access Systems, Inc. ("BAS") ("the Defendants"). As discussed further below, the Actions assert common claims based upon common factual allegations. No discovery is known to have occurred in any of the Actions, and no substantive rulings have been made. Plaintiffs anticipate that many tag-along actions are likely to be filed soon and for an indefinite time into the future. As will be set forth more fully herein, the ubiquity of implanted port implantations in the United States, coupled with the high complication rate and the outsized market share of the Defendants, could feasibly culminate in the filing of related actions in the tens of thousands. Coordination of the Actions would facilitate coordinated discovery, is necessary to avoid inconsistent pretrial rulings, and would promote judicial efficiency.

## II. BACKGROUND

Plaintiffs in these cases have filed at least ten civil actions for injuries caused by the use of Defendants' implanted port devices. These cases rest on a common core of facts and share essential characteristics as detailed next.

Each of the claims allege that (1) the Plaintiff was implanted with an implanted port manufactured by the Defendants consisting of an injection reservoir and a flexible, polymeric catheter; (2) the catheter component of the port devices were manufactured to include a radiopacity agent called barium sulfate, which is known to reduce the material integrity of the catheter when it is not encapsulated, coated or otherwise separated from the catheter surface; (3) the loss of exposed barium sulfate particles from the catheter surface leaves microfractures, fissures, and other alterations to the polymeric structure which potentiated one or more of the injuries common to these devices: catheter fracture, catheter infection, and thromboembolism; (4) Defendants misrepresented the safety of the port devices; (5) Defendants negligently designed, marketed, distributed, and sold these devices, (6) Defendants knew or should have known that these port devices were not safe for the patients to whom they were prescribed and in whom they were implanted because once implanted, the devices were prone to catheter fracture, bacterial colonization, potentiation of thromboembolism, and otherwise malfunctioning and causing serious injury; and (7) strict liability claims that these devices were defective and unreasonably dangerous and lacked proper warnings.

Shortly after the Defendants introduced these devices into the market—and long before these Plaintiffs were implanted with these devices—Defendants received numerous adverse event reports ("AERs") involving the types of device failures enumerated herein. These AERs were associated with severe injuries and complications, including

hemorrhage, cardiac/pericardial tamponade, cardiac arrhythmia, infection, sepsis, thromboembolism, and even death.

In many instances, the Defendants concealed known device failures and injuries from medical professionals and patients through submission to the FDA's controversial Alternative Summary Reporting ("ASR") program. The ASR program, which permitted device manufacturers to request exemptions, variances or alternatives to reporting requirements pursuant to 21 CFR 803.19, was in effect from 1997 through June of 2019. The FDA allowed device-related injury reports to be submitted through the ASR program if they were "well-known events associated with specific devices."[1] In contrast with the FDA's public Manufacturer and User Facility Device Experience (MAUDE) database, manufacturer reports of device failures submitted through the ASR program were not available to the public, including healthcare providers, until 2019. From 2004 to 2018 approximately 65% of all reported adverse events related to implanted port devices (the vast majority of them associated with Defendants' products) were reported through the non-public ASR program rather than MAUDE. The FDA halted its ASR program after its existence was exposed by a multi-part investigative report, prompting a widespread outcry from medical professionals and patient advocacy groups.

More recently, the ubiquity and breadth of injuries related to implanted port devices has become better understood. In 2020, a large study evaluating the long-term

[1] "Statement on agency's efforts to increase transparency in medical device reporting," FDA Center for Devices and Radiologic Health, June 21, 2019

complication profile associated with port placement was published.[2] The pool of participants of the study included 93,756 patients who had a port implanted. The results from the study found it was very common for a complication to occur within 5 years following implant and included arrhythmogenic and thromboembolic complications as well as infection and mechanical complications such as catheter fracture. Indeed, the complication rate was 59.04% across all of the complication types studied. This complication rate is all the more staggering in light of the facts that (1) implants of port devices in the United States are estimated at over 300,000 annually and (2) Defendants are the undisputed market leaders in the United States, accounting for more than fifty percent (50%) of domestic implanted port sales. These study results follow numerous studies over the last thirty years indicating that the very injuries observed in such high numbers in the *Khalid* paper are caused by the same unreasonably dangerous design elements alleged in the Actions. The Actions seek to hold Defendants liable for injuries caused by their wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and sale of their implanted port products.

## III. ARGUMENT

### A. Transfer to One District Court for Consolidation and Coordination Is Appropriate Under 28 U.S.C. § 1407.

[2] Khalid, et al., *Outcomes following port-a-catheter placement in the Medicare population*, 3 Surgery Open Science 39 (2021).

The creation of a multidistrict litigation ("MDL") is appropriate where "civil actions involving one or more common questions of fact are pending in different districts," and transfer will serve "the convenience of parties and witnesses" and "promote the just and efficient conduct of such actions." 28 U.S.C. § 1407(a). As this Panel has emphasized, "[c]entralization [permits] all actions to proceed before a single transferee judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs, while ensuring that common parties and witnesses are not subjected to duplicative discovery demands." *In re Katz Interactive Call Processing Patent Litig.*, 481 F. Supp. 2d 1353, 1355 (J.P.M.L. 2007).

There are—and will continue to be—numerous actions with common questions of fact filed in multiple districts. Given the common nature of these cases, the number of current actions, and the likely number of additional actions to be filed across the country, transfer and coordination are necessary to avoid "multiplied delay, confusion, conflict, inordinate expenses and inefficiency." *In re Plumbing Fixture Cases*, 298 F. Supp. 484, 495 (J.P.M.L. 1968). The high likelihood of inconsistent judicial rulings affecting the possible tens of thousands of plaintiffs is why Section 1407 was enacted.

**1.** <u>These Actions Involve Common Questions of Fact, and Centralization of the Actions will Minimize the Risk of Inconsistent Rulings</u>

The first requirement of 28 U.S.C. § 1407 is the presence of common questions of fact. Transfer and pretrial coordination of actions sharing common questions of fact "conserve[s] the resources of the parties, their counsel, and the judiciary." *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Products Liab. Litig.*, 254 F. Supp. 3d 1381,

1382 (J.P.M.L. 2017). However, these common questions of fact do not require complete identity or even a majority of common questions to justify transfer. *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004), See also *In re: Rembrandt Techs., L.P., Patent Litig.*, 493 F. Supp. 2d 1367, 1369 (J.P.M.L. 2007) ("Section 1407 does not require a complete identity or even a majority of common factual or legal issues as a prerequisite to transfer.").

Transfer and centralization are appropriate here because the Actions all have substantial commonality of questions of fact and law. Here, the Actions allege that Defendants engaged in wrongful conduct in the design, manufacture, marketing, sale, and post-market surveillance of their implanted port products. The Actions further 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. Moreover, these Actions allege that the Defendants knew of these defects and failed to correct them by incorporating a safer feasible alternative design and failed to adequately warn healthcare providers of the nature and magnitude of the risks attendant to these defects.

The common questions of fact concerning the development, testing, manufacturer, sale, marketing, and adequacy of warnings for Defendants' implanted port products—including industry knowledge of the products' danger—clearly warrant transfer and consolidation of these Actions.

**2.** Centralization of the Actions Will Promote the Just and Efficient Litigation of the Actions and Will Serve the Convenience of the Parties and Witnesses

The J.P.M.L. considers multiple factors when deciding if transfer and consolidation will promote the just and efficient litigation of the Actions, including (1) avoiding inconsistent rulings among and between cases; (2) prevention of duplicate discovery on common issues; (3) avoidance of undue burden and expense to the parties; and (4) promoting efficiency and judicial economy. See, *e.g.*, 4 MANUAL FOR COMPLEX LITIGATION, § 20.13, FEDERAL JUDICIAL CENTER (2004) (transfer is proper when it serves "the convenience of the parties and witnesses and will promote the just and efficient conduct of such actions"); see also *In re Bristol Bay, Salmon Fishery Antitrust Litig.*, 424 F. Supp. 504, 506-07 (J.P.M.L. 1976). These factors warrant the transfer and coordination of the Actions here.

Centralizing these Actions before a single judge is the most efficient way to manage this litigation. As described herein, these Actions will turn upon common questions of fact, including whether the Plaintiffs have adequately established a causal connection between the changes to the structural integrity of the product and its subsequent failure, whether Defendants acted negligently in the design, testing, manufacture, sale of these devices, whether Defendants should be strictly liable for injuries caused by these devices, and whether Defendants failed to satisfy their duty to warn healthcare providers of the risks posed by these products. Such questions are common to every Action and will be answered through fact and expert discovery that will likely be extensive, expensive, and time-

consuming. Failure to centralize and coordinate these Actions will only serve to duplicate these burdens on all parties.

The likely number of cases involving these products makes centralization critical. More than 300,000 implanted port products are used on patients in the United States each year. Numerous counsel representing Plaintiffs named in the Schedule of Actions have informally met to assess the merits of these cases and their suitability for centralization. Given the millions of devices implanted over the potential statutes of limitation periods, counsel believes that thousands (and possibly tens of thousands) of similar follow-on cases are likely to be filed in federal districts across the country. This type of voluminous, complex litigation is precisely why the MDL system exists. See *In re Camp Lejeune, N.C. Water Contamination Litig.*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011) (considering the potential for "a large number of additional related actions to be filed" as a factor weighing in favor of centralization).

The Panel, likewise, has acknowledged that centralization is still appropriate where the number of follow-on cases is fewer—even where only a handful of cases may be pending. For example, the Panel ordered the consolidation of only two actions and one potential tag-along because it was "necessary in order to eliminate duplicative discovery; prevent inconsistent rulings on pretrial motions, including those with respect to whether the actions should proceed as collective actions; and conserve the resources of the parties, their counsel and the judiciary." *In re Starmed Health Pers. FLSA Litig.*, 317 F. Supp. 2d 1380, 1381 (J.P.M.L. 2004). See also *In re First Nat'l Collection Bureau, Inc.*, 11 F. Supp.

3d 1353, 1354 (J.P.M.L. 2014) ("Although there are relatively few parties and actions at present, efficiencies can be gained from having these actions proceed in a single district."); *In re Porsche Cars N. Am., Inc.*, 787 F. Supp. 2d 1349, 1360 (J.P.M.L. 2011) (consolidating three pending actions in two districts); *In re Toys "R" Us-Del., Inc., Fair Accurate Credit Transactions Act (FACTA) Litig.*, 581 F. Supp. 2d 1377, 1379 (J.P.M.L. 2008) (consolidating two pending actions in two districts); *In re Milk Antitrust Litig.*, 530 F. Sup.2d 1359, 1360 (J.P.M.L. 2008) (consolidating four pending actions in two districts); *In re Camp Lejeune*, 763 F. Supp. 2d at 1381-82 (consolidating four pending actions in four districts).

These Actions have only recently been filed, and prompt centralization minimizes the risk of inconsistent rulings. As the Panel recognized in *Camp Lejeune*, delaying centralization "only invites inconsistent rulings," which Section 1407 is designed to avoid. 763 F. Supp. 2d at 1382. Moreover, early centralization of these Actions avoids potential prejudice to a party by transfer and consolidation. No substantive rulings have been made in any of the Actions, and no party has yet had an opportunity to conduct discovery. The timing of the filing of these Actions and this Motion places these cases in the best position to reap the full benefits of Section 1407.

Early centralization will maximize the benefits of the transfer and coordination under Section 1407. Plaintiffs with Actions in this litigation will seek substantially the same discovery from defendants; review the same documents produced in discovery; take depositions of the same corporate officers and other witness, as well the same or

substantially similar expert witnesses; and will involve the same questions of law surrounding expert qualifications under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and issues raised under motions for summary judgment. Coordination of these Actions will avoid unnecessarily duplicative discovery across multiple Actions and eliminate potentially conflicting or inconsistent rulings. See *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 802 F. Supp. 2d 1374, 1376 (J.P.M.L. 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and] prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort.").

Centralizing the Actions for coordination under Section 1407 is necessary to prevent inconsistent judicial rulings, eliminate duplicative discovery and motion practice, promote convenience and efficiency to the parties and witnesses, and conserve judicial resources. See, *e.g.*, *In re Smitty's/CAM2 303 Tractor Hydraulic Fluid Mktg., Sales Practices and Prods. Liab. Litig.*, 466 F. Supp. 3d 1380, 1381 ("Centralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings, especially with respect to … *Daubert* motions; and conserve the resources of the parties, their counsel and the judiciary."). The Panel, therefore, should grant Plaintiff's Motion to Transfer for Coordinated or Consolidated Pretrial Proceedings.

**B. These Actions Should Be Transferred to the Western District of Missouri**

Plaintiffs urge the Panel to transfer the Actions to the Western District of Missouri, where a court with Multidistrict Litigation experience can efficiently, justly, and capably manage them. The Western District of Missouri is the optimal court to manage a complex product liability case like this one.

In determining an appropriate transferee forum, the Panel balances several factors, including the experience, skill, and caseloads of the available judges; the number of cases pending in the jurisdiction; convenience of the parties; location of the witnesses and evidence; and the minimization of cost and inconvenience to the parties. See, *e.g.*, *In re Regents of University of California*, 964 F.2d 1128, 1136 (Fed. Cir. 1992); *In re Wheat Farmers Antitrust Class Action Litig.*, 366 F.Supp. 1087, 1088 (J.P.M.L. 1973); *In re Preferential Drugs Prods. Pricing Antitrust Litig.*, 429 F.Supp. 1027, 1029 (J.P.M.L. 1977); *In re Tri-State Crematory Litig.*, 206 F.Supp. 1376, 1378 (J.P.M.L. 2002); Annotated Manual of Complex Litigation (Fourth) (2004), § 20.131, 15 303-04. Factors including experience, number of pending cases, available resources, and convenience to the parties and witnesses all weigh heavily in favor of transferring all related cases to the Western District of Missouri.

The Western District of Missouri judges are well-versed in handling multidistrict litigations and have guided numerous MDLs to successful partial or complete resolutions. Examples include: *Dollar General Corp. Motor Oil Marketing and Sales Practices Litigation* - MDL Number 16-md-2709, *Smitty's/Cam2 303 Tractor Hydraulic Fluid*

*Marketing, Sales Practices and Products Liability Litigation* – MDL Number 20-md-2936, and *T-Mobile Customer Data Security Breach Litigation* - MDL Number 21-md-3019. These are but a few of the examples showing that the Western District of Missouri is an efficient, well-run District with impressive case-processing statistics. For example, of all of the District Courts in which the Actions are pending, the Western District of Missouri currently boasts the shortest median time from case filing to disposition for civil cases.[3]

The Panel has also held that the pendency of a related action in a particular forum is an important factor in selecting the forum. *See In re: Sugar Industry Antitrust Litig.*, 395 F.Supp. 1271, 1274 (J.P.M.L. 1975) (citations omitted). Of the ten Actions currently on file, six are on file in the Western District of Missouri. The remaining cases not pending before the Western District of Missouri have been filed across at least three District Courts with no other District presiding over more than one related Action. See David F. Hen, Multidistrict Litigation Manual § 6:8 (2010) ("[T]he Panel will not normally transfer actions to a district in which no action is then pending and the panel clearly considers the number of actions pending in various districts to determine the selection.").

In addition to other factors, consolidation in the Western District of Missouri offers a convenient and affordable location for both the Plaintiffs and Defendants in these Actions. Kansas City recently opened a new $1.5 billion airport that has transformed air travel into and out of the Kansas City metropolitan area. Kansas City's central location

[3] See Federal Judicial Caseload Statistics; U.S. District Courts—Median Time From Filing to Disposition of Civil Cases, by Action Taken—During the 12-Month Period Ending March 31, 2022 (https://www.uscourts.gov/statistics/table/c-5/federal-judicial-caseload-statistics/2022/03/31)

provides direct flights from more than 50 U.S. cities daily. Kansas City's centralized geographic location will make it an easily accessible destination for the Plaintiffs, Defendants, witnesses, experts, and others involved in this litigation. Indeed, the Panel has previously acknowledged the Western District of Missouri as "centrally located and easily accessible, making it a convenient forum for … nationwide litigation." *In re Smittys*, 466 F. Supp. 3d at 1382.

Each judge serving in the Western District of Missouri is eminently qualified to oversee these Actions, and several of the judges in the District have already demonstrated the ability to steer an MDL on a prudent course. The Honorable Brian C. Wimes is currently presiding over one of the subject Actions ([redacted] 2:23-cv-04087-BCW) and is well-suited to oversee this litigation. Judge Wimes is vastly experienced, as he has been on the federal bench for approximately twelve years. Judge Wimes has overseen complex litigations including at least two MDL cases. *See In re T-Mobile Customer Data Security Breach Litigation*, 576 F.Supp.3d 1373, 1375 (J.P.M.L. 2021) (data breach case involving more than 54 million potential claimants); *In re National Ski Pass Insurance Litigation*, 492 F.Supp.3d 1352, 1355 (J.P.M.L. 2020). In *T-Mobile*, Judge Wimes shepherded the case to resolution just seven months after he received the assignment, demonstrating his ability to efficiently resolve cases and decide complex issues, while conserving judicial resources and the time and expense required of litigants.

The Actions would also be prudently and efficiently managed if assigned to the Honorable Stephen R. Bough. Judge Bough is an experienced jurist with a professional

background involving substantial complex litigation. Judge Bough's comprehensive and unique experience, including presiding over other MDL cases, makes him an excellent choice to oversee this litigation. Judge Bough has shown particular skill in efficiently shepherding cases through discovery and trial to reach final adjudication of issues. His guidance would be instrumental in these cases, which are expected to involve voluminous discovery and complex questions of law. The Panel previously expressed confidence in Judge Bough's ability to steer a complex MDL on a prudent course given his experience as a jurist and ability and willingness to manage complex litigation efficiently. *In re Smitty's*, 466 F. Supp. 3d at 1382.

Additionally, Judge Bough's knowledge and expertise regarding complex MDL litigation is demonstrated in the article he co-authored with Elizabeth Chamblee Burch, "Collected Wisdom on Selecting Leaders and Managing MDLs," where he discusses, among other things, the importance of cultivating diversity when choosing MDL leadership. Even more, Judge Bough has actively participated in continuing legal education programs addressing the uniqueness of MDL litigation. One recent example, "Hot Topics in MDLs," presented on March 29, 2023, allowed Judge Bough and other presenters to directly address some current topics related to MDL litigation like early vetting and the process of determining appropriate MDL leadership.

## IV. CONCLUSION

For all the reasons herein, Movants respectfully request the Panel order coordinated and centralized pretrial proceedings for the Actions and transfer all pending and future

related actions to the Western District of Missouri before either the Honorable Brian C. Wimes or the Honorable Stephen R. Bough.

Respectfully submitted,

Dated: May 24, 2023

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