BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION

MDL No. _____

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR TRANSFER OF RELATED COVIDIEN HERNIA MESH PRODUCTS LIABILITY ACTIONS FOR COORDINATION PURSUANT TO 28 U.S.C. § 1407

The Panel has already established four MDLs for hernia mesh litigation. In 2016, the Panel centralized all product liability actions alleging defects in the hernia mesh products manufactured by Atrium Medical Corporation, *In re: Atrium Medical Corp. C-QUR Mesh Prods. Liab. Litig.*, 223 F. Supp. 3d 1355 (J.P.M.L. 2016). In 2017, the Panel did the same for product liability actions alleging defects in a hernia mesh product of Ethicon, Inc. and Johnson & Johnson, *In re: Ethicon Physiomesh Flexible Composite Hernia Mesh Prods. Liab. Litig.*, 254 F. Supp. 3d 1381 (J.P.M.L. 2017). And, in 2018, the Panel centralized all product liability actions alleging defects in the hernia mesh products of C.R. Bard, Inc. and Davol, Inc., *In re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, 316 F. Supp. 3d 1380 (2018).[1] It is now necessary and appropriate for the Panel to establish a fifth MDL proceeding for the copy-cat cases that allege manufacturing, design, and warning defects in the hernia mesh products of the Covidien Defendants.[2]

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[1] A decade earlier, in 2007, the Panel established *In re Kugel Mesh Hernia Patch Products Liability Litigation*, in the District of Rhode Island, following the filing of personal injury lawsuits related to the recall of a specific product, the Kugel Hernia Patch. 493 F. Supp. 2d 1371 (J.P.M.L. 2007).

[2] The Covidien Defendants are Covidien LP, Covidien Holding Inc., Covidien, Inc., Covidien plc, Tyco Healthcare Group, Tyco International, Sofradim Productions SAS, Medtronic, Inc., and Medtronic USA, Inc. (collectively, "Covidien"). Covidien does not concede that all of these entities are proper parties, and many of them are not.

The litigation currently consists of twelve pending federal actions in nine districts.[3] In addition, there are 141 pending state actions in six states. The twelve federal actions are brought by seven different law firms. These numbers are certain to balloon for two reasons. First, the number of cases ballooned in the Atrium, Ethicon, and Bard MDLs. When the Panel was petitioned to create MDLs for those litigations, there were thirteen actions pending against Atrium in seven districts; eighteen actions against Ethicon in ten districts; and fifteen actions against Bard in seven districts. The number of cases in those MDLs are now 2,044 (Atrium), 2,708 (Ethicon), and 3,570 (Bard). Second, plaintiffs' counsel continue to engage in national advertising that targets hernia mesh products on an industry-wide basis—and Covidien hernia mesh products command a significant share of the market (approximately 20 percent, which is little different than that of Ethicon and Bard).

The Related Actions are at an early stage. Discovery has not begun in most cases, and is just beginning in others. Accordingly, the reasons that led the Panel to centralize the litigations involving the hernia mesh products of Atrium, Ethicon, and Bard are present here: (1) there are common factual questions arising out of allegations that defects in the Covidien products led to complications following hernia repair surgery, and (2) centralization will eliminate duplicative discovery and prevent inconsistent pretrial rulings, while (3) conserving the resources of the parties, their counsel, and the judiciary.

The prevention of inconsistent rulings has particular significance here. To date, seven cases against Covidien in six districts have been dismissed with prejudice. Another seven cases

[3] The pending cases are listed in the accompanying Schedule of Actions (collectively, "the Related Actions").

in four districts have been dismissed without prejudice.[4] Covidien believes that the claims involving its hernia mesh products are without merit. Its products, unlike many of those that are the subject of the other MDL proceedings, have not been recalled or withdrawn from the market, nor have they been identified in the scientific literature as having particular problems. In similar circumstances, other medical device and pharmaceutical manufacturers have opposed MDL centralization on the ground that creating an MDL forum would invite the filing of non-meritorious claims—that "if you build it, they will come." In the circumstances here, Covidien embraces the Panel's viewpoint that "the transferee court handling several cases in an MDL *likely is in a better position* … to properly address meritless claims." *In re: Cook Medical, Inc., IVC Filters Mktg., Sales Practices & Prods. Liab. Litig.*, 53 F. Supp. 3d 1379, 1381 (J.P.M.L. 2014); *In re: Seroquel Prods. Liab. Litig.*, 447 F. Supp. 2d 1376, 1379 (J.P.M.L. 2006) ("The response to such concerns more properly inheres in assigning all related actions to one judge committed to disposing of spurious claims quickly."). The creation of an MDL for Covidien hernia mesh products would make possible the filing of a master complaint, to which Covidien could address its heretofore broadly successful arguments for dismissal of all or most claims.

Covidien respectfully suggests that the Panel transfer the Related Actions (and tag-along cases) to the Southern District of New York, where four of the twelve Related Actions are pending (more than any other district) and where several judges have already ruled on initial motions to dismiss. Judges in that district, of course, have extensive MDL experience.

[4] Among those cases that have proceeded, there is no consistency regarding which claims the courts have permitted to proceed.

FACTUAL BACKGROUND

A. Hernia Mesh Products

A hernia is a common medical condition that affects more than four million people in the United States each year. Risk factors for hernias include obesity, diabetes, smoking, pregnancy, prior surgeries, and family history. Surgery is the only treatment available to repair a hernia, but like all surgical procedures, hernia repair has inherent risks, regardless of whether a mesh product is used. According to the U.S. Food & Drug Administration ("FDA"), these risks include "pain, infection, hernia recurrence, scar-like tissue that sticks tissues together (adhesion), blockage of the large or small intestine (obstruction), bleeding, abnormal connection between organs, vessels, or intestines (fistula), fluid build-up at the surgical site (seroma), and a hole in neighboring tissues or organs (perforation)."[5] It is well-known that a significant percentage of all hernias will recur within a few years of surgery—a risk that is lower when mesh is used and higher in patients who are obese or have large hernias.

Hernia mesh products were introduced in the United States in the mid-1940s and quickly revolutionized the field of hernia surgery. Since then, a large body of scientific evidence has established that the use of hernia mesh strengthens surgical repair, reduces the rate of hernia recurrence, and decreases the need for reoperation. Clinical studies also suggest that surgical mesh improves patient outcomes and reduces recovery times. For these reasons, the vast majority of surgeons now use mesh to repair all but the smallest hernias.

A number of different manufacturers provide a wide range of surgical meshes. Covidien, for example, manufactures and sells more than 20 hernia mesh products which differ in

[5] *See* FDA, *Hernia Surgical Mesh Implants*, https://www.fda.gov/medical-devices/implants-and-prosthetics/hernia-surgical-mesh-implants (last updated Feb. 4, 2018).

materials, size, density, and other characteristics, allowing surgeons to choose the mesh appropriate for the individual patient and the specific procedure. Surgeons use mesh products safely in hundreds of thousands of hernia repair procedures each year.

B. Origins of the Hernia Mesh Litigation

A few hernia mesh products manufactured by other companies have been subject to recalls, withdrawals, or performance issues for product design or packaging defects. Those problems led to litigation and the Panel's creation of two MDLs, *In re Atrium Medical Corp. C-QUR Mesh Products Liability Litigation*, MDL-2753 (D.N.H.), and *In re Ethicon Physiomesh Flexible Composite Hernia Mesh Products Liability Litigation*, MDL-2782 (N.D. Ga.).

Plaintiffs' counsel then decided, however, to pursue hernia mesh litigation on an industry-wide basis, alleging that virtually all hernia mesh products are defective, regardless of whether they have been recalled, withdrawn, or had recognized problems. Plaintiffs filed personal injury lawsuits alleging that 21 different hernia mesh products manufactured by Davol and Bard, none of which had been recalled or withdrawn from the market, are defective. Plaintiffs' counsel are advertising nationwide, asserting in radio, television, and internet advertisements that *all* hernia mesh products are defective, including Covidien hernia mesh products.[6] Counsel's websites make the same claim.[7] As a result of that advertising, the Atrium,

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[6] *See, e.g.*, Shouse Law Group, Hernia Mesh Lawsuit–A Lawyer's Guide to the Process, https://www.shouselaw.com/herniamesh.html (identifying the "manufacturers of defective hernia mesh implants sued for injuries" as Atrium Medical Corporation, Covidien, C.R. Bard, Ethicon, Gore Medical, and Genzyme Corporation).

[7] *See e.g.*, Andrus Wagstaff, *Hernia Mesh*, https://www.andruswagstaff.com/hernia-mesh/; Hollis Law, *Parietex Lawsuit: Who is the FDA Protecting?*, https://hollislawfirm.com/case/hernia-mesh-lawsuit/parietex/; Surgical Mesh Help: Blasingame Burch Garrard Ashley, P.C., *Hernia Mesh Products*, http://www.surgicalmeshhelp.com/hernia-mesh-products/; Weitz & Luxenberg, *Covidien Hernia Mesh Complications*, https://www.weitzlux.com/defective-drugs-and-devices/covidien-hernia-mesh-complications/.

Ethicon, and Bard MDLs each now involve more than two thousand cases. One vendor of legal conferences has recognized the industry-wide direction of the litigation and has hosted several hernia mesh conferences, with separate sessions devoted to each major hernia mesh manufacturer, including Covidien.[8] The various plaintiffs suing Covidien have alleged that more than 20 different Covidien hernia mesh products are defective.

C. The Covidien Hernia Mesh Litigation

Perhaps because no Covidien hernia mesh products have been subject to broad recalls or withdrawals, federal courts have appropriately been skeptical of these claims. Fourteen different judges in eleven district courts have granted motions to dismiss complaints (with or without prejudice),[9] because the plaintiff failed to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6) or the claims were time-barred or both.[10] Two courts have granted Covidien summary judgment.[11]

The twelve Related Actions are pending in eight districts and involve seven plaintiffs' law firms. Four of the twelve Related Actions are located in the Southern District of New York. No other district has more than one case.

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[8] *See* HarrisMartin Hernia Mesh Litigation Conference Agendas, https://harrismartin.com/conference/agenda/923/ (dated June 13, 2017), https://harrismartin.com/conference/agenda/931/ (dated Sept. 27, 2017).

[9] Filed with this Motion is a Schedule of Actions Dismissed.

[10] The courts held that the complaints failed: (1) to explain adequately how the hernia mesh product at issue departed from its performance specifications to satisfy a manufacturing defect claim, (2) to identify which warnings were missing or defective to satisfy a failure to warn claim, (3) to explain how the mesh was defective and/or identify a safer alternative design to satisfy a design defect claim, and/or (4) to explain adequately any causal relationship between the alleged defects and plaintiffs' alleged injuries.

[11] *See, e.g., Avendt v. Covidien Inc.*, 262 F. Supp. 3d 493 (E.D. Mich. 2017) (granting summary judgment because plaintiff failed to proffer evidence that the hernia mesh product caused his injuries); Min. Entry, *Emery v. Medtronic, Inc.*, No. 4:18-cv-00358 (S.D. Tex. Apr. 24, 2019) (same), *aff'd*, 793 Fed. Appx. 293 (5th Cir. Dec. 9, 2019).

There are 141 cases (in six states) pending in state court. The overwhelming majority of those cases are in Massachusetts state court, where they have recently been coordinated before Associate Justice Hélène Kazanjian.[12] Like the Related Actions, those cases are at an early stage and lend themselves to coordination with a federal MDL proceeding.

ARGUMENT

I. COORDINATION OF THE RELATED ACTIONS IS APPROPRIATE.

Civil actions that involve "one or more common questions of fact" and that "are pending in different districts, … may be transferred to any district for coordinated … pretrial proceedings." 28 U.S.C. § 1407. Transfer is appropriate where the Panel determines that a coordinated proceeding "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." *Id.* The Panel considers whether centralization "will eliminate duplicative discovery; prevent inconsistent pretrial rulings; and conserve the resources of the parties, their counsel, and the judiciary." *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 138 F. Supp. 3d 1381, 1382 (J.P.M.L. 2015). Here, coordination of the Related Actions satisfies all of these factors, as did the similar hernia mesh litigations involving the Atrium, Ethicon, and Bard defendants.

A. The Related Actions Involve Certain Common Questions of Fact.

Plaintiffs' complaints concerning Covidien hernia mesh products present the same common questions of fact as did the complaints concerning the Atrium, Ethicon, and Bard products—questions arising out of allegations that the products are defective in their design, manufacture, and warnings and lead to complications when implanted in patients. As noted above, plaintiffs complain about the whole range of Covidien hernia mesh products. But the

[12] The parties have not yet appeared for an initial court conference.

same was true of plaintiffs suing Davol/Bard, and the Panel determined that "[a]ll the actions share common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients …." *In re: Davol, Inc./C.R. Bard, Inc. Polypropylene Hernia Mesh Prods. Liab. Litig.*, 316 F. Supp. 3d at 1380. The Panel has often "ordered centralization in other dockets involving multiple devices made by a single (or related) manufacturers." *In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 802 F. Supp. 2d 1374, 1376 (J.P.M.L. 2011) (citing *In re Medtronic, Inc., Implantable Defibrillators Prods. Liab. Litig.*, 408 F. Supp. 2d 1351 (J.P.M.L. 2005); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig*., 398 F. Supp. 2d 1371 (J.P.M.L. 2005)).

B. Centralization Will Eliminate Duplicative Discovery.

As the Panel recognized in the other hernia mesh litigations, centralization also will eliminate unnecessarily duplicative discovery. Establishing an MDL will streamline the discovery process and facilitate coordination with the newly-created Massachusetts "MDL" proceeding before Associate Justice Kazanjian.[13] Clearly, "coordination of discovery across all actions, with the use of common and individual discovery tracks, can offer efficiencies to all

[13] The Panel has recognized that the opportunity for federal and state coordination supports centralization. *See, e.g.*, *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 787 F. Supp. 2d 1355, 1357 (J.P.M.L. 2011) ("Centralization in this district could facilitate coordination between the federal and state courts."); *In re Nexium (Esomeprazole) Prods. Liab. Litig.*, 908 F. Supp. 2d 1362, 1364–65 (J.P.M.L. 2012) (same); *In re Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345, 1347 (J.P.M.L. 2013) (same). "The pendency of the state court litigation thus demonstrates the need for centralization of this litigation." *In re Johnston & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1358 (J.P.M.L. 2016).

Atrium, Ethicon, and Bard are defendants in state coordinated actions that parallel the federal MDLs. *See Jean A. Downie v. Atrium Medical Corporation*, No. 226-2013-cv-00155 (N.H. Super. Ct.); *In re Physiomesh Litig. (Flexible Composite Mesh)*, No. 627 (N.J. Super. Ct.); *In re Davol/C.R. Bard Hernia Mesh Multi-Case Mgmt.*, No. PC-2018-9999 (R.I. Super. Ct.).

parties." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 856 F. Supp. 2d 1347, 1348 (J.P.M.L. 2012); *see also In re MI Windows & Doors, Prods. Liab. Litig.*, 857 F. Supp. 2d 1374, 1375 (J.P.M.L. 2012) ("Centralized proceedings will provide for the efficient conduct of discovery, particularly with respect to expert discovery, which will be common among the actions.").

C. Centralization Will Prevent Inconsistent Pretrial Rulings.

As the Panel also has recognized in establishing MDLs for the other hernia mesh litigations, centralization of the Related Actions will prevent inconsistent pretrial rulings. As discussed above, the majority of federal courts have granted Covidien's motions to dismiss hernia mesh complaints. Some courts dismissed the complaints in their entirety with prejudice, others without prejudice, and a few courts allowed some or all claims to proceed. MDL coordination would permit the filing of a master complaint and, Covidien believes, dismissal of plaintiffs' claims and an efficient conclusion to the litigation. Covidien's arguments that (i) plaintiffs have failed to allege a product defect or a safer alternative design, (ii) the FDA-approved warnings are adequate as a matter of law, and (iii) the claims are time-barred all warrant consistent treatment.

Even if certain claims proceeded, however, MDL coordination would ensure consistency. That has not been true to date. One court has allowed the plaintiff to go forward with a strict liability manufacturing defect claim, while every other court to consider the issue has dismissed manufacturing defect claims for failure to allege sufficient facts demonstrating a flaw in the manufacturing process or that the hernia mesh product at issue deviated from its intended specifications. Further, even if claims proceed, expert testimony will be essential to sustain a defect claim of any kind. The Panel has noted repeatedly that centralization helps ensure consistency concerning key evidentiary decisions, such as *Daubert*. *See In re Viagra (Sildenafil*

Citrate) Prods. Liab. Litig., 176 F. Supp. 3d 1377, 1378 (J.P.M.L. 2016) ("Centralization will . . . prevent inconsistent pretrial rulings on *Daubert* and other issues."); *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 148 F. Supp.3d 1383, 1385 (J.P.M.L. 2015) (same).

D. Centralization Will Conserve Resources.

As the Panel determined in ordering centralization of the other hernia mesh litigations, centralization will conserve the resources of the parties, their counsel, and the judiciary. Given the common questions among the Related Actions, there is no need for numerous federal courts to engage in substantially similar pretrial proceedings, including extensive motions practice on a variety of issues as set forth above. *See In re Tribune Co. Fraudulent Conveyance Litig.*, 831 F. Supp. 2d 1371, 1372 (J.P.M.L. 2011) (noting that, due to centralization, "prudent counsel likely will combine their forces and apportion their workload in order to streamline the efforts of the parties, their counsel and the judiciary" thus resulting in "a significant savings of time and money for the parties and the courts"); *In re Ephedra Prods. Liab. Litig.*, 314 F. Supp. 2d 1373, 1375 (J.P.M.L. 2004) (citing *In re Multi-Piece Rim Prods. Liab. Litig.*, 464 F. Supp. 969, 974 (J.P.M.L. 1979)). This factor carries special weight given the limitations necessitated by the Covid-19 pandemic. It is not only more efficient, *but safer*, for travel (when it is possible) to be limited to one courthouse, not dozens.

For all of these reasons, coordination here satisfies the requirements of 28 U.S.C. § 1407: it will serve the convenience of the parties and witnesses and will promote the just and efficient conduct of the Related Actions.

II. THE SOUTHERN DISTRICT OF NEW YORK IS THE MOST APPROPRIATE JURISDICTION FOR TRANSFER OF THE RELATED ACTIONS.

The Southern District of New York is ideally situated for transfer of the Related Actions. First, it has a meaningful nexus to the parties. Four of the twelve Related Actions are pending in

the district, including one action that has proceeded beyond the pleading stage. No other district has more than one action. This concentration of cases supports transfer to the Southern District of New York. *See In re N. Sea Brent Crude Oil Futures Litig.*, 978 F. Supp. 2d 1384, 1385 (J.P.M.L. 2013) (centralizing actions in the Southern District of New York where "five of the six constituent actions already are pending"); *In re Fosamax Prods. Liab. Litig.*, 444 F. Supp. 2d 1347, 1349 (J.P.M.L. 2006) (centralizing actions in the Southern District of New York where "[m]ost of the actions are already pending").

Second, the Southern District of New York is a convenient location for discovery. Nearly all of the Covidien hernia mesh products were developed and manufactured at a facility in Trevoux, France.[14] Most of the relevant witnesses and documents are located in Trevoux, France. To the extent that witnesses are required to travel from France, New York City is a convenient location because it is served by three major international airports (John F. Kennedy, LaGuardia, and Newark).

Third, for these witnesses, and likely for many counsel as well, New York City may also be a safer location in terms of the amount of travel required to reach it. That is, for witnesses coming to the United States from France, travel to New York City requires one flight, not the additional connecting flights that might be necessary to reach cities in the Midwest or West. The

[14] The exception is a low-volume product (SurgiPro) that is not the subject of any of the twelve pending federal lawsuits. SurgiPro was developed and is manufactured in Connecticut.

same is true for counsel located in any midsize or large city: they can reach New York City with one flight.[15]

Fourth, the pandemic aside, the Panel frequently has recognized that the Southern District of New York is a convenient forum for MDLs. *See, e.g.*, *In re Kind LLC (All Natural) Litig.*, 118 F. Supp. 3d 1380, 1381 (J.P.M.L. 2015) (centralizing actions in Southern District of New York because it "is both convenient and accessible for the parties and witnesses"); *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 24 F. Supp. 3d 1361, 1363 (J.P.M.L. 2014) (noting that Southern District of New York "is conveniently located for this nationwide litigation"); *In re Tribune Co. Fraudulent Conveyance Litig.*, 831 F. Supp. 2d 1371, 1372 (J.P.M.L. 2011) (holding that Southern District of New York "is a convenient and accessible forum for most parties").

Fifth, the Southern District of New York also is a suitable forum because of its significant experience in handling MDLs, specifically products liability MDLs,[16] and the capability of its MDL jurists. Judge Paul Engelmayer has overseen two MDLs, including the recently-concluded *Mirena* medical-device MDL, which (as will be true here) involved extensive *Daubert* motions practice. Judge Paul Gardephe has overseen three prior MDLs and currently is presiding over

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[15] To be sure, New York City has been the city most hard-hit by the pandemic to date, but new cases have been steadily declining. Looking forward, all metropolitan areas may be equally at risk for a second wave of the virus.

[16] In recent years, the Panel has transferred to the Southern District of New York two prominent medical device MDLs, *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (No. II)*, MDL No. 2767, and *In re Zimmer M/L Taper Hip Prosthesis or M/L Taper Hip Prosthesis with Kinectiv Tech. & VerSys Femoral Head Products Liability Litigation*, MDL No. 2859; three pharmaceutical MDLs, *In re Rezulin Products Liability Litigation*, MDL No. 1348, *In re Fosamax Products Liability Litigation*, MDL No. 2243, and *In re: Eliquis (Apixaban) Products Liability Litigation*, MDL No. 2754; and other significant products liability MDLs, *see In re General Motors LLC Ignition Switch Litigation*, MDL No. 2543.

one of the Related Actions, *Green v. Covidien LP*, No. 1:18-cv-02939.[17] Other judges in the Southern District of New York with significant MDL experience, including products liability MDLs, include Judges Jesse M. Furman, Denise L. Cote, and Cathy Seibel.

CONCLUSION

For the reasons set forth above, Defendants request that the Panel transfer the Related Actions for coordinated pretrial proceedings to the United States District Court for the Southern District of New York.

[17] The court dismissed the first amended complaint with leave to amend, 2019 WL 4142480 (S.D.N.Y. Aug. 30, 2019), and Covidien has moved to dismiss the second amended complaint (*see* ECF Nos. 28-30).

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