**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: C. R. BARD, INC. PELVIC**
**REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2187**

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**THIS DOCUMENT RELATES TO ALL CASES**

# PLAINTIFFS' MOTION FOR CONSOLIDATION OF CERTAIN TRIAL SELECTION "WAVE" CASES FOR TRIAL

COME NOW Plaintiffs and move the Court to consolidate cases for trial pursuant to Federal Rule of Civil Procedure 42(a), and in furtherance thereof show the following:

## Statement of Factual and Procedural Background

This MDL has been pending in this Court for more than four years. The individual bellwether trial process has proven largely unproductive in bringing about resolution in this MDL, or in any of the related pelvic mesh MDLs now pending before this Court. The course of these MDLs generally, and this MDL in particular, have proven that preparing cases for trials one-by-one will simply not accomplish the Court's objective of fairly and efficiently moving these cases towards resolution. In recognition that the status quo was not achieving the intended goals of this process, this Court has employed innovative procedures, including working up hundreds of cases for trial simultaneously.

In Pretrial Order # 118 entered March 25, 2014, the Court ordered 200 cases (100 to be chosen by each side) to be worked up for potential trials ("Wave 1 and Wave 2"). The approximately 185 cases that remain in Waves 1 and 2 have now proceeded through depositions of the Plaintiffs and the Plaintiffs' treating providers, and Plaintiffs' experts have been named with many of Plaintiffs' experts having been deposed. Bard's experts were recently named and the parties are currently working to schedule depositions of Bard's experts. Per PTO #118, all

fact discovery and expert discovery must be concluded by January 5, 2015, and these cases will be "trial-ready" as of January 30, 2015 or after a ruling on the parties' dispositive motions, whichever is later. These cases are rapidly approaching being ready for trial.[1]

By coupling this Court's innovative trial "wave" work-up process with consolidated trials in multiple jurisdictions, the Plaintiffs respectfully submit that the goal of resolution of cases can be accomplished with maximum efficiency and economy. Rule 42 consolidated trials were recently successfully employed to move several similar cases forward in the Boston Scientific MDL. Trying individual cases one-by-one that are triable in the same District Court which involve the same allegations of defect against the same product or substantially equivalent products is a waste of the limited resources of the parties and the judiciary, and imposes a nearly impossible burden on the plaintiffs, their counsel, and their experts. Each case which involves the same product – or similar products from the same manufacturer – will necessarily involve much of the same documentary evidence and testimony from the same expert witnesses on both sides. The effort and expense associated with bringing the same witnesses and experts to trial to meet the Plaintiffs' burden of proving the same liability case multiple times will enable Bard to use its superior resources to continue to exert undue economic pressure on the Plaintiffs, rather than having these cases considered or resolved on their merits. In short, the consolidation of these trial selection wave cases for trial is an effective way to meaningfully move this MDL forward towards a needed resolution.

## Argument and Citation of Authority

**The Court should order cases involving the same or substantially equivalent products triable under the same State's law in the same District Court consolidated for trial pursuant to Federal Rule of Civil Procedure 42(a).**

[1] In addition to the Wave 1 and Wave 2 cases, Plaintiffs have included certain Wave 3 cases pending in either the Southern District or Northern District of West Virginia.

As stated in *In re Managed Care Litig.*, 236 F.Supp.2d 1336, 1341 (S.D.Fla.2002), "'[a] principal purpose of § 1407 is to allow one judge to take control of complex proceedings....'" This Court is faced with a historically large and complex docket in this MDL, and innovative means are necessary to move this sprawling litigation forward.[2] Consolidation for trial is within this Court's inherent authority in controlling the proceedings of this nearly unprecedented litigation.

Rule 42(a) of the Federal Rules of Civil Procedure provides as follows:

> If actions before the court involve a common question of law or fact, the court may:
>
> (1) join for hearing or trial any or all matters at issue in the actions;
> (2) consolidate the actions; or
> (3) issue any other orders to avoid unnecessary cost or delay.

The cases sought to be consolidated for trial by way of this motion are cases that involve the same product, or else involve the related Avaulta Plus and Avaulta Solo, and are capable of being tried in the same District Court under the same State's law. A list of the cases proposed for consolidated trials is attached as **Exhibit 1**. For purposes of Rule 42 consolidation, these cases are governed by the law of the Fourth Circuit (West Virginia), the Fifth Circuit (Texas), and the Eleventh Circuit (Georgia and Florida), respectively. In the recent Good v. American Water Works Co., Inc., 2014 WL 2481821, *2 (S.D.W.Va.2014), in which multiple actions arising from the Freedom Industries chemical spill were consolidated under Rule 42, Judge Copenhaver noted that "[o]ur [Fourth Circuit] court of appeals affords broad discretion to district courts in assessing the desirability of consolidation, recognizing the superiority of the trial court

[2] The Court outlined the necessity of these actions in PTO # 131, wherein the Court ordered 300 additional cases into a trial work-up process ("Wave 3") simultaneously with the 200 "Wave 1 and Wave 2" cases. *See, e.g.*, Dkt. No. 1007 (PTO # 131), p. 1 ("I currently have more than 60,000 unique cases in seven different MDLs."); pp. 2-3 (Outlining previous measures taken to streamline this MDL, and explaining "I now have more than 30,000 times the number of cases that spurred Congress to establish the JPML. Extraordinary procedures are once again necessary in order to move the cases forward.").

in determining how best to structure similar pieces of litigation." Citing, Arnold v. Eastern Air Lines, Inc., 681 F.2d 186, 193 (4th Cir.1982) (upholding consolidation for trial of injury claims of three airplane crash victims along with the defendant airline's insurer's contribution claims against the U.S. and air traffic controllers). The Fifth Circuit has also long recognized the propriety of consolidated trials for purposes of complex, multi-plaintiff product liability litigation. See, e.g., Jenkins v. Raymark Industries, Inc., 782 F.2d 468 (5th Cir.1986)[3]; Wilson v. Johns-Manville Sales Corp., 107 F.R.D. 250 (S.D.Tex.1985) (consolidating fifty asbestos cases for single trial on liability and punitive damages). Likewise, as recognized in French v. Sellers, 2007 WL 2029335, *1 (M.D.Ga. 2007), "[d]istrict judges in [the Eleventh Circuit] have been urged to make good use of Rule 42(a) in order to expedite trial and eliminate unnecessary repetition and confusion." (Citing Young v. City of Augusta, 59 F.3d 1160, 1169 (11th Cir. 1995)).

In In re: Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig., 2010 WL 797273 (M.D.Ga. 2010),[4] another MDL product liability proceeding involving an implantable polypropylene female pelvic repair device, the court observed the following with respect to Rule 42 consolidation:

> In exercising its discretion [to consolidate cases for trial under Rule 42(a)], the court must determine whether the specific risks of prejudice and possible confusion are overborne by the risk of inconsistent adjudications of common factual and legal issues, the burden on parties, witnesses, and available judicial resources posed by multiple lawsuits, the length of time required to conclude multiple suits as against a single one, and the relative expense to all concerned of the single-trial, multiple trial alternatives….

[3] In Jenkins, the 5th Circuit approved the district court's use of "mini-trials" of between 7 and 10 plaintiffs in class action. 782 F.2d at 471.

[4] Henry Garrard, co-lead counsel for Plaintiffs in this MDL, also served as lead counsel for the Plaintiffs in the Mentor ObTape litigation.

> The Court should also be cognizant that certain risks of prejudice and confusion may be minimized with cautionary jury instructions and by controlling the manner in which evidence is submitted to the jury.[5]

The threshold question of whether consolidation is authorized under Rule 42 is answered in the affirmative. As the Judicial Panel for Multidistrict Litigation recognized in transferring these cases to this Court, the actions in this MDL proceeding involve common questions of fact. (See, Dkt. No. 1 (JPML Transfer Order), p. 2 ("**all actions involving any of the three Avaulta models will share questions of fact**.")) (Emphasis added).[6] As shown below, the numerous recognized benefits of consolidating these cases for trial will far outweigh any potential risks of confusion or prejudice that Bard may assert.

Courts and commentators have recognized that the consolidation of cases for trial is an extremely useful procedural tool, particularly in product liability actions which typically involve multiple plaintiffs asserting similar claims arising out of the same allegedly defective product, thus involving common facts and evidence. "[A]ctions by different plaintiffs arising out of the same tort, such as a single accident or disaster or **the use of a common product**, frequently are ordered consolidated under Rule 42(a)." Wright & Miller, 9 Fed. Prac. & Proc. Civ. 2d. § 2384 (Emphasis added). In addition to cases involving implanted medical devices (e.g., In re Dow Corning Corp., 211 B.R. 545, 581-89 (Bankr.E.D.Mich.1997) (consolidating cases of 588 breast

[5] The Court in In re: Mentor quoted from Hendrix v. Raybestos-Manhattan, Inc., 776 F.2d 1492, 1495 (11th Cir.1985), wherein the Eleventh Circuit affirmed the decision of the Southern District of Georgia to consolidate, over the defendants' objection, four asbestos cases for trial pursuant to Rule 42. In turn, the Hendrix case quoted from the Fourth Circuit's opinion in Arnold, supra at 193. Both In re: Mentor and Arnold were cited by this Court in its decision to consolidate certain of the Boston Scientific MDL cases for trial, as more fully discussed below.

[6] Dkt. No. 1, p. 1 (observing that constituent actions at the time of transfer involve "allegations of defects in various models of the Avaulta Biosynthetic Support Systems manufactured, sold and/or distributed by Bard and/or Covidien. Therefore, **all actions share factual questions concerning such matters as the design, manufacture, safety, testing, marketing, and performance of these devices**.") (Emphasis added). This MDL was subsequently expanded, with the consent of the defendants, to include other pelvic repair devices sold by C.R. Bard, Inc., including the Align SUI device. (Dkt. No. 163).

implant plaintiffs), Suhn v. Breg, Inc., 2011 WL 1527263 (D.S.D. 2011) and McClellan v. I-Flow Corp., D. Or. Case No. 6:07-cv-1309 (7/23/10 Opinion and Order) (copy attached hereto as "**Exhibit 2**") (consolidating multiple plaintiffs' cases alleging chondrolysis caused by a shoulder pain pump) and Todd-Stenberg v. Dalkon Shield Claimants Trust, 48 Cal.App.4th 976 (1996) (consolidating for trial cases filed by three women with injuries resulting from implantation of intrauterine device)), courts have consolidated for trial product liability actions involving many other products, including: "popcorn lung" arising out of inhalation of diacetyl (Blood v. Givaudan Flavors Corp., 2009 WL 982022 (N.D.Iowa 2009)); multi-defendant actions involving defective paint product (Cruickshank v. Clean Seas Co., 402 F.Supp.2d 328 (D.Mass. 2005); and pharmaceutical product liability actions. (Kershaw v. Sterling Drug, Inc., 415 F.2d 1009 (5th Cir. 1969)). There are also many examples of the effective use of Rule 42 consolidation in cases involving exposure to asbestos. (See, e.g., Cimino v. Raymark Industries, Inc., 151 F.3d 297 (5th Cir. 1998)[7]; In re: Asbestos Litigation, 173 F.R.D. 81 (S.D.N.Y.1997); Carpenter v. GAF Corp., 1994 WL 47781 (6th Cir. 1994); Johnson v. Celotex Corp., 899 F.2d 1281 (2nd Cir.1990); In re: Joint Eastern and Southern Dists. Asbestos Litigation, 125 F.R.D. 60 (E.D.N.Y. 1989)[8]; Jenkins

[7] Plaintiffs' co-lead counsel, Henry G. Garrard, III, was lead trial counsel for one of the several defendants in the Cimino litigation. Over all defendants' objections, the district court judge in Cimino consolidated some 3,130 asbestos cases for trial of certain common issues under Rule 42(a), and "Phase I comprised a complete jury trial of the entire individual cases of the ten class representatives and also a class-wide determination of product defectiveness, warning, and punitive damages (including a multiplier as to each defendant)." 151 F.3d at 299-300. The jury returned plaintiff's verdicts for 9 of the 10 class representatives in the "Phase I" case against the undersigned's client (with one defense verdict), Id. at 300, and those verdicts were upheld on appeal. Id. at 329.

[8] As discussed on appeal in In re: Brooklyn Navy Yard Asbestos Litigation, 971 F.2d 831, 836 (2nd Cir. 1992), this case involved three phases of plaintiffs and two separate consolidated trials, with 64 "Group 1" cases tried together, and 15 "Group 1I and III" cases jointly tried (the phases were determined by the percentage of exposure to asbestos at the same shipyard).

v. Raymark Industries, Inc., 782 F.2d 468 (5th Cir.1986)[9]; Wilson v. Johns-Manville Sales Corp., 107 F.R.D. 250 (S.D.Tex.1985); Neal v. Carey Canadian Mines, Ltd., 548 F.Supp. 357 (E.D.Pa. 1982)).

Courts have also ordered the consolidation of multiple cases specifically for purposes of "bellwether" trials in the context of MDL product liability proceedings, including two federal district courts in Georgia. For example, in In re: Welding Fume Prods. Liab. Litig. MDL, 2006 WL 2869548 (N.D. Ohio 2006), the court concluded that the benefits of a consolidated bellwether trial of two MDL plaintiffs claiming injury from welding rod fumes outweighed any potential risk of confusion of the jury or prejudice to the defendant. In In re Stand 'N Seal Prods. Liab. Litig., 2009 WL 2224185, *2 (N.D.Ga. 2009), the Hon. Thomas W. Thrash, Jr. of the Northern District of Georgia denied the defendant's motion to order separate trials for seven MDL plaintiffs who asserted similar claims involving a common product. The court there observed that based on the similarity of the plaintiffs' claims, "separate trials would require redundant testimony that is not in the interest of judicial economy." Id. While the court acknowledged "some risk of jury confusion and prejudice [to the defendant manufacturer]," it concluded "that risk is minimized by the straightforward nature of the Plaintiffs' claims and the appropriate use of jury instructions." Id. Importantly, Judge Thrash there also concluded that "**a single trial will serve more effectively as a bellwether trial in this multidistrict litigation**." Id. (Emphasis added). Similarly, in In re: Mentor, the Hon. Clay D. Land of the Middle District of Georgia consolidated four MDL plaintiffs' cases for trial, concluding that "[**f**]**or the bellwether trial concept to be an effective gauge of other cases, it would appear that the more bellwether trials conducted, the more reliable the gauge**," and that a consolidated

[9] In Jenkins, the 5th Circuit approved the district court's use of "mini-trials" of between 7 and 10 plaintiffs in class action. 782 F.2d at 471. See also, Cimino, 151 F.3d at 301, n. 8 (discussing 5th Circuit's approval in Jenkins of district court's trial plan of "consolidated mini-trials of four to ten plaintiffs….").

bellwether trial "would provide the parties with **an opportunity to obtain results for multiple claims without burdening the court or the parties with the substantial costs of multiple separate trials**." 2010 WL 797273, *3 (M.D.Ga. 2010) (Emphasis added). Bard has repeatedly complained about a lack of information regarding the merits of cases as a justification for its failure to achieve meaningful resolution.[10] This Court's "wave" trial work-up procedure has given Bard that information regarding these cases, and thereby addressed that excuse. Consolidation will serve to provide the maximum amount of information about how juries view multiple cases, and will avoid the unnecessary waste of time and resources in requiring the same evidence to be presented multiple times before different juries.

Recently, in the Boston Scientific pelvic mesh MDL, this Court ordered consolidated trials of multiple cases involving two of the Boston Scientific pelvic mesh products. See, Eghnayem, et al. v. Boston Scientific Corp., 2:13-cv-07965 (Dkt. No. 10) (PTO #91, Order Consolidating above Cases for Trial on All Issues); Tyree, et al. v. Boston Scientific Corp., 2:12-cv-08633 (Dkt. No. 9) (PTO #78, Order Consolidating above Cases for Trial on All Issues). In its Orders regarding consolidated trials, the Court carefully considered the factors discussed in the Fourth Circuit's decision in Arnold, supra, and concluded that those factors weighed in favor of consolidation for trial. The Court specifically noted that the unique nature of the Boston Scientific MDL, with several thousand cases involving similar injuries and similar allegations arising from the same allegedly defective device, is well-suited to consolidation as a means to move cases forward. Subsequently, when Boston Scientific moved to sever those cases before

[10] Before this "wave" work-up procedure, this Court previously ordered every plaintiff in this MDL to provide "census" information about these cases. (Dkt. No. 716, PTO # 97 (Census Spreadsheet Order)). This time-consuming process (from the Plaintiffs' perspective) did little to move these cases forward, and Bard has continued to complain about its professed lack of case-related information. Plaintiffs respectfully submit that each of Bard's proffered excuses have been revealed as hollow, and have only generated more delay and expenditure of money and effort.

those trials commenced, the Court denied its motion. Eghnayem, 2:13-cv-07965 (Dkt. No. 171, PTO # 111); Tyree, 2:12-cv-08633 (Dkt. No. 115, PTO #115). These consolidated trials moved forward, and were recently concluded by way of jury verdicts. In the process, eight Plaintiffs were able to have their day in Court in roughly the same amount of time and with roughly the same effort and expenditure of resources that it would have taken to try just two cases had these not been consolidated.

The facts and circumstances of this MDL militate even more strongly in favor consolidated trials. The Bard MDL was created and transferred to this Court in October 2010, some fourteen months before the other three related pelvic MDLs were assigned to this Court by the JPML. Many of the Plaintiffs' cases in this MDL have thus been pending for over four years in this Court. The Court's recognition in the Boston Scientific cases that "the bellwether process is not viable in this MDL, and, as a result, consolidation and transfer to another jurisdiction for trial of multiple cases is an equally efficient means of providing meaningful information to the parties in the absence of a bellwether process," applies even more strongly here. This MDL has already had an individual bellwether process. The Court has seen first-hand that the time-consuming, effort-intensive and costly workup and trials (or pre-trial resolution) of individual bellwether cases has done little to bring about meaningful resolution in this MDL. Consolidation is thus particularly appropriate here.

Under the facts and circumstances here, any arguable potential for prejudice or confusion that Bard will inevitably raise would be far outweighed by the demonstrable benefits of consolidating cases for trial. Many courts have discussed the several advantages of consolidating similar cases for trial, including avoidance of repetitious presentation of facts and the consequent reduction of the burden and expense for all parties inherent in trying cases separately that involve

common facts. For example, in his concurrence in In re: Tobacco Litigation, 218 W.Va. 301, 307-08 (2005), former Justice Starcher of the West Virginia Supreme Court observed the following with reference to the evolution of consolidated asbestos trials in West Virginia:

> Circuit courts started to try the cases one at a time, but quickly abandoned that route; trying each case would have required hundreds of years. The same lawyers and the same witnesses were employed, using the same documents and evidentiary exhibits, on a full-time basis in counties throughout the State. Every trial involved weeks of testimony to try the same issues about the same defendants again and again and again. Virtually everything pertaining to the defendants remained the same. The only issue that changed concerned the plaintiffs….

The lessons learned in the asbestos litigation and similar large scale mass torts are instructive and applicable here. As Justice Starcher recognized, Rule 42 consolidation is available specifically to eliminate the sort of redundancy and resulting onerous expense and backlog that would result from trying the same liability in these cases over and over – which would literally take decades. Id. at 308. See also, Wilson v. Johns-Manville Sales Corp., 107 F.R.D. 250, 252 (S.D.Tex.1985) ("The Court's consolidation will save these defendants the expense of litigating the [common] issues of product defectiveness and punitive damages in 50 separate trials."); In re Joint Eastern and Southern Dists. Asbestos Litigation, 125 F.R.D. 60, 63 (E.D.N.Y. 1989) ("Consolidation will result in substantial time-savings….When six to eight claims are consolidated for trial, [common evidence] can be presented once rather than six to eight times in individual trials.").

The liability case will necessarily be the same in cases involving the same product. Even in the case of consolidation of cases involving Avaulta Plus with cases involving Avaulta Solo, the liability evidence will be largely the same. The Avaulta Plus is the Avaulta Solo product – the polypropylene portion is identical – with a sheet of porcine dermal (pig skin) collagen sewn onto the central portion. Both of these products at issue are "Bard-only," and would involve

none of the other defendants in this MDL. The Avaulta Plus and the Avaulta Solo were submitted to the FDA together in the same 510(k) (K063712), and both were cleared together. Both the Avaulta Plus and Avaulta Solo were designed and developed by the same Research and Development team in a single design "project" (the "Summit" project).[11] Throughout this litigation, Bard has relied heavily on the "testing" that it claims was done relative to the Avaulta Plus and Solo products before they were brought to market. The testing of the polypropylene mesh component of the Avaulta Plus and Solo for purposes of the single 510(k) submitted to the FDA for both products was the same. In fact, with the exception of submerging the finished products in an aqueous solution to test for particulate, Bard chose not to conduct biocompatibility testing on either the Avaulta Plus or the Avaulta Solo. Rather than conducting testing on the Avaulta Plus or Solo, Bard rationalized that it had conducted testing many years earlier on other Bard products sold for use in hernia repair, and thus it reasoned that testing on the Avaulta Plus and Solo was not required. (See, Biocompatibility of Summit Anterior/Posterior Support System (**Exhibit 3** hereto)). The implantation devices used to put both products in the body are the same. The method of implantation is the same for both products. The "adverse events" warning statements contained within the IFU's for both products are the same. Avaulta Plus and Avaulta Solo complications were reported to and handled by the same personnel at Bard. Many of the same Bard corporate documents produced in discovery that will be utilized by Plaintiffs at trial with respect to the Avaulta Solo are also applicable to the Avaulta Plus, and vice versa. The same Bard corporate witnesses who are expected to testify relative to the Avaulta Plus are likewise expected to testify with respect to the Avaulta Solo. Common experts

[11] 21 C.F.R. 820.30 provides that "[e]ach manufacturer shall establish and maintain a [design history file] for each type of device." Bard maintains just one design history file that includes both the Avaulta Plus and Solo products, which would refute any contention by Bard that an Avaulta Plus and Avaulta Solo case cannot be tried together.

will testify in these cases with respect to issues such as the defectiveness of the products, general causation, bioengineering, pelvic repair surgery, and related common subjects.[12] Bard has likewise named the same general experts in all Wave 1 and Wave 2 cases, and it is anticipated that the same general experts will be identified by Bard in the Wave 3 cases.[13] In short, to require the parties to prepare and present this same evidence, and bring these same experts to trial to testify to the same issues, in three separate cases would be the very sort of unnecessary duplication of effort and unnecessary expense that both the MDL process and Rule 42 were created to avoid.

If each of these cases listed in **Exhibit 1** are required to be tried one-by-one, the burden and expense will be onerous for everyone involved, but would be unfairly and disproportionately burdensome for the Plaintiffs. The effort and expense associated with bringing the same witnesses and experts to trial to meet Plaintiffs' burden of proving the same liability case multiple times – when these cases could be tried together with this same evidence being presented just once – will enable the Defendants in this litigation to use their superior resources[14] to exert undue economic pressure on the Plaintiffs, rather than having these cases decided solely on their merits. See, Manual for Complex Litigation, Fourth, § 11.63 (acknowledging Rule 42's

[12] These experts are all busy professionals from throughout the country, and they will have to take time away from their work to come and testify as experts at trial. Also, one of Plaintiffs' experts resides in Germany. The logistics and expense of getting all of these experts to trial once is difficult enough; to have to do it multiple times in cases that could be tried together would be unreasonably difficult and costly.

[13] The Rule 26 Reports from Bard's general experts on issues of product design and warnings (biomaterials/polymer science; bioengineering; human factors/warnings) address both the Avaulta Plus and Solo.

[14] Bard is an international medical device manufacturer represented in these cases by three of the largest law firms in the United States. For purposes of these bellwether cases, Bard is represented by many lawyers from two different offices (Atlanta and Huntington) of the Nelson Mullins law firm, many attorneys from multiple offices of the international law firm of Greenberg Traurig, as well as numerous attorneys from multiple offices of the international law firm of Reed Smith.

potentially disparate impact on the parties "given the parties' respective trial burdens and possibly unequal resources.").

Trials in MDL proceedings can provide valuable information to similarly-situated litigants and the MDL court about the parties' respective legal positions, as well as the potential damages that jurors could award in a case in the event of a finding of liability. As observed in the Stand 'N Seal and the Mentor litigation, a consolidated bellwether trial of multiple plaintiffs will provide more information about the litigation than would a one-plaintiff case, and thus serve as a better guide than any single-plaintiff case. Trying cases together would allow a jury to hear from the common experts and to consider all of the "common" evidence about these products and provide valuable insight and information about the jury's view of the products at issue.

Any argument that a jury would be confused by hearing claims of more than one plaintiff underestimates the capacity of the juror. In concluding that consolidation was appropriate in Stand 'N Seal, Judge Thrash relied on Hanley v. First Investors Corp., 151 F.R.D. 76, 80 (E.D.Tex.1993), wherein the district court rejected the defendants' arguments of undue prejudice and potential for confusion in opposition to consolidation of nineteen plaintiffs for trial. The court in Hanley observed "[b]ased on the court's experience, it seems well within the jury's abilities to distinguish between the idiosyncrasies of each case." The same would certainly hold true for a trial of a few plaintiffs.

As the Court has seen in conducting multiple bellwether trials in these related pelvic repair MDLs, the common issues in these cases – for example, those relating to whether the products were defectively designed and/or manufactured, Bard's testing of the products (or lack thereof), Bard's physician training program for these products, Bard's sales and marketing

efforts, whether Bard's "warnings" and instructions were adequate, and general causation[15] – will consume a substantial portion of the trial of these cases, and will be substantially similar as to each of these Plaintiffs. To have to try these issues over and over would not foster judicial economy. A single jury hearing the same evidence as to all three Plaintiffs would be a wiser and more efficient use of the Court's, the parties', and their witnesses' time and resources.

Further, cautionary instructions to the jury to consider the Plaintiffs' claims separately would mitigate or eliminate any potential for prejudice or confusion that Bard would contend would result from a joint trial in this case. In Hendrix, supra, the trial court consolidated the trials of four workers who alleged they were injured by asbestos exposure. The Eleventh Circuit there observed that the plaintiffs' "exposure to asbestos and the extent of their disease were similar and the liability theories of the claims were identical." Id. at 1496. After noting that the trial court took special care in instructing the jury to consider each of the plaintiff's claims separately, the Eleventh Circuit not only affirmed the district court's consolidation of the cases, but called them "precisely the kind of tort claims a court should consider consolidating for trial." Id. To the extent any such risk is claimed to exist, it could be adequately addressed by careful presentation of the issues and instructions from the Court. See, e.g., French v. Sellers, 2007 WL 2029335, *2 (M.D.Ga. 2007) ("Although the specific circumstances of each case are factually different, the Court finds that a jury will be able to distinguish between the two cases and keep track of the evidence concerning the Plaintiffs' respective claims. Moreover, Defendants' concerns regarding potential prejudice and confusion may be mitigated by cautionary

[15] These "common issues" have already generated millions of pages of documents in discovery, and hundreds of persons have been identified as having relevant knowledge regarding these issues. These common issues will be the subject of multiple competing expert opinions. Several non-expert witnesses will be called to testify to these common issues at trial on both sides. These same common issue documents and the same common issue testimony from the same lay individuals and the same experts will be presented at every trial involving these products.

instructions to the jury."). This Court similarly recognized in the Boston Scientific MDL that "carefully crafted jury instructions and special interrogatories can avoid the confusion that may arise due to these differences" between cases. Eghnayem, et al. v. Boston Scientific Corp., 2:13-cv-07965 (Dkt. No. 10) (PTO #91, Order Consolidating above Cases for Trial on All Issues); Tyree, et al. v. Boston Scientific Corp., 2:12-cv-08633 (Dkt. No. 9) (PTO #78, Order Consolidating above Cases for Trial on All Issues).

Bard cannot demonstrate that it will be prejudiced by introduction of evidence regarding injuries to another victim in any given plaintiff's case. Plaintiffs will offer evidence of other "similar incidents" involving these products as relevant in *every* plaintiff's case in this litigation on a number of grounds. Evidence of similar occurrences or incidents is admissible in product liability actions for a variety of purposes, including "to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." Reid v. BMW of N. Amer., 464 F.Supp.2d 1267, 1271 (N.D.Ga.2006). In fact, it has been recognized that "few things could be more relevant in a products action than the occurrence or non-occurrence of other accidents or failures under similar circumstances." Rhodes v. Michelin Tire Corp., 542 F.Supp. 60, 62 (E.D.Ky.1982). See also, Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1313 (11th Cir.2000) (district court did not err in admission of 270 complaints relating to defendant's silicone gel breast implant in plaintiff's case to establish notice of the product's defectiveness); Hahn v. Sterling Drug, Inc., 805 F.2d 1480, 1483 (11th Cir.1986) (noting that evidence of similar accidents involving ingestion of defendant's topical analgesic could be admissible for several purposes); Worsham v. A.H. Robins Co., 734 F.2d 676, 688-89 (11th Cir.1984) (district court's decision to allow

testimony regarding similar injuries caused by defendant's intrauterine contraceptive device affirmed); Benedi v. McNeil-P.P.C., Inc., 66 F.3d 1378, 1385-86 (4th Cir.1995) (citing Worsham in concluding that district court properly allowed FDA Drug Experience Reports relating to defendant's painkiller). Evidence of other similar incidents will also be relevant to these Plaintiffs' respective claims for punitive damages. Reid v. BMW of N. Amer., 430 F.Supp.2d 1365, 1372 (N.D.Ga.2006) ("Evidence of other incidents involving the product is admissible and relevant to the issue[] of…punitive damages."). See also, In re Tobacco Litigation, 218 W.Va. 301, 303 (2005) (proposed consolidated trial involving personal injury claims of approximately 1,000 individual smokers; Held: jury may consider whether and how often the defendant engaged in similar conduct in the past for purposes of punitive damages). Plaintiffs in this MDL intend to offer evidence of numerous similar incidents in *every* case, so any argument of prejudice from hearing about the injuries to two other Plaintiffs cannot stand. As this Court recognized, "[e]ven if these cases were not consolidated, evidence of substantially similar accidents and injuries are admissible to show 'the dangerous character of an instrumentality and also to show the defendant's knowledge.'" Eghnayem, et al. v. Boston Scientific Corp., 2:13-cv-07965 (Dkt. No. 10) (PTO #91, Order Consolidating above Cases for Trial on All Issues). Bard will not be able to avoid evidence of injuries to other women caused by its products at trial, so any complaint of prejudice or confusion relating to a consolidated trial is not well-founded.

## CONCLUSION

All of these cases involve common questions of law and fact. The consolidation of these cases for a single trial will reduce the burden on all parties, their witnesses and experts versus multiple trials for each individual Plaintiff, and would likewise further the interests of judicial economy. Additionally, rather than present an undue risk of confusion or prejudice to any party,

consolidation will ensure consistent adjudication of the common factual and legal issues that will have to be decided in each of these cases. Plaintiffs respectfully request that this Court grant their motion and order the consolidation of the cases identified in **Exhibit 1** hereto for trial in their respective remand jurisdictions as identified therein.

This 24th day of November, 2014.

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**IN RE: C. R. BARD, INC. PELVIC**
**REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**

**MDL NO. 2187**

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**THIS DOCUMENT RELATES TO ALL CASES**

## CERTIFICATE OF SERVICE

I hereby certify that on November 24, 2014, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: */s/ Henry G. Garrard, III*

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# EXHIBIT 1

| PLAINTIFF | CIVIL ACTION FILE NUMBER | REMAND | FIRM |
|---|---|---|---|
| **WEST VIRGINIA (Avaulta Plus)** | | | |
| Havens, Deborah Kaye | 2:12-cv-01160 | USDC, WV, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Poole, Debra | 2:13-cv-07925 | USDC, WV, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Zgurski, Pamela J. | 2:12-cv-04555 | USDC, WV, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Blake, Aricia | 2:10-cv-01380 | USDC, WV, SOUTHERN | Blasingame, Burch, Garrard & Ashley |
| Wise, Debbie | 2:12-cv-01378 | USDC, WV, SOUTHERN | Blasingame, Burch, Garrard & Ashley |
| **GEORGIA - NORTHERN DISTRICT (Avaulta Plus)** | | | |
| Griffin, Allene | 2:13-cv-06162 | USDC, GA, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Pennington, Beverly | 2:11-cv-00010 | USDC, GA, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Stafford, Patricia | 2:12-cv-00437 | USDC, GA, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| **FLORIDA - NORTHERN DISTRICT (Avaulta Plus)** | | | |
| Carter, Barbara | 2:11-cv-00121 | USDC, FL, NORTHERN | Blasingame, Burch, Garrard & Ashley |
| Devries, Denise | 2:13-cv-13354 | USDC, FL, NORTHERN | Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A. |
| **FLORIDA - MIDDLE DISTRICT (Avaulta Plus)** | | | |
| Lancaster, Magdalene | 2:13-cv-30510 | USDC, FL, MIDDLE | Clark, Love & Hutson |
| Rotter, Myrta | 2:12-cv-01229 | USDC, FL, MIDDLE | Motley Rice |
| Tinnen, Faye | 2:11-cv-00814 | USDC, FL, MIDDLE | Blasingame, Burch, Garrard & Ashley |

| PLAINTIFF | CIVIL ACTION FILE NUMBER | REMAND | FIRM |
|---|---|---|---|
| **FLORIDA - SOUTHERN DISTRICT (Avaulta Plus)** | | | |
| Alonso, Rosaida | 2:14-cv-07112 | USDC, FL, SOUTHERN | Aylstock,Witkin, Kreis & Overholtz, PLLC |
| Chery, Delores | 2:12-cv-08208 | USDC, FL, SOUTHERN | Schlesinger Law Offices, PA |
| Kaiser, Donna | 2:12-cv-03655 | USDC, FL, SOUTHERN | Wagstaff & Cartmell LLP |
| **FLORIDA - MIDDLE DISTRICT (Avaulta Solo) GROUP 1** | | | |
| Adamo, Patricia | 2:12-cv-07043 | USDC, FL, MIDDLE | Blasingame, Burch, Garrard & Ashley |
| Atwell-Jackson, Stephanie | 2:13-cv-07787 | USDC, FL, MIDDLE | Blasingame, Burch, Garrard & Ashley |
| Bulthius, Cathy | 2:13-cv-06047 | USDC, FL, MIDDLE | Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A. |
| Campbell, Barbara | 2:11-cv-00501 | USDC, FL, MIDDLE | Blasingame, Burch, Garrard & Ashley |
| Gold, Patricia | 2:14-cv-11565 | USDC, FL, MIDDLE | Blasingame, Burch, Garrard & Ashley |
| **FLORIDA - MIDDLE DISTRICT (Avaulta Solo) GROUP 2** | | | |
| Groover, Kristia | 2:12-cv-00173 | USDC, FL, MIDDLE | The Potts Firm |
| Lopez, Judith | 2:13-cv-18089 | USDC, FL | Watts Guerra, LLP |
| Ullrich, Melissa | 2:12-cv-01227 | USDC, FL, MIDDLE | Searcy, Denney, Scarola, Barnhart & Shipley |
| Wheeler, Martina | 2:12-cv-04580 | USDC, FL, MIDDLE | Aylstock,Witkin, Kreis & Overholtz, PLLC |
| **TEXAS - EASTERN DISTRICT (Avaulta Plus and Solo)** | | | |
| Grether, Helen | 2:13-cv-06729 | USDC, TX, EASTERN | Watts Guerra, LLP |
| Kerr, Patsy | 2:14-cv-04715 | USDC, TX, EASTERN | The Nations Law Firm |

| PLAINTIFF | CIVIL ACTION FILE NUMBER | REMAND | FIRM |
|---|---|---|---|
| White, Myra | 2:13-cv-02038 | USDC, TX, EASTERN | The Potts Firm |
| **TEXAS - WESTERN DISTRICT (Avaulta Plus and Solo)** | | | |
| Gray, Linda | 2:10-cv-01342 | USDC, TX, WESTERN | Motley Rice |
| Surita, Yolunda | 2:13-cv-09501 | USDC, TX, WESTERN | Clark, Love & Hutson |
| Gutierrez, Alma R. | 2:14-cv-01204 | USDC, TX, WESTERN | Clark, Love & Hutson |

# EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

CHRISTINA MCCLELLAN,

Plaintiff,

v.

I-FLOW CORPORATION, a Delaware corporation, et al.,

Defendants.

Civ. No. 07-1309-AA
OPINION AND ORDER

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DONNELL COX; DAVID DOOLITTLE and CAROLYN DOOLITTLE, husband and wife; JUAN A. HUERTA; and KATHERINE FORREST,

Plaintiffs,

v.

DJO, LLC, a Delaware corporation, et al.,

Defendants.

Civ. No. 07-1310-AA
OPINION AND ORDER

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GORDON J. ADDIS,

Plaintiff,

v.

MCKINLEY MEDICAL, L.L.C., a Colorado corporation, et al.,

Defendants.

Civ. No. 07-1318-AA
OPINION AND ORDER

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DANNY E. ARVIDSON and ANN E. ARVIDSON as husband and wife; and MARCY J. LANDOLFO,

Plaintiffs,

v.

DJO, LLC, a Delaware corporation, et al.,

Defendants.

Civ. No. 08-478-AA
OPINION AND ORDER

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AIKEN, Chief Judge:

Plaintiffs filed suit alleging negligence and products liability arising from the post-operative use of pain pump devices in their shoulder joints. Before the court are motions for clarification filed by defendants I-Flow Corporation (I-Flow) and McKinley Medical, LLC (McKinley) and joined by the DJO defendants (DJO). Defendants seek clarification that the cases are scheduled to be tried separately, one after another, rather than as consolidated cases. In the event the court intended to consolidate cases for trial, defendants object and move for severance pursuant to Fed. R. Civ. P. 20 and 42. I clarify that cases are consolidated for trial as set forth in my Order of March 18, 2010 and deny defendants' objections, with the exception of the Landolfo case.

## DISCUSSION

In my order dated March 18, 2010, I scheduled cases for trial in groups based on common manufacturer defendants, with the intent

that the cases would be consolidated. Although my order was issued four months ago, defendants now seek clarification of the court's order, two months prior to commencement of the first trial. Defendants make much of the fact that in previous status conferences, I voiced an intent not to consolidate multiple plaintiffs' claims for trial. While defendants are correct to a point, I was primarily referring to the Cox cases, which involved different manufacturer defendants, a problem since resolved by severing Huerta for trial. Also, my previous statements were made without the context of the parties' trial proposals submitted in March, and I reconsidered my earlier inclination after hearing the evidence presented at the Daubert hearings and reviewing the parties' competing trial proposals. I reaffirm my finding that consolidation based on the manufacturer defendant is appropriate in these cases and consistent with the spirit and purposes of Federal Rules 20 and 42.

The joinder of multiple parties is governed by Federal Rule of Civil Procedure 20(a). Multiple plaintiffs or defendants may be joined if the claims asserted arise "out of the same transaction, occurrence, or series of transactions or occurrences," and questions of law or fact are common to all plaintiffs or defendants. Fed. R. Civ. P. 20(a)(1), (2). Rule 20(a) "is to be construed liberally in order to promote trial convenience and to expedite the final determination of disputes, thereby preventing

multiple lawsuits." League to Save Lake Tahoe v. Tahoe Reg'l Planning Agency, 558 F.2d 914, 917 (9th Cir. 1977).

Similarly, Rule 42(a) authorizes the court to consolidate for trial cases involving "common question[s] of law or fact," although the court may order separate trials "[f]or convenience, to avoid prejudice, or to expedite and economize." Fed. R. Civ. P. 42(a)(1),(b). In making this determination, the court must weigh the interest "in judicial convenience against the potential for delay, confusion and prejudice caused by consolidation." Paxonet Commc'n, Inc. v. TranSwitch Corp., 303 F. Supp. 2d 1027, 1028 (N.D. Cal. 2003). The district court has broad discretion to decide whether to consolidate cases for trial. In re Adams Apple, Inc., 829 F.2d 1484, 1487 (9th Cir. 1987).

Here, the primary issue is consolidation of certain plaintiffs' claims for trial; although several defendants will also joined for trial, they are consolidated primarily according to common defendants who would be joined for trial in most instances even if each case was tried separately. In all cases, plaintiffs assert claims of negligence and products liability against defendants that arise out of the same transaction or occurrence, or series of transactions or occurrences, regarding defendants' actions in promoting, and marketing, and distributing the accused pain pumps. Specifically, plaintiffs allege common theories of liability based on their assertion that defendants manufactured,

marketed, promoted, and sold pain pumps for intra-articular uses with knowledge that the pain pumps had not been approved for such uses, thus causing the harm (chondrolysis) suffered by all plaintiffs. The plaintiffs joined for trial also share common facts with respect to their individual surgeries. Further, the same expert witnesses will testify in most cases and rely on similar evidence. In other words, not only are plaintiffs' theories of liability common to all defendants, issues of fact and law are common to all joined plaintiffs and defendants.

For example, with respect to plaintiffs in McClellan, Huerta, and Arvidson, all assert the same claims of negligence and products liability, arguing that defendants promoted the I-Flow pain pump for intra-articular uses even though it had not been cleared for such uses and without regard for potential injury or harm. Plaintiffs' claims share many common facts, though factual distinctions exist, as set forth below:

| | ***McClellan*** | ***Huerta*** | ***Arvidson*** |
|---|---|---|---|
| Pain Pump | I-Flow | I-Flow | I-Flow |
| Anesthetic | Marcaine epinephrine | lidocaine epinephrine | Marcaine epinephrine |
| Surgeon | DiPaola | Benz | Bowman |
| Date | 9/1/04 | 9/27/04 | 7/14/04 |

Notably, Drs. Bowman and DiPaola are purportedly colleagues at Occupational Orthopedics and used the same medications during surgery in the McClellan and Arvidson. While I recognize that

plaintiff Huerta's claims involve a different surgeon and anesthetic, I find that these distinctions are outweighed by the common legal and factual issues present in all three cases, the common witnesses that will testify, and by the interests of cost, efficiency, and judicial economy.

With respect to Cox, Doolittle, Forrest, and Addis, the plaintiffs assert the same theories of negligence and products liability, in that defendants allegedly promoted the McKinley (or DonJoy) pain pump for intra-articular uses without obtaining approval for such uses and without regard for potential injury or harm. Further, these plaintiffs share common issues of fact with respect to their individual surgeries, as set forth below:

| | ***Cox*** | ***Doolittle*** | ***Forrest*** | ***Addis*** |
|---|---|---|---|---|
| Pain Pump | DonJoy | DonJoy | DonJoy | DonJoy |
| Anesthetic | Marcaine 5% epinephrine | Marcaine 5% epinephrine | Marcaine 5% epinephrine | Marcaine 5% epinephrine |
| Surgeon | Bowman | Bowman | Bowman | Bowman |
| Date | 5/12/04 | 5/12/04 | 3/22/04 | 3/31/04 |

Notably, the defendants are the same in each case, and the same physician performed all plaintiffs' surgeries over a two-month period using the same dosage of the same anesthetic. Plaintiffs further note that Dr. Bowman has testified that he learned how to place the pain pump catheter in the shoulder joint from DJO's sales representative and from his colleague, Dr. DiPaola. Thus, in addition to the legal theories of liability applicable to all

defendants, numerous issues of fact are common to all four plaintiffs. Finally, all three defendants - McKinley, DJO, and PacMed - would be involved in each case even if they were tried separately, with all defendants presenting similar evidence regarding their actions in manufacturing, marketing, promoting, selling, and distributing the accused pain pumps.

Defendants also argue that consolidation will cause confusion and prejudice. Defendants maintain that plaintiff-specific issues of product use, causation, and damages along with plaintiffs' different ages, social histories, and work histories would require repeated separation of issues by the court and lead to confusion by the jury. Further, defendants argue that presentation of multiple plaintiffs with similar injuries might cause the jury to conclude that there must be a basis for plaintiffs' allegations and improperly assume that defendants engaged in the alleged wrongful conduct.

If the court accepted defendants' arguments, consolidation would be precluded in almost any circumstance. Courts and juries routinely distinguish evidence presented by different plaintiffs or against different defendants, and I do not find these cases so complicated as to require separate trials. Recently, a district court granted the plaintiffs' motion for consolidation of four product liability cases against a medical device manufacturer. See In re Montor Corp. Obtape Transobturator Sling Prods. Liab. Litig.,

2010 WL 797273 (M.D. Ga. Mar. 3, 2010). There, the plaintiffs sought consolidation for trial, arguing that the defendants made similar representations to plaintiffs' physicians, the plaintiffs suffered similar injuries, and common experts relied on similar evidence. The defendant objected, arguing that consolidating the plaintiffs' claims was prejudicial and would confuse the jury, because the plaintiffs had different medical histories and backgrounds. Id. at *2. The district court disagreed, finding that differences in the plaintiffs' medical conditions could be explained to a jury and that consolidation "would provide the parties with an opportunity to obtain results from multiple claims without burdening the Court or parties with the substantial cost of multiple separate trials." Id. at *4. The district court reasoned that "[s]o long as the evidence is introduced in an organized fashion," with appropriate jury instructions, potential prejudice to the defendant would be minimized. Id. at *3-4; see also Munjak v. Signator Investors, Inc., 2003 WL 23506989, *2 (D. Kan. Dec. 10, 2003) ("The court believes that jury instructions can be written to avoid confusion when multiple plaintiffs are involved.").

In sum, I agree with plaintiffs that the interests of convenience, efficiency, and judicial economy outweigh the risk of confusion and potential prejudice, given the common facts and legal issues, the costly burden of separate trials, and the length of time saved through consolidation. Further, I am persuaded by the

reasoning in In re Montor that any potential prejudice to defendants can be alleviated through careful and thoughtful presentation of evidence and specific instructions to the jury.

The sole exception is Landolfo. Because plaintiff's claims against I-Flow have been dismissed and DJO's motion to reinstate McKinley as the manufacturer defendant was denied, DJO is the only defendant in Landolfo. I find consolidation of Landolfo with the McKinley cases problematic, given DJO's status as a distributor and the number of cases already consolidated for trial. Therefore, Landolfo shall be severed from Arvidson for trial and tried separately.

## CONCLUSION

Defendants' Motions for Clarification and Joinder are GRANTED to the extent that the court clarifies its Order of March 18, 2010. Defendants' objections to consolidation are DENIED, with the exception of Landolfo v. DJO, LLC, et al., 08-478-AA, which is HEREBY SEVERED for trial. Accordingly, these cases are consolidated and set for trial as follows:

In McClellan v. I-Flow, et al., 07-1309-AA, Huerta v. I-Flow, 07-1310-AA, Arvidson v. DJO, LLC, et al., 08-478-AA, a fifteen-day consolidated jury trial shall commence on **September 20, 2010 at 9:00 a.m.** in Courtroom 12A of the Hatfield Courthouse in Portland, Oregon. The pretrial conference in these consolidated cases shall remain as scheduled on **September 8, 2010 at 9:00 a.m.** in Courtroom

12A of the Hatfield Courthouse in Portland, Oregon. The parties are reminded that proposed voir dire and jury instructions, witness lists (including a time estimate for each witness and a brief description of their testimony), exhibit lists, trial memoranda, motions in limine and proposed verdict forms shall be filed on or before **August 6, 2010.** Proposed verdict forms and jury instructions shall be submitted to the court on disk in WordPerfect 10 for Windows (previous versions of WordPerfect are acceptable). The parties are also reminded that copies of exhibits and objections to exhibits shall be filed on or before **August 20, 2010** after conferral among the parties.

In Cox, Doolittle, Forrest v. DJO, LLC, et al., 07-1310-AA and Addis v. McKinley Medical, et al., 07-1318-AA, a fifteen-day jury trial shall commence on **October 18, 2010 at 9:00 a.m.** in Courtroom 12A of the Hatfield Courthouse in Portland, Oregon. The pretrial conference in the above cases will be held on **October 12, 2010 at 9:00 a.m.** in Courtroom 12A of the Hatfield Courthouse in Portland, Oregon. Proposed voir dire and jury instructions, witness lists (including a time estimate for each witness and a brief description of their testimony), exhibit lists, trial memoranda, motions in limine and proposed verdict forms shall be filed on or before **September 28, 2010.** Proposed verdict forms and jury instructions shall be submitted to the court on disk in WordPerfect 10 for Windows (previous versions of WordPerfect are acceptable). Copies

of exhibits and objections to exhibits shall be filed on or before **October 5, 2010** after conferral among the parties.

In Landolfo v. DJO LLC, et al., 08-478-AA, an eight-day jury trial shall commence on **November 29, 2010 at 9:00 a.m.** in Courtroom 12A of the Hatfield Courthouse in Portland, Oregon. The pretrial conference will be held **November 22, 2010 at 9:00 a.m.** in Courtroom 12A of the Hatfield Courthouse in Portland, Oregon. Proposed voir dire and jury instructions, witness lists (including a time estimate for each witness and a brief description of their testimony), exhibit lists, trial memoranda, motions in limine and proposed verdict forms shall be filed on or before **November 8, 2010.** Proposed verdict forms and jury instructions shall be submitted to the court on disk in WordPerfect 10 for Windows (previous versions of WordPerfect are acceptable). Copies of exhibits and objections to exhibits shall be filed on or before **November 15, 2010** after conferral among the parties.

Finally, the parties are reminded that ***the court will not consider objections to exhibits unless and until the parties confer - in person or by telephone - as to each objection of the opposing party.*** Conferral by e-mail is not acceptable. Objections to exhibits must include detailed identification of the challenged exhibits, the basis for the objection, the amount of time spent conferring on the objection, and the reasons the parties could not reach agreement. The parties should be prepared to discuss

objections to exhibits at their respective pretrial conferences.

IT IS SO ORDERED.

DATED this 22 day of July, 2010.

Ann Aiken
Chief United States District Judge

# EXHIBIT 3

Bard Urological Division

**To:** Project File 03-4661 **Date:** 11/1/2006

**xc:** **From:** Kim Darnell;

Subject: **Biocompatibility of Summit Anterior/Posterior Support System**

## 1. Objectives:

1.1 The objectives of this report are as follows:

- To document the consideration of the ISO 10993 tests recommended for implantable medical devices in contact with tissue for greater than 30 days as it relates to the Summit Anterior/Posterior Support System.
- To provide a rationale for the selection and/or waiving of the ISO 10993-1 tests; and,
- To provide information to justify the use of studies conducted using predicate products.

## 2. References

2.1 Bard Collamend Implant 510(K) K052322

2.2 Bard Large Pore Soft Mesh 510(K) K052155

2.3 ANSI/AAMI/ISO 10993:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing

2.4 Bard Shared Services Laboratories Lab Reports LR-6013 and LR-6017

## 3 Introduction

The subject product is intended to be used in the treatment of vaginal wall prolapse by providing structural support for the internal anatomy. In its intended use, the product will have permanent tissue contact, as it will be implanted in the soft tissues of the pelvic cavity. Summit is a composite product consisting of two primary components that are: 1) A woven polypropylene mesh material and 2)a matrix of acellular porcine collagen. In accordance with ISO 10993, Biological evaluation of medical devices the product is categorized as an implant product with tissue/bone contact and permanent duration.

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**PLAINTIFF EXHIBIT 013**

## 4 Evaluation

The two materials that comprise the implant are both currently used on products approved for commercial distribution for the body contact profile indicated for the Summit product. A summary of each of these materials and the predicate device test data are as follows:

Acellular porcine dermis

The porcine dermis used in the Summit product is equivalent to the Collamend product currently marketed by Davol (ref 510(K) K052322). The Collamend product is used for hernia repair and as such is an implant product with tissue contact and permanent duration which is the exact contact profile as Summit. The Summit product utilizes the identical manufacturing process as Collamend with the only exceptions being the Summit product is thinner and is perforated to enhance product performance. Biocompatibility for the Collamend product was established as an implant product with tissue/bone contact and permanent contact in accordance with ISO 10993 (reference table 1).

Polypropylene Mesh

The polypropylene mesh is a knitted fabric composed of a polypropylene fiber material identical to the Bard Large Pore Soft mesh except for the diameter of the monofiliament and the knit pattern. Additionally, the same type of polypropylene fiber is used to sew the mesh to the collagen matrix. The material is the same polypropylene, from the same source and is manufactured using the same process as the Large Pore Soft Mesh. The fiber diameter is slightly smaller and the knit pattern is different however these factors are not relevant to biocompatibility in this case. Bard Davol markets products made of the material for soft tissue repair of hernias or the chest wall. Therefore, this product has the same contact profile per ISO 10993 as the Summit product. Biocompatibility of the Bard Large Pore Soft mesh was established on the basis of data on file for Spermatex mesh (reference Table 1). Finally, the Summit product will include 4 threads of blue polypropylene suture which serve as visual guides for the physician. These sutures are an off-the-shelf item produced and legally marketed by US Surgical. In that sutures are typically used in situations that would include tissue contact for periods of time greater than 30 days this component indication for use includes the contact profile of the subject product.

Therefore, biocompatibility was established for the component materials of the Summit product in that the predicate products used for Summit include the same materials, manufacturing, sterilization, and tissue contact profile. This data alone is sufficient to establish biocompatibility for Summit however, to provide additional confirmation, actual finished, sterilized Summit product was subjected to an additional battery of selected biological and chemical assays to provide further confirmation of biological acceptability. These tests include:

Chemical Characterization – GC/MS Characterization, USP Physicochemical testing

BARD

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Biological Characterization – Sensitization, Irritation, Cytotoxicity

All chemical and biological tests carried out on the Summit product were completed with all results confirming the biocompatibility of the subject product (reference Table 2).

## 5 Conclusions:

Biological testing of the mesh and porcine dermis components of the Summit product were tested in accordance with ISO 10993 for an implant product with tissue/bone contact of permanent duration. The blue suture component of the mesh is a product in commercial distribution with a similar patient contact profile and is also composed of polypropylene, the same base material as the mesh.

Confirmatory biocompatibility testing on the final finshed and sterilized product consisting of cytotoxicity, sensitization, and mucosal irritation studies were conducted with acceptable results.

The final finished and sterilized product was evaluated chemically using GC/MS characterization that determined that there were no extractable chemicals in either water or ethanol detectable by the method. The product was also evaluated via USP Physicochemical testing that met the requirements of the test. The results of both chemical tests indicate that there are no chemicals being extracted from the product in amounts that are likely to be toxicologically significant.

On the basis of test data on file for both materials in the graft, acceptable confirmatory biological testing of the composite graft, & acceptable chemical characterization of the hybrid graft the Summit Anterior Hybrid Graft product has met the requirements of ISO 10993 Biological evaluation of medical devices to establish biocompatibility for the products intended use.

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**PLAINTIFF EXHIBIT 013**