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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Maria E. Barraza, et al.,

Plaintiffs,

v.

C. R. Bard Inc., and Bard Peripheral Vascular Inc.,

Defendants.

No. CV16-01374-PHX-DGC

ORDER

Plaintiffs Maria E. Barraza and others bring this case against Defendants C.R. Bard, Inc. and Bard Peripheral Vascular Inc. (collectively, "Bard") seeking medical monitoring. Plaintiffs sue on behalf of themselves and classes of individuals who have been implanted with a Bard inferior vena cava filter, have not had that filter removed, and have not filed a claim or lawsuit for personal injury related to the filter. Doc. 57-2 at 36-41, ¶ 206. Plaintiffs have filed a motion for class certification. Doc. 54. The motion is fully briefed, and the Court heard oral arguments on August 21, 2017. Docs. 54, 72, 78, 94.[1] For reasons that follow, the Court will deny Plaintiffs' motion.

I. Background.

The inferior vena cava ("IVC") is a large vein that carries de-oxygenated blood from the lower body to the heart. This case concerns seven of Defendants' IVC blood

[1] Some portions of these documents have been redacted. Unredacted versions have been filed under seal. In some places, this order cites to sealed documents without identifying the sensitive information that resulted in their being sealed.

filters that were manufactured and marketed starting in 2003 for either permanent or temporary use. Doc. 54-1 at 9.[2] IVC filters are small devices placed in the IVC to stop blood clots from travelling to the lungs. The Bard IVC filters at issue in this case are the Recovery®, G2®, G2® Express, G2®X, Eclipse®, Meridian®, and Denali® filters. Doc. 72 at 9.

Plaintiffs allege that these filters have defects that put users at an unacceptable risk of serious injury or death. *Id.* at 5-6. Plaintiffs contend that the Bard filters tilt, perforate the IVC, and fracture and migrate to neighboring organs such as the heart and lungs. *Id.* Fractures can occur without notice or symptoms until serious physical injury or death occurs. *Id.* Plaintiffs cite a wide range of medical sources and Bard documents to support their claim that Bard IVC filters are more dangerous than other kinds of IVC filters. Doc. 54-1 at 5-20.

Defendants dispute Plaintiffs' allegation of high risk levels, contending that the overall complication rates associated with Bard IVC filters are low. Doc. 72 at 11. Defendants note that there are many IVC blood filters on the market, that all of these products involve risks that physicians and patients must consider when deciding whether the patient's medical condition warrants the implant of a blood filter, and that failure rates for Bard filters are comparable to those of other IVC filters. Defendants contend that the various warnings cited by Plaintiffs – issued by the FDA and other professional groups – apply to all blood filters, not just Bard filters. *Id.* at 9-11.

Although the FDA and various medical organizations have recommended monitoring of all patients with IVC filters, physicians follow-up with such patients at relatively low rates. Doc. 54-1 at 16-19; Doc. 72 at 10. Removals of IVC filters, even those intended to be temporary, also occur at low rates. *Id.* Each of the Plaintiffs and proposed class members currently have Bard filters implanted in their IVC's, and bring this action to obtain medical monitoring to reduce the risk presented by such filters. This

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[2] Page citations are to numbers placed at the top of each page by the Court's CM/ECF electronic filing system rather than the document's original page numbers.

Court currently is presiding over a multidistrict litigation proceeding (MDL) involving more than 2,500 personal injury cases arising out of Bard filters. This class action involves many of the same attorneys and has been following a coordinated litigation track with the MDL, but is otherwise separate.

Plaintiffs filed their motion for class certification on June 5, 2017, after almost a year of class-related discovery and expert disclosures. Docs. 22, 54. The motion recognized that only 16 states permit claims for medical monitoring, and sought certification of a single class that includes filter recipients who reside in those states:

> Plaintiffs move to certify a class covering each of the states that allow medical monitoring as a cause of action or remedy. The proposed class is defined to include all individuals in the sixteen jurisdictions that allow medical monitoring without manifest physical injury, who have been implanted with a Bard retrievable filter since July 25, 2003 (the date Bard received clearance to market the first of its filters as retrievable) to the present, who have not had their filters removed (and are at least ninety days post-implant), and who have not filed a personal injury lawsuit concerning their Bard filter.

Doc. 54-1 at 21.

The motion recognizes that this case includes only 11 named Plaintiffs from 11 of the 16 states, but asserted that these individuals could represent persons from the five states that have no named Plaintiff. *Id.* at 23 n.20. To demonstrate the feasibility of this class and a trial that encompasses all 16 states, Plaintiffs presented a trial plan which asserts that the elements of medical monitoring claims are the same in all 16 states. *Id.* at 37-69. Plaintiffs identify these common elements: (1) exposure, (2) to a toxic substance or hazard, (3) which exposure was caused by Defendants' negligence or tortious conduct, (4) resulting in an increased risk of a serious illness or injury, (5) for which a medical test for early detection exists, (6) is reasonably necessary, and (7) is beyond that which is offered in the ordinary course. *Id.* at 27.

Defendants responded to this proposed class, noting significant differences among the laws of the 16 states to be included in the proposed class. Doc. 72-8. Defendants made other arguments regarding the suitability of the proposed class under Rule 23.

Things changed significantly at the class certification hearing. Plaintiffs' counsel stated that they were not seeking certification of a single class for all 16 states, but instead were seeking certification of 16 separate classes, one for each state that allows medical monitoring claims. Doc. 94 at 50-51. Plaintiffs stated that they had provided the Court with a single trial plan because they seek a consolidated trial of all 16 classes, and they believe the Court could give a single set of jury instructions that blended the laws of the 16 states.[3] When it was noted that 5 of the 16 states have no class representative, Plaintiffs' counsel argued that the Court could certify the classes for these 5 states without a class representative. *Id.* at 74. When this proposition was challenged – the Court noted that Rule 23(a) cannot be satisfied without a class representative – Plaintiffs' counsel changed tack again, stating that "[w]e are only asking that you certify the states at this time where we have identified a rep. If the Court does certify those states, we would ask for leave to add additional reps in the states that don't have reps at the moment." *Id.* at 74-75. This was Plaintiff's final position, and the one the Court will address in this order.[4]

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[3] This proposal, although not important in light of the Court's ruling in this order, makes no sense. If a class is governed by California law (setting aside individual class member choice of law issues, as discussed below), the Court must instruct the jury using California law, not some hybrid version of the law that the Court develops by combining California with the laws of other states. *See Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1300 (7th Cir. 1995) ("If one instruction on negligence will serve to instruct the jury on the legal standard of every state of the United States applicable to a novel claim, . . . one wonders what the Supreme Court thought it was doing in the *Erie* case when it held that it was *unconstitutional* for federal courts in diversity cases to apply general common law rather than the common law of the state whose law would apply if the case were being tried in state rather than federal court.") (emphasis in original).

[4] The Court will not allow Plaintiffs to amend their complaint to name class representatives for the five proposed classes that lack named plaintiffs. Plaintiffs had months to seek such amendments, and did in fact change named Plaintiffs several times. Adding new Plaintiffs now would require the class discovery period (*see* Doc. 22) to start over, would prejudice Defendants, and would thwart the schedule the Court has sought to follow in this case and the related MDL.

Thus, Plaintiffs seek certification of classes consisting of persons with Bard filters in the following 11 states: Arizona, California, Colorado, Florida, Illinois, Maryland, Massachusetts, Missouri, Ohio, Pennsylvania, and West Virginia. Each of these classes is represented by a single named Plaintiff.[5]

II. Class Certification.

Under Rule 23(a), a district court may certify a class only if (1) it is so numerous that joinder of all members is impractical, (2) there are questions of law or fact common to the class, (3) the claims of the representative parties are typical of the claims of the class, and (4) the representatives will fairly and adequately protect the interests of the class. Fed. R. Civ. P. 23(a)(1)-(4). For reasons explained later in this order, the Court finds that the named Plaintiffs are not typical of the class members. The other requirements of Rule 23(a) are satisfied.

The Court must also find that one of the requirements of Rule 23(b) has been met. Plaintiffs seek class certification under both Rule 23(b)(2) and 23(b)(3). Doc. 54. Rule 23(b)(2) permits certification if "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P 23(b)(2). Rule 23(b)(3) provides that class certification is appropriate if questions of law or fact common to the class predominate over questions affecting only individual class members, and if a class action would be superior to other available methods for resolving the controversy. Fed. R. Civ. P. 23(b)(3).

The Court must rigorously analyze the proposed classes to ensure they comport with Rule 23. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 351 (2011).

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[5] At the end of this order, the Court addresses and grants a motion to amend the complaint to modify the relief sought by Plaintiffs, and to make other modest changes to the class definition. Doc. 57. The Court will address the motion for class certification in light of these amendments. The Court also grants a motion to exclude two of Plaintiffs' expert reports. Doc. 68. The Court enters this order without considering those experts reports, but the Court would not have reached a different conclusion even if they were considered.

A. Rule 23(b)(3).

1. Predominance.

"The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997); *accord In re Wells Fargo Home Mortg. Overtime Pay Litig.*, 571 F.3d 953, 957 (9th Cir. 2009). "This calls upon courts to give careful scrutiny to the relation between common and individual questions in a case." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016).

"Considering whether 'questions of law or fact common to class members predominate' begins, of course, with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 563 U.S. 804, 809 (2011). Plaintiffs argue that medical monitoring claims in all the relevant jurisdictions have the following elements: (1) exposure, (2) to a toxic substance or hazard, (3) which exposure was caused by the defendant's negligence or tortious conduct, (4) resulting in an increased risk of a serious illness or injury, (5) for which a medical test for early detection exists, (6) is reasonably necessary, and (7) is beyond that which is offered in the ordinary course. Doc. 54-1 at 27. The Court will focus on these elements in deciding whether common or individual issues predominate in the proposed classes.[6]

a. Elements One & Two: Exposure to a Toxicity or Hazard.

The first two elements of the medical monitoring claim – exposure to a toxic substance or hazard – will not produce significant individual issues. Defendants do not dispute that the named Plaintiffs each have been implanted with Bard IVC filters, nor that thousands of additional individuals currently carry such filters. Thus, unlike a case where

[6] Both parties dedicated significant portions of their briefing to whether these elements were truly representative of the law in all of the states, with Defendants arguing that there were significant differences among the various state laws that would defeat class certification. Because Plaintiffs took the position during oral argument that they do not seek to certify a single multi-state class, but instead seek eleven classes covering specific states, differences among state laws will not affect predominance. The Court normally would look to the law of each state to identify the elements of the claim and address predominance, but the Court concludes that such detail is unnecessary. Even using Plaintiffs' seven elements, individual issues will predominate.

exposure to toxic substances might require individualized proof, exposure to Bard filters exists for each person who has received such a filter. Although proof that class members received Bard filters would be required during the claim phase if the classes were certified and successful, that fact could be established with relative ease in an administrative process.

With respect to the alleged hazards of Bard filters, Plaintiffs intend to make their case through generalized evidence of failure rates, FDA warnings, expert testimony, and other common evidence. Defendants will respond with similar general evidence. Defendants do not contend that individual issues will predominate on this element.

b. Element Three: Negligence and Causation.

To satisfy the third element, Plaintiffs must show that they face an increased risk of injury and require monitoring because of Defendants' negligence in designing the filters and failing to warn of their risks. Doc. 54-1 at 28.[7] Plaintiffs argue that they can establish this element with class-wide law and evidence – whether Defendants owed a duty to Plaintiffs is a question of law that will not vary among class members, and whether Defendants were negligent in designing and marketing the filters will be decided on the basis of Defendants' actions, not individual issues.

Defendants disagree. They assert that Plaintiffs' proof of negligence will raise a wide range of issues. The classes include seven different Bard filters manufactured and marketed at different times over the course of more than 15 years. Doc. 72 at 20-21. Defendants contend that the design processes and warnings for these filters varied across kinds of filters and over time, as did Defendants' knowledge concerning the risks associated with the filters. *Id.* (citing Doc. 74-4, Exhibit 11).

[7] Plaintiffs' counsel clarified during oral argument that they allege injury resulting only from Defendants' negligence. Failure to warn and design defect are the alleged bases for Defendants' negligence, but Plaintiffs are not asserting any separate failure to warn or design defect claims.

i. Design and Testing Issues.

Each of Plaintiffs' proposed state classes includes all seven of the Bard filters at issue in this case. Plaintiffs allege that each of the filters was negligently designed. Trial of each of the classes will therefore include the design history and risks of each of these seven filters. And these facts must be evaluated in the context of what was reasonable at the time each filter was designed and marketed. *See, e.g.*, *Muller v. Synthes Corp.*, No. 99 C 1492, 2002 WL 460827, at *7 (N.D. Ill. Mar. 26, 2002) (to prove negligent design under Illinois law, the plaintiff must show that the defendant deviated from the standard of care that other manufactures of similar products followed at the time the relevant product was designed). In at least some of the states, proof of negligent design requires consideration of safer alternatives or the state of the art at the time the filter was designed or first sold.[8] *See, e.g.*, A.R.S. 12-683(1) (a defendant shall not be liable in a product liability case if "[t]he defect in the product is alleged to result from inadequate design or fabrication, and if the plans or designs for the product or the methods and techniques of manufacturing, inspecting, testing and labeling the product conformed with the state of the art at the time the product was first sold by the defendant."). Thus, the Court and the jury will need to consider the design of each filter.

The seven Bard IVC filters were introduced to the market in the following years: Recovery® in 2002 for permanent use and 2003 for retrievable use; G2® in 2005 for permanent use and 2008 for retrievable use; G2® Express and G2®X in 2008; Eclipse® in 2010; Meridian® in 2011; and Denali® in 2013. Doc. 74-4. Each of these filters was a variation of earlier generations, but with several changes. *Id.* For example, the G2® filter had the following changes from the Recovery® filter: (1) increased hook wire diameter of approximately 24%; (2) increased nominal leg span of 25%; (3) increased nominal arm length of approximately 50%; (4) curved instead of straight arm tips; and (5) increased radius of curvature on arms at the sleeve. Doc. 74-4 at 8.

[8] For ease of explanation, the Court will discuss the required proof and affirmative defenses using only one or two jurisdictions as examples. Defendants provide a chart of the law in each of the relevant states. *See* Doc. 72-8.

The G2® Express and G2®X filters had the following changes from earlier versions: (1) modification of the filter tip to include a snare tip to allow retrievability with commercially available snares; (2) the snarable tip was electropolished instead of having a machine polished straight tip with no snare; and (3) the filter height was greater with the addition of a snarable tip. *Id.* at 13.

The Eclipse® filter was introduced with these changes over prior versions: the nitinol wire used to form the arms and legs was electropolished prior to filter assembly and annealing. *Id.* at 14. The Meridian® filter added to alternating filter arms (1) a "shoulder anchor" made out of titanium alloy tube with an in-line anchor tip to improve caudal movement/migration resistance, and (2) a "wrist anchor" made out of titanium alloy tube with an offset anchor tip to improve caudal movement/migration resistance. *Id.* at 15.

The Denali® filter included these modifications: (1) fabricated differently; (2) different leg spans; (3) different arm spans; (4) different unconstrained height; (5) staggered leg lengths; (6) four instead of six legs with cranial anchors; (7) addition of caudal anchors to two filter legs; (8) addition of penetration limiter on each filter leg; and (9) electropolished following filter assembly. *Id.* at 17.

The various generations of Bard filters also underwent separate testing. For example, the Recovery® filter underwent bench testing of clot trapping efficiency, migration resistance, hook strength, radial strength, weld integrity, creep study of filter hooks, EnduraTEC fatigue testing, simulated use, rotating-beam corrosion fatigue testing, optimum welding parameters, wire tensile test, and finite element analyses. *Id.* at 4. The Recovery® filter also underwent the following animal studies: in-vivo evaluation for permanent indication and early removal, and in-vivo evaluation for long-term removal indication. *Id.* at 5. A clinical study was conducted by Dr. Murray Asch, who investigated the safety and effectiveness of the Recovery® filter in approximately 60 patients. *Id.* Other tests were performed for other generations of filters. *See* Doc. 74-4.

Plaintiffs allege that structural and manufacturing differences between the filters are insignificant and that tests on the various filters were deficient. They note that the filters were approved by the FDA through the § 510(k) clearance process, not the FDA's more onerous pre-market approval process for new devices. *See* 21 C.F.R. § 807.87, 807.92, 807.93 (2012). But even in the face of these arguments, there are still design, manufacturing, and testing differences between the various generations of Bard filters that would need to be addressed at trial. Whether the manufacturing changes and product tests were sufficient to ensure the safety of the filters is hotly contested and would be decided by the trier of fact, but only in the context of seven generations of filters with differing specifications and testing histories. And for states that require a comparison to the state of the art, the design and manufacturing standards for blood filters generally would also have to be considered for each year.

ii. Failure to Warn Issues.

The Recovery® filter was approved by the FDA for permanent use in November 2002 and for retrievable use in July 2003. Doc. 74-4 at 5. Bard's "instructions for use" included the following warnings:

> Migration of the filter. This may be caused by placement in oversized vena cava diameters exceeding 28 mm or if proper anchoring techniques are not utilized.
>
> Perforation of the vena cava wall. This may occur if improper insertion technique is not utilized.
>
> Caval occlusion. The probability of this occurring should be weighed against the inherent risk/benefit ratio for a patient who is experiencing pulmonary embolism, or who is likely to do so without intervention.

Id.

In October 2003, the warnings were revised to include this language:

> Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques.

> Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.
>
> Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have been reported in association with improper deployment, deployment into clots and/or dislodgment due to large clot burdens.
>
> Procedures requiring percutaneous interventional techniques should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure. Possible complications include, but are not limited to, the following: Movement or migration of the filter is a known complication of vena cava filters. . . . Filter fracture is a known complication of vena cava filters. . . . Perforation or other acute or chronic damage of the IVCwall; Acute or recurrent pulmonary embolism. This has been reported despite filter usage. It is not known if thrombi passed through the filter, or originated from superior or collateral vessels; Caval thrombosis/occlusion; Extravasation of contrast material at time of venacavogram; Air embolism; Hematoma or nerve injury at the puncture site or subsequent retrieval site; Hemorrhage; Restriction of blood flow; Occlusion of small vessels; Distal embolization; Infection; Intimal tear; Stenosis at implant site. All these above complications have been associated with serious adverse events such as medical intervention and/or death. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

Id. at 6-8. Bard also sent letters to doctors in December 2004 or January 2005 alerting them to these revised instructions for use. *Id.* at 8.

The G2® filter was approved by the FDA for retrievable use in 2008. The instructions for use included these warnings:

> There have been reports of complications, including death, associated with the use of vena cava filters in morbidly obese patients.
>
> * * *
>
> NOTE: It is possible that complications such as those described in the 'Warnings, Precautions, and Potential Complications' section of this

> Instructions for Use may affect the recoverability of the device and result in the clinician's decision to have the device remain permanently implanted.

Id. at 10.

The instructions were revised in July 2009 to include the following statement, in bold type:

> Note: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device. See Reporting Standards for Inferior Vena Caval Filter Placement and Patient Follow-Up: Supplement for Temporary and Retrievable/Optional Filters. Millward, S., et al.: J. Vasc Interv Radiol 2005; 16:441-443; Recommend Reporting Standards for Vena Cava Filter Placement and Patient Followup. The Participants in the Vena Caval Filter Consensus Conference: J Vasc Inter Radiol 2003; 14:S427-S432; Guidelines for the Use of Retrievable and Convertible Vena Cava Filters: Report from the Society of Interventional Radiology Multidisciplinary Consensus Conference. Kaufman, J., et al.: J Vasc Interv Radiol 2006; 17:449-459.

Id. at 11.

Later versions of Bard filters at issue in this case contained additional warnings. For example, the Meridian® filter's 2011 warnings included this language in bold type:

> FDA recommends that implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters consider removing the filter as soon as protection from [pulmonary embolism] is no longer needed. FDA encourages all physicians involved in treatment and follow-up of IVC filter recipients to consider the risks and benefits of filter removal for each patient.

Id. at 16-17.

Plaintiffs contend that Bard's warnings were inadequate and incomplete. But these examples show that the trial for each class would need to assess the warnings in place at a particular time for the particular filter implanted in each class member. Trial of a single class representative's claim would not suffice because the representative would have received a different filter with different warnings than many members of the class.

iii. Affirmative Defenses.

Class members would also be subject to affirmative defenses that turn on individual factual allegations. Plaintiffs contend that affirmative defenses should not be considered when determining whether individual issues will predominate, but they cite no authority for this assertion in their briefing or oral argument. While it is true that the mere existence of affirmative defenses "does not compel a finding that individual issues predominate over common ones," *Williams v. Sinclair*, 529 F.2d 1383, 1388 (9th Cir. 1975), such defenses cannot be ignored when making a predominance decision. "[A] class cannot be certified on the premise that [the defendant] will not be entitled to litigate its . . . defenses to individual claims." *Dukes*, 564 U.S. at 367. "The potentially individualized nature of affirmative defenses requires that courts consider such defenses in undertaking the predominance analysis." *See* Newberg on Class Actions § 4:55 (5th ed. 2017); *see also* S. Gensler, *Federal Rules of Civil Procedure, Rules and Commentary* at 533 (2016) ("The court must determine what impact, if any, the affirmative defenses will have on the mix of common versus individualized issues[.]"); *Myers v. Hertz Corp.*, 624 F.3d 537, 551 (2d Cir. 2010) ("[T]here is no reason the district court ought to have given the 'defense' less weight in determining whether overall class certification would serve the goals of the predominance requirement. [W]hile it is well established that the existence of a defense potentially implicating different class members differently does not *necessarily* defeat class certification, it is equally well established that courts must consider potential defenses in assessing the predominance requirement.") (citations omitted; emphasis in original); *Valenzuela v. Union Pac. R.R. Co.*, No. 15-1092-PHX-DGC, 2016 WL 679095 at *14 (D. Ariz. 2016) (considering affirmative defenses in predominance analysis); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, No. CIV. A. 93-7074, 1995 WL 273597, at *11 (E.D. Pa. Feb. 22, 1995) (acknowledging that Rule 23(b)(3) certification was not appropriate in part because defendants asserted defenses that differ dramatically from one plaintiff to the next).

Defendants assert various affirmative defenses. Doc. 9 at 20-35; Doc. 72 at 27-29. For example, the eleven relevant states each recognize assumption of the risk, or comparative or contributory negligence, as defenses to negligence that either negate or reduce a defendant's liability. Doc. 72-8; *see, e.g.*, *Franklin v. Clemett*, 382 P.3d 802, 807 (Ariz. Ct. App. 2016) (recognizing assumption of the risk and contributory negligence as defenses under Arizona law; the presence and effect of these defenses on liability must be left to the jury). Additionally, most of the jurisdictions recognize the learned intermediary defense, albeit with some differences. *Compare Watts v. Medicis Pharm. Corp.*, 365 P.3d 944, 948, 949 (Ariz. 2016) ("a learned intermediary (the prescribing physician) who received an adequate warning regarding a drug's side effects or proper use but unforeseeably disregarded the warning constituted an intervening, superseding event that broke the chain of causation between the manufacturer and the patient[,]" but the doctrine does not apply "if the manufacturer fails to provide adequate warning to the learned intermediary"), *and Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1367 (M.D. Fla. 2015) (recognizing that the learned intermediary doctrine applies to claims of negligent failure to warn under Florida law, and finding that "the failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated").[9]

As a result, to decide liability, the jury would need to consider what each class member and her treating physicians knew about the risks associated with the relevant Bard filters and when they knew it. Plaintiffs cite evidence showing that the FDA and other organizations, as well as expert medical literature, have called for monitoring of patients with embedded blood filters. Doc. 54-1 at 17-19. These sources advocate timely removal of IVC filters. *Id.* But it is likely that at least some of the class members'

[9] Plaintiffs' counsel contended during oral argument that "downstream" conduct by Plaintiffs and their physicians should not impact the "upstream" tortious conduct of Bard. But many of these affirmative defenses go to the question of liability, a plainly "upstream" consideration. Plaintiffs offered no support for their argument that principles of comparative and contributory negligence, assumption of risk, and the learned intermediary doctrine should not apply to their claims.

treating physicians were aware of these warnings. Indeed, some class members were aware of the risks as well. For example, testimony shows that at least one named plaintiff was advised to have his filter removed in 2005, but declined to do so and did not follow up with any medical providers. Doc. 74-1 at 9. A former named plaintiff allegedly ignored no less than five letters from her implanting physician requesting clinical follow-up regarding removal of her filter. Doc. 74-2 at 16. While this individual was replaced as a class representative, she serves as an example of the individual circumstances of each class member that would need to be considered in assessing issues of comparative or contributory negligence and assumption of risk. Moreover, evidence suggests that other named plaintiffs did not follow up with their physicians after being advised to do so or to have their filters removed. Doc. 74-1 at 2-8; 74-2 at 16.[10]

Plaintiffs contend that these affirmative defenses "do not undercut the case-critical predominant issues of risk and need for monitoring, as many of them only apply to either failure to warn (learned intermediary) or negligent design (proof of safer alternative; risk/benefit analysis) claims." Doc. 78 at 15 n.12, 18. But there are two problems with this argument.

First, Plaintiffs' negligence claims *are* based on failure to warn and negligent design. Although Plaintiffs' say in their briefing that their claims are "not so limited" (Doc. 78 at 15), they identify no other basis for their negligence claims.[11]

Second, the classes cannot be certified simply because Plaintiffs allegedly face a common risk and need medical monitoring. Tortious conduct by Defendants is required

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[10] Defendants allege various other affirmative defenses, such as judicial estoppel. Doc. 72 at 28 & n.35 (contending that named plaintiff Barraza's claim should be barred by judicial estoppel – an affirmative defense unique to Barraza's claim – because she failed to disclose her lawsuit in her bankruptcy petition).

[11] Plaintiffs' reply brief provides this explanation of other grounds for their negligence claim: "Opening Br. at 7 (noting that Bard never shared with doctors or patients their internal assessment that their filters were associated with a significant increase in deaths compared to SNF) (citing Ex. 6 (Kessler Rep.)); and 8 ('Bard conceded internally that "now that we have more experience with Recovery the position of tilt-resistance should probably be down played"') (citing Ex. 8))." Doc. 78 at 15. But both of these examples appear to be failures to warn.

for medical monitoring claims in all the relevant jurisdictions. The fact that Plaintiffs face a common risk and require medical monitoring to reduce that risk is not sufficient to state a claim for relief; Plaintiffs must also show that Defendants were negligent and caused Plaintiffs' increased risk. And it is in proving negligence that individual issues will proliferate. Filter-by-filter inquiries into design and manufacturing defects will be required; at each step, the state of the art must be examined; failures to disclose will vary from year to year and filter to filter; the knowledge possessed by each class member's physician must be established to resolve the learned intermediary defense; and each class member's knowledge of the risk and response to suggestions of removal or medical monitoring will be needed to resolve defenses of assumption of the risk and contributory or comparative negligence. In short, common issues will not predominate on the third element of medical monitoring.

c. Element Four: Increased Risk.

Plaintiffs contend that they will establish the fourth element – increased risk – for all class members by "present[ing] common evidence, based on the medical literature and expert opinion, on the common increased risks of each filter, the modest changes from filter to filter, and how those modest changes do not mitigate those risks." Doc. 78 at 19. Plaintiffs cite heavily to medical literature and expert opinion concerning the heightened health risks allegedly caused by all seven of the relevant Bard IVC filters.

Defendants contend that establishing increased risk will require individualized proof for two reasons.

First, Defendants contend that "[u]nlike medical monitoring for toxic exposure, the increased risk in the medical device context is measured against the risks from exposure to a non-defective filter, rather than exposure to no filter at all." Doc. 72 at 26. Defendants cite no authority for this proposition. And even if it is true, Defendants present no reason to conclude that this comparison could not be made through common evidence.

Second, Defendants argue that Plaintiffs "will actually need to quantify the increased risk of injury for each individual class member to be entitled to medical monitoring." *Id.* at 27. But Defendants cite cases concerning levels of exposure to toxic substances that are common in the environment. *See, e.g.*, *Exxon Mobil Corp. v. Ford*, 71 A.3d 105, 132-33 (Md. 2013). This case is different. The level of exposure is not disputed – each class member is 100% exposed to the IVC filter in his or her body. Plaintiffs contend that the filters create an increased risk of adverse health consequences, a fact they intend to prove by common expert evidence. The Court does not find that individual issues will predominate on this issue.

d. Elements Five, Six, and Seven.

Defendants do not appear to dispute that Plaintiffs can show the fifth element with common evidence – that a medical test exists for early detection of filter-related medical problems. They do, however, contest that Plaintiffs can show by common evidence that their proposed medical monitoring is necessary for all class members (element six) and different from the ordinary course of treatment for those class members (element seven).

Cases have held that element six – the necessity of the proposed monitoring scheme – raises individual issues. Plaintiffs cite no contrary authority. *See In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) ("Every patient in the 17-state class who has ever been implanted with a mechanical heart valve already requires future medical monitoring as an ordinary part of his or her follow-up care. A patient who has been implanted with the Silzone valve may or may not require additional monitoring, and whether he or she does is an individualized inquiry depending on that patient's medical history, the condition of the patient's heart valves at the time of implantation, the patient's risk factors for heart valve complications, the patient's general health, the patient's personal choice, and other factors."); *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 146 (3d Cir. 1998) ("In order to state a claim for medical monitoring, each class member must prove that the monitoring program he requires is 'different from that normally recommended in the absence of exposure.' To satisfy this requirement, each plaintiff

must prove the monitoring program that is prescribed for the general public and the monitoring program that would be prescribed for him.") (citation and footnote omitted).

Similarly, cases have held that element seven – whether a particular plaintiff's ordinary course of treatment would include the monitoring sought in this case – presents individualized issues. *See Lewallen v. Medtronic USA, Inc.*, No. C 01-20395 RMW, 2002 WL 31300899, at *4 (N.D. Cal. Aug. 28, 2002) ("[A]ssuming that there has been an increased need for medical monitoring, each individual plaintiff would only be able to recover to the extent of that increase. Whatever monitoring was expected as a[] part of the anticipated course of treatment would not be recoverable, again a particularly individualized inquiry."); *Lockheed Martin Corp. v. Super. Court*, 63 P.3d 913, 924-25 (Cal. 2003) ("First, determining the extent of monitoring required by each class member absent exposure poses a highly individualized inquiry. . . . Second, determining whether each class member requires additional monitoring due to exposure requires individual litigation of numerous and substantial questions. A class member's need for additional monitoring hinges on the particular traits or characteristics of each class member.").

Here, the amount of monitoring a class member would require in the normal course of her treatment and illness, without the monitoring sought in this case, is an individualized inquiry into the medical needs and ongoing course of treatment for each class member. For example, testimony from the named plaintiffs shows that not all class members may need or would benefit from the proposed monitoring. One named plaintiff was told that a CT scan would not be capable of showing the filter position due to his size. Doc. 74-1 at 3. Another reported that her doctor monitored her filter position in August 2016 using an x-ray and concluded that the filter was fine. *Id.* at 4. Yet another named plaintiff stated that he regularly receives chest x-rays and CT scans for health complications independent of his Bard filter, while a fourth claimed that she had received a CT scan of her filter in October 2016 that showed that her filter was intact. *Id.* at 5, 11.

Plaintiffs argue that CT scans are needed for class members because most doctors do not follow their patients carefully and monitor the condition of their filters. Even if

that is true, can that failure be blamed on Defendants without an inquiry into whether the doctor's actions are due to the doctor's own failings or a failure by Bard to adequately advise the doctor? Further, Plaintiffs' motion acknowledges that some doctors implement a dedicated tracking protocol, monitor their patients carefully, and remove IVC filters when warranted. Doc. 56 at 32. Class members under the care of such diligent doctors likely could not show the need for additional tracking or that the relief offered in this case would result in different monitoring than they already are receiving. This further illustrates the member-by-member inquiry required for elements six and seven.

What is more, as Defendants' expert notes, there are risks associated with exposing individuals to CT scans due to "ionizing radiation inherent in a CT scan[.]" Doc. 74-2 at 19. Whether a class member and her doctor decide that these risks are worth the potential benefits of a CT scan, especially where the class member has received previous scans, is an individualized question not capable of proof by common evidence.

e. Choice of Law.

Plaintiffs emphasize that they selected states that recognize medical monitoring claims. They seek certification of classes of persons with Bard filters who reside in these states. But Plaintiffs have not shown that the place of residence of each class member will control the law that applies to her case.

Choice-of-law issues are relevant to class certification under Rule 23(b)(3). Where "'class certification is sought in a case based on common law claims, the question of which law governs is crucial in making a class certification determination. Not only must the choice-of-law issue be addressed at the class certification stage – it must be tackled at the front end since it pervades every element of [Rule] 23.'" *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 291 (N.D. Ohio 2007) (quoting *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555, 561 (E.D. Ark. 2005)).

In a diversity case such as this, "the district court must apply the choice-of-law rules of the state in which it sits." *Abogados v. AT&T, Inc.*, 223 F.3d 932, 934 (9th Cir.

2000). Arizona follows the "most significant relationship" test of the Restatement (Second) of Conflict of Laws. *See Bates v. Super. Ct.*, 749 P.2d 1367, 1369 (Ariz. 1988); *Magellan Real Estate Inv. Tr. v. Losch*, 109 F. Supp. 2d 1144, 1155 (D. Ariz. 2000). Under this test, the law of the state that has the most significant relationship to an issue applies to that issue. Factors to consider include: "(a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place or incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered." *Magellan*, 109 F. Supp. 2d at 1155-56. "These contacts are to be evaluated according to their relative importance with respect to the particular issue." *Id.* at 1156.

Plaintiffs asserted during oral argument that medical monitoring cases always apply the law of the place of residence of the plaintiff, but they provide no citation in support. Even if this were true, the typical practice of medical monitoring cases does not decide the choice-of-law issue in Arizona. The Court must determine the state with the most significant relationship to the claim of each class member. This may be the place of residence for some class members, but not for others. For example, named plaintiff Flournay resides in Colorado, but his filter was implanted in Texas and his implanting physician presumably practices there. Doc. 74-1 at 3. The Court must consider whether Colorado, Texas, or some other state has the most significant relationship to the alleged tort and the parties. If the Court determines that Texas has the most significant relationship, Texas does not recognize medical monitoring claims. Because other class members, like Flournay, may have received their filters or their primary medical care in states other than their current state of residence, a member-by-member inquiry would be needed to decide what law governs their claims.

f. Conclusion.

The Court concludes that individual issues would predominate if the classes were certified. Individual issues would arise from several key elements of Plaintiffs' claim: (1) whether Defendants were negligent in the design of various generations of filters,

considering not only the unique characteristics of the specific filters and the tests that were or were not performed, but also whether the design met the then-available state of the art; (2) whether Defendants were negligent in failing to disclose risks for various kinds of filters at various points in time, given what was known about the risks at the time; (3) whether the learned intermediary defense applies based on what the class member's doctor knew at the time of implant; (4) whether contributory or comparative negligence or assumption of risk apply based on what the class member has been told about the need for monitoring or removal of the filter; (5) whether the proposed medical monitoring is necessary and distinct from the ordinary course of treatment the class member is receiving; and (6) what state's law should apply to each class member's claim. Defendants note that a California state court judge previously refused to certify a California medical monitoring class of persons implanted with the same Bard IVC filters, for the same reason. *See* Doc. 72-1.

2. Superiority.

The superiority inquiry asks whether "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). This requirement must be met in addition to the predominance of common issues – it is not an alternative means for certification under Rule 23(b)(3). *See id.* (requiring predominance "and" superiority). Thus, if predominance of common issues is not present, superiority cannot save the day. Because the Court finds that individual issues will predominate, it need not address superiority.

B. Rule 23(b)(2).

Rule 23(b)(2) permits certification of a class if the requirements of Rule 23(a) are satisfied and "the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2).

1. Nature of the Relief Sought.

"Class certification under Rule 23(b)(2) is appropriate only where the primary relief sought is declaratory or injunctive." *Zinser v. Accufix Research Inst., Inc.*, 253 F.3d 1180, 1195 (9th Cir. 2001). "A class seeking monetary damages may be certified pursuant to Rule 23(b)(2) where such relief is merely incidental to the primary claim for injunctive relief." *Id.* (citation and quotations marks omitted, alterations incorporated). The parties dispute whether the relief sought by Plaintiffs should be considered injunctive or monetary in nature.

"Courts have split on whether medical monitoring relief is primarily compensatory or injunctive[,]" and the Ninth Circuit has noted that "[a] request for medical monitoring cannot be categorized as primarily equitable or injunctive *per se*." *Id.* at 1195-96 (compiling cases). Rather, the Court must examine "the precise relief sought and the circumstances of the particular case." *Id.* at 1196.

In *Zinser*, the Ninth Circuit found that the complaint sought primarily monetary relief and the proposed class therefore could not be certified under Rule 23(b)(2). *Id.* The Ninth Circuit explained:

> The amended class action complaint here seeks the establishment of a reserve fund for past and future damages, compensation for future medical treatment, plus other compensatory and punitive damages. Although the complaint also seeks "full and proper research into alternative methodologies for remedying the condition of each patient/class member," this injunctive relief is merely incidental to the primary claim for money damages.

Id. at 1196. Defendants contend that *Zinser* controls this case, but the relief sought in this case is distinguishable from the relief sought in *Zinser*. Plaintiffs do not seek direct compensatory or punitive damages, nor do they seek compensation for medical treatment.

While *Zinser* does not control the outcome in this case, many other courts have considered whether requests for medical monitoring constitute primarily injunctive or monetary relief. An oft-cited decision from the Southern District of Ohio provides a helpful discussion of the issue:

> Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute injunctive relief as required by rule 23(b)(2).
>
> However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the court to address issues as they develop during program administration. Under these circumstances, the relief constitutes injunctive relief as required by rule 23(b)(2).

Day v. NLO, Inc., 144 F.R.D. 330, 335-36 (S.D. Ohio 1992), *vacated in part on other grounds sub nom. In re NLO, Inc.*, 5 F.3d 154 (6th Cir. 1993). Citing *Day*, the District Court for the Eastern District of Pennsylvania further elaborates on the distinction:

> The dispositive factor that must be assessed to determine whether a medical monitoring claim can be certified as a Rule 23(b)(2) class is [] what type of relief do plaintiffs actually seek. If plaintiffs seek relief that is a disguised request for compensatory damages, then the medical monitoring claim can only be characterized as a claim for monetary damages. In contrast, if plaintiffs seek the establishment of a court-supervised medical monitoring program through which the class members will receive periodic examinations, then plaintiffs' medical monitoring claim can be properly characterized as claim seeking injunctive relief.

Arch v. Am. Tobacco Co., 175 F.R.D. 469, 483 (E.D. Pa. 1997).

Other courts considering the nature of medical monitoring relief have reached various conclusions. Some courts have found requested relief to be injunctive in nature. *See, e.g.*, *Donovan*, 268 F.R.D. at 22 (finding a request for medical monitoring to be a request for injunctive relief where "the plaintiffs seek a structured program, monitored by and staffed with medical personnel, in which class members will receive regular medical screenings . . . [and] would have to hire medical and administrative personnel, purchase

equipment, and establish procedures for intake, informed consent, record keeping, and so on"); *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. at 290 (finding injunctive relief where the plaintiffs sought a court-supervised medical monitoring program rather than an order that defendants pay their medical expenses directly so that they may be monitored by the physician of their choice, or an order that defendants pay a certain sum of money that plaintiffs may or may not choose to use to monitor their medical conditions); *Cook v. Rockwell Int'l Corp.*, 181 F.R.D. 473, 479 (D. Colo. 1998) (finding a request for "diagnostic testing and medical screening necessary to facilitate the early detection and permit the early treatment of disease, rather than damages for past, present or future injury," to be a request for injunctive relief); *Barnes*, 989 F. Supp. at 666 (finding it "obvious that the use of a medical monitoring fund to administer medical surveillance payments is an exercise of the Court's equitable powers"); *Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 406 (M.D. Tenn. 1996) (finding medical monitoring of exposed plaintiffs to be injunctive relief); *Yslava v. Hughes Aircraft Co.*, 845 F. Supp. 705, 713 (D. Ariz. 1993) (finding relief to be injunctive where it included the implementation of a "court-supervised program requiring ongoing, elaborate medical monitoring").

Other courts have found requests for medical monitoring to be monetary in nature. *See, e.g.*, *Lewallen*, 2002 WL 31300899, at *3 (finding primarily monetary relief where the plaintiffs sought establishment of a medical monitoring fund, rather than the establishment of a medical monitoring program, as well as compensatory and punitive damages); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 529 (N.D. Ill. 1998) (finding request for funding of treatment and monitoring to be monetary relief); *Arch*, 175 F.R.D. at 483 (finding plaintiffs' claim "identical to a traditional damage claim" because the relief includes "not only a fund for the detection of disease but also a fund for its treatment" and the "request for actual medical monitoring examinations is but a small portion of the relief requested"); *O'Connor v. Boeing N. Am., Inc.*, 180 F.R.D. 359, 379 (C.D. Cal. 1997) (finding relief primarily monetary where the plaintiffs sought establishment of a fund to pay for medical monitoring, including treatment, as well as

other compensatory and punitive damages); *Thomas v. FAG Bearings Corp. Inc.*, 846 F. Supp. 1400, 1404 (W.D. Mo. 1994) (finding a request for the "future costs of medical monitoring" to be nothing more than a request for "compensation for necessary medical expenses reasonably anticipated to be incurred in the future" because absent "anything more than an exchange of money, as requested by plaintiffs, these damages cannot be injunctive in nature").

Several trends emerge from these cases. First, a request for medical monitoring coupled with a request for compensatory or punitive damages is likely to be considered primarily monetary. *Donovan*, 268 F.R.D. at 23 (collecting cases). Second, a request for a fund for the treatment of injury, as opposed to detection of injury, is likely to be considered monetary. *See Arch.*, 175 F.R.D. at 484. Third, a request for a transmission of money with little supervision from the court or further engagement by the defendants is likely to be considered primarily monetary. *See Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 611 (W.D. Wash. 2001). Ultimately, whether requested relief is injunctive or monetary in nature should be resolved by close scrutiny of the specific relief sought and the circumstances of the case.

Plaintiffs' amended complaint seeks an order requiring Defendants "to establish a Court-supervised and Court-administered trust fund, in an amount to be determined, to pay for the medical monitoring protocol for all Class members[.]" Doc. 57-2 at 45, ¶ 228. During oral argument, Plaintiffs' counsel explained that a class member who elected to pursue this monitoring would see her own treating physician or another physician of her choice to obtain a prescription for a CT scan. The fund would pay for the doctor visit. If the physician prescribed the CT scan, the class member would obtain the scan from a provider of her choice. The fund would pay for the scan. The scan would be read at one of several already-existing centers around the country that specialize in reading CT scans. The fund would pay the center for review of the scan and issuance of a report. Defendants and the Court would not set up a structured medical monitoring program staffed by medical personnel hired for that purpose, as in some

medical monitoring cases. Nor would data generated by the monitoring be used for research purposes or to benefit the class; it would be maintained only for fund administrative purposes.

Although this proposed program is less clearly monetary than cases where plaintiffs sought compensatory and punitive damages in addition to monitoring, the Court concludes that the relief sought primarily constitutes monetary rather than injunctive relief. Under Plaintiffs' proposed remedy, Defendants would do nothing more than pay money. The money would be used to pay for class members to see their own physicians, receive a scan from a CT provider of their choice, and receive a report on the scan from a designated reviewing radiologist. The Court has difficulty distinguishing this remedy from a simple claim for money damages that a plaintiff will use to pay for a doctor visit, a CT scan, and review of the scan. True, pure monetary recoveries generally do not come with limitations on use of the funds – the plaintiff can just as readily buy a new sofa as a doctor's visit. But does that single distinction – that the funds in this case can be used only for a doctor visit, a scan, and review of the scan – transform this from monetary to injunctive relief? The Court does not think so.

Injunctions require defendants to take some action or refrain from acting. Black's Law Dictionary defines an injunction as "[a] court order commanding or preventing an action." Injunction, Black's Law Dictionary (10th ed. 2014). It is "a judicial process or mandate operating in personam by which, upon certain established principles of equity, a party is required to do or refrain from doing a particular thing." *Id.*

"Damages," by contrast, are defined as "[m]oney claimed by, or ordered to be paid to, a person as compensation for loss or injury." *Id.* That is what Plaintiffs seek here – an order that Defendants pay money to compensate them for an injury (the need for medical monitoring created by Defendants' negligence). Plaintiffs cannot transform a claim for damages into injunctive relief simply by asking for an injunction that orders the payment of money. As other courts have recognized, "[a]bsent anything more than an exchange of money, as requested by plaintiffs, these damages cannot be injunctive in

nature." *Thomas*, 846 F. Supp. 2d at 1404; *see also Werlein v. United States*, 746 F. Supp. 887, 895 (D. Minn. 1990), *vacated in part on other grounds*, 793 F. Supp. 898 (D. Minn. 1992) ("Plaintiffs propose that defendants be forced to pay a lump sum of cash into a fund, and that persons eligible for medical monitoring use that pot of cash to obtain reimbursement costs incurred as the result of medical screening examinations. Payment of cash by one party to reimburse other parties for costs incurred is not injunctive relief.").

Nor can Plaintiffs bring their claim within Rule 23(b)(2) simply by crafting it in way that looks like equitable relief. Rule 23(b)(2) "does not speak of 'equitable' remedies generally but of injunctions and declaratory judgments." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 365 (2011). The relief must be injunctive to come within the rule, and the Court cannot conclude that a remedy requiring Defendants to do nothing more than write a check can properly be viewed as an injunction.

2. Cohesiveness.

Defendants argue that Rule 23(b)(2) contains a "cohesiveness" requirement. Doc. 72 at 19. Plaintiffs acknowledge this requirement, but appear to disagree on its content. Doc. 54-1 at 25. A cohesiveness requirement has been widely applied by other circuits and by district courts within the Ninth Circuit, but the Ninth Circuit has yet to speak unequivocally regarding it.

The Third Circuit has explained that while Rule 23(b)(2) class actions "have no predominance or superiority requirements, it is well established that the class claims must be cohesive." *Barnes*, 161 F.3d at 143. "This is so because in a (b)(2) action, unnamed members are bound by the action without the opportunity to opt out." *Id.* at 142-43; *accord Gates v. Rohm & Haas Co.*, 655 F.3d 255, 264 (3d Cir. 2011). Thus, a district court "has the discretion to deny certification in Rule 23(b)(2) cases in the presence of disparate factual circumstances." *Barnes*, 161 F.3d at 143 (citation and quotation marks omitted).

In addition to the Third Circuit in *Barnes*, at least five circuits have found a cohesiveness requirement in Rule 23(b)(2). Some find the requirement in the text of the rule, but all view cohesiveness as similar to a predominance test, asking whether significant individual issues are present in the proposed class. *See In re St. Jude Med.*, 425 F.3d at 1121-22 ("Although Rule 23(b)(2) contains no predominance or superiority requirements, class claims thereunder still must be cohesive."); *In re Monumental Life Ins. Co.*, 365 F.3d at 415 (Rule 23(b)(2) "presumes a class best described as a homogenous and cohesive group with few conflicting interests among its members") (citation and quotation marks omitted)); *Lemon v. Int'l Union of Operating Eng'rs*, 216 F.3d 577, 580 (7th Cir. 2000) ("Rule 23(b)(2) operates under the presumption that the interests of the class members are cohesive and homogeneous such that the case will not depend on adjudication of facts particular to any subset of the class nor require a remedy that differentiates materially among class members."); *Romberio v. Unumprovident Corp.*, 385 F. App'x 423, 433 (6th Cir. 2009) ("Rule 23(b)(2) classes must be *cohesive*. . . . Thus, the court must ensure that significant individual issues do not pervade the entire action because it would be unjust to bind absent class members to a negative decision where the class representative's claims present different individual issues than the claims of the absent members present.") (emphasis in original); *Shook v. Bd. of Cty. Comm'rs of Cty. of El Paso*, 543 F.3d 597, 604 (10th Cir. 2008) (the proposed class does not satisfy the cohesiveness requirement of Rule 23(b)(2) "if redressing the class members' injuries requires time-consuming inquiry into individual circumstances or characteristics of class members or groups of class members"); *see also* 1 McLaughlin on Class Actions § 5:19 (13th ed. 2016) ("Courts addressing attempts to certify Rule 23(b)(2) medical monitoring classes have also analyzed whether 'individual issues exist among class members that would destroy the 'cohesive nature' of the class claims,' a requirement for certification of any (b)(2) class. A (b)(2) class must have more

cohesiveness than a (b)(3) class because in a (b)(2) action, unnamed members are bound by the action without notice or the opportunity to opt out.").[12]

District courts in the Ninth Circuit have also applied a cohesiveness requirement to Rule 23(b)(2) class certification motions. *See Connelly v. Hilton Grand Vacations Co., LLC*, 294 F.R.D. 574, 579 (S.D. Cal. 2013) ("Although Rule 23(b)(2) classes need not meet the predominance and superiority requirements, 'it is well established that the class claims must be cohesive.'") (citation and quotation marks omitted); *Fosmire v. Progressive Max Ins. Co.*, 277 F.R.D. 625, 635-36 (W.D. Wash. 2011) ("Because . . . the individual issues contained within this proposed multistate class action overrun the common issues, the cohesiveness requirement for class certification under Rule 23(b)(2) is not met here."); *Grayson v. 7-Eleven, Inc.*, No. 09-CV-1353 MMA WMC, 2011 WL 2414378, at *2 (S.D. Cal. June 10, 2011) (recognizing that "[c]ourts have held that class claims under Rule 23(b)(2) must be cohesive" and opining as to the meaning of this requirement); *Sweet v. Pfizer*, 232 F.R.D. 360, 374 (C.D. Cal. 2005) ("Additionally, courts have held that even though Rule 23(b)(2), unlike Rule 23(b)(3), does not specifically contain predominance and superiority requirements, a class under Rule 23(b)(2) must not be overrun with individual issues."); *Lewallen*, 2002 WL 31300899, at *3 ("Additionally, to be certified under Rule 23(b)(2), the class claims must be cohesive. Even though the rule does not contain a predominance and superiority requirement, the requisite cohesiveness is lacking where individual issues predominate."); *but see O'Connor*, 197 F.R.D. at 411-12 ("Although common issues must predominate for class

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[12] In *Shook*, the Tenth Circuit found the cohesiveness requirement in Rule 23(b)(2) itself: "By its terms, then, Rule 23(b)(2) imposes two independent but related requirements. In the first place, the defendants' actions or inactions must be based on grounds generally applicable to all class members. The second requirement is more restrictive, and it is on this aspect of the Rule that we affirm the district court's ruling. The latter half of Rule 23(b)(2) requires that final injunctive relief be appropriate for *the class as a whole.* The rule therefore authorizes an inquiry into the relationship between the class, its injuries, and the relief sought, and we have interpreted the rule to require that a class must be 'amenable to uniform group remedies.' Put differently, Rule 23(b)(2) demands a certain cohesiveness among class members with respect to their injuries, the absence of which can preclude certification." 543 F.3d at 604 (citation omitted; emphasis in original).

certification under Rule 23(b)(3), no such requirement exists under 23(b)(2). It is sufficient if class members complain of a pattern or practice that is generally applicable to the class as a whole. Accordingly, for purposes of Rule 23(b)(2) certification, a class is cohesive if plaintiffs meet the requirements of Rule 23(a).") (citation omitted); *Mad Rhino, Inc. v. Best Buy Co.*, No. CV 03-5604 GPS AJWX, 2008 WL 8760854, at *6-7 (C.D. Cal. Jan. 14, 2008) (noting a lack of clarity as to the Ninth Circuit's position on cohesiveness).

The Ninth Circuit has not clearly determined whether Rule 23(b)(2) includes a cohesiveness requirement. Plaintiffs cite the *Walters* case, which addressed a class action alleging that nationwide administrative procedures used by the INS violated the class members' procedural due process rights. 145 F.3d at 1036. The class sought an injunction requiring the INS to revise their procedures and forms, engage in a notice campaign, and reopen proceedings for class members who had been injured by the INS policy. *Id.* at 1037. Upholding the district court's certification of the class under Rule 23(b)(2), the Ninth Circuit explained:

> We note that with respect to 23(b)(2) in particular, the government's dogged focus on the factual differences among the class members appears to demonstrate a fundamental misunderstanding of the rule. Although common issues must predominate for class certification under Rule 23(b)(3), no such requirement exists under 23(b)(2). It is sufficient if class members complain of a pattern or practice that is generally applicable to the class as a whole.

Id.

Plaintiffs rely on this language to support their version of cohesiveness – a "uniformity of both the defendant's actions toward the class and the injunctive relief applicable to the class." Doc. 54-1 at 25 (citation omitted). But as the discussion above demonstrates, this case fails even under this definition of cohesiveness. Defendants have not engaged in uniform action toward all class members; they have produced different filters at different times and accompanied them with different warnings. The claims in *Walters* were different. All class members asserted the same claim based on the same

conduct by the defendant: "In this case, each class member raises the same constitutional question: whether the nationwide procedures used by INS in document fraud proceedings sufficiently apprise aliens of their constitutional right to a hearing, thereby satisfying the notice component of due process." 145 F.3d at 1045.

For these reasons, the Court concludes that *Walters* is distinct from this case. The Court also concludes that given the nature of the claim at issue in *Walters*, the brief discussion in that case cannot be viewed as a rejection of the cohesiveness requirement recognized by at least six other circuits and numerous district court cases in this circuit.

The Supreme Court in *Dukes* provided additional helpful clarification of Rule 23(b)(2). *Dukes* made clear that Rule 23(b)(2) class certification "applies only when a single injunction or declaratory judgment would provide relief to each member of the class. It does not authorize class certification when each individual class member would be entitled to a *different* injunction or declaratory judgement against the defendant" or "when each class member would be entitled to an individualized award of monetary damages." 564 U.S. at 360-61 (emphasis in original). The Supreme Court found that "[t]he key to the (b)(2) class is the indivisible nature of the injunctive or declaratory remedy warranted – the notion that the conduct is such that it can be enjoined or declared unlawful only as to all of the class members or as to none of them." *Id.* at 360 (quotation marks and citation omitted). Thus, (b)(2) certification is proper where "the relief sought must perforce affect the entire class at once." *Id.* at 361-62.

Dukes emphasized that because Rule 23(b)(2) provides no mandatory notice or opportunity to opt out, it allows certification in a much narrower set of circumstances than Rule 23(b)(3), which requires notice and an opportunity to opt out for all potential class members. *Id.* at 362. As the Supreme Court explained:

> The procedural protections attending the (b)(3) class – predominance, superiority, mandatory notice, and the right to opt out – are missing from (b)(2) not because the Rule considers them unnecessary, but because it considers them unnecessary *to a (b)(2) class*. When a class seeks an indivisible injunction benefitting all its members at once, there is no reason to undertake a case-specific inquiry into whether class issues predominate

> or whether class action is a superior method of adjudicating the dispute. Predominance and superiority are self-evident.

Id. at 362-63 (emphasis in original). This language makes clear that a predominance of common issues is indeed part of Rule 23(b)(2) classes – it is assumed, "self-evident." This is not because the rule requires the trial court to examine the proposed class and find such predominance, but because the very nature of the relief available under (b)(2) – injunctive or declaratory relief obtained in a trial of the class representative's claim and applicable to all members of the class – works only when common issues predominate. As the Seventh Circuit explained: "By virtue of its requirement that the plaintiffs seek to redress a common injury properly addressed by a class-wide injunctive or declaratory remedy, Rule 23(b)(2) operates under the presumption that the interests of the class members are cohesive and homogeneous such that the case will not depend on adjudication of facts particular to any subset of the class nor require a remedy that differentiates materially among class members." *Lemon*, 216 F.3d at 580.

This condition does not exist here. Trial of the class representative's claims will not fairly adjudicate the claims of all class members because most of the class members have different filters, implanted at different times, with different warnings by Defendants, and are subject to different affirmative defenses. Stated differently, the named Plaintiffs cannot, by trying their claims, obtain "final injunctive relief or corresponding declaratory relief [that] is appropriate respecting the class as a whole." Fed. R. Civ. P. 23(b)(2). Whether this defect is labelled a lack of cohesion or a simple failure to come within the requirements of Rule 23(b)(2), it defeats class certification.

C. Typicality.

The Court also concludes that Plaintiffs cannot show typicality under Rule 23(a)(3). This defect prevents certification under both 23(b)(2) and (b)(3).

"The test of typicality is whether other members have the same or similar injury, whether the action is based on conduct which is not unique to the named plaintiffs, and whether other class members have been injured by the same course of conduct." *Hanon*

v. Dataproducts Corp., 976 F.2d 497, 508 (9th Cir. 1992) (quotation marks and citation omitted); *accord Rodriguez v. Hayes*, 591 F.3d 1105, 1124 (9th Cir. 2010). In a general sense in this case, it can be said that the named Plaintiffs and class members have been subjected to the same course of conduct – Bard's production of allegedly defective filters and its dissemination of allegedly inadequate warnings. But as noted above, important factual distinctions separate class members from the named Plaintiffs. These differences include: (1) whether Defendants were negligent in the design of the filters implanted in the class members, which often will be different from filters implanted in the named Plaintiff; (2) whether Defendants were negligent in failing to disclose risks for various kinds of filters at the point in time when the class members received their implants, as opposed to when the named Plaintiff received theirs; (3) whether the learned intermediary defense applies based on what the class member's doctor knew at the time of implant, versus what the named Plaintiff's doctor knew; (4) whether contributory or comparative negligence or assumption of risk apply based on what the class member has been told about the need for monitoring or removal of the filter, as compared to what the named Plaintiff has been told; (5) whether the proposed medical monitoring is necessary and distinct from the ordinary course of treatment the class member is receiving, as opposed to what the named plaintiff is receiving; and (6) what state's law should apply to each class member's claim as opposed to the named Plaintiff's claim. And these all go to the elements of the claims that must be proved for liability to arise.

Defenses also affect typicality. *Hanon* concluded that typicality is not satisfied, and class certification should not be granted, if "there is a danger that absent class members will suffer if their representative is preoccupied with defenses unique to it." *Id.* (quotation marks and citation omitted); *accord Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 984 (9th Cir. 2011) (relying on *Hanon* to overturn a district court's holding that, "as a general matter, individualized defenses do not defeat typicality"). As discussed above, a number of affirmative defenses are likely to apply differently to the class members than to the named Plaintiffs.

Plaintiffs' counsel asserted during oral argument that, at trial, the parties could introduce facts, allegations, and defenses that pertain to individual class members and not to the named Plaintiffs. Doc. 94 at 65. But such an approach is contrary to the representative nature of class actions, under which the named Plaintiff's claim is tried and binds the absent class members. *See* Newberg on Class Actions § 1:5 (5th ed. 2017) ("Class actions are representative suits on behalf of others similarly situated. Class members are not named adversary parties before the court. They are absent, unnamed parties who did not initiate the action but who will be bound by any class judgment, whether favorable or adverse, assuming that they have been adequately represented with respect to issues that they share in common with the class representative."). Plaintiffs' proposed approach would also make the trial entirely unworkable. Evidence regarding the unique issues related to hundreds of class members (or more) would overwhelm the trial and make it confusing to the jury and otherwise unmanageable. This is because the named Plaintiffs' claims are not truly typical of those of all absent class members.

III. Leave to Amend.

Plaintiffs filed their original complaint on May 5, 2016. Doc. 1. Since that date, they have amended the complaint several times to substitute plaintiffs. Docs. 24, 33, 36, 47. On June 5, 2017 – the same date Plaintiffs filed their motion for class certification – Plaintiffs filed a motion to amend the complaint by altering the form of the medical monitoring relief sought and the definition of the class. *See* Doc. 57-2.[13] More specifically, the proposed amended complaint retains the original request for a court-administered fund to pay for the proposed medical monitoring program and related notice campaign, but seeks to alter the content of that program. *Id.* at 45, ¶ 228.

The monitoring program set out in the original complaint would provide a "catheter venography" by an interventional radiologist for every class member, followed by a consultation with the class member's treating physician to determine if removal of

[13] The amended complaint also substitutes a former named plaintiff with plaintiff Ana Hernandez, a move already approved by the Court, and makes several typographical corrections. Defendants do not object to these changes. Doc. 64 at 2 n.1.

the filter is appropriate. *Id.* The monitoring program set out in the amended complaint does not include a "catheter venography," but instead seeks to provide an abdominal CT scan to assess the condition of the Bard filter. *Id.*

With respect to the scope of the class, the original complaint defined class members as those who had been implanted with a Bard IVC filter between July 25, 2003 and the date of filing of the complaint. *Id.* at 37, ¶ 206. The amended complaint would remove the second limit, expanding the class to anyone who had received a Bard IVC filter after July 25, 2003. *Id.*

Leave to amend may be denied if the Court finds that the "amendment would cause prejudice to the opposing party, is sought in bad faith, is futile, or creates undue delay." *Madeja v. Olympic Packers, LLC*, 310 F.3d 628, 636 (9th Cir. 2002) (citation omitted). "The party opposing amendment bears the burden of showing prejudice," futility, or one of the other reasons for denying a motion to amend. *DCD Programs*, 833 F.2d at 187.

Defendants object to the proposed amendment on grounds of undue delay and prejudice, contending that the amendment would "fundamentally alter the relief being requested and would significantly expand the scope of the proposed class." Doc. 64 at 2, 5-11. The Court is not persuaded. Defendants concede that Plaintiffs' new remedy was identified in Plaintiffs' February 3, 2017 expert report as preferable to the venography proposed in the class complaint, and that their own expert was able to address this new medical monitoring approach in Defendants' expert reports.

Defendants contend that they were "still denied the opportunity to pursue discovery from the named plaintiffs/proposed class representatives on the new remedy." *Id.* But it is not clear why Defendants would need to depose the named plaintiffs about the suitability of the new medical monitoring relief. That issue is properly determined by experts, not by the testimony of lay Plaintiffs.

Defendants have not identified any specific discovery they would have sought from the named plaintiffs with respect to the proposed CT scans. Defendants obtained all

available medical records for the named plaintiffs and deposed them extensively about their medical histories, including any scans they have had since their implants of the Bard filters. Doc. 64 at 9 n.3; Doc. 71 at 6-7. Defendants suggest that they need to consider taking depositions of Plaintiffs' current treating radiologists concerning the new proposed remedy, but Defendants have not explained why such depositions would be relevant or necessary.

Defendants argue briefly that they are prejudiced by the change in class definition. But the change does not alter the substance of the class, but only extends the cut-off date from the filing of the class complaint to the date of class notice, a likely extension of 18 months or so if the class is certified. Defendants do not explain how this change affects "the named plaintiffs' ability to serve as class representatives under Rule 23[,]" what additional discovery they would have conducted with such an extended class period, or how they have otherwise been prejudiced. Doc. 64 at 9.

Defendants additionally argue that Plaintiffs do not offer any valid reason for their delay in seeking to amend the class definition and remedy in their complaint. The Ninth Circuit has made clear, however, that "[d]elay alone does not provide sufficient grounds for denying leave to amend." *Hurn v. Ret. Fund Tr. of Plumbing, Heating & Piping Indus. of S. Cal.*, 648 F.2d 1252, 1254 (9th Cir. 1981). "Where there is lack of prejudice to the opposing party and the amended complaint is obviously not frivolous, or made as a dilatory maneuver in bad faith, it is an abuse of discretion to deny such a motion." *Id.* (citation omitted).

The Court concludes that Defendants have not shown prejudice or bad faith. Plaintiffs clearly should have been more diligent and sought to amend once they knew that their expert recommended a remedy different than the remedy pleaded in their complaint. But Plaintiffs did disclose their proposed new remedy in expert reports months ago, Defendants' experts were able to respond to the new remedy, and the experts were deposed on the new remedy. The motion to amend will be granted.

IV. Motion to Exclude.

Defendants ask the Court to preclude Plaintiffs from relying on two papers: (1) a "white paper" titled *Background White Paper from a Medical Monitoring Program Administrator: IVC Retrievable Filter Medical Monitoring Program Design*, authored by Garretson Resolution Group (specifically, Candace Young and Amy Gernon) ("the "White Paper"); and (2) a supporting expert report titled *Estimated Range Number of People with Bard IVC Filters*, authored by Dennis Tolley (the "Tolley Report"). Defendants also ask the Court to exclude any testimony or opinions of Plaintiffs' experts that rely on the White Paper or the Tolley Report. Doc. 68 at 2. Defendants contend that the White Paper and Tolley Report (collectively, the "Papers") are expert reports that were not timely disclosed under Federal Rule of Civil Procedure 26. *Id.*

The Court's case management order required that expert disclosures related to class certification be made by January 13, 2017. Doc. 22 at 1. Rebuttal expert reports were due by March 24, 2017. *Id*. at 1-2.

Plaintiffs did not disclose the Papers or the identity of their authors by these deadlines. Defendants first learned of the Papers during the deposition of one of Plaintiffs' other experts on May 9, 2017, well after the deadlines for expert disclosures had passed. Doc. 68 at 2. Plaintiffs argue that they did not violate Rule 26 because the Papers are not expert reports, but rather are counsel-generated reports intended to be used solely for background information. The Court does not agree.

Expert testimony is based on "scientific, technical, or other specialized knowledge[.]" Fed. R. Evid. 702(a). The White Paper sets forth such testimony. It is a compilation of information and recommendations from persons who hold themselves out as experts in creating and administering medical monitoring programs. The authors say it is "based on our experience in this area," and include a description of their specialized qualifications. Doc. 68-1 at 2, 11. The Tolley report also sets forth expert opinions. Dr. Tolley begins his report with a statement of his specialized qualifications, and then provides "estimates" of the class size based on his expertise. *Id.* at 12.

Plaintiffs argue that the Papers rely on public information, public cases, and information from Defendants, but such reliance does not change the fact that their authors are experts within the meaning of Rule 702 providing their compilations and evaluations of that information. The Papers clearly contain expert evidence that should have been disclosed under Rule 26(a)(2).

A party that fails to provide information required by Rule 26(a) or (e) "is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Plaintiffs do not address the "substantially justified" prong of the Rule 37 standard. Instead, they argue that any failure to disclose was harmless.

Plaintiffs contend that "Bard's own sales data, along with numerous documents reflecting sales of thousands of Bard's filters during the class period, readily establish the minimal numerosity requirement." Doc. 76 at 8 . But whether other evidence exists to support the numerosity requirement for class certification is not the issue. Plaintiffs must show that Defendants will not be prejudiced by their failure to disclose the Papers. *See R & R Sails, Inc. v. Ins. Co. of Pa.*, 673 F.3d 1240, 1246 (9th Cir. 2012). They have not done so. The Papers include expert opinions bearing directly on class certification, and Plaintiffs cite them several times in the briefing on class certification. Because the Papers were not timely disclosed under the Court's case management order, Defendants were denied the opportunity to depose the authors, assess their qualifications, or provide rebuttal expert reports.

Plaintiffs also contend that Defendants first received the Papers on May 9, 2017, and then again on May 16, 2017, but failed to ask more than a few questions about them at the expert depositions. But Defendants had no opportunity to depose the authors of the Papers, and questioning experts in other fields who read the Papers is no substitute. Nor do Plaintiffs dispute that Defendants had no chance to produce rebuttal expert reports.

Because Plaintiffs have not shown that their failure to disclose the Papers was substantially justified or harmless, they cannot rely on the Papers in their motion for class certification. Fed. R. Civ. P. 37(c).[14]

IT IS ORDERED:

1. Plaintiffs' motion to certify (Doc. 54) is **denied**.
2. Plaintiffs' motion to amend (Doc. 57) is **granted**. The Clerk is directed to accept for filing document lodged as Doc. 58 in this case.
3. Defendants' motion to exclude (Doc. 68) is **granted**.
4. The Court will hold a telephone conference with counsel on **September 29, 2017 at 1:00 p.m.**, to discuss future proceedings in this case. Counsel for Plaintiffs shall initiate a conference call to include counsel for all parties and the Court. If a dial-in number is used, the dial-in information shall be provided to the Court and all parties no later than September 28, 2017 at 4:00 PM.

Dated this 11th day of September, 2017.

David G. Campbell
United States District Judge

[14] Defendants ask the Court to strike the testimony or opinions of two of Plaintiffs' experts – Drs. Hertz and Bates – that rely on the Papers, but do not identify any testimony or opinions that meets this description.