

1 **WO**

2
3
4
5
6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

8
9 IN RE: Bard IVC Filters Products Liability
10 Litigation,

No. MDL 15-02641-PHX DGC

ORDER

11
12
13
14 This multidistrict litigation (“MDL”) involves thousands of personal injury
15 cases related to inferior vena cava (“IVC”) filters manufactured and marketed by
16 Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, “Bard”).
17 Bard has filed a motion to exclude the opinions of Dr. Derek Muehrcke. Doc. 7304. The
18 motion is fully briefed, and the Court heard arguments on January 19, 2018. The Court
19 will grant the motion in part.

20 **I. Background.**

21 The IVC is a large vein that returns blood to the heart from the lower body. IVC
22 filters are small metal devices implanted in the IVC to catch blood clots before they reach
23 the heart and lungs. This MDL involves seven different versions of Bard IVC filters –
24 the Recovery, G2, G2 Express, G2X, Eclipse, Meridian, and Denali.

25 Each Plaintiff in this MDL was implanted with a Bard IVC filter and claims it is
26 defective and has caused serious injury or death. Plaintiffs allege that Bard filters tilt,
27 perforate the IVC, or fracture and migrate to neighboring organs. Plaintiffs claim that
28 Bard filters are more dangerous than other IVC filters, and that Bard failed to warn about

1 the higher risks. Plaintiffs assert a host of state law claims, including manufacturing and
2 design defects, failure to warn, breach of warranty, and consumer fraud and unfair trade
3 practices. Doc. 303-1. Bard disputes Plaintiffs' allegations, contending that overall
4 complication rates for Bard filters are comparable to those of other IVC filters and that
5 the medical community is aware of the risks associated with IVC filters.

6 The parties intend to use various expert witnesses at trial, including medical
7 professionals. Plaintiffs have identified Dr. Muehrcke, a cardiothoracic surgeon, as an
8 expert witness on various issues in each of the five cases selected for bellwether trials.
9 He has prepared case-specific reports that share certain opinions in common. Doc. 7307.
10 Defendants ask the Court to exclude seven categories of opinions: (1) Bard filters have
11 design defects; (2) adoption of opinions of other experts; (3) reasonable expectations of
12 physicians regarding filter performance; (4) Bard filters have an "unacceptable" risk of
13 caudal migration; (5) Bard acted unethically in selling its filters; (6) Bard's state of mind,
14 motive, and intent; and (7) the failure of Plaintiff Lisa Hyde's filter resulted in an
15 increased risk for arrhythmias and sudden death, and the need for an implantable
16 defibrillator. Doc. 7304 at 2.¹ The Court will address each category.²

17 **II. Legal Standard.**

18 Under Rule 702, a qualified expert may testify on the basis of "scientific,
19 technical, or other specialized knowledge" if it "will assist the trier of fact to understand
20 the evidence," provided the testimony rests on "sufficient facts or data" and "reliable
21 principles and methods," and "the witness has reliably applied the principles and methods
22 to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify
23 based on his or her "knowledge, skill, experience, training, or education." *Id.*

24 The proponent of expert testimony has the ultimate burden of showing that the
25 expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v.*

26 ¹ Page citations are to the numbers placed at the top of each page by the Court's
27 electronic filing system.

28 ² The bellwether cases are those brought by Plaintiffs Sherr-Una Booker, Lisa
Hyde, Doris Jones, Carol Kruse, and Debra Mulkey.

1 *Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a
2 gatekeeper to assure that expert testimony “both rests on a reliable foundation and is
3 relevant to the task at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597
4 (1993). Rule 702’s requirements, and the court’s gatekeeping role, apply to all expert
5 testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S.
6 137, 147 (1999).

7 **III. Discussion.**

8 **A. Design Defects.**

9 Dr. Muehrcke is a cardiothoracic surgeon who received his specialty training at
10 Harvard Medical School and Massachusetts General Hospital. Doc. 7307 at 2. He serves
11 as Chief of Cardiothoracic Surgery at Flagler Hospital in St. Augustine, Florida, and is
12 part of a private medical group that performs heart surgeries at seven area hospitals.
13 *Id.* at 3. He implants or removes nearly 50 IVC filters per year, and has more than
14 20 years’ experience treating patients with IVC filters. *Id.* at 2-3.

15 Defendants argue that Dr. Muehrcke is not qualified to offer design related
16 opinions because he has never designed or tested an IVC filter and has no background in
17 engineering, metallurgy, or materials science. Doc. 7304 at 3. Defendants ask the Court
18 to exclude this design opinion:

19 Due to the filters [sic] inadequate design, Ms. Booker’s filter tilted, became
20 embedded in the vena cava, punctured through the vena cava and
21 surrounding organs and structures, multiple strut fractures occurred, and
22 filter fragments embolized to the heart. Specifically, the device’s
23 inadequate migration resistance, and lack of strength and stability, caused
24 by its weak anchoring hooks and lack of radial force and inadequate leg
25 span to accommodate vessel distention were substantial factors in causing
26 this device to migrate in a caudal direction, tilt, perforate the vena cava, and
fracture. In reaching this opinion, I reviewed Ms. Booker’s medical records
and radiology, and performed a differential diagnosis, and there is no other
reasonable cause for the failures of the filter.

27 Doc. 7307 at 10. Dr. Muehrcke offers similar opinions in other bellwether cases. *See*
28 Docs. 7307-1 at 9 (inadequate migration resistance and lack of strength and stability

1 caused Plaintiff Hyde’s G2 filter to migrate, tilt, perforate the IVC, and fracture); 7307-2
2 at 9 (lack of strength and stability caused Plaintiff Jones’s Eclipse filter to fracture);
3 7307-3 at 9 (inadequate migration resistance and lack of strength and stability caused
4 Plaintiff Kruse’s G2 filter to migrate, tilt, and fracture).

5 The quoted opinion states that several specific structural characteristics of the
6 G2 filter were substantial factors in causing it to migrate, tilt, perforate the IVC, and
7 fracture. These include the filter’s inadequate migration resistance and lack of strength
8 and stability caused by its (1) weak anchoring hooks, (2) lack of radial force, and
9 (3) inadequate leg span. Doc. 7307 at 10. Clearly, Dr. Muehrcke is not qualified to
10 testify about anchoring hooks, radial force, or leg span as an engineer, metallurgist, or
11 product designer – he claims none of those qualifications. Thus, to the extent Plaintiffs
12 offer his testimony as a design or engineering expert on characteristics of IVC filters, he
13 is not qualified and will be excluded.

14 But Dr. Muehrcke identifies a different basis for his opinion: “In reaching this
15 opinion, I reviewed Ms. Booker’s medical records and radiology, and performed a
16 differential diagnosis, and there is no other reasonable cause for the failures of the filter.”
17 *Id.* In other words, he reviewed Booker’s medical records and the x-rays of her filter and,
18 as a thoracic surgeon with years of experience in implanting and removing IVCs, could
19 find no other cause for the failure of her Bard filter than inadequate migration resistance.
20 Dr. Muehrcke is qualified to give this opinion. As a trained and experienced thoracic
21 surgeon who regularly uses IVC filters and engages in differential diagnoses, he is
22 qualified to opine on factors that caused a filter’s failure – in this case, an inability to
23 resist migration in the IVC. Whether he can also opine on more specific design problems
24 such as a lack of strength and stability caused by weak anchoring hooks, lack of radial
25 force, and inadequate leg span depends on whether his medical training and experience
26 provides expertise on these specific aspects of IVC filters, something the Court cannot
27 determine on this record.

28

1 The Court will permit Dr. Muehrcke to opine that Ms. Booker's problems arose
2 because the Bard filter's design had inadequate migration resistance. Whether he can
3 provide more specific testimony on the cause of this inadequacy will depend on the
4 foundation laid at trial.

5 **B. Reliance on Other Expert Reports.**

6 Defendants contend that Dr. Muehrcke's opinions are unreliable because he adopts
7 the opinions of Drs. Kinney, Kalva, Roberts, and Eisenberg. Doc. 7304 at 5-6. As the
8 Court previously has found, Rule 703 permits experts to rely on opinions of other experts.
9 *See* Doc. 9434 at 3-4 (citing *In re Toyota Motor Corp. Unintended Acceleration Mktg.,*
10 *Sales Practices, & Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013);
11 *E. Allen Reeves, Inc. v. Michael Graves & Assocs., Inc.*, No. 10-1393 (MAS), 2015 WL
12 105825, at *5 (D.N.J. Jan. 7, 2015); *Eaves v. United States*, No. 4:07-CV-118-M, 2009
13 WL 3754176, at *9 (W.D. Ky. Nov. 5, 2009)). Neither Dr. Muehrcke nor any other
14 expert will be permitted at trial to simply parrot the opinions of other experts, or to vouch
15 for those experts, but they can rely on opinions stated by other experts.

16 **C. Opinions Regarding the Reasonable Expectations of Physicians.**

17 Dr. Muehrcke offers this opinion in the Booker case:

18 Based upon the information available to Bard at the time the filter was
19 implanted in Ms. Booker, it was clear that the risks of the Bard . . . filter
20 exceeded its benefits and that this filter did not perform in a manner
21 reasonably expected by physicians and patients, nor in the manner
22 represented by Bard.

23 In using Bard's . . . filter, physicians reasonably expected that if the filter
24 was properly placed it would not migrate, tilt, perforate the vena cava and
25 adjacent organs/structures, fracture, or have filter fragments embolize to the
26 heart. In my opinion, because this filter failed in the manner previously
described, Ms. Booker was exposed to risks that exceeded any benefits
allegedly offered by this particular filter nor would a physician or patient
reasonably expect this constellation of failure modes to occur.

27 Doc. 7307 at 10. Similar opinions are rendered in the other bellwether cases. *See*
28 Docs. 7307-1 – 7307-3 at 9; 7307-4 at 8.

1 Defendants ask the Court to exclude these opinions on the ground that Dr.
2 Muehrcke cannot speak on behalf of all physicians regarding reasonable expectations of
3 IVC filters. Docs. 7304 at 6-8; 8224 at 7-10. Defendants claim that Dr. Muehrcke is not
4 qualified to offer such opinions and has identified no reliable methodology, noting that he
5 cites no supporting scientific literature, has conducted no survey as to what other
6 physicians think, and acknowledges that the risk-benefit analysis performed by individual
7 physicians is a subjective art form, not a science. *Id.*

8 Plaintiffs assert that Dr. Muehrcke is not purporting to speak on behalf of other
9 physicians, but instead is offering an opinion about the adequacy of Bard's warnings.
10 Doc. 7813 at 10. Plaintiffs state that in "giving the opinion that the Bard G2 filter 'did
11 not perform in a manner reasonably expected by physicians and patients, nor in the
12 manner represented by Bard,' Dr. Muehrcke is clearly opining that the warnings and
13 other information provided by Bard to physicians was insufficient." *Id.* at 10-11 (quoting
14 Doc. 7307-1 at 9). Plaintiffs further state that "Dr. Muehrcke's opinion – which
15 expressly mentions 'the manner represented by Bard' – is an opinion that Bard did not
16 provide physicians with adequate information about the risks presented by its IVC
17 filters." *Id.* at 11. Plaintiffs conclude by stating that based on his extensive experience
18 implanting and removing IVC filters, Dr. Muehrcke's "warnings opinions" are reliable.
19 *Id.* at 12.

20 Given this response and Plaintiffs' focus on Dr. Muehrcke's "warnings opinions,"
21 it is not clear whether Plaintiffs intend to have Dr. Muehrcke testify at trial about the
22 reasonable expectations of physicians regarding filter performance. He clearly expresses
23 such opinions in each report. *See, e.g.*, Doc. 7307 at 10. He also opines in each report
24 that "the risks of the Bard . . . filter exceeded its benefits" and that each Plaintiff "was
25 exposed to risks that exceeded any benefits allegedly offered by [their] particular filter."
26 *See id.* Plaintiffs do not address these risk-benefit opinions in their response brief.

27 The admissibility of similar opinions was addressed in a recent order concerning
28 Drs. Kinney, Roberts, and Kalva. Doc. 9434. Given the doctors' qualifications and

1 experience as interventional radiologists, the Court found that they should not be
2 precluded from testifying about what disclosures reasonable physicians expect to receive
3 from manufacturers of IVC filters. *Id.* at 6-9. With respect to testimony about what
4 physicians would have done with additional information, however, the Court concluded
5 that the admissibility of such testimony must be determined at trial. *Id.* at 9.

6 The Court reaches similar conclusions regarding Dr. Muehrcke. Defendants do
7 not dispute that Dr. Muehrcke is a well-qualified cardiothoracic surgeon. During the past
8 20 years, he has implanted and removed hundreds of IVC filters, including those
9 manufactured by Bard. Doc. 7307 at 2-3. Under Rule 702 and *Daubert*, expert
10 testimony “is reliable if the knowledge underlying it has a reliable basis in the knowledge
11 and experience of the relevant discipline.” *Primiano*, 598 F.3d at 565 (citation omitted).
12 The Court finds that Dr. Muehrcke has sufficient knowledge and experience to offer his
13 opinion as to the information reasonable physicians expect to receive from IVC
14 manufacturers, and whether physicians who implant IVC filters reasonably expect a
15 properly implanted filter to tilt, perforate the IVC, or fracture and migrate to neighboring
16 organs. Defendants may, of course, challenge the reliability of these opinions through
17 cross examination or qualified experts of their own.

18 Dr. Muehrcke’s risk-benefit opinions are more problematic. Whether the risks of
19 using a particular medical device outweigh the benefits is a fact- and patient-specific
20 decision not amenable to broad generalizations about what a “reasonable” patient or
21 physician would decide. The propriety of testimony on this subject will depend heavily
22 on the context and relevancy of the question. The Court will make these rulings during
23 trial.

24 **D. Opinions on the “Unacceptable” Risk of Migration.**

25 In his report for the Booker case, Dr. Muehrcke offers this opinion regarding the
26 G2 filter’s migration risk:

27 Bard had been aware since late 2005/early 2006 of the need to correct the
28 “unacceptable” caudal migration risk with the G2 filter. Bard was also
aware that caudal migration leads to tilt, perforation, penetration,

1 other testifying experts. Rather, [the expert] repeats and concurs with their opinions,
2 without additional analysis. The Court does not need an expert to reiterate other experts'
3 testimony.”).

4 His opinion that the G2 filter poses an “unacceptable risk” of caudal migration
5 is based on a Bard internal document. A report titled “G2 Caudal Migration Update,”
6 prepared by Bard product quality engineer Natalie Wong, states that in certain
7 circumstances the G2 filter had an “[u]nacceptable risk” of caudal migration per
8 Bard’s failure modes and effects analysis. Doc. 7825 at 21. Again, however, Dr.
9 Muehrcke does not identify any steps he has taken to verify the conclusion in the Wong
10 report. Nor does he identify the person or entity to whom the risk he mentions is
11 unacceptable – physicians, patients, medical manufacturers, the FDA, etc. Indeed, in his
12 deposition he steadfastly refused to identify an acceptable failure rate, saying only that it
13 should be as close to zero as possible. Doc. 7304 at 10 (quoting Dep. Tr. 65:2-5).

14 Dr. Muehrcke could opine, as a treating physician who must make decisions about
15 IVC filter use, that Bard should have disclosed any risks it found in its products that
16 would be unacceptable to doctors and patients. But he cannot opine that Bard filters
17 present an “unacceptable risk” unless that opinion is based on sufficient facts and data he
18 has identified, to which he has applied reliable principles and methods. Fed. R. Evid.
19 702(b), (c). Merely repeating conclusions in the Wong report as his own opinion does
20 not meet this requirement.

21 Nor can Dr. Muehrcke opine about the failure rates of Eclipse filters. Plaintiffs
22 identify no study or articles he reviewed on Eclipse failure rates, much less any he
23 verified.

24 **E. Opinions Regarding State of Mind and Ethics.**

25 Defendants argue that Dr. Muehrcke’s opinions about what Bard knew or should
26 have done, and Bard’s underlying motives and intent, are classic jury questions outside
27 the bounds of appropriate expert testimony. Doc. 7304 at 12-13. Plaintiffs state that the
28 doctor will not opine as to motives or intent, but contend that the degree of Bard’s

1 knowledge about the dangers posed by its filters is relevant to the failure-to-warn claims.
2 Doc. 7813 at 17-18.

3 Dr. Muehrcke will not be permitted to opine about Bard's knowledge, intent, or
4 ethics. See Doc. 9434 at 17. He does not purport to be an expert on corporate
5 information processing and he has not conducted any study of Bard internal operations,
6 information gathering, or corporate ethics. Plaintiffs propose to have him opine about
7 what Bard knew based on selected documents, but identify no expertise that enables him
8 to opine on Bard's knowledge. Dr. Muehrcke may opine that Bard should have provided
9 warnings to physicians and patients if it knew of excess risks, but it will be up to other
10 evidence to show that Bard had such knowledge.

11 **F. Opinions on the Future Medical Risks and Needs in the Hyde Case.**

12 Dr. Muehrcke opines that as a result of the failure of Plaintiff Hyde's G2 filter, she
13 is at risk for arrhythmias and sudden death, and will need an implantable defibrillator.
14 Doc. 7307-1 at 8-9. Defendants challenge this opinion on the ground that Dr. Muehrcke
15 cannot quantify the future medical risks and needs. Doc. 7304 at 13-14. The Court
16 concludes that it will be better able to address this issue in the context of the Hyde trial
17 and after trying a few bellwether cases, and therefore will withhold ruling until the Hyde
18 case is ready for trial. Defendants may reassert their arguments in a motion in limine.

19 **IT IS ORDERED** that Defendants' motion to exclude the opinions of Dr. Derek
20 Muehrcke (Doc. 7304) is **granted in part** and **denied in part** as set forth in this order.

21 Dated this 22nd day of January, 2018.

22
23
24 

25 _____
26 David G. Campbell
27 United States District Judge
28