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6 **IN THE UNITED STATES DISTRICT COURT**
7 **FOR THE DISTRICT OF ARIZONA**

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

No. MDL 15-02641-PHX DGC

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12 **ORDER**

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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. Mark Eisenberg. Doc. 7291. 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 Plaintiffs have identified Dr. Eisenberg as an expert witness on various issues,
7 including concerns about the safety and efficacy of Bard filters, Bard's obligations to
8 perform safety studies and inform physicians and patients about them, whether the filters
9 were as safe and effective as their predicate devices, and the interpretation of certain
10 clinical studies. Dr. Eisenberg is a board-certified interventional cardiologist. He
11 regularly treats patients with deep vein thromboses and pulmonary emboli, including
12 patients implanted with IVC filters and those who may be candidates for implantations,
13 although he does not implant filters himself. He is also a clinical epidemiologist, having
14 obtained a master's degree from the Harvard School of Public Health. Doc. 7293 at 4-5.¹

15 Defendants challenge Dr. Eisenberg's opinions on several grounds. Defendants
16 contend that his opinions about Bard's responsibilities and alleged unethical conduct are
17 not the proper subject of expert testimony, and that he is not qualified to render such
18 opinions. Doc. 7291 at 3-4, 6-11. Defendants make the same arguments as to opinions
19 regarding Bard's knowledge, motives, intent, and state of mind. *Id.* at 11-13. Defendants
20 further argue that factual narratives and "common sense" opinions will not assist the jury.
21 *Id.* at 13-18. Finally, Defendants argue that Dr. Eisenberg cannot speak on behalf of all
22 physicians and patients. *Id.* The Court will address each argument.

23 **II. Legal Standard.**

24 Under Rule 702, a qualified expert may testify on the basis of "scientific,
25 technical, or other specialized knowledge" if it "will assist the trier of fact to understand
26 the evidence," provided the testimony rests on "sufficient facts or data" and "reliable

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

1 principles and methods,” and “the witness has reliably applied the principles and methods
2 to the facts of the case.” Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify
3 based on his or her “knowledge, skill, experience, training, or education.” *Id.*

4 The proponent of expert testimony has the ultimate burden of showing that the
5 expert is qualified and the proposed testimony is admissible under Rule 702. *See Lust v.*
6 *Merrell Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a
7 gatekeeper to assure that expert testimony “both rests on a reliable foundation and is
8 relevant to the task at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597
9 (1993). Rule 702’s requirements, and the court’s gatekeeping role, apply to all expert
10 testimony, not only to scientific testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S.
11 137, 147 (1999).

12 **III. Discussion.**

13 **A. Opinions Regarding Ethics and State of Mind.**

14 Plaintiffs agree that Dr. Eisenberg may not opine on Bard’s “ethics, motivations,
15 intentions, and state of mind” (Doc. 7810 at 2), but the parties disagree on whether
16 Plaintiffs intend to have him testify on those topics. Plaintiffs assert that his 47-page
17 report contains no opinion that Bard’s conduct was unethical, but instead states opinions
18 on “the evidence concerning safety and efficacy of Bard’s filters, the information that
19 physicians and patients need for proper informed consent and medical decision-making,
20 and an evaluation of Bard’s disclosures of the information it had.” Doc. 7810 at 2.
21 Defendants counter that Plaintiffs are attempting to recast Dr. Eisenberg’s report and
22 sworn testimony as anything other than ethics opinions, and note that another court has
23 rejected a similar attempt. Doc. 8222 at 2; *In re Trasylol Prod. Liab. Litig.*, No. 08-MD-
24 1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010).

25 The Court does not find it helpful to cast the issue in terms of ethics vs. non-ethics,
26 but instead will focus on Dr. Eisenberg’s specific assertions and the bases for them. He
27 opines that, in light of various “safety signals,” Bard had a responsibility to perform large
28 prospective safety studies and randomized controlled clinical trials. Doc. 7293 ¶¶ 30, 34,

1 197-98, 202, 207, 213. He devotes an entire section of his report to Bard’s responsibility
2 to do safety studies. *Id.* ¶¶ 193-210 (§ IV.K). He asserts that Bard did not conduct such
3 studies, but instead “downplayed the documented high rates of adverse events with the
4 Recovery and G2 filters” and had a “corporate policy to not share any of these
5 complication rate analyses with anyone outside the company.” *Id.* ¶¶ 85-86, 173. He
6 opines that Bard looked “for ways to avoid being forthright” and spent “time, money and
7 company resources on a media company and PR for ‘spin control.’” *Id.* ¶ 95. He claims
8 that Bard performed no studies because it did not want to know the answer – “If you
9 don’t want to know the answer, then don’t look” – and that Bard “effectively allowed
10 patients to be experimental subjects.” *Id.* ¶¶ 35-36.

11 In short, Dr. Eisenberg expresses strong opinions on what Bard knew, what Bard
12 was obligated to do in light of that knowledge, and how Bard failed to fulfill its
13 obligation and chose instead to mislead physicians. The Court concludes that the cited
14 bases for these opinions either are not relevant, fail to satisfy Rule 702(c), or are outside
15 his area of expertise.

16 Dr. Eisenberg cites the American Medical Association Code of Medical Ethics and
17 an American College of Radiology practice guideline for informed consent. Doc. 7293
18 ¶ 24-26. These documents contain ethical and practice guidance for doctors; they say
19 nothing about the legal responsibilities of device manufacturers. Later, Dr. Eisenberg
20 cites an FDA guidance document and a World Health Organization report on
21 pharmacovigilance (*id.* ¶ 42), but he does not purport to be an FDA regulatory expert or
22 an expert in pharmacovigilance. Doc. 7291-2 at 11-12. Dr. Eisenberg also cites an
23 internal Bard Standard Operating Procedure and states: “In my opinion, this Standard
24 Operating Procedure sets a *minimum standard* for when a device failure rate is
25 unacceptable and must be corrected.” Doc. 7293 ¶ 49 (emphasis added). But his only
26 explanation for the source of this “minimum standard” is what a “reasonably prudent
27 physician” would expect of a medical device manufacturer. *Id.* What a reasonably
28 prudent physician would expect may be relevant in a medical malpractice case where the

1 medical standard of care is at issue, but Plaintiffs cite no authority to show that it sets the
2 legal standard for medical device manufacturers under the state tort laws applicable in
3 this MDL proceeding. Finally, Dr. Eisenberg states that the standards underlying his
4 opinions “form the foundation of our medical system” (*id.* ¶ 42), but citing such
5 imprecise and general standards does not satisfy Rule 702(c).

6 Dr. Eisenberg’s deposition makes clear that his opinions are based not on any
7 “scientific, technical, or otherwise specialized knowledge” as required by Rule 702(a),
8 but on his own personal views about proper corporate behavior. He admitted that it was
9 fair to describe his opinions as “based on what [he] believe[s] a responsible, ethical and
10 moral device manufacturer” would have done. Doc. 7291-2 at 28 (Dep. Tr. 89:21-15).
11 Personal views on proper corporate behavior are not appropriate expert opinions. *In re*
12 *Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007); *see also*
13 *Trasyol*, 2010 WL 1489793, at *9 (finding Dr. Eisenberg’s opinions on Bard’s
14 responsibilities inadmissible under Rule 702 because they were based on speculation and
15 the doctor’s subjective beliefs rather than any objective standard or specialized
16 knowledge); *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 542-43 (S.D.N.Y.
17 2004) (“The opinions of plaintiffs’ witnesses, however distinguished these individuals
18 may be as physicians and scientists, concerning the ethical obligations of pharmaceutical
19 companies and whether the defendants’ conduct was ethical are inadmissible[.]”);
20 Doc. 9433 at 17 (holding that no expert, on either side, will be permitted to opine on
21 intent or ethics).

22 Dr. Eisenberg also expresses opinions about what Bard knew based on various
23 internal documents, how Bard tracked adverse event reports, and what Bard failed to take
24 into account in designing its filters. *See, e.g.*, Doc. 7293 ¶¶ 31, 69, 75, 82-85, 97, 106,
25 112, 115. But Dr. Eisenberg is not an expert on corporate communications, behavior, or
26 regulation, and he admits that he has no “specific training looking at company documents
27 and identifying what the company knows or doesn’t know[.]” Doc. 7291-3 at 4-5 (Dep.
28 Tr. 59:5-60:67). Nor has he conducted any study of Bard internal operations, information

1 gathering, or design processes. To the extent Dr. Eisenberg “offers opinions on Bard’s
2 intent, state of mind, or motivations, this testimony is outside the bounds of appropriate
3 expert testimony.” *Tillman v. C. R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1326 (M.D. Fla.
4 2015).

5 Plaintiffs assert that Dr. Eisenberg should be allowed to testify, within scope of his
6 specialized knowledge, regarding the information physicians must possess if they are to
7 obtain informed consent from their patients. Doc. 7810 at 8. But even if such physician
8 information is relevant for the jury to decide whether Bard is liable for a failure to warn,
9 it is not relevant in the way Dr. Eisenberg intends to use it – to establish Bard’s legal
10 obligations. It cannot be used, as Plaintiffs propose, to establish “what steps must be
11 taken” by a medical device manufacturer “in response to safety signals in order
12 to improve patient safety.” *Id.* The Court will instruct the jury on how to determine
13 Defendants’ duty in this case, and testimony from FDA regulatory experts may be
14 relevant to that determination. But Dr. Eisenberg’s personal opinions cannot supply the
15 standard.

16 In summary, Dr. Eisenberg will not be permitted to render opinions about what
17 Bard did or should have done; to testify about Bard’s corporate knowledge, internal
18 conduct, or intent; or to testify about what steps must be taken by a medical device
19 manufacturer in response to safety signals or to improve patient safety. He is an
20 interventional cardiologist with training in clinical epidemiology; Plaintiffs have not
21 shown that he is qualified to testify on these subjects or that his proposed testimony is
22 based on reliable principles and methods. Fed. R. Evid. 702.

23 **B. Narrative Testimony.**

24 Dr. Eisenberg’s report includes a discussion of the history of Bard filters and
25 internal company documents. *See, e.g.*, Doc. 7293 ¶¶ 56-72. Defendants contend that
26 these factual narratives are not helpful to the jury or appropriate subjects of expert
27 testimony, and serve only to circumvent the proper presentation of evidence at trial.
28 Doc. 7291 at 13-16. The Court previously has explained that although experts in this

1 case may explain the factual basis for their opinions, they will not be permitted to
2 gratuitously comment on factual evidence or engage in lengthy factual narratives not
3 necessary to the jury's understanding of their opinions. Doc. 9434 at 4. At trial, the
4 Court will seek to strike the proper balance between allowing experts to reasonably
5 explain their opinions in a manner helpful to the jury, and avoiding unnecessary factual
6 recitation or argument. *See id.* The Court cannot draw lines now.

7 **C. "Common Sense" Opinions.**

8 Defendants cite portions of Dr. Eisenberg's deposition where he testified that the
9 significance of some Bard internal documents would be readily apparent to the jury, or
10 where he expressed views based on common sense. Doc. 7291 at 18. To the extent
11 Plaintiffs intend to have Dr. Eisenberg review internal Bard documents and simply
12 confirm what he believes they would show to any reasonable juror, or state what he
13 believes they show as a matter of common sense, such testimony will not be permitted.
14 It is not based on expertise and would not assist the jury as required by Rule 702(a).

15 **D. Opinions About Other Physicians.**

16 Defendants ask the Court to exclude Dr. Eisenberg's opinions about the reasonable
17 expectations all physicians have of medical device companies like Bard. Doc. 7291
18 at 16-17. Plaintiffs counter that Dr. Eisenberg opines about informed consent standards,
19 not other physicians' states of mind. Doc. 7810 at 18. Plaintiffs assert that "[w]hile Bard
20 focuses on whether Dr. Eisenberg can testify to how other physicians would react to
21 complication rates, the principle focus of [his] testimony is what physician's need to
22 perform their duties[.]" *Id.* at 19.

23 As noted above, Dr. Eisenberg will not be allowed to use physician expectations to
24 establish Bard's legal obligations.

25 Furthermore, throughout his report Dr. Eisenberg offers opinions about what other
26 physicians would think and do with certain information about Bard filters. He opines that
27 "physicians who use IVC filters would agree that Bard's standard [operating procedure]
28 is at best a minimum standard" (Doc. 7293 ¶ 49), that physicians "who became aware of

1 the adverse event rates that Bard was observing would likely have stopped using these
2 devices immediately” (¶ 86), and that the adverse event rates “would have persuaded
3 most physicians from using [the Recovery] device” (¶ 137). But Dr. Eisenberg has never
4 implanted or removed an IVC filter and does not claim to be an expert on IVC filters.
5 Doc. 7291-2 at 5-6. He has done no research on IVC filters prior to his retention in this
6 litigation. *Id.* at 5. He lacks the specialized knowledge and experience needed to opine
7 about how IVC-filter physicians would respond to facts at issue in this case, and will not
8 be permitted to give such opinions. Fed. R. Evid. 702.

9 **IT IS ORDERED** that Defendants’ motion to exclude the opinions of Dr. Mark
10 Eisenberg (Doc. 7291) is **granted** to the extent set forth in this order.

11 Dated this 22nd day of January, 2018.

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David G. Campbell
United States District Judge