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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

ORDER

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14 This multidistrict litigation proceeding (“MDL”) involves thousands of personal
15 injury 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 Robert Ritchie, Ph.D. Doc. 7316.
18 The motion is fully briefed, and the parties agree that oral argument is not necessary.
19 The Court 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. IVC filters, such as Bard’s Simon Nitinol Filter (“SNF”), originally
24 were designed to be implanted permanently. Because some patients need only temporary
25 filters, however, medical device manufacturers such as Bard developed retrievable filters.

26 Bard retrievable filters are spider-shaped devices with multiple limbs fanning out
27 from a cone-shaped head. The limbs consist of legs with hooks that attach to the IVC
28 wall, and shorter curved arms that serve to catch or break up blood clots. Seven different

1 versions of Bard retrievable filters are at issue in this MDL – the Recovery, G2, G2
2 Express, G2X, Eclipse, Meridian, and Denali. Each of these filters is a variation of its
3 predecessor. Bard first obtained Food and Drug Administration (“FDA”) clearance to
4 market the Recovery in 2003. The last-generation Denali received FDA clearance in
5 2013.

6 Each Plaintiff in this MDL was implanted with a Bard filter and claims it is
7 defective and has caused serious injury or death. Plaintiffs, among other things, allege
8 that Bard filters are more dangerous than other IVC filters because they have a higher
9 risk of tilting, perforating the IVC, or fracturing and migrating to vital organs. Plaintiffs
10 assert a host of state law claims, including manufacturing and design defects, failure to
11 warn, breach of warranty, and consumer fraud and unfair trade practices. Doc. 303-1.
12 Bard disputes Plaintiffs’ allegations, contending that Bard filters are not defective and
13 their overall complication rates are comparable to those of other IVC filters.

14 Plaintiffs have identified Dr. Ritchie, a mechanical engineer and materials
15 scientist, as an expert witness on the design and manufacture of certain Bard filters.
16 Dr. Ritchie received a bachelor’s degree in physics and metallurgy, a master’s degree in
17 materials science, and a doctorate degree in materials science, all from Cambridge
18 University. He has taught engineering courses at Massachusetts Institute of Technology,
19 and currently teaches materials science as a distinguished professor at the University of
20 California, Berkeley. He is a member of prestigious science and engineering academies,
21 has published hundreds of peer-reviewed articles in the technical literature, and is highly
22 regarded for his research in the fields of fatigue and fracture mechanics. With respect to
23 medical devices, Dr. Ritchie has testified before the FDA about device fatigue and
24 fracture and has served as a consultant to leading manufacturers of medical implants.
25 Docs. 7319-1 at 3, 7319-2 at 49-50.¹

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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 Dr. Ritchie has authored a report assessing the structural integrity of Bard's G2,
2 G2 Express, and Eclipse filters. He examined more than two dozen Bard filters that had
3 experienced fractured limbs and other failures while implanted. Doc. 7319-1 at 3. He
4 also reviewed internal Bard documents, medical records, medical and technical literature,
5 other expert reports, and certain deposition testimony. *Id.* at 3-4. He opines that the
6 fractures resulted from high cycle fatigue, which is the failure of a metal component over
7 time due to cyclically varying physiological loading. *Id.* at 4, 25-30, 35-38. He further
8 opines that contributing factors to the fatigue and resulting fractures include the lack of a
9 chamfered filter head, poor surface conditions, rough grinding markings, and increased
10 stress due to filter tilt and migration. *Id.*

11 Defendants do not challenge Dr. Ritchie's qualifications to opine about the
12 manufacture and design of Bard filters from a technical perspective, nor do they seek to
13 exclude his opinions about filter fatigue and fracture. Rather, Defendants ask the Court
14 to exclude several categories of opinions: (1) Bard filters have "unacceptably high"
15 complication rates; (2) one filter complication leads to others in a "vicious circle" of
16 adverse events; (3) Bard's testing was insufficient; and (4) the SNF is a safer, alternative
17 device. Doc. 7316 at 2. The Court will address each category.

18 **II. Legal Standard.**

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

25 The proponent of expert testimony has the ultimate burden of showing that the
26 expert is qualified and the testimony is admissible under Rule 702. *See Lust v. Merrell*
27 *Dow Pharm., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The trial court acts as a gatekeeper
28 to assure that expert testimony "both rests on a reliable foundation and is relevant to the

1 task at hand.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

2 **III. Discussion.**

3 **A. Bard Filters Have “Unacceptably High” Complication Rates.**

4 Dr. Ritchie opines in his report that Bard filters have “totally unacceptable failure
5 rates.” Docs. 7319-1 at 45, 7319-2 at 48. His rebuttal report states that the filters have an
6 “unacceptably high incident of filter fractures.” Doc. 7319-3 at 6. And he testified in his
7 deposition that fracture rates are “particularly high” and “unacceptable.” Doc. 7319
8 at 34. Defendants concede that Dr. Ritchie can testify about his own observations of
9 filter fracture, but argue that any opinion about “high” or “unacceptable” complication
10 rates should be excluded because Dr. Ritchie is not qualified to offer such opinions and
11 has provided no reliable foundation for them. Doc. 7316 at 4-10. The Court agrees.

12 Dr. Ritchie’s expertise is in the fields of mechanical engineering and materials
13 science. He is not a medical doctor, biostatistician, or epidemiologist experienced in
14 interpreting medical studies and data about device failure rates. Docs. 7319 at 43, 7319-4
15 at 4. And he has identified no other expertise or specialized knowledge that enables him
16 to opine that Bard filters have unacceptably high complication rates.

17 Nor has Dr. Ritchie provided sufficient facts and data to support his opinions
18 regarding filter complication rates, or identified any reliable principles and methods he
19 used in forming such opinions. He testified that he read some small studies, but does not
20 describe them or claim to have taken any steps to verify their conclusions. Doc. 7319
21 at 32-35. Plaintiffs themselves acknowledge that Dr. Ritchie’s opinions “simply echo
22 what is already reported in the literature.” Doc. 7807 at 5. Dr. Ritchie stated that he uses
23 the “unacceptably high” term “loosely” and only as a “personal statement” (Doc. 7319
24 at 33-34), and yet subjective personal beliefs are not appropriate expert opinions. *See*
25 *Daubert*, 509 U.S. at 590 (noting that the word “knowledge” in Rule 702 “connotes more
26 than subjective belief or unsupported speculation”); *In re Trasylol Prod. Liab. Litig.*,
27 No. 08-MD-1928, 2010 WL 1489793, at *8-9 (S.D. Fla. Feb. 24, 2010) (excluding
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1 opinions under Rule 702 where they were based on subjective beliefs rather than any
2 objective standard or specialized knowledge).

3 Plaintiffs note that Dr. Ritchie relies on Dr. Betensky's opinions, and contend that
4 such reliance is permissible to the extent those opinions satisfy the *Daubert* requirements.
5 Doc. 7807 at 5. But even if Dr. Betensky's opinions about adverse event rates are
6 reliable, Dr. Ritchie has taken no steps to verify her work. Doc. 7319 at 41. He read
7 Dr. Betensky's report and mentions it briefly in the introduction of his report (Doc.
8 7319-1 at 6), but he concedes that he does not discuss her analysis further or rely on it for
9 his opinions (Doc. 7319 at 40). Plaintiffs fail to explain how Dr. Ritchie's expertise in
10 engineering or materials science support an opinion that filter complication rates are too
11 high, and he never identifies the person or entity for whom the rates are unacceptable –
12 physicians, patients, manufacturers, or the FDA.

13 Dr. Ritchie will not be permitted to opine that Bard filters have "high" or
14 "unacceptable" complication rates.

15 **B. The "Vicious Circle" of Filter Complications.**

16 Dr. Ritchie concludes his report with this opinion about the synergistic effect of
17 filter failure modes:

18 *The "Vicious Circle"*: Finally, it should be recognized that many of
19 these adverse events or modes of failure are coupled. For example, a
20 "vicious circle" can be created by the rough grinding markings, not
21 polished out by Bard in the ankle regions of the legs, which clearly can
22 result in fatigue fractures of the feet; such a loss of one or more "anchors"
23 of the filter can make the device far more prone to tilting and/or migration,
24 which can change the stress states and/or promote the possibility of
25 penetrations/perforations of the filter struts through the vena cava, which in
26 turn can increase the likelihood of fractures of the arms[.]

27 Doc. 7319-1 at 38. This opinion is unreliable, Defendants contend, because the only
28 basis for it is Dr. Ritchie's intuition. Doc. 7316 at 10-12. The Court does not agree.

Relying on his knowledge and experience as a materials scientist and his
examination of Bard filters and review of medical records, Dr. Ritchie sufficiently

1 describes the basis for his opinion that fracture and other failure modes can work
2 synergistically. He explains in his report that the effect of a fractured leg would be to
3 “de-anchor” the filter from the IVC wall and both increase the load on remaining intact
4 legs, making them more susceptible to fracture, and lower the filter’s resistance to tilt and
5 migration. Doc. 7319-1 at 18, 24, 28, 37. He further explains that evidence from certain
6 G2 filters he examined shows that perforation by filter arms (and to a lesser extent the
7 legs) can promote the fracture of limbs because perforation significantly elevates stresses
8 on the limbs and changes the magnitude and direction of the applied loading on the filter
9 as a whole. *Id.* at 4, 25, 29-30, 37, 47.

10 When asked during his deposition about his opinion that tilt can lead to
11 perforation, Dr. Ritchie provided this explanation:

12 Some degree of tilt means that you have an anchor that’s not anchored, and
13 that means that the ability of the filter to move is obviously elevated
14 because you’re not fully anchored. Once the filter starts to move, the
15 probability of perforation is likely, and all these things relate to the
16 possibility of fracture and . . . that’s what we talked about earlier with the
17 crack growing in different directions. So I’ve always seen this as what I
18 call a vicious circle. It’s a synergy of events.

19 Doc. 7807-1 at 21; *see* Doc. 7319-1 at 47 (explaining that the different direction of
20 fatigue cracks in filter arms is associated with perforation).

21 Defendants note that Dr. Ritchie is not able to identify with certainty the
22 probability of one failure mode causing another, or predict which failure may occur first.
23 Doc. 7316 at 10-11. But this lack of certainty does not require exclusion of his opinions
24 under Rule 702. The Supreme Court has explained that “it would be unreasonable to
25 conclude that the subject of scientific testimony must be ‘known’ to a certainty.”
26 *Daubert*, 509 U.S. at 590; *see also Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)
27 (“Lack of certainty is not, for a qualified expert, the same thing as guesswork.”).

28 Defendants also challenge Dr. Ritchie’s opinions on the ground that he
impermissibly relies on Dr. McMeeking’s analysis of the strains caused by perforation.
Doc. 7316 at 11. But Dr. Ritchie made clear that while his opinions are confirmed by

1 Dr. McMeeking's calculations, he did not rely on the calculations as the basis for his
2 opinions. Doc. 7319 at 10-11.

3 Dr. Ritchie's opinion that different filter failure modes can have a synergistic
4 effect on one another is sufficiently reliable and will not be excluded.

5 **C. Bard's Testing Was Insufficient.**

6 Defendants contend that Dr. Ritchie is not qualified to opine about Bard's testing,
7 but do not explain why or otherwise identify the requisite expertise that may be lacking.
8 Doc. 7316 at 12. Dr. Ritchie is a well qualified materials scientist who has been studying
9 fatigue and material failure for nearly 50 years. He has worked with Nitinol since the late
10 1970s, and has evaluated various medical implants such as heart valves and stents. His
11 testing experience includes protocol design and using test equipment in a laboratory
12 environment. Doc. 7319 at 4. Dr. Ritchie is qualified to opine about Bard's testing of its
13 IVC filters.

14 Defendants further contend that Dr. Ritchie employed no scientific or engineering
15 methodology, claiming that he refers to Bard's testing only as "inadequate." Doc. 7316
16 at 12. To the contrary, Dr. Ritchie provides the basis for his opinions both in his report
17 and his deposition testimony. He testified that his general criticism of Bard's testing is
18 that it "never reproduced the problem when it comes to fracture." Doc. 7319 at 28. He
19 expanded on this view by explaining that bench testing should simulate real life results:

20 So the details of the test are almost less important, but if you've got a test
21 where everything passes and yet you put it in people's bodies and things are
22 happening, – you know, the actual implant in the body is the better test, and
23 so your lab test is obviously not reflecting reality.

24 *Id.*; see also Doc. 7807-1 at 23 ("I've been critical of a lot of the tests that Bard did,
25 because they never had a failure.").

26 In his report, Dr. Ritchie discusses two corrosion and fatigue tests Bard conducted
27 on the Recovery filter. He finds the first one to be inadequate because "[t]oo few filters
28 were tested, the test was too short (respiratory cycles are typically 15/min meaning that

1 [the] test simulated ~4 rather than 10 years), [and] it was conducted on one size filter
2 (which may not have been the most highly stressed filter).” Doc. 7319 at 33. He opines
3 that the most critical deficiency is that the test “did not simulate all modes of loading that
4 the filter experiences *in vivo*” and was “never truly validated as no filters ever failed[.]”
5 *Id.* He finds the second test to be deficient for similar reasons, explaining that the stress
6 employed was “below the fatigue limit for [the] Nitinol wire, implying these test
7 specimens would never fail, regardless of the number of loading cycles applied.” *Id.*
8 at 34. He further opines that no similar independent testing appears to have been
9 performed for the G2 filter, and that Bard instead “relied on the same inadequate fatigue
10 and corrosion testing performed on the Recovery.” *Id.*

11 Bard disagrees with Dr. Ritchie’s opinion that its testing was flawed because it
12 failed to replicate filter failures (Doc. 8230 at 7), but this disagreement does not render
13 his opinions unreliable for purposes of Rule 702. Bard will be free to cross examine
14 Dr. Ritchie at trial. The Court will not exclude his opinions about Bard’s testing.

15 **D. The SNF is a Safer Alternative Filter.**

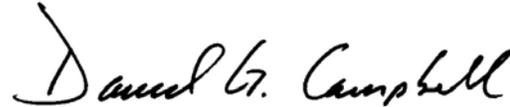
16 Dr. Ritchie testified that the SNF is a safer filter than the Recovery and G2.
17 Doc. 7319 at 42-44. The Court agrees with Defendants that Dr. Ritchie employed no
18 reliable methodology in forming this opinion. Doc. 7316 at 13. As Plaintiffs concede,
19 “his opinion regarding SNF is based on the statistical analysis performed by Dr. Betensky
20 of SNF’s adverse events relative to other Bard filters as well as studies in the published
21 literature regarding comparative filter complication rates.” Doc. 7807 at 9. But as
22 explained above, Dr. Ritchie made no effort to verify Dr. Betensky’s work, and mentions
23 her analysis in his report only by way of background. Doc. 7319 at 41. Dr. Ritchie
24 cannot simply repeat Dr. Betensky’s opinions as his own.

25 Moreover, unlike Dr. McMeeking, Dr. Ritchie has performed no assessment of the
26 SNF’s design, manufacture, or structural integrity. *See* Doc. 7318-4 at 9-17. And he
27 mentions the SNF only briefly in his report. Doc. 7319-1 at 15 (noting that the filter’s
28 original design drawings called for a 45° chamfer).

1 Plaintiffs have failed to establish a reliable foundation for Dr. Ritchie's opinion
2 that the SNF is a safer, alternative filter. The opinion will be excluded.²

3 **IT IS ORDERED** that Defendants' motion to exclude the opinions of Robert
4 Ritchie, Ph.D. (Doc. 7316) is **granted in part** as set forth in this order.

5 Dated this 8th day of February, 2018.

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11 David G. Campbell
12 United States District Judge
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² Defendants also assert that the opinions of Dr. Ritchie challenged in their motion will not assist the jury, but provide no explanation for this argument. Doc. 7316 at 3.