UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to:	)	
Tonya Brand, 1:14-cv-06018-RLY-TAB	)	

ENTRY ON PLAINTIFF'S MOTION TO EXCLUDE THE TESTIMONY OF SCOTT W. ROBERTSON, PH.D.

The Cook Defendants offer the expert testimony of Scott W. Robertson, Ph.D. Dr. Robertson is a mechanical and materials science engineer who offers three opinions in this case. Plaintiff challenges only one of them: his Opinion 2 that the Celect IVC filter design is not defective and the benefits of the filter or utility far outweigh the risks. For the reasons explained below, the court **DENIES** Plaintiff's Motion.

I. Standard for Expert Testimony

Federal Rule of Evidence 702 and the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) establish the framework for analyzing the admissibility of expert testimony. *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 607 (7th Cir. 2006). To be admissible, expert testimony must satisfy four requirements under Rule 702: (1) the expert must be qualified by knowledge, skill,

experience, training, or education; (2) the proposed expert testimony must assist the trier of fact in determining a relevant fact at issue in the case; (3) the expert's testimony must be based on sufficient facts or data and reliable principles and methods; and (4) the expert must have reliably applied the principles and methods to the facts of the case. *Lees v. Carthage College*, 714 F.3d 516, 521-22 (7th Cir. 2013) (citations omitted). As the proponent of the expert testimony at issue, the Cook Defendants have the burden of demonstrating the expert's admissibility. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009).

II. Discussion

A. Qualifications

Dr. Robertson has a Master of Science and Doctor of Philosophy in Materials Science & Engineering from the University of California in Berkley, and a minor in Biomedical Engineering. (Expert Report[1] of Dr. Scott Robertson at D2). Of particular relevance to the present case, from 2009-2011, Dr. Robertson served as General Manager of Teneo Medical Development, whose sole product was an optionally-retrievable IVC filter. (*Id.* at 32). As General Manager, he "led all engineering activities for both the implant and delivery system, designed and performed both benchtop and animal experiments to evaluate the safety and efficacy of the system, and managed the quality and regulatory functions of the company." (*Id.*). As part of his work developing the Teneo IVC filter, Dr. Robertson studied many other IVC filters and performed

[1] The Expert Report is designated in Filing Nos. 8679-1, 8679-2, and 8679-3.

comparative bench experiments and analysis on Cook IVC filters. (Robertson Dep. at 45, 114-15).

Plaintiff argues Dr. Robertson is not qualified to offer an opinion on the medical benefits of Cook's IVC filters. But he is not offering an opinion on the benefits of an IVC filter from a medical perspective; rather, he is opining on them from an *engineering* perspective. And from that perspective, the court easily finds he is qualified, based on his education and experience developing the Teneo IVC filter, to offer an opinion on the benefits of an IVC filter. *See Smith v. Ford*, 215 F.3d 713, 721 (7th Cir. 2000) ("[A] court should consider a proposed expert's full range of practical experience as well as academic or technical training when determining whether that expert is qualified to render an opinion in a given area.").

B. Methodology

Next, Plaintiff challenges the methodology supporting Dr. Robertson's risk-benefit analysis. He identified the primary performance feature or benefit of the Celect IVC filter to be the ability to capture clots. He then considered the performance features or risks to include migration resistance, fracture resistance, perforation resistance, tilt resistance, optional retrievability, and occlusion resistance. (Expert Report at 27-31). Dr. Robertson testified that he used this same methodology to design and develop the

Teneo IVC filter. (Deposition[2] of Scott Robertson ("Robertson Dep.") at 51, 246-47, 426, 445-448). This methodology is also espoused in the peer-reviewed *Morales* paper.[3]

In forming his opinions, Dr. Robertson reviewed the available data regarding IVC filters, including MAUDE data. (Expert Report at F15). He also considered peer-reviewed literature, Cook's testing records, Cook's design and engineering records, the opinions and testimony of other experts, and the depositions of Cook employees. (*Id*. at F1-F31). This is an acceptable methodology. *See, e.g., Tucker v. SmithKline Beecham Corp.*, 701 F.Supp.2d 1040, 1062-63 (S.D. Ind. 2010) (finding expert's "review of experimental, statistical or other scientific data gathered by others may suffice as a reasonable methodology upon which to base an opinion") (quoting *Walker v. Consolidated Rail Corp.*, 111 F.Supp.2d 1016, 1017 (N.D. Ind. 2000)).

1. Analysis of Benefit

Dr. Robertson testified that the primary benefit of IVC filters is to prevent pulmonary embolism. (Robertson Dep. at 230-31). But, Plaintiff argues, Dr. Robertson failed to provide any data or studies demonstrating whether, or the extent to which, *pulmonary embolism* is actually prevented by Cook filters. (*Id.* at 323 ("Q: What percentage of the hundreds of thousands[4] of what you call successful Celect []

[2] Dr. Robertson's deposition is found in Filing Nos. 6526-2, 8679-4, 8679-5, 8679-6, 8679-7, and 8679-8.

[3] Morales, et al., "Decision Analysis of Retrievable Inferior Vena Cava filters in patients without pulmonary embolism," J. Vasc. Surgery, Vol. 1, No. 4, pp. 376-84 (Oct. 2013). Dr. Robertson testified that the authors of the paper "perform[] a risk-benefit analysis of IVC filters in general showing that the benefits always outweigh the risks over the time period that they looked at." (Robertson Dep. at 251).

[4] In his Expert Report, Dr. Robertson stated:

implantations actually prevented a pulmonary embolism? A: I don't know.")). The court does not agree. Dr. Robertson's Expert Report, as noted above, states that the primary performance benefit of an IVC filter is its ability to capture clots; this is the means by which pulmonary embolism is prevented. To quantify that benefit, Dr. Robertson "relied upon the publications that were done by numerous authors using numerous clot sizes, individual clot -- individual clots, a cascade of clots, tilted filters, centered filters, and comparing those filters from Cook to other filters that are on the market that have a proven effectiveness in preventing PE." (*Id.* at 249; *see also* Expert Report at 27 ("When compared statistically against the Gunther Tulip predicate device, the Celect maintained or exceeded the clot trapping characteristic under simulated single clots, cascade of multiple clots, eccentric and concentric deployment, and large and small IVC diameters. This robust testing covered all foreseeable permutations of deployment and clot type")). Dr. Robertson also relied upon the PRECIP I study, a randomized clinical trial "that

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> Even when medical devices are designed with state-of-the-art methods and testing, adverse events are to be expected. Evaluating the reported adverse events alone without considering the hundreds of thousands of successful Celect implants is an inaccurate and inappropriate way of gauging the safety and efficacy of a medical device. When taking into account these hundreds of thousands of successful Celect IVC filter implantations, the rates of adverse events reported to Cook Medical from 2008-2016 were calculated to be exceedingly small:
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> - Successfully resist migration > 99.9%
> - Successfully resist fracture > 99.9%
> - Successfully resist perforation > 99.9%
> - Successfully resist tilt > 99.9%

(Expert Report at 26).

demonstrates that IVC filters are capable of preventing PE versus a randomized control group." (Robertson Dep. at 243-44).

The court finds Dr. Robertson's inability to quantify the number of Cook IVC filters which have actually prevented pulmonary embolism from the hundreds of thousands that have been successfully implanted in patients does not warrant the exclusion of his testimony. Rather, it goes to the weight of his testimony. *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 762 (7th Cir. 2010) (criticisms of the quality of an expert's opinions "do not go to the admissibility but to the appropriate weight that should be accorded to the evidence").

Relatedly, Plaintiff argues that Dr. Robertson "conceded that he will not be offering an opinion at trial regarding whether the Celect filter is efficacious in decreasing the risk of pulmonary embolism." Consequently, he cannot offer an opinion weighing that benefit against the risks of the Celect filter. The deposition testimony Plaintiff relies upon belies her argument. There, Dr. Robertson testified, "If you're talking about medical efficacy, no, I do not plan to render that opinion." (Robertson Dep. at 199). Dr. Robertson is not a medical doctor, and so he appropriately declined to give a medical opinion. He is, however, a biomedical engineer; consequently, he can testify about the benefits and ability of the Celect IVC filter to catch blood clots from a biomedical design and engineering perspective. Moreover, in concluding that the IVC filter is not defective, he based his opinion in part on other experts' opinions demonstrating the medical efficacy of IVC filters in general, and the Celect in particular. He is entitled to rely on the opinions of other experts. *Dura Auto. Sys. of Ind. v. CTS Corp.*, 285 F.3d 609, 613

(7th Cir. 2002) ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert.").

Next, Plaintiff criticizes Dr. Robertson's reliance on Cook's clot-trapping study to demonstrate efficacy because, although it is a method used to compare one filter to another, "it has not been validated in terms of its relevance to human patients." (Filing No. 8679, Motion at 6). Plaintiff bases her argument on an assertion that "[m]ultiple Cook scientists [Dr. Brian Choules and Arne Molgaard-Nielsen] have conceded that this laboratory experiment does not and cannot provide information about whether pulmonary emboli are prevented in human patients." (*Id.*).

Dr. Choules testified, "These are bench testing data. I think you need to go to clinical data to look at the efficacy of filters." (Filing No. 8679-9, Deposition of Brian Choules ("Choules Dep." at 138-39). But he explained that "no bench test is ever absolutely perfect in predicting what happens in vivo. [Cook's clot-trapping study] is the best you can do without actually doing the clinical work." (*Id.* at 139). Arne Molgaard-Nielsen testified that the clot-trapping study is an in vitro test and is "artificial." (Filing No. 8679-10, Deposition of Arne Molggard-Nielsen at 346). "It does not fully simulate the human body." (*Id.* at 352). But, he clarified, "it gives us some numbers, some idea of the filter, how it works, and that's why it's in the testing report itself." (*Id.* at 346). Thus, while the clot-trapping study is not perfect, it provided some evidence "that we should expect efficacy from the Celect filter." (Choules Dep. at 139). At any rate,

Plaintiff's criticism of the clot-trapping study goes to the weight, not the admissibility, of Dr. Robertson's opinion.

Notably, Dr. Robertson does not base his opinion solely on Cook's clot-trapping studies. He also based it on the *Morales* article and the PREPIC I study. (Robertson Dep. at 243-44). He correlated the data from PREPIC I with the bench-top experiments performed by numerous researchers and concluded "that the clot-trapping ability of the Cook filters is the same or superior to the filters that were used in [PREPIC I]." (*Id.* at 244). He also spoke to key opinion leaders and listened to members of a scientific advisory board consisting of medical doctors during the development of the Teneo filter. (*Id.* at 215-16). These sources are appropriate for Dr. Robertson to rely upon in forming his opinion on the benefits of IVC filters.

2. Analysis of Risk

Plaintiff also takes issue with Dr. Robertson's analysis of risk. In formulating that opinion, Dr. Robertson relied on Cook's IVC Filter Data Summary and Cook's epidemiology expert, Dr. Fryzek, regarding the complaint and adverse event data for Cook IVC filters. (Robertson Dep. at 200-01, 335). Plaintiff criticizes Dr. Robertson and Dr. Fryzek for "treat[ing] complaints to Cook as if they are a reflection of the occurrence rate in the real world." (Motion at 6). Plaintiff also criticizes Dr. Robertson for not knowing "what percent of adverse events from Cook filters are reported to Cook" or "the real world complication rates of the Celect." (*Id.* at 6-7). These criticisms fail for two reasons. First, no one knows the actual complication rate for IVC filters or for the Celect

in particular. Second, Plaintiff's objections go to the weight of Dr. Robertson's testimony, not to its admissibility.

Lastly, Plaintiff argues Dr. Robertson failed to take into consideration the risk of thromboembolic disease in his risk-benefit analysis, citing one scholarly article.[5] But Plaintiff has not alleged that she ever experienced thromboembolic disease. Consequently, at most, this is a topic for cross-examination.

III. Conclusion

The court finds Dr. Robertson's testimony is relevant, reliable, and will assist the jury with the facts at issue in this case. Therefore, Plaintiff's Motion to Exclude or Limit the Expert Testimony of Dr. Robertson (Filing No. 8678) is **DENIED**.

SO ORDERED this 7th day of November 2018.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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[5] Jeffrey W. Hull & Scott W. Robertson, "Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration." 20 J. Vasc. Radiol. 52, 58 (Jan. 2009).