UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, Plaintiff, v. EDWARDS LIFESCIENCES, CORP. AND JENAVALVE TECHNOLOGY INC., Defendants.	Civil Action No. 1:25-cv-02569 Hon. Rudolph Contreras

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO EXCLUDE TESTIMONY FROM DR. VINOD THOURANI AND DR. STANLEY CHETCUTI

INTRODUCTION

Despite claiming to be acting for the "more than 100,000 patients suffering from severe aortic regurgitation,"[1] Plaintiff seeks to preclude this court from hearing from two physicians who are pioneering clinical trials to treat this deadly disease. Dr. Vinod Thourani is the Chairman of Cardiovascular Surgery for the Piedmont Heart Institute, has performed over 5000 TAVR procedures since 2006,[2] and serves as an investigator for the J-Valve JOURNEY trial as well as a national principal investigator for the Trilogy ALIGN-AR and ARTIST trials.[3] He is widely recognized by his peers as a "world leader" in the TAVR space.[4] Dr. Stanley Chetcuti, Director of the Cardiac Catheterization Laboratory and Interventional Cardiology Group at the University of Michigan, is the site primary investigator for the Trilogy ALIGN-AR and ARTIST pivotal trials at the University of Michigan.[5] Both physicians are uniquely positioned to offer highly relevant and helpful testimony on key issues, including their direct personal experience with JenaValve's limited resources and capabilities, Edwards' abilities and track record of innovation with TAVR-AS, and the importance of this life-saving technology to their patients.

Plaintiff argues that Dr. Thourani and Dr. Chetcuti (the "Doctors") should be barred from testifying solely because Edwards is covering their legal representation in this matter. But Plaintiff cites no case in which any court has ever excluded witnesses on this basis. Nor does Plaintiff cite any ethical rule suggesting that it is improper for Edwards to have covered the legal representation for third-party witnesses. That is because the ethical rules and cases are clear that "payment of

[1] Dkt. No. 105 at 1 (FTC Memorandum in Support of Preliminary Injunction).
[2] Ex. A (Thourani Dep.) 13:1-8, 16:3-12, 20:2-21:4.
[3] *Id.* at 82:2-9, 83:2-11, 93:22-94:12.
[4] Ex. B (Chetcuti Dep.) 175:9-11.
[5] *Id.* at 23:20-24:7, 73:7-12, 80:16-22.

deposition-related expenses, including reasonable attorney's fees, is permissible." *United States v. Philip Morris USA Inc.*, No. 99-2496 (GK), 2003 WL 27410570, at *4 (D.D.C. Aug. 18, 2003).

Instead of offering any sound basis for excluding these witnesses' testimony, Plaintiff lodges baseless suggestions that these physicians' testimony was "influenced" or "tainted" by Edwards' agreement to pay for their counsel, and alleges that Defendants "interfered" with Plaintiff's discovery efforts by not proactively disclosing this arrangement. There is absolutely no support for Plaintiff's allegations—none. On the contrary, Dr. Chetcuti testified that his counsel assisted primarily with the logistics of responding to Plaintiff's subpoenas and that he did not discuss the merits of the case with his counsel.[6] It would be inappropriate for *any* litigant to besmirch the credibility of non-party witnesses without any evidentiary basis. For such baseless accusations to be levied by a government agency tasked with acting in the public interest is, to put it mildly, disconcerting.

It was entirely reasonable that the Doctors wished to be represented by counsel, and given the expedited nature of this proceeding, it was equally reasonable for Edwards to agree to cover the cost of their representation, particularly under these circumstances. After their inclusion on Defendants' preliminary witness list, Plaintiff served both physicians with incredibly broad and burdensome discovery requests on an expedited timeline and demanded that these physicians comply with their subpoenas or risk repeat depositions, but offered to withdraw their subpoenas if Defendants removed these physicians from their witness list. In the case of Dr. Chetcuti, Plaintiff went so far as to threaten to send a process server to the hospital where he cares for patients.[7] To

[6] Ex. B (Chetcuti Dep.) 135:8-136:2 ("[N]ot once did we discuss the merits of the case itself. It was more to counsel me of what to expect from a deposition. And to help me facilitate the transfer of records from me to [Plaintiff]…").

[7] Dkt. No. 108-4 at 181 (September 22, 2025 Email from Jacob Danziger to Defendants). Plaintiff claims that this email was not a threat because it was communicated to defense counsel, rather than

provide relevant information here, these physicians necessarily had to take time away from caring for patients to provide testimony but also to deal with Plaintiff's burdensome subpoenas.[8] To alleviate the imposition on these busy, practicing clinicians and to defray the associated costs, Edwards agreed to pay for counsel to help them deal with this highly expedited process.

Plaintiff had every opportunity to, and in fact did, seek discovery from both witnesses, including questions regarding their representation. Plaintiff specifically examined Dr. Chetcuti about his representation at his deposition and could have asked similar questions of Dr. Thourani on the same issue but chose not to. When asked (well after the close of fact discovery), counsel for Defendants also disclosed that Edwards had agreed to pay for these physicians' independent legal counsel. To the extent Plaintiff believes that information about who is paying for their representation is relevant, they will have the ability to cross-examine the Doctors at the hearing as they did at their depositions. There is no legitimate basis to exclude highly relevant testimony from physicians who have devoted their professional lives to caring for patients suffering from aortic regurgitation and other heart-valve diseases.

ARGUMENT

I. Testimony from Dr. Thourani and Dr. Chetcuti is relevant and admissible.

Testimony from the Doctors is directly relevant to several of the central issues in this case, including the limitations JenaValve has faced and likely will face if the transaction is blocked and the experience and capabilities Edwards will bring if the transaction is allowed to proceed. The perspective and experience of these leading physicians, including their professional interaction

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to Dr. Chetcuti directly. Mot. at 3. But Edwards' offer to connect Dr. Chetcuti was spurred directly by Plaintiff's statement that, if Dr. Chetcuti did not respond to their subpoenas "today," Plaintiff would send a process server to his hospital. Dkt. No. 108-4 at 181.

[8] *See* Ex. A (Thourani Dep.) 7:11-14 (testifying that he had to cancel surgeries to appear for the deposition). Dr. Thourani appeared for his deposition in hospital scrubs after rounding on patients in the ICU earlier that morning.

with the parties, is directly relevant to Plaintiff's burden to show that the transaction is likely to harm competition and to show that a preliminary injunction is in the public interest.

Plaintiff argues that the Doctors should be excluded from offering "opinion" testimony because they do not have the requisite knowledge or expertise under Rule 702 or *Daubert*. Defendants are offering the Doctors as fact witnesses, not experts, so Rule 702 and *Daubert* do not apply. And both physicians' testimony easily meets the standards for admissibility under the Federal Rules. A fact witness may offer testimony for which they have "personal knowledge of the matter." Fed. R. Evid. 602. They may also offer testimony in the form of an opinion if it is "rationally based on the witness's perception" and if "helpful to clearly understanding the witness's testimony or to determining a fact in issue." Fed. R. Evid. 701. The Doctors have worked extensively with Edwards, JenaValve, and other medical device companies in the TAVR space, on clinical trials and with commercially available products. Their testimony is based on their personal experience working with these companies and is both relevant and admissible.

For example, Dr. Thourani's testimony regarding JenaValve's limited resources and the potential impact of blocking this deal on AR patients[9] is grounded in his extensive experience as a principal investigator for the Trilogy ALIGN-AR and ARTIST trials.[10] Dr. Thourani's testimony that, if this transaction is enjoined and JenaValve is "by itself," he and other heart valve specialists will continue to "treat a miniscule amount of patients" is based on his direct, long-term involvement with the company.[11] "I've got seven, eight patients that we're waiting to get scheduled. Guess what, they're not scheduled. And so if I had a bigger workforce, I had better engineers, then I could get this. This is no knock on JenaValve. This is the flavor of a . . . startup

[9] *See, e.g.,* Ex. A (Thourani Dep.) 109:1-110:22.
[10] *Id.* at 85:18-87:20.
[11] *Id.* at 122:12-125:1. *See also id.* at 109:14-19 ("I've been living this for 10 years . . . with JenaValve. I have to sometimes put patients off because they don't have the resources.").

company. They just don't have the resources to be able to do it."[12] Dr. Thourani's observations about Edwards' vastly greater capabilities are also informed by his personal experience working with Edwards, including as an investigator for multiple TAVR-AS clinical trials for Edwards' SAPIEN platform.[13] Dr. Thourani has never encountered supply issues in his 19 years working with Edwards valves,[14] and currently has two Edwards clinical support team members dedicated specifically to his hospital.[15]

Similarly, when Dr. Chetcuti testifies that "the size of Edwards and the experience of Edwards will be able to deliver this care to other sites that currently do not have it, at a quicker pace and with better expertise,"[16] his testimony is based on his direct experience, including Edwards' "track record of valve expertise."[17] When asked for the basis for his expectation that Edwards will invest in continuing to innovate with the Trilogy platform, Dr. Chetcuti explained:

> It's based on my experience what I've seen Edwards do in every platform they had. So if you look at their surgical valves, they're always improving. If you look SAPIEN, it went from . . . SAPIEN to . . . SAPIEN 3, SAPIEN Ultra RESILIA, and then SAPIEN 4 coming down the road. So they have a track record. PASCAL. PASCAL has improved. Everything they've done. EVOQUE. . . . [T]here's an EVOQUE second generation. There's an EVOQUE third generation. So in those domains, I have seen a track record of Edwards always improving their devices.[18]

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[12] Ex. A (Thourani Dep.) 122:12-125:1. Dr. Chetcuti provided similar testimony, based on his own experience in the JenaValve ALIGN-AR clinical trial. Ex. B (Chetcuti Dep.) 141:4-21 ("Q. Based on your experience, do you expect that JenaValve, as a standalone company, has the resources and capabilities needed to support a national commercial launch of the Trilogy device . . . ? [A.] I do not believe that's possible. In fact, even now within the frame of ALIGN AR, we have difficulty scheduling cases because Jena's resources are limited as to how many cases . . . they can support in any given day.").

[13] Ex. A (Thourani Dep.) 48:2-10.

[14] *Id.* at 130:12-131:1.

[15] *Id.* at 115:19-22.

[16] Ex. B (Chetcuti Dep.) 166:13-17.

[17] *Id.* at 124:5-125:5.

[18] *Id.* at 128:15-129:13.

Dr. Thourani provided similar testimony, explaining that the investments Edwards has made in improving the SAPIEN valve system are a "Harvard Business Review model of how you take a device and make it successful."[19] Based on that experience, Dr. Thourani expects Edwards will devote "a whole division of Edwards engineers that's just dedicated to aortic regurgitation, and that would be the expectation that us physicians would have for them, because that's what they have proven . . . in their previous . . . renditions of the SAPIEN valve."[20]

The experience that these leading heart-valve specialists have had treating patients with aortic stenosis, aortic regurgitation, and other heart-valve diseases, and their experience working closely with Edwards and JenaValve, is undeniably relevant. To the extent that Plaintiff believes Dr. Thourani or Dr. Chetcuti lack foundation for specific testimony, it is welcome to make objections or cross-examine the physicians at the hearing, as they did in their depositions.

II. There is no legal or factual basis to exclude these physicians' testimony.

Plaintiff's motion fails to cite a single case in which a court has excluded a witness's testimony because a party agreed to pay for the witness's legal counsel. In fact, the only cases Plaintiff cites involve courts granting discovery from third-party witnesses, not excluding their testimony. The court in *Pons v. Walter Kidde Portable Equipment Inc.* denied a motion to quash by plaintiffs seeking to prevent defendants from subpoenaing communications between plaintiffs and a fact witness who plaintiffs had communicated with as a potential expert witness. No. 1:25-mc-91106-JEK, 2025 WL 1424519, at *9 (D. Mass. May 16, 2025). Similarly, the court in *Ayotte v. Nat'l Basketball Ass'n* granted defendant's motion to compel production of communications between plaintiff's counsel and a non-retained physician expert witness. No. 22-CV-9666 (VSB)

[19] Ex. A (Thourani Dep.) 134-20:135:13; *see also id.* 139:3-8 (describing his experience with Edwards' engineering team's ability to develop improved versions of the SAPIEN valve).
[20] *Id.* at 140:8-141:1.

(RWL), 2024 WL 3409027, at *3 (S.D.N.Y. July 15, 2024). The witness was the plaintiff's "treating psychologist" in a tort case alleging emotional distress. *Id*. at *1. The holding in Ayotte was predicated on the witness' unique status as a "treating physician" and a "hybrid fact-expert witness[]." *Id*. at *3. This is not a holding applicable to physicians generally and certainly does not apply to Drs. Thourani and Chetcuti, who are not testifying as expert witnesses in this matter. Finally, in *Patane v. Nestle Waters N. Am. Inc.*, the court denied defendant's motion to quash plaintiff's subpoenas for communications with "third-party state regulators, whose decisions are the foundation of certain defenses." No. 3:17-cv-1381 (JAM), 2022 WL 6569823, at *2 (D. Conn. Oct. 4, 2022). The court rejected the argument that materials shared with these witnesses prior to their depositions were protected from disclosure under the work product doctrine, and that the plaintiff should be precluded from asking questions about the information exchanged between defendant and third-party witnesses during their depositions. *Id*. "The Court does not suggest that the communications with the third-party witnesses were improper; however, plaintiffs are certainly entitled to explore whether their anticipated testimony in this matter has been shaped or influenced in any way through their exchanges with defendant or its counsel." *Id*. In short, each of these cases involved request to seek discovery of the type Plaintiff has already sought and obtained from Dr. Thourani and Dr. Chetcuti, and none of these cases remotely stands for the proposition that Edwards' agreement to pay for independent counsel for these witnesses somehow warrants precluding them from testifying in this bench trial.

Not only does Plaintiff fail to cite any case in which any court has ever excluded witness testimony in these circumstances, but they fail to cite any ethical rule, advisory opinion, or other authority to suggest that it was improper in any way for Edwards to cover the legal costs for these physicians to respond to Plaintiff's discovery requests. On the contrary, ethical opinions on the subject show that it is not uncommon for one person to have legal costs paid by someone else. The

District of Columbia Rules of Professional Conduct state: "it is not improper to pay a witness's expenses or to compensate a witness for loss of time in preparing to testify, in attending, or in testifying." D.C. Rule Pro. Conduct R. 3.4(b), cmt. 8. So long as the witness is not being paid contingent on the content of their testimony, "payment of deposition-related expenses, including reasonable attorney's fees, is permissible." *Philip Morris*, 2003 WL 27410570 at *4. Plaintiffs have offered no evidence that Edwards' agreement to pay the Doctors' legal expenses is contingent on the content of their testimony. Therefore, the agreement to pay their expenses is permissible.

In this case, Plaintiff has already had ample opportunity to seek discovery from these physicians and has, in fact, obtained both documents and sworn deposition testimony from both witnesses. Moreover, it is perfectly reasonable and appropriate for Edwards to have agreed to pay for Dr. Thourani and Dr. Chetcuti's legal representation in this matter. Both witnesses have demanding clinical and research responsibilities. Plaintiff issued massively overbroad document subpoenas to these individual physicians, along with the other physicians named on Defendants' preliminary witness list, but *not* to any of the other physicians who provided testimony in this matter.[21] Plaintiff then offered to back down from these overbroad subpoenas, but only if Defendants agreed to remove them from their witness list.[22] Using document subpoenas to coerce witnesses not to testify, rather than to obtain documents reasonably necessary to prepare its case, is improper. *See, e.g., Mattel, Inc. v. Walking Mountain Prods.*, 353 F.3d 792, 813–14 (9th Cir.

[21] Dkt. No. 108-4 at 20-26 (letter, subpoena, and list of documentary requests to Dr. Thourani), 55-61 (same for Chetcuti), 223 (October 2, 2025 Email from Michael Perry to Plaintiff observing Plaintiff has "[i]ssued document subpoenas only to the physicians on the Defendants' witness list").

[22] *Id.* at 211 (September 23, 2025 Email from Brian Robison to Defendant's counsel explaining that the FTC "said that if the defendant would take Dr. Thourani off the witness list, then the FTC would stop asking him for documents").

2003). In the case of Dr. Chetcuti, Plaintiff went so far as to threaten to send a process server to the hospital where he cares for patients if he did not immediately respond to the subpoena.[23]

Facing this aggressive discovery campaign, the Doctors understandably sought counsel. As Dr. Chetcuti testified at his deposition: "[Y]ou have no idea when a nonlegal person, when you're subpoenaed by a federal agency, the amount of fear that happens."[24] Although Dr. Chetcuti considered getting counsel from his employer, they could not provide counsel in time to represent him at his deposition.[25] It was likewise understandable and appropriate for Edwards to cover the cost of the physicians' counsel, so they need not be out of pocket as a result of their willingness to provide relevant testimony and the burden of responding to Plaintiff's discovery requests. Indeed, Edwards connected Dr. Chetcuti with counsel and agreed to pay his legal expenses the day *after* Plaintiff threatened to send a process server to his hospital.[26] In the case of Dr. Thourani, Plaintiff threatened to call him for a second deposition if he failed to produce additional documents.[27]

Plaintiff also faults Edwards' counsel for providing background materials to help get counsel for the Doctors up to speed on the proceeding, including both Plaintiff's allegations in a redacted version of the complaint and Defendants' positions described in a white paper that contained only Defendants' confidential information.[28] There is nothing improper about providing

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[23] Dkt. No. 108-4 at 181 (September 22, 2025 Email from Jacob Danziger to Defendants stating "[t]o the extent we do not receive confirmation today, we will proceed with service through a process server, and [Dr. Chetcuti] will be served at his hospital location.")
[24] Ex. B (Chetcuti Dep.) 168:1-3.
[25] *Id.* at 134:9-14. ("I had the option of getting counsel from University of Michigan. But as you know, academic places are slow and laborious, and you didn't give me -- I would not have had enough time to be in this meeting with proper representation.").
[26] Dkt. No. 108-4 at 214 (September 23, 2025 Email from Connor Leydecker to Brian Robison)
[27] *Id.* at 172 (September 29, 2025 Email from Brian Robison to Defendants' counsel)
[28] *Id.* at 234 (September 15, 2025 Email from Josh Lipton to Brian Robison attaching public hearing transcript); *id.* at 333 (September 15, 2025 Email from Josh Lipton to Brian Robison attaching FTC Complaint); *id.* at 133 (September 17, 2025 Email from Josh Lipton to Brian Robison attaching Edwards FTC Submission).

information to counsel for a third party to ensure they understand the issues in the case. The protective order in this matter allows Defendants to voluntarily disclose their own confidential information. Dkt. No. 47 at 5 (Joint Stipulated Protective Order at ¶ 7). Finally, contrary to Plaintiff's baseless speculation, the record indicates that the role of legal counsel for the Doctors was focused on responding to Plaintiff's subpoenas, not on the merits of the case.[29]

Finally, Plaintiff was not prejudiced in any way by the agreed-upon limitations on deposition length and document discovery for the Doctors. The parties mutually agreed to limit the depositions of these and other physician witnesses—including those on Plaintiff's witness list—to four hours, recognizing the significant demands on their time. As Dr. Thourani testified, he "canceled a bunch of surgeries to be here today."[30] Plaintiff also agreed to narrow the scope of the document production from both physicians (in response to incredibly broad subpoenas that provided for mere weeks to respond), just as they have with other third parties in this case.[31] These reasonable limitations were applied uniformly and do not constitute prejudice to Plaintiff.

Plaintiff had the opportunity to obtain documents and deposition testimony from both Dr. Thourani and Dr. Chetcuti and will have the opportunity to cross-examine both witnesses at trial. In this bench trial, the court will be able to make its own determination as to the weight to accord each witness's testimony, but there is no valid basis for excluding or limiting their testimony.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiff's motion.

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[29] Ex. B (Chetcuti Dep.) 135:8-136:2 ("[N]ot once did we discuss the merits of the case itself. It was more to counsel me of what to expect from a deposition. And to help me facilitate the transfer of records from me to [Plaintiff]…").
[30] Ex. A (Thourani Dep.) 7:11-12.
[31] In fact, these two non-party witnesses produced a larger volume of documents than nearly any other non-party in this case, including several of the largest medical device companies in the world.

Dated: November 6, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 6, 2025, I caused the foregoing to be served on the following counsel via the Court's CM/ECF system:

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