IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DISTRICT OF COLUMBIA

Federal Trade Commission, *Plaintiff*, v. Edwards Lifesciences Corporation, and JenaValve Technology, Inc., *Defendants*.	Case No. 1:25-cv-02569-RC Judge Rudolph Contreras

DEFENDANTS' POST-TRIAL BRIEF
REDACTED

The fundamental question in this case is who will commercialize life-saving TAVR-AR devices to more American patients more effectively: Edwards with JenaValve, or JenaValve alone? To answer this question, under 15 U.S.C. § 53(b), the Court assesses whether the FTC is likely to succeed under Section 7 and whether an injunction serves the "public interest." Both assessments require the Court to compare the world with the proposed Transaction to the world without it. *FTC v. Arch Coal*, *Inc.*, 329 F. Supp. 2d 109, 116–17 (D.D.C. 2004); COL I (FTC economist conceding the Court must "evaluate what the merger would be likely to lead to relative to . . . the counterfactual non-merger world"). Here, the evidence leads to one conclusion: patients are better off with the Transaction and so the injunction should be denied.

I. The FTC Has Failed To Show A Likelihood Of Success On The Merits Under Section 7

Under Section 7, the Court must take a "totality-of-the-circumstances approach," considering all the benefits and potential harms from the Transaction. *United States v. Baker Hughes Inc.*, 908 F.2d 981, 984 (D.C. Cir. 1990); *United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 193 (D.D.C. 2018) (court must consider "both the positive and negative impact[s] on consumers").

The FTC has not carried its threshold burden to establish a "prima facie case" that the Transaction is likely to have substantial anticompetitive effects. *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019). The FTC promised to prove "patients will suffer" and the "pace of innovation in TAVR-AR devices is likely to slow" due to the Transaction, Compl. ¶¶ 7, 11, 53, but the totality of the evidence shows the opposite. The Transaction will increase output of desperately needed TAVR-AR devices, spur innovation, and enhance competition in TAVR-AR—ultimately saving lives—compared to a world in which JenaValve is left struggling on its own.

The FTC's arguments are all based on the false premise that a standalone JenaValve has the ability and resources to compete effectively going forward—manufacturing and

commercializing its TAVR-AR device (Trilogy) at the scale necessary to supply hundreds of hospitals to treat thousands of patients and innovating next-generation devices. The FTC has no evidence beyond baseless speculation to support that false premise, which is reason alone to deny the injunction. *See United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 506 (1974) (rejecting merger challenge that would have left a standalone competitor with "weak coal resources" such that it would be "unable to compete effectively for future contracts").

A. The Transaction will save lives and spur TAVR-AR innovation.

1. JenaValve is a resource-constrained startup, unable to secure FDA approval.

JenaValve has struggled to grow its TAVR-AR business, including—critically—in manufacturing, research and development, and commercialization. FOF II.B.iii; FOF II.A.ii–iii. Today, more than three years after completing its pivotal trial, JenaValve still does not have FDA approval for Trilogy. In fact, in [redacted]—shortly after the FTC claimed approval was "imminent," Compl. ¶ 45—the FDA sent JenaValve a deficiency letter [redacted]. FOF II.A.i. [redacted] FOF II.A.i, FOF IV.A.i.

JenaValve is in no position to turn the tide. It incurred almost [redacted] in 2024 and projects [redacted] in 2025 and 2026, respectively. FOF II.A.ii. Its poor performance has real consequences. JenaValve missed its [redacted] FOF II.A.ii. In the US, JenaValve's problems have left patients in clinical trials waiting months for treatment.

2. Edwards can accelerate Trilogy's approval and commercialize at scale.

Edwards, by contrast, has the crucial resources and engineering expertise JenaValve lacks. *See* FOF II.B.i–iii; FOF II.D.i. Edwards has an immediate plan and has allocated approximately

$100 million—in just year one post-acquisition, with more to follow—to address the serious testing and operational issues preventing Trilogy's FDA approval and to support a full commercial launch. FOF II.B.i–iii. In fact, this litigation has *already* harmed the public interest: JenaValve's Chairman testified that JenaValve could already have passed AWT and received FDA approval if it had been allowed to merge with Edwards last year, given Edwards' extensive AWT testing expertise. FOF II.B.ii. The FTC introduced no evidence that a standalone JenaValve could commercialize Trilogy with anywhere near Edwards' scale, speed, and efficiency.

Seven industry-leading interventional cardiologists and cardiac surgeons[1] testified in support of these procompetitive effects. Not one supported the FTC's theory that the Transaction would reduce innovation and harm patients. Instead, these physicians—including those called by the FTC—testified that they have been forced to delay surgeries for patients in need because JenaValve cannot supply enough devices. *See* FOF II.A.ii. They agreed that Edwards, with its unique focus on structural heart and proven success innovating novel therapies, is best positioned to bring TAVR-AR to American patients quickly and at scale. FOF II.B.iii.

3. Edwards will develop successive generations of TAVR-AR devices.

The FTC also has no credible response to Edwards' long-term plans to use clinical data and physician feedback for SOJOURN and Trilogy to improve and accelerate the development of additional generations of TAVR-AR devices (as Edwards has for its other products). *See* FOF II.D.ii. Edwards plans to develop multiple generations of TAVR-AR using a "toolbox approach" to harness learnings from both TAVR-AR devices, along with Edwards' internal know-how, to construct innovative TAVR-AR solutions, just as it did in developing TAVR-AS. FOF II.D.ii. This

[1] Drs. Vinod Thourani, Torsten Vahl, Dean Kereiakes, James McCabe, Stanley Chetcuti, Duane Pinto, and Mark Turco.

strategy of acquiring and building from multiple devices is common in the med-tech space, FOF I.B.iii, and contrasts starkly with JenaValve's inability to improve Trilogy due to its limited resources. FOF II.A.iii.

As with TAVR-AS, Edwards has every incentive to innovate against the disease in TAVR-AR to expand the treatable patient population, which will boost its revenue and competitiveness. FOF IV.B.i–iv. The FTC offers no evidence in response to this incentive. In fact, the FTC's own FDA expert, Dr. Kesselheim, agreed that TAVR-AS is likely to be a good model for the future of TAVR-AR and acknowledged that Edwards made lifesaving innovations in TAVR-AS even before other competitors began US trials. FOF IV.B.i.

4. The acquisition will likely increase competition by prompting "fast followers."

[redacted] FOF II.C, FOF II.E. Based on its past experience, however, Edwards expects competitors to enter quickly once it proves the TAVR-AR market. FOF II.C. As Edwards' former head of Transcatheter Heart Valves explained: "the one certainty in med-tech is you are going to be obsoleted. You have a choice: either you obsolete yourself or someone else will obsolete you." FOF IV.B.ii. In fact, [redacted] FOF II.C This strategy is common in the med-tech space, *id*., and will foster competition and increase innovation if Edwards is allowed to acquire JenaValve and launch Trilogy at scale.

Overall, rather than address the evidence establishing the Transaction's benefits and the harms of blocking it, the FTC—relying on legal arguments rejected by (among others) the Supreme Court—asks the Court to ignore that evidence. *E.g.*, *Gen. Dynamics*, 415 U.S. at 507–08

(considering the benefits of acquiring a struggling firm is not a failing firm defense); *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054–55 (8th Cir. 1999) (considering benefits regardless of "efficiencies defense").

B. The FTC has failed to show harm in any alleged market.

Ignoring these procompetitive effects, the FTC advances three theories of competitive harm, but fatally fails to tie such harm to a valid market, much less show any harm is *likely* and *substantial*. *In re Google Play Store Antitrust Litig.*, 147 F.4th 917, 935 (9th Cir. 2025) ("[M]arket definition must be relevant to the theory of harm[.]").

1. The FTC fails to show harm to future commercial competition.

No market for commercially approved TAVR-AR devices exists in the US today. The FTC's hypothetical future commercial TAVR-AR theory requires the Court to accept the FTC's speculation that years from now, without the merger: (i) both JenaValve's and Edwards' devices will be FDA-approved *and* concurrently commercially available for some substantial period of time and (ii) no other TAVR-AR device enters during that time. The FTC's speculation fails to satisfy basic principles of Section 7, including in "potential competition" cases.

Whether, or when, either Trilogy or SOJOURN may receive FDA approval is uncertain, FOF II.E, FOF IV.A.i, and the FTC's experts never opined on the likelihood that both will be approved. FOF II.A.i, FOF IV.A.i. Even average FDA-approval rates (likely too optimistic given Trilogy's issues) suggest that the probability of both devices being approved is less than 50%—in other words, the FTC's theory is more likely to be wrong than right. FOF IV.A. These probabilities are undisputed by the FTC and even relied on by Dr. Kesselheim. FOF II.A.i; FOF IV.A.i; *FTC v. Meta Platforms Inc.*, 654 F. Supp. 3d 892, 927 (N.D. Cal. 2023) ("[L]ikelihood [of entry] noticeably greater than fifty percent" required for potential competition claim).

Moreover, the earliest that both Trilogy and SOJOURN could be commercially available in the US is 2029, and Dr. Wilson testified that there would only be an issue if Edwards obtains durable monopoly power, *i.e.*, power lasting two to five years. FOF IV.A.ii, COL I.C.ii Taken together, this means that the harm the FTC purportedly identifies from a commercial overlap would occur, if ever, in 2031 at the earliest. Section 7 does not permit speculation so far into the future. *United States v. Marine Bancorp. Inc.*, 418 U.S. 602, 623 & n.22 (1974) (harm must be imminent to avoid ephemeral possibilities); *Meta*, 654 F. Supp. 3d at 934 (near future).

Finally, the FTC did not account for the likelihood that other competitors may commercialize rival products within two to five years of 2029 (i.e., by 2031–2034). FOF IV.A.ii. As the TAVR-AS experience shows, strategic competitors, like Medtronic, can easily acquire one (or more) of the companies developing TAVR-AR devices to rapidly enter, FOF II.C, or accelerate entry by developing a TAVR-AR project internally, FOF I.B. There is no basis beyond pure speculation to assume a commercial market over four years from now that's limited to Trilogy and SOJOURN for any substantial period of time.

2. The FTC fails to show harm to innovation.

The FTC's innovation theory relies on an artificially narrow market and fails to consider all of Edwards' incentives to innovate. First, the FTC's US-only market definition is gerrymandered to cover only Defendants and ignores that Edwards is driven to innovate by competitive pressure from many international competitors (*infra* I.B.iii) that are routinely tracked by Defendants in competitive assessments. FOF III.A, FOF IV.B.ii.

Second, the FTC myopically focuses only on one incentive: the incentive that comes from developers in US clinical trials. But the Court must consider *all* incentives in determining whether innovation is likely to be lessened substantially. *United States v. Booz Allen Hamilton Inc.*, No. 22-cv-1603, 2022 WL 9976035, *6–9 (D. Md. Oct. 17, 2022). As the evidence shows, Edwards

recognized even before the Transaction that it must "move at best speed" to avoid being overtaken by anticipated competition from the "fast followers" that Edwards saw enter TAVR-AS and other markets. FOF IV.A.ii (describing ordinary course Edwards and JenaValve decks looking at ex-US competition in TAVR-AR). Indeed, strategic competitors are watching the TAVR-AR space for opportunities and tracking companies developing similar products worldwide—before those programs have enrolled in US clinical trials. FOF IV.B.ii.

Finally, the FTC ignores entirely Edwards' powerful incentive to expand TAVR-AR to additional patient populations, allowing Edwards to sell more products. This was the primary growth driver in the early years of TAVR-AS. FOF IV.B.i. Nothing in the record suggests Edwards would delay or stop developing Trilogy or SOJOURN, thereby slowing both the commercialization of a TAVR-AR device and Edwards' ability to harness two differentiated platforms to develop next-generation devices to reach more patients faster than Edwards could alone. FOF II.D.ii, FOF IV.B.iii. Rather than *reduce* innovation, the Transaction brings together parallel R&D streams to accelerate TAVR-AR innovation. FOF II.D.ii.

3. The FTC fails to demonstrate harm in the "pre-market" market.

The FTC's final theory is in a so-called "FDA pre-market market," which even the FTC's own expert agrees is not a commercial market: "the relevant products are still in the pre-commercial stage" where "[i]t is not a priority for [developers] to maximize profits in [clinical] trials." FOF IV.C.i. This "market" fails on its own terms, *see* COL I.C.iv, and the FTC also did not prove likely price or output effects.

First, with respect to price, Dr. Bailey's econometric analysis demonstrates that SOJOURN's entry into clinical trials had no effect on JenaValve's reimbursement rate or trial "pricing." FOF IV.C.i. In other words, the data (accounting for all aspects of price, including rebates) show no price competition between Defendants in the FTC's purported market. The FTC's

economist, Dr. Wilson, did not quantify any pricing effect. FOF IV.A.iii. And the FTC's primary fact witness on the issue testified that Edwards generally charges the same "price" regardless of whether it is the only company running a trial. FOF IV.C.i.

Second, with respect to output, companies in clinical trials are not trying to sell as many devices as they can. As Larry Wood explained with respect to pivotal trials, it's "all about getting your device to a commercial approval . . . you're trying to figure out, what's the minimum number of patients that I need[.]" FOF IV.C.i.

Third, entering the FTC's alleged pre-commercial market of "devices with some form of FDA approval" to conduct clinical trials, 11/18 AM (Pl's Opening) 20:2–16, is straightforward and fast for any developer that has completed some preclinical work. The only requirement for enrolling in a clinical trial is applying for and receiving an Investigational Device Exemption ("IDE"), which the FTC's expert Dr. Kesselheim confirmed can take as little as a month. FOF IV.C.ii. Both Drs. Kesselheim and Wilson conceded that they did not analyze the barriers to receiving an IDE—the purported point of entry into the "pre-market market." *Id.*

Dr. Wilson also conceded that a relevant antitrust market should include not only those companies *already* competing, but also firms positioned to enter within "*two to three years*." COL I.C.iv. Currently, there are at least nine other TAVR-AR devices under development worldwide, many of which have completed preclinical work and in-human studies. FOF III.A, FOF IV.B.ii. Some of these devices have already been commercialized abroad or are enrolled in large clinical trials, and their developers have shown the intent to enter the US clinical trial process (and some already have other devices in US clinical trials). FOF IV.B.ii. These companies, either alone or in partnership with a large strategic like Medtronic or Boston Scientific, can use their nonclinical data

to apply for an IDE and can use ex-US clinical data to *expedite* the FDA approval process, quickly entering the "pre-market market." FOF I.B, FOF IV.B.ii, FOF IV.C.ii.

Clinical trial site participation also is neither rivalrous nor concentrated. Sites often host simultaneous trials. FOF IV.C.i. And there are over 800 sites capable of implanting a TAVR-AR device, only about 5% of which are currently involved in TAVR-AR trials. *Id.* Finally, device manufacturers are prohibited by regulation from taking a profit through clinical trial reimbursement rates. *Id.* Participation in clinical trials is thus not commercial competition in the global race to develop TAVR-AR devices. *Id.*

C. The FTC fails to show anticompetitive effects outweigh procompetitive effects.

Even if the FTC had shown any anticompetitive effects, the FTC fell far short of showing a *substantial* loss of competition outweighing the Transaction's procompetitive effects. *Baker Hughes*, 908 F.2d at 983. Dr. Wilson conceded that he did not estimate the degree of price or non-price harms that will likely result from the Transaction, and the FTC introduced no evidence showing the extent to which pre-Transaction competition between JC Medical and JenaValve resulted in lower prices or increased output or innovation. FOF II.B.iii, FOF IV. Nor did the FTC quantify any alleged increase in price, FOF IV.A.iii, or reduction in output, FOF II.B.iii, or innovation, FOF IV.B.iv, from the Transaction. In short, the FTC provided no basis to find a "substantial" lessening of competition under the Clayton Act. *AT&T*, 916 F.3d at 1032 ("substantial" harm to competition required). Nor did Dr. Wilson attempt to weigh the Transaction's procompetitive effects against the alleged harms, FOF IV, failing to meet the FTC's burden of persuasion. *Baker Hughes*, 908 F.2d at 984.

II. <u>The balance of equities weighs against an injunction.</u>

The FTC has failed to meet its "heavy" burden to show that an injunction is in the public interest after weighing the "harm to the parties and to the public" against any alleged harm to

competition. *F.T.C. v. Occidental Petroleum Corp.*, No. 86-900, 1986 WL 952, at *12–13 (D.D.C. Apr. 29, 1986). At bottom, the evidence showed that Edwards bought a technology no one else wanted (SOJOURN) from a company (JC Medical) that lost its financial backing, and another technology (Trilogy) from a struggling company (JenaValve) that garnered no other serious offer after shopping itself to all available potential buyers. Far from showing these transactions were a plot to destroy competition, the FTC offered only speculation that, in the future, competition *might* be reduced, or innovation *might* be slowed, by some unmeasured amount, and solely on the basis of one of the many incentives pressuring Edwards to innovate while ignoring all of the others. But "antitrust theory and speculation cannot trump facts." *AT &T*, 310 F. Supp. 3d at 190.

The weight on the benefit side of the scale, by contrast, is heavy. Allowing the Transaction to close will save lives, unquestionably serving the public interest. On its own, JenaValve is "[redacted]," with at most [redacted], FOF II.E. It must [redacted], but has attracted no other buyers or significant investors, *id.* An injunction would leave JenaValve struggling to supply devices, uncertain of obtaining FDA approval, and facing, at best, a small-scale launch. *Supra* I.A.i; *see also* FOF II.A.i–ii, FOF II.A.iv, FOF V. Edwards, by contrast, has made TAVR-AR a priority and has the resources to do what JenaValve simply cannot. FOF II.B. Weighed against any allegations of anticompetitive effect, the opportunity for Edwards to resolve JenaValve's issues and bring a lifesaving treatment to thousands of patients holds "paramount importance."[2]

[2] Statement of Chairman Timothy J. Muris in the Matter of Genzyme Corporation/Novazyme Pharmaceuticals, Inc., at 17–20, available at www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./murisgenzymestmt.pdf.

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