UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION,	:	
	:	
Plaintiff,	:	Civil Action No.: 25-2569 (RC)
	:	
v.	:	Re Document Nos.: 1, 104
	:	
EDWARDS LIFESCIENCES CORP., *et al.*,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING PLAINTIFF'S PETITION FOR A PRELIMINARY INJUNCTION

I. INTRODUCTION

Over 100,000 Americans suffer from severe aortic regurgitation ("AR"), a life-threatening disease of the aortic heart valve. Today in the United States, the only treatment that has been approved by the Food and Drug Administration ("FDA") for the treatment of AR is open-heart surgery. In the last several years, however, two medical device companies began clinical trials for a promising new treatment: transcatheter aortic valve replacement ("TAVR") for aortic regurgitation ("TAVR-AR"). The TAVR-AR devices offered by these two companies—JenaValve Technology, Inc. ("JenaValve") and JC Medical, Inc. ("JC Medical")—allow interventional cardiologists to replace a diseased aortic valve through a catheter, without the need for open-heart surgery. Historically, AR patients have benefitted from competition between JenaValve and JC Medical, which has spurred the two companies to accelerate the development of their competing TAVR-AR devices. But over the course of two days in July 2024, another company, Edwards Lifesciences Corporation ("Edwards"), separately and secretly agreed to acquire both JC Medical and JenaValve, the only two companies in the United States with TAVR-AR devices in clinical trials.

Edwards's simultaneous acquisitions of JenaValve and JC Medical caught the two former competitors by surprise. JenaValve's CEO was "totally blindsided" by the news. PX-2162 at 1. Another JenaValve employee remarked, after learning about the two deals, that Edwards had "just bought the AR market." PX-2052 at 2. JenaValve's CEO immediately expressed concerns to Edwards about the deals' antitrust implications, later telling Edwards's Corporate Vice President that if JenaValve had known about the JC Medical acquisition, it "more than likely" would not have agreed to a deal with Edwards. *See* PX-2162 at 1; PX-2373 at 1. Edwards's acquisition of JC Medical has now closed, while its acquisition of JenaValve has been paused for regulatory review.

On August 6, 2025, the Federal Trade Commission ("FTC") voted 3-0 to initiate an administrative proceeding to determine whether the proposed merger between Edwards and JenaValve ("Defendants") would substantially lessen competition or tend to create a monopoly, in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18. On the same day, the FTC filed suit in this Court to halt the merger ("Proposed Transaction") between Defendants. Specifically, under Section 13(b) of the Federal Trade Commission Act, the FTC seeks an order preliminarily enjoining Defendants from consummating the Proposed Transaction pending the resolution of an administrative merits proceeding, which is scheduled to begin on April 8, 2026.

On September 4, 2025, the Court entered a scheduling order providing for expedited discovery and briefing on the FTC's petition for a preliminary injunction. Within a two-month period, the parties reviewed thousands of documents, deposed dozens of witnesses, exchanged expert reports, filed preliminary injunction briefing, and prepared for an evidentiary hearing, which began on November 18, 2025. Over the course of six days, the Court heard live testimony from Defendants, third parties, and several economic and industry experts. The parties then

submitted proposed findings of fact and proposed conclusions of law ("PFOF-PCOL") on December 10, 2025.

Having considered all evidence and testimony in this case, the Court concludes that the FTC has established a likelihood of success on the merits. In particular, because the Proposed Transaction would eliminate the vigorous competition in which Edwards and JenaValve currently engage, there is a reasonable probability that it violates Section 7 of the Clayton Act. The Court further finds that the equities weigh in favor of the FTC. Accordingly, the Court **GRANTS** the FTC's petition for a preliminary injunction.

II. FACTUAL BACKGROUND

A. Aortic Regurgitation and Transcatheter Heart Valves

The aortic valve separates the heart from the aorta, the body's main blood vessel. *See* McCabe Dep. at 21:1–19, PX-7011. It consists of three leaflets that, in healthy individuals, open and close with each heartbeat to allow oxygenated blood to flow out of the heart to every tissue in the body. *See id*. Aortic regurgitation ("AR") is a disease of the aortic valve that is often deadly. In patients with AR, the aortic valve's leaflets fail to fully close after each heartbeat, causing blood to flow back through the valve. *See* FTC's PFOF-PCOL ¶ 17 (citing PX-2327 at 5; PX-6006 at 1; DX-0297 at 1–2), ECF No. 163-1. As a result, the heart is forced to work harder to pump blood throughout the body, and over time, it can weaken irreversibly. Severe symptomatic AR is an advanced form of the disease that afflicts over 100,000 individuals in the United States. *See* Defs.' PFOF-PCOL ¶ 10 (citing Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at

132:18–20), ECF No. 166-1. Nearly one in four patients with severe symptomatic AR[1] will die within one year of diagnosis without treatment. *See id.*

Treatments for AR are limited. In the United States today, the only FDA-approved treatment for AR is open-heart surgery, or surgical aortic valve replacement ("SAVR"). *See* FTC's PFOF-PCOL ¶ 18 (citing PX-6006 at 1; PX-1390 at 1; DX-0297 at 1–2); Defs.' PFOF-PCOL ¶ 11 (citing Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 83:20–84:1). A highly invasive procedure, SAVR requires a physician to surgically open a patient's chest, stop the heart, cut open the aorta, and replace the malfunctioning native valve with a manufactured replacement. *See* FTC's PFOF-PCOL ¶ 18 (citing Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 123:15–23; Kesselheim Rep. ¶¶ 24–25, PX-8000). Although SAVR is an effective option for AR patients who are at low or intermediate surgical risk, it is a poor option for patients at high risk for mortality and complications from surgery. *See id.* ¶ 19 (citing Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 84:4–85:17); Defs.' PFOF-PCOL ¶ 11 (citing Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 85:9–17). Some high-risk AR patients are altogether ineligible for SAVR, and even eligible patients sometimes decline surgical treatment due to fear of open-heart surgery. *See* FTC's PFOF-PCOL ¶ 19 (citing Nov. 21 AM Hr'g Tr. (Vahl) at 66:12–67:3). The lack of nonsurgical alternatives for treating AR leads to nearly 75% of AR patients in the United States going untreated. *See id.* ¶ 20 (citing PX-1010 at 4; PX-1394 at 3).

A new medical technology—transcatheter aortic valve replacement ("TAVR")—promises to improve that statistic. TAVR is a nonsurgical procedure through which a manufactured heart valve is attached to a catheter and guided to the aorta for implantation. *See*

[1] Unless otherwise noted, "AR" henceforth refers to severe symptomatic aortic regurgitation.

id. ¶ 21 (citing Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 127:10–21). TAVR already provides a minimally invasive treatment option for patients suffering from aortic stenosis ("AS"), a different disease of the aortic valve. *See id.*; Defs.' PFOF-PCOL ¶ 2 (citing DX-0288; Nov. 21 AM Hr'g Tr. (Vahl) at 15:7–15). In patients with AS, calcium buildup in the aorta prevents the aortic valve from opening fully, whereas in AR patients, the valve fails to fully close. *See* FTC's PFOF-PCOL ¶ 22 (citing PX-6006 at 1–3). Numerous companies across the world have developed TAVR valves to treat AS, and a handful of them, including Edwards, have obtained commercial approval for their TAVR-AS devices in the United States. *See id.*; Defs.' PFOF-PCOL ¶ 3 (citing Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 120:9–13). TAVR-AS valves are generally ill-suited for treating AR, however, because they rely on calcium buildup around the aorta for proper anchoring, and AR often presents without calcification. *See* Thourani Dep. at 74:9–78:1, PX-7029.

To solve this problem, several companies are developing TAVR devices designed specifically to treat AR, with unique anchoring systems that clip onto the aortic valve's native leaflets and therefore do not require calcification. *See* FTC's PFOF-PCOL ¶ 22 (citing DX-0297 at 3). Although TAVR-AR devices have been approved for commercial use in other jurisdictions, including Europe and China, no TAVR-AR device has yet received commercial approval in the United States. Edwards and JenaValve are currently the only two companies conducting clinical trials for TAVR-AR devices in the United States. *See id.* ¶ 69 (citing Nov. 21 AM Hr'g Tr. (Vahl) at 62:1–23; Nov. 25 AM Hr'g Tr. (Chetcuti) at 40:15–21; Kereiakes Dep. at 29:17–22, PX-7020; PX-6006 at 2).

B. The FDA's Regulatory Approval Process for Medical Devices

To market a medical device in the United States, the device manufacturer must satisfy the requirements of the Food and Drug Administration's ("FDA") regulatory approval process. *See* Kesselheim Rep. ¶¶ 14, 30, 37–40. The FDA categorizes medical devices into three levels of risk. Replacement heart valves, including Edwards's and Jenavalve's TAVR-AR devices, are classified as Class III devices, being those that pose the highest risk to patients. *See* Wilson Rep. ¶ 17, PX-8001; Bailey Rep. ¶ 62, DX-0289. Class III devices require premarket approval ("PMA") prior to commercialization, which is the most stringent review that the FDA can conduct of new medical devices. *See* Kesselheim Rep. ¶ 40. A PMA application must be supported with pre-clinical data, such as from laboratory or *in vivo* animal studies, and clinical data assessing the device's safety and effectiveness in humans. *See id.* For high-risk medical devices, the PMA process takes an average of eight and a half years. *See id.* ¶ 60; Bailey Rep. ¶ 82; Nov. 25 PM Hr'g Tr. (Bailey) at 28:25–29:14.

1. Investigational Device Exemption

Once a manufacturer demonstrates proof of concept for a medical device through pre-clinical studies, the manufacturer's first step to obtaining FDA approval is typically to apply for an Investigational Device Exemption ("IDE"), which permits a new device to be clinically tested in humans. *See* Wilson Rep. ¶ 17; Bailey Rep. ¶ 63. An IDE application generally includes an outline of the proposed clinical study protocol, pre-clinical data, and, if applicable, data from prior clinical studies. *See* Kesselheim Rep. ¶ 45; Nov. 21 PM Hr'g Tr. (Kesselheim) at 44:1–11. The application can include data gathered in other countries. *See* Nov. 21 PM Hr'g Tr. (Kesselheim) at 44:5–19. In fact, any prior clinical studies must have occurred abroad, as the

United States does not allow clinical testing of high-risk medical devices in humans without an IDE. *See id.*

By regulation, the FDA has 30 days to review an IDE application, but it does not have to issue a decision at the end of that period. *See* Kesselheim Rep. ¶ 45. If it has concerns about the application, it can request additional information or changes from the device manufacturer. *See* Kesselheim Reply Rep. ¶ 21, PX-8004; Wood (Edwards) Dep. at 35:1–36:2, PX-7019. The FDA can require multiple rounds of questions and answers with the manufacturer before authorizing an IDE. *See* Kesselheim Rep. ¶ 45. The FDA can also ultimately reject an IDE application if it believes that a medical device's risks to human subjects are not outweighed by the device's anticipated benefits. *See id.*

2. Feasibility Study

If the FDA approves the IDE, the medical device manufacturer can initiate human clinical studies in the United States. *See id.* ¶ 41. For high-risk medical devices, clinical testing typically begins with one or more feasibility studies, which can be early feasibility studies ("EFS") or traditional feasibility studies. *See id.* ¶ 47; McWilliams Rep. ¶¶ 34–35, DX-0288. An EFS allows a manufacturer to test a device that is early in development in small cohorts (sometimes fewer than ten patients) to gather preliminary safety and effectiveness data and identify necessary device modifications. *See* Kesselheim Rep. ¶ 47. A traditional feasibility study, which may or may not be preceded by an EFS, is commonly used to capture clinical data from near-final medical devices. *See id.*

3. Pivotal Trial

After a successful feasibility study, a medical device generally proceeds to a pivotal trial. *See id.* A pivotal trial is a larger, more rigorous study that can involve hundreds or even

thousands of patients. *See* McWilliams Rep. ¶ 35. Data from the pivotal trial will ultimately form the primary basis for FDA approval of the medical device. *See* Nov. 21 PM Hr'g Tr. (Kesselheim) at 19:6–10. Accordingly, the pivotal trial is designed to collect definitive evidence of the device's safety and effectiveness in the specific patient group, or "indication," for which the manufacturer will seek premarket approval. *See id.*; Kesselheim Rep. ¶ 50. For example, a TAVR manufacturer might focus an initial clinical investigation on patients who are at high surgical risk and therefore ineligible for SAVR. If the FDA approves the TAVR device for that indication, the manufacturer might later seek to expand the indications that the device can treat through subsequent pivotal trials.

4. Premarket Approval Application

If the pivotal trial is successful, the device manufacturer proceeds to prepare a PMA application for the FDA's review. The FDA may allow a manufacturer to submit the PMA application in separate sections, or "modules," as each module is completed. *See id.* ¶ 69. The PMA application includes data from the pivotal trial; results from prior feasibility studies and other clinical studies in foreign jurisdictions, as applicable; findings from pre-clinical studies; and detailed information on device design and engineering, the device manufacturing process and quality controls, and proposed labeling for the device. *See id.* ¶ 51; Nov. 21 PM Hr'g Tr. (Kesselheim) at 19:11–20. In reviewing a PMA application, the central question that the FDA must answer is whether the manufacturer's evidence gives a "reasonable assurance" of safety and effectiveness for the device's intended use. *See* Kesselheim Rep. ¶ 52.

Upon receipt of the PMA application, the FDA has 180 days to review it. *See* Kesselheim Rep. ¶ 53. The FDA does not start the clock until it determines that the application is complete, however. *See id.* And if it determines that the PMA application is missing critical

information, it can issue a "deficiency letter," often with the option for the manufacturer to amend and resubmit the PMA application with additional data. *See id.* ¶ 55. A deficiency letter generally conveys at least one major issue and places the PMA application on hold pending the FDA's receipt of additional information from the manufacturer. *See id.* Once a manufacturer corrects any deficiencies identified by the FDA, the FDA can decide to approve the PMA application or approve it with conditions. *See id.* The manufacturer can thereafter market and sell its medical device in the United States for the approved indication. *See id.*

C. The Parties to the Proposed Transaction

1. Edwards Lifesciences Corporation

Edwards, headquartered in Irvine, CA, is a global supplier of medical devices for treating structural heart disease. *See* Defs.' PFOF-PCOL ¶ 1 (citing Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 7:2–8). Founded in 1958, it developed the world's first heart valve soon thereafter. *See* Defs.' PFOF-PCOL ¶ 2 (citing Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 86:10–13). Since then, it has established itself as a leader in structural heart valve technology. Currently, Edwards employs thousands of R&D engineers, hundreds of field technicians, and over 9,000 manufacturing employees. *See id.* ¶ 6 (citing Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 81:5–10; DX-0211 at 6). It also boasts extensive in-house valve-testing resources, multiple engineering research centers, and an expansive field clinical support team. *See id.* ¶¶ 2, 6, 134 (citations omitted).

Edwards has pioneered various surgical and transcatheter therapies for aortic-valve disease. *See id.* ¶ 2 (citing Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 86:10–17). In the early 2000s, it began working on a TAVR therapy for patients suffering from AS, which at that point could be treated only with open-heart surgery. *See id.* To augment its internal program, it

acquired a small, Israeli startup that had developed a TAVR-AS device. *Id.* (citing Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 62:2–63:2). Edwards combined the two companies' R&D workstreams and succeeded in introducing the first commercially available TAVR-AS device in the United States, SAPIEN, which received FDA approval in 2011. *See id.* ¶ 3 (citing Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 63:3–10).

Edwards is currently developing SOJOURN, a TAVR device designed to treat AR. *See id.* ¶ 12; FTC's PFOF-PCOL ¶ 4 (citing PX-1263 at 1; Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 15:12–16:5, 17:4–9). Edwards obtained SOJOURN through its acquisition of JC Medical, a small medical device startup, in July 2024. *See* FTC's PFOF-PCOL ¶ 4 (citing Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 46:12–15). Prior to Edwards's acquisition, JC Medical had received an IDE to begin a pivotal trial in the United States for its TAVR-AR device, J-Valve (which Edwards rebranded as SOJOURN). *See id.* (citing Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 79:8–11, 79:14–20, 80:2–9; PX-1171 at 1; PX-1011 at 6). In October 2024, Edwards launched this pivotal trial (the "JOURNEY trial"), which studies SOJOURN in AR patients who are ineligible for surgical aortic valve replacement or at high surgical risk. *See* Defs.' PFOF-PCOL ¶ 31 (citing Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 17:4–6). As further described below, enrollment for the JOURNEY trial is currently paused, and Edwards anticipates receiving FDA approval for SOJOURN no sooner than 2029. *See id.* (citing Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 19:9–20:25).

2. JenaValve Technology, Inc.

JenaValve, also headquartered in Irvine, CA, is a small medical startup that develops and manufactures TAVR devices. *See* Defs.' PFOF-PCOL ¶ 7 (citing Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 123:16–124:8); Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 151:11–

23). Founded in Germany in 2006, it currently employs about twelve R&D engineers, twelve sales employees, and eight marketing employees. *See* Defs.' PFOF-PCOL ¶ 7.

JenaValve is developing Trilogy, a TAVR device designed to treat AR. Trilogy received commercial approval in Europe in 2021, becoming the first TAVR device in the world approved for the treatment of AR in patients at high surgical risk. *See id.* ¶ 9; McWilliams Rep. ¶ 28 n.36. JenaValve now seeks to commercialize Trilogy in the United States. In 2022, it completed a U.S. pivotal trial for Trilogy (the "ALIGN-AR Trial"), which studied the device in AR patients who were inoperable or at high surgical risk. *See* Defs.' PFOF-PCOL ¶ 18 (citing Nov. 19 PM Hr'g Tr. (Wood (Edwards)) at 79:14–80:6; Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 91:8–17). JenaValve has submitted a PMA application to the FDA and forecasts receiving FDA approval in [redacted]. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 85:3–8. However, as further detailed below, recent developments have injected some uncertainty into this timeline.

D. The Trilogy and SOJOURN Valves

At present, JenaValve's Trilogy device and Edwards's SOJOURN (formerly J-Valve) device are the sole TAVR-AR valves that are undergoing clinical investigation in the United States. *See* PX-6006 at 2–3. These devices share several characteristics. Early in their development, both were implanted transapically, meaning directly into the apex of the heart through an incision in the chest wall. *See* Nov. 20 PM Hr'g Tr. (Pinto (Jenavalve)) at 127:10–128:3; Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 100:13–101:12. Currently, though, both devices feature transfemoral delivery systems, which allow doctors to insert the valves through a small incision in the groin and guide them through the femoral artery up to the heart. *See id.*

Furthermore, the Trilogy and SOJOURN valves are both contained within self-expanding nitinol frames. *See* PX-6006 at 2–3.

Trilogy and SOJOURN differ in other respects, though. Each device has a unique anchoring mechanism that enables attachment to the aortic valve's native leaflets. *See* PX-6006 at 2–3; DX-0297 at 3. Furthermore, Trilogy uses porcine pericardial (pig heart) tissue in its manufactured leaflets, while SOJOURN uses bovine pericardial (cow heart) tissue. *See* PX-6006 at 2–3; DX-0078 at 1, 8. And the valves come in different sizes. The Trilogy system, which uses a "taller, rigid valve," has valve sizes that can treat patients whose aortic annulus—the perimeter of the aortic valve—is between 66 and 90 millimeters. *See* Defs.' PFOF-PCOL ¶ 141 (citing Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 95:12–12); PX-6006 at 2. In contrast, the SOJOURN system, with its "lower profile" valve, offers valve sizes to treat aortic annuli between 57 and 104 millimeters. *See* Defs.' PFOF-PCOL ¶ 142 (citing Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 83:13–17; DX-0078 at 1–2; DX-0160 at 26); PX-6006 at 3.

1. Trilogy's Timeline for FDA Approval

JenaValve began working toward FDA approval for the Trilogy system over a decade ago. In October 2015, the FDA approved JenaValve's initial IDE application, which proposed an early feasibility study using a transapical valve. *See* Kesselheim Rep. ¶ 74; Kilcoyne (JenaValve) Dep. at 66:4–7, PX-7038. Following further development of the Trilogy delivery system, JenaValve submitted an IDE supplement to incorporate a transfemoral approach into its EFS, which the FDA authorized in January 2016. *See* Kesselheim Rep. ¶ 74, PX-8000; Kilcoyne (JenaValve) Dep. at 66:22–67:8. JenaValve later removed the transapical approach due to a lack of physician interest in that option. *See* Kesselheim Rep. ¶ 74; Kilcoyne (JenaValve) Dep. at 67:14–68:6.

In early 2017, JenaValve received a Humanitarian Device Exemption ("HDE") designation for its EFS. *See* Kesselheim Rep. ¶ 75; PX-0043 at 36. This designation, available for devices that treat conditions affecting fewer than 8,000 individuals in the United States, provided JenaValve a less demanding pathway to FDA approval compared to the standard PMA process. *See* Kesselheim Rep. ¶¶ 70, 75; PX-0043 at 036. JenaValve enrolled its first patient in its HDE-designated EFS in 2018. *See* Kesselheim Rep. ¶ 75; PX-2457 at 40. The following year, though, it paused enrollment in the study for six months after a patient died in Europe, where clinical testing was also taking place. *See* PX-0043 at 36. JenaValve eventually submitted an IDE to transition to an HDE-designated pivotal trial, which the FDA approved in May 2020. *See* Kesselheim Rep. ¶ 76; PX-2457 at 40–41. But in early 2021, the FDA revoked JenaValve's HDE designation due to new evidence suggesting a treatable patient population of greater than 8,000 individuals. *See* Kesselheim Rep. ¶ 76. JenaValve thus prepared an IDE outlining a new pivotal trial protocol that would satisfy the standard PMA requirements. *See* PX-0043 at 37.

In July 2021, the FDA approved JenaValve's IDE for a pivotal trial. *See* Kesselheim Rep. ¶ 76. This trial, known as the ALIGN-AR trial, was designed to evaluate Trilogy's safety and effectiveness in AR patients who were at high surgical risk, and required the enrollment of 180 patients. *See id.*; PX-0043 at 37. JenaValve completed enrollment for the ALIGN-AR trial in August 2022. *See* Kesselheim Rep. ¶ 76. Based on its ALIGN-AR trial data, it submitted its first PMA application module in March 2023. *See* PX-0043 at 37.

While review of that PMA application was pending, JenaValve submitted an IDE for an additional pivotal trial—the ARTIST trial—which the FDA authorized in August 2024. *See id.* The ARTIST trial seeks to expand Trilogy's indications to include AR patients who are at low or

intermediate surgical risk. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 136:20–137:6. Enrollment is ongoing for the ARTIST trial, which JenaValve anticipates will involve a thousand patients and last at least eighteen months. *See id.* at 136:24–137:3.

On June 30, 2025, JenaValve made its final PMA submission based on data from its ALIGN-AR pivotal trial. *See* Kesselheim Rep. ¶ 77. However, on September 26, 2025—after the FTC had filed its complaint in this matter—the FDA sent JenaValve a deficiency letter. *See generally* DX-0283. In that letter, the FDA identified [redacted] "significant deficiencies" with JenaValve's PMA application, which the FDA has instructed JenaValve to resolve before review of the PMA application can continue. *See id.* at 1.

Defendants fixate on one of these deficiencies: [redacted]

[2] In addition to the [redacted], the FDA's letter identified [redacted] Nothing in the record suggests that Defendants view [redacted] as significant obstacles to obtaining FDA approval.

In September 2025, however, after JenaValve had made its final PMA submission to the FDA, [redacted] *See* DX-0283 at 1. As JenaValve explained [redacted] *See id.*; Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 117:8–13. [redacted] *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 117:14–19. [redacted] *See* Nov. 19 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 12:1–14.

Although the FDA acknowledged JenaValve's [redacted] in the deficiency letter, it nevertheless requested that JenaValve run a new [redacted] to confirm the [redacted] *See* DX-0283 at 1. John Kilcoyne, JenaValve's CEO, testified that JenaValve is in talks with the FDA to attempt to convince it that a [redacted]—which would take [redacted] to complete—is not needed. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 118:4–5, 119:2–6. If JenaValve succeeds in doing so, Mr. Kilcoyne contemplates receiving FDA approval for Trilogy and launching [redacted] *See id.* at 85:3–8. However, if the FDA holds firm to a new test, and assuming JenaValve passes it, that timeline could get pushed back [redacted]. *See id.* at 119:10–13.

2. SOJOURN's Timeline for FDA Approval

Prior to its acquisition by Edwards in July 2024, JC Medical had developed and received commercial approval in China for a transapical version of its TAVR-AR device, J-Valve, and had begun clinical trials in China for a transfemoral version. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 100:7–12. Following successful commercialization of the transapical J-Valve

system in China, JC Medical looked to obtain FDA approval for the transfemoral version in the United States. JC Medical began transfemoral implants of J-Valve in U.S. patients around 2018 or early 2019. *See id.* at 79:8–11; *See* Kesselheim Rep. ¶ 79. The earliest implantations were under the FDA's compassionate use program, which allows medical device manufacturers to petition the FDA to treat patients with life-threatening conditions even without an IDE. *See* Kesselheim Rep. ¶ 79 & n.170.

In May 2019, JC Medical submitted an IDE to conduct a clinical study with J-Valve. *See* Kesselheim Reply Rep. ¶ 22. The FDA did not approve the IDE, however, but sent JC Medical a deficiency letter. *See id.*; Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 102:3–6. Although JC Medical initially engaged with the FDA regarding the deficiency letter, the company then became "relatively dormant" and failed to resolve the multiple deficiencies identified by the FDA. *See* Kesselheim Reply Rep. ¶ 22; Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 101:18–102:11. Mark Turco, JC Medical's former President and CEO, testified that when he took over JC Medical in May 2023, the company's approach had been to use data from compassionate use cases to attempt to bypass an EFS and proceed directly to a pivotal trial—"which was not something that the FDA took kindly on." *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 102:7–21. Dr. Turco thus redirected JC Medical's focus to correcting J-Valve's deficiencies. *See id.* at 102:22–103:4.

Once JC Medical had addressed these deficiencies, the FDA approved the company's IDE for an EFS in August 2023. *See* Kesselheim Reply Rep. ¶ 22. JC Medical began its EFS in October 2023 and completed enrollment—a total of 15 patients—within six months. *See* Kesselheim Rep. ¶ 80; DX-0078 at 1. JC Medical then submitted an IDE for a pivotal study—the JOURNEY trial—which the FDA authorized in May 2024. *See* Nov. 21 AM Hr'g Tr. (Turco

(JC Medical)) at 80:6–9. The JOURNEY trial aims to assess J-Valve's safety and effectiveness in AR patients who are at high surgical risk. *See* Kesselheim Rep. ¶ 80.

After Edwards acquired JC Medical in mid-2024, it enrolled the first patient in the JOURNEY trial for J-Valve (now rebranded as SOJOURN) in October 2024. *See id.* ¶ 81. Since then, the JOURNEY trial has been paused twice. Edwards first paused patient treatment in May 2025 because the SOJOURN valve [redacted] *See* Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 87:5–88:1; Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 19:5–16. The JOURNEY trial resumed in July 2025, after Edwards developed procedural guidelines to help physicians [redacted] *See* Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 19:20–20:10. Later that month, though, Edwards paused both enrollment and treatment after [redacted] *See id.* at 20:11–25. Edwards attributed [redacted] *See* Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 90:16–91:4; Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 21:12–20. [redacted] *See* Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 22:2–7.

Edwards hopes to resume the JOURNEY trial by the end of [redacted], assuming the FDA provides authorization to do so. *See id.* at 22:8–10. Given these delays, Edwards estimates that under the "best case scenario," it will obtain FDA approval for SOJOURN sometime in 2029. *See* Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 95:2–5; Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 106:12–23.

E. The Proposed Transaction

According to Edwards's CEO, Bernard Zovighian, it is a "top priority" for the company to develop a TAVR technology that can treat AR patients. Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 95:17–20. Over a decade ago, it pioneered and received FDA approval for a TAVR device to treat AS: the SAPIEN valve. Edwards investigated whether SAPIEN could be used to treat AR patients but concluded this would not be feasible. *See* Nov. 19 PM Hr'g Tr. (Wood (Edwards)) at 79:2–13; Zovighian (Edwards) Dep. at 140:8–10, PX-7009. Edwards then looked into developing an internal TAVR-AR valve but abandoned that effort, finding that it "d[idn't] have . . . the capability to do so" within a reasonable timeframe. Zovighian (Edwards) Dep. at 140:1–4. Accordingly, Edwards decided to explore external options. *See id.* at 140:8–10. As detailed below, its negotiations with JenaValve and JC Medical culminated in Edwards agreeing to acquire both companies (the "Proposed Transaction").

1. Negotiations between Edwards and JenaValve

In October 2023, Edwards began negotiations with JenaValve regarding a potential merger after JenaValve presented compelling data on the Trilogy valve from its ALIGN-AR pivotal trial. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 79:14–80:6. Negotiations with JenaValve continued into 2024, as Edwards conducted diligence into JenaValve and the Trilogy system. *See* Defs.' PFOF-PCOL ¶ 18.

During diligence, Edwards identified several product development issues, which it worried would impact JenaValve's capacity to manufacture the Trilogy valve at full commercial scale. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 80:11–15. As Jeremy Bierman, Edwards's Vice President of Strategy and Analytics, testified, JenaValve's cost to produce each valve was "astronomical," and [redacted]. Nov. 20

AM Hr'g Tr. (Bierman (Edwards)) at 102:16–103:15. And JenaValve could not explain the gap between its anemic output and its optimistic future sales projections. *See id.* at 103:16–104:21.

Despite these issues, Edwards believed that it could harness "its TAVR-AS experience and superior resources and capabilities" to improve manufacturing capacity and "provide the best chance to obtain approval for, and successful commercialization of, Trilogy." *See* Defs.' PFOF-PCOL ¶ 21 (citing Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 115:18–116:3). Edwards thus made a purchase offer to JenaValve in January 2024. This offer was short-lived, however. Around that time, JenaValve experienced [redacted], and once it shared this information with Edwards, Edwards "stepped away." *See* Nov. 19 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 7:10–16; Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 132:10–16.

A few months later, Edwards returned to the negotiating table with a second offer that was [redacted]. *See* Nov. 19 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 7:17–22. The second offer included a provision [redacted] *See id.* at 8:24–9:11. Edwards's second offer ultimately became the agreement establishing the Proposed Transaction. *See id.* at 7:23–25.

2. Negotiations between Edwards and JC Medical

In February 2024, while Edwards was in potential merger discussions with JenaValve, Edwards was approached by another small startup—JC Medical—looking to sell its TAVR-AR device. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 80:19–81:6. At that point, JC Medical had completed an EFS for J-Valve and planned to begin a pivotal trial later that year. *See* DX-0078 at 1. As Edwards's former Corporate Vice President of TAVR testified, JC Medical's then CEO, Dr. Turco, called him "out of the blue" to pitch a sale because JC Medical's

Singapore-based parent company, Genesis MedTech ("Genesis"), could no longer afford to pursue FDA approval for J-Valve. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 80:19–81:6; *see also* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 80:13–24. Apparently, Genesis was facing financial pressure from its Board of Directors and had decided to concentrate its resources on JC Medical's operations in China. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 104:16–105:10. Genesis instructed Dr. Turco to shut down JC Medical's U.S. operations by the end of May 2024 if he was unable to secure a buyer or other funding for the company by then. *See id.* at 106:12–22.

After Dr. Turco's initial outreach, Edwards undertook diligence of JC Medical. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 30:11–22. Given FDA skepticism about the accuracy of Chinese product data, Edwards expressed some hesitation about acquiring J-Valve, which was being manufactured in China. *See* Nov. 19 PM Hr'g Tr. (Bobo (Edwards)) at 128:7–129:8. Nevertheless, Edwards ultimately "g[o]t comfortable" with J-Valve's product and clinical data and decided to pursue JC Medical as a potential acquisition candidate alongside JenaValve. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 30:11–31:12. Edwards's Corporate Vice President of Strategy and Corporate Development testified that the "tipping point" for Edwards was that J-Valve's larger valve size offerings allowed it to treat about 30 percent more patients compared to JenaValve's Trilogy, which would be "valuable to [Edwards's] broader AR strategy." *See id.* at 31:12–33:8.

In early negotiations with Edwards, Dr. Turco and Genesis floated purchase prices for JC Medical between $100 million and $150 million. *See* Nov. 19 PM Hr'g Tr. (Bobo (Edwards)) at 131:5–15. In April 2024, Edwards sent JC Medical a term sheet offering $115 million upfront for the acquisition. *See* Nov. 21 AM Tr. (Turco (JC Medical)) at 84:11–18, 92:21–24.

Significantly, the FTC argues, this number was just below an important reporting threshold in U.S. antitrust law. Under the Hart-Scott-Rodino Antitrust Improvements Act ("HSR Act"), proposed transactions then valued above $119.5 million had to be reported to the FTC and the Department of Justice prior to closing for antitrust review. *See id.* at 91:14–20; Nov. 19 PM Hr'g Tr. (Bobo (Edwards)) at 135:16–18. During negotiations, Edwards had apparently raised an "H[SR] concern" with Dr. Turco, which Dr. Turco concluded was "real," judging from the FTC's recent "anti M&A" bent. PX-1039 at 1. But Dr. Turco was not fully satisfied with Edwards's below-HSR Act offer, which was $10 to $35 million dollars lower than Genesis's valuation of JC Medical. *See id.*; Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 92:16–93:6. Dr. Turco thus proposed to Genesis that "[if] the HSR component [wa]s a no-go for the deal structure," Edwards could close the valuation gap by making a separate investment in Genesis. *See* PX-1039 at 1; Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 93:3–23. As detailed below, Edwards and JC Medical did, in fact, end up agreeing to this proposal.

3. Edwards's Simultaneous Acquisitions of JenaValve and JC Medical

On July 23, 2024, Edwards and JenaValve signed an agreement and plan of merger, whereby Edwards agreed to acquire JenaValve for approximately $945 million. *See* Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 46:19–21; PX-6002 at 41. The agreement provides for an aggregate cash purchase price of $500 million and up to an additional $445 million upon achievement of certain regulatory and sales milestones. *See* PX-6002 at 41. Edwards reported this agreement in its Form 10-Q filing to the U.S. Securities and Exchange Commission, noting its plan to acquire "JenaValve Technology, Inc., a developer of a catheter-based system to treat patients suffering from aortic regurgitation." *See id.*

Just one day before, on July 22, Edwards agreed to acquire JC Medical. *See* Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 46:12–15. The acquisition closed for a purchase price of $115 million. *See* PX-6002 at 42. Edwards also reported this agreement in its 10-Q filing, but it did not mention JC Medical by name, referring to it as "an early-stage medical device company that is developing a catheter-based system to treat patients suffering from a valvular disease." *See id*. Edwards also invested $25 million in Genesis, but it did not disclose this investment in the 10-Q filing. *See* Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 49:23–50:9. And Edwards did not make an HSR filing prior to acquiring JC Medical. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 94:19–21.

Edwards's acquisition of JC Medical caught JenaValve by surprise. Bernard Zovighian, Edwards's CEO, testified that for competitive reasons—namely, to avoid disrupting the JenaValve acquisition—Edwards did not want JenaValve to find out about the JC Medical acquisition before the deal with JenaValve had closed. *See* Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 48:25–49:9. When Edwards issued a press release announcing the JenaValve acquisition on July 24, it did not disclose the simultaneous JC Medical acquisition. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 30:20–23. Jan Keltjens, JenaValve's Chairman of the Board, learned of the JC Medical acquisition later that day from a screenshot of an internal Edwards announcement, which he believed to be "fake news" at first. *See* PX-2198 at 2. JenaValve's CEO was similarly "blindsided" by the acquisition, which was "never discussed, intimated or socialized" in Edwards's negotiations with JenaValve. *See* PX-2162 at 1.

III. LEGAL STANDARD

A. Clayton Act

Section 7 of the Clayton Act prohibits a merger between two companies "where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such [merger] may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18; *see also United States v. Anthem, Inc.* (*"Anthem II"*), 855 F.3d 345, 349 (D.C. Cir. 2017). "Congress has empowered the FTC, *inter alia*, to weed out those mergers whose effect 'may be substantially to lessen competition' from those that enhance competition." *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 713 (D.C. Cir. 2001). "The United States has the ultimate burden of proving a Section 7 violation by a preponderance of the evidence." *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 49 (D.D.C. 2011) (quoting *United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 180 (D.D.C. 2001)).

To establish a Section 7 violation, the United States "must show that a pending [merger] is reasonably likely to cause anticompetitive effects." *Id.* (quoting *Sungard*, 172 F. Supp. 2d at 180). In drafting this statute, "Congress used the words '*may* be substantially to lessen competition' (emphasis supplied), to indicate that its concern was with probabilities, not certainties." *Heinz*, 246 F.3d at 713 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)). Although certainty of anticompetitive harm is not required, Section 7 nevertheless demands that the United States "demonstrate that the substantial lessening of competition will be 'sufficiently probable and imminent' to warrant relief." *United States v. AT&T Inc.*, 310 F. Supp. 3d 161, 189 (D.D.C. 2018) (quoting *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004)).

In assessing a Section 7 case, "the Court must undertake a 'comprehensive inquiry' into the 'future competitive conditions in a given market.'" *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 18 (D.D.C. 2017) (quoting *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 988 (D.C. Cir. 1990)). This inquiry "requires determinations of (1) the relevant product market in which to assess the transaction, (2) the geographic market in which to assess the transaction, and (3) the transaction's probable effect on competition in the relevant product and geographic markets." *Arch Coal*, 329 F. Supp. 2d at 117 (citing *United States v. Marine Bancorp.*, 418 U.S. 602, 618–23 (1974); *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 510–11 (1974)).

B. Federal Trade Commission Act

"Congress has empowered the Federal Trade Commission to seek preliminary injunctive relief preventing parties from consummating a merger until the FTC has had an opportunity to adjudicate the merger's legality." *Arch Coal*, 329 F. Supp. 2d at 115. Section 13(b) of the Federal Trade Commission Act ("FTC Act") provides for the grant of a preliminary injunction "[u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest." 15 U.S.C. § 53(b)(2). In enacting Section 13(b), Congress "demonstrated its concern that injunctive relief be broadly available to the FTC by incorporating a unique 'public interest' standard . . . rather than the more stringent, traditional 'equity' standard for injunctive relief." *FTC v. Exxon Corp.*, 636 F.2d 1336, 1343 (D.C. Cir. 1980). Accordingly, to obtain a preliminary injunction under Section 13(b), "the FTC need not show any irreparable harm," as required under the traditional standard, and "the 'private equities' alone cannot override the FTC's showing of likelihood of success." *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1034–35 (D.C. Cir. 2008) (quoting *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1082–83 (D.C. Cir. 1981)).

"In deciding the FTC's request for a preliminary injunction blocking a merger under [Section 13(b)], a district court must balance the likelihood of the FTC's success against the equities, under a sliding scale." *Id.* at 1035. Because Congress's specific "public equity consideration" in enacting Section 13(b) was "the public interest in effective enforcement of antitrust laws," *id.* (quoting *Heinz*, 246 F.3d at 726), "a showing of likely success on the merits will presumptively warrant an injunction," *Arch Coal*, 329 F. Supp. 2d at 116. Nevertheless, "the merging parties may rebut that presumption, requiring the FTC to demonstrate a greater likelihood of success, by showing equities weighing in favor of the merger." *Whole Foods*, 548 F.3d at 1035.

In any event, in a Section 13(b) preliminary injunction proceeding, the FTC "is not required to prove, nor is the court required to find, that the proposed merger would in fact violate Section 7 of the Clayton Act." *Arch Coal*, 329 F. Supp. 2d at 115–16 (quoting *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1070 (D.D.C. 1997)); *see also FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976) ("The district court is not authorized to determine whether the antitrust laws have been or are about to be violated. That adjudicatory function is vested in the FTC in the first instance."). All that is required is a "reasonable probability" that the proposed merger violates Section 7. *Arch Coal*, 329 F. Supp. 2d at 116 (quoting *Staples*, 970 F. Supp. at 1072). In other words, the FTC need only show, based on a "predictive judgment," that there is an "appreciable danger" of "future coordinated interaction" between the merging parties. *Id.* (quoting *Heinz*, 246 F.3d at 719). Nevertheless, the district court may not simply "rubber-stamp an injunction whenever the FTC provides some threshold evidence," but must "evaluate the FTC's chance of success on the basis of all the evidence before it, from the defendants as well as from the FTC." *Whole Foods*, 548 F.3d at 1035.

IV. ANALYSIS

A. Likelihood of Success on the Merits

To determine whether the FTC is entitled to a preliminary injunction under Section 13(b) of the FTC Act, the Court must gauge the probability that, at the administrative merits proceeding, the FTC will be able to prove that the effect of the Proposed Transaction "may be substantially to lessen competition, or to tend to create a monopoly" in violation of Section 7 of the Clayton Act. 15 U.S.C. § 18. The standard for likelihood of success on the merits is met if the FTC "has raised questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance." *Heinz*, 246 F.3d at 714–15 (quoting *FTC v. Beatrice Foods Co.*, 587 F.2d 1225, 1229 (D.C. Cir. 1978)); *see also Whole Foods*, 548 F.3d at 1035.

Courts apply a burden-shifting framework to determine whether a proposed merger violates the Clayton Act. *See Baker Hughes*, 908 F.2d at 991. Under this framework, the FTC "must first establish its prima facie case by (1) identifying the relevant product and geographic market and (2) showing that the proposed merger is likely to 'substantially lessen competition' in that market." *AT&T*, 310 F. Supp. 3d at 191 (quoting *Baker Hughes*, 908 F.2d at 982). If the FTC successfully does so, the defendants can rebut the prima facie case by "provid[ing] sufficient evidence that the prima facie case 'inaccurately predicts the [merger's] probable effect on future competition'" or by "sufficiently discredit[ing]" the FTC's evidence. *Anthem II*, 855 F.3d at 349 (quoting *Baker Hughes*, 908 F.2d at 991). If the FTC's prima facie case is rebutted, "the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 983. In practice, courts apply this burden-shifting framework

flexibly, often considering evidence all at once and analyzing the burdens together. *See Illumina, Inc. v. FTC*, 88 F.4th 1036, 1048 (5th Cir. 2023).

Below, the Court first considers the relevant market in which to assess the likely effects of the Proposed Transaction, which it concludes is the market for the research, development, and commercialization of TAVR-AR devices in the United States. Next, the Court assesses whether the Proposed Transaction is likely to substantially lessen competition in that market, in violation of Section 7 of the Clayton Act. It finds that Edwards and JenaValve are currently engaged in active competition to develop superior TAVR-AR valves and bring their respective valves to market as quickly as possible, and that because the Proposed Transaction would eliminate this competition, there is a "reasonable probability" that it violates Section 7. *Arch Coal*, 329 F. Supp. 2d at 116 (quoting *Staples*, 970 F. Supp. at 1072). Although Defendants dispute this finding by arguing, among other things, that the Proposed Transaction would benefit consumers, the Court determines that Defendants have not rebutted the FTC's prima facie case. Accordingly, the Court finds that the FTC has met its burden of showing a likelihood of success on the merits.

1. The Relevant Antitrust Market

"The FTC's initial burden is to define a relevant market in which the proposed acquisition is likely to harm competition." *FTC v. IQVIA Holdings Inc.*, 710 F. Supp. 3d 329, 352 (S.D.N.Y. 2024); *see also United States v. Bertelsmann SE & Co. KGaA*, 646 F. Supp. 3d 1, 23 (D.D.C. 2022) ("The first step in merger analysis is the identification of a relevant market."). "Defining the relevant market is a 'necessary predicate' to finding a Clayton Act violation because the proposed merger 'must be one which will substantially lessen competition within the

area of effective competition.'" *FTC v. RAG-Stiftung*, 436 F. Supp. 3d 278, 291 (D.D.C. 2020) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957)).

A relevant antitrust market comprises two parts. First, the "relevant product market" is the universe of products "with which the defendants' products compete." *Arch Coal*, 329 F. Supp. 2d at 119. Second, the "relevant geographic market" refers to the geographic area in which the defendants compete to sell their products. *See id.* Defining the product and geographic markets helps courts ascertain the "locus of competition." *Bertelsmann*, 646 F. Supp. 3d at 24. Ultimately, this is "a pragmatic, factual" analysis, rather than a "formal, legalistic one." *Id.* (quoting *Brown Shoe*, 370 U.S. at 336).

The FTC argues that the relevant market in this case encompasses the research, development, and commercialization of TAVR-AR devices in the United States. *See* FTC's PFOF-PCOL ¶¶ 36–63. In its view, Defendants' ordinary course documents and third-party testimony demonstrate that the "locus of competition," FTC's Prelim. Inj. Mot. at 14 (quoting *Bertelsmann*, 646 F. Supp. 3d at 24), ECF No. 104-1, is "among TAVR-AR device companies that are pursuing FDA approval in the United States and have begun implanting valves in patients in FDA-approved clinical trials," *id*. The FTC further contends that its proposed product and geographic markets find support in the economic analysis and testimony of its economic expert, Dr. Nathan Wilson. *See* FTC's PFOF-PCOL ¶ 56.

Defendants, on the other hand, urge the Court to reject the FTC's "novel, pre-commercial market" because no TAVR-AR device is currently approved for commercial sale in the United States. Defs.' PFOF-PCOL ¶ 281. Furthermore, Defendants allege that the FTC's proposed market is "gerrymandered" to ensure that only Edwards and JenaValve can be considered market participants. *Id.* ¶¶ 167, 280. For example, Defendants argue that the FTC's product market

unjustifiably excludes alternative AR treatment options that could reasonably be said to compete with TAVR-AR devices. They also maintain that the "competitive landscape" includes "*all* TAVR-AR devices," including those that are in development and clinical studies outside of the United States. *Id.* ¶ 178. Defendants offer the economic analysis and testimony of their own economic expert, Dr. Elizabeth Bailey, in support of their proposed market. *See id.* ¶¶ 173–76.

The Court is persuaded by the FTC's proposed market. In the sections that follow, the Court examines the relevant product and geographic markets, and finally considers whether a pre-commercial product market is cognizable under Section 7.

a. The Relevant Product Market

A relevant product market's "outer boundaries" are "determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325. "[I]nterchangeability of use" and "cross-elasticity of demand" refer to the extent to which "there are other products offered to consumers which are similar in character or use" to the product in question. *Staples*, 970 F. Supp. at 1074. In other words, courts look at "whether two products can be used for the same purpose, and if so, whether and to what extent purchasers are willing to substitute one for the other." *Id.* (quoting *Hayden Pub. Co. v. Cox Broadcasting Corp.*, 730 F.2d 64, 70 n.8 (2d Cir. 1984)). If two products are sufficiently similar and reasonably interchangeable, they can be considered part of the same product market. *See Buccaneer Energy (USA) Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1313 (10th Cir. 2017).

"Courts generally consider two categories of evidence when defining the relevant product market: the 'practical indicia' identified by the Supreme Court in *Brown Shoe Company v. United States*, 370 U.S. 294 (1962), and quantitative evidence from expert economists," which

"typically comes in the form of an expert economist conducting a 'hypothetical monopolist test.'" *United States v. Google LLC*, 747 F. Supp. 3d 1, 108–09 (D.D.C. 2024) (quoting *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 33 (D.D.C. 2015)). The Court considers each category of evidence in turn. Then, it addresses Defendants' challenge to the FTC's "novel, pre-commercial" product market. Defs.' PFOF-PCOL ¶¶ 281–84.

i. *Brown Shoe* Factors

In *Brown Shoe*, the Supreme Court set forth "practical indicia" for defining a relevant product market. 370 U.S. at 325. These factors include "the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors," as well as "industry or public recognition" of the market. *Id.*; *see also Whole Foods*, 548 F.3d at 1037–38. "All the factors need not be satisfied for the Court to conclude that the FTC has identified a relevant market." *IQVIA*, 710 F. Supp. 3d at 355; *see also Staples*, 970 F. Supp. at 1075 ("Since the Court described these factors as 'practical indicia' rather than requirements, subsequent cases have found that submarkets can exist even if only some of these factors are present."). The FTC argues that several of the *Brown Shoe* factors—specifically, peculiar characteristics and uses, distinct customers, distinct pricing, and industry recognition—establish TAVR-AR devices as the relevant product market. *See* FTC's PFOF-PCOL ¶ 49.

Peculiar Characteristics and Uses

As the FTC argues, ample evidence shows that features specific to TAVR-AR devices distinguish them from other methods of treating AR. Alternative AR treatments include medical management, the "off-label" use of TAVR-AS devices, and SAVR. *See, e.g.*, PX-2327 at 6. But medical management, or the use of pharmaceuticals, is not an effective therapy because it

temporarily treats AR symptoms but not the disease. *See* PX-0033 at 6. TAVR-AS devices, meanwhile, have been used "off-label" to treat AR, but often with poor outcomes. Because AS-specific TAVR devices require calcium buildup in the aorta to attach to the aortic valve, they are ill-suited to treating AR patients, who often have little aortic calcification. *See* Thourani Dep. at 74:9–78:1. If anchoring fails, a TAVR-AS valve can dislodge—a potentially fatal complication called embolization. *See* Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 86:9–11. In contrast, AR-specific TAVR devices are designed with unique anchoring mechanisms that clip onto the aortic valve's native leaflets—a feature that lowers the risk of embolization. *See* PX-6006 at 2-3; DX-0297 at 3, 12.

SAVR, meanwhile, is an invasive surgical procedure to replace the malfunctioning native aortic valve with a manufactured replacement. *See* Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 123:15–23; Kesselheim Rep. ¶¶ 24–25. Defendants do not dispute that SAVR is a poor option for AR patients who are inoperable or at high risk for surgery. PX-0033 at 6; *see also* Defs.' PFOF-PCOL ¶ 11. AR patients at high surgical risk amount to over a third of the total addressable AR population in the United States. *See* Wilson Rep. ¶ 46 & n.96. Defendants nevertheless suggest that for patients at low to medium surgical risk, SAVR is a "tried and true" treatment for AR and thus competes with TAVR-AR among this patient indication. Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 142:4–142:6; *see also* Defs.' PFOF-PCOL ¶ 168. The Court agrees that SAVR is an effective AR treatment for patients at low to medium surgical risk. *See, e.g.*, PX-6006 at 1. Furthermore, Defendants' internal documents show that TAVR developers expect that, at least in the near term, SAVR will outcompete TAVR-AR as the preferred AR treatment among patients at low to medium surgical risk. *See, e.g.*, PX-1394 at 3; PX-1049 at 7.

But although SAVR is effective for AR patients at low to medium surgical risk, Defendants have not established that SAVR and TAVR-AR are so "similar in character or use" that these patients would be "willing to substitute one for the other." *Staples*, 970 F. Supp. at 1074 (citation modified). To the contrary, testimony from interventional cardiologists indicates that, for many of these patients, SAVR and TAVR are not interchangeable. As Dr. Dean Kereiakes explained, patients who undergo TAVR procedures typically "go home the next day and can function normally within a week," whereas with SAVR, the "recovery is more prolonged" and "possibly more painful." Kereiakes Dep. at 9:24–10:12. Moreover, Dr. Torsten Vahl testified that in his own practice, he has had AR patients decline SAVR despite being at low to medium surgical risk. *See* Nov. 21 AM Hr'g Tr. (Vahl) at 66:20–67:3. It is easy to understand why: when faced with the prospect of their "chest being cracked open and their heart being stopped," "a lot of patients just [refuse] intervention." Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 129:18–130:5.

Even if TAVR-AR differs from non-transcatheter AR treatment options, Defendants argue that the FTC improperly excludes other transcatheter treatment options—namely, transapical TAVR-AR devices[3]—from its proposed market. *See* Defs.' PFOF-PCOL ¶¶ 171–72.

[3] Defendants additionally argue that the FTC improperly excludes transcatheter valve *repair* devices. *See* Defs.' PFOF-PCOL ¶ 172. In contrast to transcatheter aortic valve replacement ("TAVR") devices, which replace the native aortic valve with a bio-prosthetic valve, transcatheter valve repair devices "modify the native valve" to "restore heart function." Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 110:4–10. Little evidence regarding repair devices was presented at the hearing. One non-U.S. company—Cuspa Medical—appears to have developed a repair device, Cusper. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 13:19–14:1. Although Cusper is a transcatheter device that aims to treat AR, *see* Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 110:11–14, JenaValve's CEO testified that Cusper has a "different design" than TAVR-AR devices and that the FDA-approved indication for Cusper would be different from that of a TAVR-AR device in that Cusper would treat AR patients "that need[] repair versus replacement," *see* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 14:3–24. This suggests to the Court that Cusper has different characteristics, uses, and customers than

The FTC's expert, Dr. Wilson, distinguishes between transapical and transfemoral TAVR-AR devices because transapical access is "invasive," requiring incisions in the chest and heart for implantation, while transfemoral access requires only a small incision in the groin. *See* Wilson Rep. ¶ 27. Defendants reject this distinction, noting that both types of devices are definitionally TAVR-AR devices, even if the access points for implantation differ. *See* Defs.' PFOF-PCOL ¶¶ 171, 279; Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 136:20–137:20. That difference does not strike the Court as insignificant, however. At the evidentiary hearing, the Court heard testimony that compared to transfemoral access, transapical access is not only more invasive—often requiring a rib-spreading procedure—but is also associated with longer recoveries and worse patient outcomes. *See, e.g.*, Nov. 21 AM Hr'g Tr. (Vahl) at 61:5–25; Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 6:23–7:3. Such differences suggest that transfemoral and transapical TAVR-AR devices are not interchangeable. *See* Nov. 18 AM Hr'g Tr. (FTC Opening Statement) at 22:19–23.

Distinct Customers

The FTC also asserts that TAVR-AR devices have distinct customers: AR patients and the interventional cardiologists who treat them via TAVR. *See* FTC's PFOF-PCOL ¶ 54. As Dr. Wilson explained, in the medical device market, there are multiple actors whose preferences influence the purchase and consumption of products, including physicians, who decide which devices to implant, and the patients who benefit from them. *See* Wilson Rep. ¶¶ 14–15.

TAVR-AR devices. Furthermore, Cusper does not appear to be available in the United States. Edwards's Vice President of Strategy testified that although Cuspa has announced plans to begin a U.S. pivotal study, those plans have been delayed. *See* Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 110:15–25. For these reasons, the Court declines to include Cusper in the relevant market.

The Court finds that at minimum, the FTC has shown that AR patients who are inoperable or at high surgical risk constitute a distinct customer base for transfemoral TAVR-AR devices, which, in contrast to SAVR and transapical TAVR-AR devices, do not require invasive surgical intervention. For this reason, interventional cardiologists who treat this patient indication also prefer transfemoral TAVR-AR devices. As JenaValve's CEO testified, physicians are "not really" interested in transapical devices because of their invasive delivery systems, "longer recovery times," and "worse outcomes." *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 8:17–9:15.

Nevertheless, to the extent that the FTC suggests that the entire population of U.S. patients with severe symptomatic AR constitutes a distinct customer base for transfemoral TAVR-AR devices, *see* FTC's PFOF-PCOL ¶ 54 (citing PX-1078 at 50), the Court finds this proposition insufficiently supported. Although the parties agree there is a subset of AR patients at low to medium surgical risk who would refuse invasive surgical treatments, the FTC has not established that this is the case for all or a significant number of AR patients. As noted, Defendants reasonably expect that SAVR will remain a "tried and true" AR treatment, at least in the near term. *See* Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 142:4–142:6; PX-1394 at 3; PX-1049 at 7.

Distinct Prices

Given "the absence of competitive pressure from non-TAVR-AR products," the FTC argues that "Defendants have adopted distinct pricing strategies for their TAVR-AR devices." FTC's PFOF-PCOL ¶ 55. Because Defendants' TAVR-AR devices are still undergoing clinical testing, FDA regulations prevent Defendants from charging prices greater than necessary to recover manufacturing and R&D costs. *See* Bailey Rep. ¶¶ 62, 63 (citing 21 C.F.R. § 812.7).

Once commercialized, though, the devices can be sold for a profit. As the FTC notes, Defendants' ordinary course documents suggest an intent to sell the Trilogy and SOJOURN valves at "premium" prices after receiving FDA commercial approval. *See, e.g.*, PX-2326 at 6; PX-1453 at 5. [redacted] *See* PX-2326 at 6; PX-1453 at 5. Furthermore, JenaValve contemplated [redacted] once it obtained FDA approval, as Trilogy would be "the only device for the treatment of aortic regurgitation in the United States" and the market could bear the higher price. Kilcoyne (JenaValve) Dep. at 196:16–197:11, PX-7007; *see also* Nov. 18 AM. Hr'g Tr. (Kilcoyne (JenaValve)) at 93:24–94:6; PX-2303 at 15.

As Defendants note, though, the FTC offered no comparative pricing evidence for SAVR valves, transapical TAVR-AR valves, or even other transfemoral TAVR-AR valves in clinical testing outside of the United States. *See* Defs.' PFOF-PCOL ¶ 182. The Court agrees that such evidence would have bolstered the FTC's case. Nevertheless, Defendants' contemplated pricing strategies assume the absence of competitive pressure from non-TAVR-AR products, as the FTC asserts. *See* FTC's PFOF-PCOL ¶ 55. In light of such evidence, the Court is comfortable with the prediction that commercialized transfemoral TAVR-AR devices in the United States will be priced differently at least from non-TAVR products.

Industry Recognition

The FTC next argues that the medical device industry recognizes TAVR-AR devices as a distinct market. *See* FTC's PFOF-PCOL ¶¶ 50–51. The Court concurs. As indicated by Defendants' ordinary course documents and testimony, medical device companies view TAVR-

AR as distinct from other methods of treating AR. For Edwards, TAVR-AR is the "next frontier of aortic valve disease." *See* PX-1394 at 5 (citation modified). In corporate presentations, JenaValve referred to AR as an "untapped market," and Edwards pitched TAVR-AR as an opportunity to expand into that market. *See id.* at 3; PX-2327 at 8. JenaValve's CEO confirmed that no "front-line therapy" exists today for AR patients at high surgical risk. Nov. 18 AM Hr'g Tr. (Kilcoyne) at 84:8–86:15; *see also* PX-0033 at 6. Edwards, JenaValve, and JC Medical agree that TAVR-AR will fill this treatment gap. *See, e.g.*, PX-1394 at 3; PX-2327 at 8; PX-1049 at 7. As Edwards wrote in a strategy presentation during deal negotiations, "a dedicated AR product is needed for a unique patient population." PX-1445 at 57 (citation modified).

Furthermore, there is evidence that medical device companies do not believe it would be viable to enter the U.S. market with a transapical TAVR-AR device. In early 2025, JenaValve's CEO commented that the approval in China of Ken-Valve, a TAVR-AR device developed by Jenscare, a Chinese competitor, was "[n]ot a real concern" given that the device is transapical. PX-1292 at 1. Later that year, at the annual Transcatheter Cardiovascular Therapeutics ("TCT") medical conference, Jenscare announced that it is developing a transfemoral TAVR-AR valve. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 121:3–122:17. According to JC Medical's former CEO, this development indicates that Jenscare "realize[s] [it] can't enter the United States market with a transapical product." *Id.* at 122:8–17.

Interventional cardiologists who perform TAVR-AR procedures also distinguish transfemoral TAVR-AR devices from other AR treatments. Dr. Torsten Vahl, Dr. Dean Kereiakes, and Dr. James McCabe testified that the off-label use of TAVR-AS to treat AR does not provide acceptable clinical outcomes for patients. *See* Nov. 21 AM Hr'g Tr. (Vahl) at 59:5–18; Kereiakes Dep. at 59:9–60:10; McCabe Dep. at 29:14–30:2, 30:17–33:4. According to an

article Dr. Vahl co-authored, "suboptimal results with off-label TAVR" have "fueled the development" of TAVR-AR, a unique technology "with design features that address the specific needs of valve implantation" in AR patients. PX-6006 at 2. Dr. Vahl further explained that although SAVR is currently the "gold standard treatment" for AR patients, a "treatment gap remains for patients at high surgical risk due to the unavailability of less invasive treatment options." PX-6006 at 1. "[T]he need for a less invasive option for these patients has become increasingly important," he wrote. *Id.*

* * *

The totality of evidence suggests that transfemoral TAVR-AR devices differ from other AR treatment options in their peculiar characteristics and uses, customers, and prices, and that the medical device industry distinguishes transfemoral TAVR-AR devices from all other AR treatments. The evidence is strongest with respect to peculiar characteristics and uses. Transfemoral TAVR-AR devices are effective at treating AR and minimally invasive, both of which are not the case for medical management, off-label TAVR-AS, SAVR, and transapical TAVR-AR devices. As a result, only transfemoral TAVR-AR devices are viable options for AR patients at high surgical risk. And although SAVR and transapical TAVR-AR devices can treat AR patients at lower surgical risk—a customer base that is thus shared with transfemoral TAVR-AR devices—the Court does not believe this one factor warrants including SAVR and transapical TAVR-AR devices in the relevant product market. As noted, industry participants recognize that a treatment gap exists among lower risk AR patients due to the unavailability of less invasive treatment options, which transfemoral TAVR-AR is expected to fill. Defendants additionally believe that U.S. market preferences favor the entry of transfemoral TAVR-AR

devices specifically. The Court therefore concludes that the *Brown Shoe* factors support recognition of transfemoral TAVR-AR devices as the relevant product market.

ii. Hypothetical Monopolist Test

In addition to using the *Brown Shoe* factors, courts can conduct an economic analysis known as the hypothetical monopolist test ("HMT") to determine whether a relevant product market is valid. *See, e.g.*, *H&R Block*, 833 F. Supp. 2d at 51–52. The HMT imagines a scenario in which all products in a candidate product market are controlled and sold by a monopolist. *See id.* It then asks whether, under that scenario, the hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price ("SSNIP"), typically five percent, on one of the merging parties' products. *See id.* If so, the merging parties' products constitute a relevant market. *See id.*

As a "common quantitative metric" used to determine the relevant product market, the HMT typically relies on quantitative data. *FTC v. Microsoft Corp.*, 681 F. Supp. 3d 1069, 1086 n.5 (N.D. Cal. 2023); *see also Google*, 747 F. Supp. at 109. Nevertheless, the Merger Guidelines issued by the Department of Justice and the FTC endorse the use of both qualitative and quantitative data in undertaking the HMT. *See U.S. Dep't of Justice & Fed. Trade Comm'n Merger Guidelines* § 4.3.C (2023) ("Merger Guidelines"). In any event, "[t]here is no legal requirement that a plaintiff supply quantitative proof to define a relevant market." *Google*, 747 F. Supp. 3d at 109. Neither is there a "requirement to use any specific methodology" to do so. *FTC v. Tempur Sealy Int'l, Inc.*, 768 F. Supp. 3d 787, 825 (S.D. Tex. 2025) (quoting *Optronic Techs., Inc. v. Ningbo Sunny Elec. Co.*, 20 F.4th 466, 482 (9th Cir. 2021)). "As such, courts have determined the relevant antitrust markets using, for example, only the *Brown Shoe* factors, or a combination of the *Brown Shoe* factors and the HMT." *Id.* at 825–26 (citation modified).

The FTC's economic expert in this matter, Dr. Wilson, conducted the HMT to determine the appropriate product market. *See* Wilson Rep. ¶¶ 43-50. Dr. Wilson first imagined a market composed of all "TAVR-AR devices available for implantation and use by American consumers" and controlled by a single firm. *See* Nov. 24 AM Hr'g Tr. (Wilson) at 23:3–17. He then considered whether patients and physicians would choose alternative forms of treatment for AR in response to a SSNIP imposed on one of those products. *See* Wilson Rep. ¶ 45. Specifically, he analyzed three alternative forms of treatment laid out in a JenaValve corporate presentation: medical management, SAVR, and off-label TAVR-AS. *See id.* ¶ 46 & n.93 (citing PX-0033 at 6); Nov. 24 AM Hr'g Tr. (Wilson) at 23:18–25. Relying on available evidence, including testimony from physicians and Defendants' ordinary course documents, Dr. Wilson determined that none of these options are adequate therapeutic alternatives for AR patients at high surgical risk. *See* Wilson Rep. ¶ 46. Accordingly, he found that "few, if any, physicians, especially those who treat high surgical risk AR patients, would choose to forego all TAVR-AR options in response to a SSNIP," and that a monopolist could therefore profitably impose a SSNIP on at least one TAVR-AR product. *Id.* ¶ 50. Because his candidate market passed the HMT, Dr. Wilson ultimately concluded that the relevant market here includes "only TAVR-AR products that can be supplied to American consumers." *See* Nov. 24 AM Hr'g Tr. (Wilson) at 22:25–23:2.

Defendants reject Dr. Wilson's HMT on several grounds. Their principal criticism hinges on Dr. Wilson's failure to "conduct any quantitative analysis." Defs.' PFOF-PCOL ¶ 291. The Court recognizes that the HMT typically involves quantitative analysis. Although this does not appear to be a strict requirement, *see, e.g.*, Merger Guidelines § 4.3.C, the Court is unaware of any case endorsing an HMT conducted entirely or predominantly with qualitative

data. Still, the Court takes Dr. Wilson's point that "in matters such as this one, where the relevant products are still in the pre-commercial stage," there is little quantitative data available on customer preferences or economic margins with which to conduct the HMT. Wilson Rep. ¶ 42. In other cases where quantitative data was unavailable, courts have deemed it reasonable for plaintiffs to forego an HMT and instead depend on qualitative analysis to define a relevant market. *See, e.g.*, *Google*, 747 F. Supp. 3d at 109.

In this case, the Court does not view the lack of quantitative data as fatal to Dr. Wilson's analysis, which, although presented in the form of an HMT, resembles the sort of qualitative analyses that courts frequently rely on to define relevant markets. *See FTC v. Tapestry, Inc.*, 755 F. Supp. 3d 386, 414 (S.D.N.Y. 2024) ("Hard data concerning cross-elasticity is not the only means of proving a relevant market." (citation omitted)); *McWane, Inc. v. FTC*, 783 F.3d 814, 829 (11th Cir. 2015). As Dr. Wilson notes, "[t]he inability to conduct econometric analysis does not prohibit the application of economic logic" to predict whether participants of a candidate market would turn to alternatives in response to a SSNIP. Wilson Rep. ¶ 42. Indeed, Dr. Wilson eliminated several potential AR treatment alternatives from his candidate market based on much of the same qualitative data that the Court relied on in conducting the *Brown Shoe* factor analysis above. And his conclusion that patients and physicians would *not* turn to these alternatives in response to a SSNIP is supported by the record. Dr. Kereiakes, for example, testified that he would "[n]ot willingly" switch to off-label TAVR-AS if the price of TAVR-AR valves increased by five to ten percent. Kereiakes Dep. at 61:6–9.

Defendants also criticize Dr. Wilson's assumption that the TAVR-AR devices in his candidate market are priced at their "profit-maximizing level." Wilson Rep. ¶ 41 n.82; *see also* Defs.' PFOF-PCOL ¶ 292. They note that the HMT asks "whether a hypothetical *profit-*

maximizing firm, not subject to price regulation, that was the only present and future seller" of a product could profitably raise prices, yet Dr. Wilson acknowledged in his report that for products in clinical trials, "it is not a priority for the firm to maximize profits." *See* Wilson Rep. ¶ 116; Defs.' PFOF-PCOL ¶ 292. But the Court is not persuaded that Dr. Wilson's assumption renders his analysis unusable. As a former Edwards executive testified, although the cost of clinical research "far exceeds" the revenue Edwards receives from selling a valve to clinical trial sites, Edwards determines the sales price of a valve in the clinical stage by approximating its expected commercial price. Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 60:3–9.

In any event, the Court is not relying on Dr. Wilson's analysis to model Defendants' behavior at the clinical stage, but to predict—based on economic logic, not mathematical precision—whether patients and doctors are likely to switch to alternative treatments in response to a SSNIP on a TAVR-AR valve. The Court agrees with Dr. Wilson that patients and physicians are unlikely to switch to medical management, SAVR, and off-label TAVR-AS in response to a SSNIP on TAVR-AR devices, and that these treatment options should therefore be excluded from the relevant product market. Dr. Wilson did not, however, analyze whether a SSNIP on transfemoral TAVR-AR devices specifically would cause patients and physicians to switch to transapical TAVR-AR devices, if available. The Court therefore does not rely on Dr. Wilson's economic analysis to conclude that the relevant product market is limited to transfemoral TAVR-AR devices.

iii. Pre-Commercial Product Markets

Defendants further challenge the FTC's proposed product market because no TAVR-AR device is currently approved for commercial sale in the United States. Defs.' PFOF-PCOL ¶ 281. A market including future commercialized TAVR-AR devices is too speculative,

Defendants argue, because "it is unclear when or even if there ever will be" an FDA-approved device. *Id.* Defendants warn that if this Court endorses the FTC's "novel" product market—which presently includes only pre-commercial TAVR-AR devices—the Court would be the first ever to do so. *Id.* ¶ 284.

Although the Court is unaware of a case recognizing a mixed market for the research, development, and commercialization of a product that is not yet commercially available, this may be because no court has yet had to consider this scenario. *See* Nov. 25 AM Hr'g Tr. (McWilliams) at 105:9–13 (testimony by Defendants' industry expert that he could not think of "a single example in U.S. history where a company had bought the two medical devices furthest along in the FDA approval pipeline"). In any event, courts, economists, and the Merger Guidelines do recognize that a relevant antitrust market can include products still in clinical development. The Merger Guidelines, for example, provide that "where a merger may substantially lessen competition by decreasing incentives to innovate, the Agencies may define relevant antitrust markets around the products that would result from that innovation if successful, even if those products do not yet exist." Merger Guidelines § 4.3.D.7.[4]

Not all mergers that eliminate competition decrease firms' incentives to innovate. *See* Wilson Rep. ¶ 88. Nevertheless, the Court agrees with the FTC's expert, Dr. Wilson, that characteristics specific to the Proposed Transaction here would decrease Edwards's incentives to innovate. Most significantly, ample evidence suggests that Edwards's SOJOURN and JenaValve's Trilogy valves are close substitutes and will compete among similar patient indications. *See id.* ¶ 74. If Edwards owns both products, it will have "less incentive to incur

[4] Although the Merger Guidelines are not binding on this Court, the D.C. Circuit and other courts have relied on them for guidance in merger cases. *See Sysco*, 113 F. Supp. 3d at 38 (citing *Heinz*, 246 F.3d at 716 n.9; *H&R Block*, 833 F. Supp. 2d at 52 n.10).

costs to develop products that will compete with each other." *Id.* ¶ 89. Accordingly, the Court finds it prudent to include TAVR-AR devices in the relevant product market, even if no device has yet received commercial approval.

This approach finds support in a recent Fifth Circuit decision, *Illumina, Inc. v. FTC*, 88 F.4th 1036 (5th Cir. 2023). In *Illumina*, the Fifth Circuit held that the FTC alleged a viable antitrust market for cancer-detection tests, including both firms in clinical trials and firms with commercialized products. *Id.* at 1049–52. The challenged transaction there involved Illumina, a manufacturer of DNA-sequencing technology, who sought to acquire Grail, a company with the only cancer-detection test available in the market. *Id.* at 1044. Grail and its competitors—whose cancer-detection tests were in development—relied on Illumina's DNA-sequencing technology for their products. *Id.* The FTC argued that, because of the acquisition, Illumina would be incentivized to withhold its technology from Grail's competitors. *Id.* at 1045. In validating the FTC's proposed market—framed as one for the research, development, and commercialization of cancer-detection tests, rather than the "*existing* commercial market" for these tests—the Fifth Circuit observed that although Grail had the most advanced test, there was "ongoing competition to bring additional products to market." *Id.* at 1049–50. To exclude products in development from the relevant market, the Fifth Circuit explained, would "prevent research-and-development [R&D] markets from ever being recognized for antitrust purposes." *Id.* at 1050.

Defendants argue that *Illumina* is inapposite because there, unlike here, the challenged transaction was a vertical merger in which the merging firms' products were already commercially available. *See* Defs.' PFOF-PCOL ¶ 283. The Court disagrees. Although the Proposed Transaction here is a horizontal merger, economic literature recognizes that the merger of firms with competing products can harm competition and innovation. *See* Wilson Rep. ¶¶ 88–

92. Furthermore, the FTC does not simply allege that "some company, someday may innovate a competing product," which, as the Fifth Circuit noted, would be too speculative to ground an antitrust market. *Illumina*, 88 F.4th at 1050. As in *Illumina*, evidence here shows that "there is indisputably ongoing competition" between Edwards and JenaValve, that Defendants' TAVR-AR devices have been clinically validated, and that both devices are expected to go to market in the next few years. *Id.* After a thorough investigation, the FTC has found reason to believe that the Proposed Transaction would harm competition and innovation in both the development and commercialization of TAVR-AR devices. *See* Compl. ¶ 28, ECF No. 1. The FTC should not be expected to wait until one of those devices is commercialized to bring its current challenge. As the Fifth Circuit found in *Illumina*, insulating R&D markets from antitrust review "would directly contravene the purpose of Section 7—'to arrest anticompetitive tendencies in their incipiency.'" *Illumina*, 88 F.4th at 1050 (quoting *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 362 (1963)).

b. The Relevant Geographic Market

The relevant geographic market encompasses "the area to which consumers can practically turn for alternative sources of the product and in which the antitrust defendants face competition." *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 49 (D.D.C. 1998) (citation modified). Like the product market, the relevant geographic market need not be identified with "scientific precision," but must correspond to the "commercial realities" of the medical device industry. *Id.* at 43, 49 (first quoting *Brown Shoe*, 370 U.S. at 336; and then quoting *United States v. Connecticut Nat'l Bank*, 418 U.S. 656, 669 (1974)).

The Court finds that the relevant geographic market is the United States. As the FTC notes, the FDA is the "gatekeeper" for high-risk medical devices in the United States, including

TAVR-AR devices. *See* FTC's PFOF-PCOL ¶ 59. TAVR-AR valves cannot be used in U.S. clinical trials without FDA authorization. *See* Nov. 24 AM Hr'g Tr. (Wilson) at 26:2–27:5; Kesselheim Rep. ¶¶ 14, 79 n.170. And they cannot be marketed or sold in the United States without premarket approval, which entails a rigorous review by the FDA to ensure a "reasonable assurance" of safety and effectiveness for the device's intended use. *See* Kesselheim Rep. ¶ 52.

Although Defendants do not dispute that FDA authorization is required to implant TAVR-AR valves in the United States, they nevertheless contend that the area of effective competition is global, encompassing "all TAVR-AR devices, no matter where they are currently being developed and no matter the stage of development." Defs.' PFOF-PCOL ¶ 301. In Defendants' view, competitor TAVR-AR devices could enter the U.S. market from abroad and "easily" catch up to Trilogy and J-Valve. *See* Defs.' Opp'n to FTC's Prelim. Inj. Mot. at 31–32, ECF No. 115-1. Just like Edwards acquired JC Medical, which developed J-Valve in China, Defendants argue that another U.S. medical device company—such as Medtronic, Boston Scientific, or Abbott Laboratories—could purchase a foreign device and pursue FDA approval for it in the United States. *See* Defs.' PFOF-PCOL ¶ 301. Alternatively, a foreign competitor developing a device abroad could itself bring the device to the United States and seek FDA approval, much like JenaValve, originally a German company, did with Trilogy. *See id.*

Despite Defendants' suggestions to the contrary, the parties' expert reports and testimony demonstrate that the FDA's premarket approval process is a significant barrier to entry for competitors seeking to commercialize a foreign TAVR-AR device in the United States. If a TAVR developer sought to begin implanting a TAVR-AR device developed or tested abroad in U.S. patients, the "most common" first step would be for it to apply for an investigational device exemption from the FDA to launch a feasibility study. *See* Wood (Edwards) Dep. at 33:17–34:5;

Nov. 21 PM Hr'g Tr. (Kesselheim) at 44:5–19. Although a developer could also submit compassionate use requests on a patient-by-patient basis, the FDA does "not . . . t[ake] kindly on" using this approach to attempt to bypass the normal premarket approval process. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 102:11–21. Defendants submit that the process to obtain an IDE for an early feasibility study ("EFS") is "quite easy." Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 95:12–18. It is true, as the FTC's FDA regulatory expert explained, that an IDE application for an EFS can be based on less pre-clinical data than one for a traditional feasibility study. *See* Kesselheim Rep. ¶ 47. But a foreign TAVR-AR device cannot skip the pre-clinical stage entirely, even if it has already undergone pre-clinical testing abroad. *See* Nov. 21 AM Hr'g Tr. (Vahl) at 26:12–27:7 (noting that, at minimum, the FDA requires 150-day data from pre-clinical studies in the United States).

After a successful feasibility study, the TAVR developer would need to apply for an IDE to begin a U.S. pivotal trial, which would allow it to gather required clinical data for an eventual premarket approval application. *See* Wood (Edwards) Dep. at 39:10–14. Even if a TAVR-AR device has previously undergone clinical testing outside of the United States, the parties agree that U.S. clinical data is all but required to obtain premarket approval. This is because the FDA is "very skeptical of data of high-risk devices that comes from outside the United States," as such data "might not be generalizable to U.S. patients." Nov. 21 PM Hr'g Tr. (Kesselheim) at 34:2–17; *see also* Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 32:10–16 (noting that JenaValve's PMA application is based only on U.S. patient data because "the FDA is reluctant to accept European data").

Given the FDA's rigorous regulatory review process, the Court agrees with the FTC that patients and doctors cannot "practically turn" to TAVR-AR devices outside of the United States

as alternatives to Defendants' products, whether in compassionate use cases, clinical testing, or, eventually, the commercial market. *See* FTC's Prelim. Inj. Mot. at 19; Wilson Rep. ¶ 51; *Cardinal Health*, 12 F. Supp. 2d at 49. Consistent with these limitations, Defendants' ordinary course documents distinguish between TAVR-AR devices on the path toward commercialization in the United States and all other TAVR-AR devices. For example, a slide from an internal Edwards presentation tracking the "AR TAVR" space shows that only JenaValve and JC Medical are on the path to FDA approval, while slides assessing "other AR TAVR players" note that none are undergoing U.S. clinical studies. PX-1267 at 6–9; *see also* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 48:1–52:9.

Other evidence shows that this distinction generally pervades U.S. TAVR developers' strategic planning and behavior in the TAVR-AR space. An internal JC Medical presentation evaluating "USA TAVR-AR Case Volumes and [JC Medical] Revenue Projections" assumes that JenaValve and JC Medical will have 100% of market share through 2035. PX-1049 at 10; *see also* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 73:16–75:10. Gilbert Madrid, CEO of LagunaTech—a U.S. medical device company that has clinically tested a TAVR-AR device in Chile—testified that he monitors Trilogy and J-Valve but is not aware of other TAVR-AR devices being developed outside of the United States. *See* Madrid Designation at 40:12–20. JenaValve, meanwhile, considered it important to undertake "messaging and engagement" regarding JC Medical's J-Valve with hospitals deciding whether to implant a commercialized Trilogy valve or a J-Valve in clinical development. Kilcoyne (JenaValve) Dep. at 73:11–74:16. JenaValve did not contemplate similar outreach related to other TAVR-AR devices in development. As JenaValve's CEO explained, doing so "would not make sense" because "no

other product is in a clinical trial in the geographies that we are engaged in." *Id.* at 78:12–19. "The other companies are irrelevant," he added, "because they're not in our universe." *Id.*

Considering the foregoing record, the Court is not persuaded that other TAVR developers whose TAVR-AR devices are not on the path toward FDA approval serve as effective competitive constraints for developers of TAVR-AR devices in the United States. The Court therefore concludes that the relevant geographic market is the United States.

2. Effects of the Proposed Transaction

Having now determined the relevant antitrust market—the research, development, and commercialization of TAVR-AR devices in the United States—the Court proceeds to assess the likely effects of the Proposed Transaction on competition within that market. As noted, Section 7 of the Clayton Act prohibits mergers whose effect "may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. To prove its entitlement to a preliminary injunction in this Section 13(b) proceeding, the FTC is not required to prove that the Proposed Transaction "would in fact violate Section 7," but "need only show that there is a 'reasonable probability'" that it does so. *Arch Coal*, 329 F. Supp. 2d at 116 (quoting *Staples*, 970 F. Supp. at 1070, 1072); *see also Whole Foods*, 548 F.3d at 1036 ("[A]t this preliminary phase [the FTC] just has to raise substantial doubts about a transaction.").

As the FTC notes, JenaValve and Edwards are currently the only competitors in the relevant market because their respective TAVR-AR devices, Trilogy and SOJOURN, are the only two TAVR-AR devices that are on the path to obtaining FDA premarket approval. According to the FTC, the Proposed Transaction, which would merge Edwards and JenaValve, violates Section 7 of the Clayton Act in three ways. First, the FTC argues that the Proposed Transaction violates Section 7 because, by allowing Edwards to acquire its only competitor, it

"tend[s] to create a monopoly." *See* FTC's PFOF-PCOL ¶ 64 (quoting 15 U.S.C. § 18); *see also id.* ¶¶ 65–77. Second, the FTC asserts that, by consolidating all current participants in the TAVR-AR market, the Proposed Transaction results in market shares and concentrations that are "so inherently likely to lessen competition" as to be presumptively unlawful. *Philadelphia Nat'l Bank*, 374 U.S. at 363; *see also* FTC's PFOF-PCOL ¶¶ 78–85. Third, the FTC maintains that the Proposed Transaction is likely to substantially lessen competition, in violation of Section 7, because it will eliminate substantial head-to-head competition between Edwards and JenaValve. *See* FTC's PFOF-PCOL ¶¶ 86–139.

The Court will focus on the FTC's second and third arguments. Although there is some support in mid-20th century Supreme Court decisions for the FTC's first argument—that the "nontrivial acquisition of a competitor" alone suffices to establish a Section 7 violation, regardless of its effect on competition, *see Hosp. Corp. of Am. v. FTC*, 807 F.2d 1381, 1385 (7th Cir. 1986) (collecting cases)—the Supreme Court has since "cast doubt on the continued vitality of such cases" by emphasizing "that the economic concept of competition, rather than any desire to preserve rivals as such, is the lodestar that shall guide the contemporary application of the antitrust laws," *see id.* at 1386. Regardless, as set forth below, the Court finds that the FTC has met its prima facie burden of showing a "reasonable probability" that an effect of the Proposed Transaction "may be substantially to lessen competition." *Arch Coal*, 329 F. Supp. 2d at 116 (quoting *Staples*, 970 F. Supp. at 1072); 15 U.S.C. § 18. Specifically, the Court is convinced by the FTC's third argument—that the Proposed Transaction will likely eliminate the vigorous competition in which Edwards and JenaValve currently engage. Below, the Court briefly discusses the FTC's second argument before turning to the third.

a. Presumption of Illegality

The FTC's second argument is that because the Proposed Transaction seeks to combine the only two participants in the U.S. TAVR-AR market, the "resulting market share and concentration entails a presumption that the merger is illegal." FTC's PFOF-PCOL ¶ 78. In *Philadelphia National Bank*, the Supreme Court held that "a merger which produces a firm controlling an undue percentage share of the relevant market, and results in a significant increase in the concentration of firms in that market is so inherently likely to lessen competition substantially that it must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects." 374 U.S. at 363. Applying *Philadelphia National Bank*, courts examining horizontal merger cases have held the FTC can establish a presumption of illegality by putting forward statistics "showing that the proposed transaction . . . will lead to undue concentration [of firms] in the [relevant] market." *Staples*, 970 F. Supp. at 1083.

Courts commonly employ the Herfindahl-Hirschman Index ("HHI")—a tool that measures changes in market concentration—to evaluate the anticompetitive effects of a contemplated merger. *IQVIA*, 710 F. Supp. 3d at 377; *see also Anthem II*, 855 F.3d at 349. The HHI is calculated as the sum of the squares of each market participant's share of the relevant market. *See, e.g.*, *Tapestry*, 755 F. Supp. 3d at 458. "By squaring individual firms' market shares, the HHI takes into account the relative size and distribution of the firms in a market, increasing both as the number of firms in the market decreases and as the disparity in size among those firms increases." *Id.* (citation modified). An HHI close to zero indicates a competitively structured market, while an HHI of 10,000 reflects a perfect monopoly. *See id.* Under the Merger Guidelines, a merger is presumed anticompetitive if it increases the HHI by more than

100 points and results in a post-merger HHI exceeding 1,800. *See id.* at 458–59; Merger Guidelines § 2.1.

The FTC maintains that the Proposed Transaction is presumptively illegal because it will dramatically increase concentration in the U.S. TAVR-AR device market. *See* FTC's PFOF-PCOL ¶ 85. The FTC's economic expert, Dr. Wilson, reached this conclusion by calculating HHIs for the Proposed Transaction based on two metrics: the number of U.S. clinical trial sites enrolled in Edwards's and JenaValve's respective clinical trials and the number of TAVR-AR devices implanted by each company. *See* Wilson Rep. ¶¶ 61–65. According to Dr. Wilson's calculations, after the Proposed Transaction, the HHI based on clinical trial sites would increase from 5,356 to 10,000, as Edwards would be taking over all JenaValve sites, and the HHI based on units implanted would increase from 8,063 to 10,000, as Edwards would be implanting both the Trilogy and SOJOURN devices. *See id.* Regardless of metric, the FTC asserts that the HHIs demonstrate an "undue concentration" in the U.S. TAVR-AR market. *See Staples*, 970 F. Supp. at 1083; *see also* FTC's PFOF-PCOL ¶ 85.

Defendants challenge the FTC's attempt to use a "short cut"—the *Philadelphia National Bank* presumption—to establish its prima facie case. Defs.' PFOF-PCOL ¶ 266. Although a presumption of anticompetitive effect might properly be applied in a commercial market from which market shares can be calculated, Defendants caution that no court has ever applied this presumption in an "innovation market" encompassing competitors in the research and development ("R&D") of a *future* product. *See* Defs.' Opp'n at 4; Michael L. Katz & Howard A. Shelanski, *Mergers and Innovation*, 74 Antitrust L.J. 1, 4–5 (2007). As Defendants urge, the Court should decline the FTC's invitation to apply this presumption here because neither JenaValve nor Edwards has been authorized to market and sell their TAVR-AR devices,

meaning "there are no real market shares." Defs.' PFOF-PCOL ¶ 267. Defendants further contend that in an innovation market, "the fact that a merger combines two previously independent R&D streams tells the Court nothing about whether such combination will enhance or diminish innovation." *Id.*

Given that the FTC's proposed market currently includes only pre-commercial products, the Court is not convinced that the FTC should be entitled to a presumption of illegality simply based on market share and concentration statistics. In establishing this presumption, the *Philadelphia National Bank* Court reasoned that it comported with economic theory showing that in commercial markets, "competition is likely to be greatest when there are many sellers, none of which has any significant market share." 374 U.S. at 363 (citation modified); *see also* Katz & Shelanski, *supra*, at 2 ("[W]hen producers face rivalry, they seek to attract customers through lower prices and higher quality."). But the FTC has not shown that this presumption typically holds in innovation markets. Indeed, as Defendants note, the FTC once took the position that "a general causal relationship between innovation and competition" had not been established in such markets. Fed. Trade Comm'n, 1 Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace ch. 7, at 16 (1996), https://www.ftc.gov/system/files/documents/reports/anticipating-21st-century-competition-policy-new-high-tech-global-marketplace/gc_v1.pdf [https://perma.cc/69EP-DMR7]. A former FTC Chairman even warned that "[f]ar from serving to protect consumer interests," applying the presumption in innovation markets would "routinely block[] mergers likely to accelerate innovation." Statement of Chairman Muris at 23, *In re Genzyme Corp.*, No. 021-0026 (F.T.C. Jan. 13, 2004), https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-

inc./murisgenzymestmt.pdf [https://perma.cc/8NNR-RLN5]; *see also* Katz & Shelanski, *supra*, at 5 ("[M]arket consolidation may in fact help to speed innovation by bringing complementary assets together."). *But see* Dissenting Statement of Commissioner Thompson at 3, *In re Genzyme Corp.*, No. 021-0026 (F.T.C. Jan. 13, 2004) ("I see no compelling reason why innovation mergers should be exempt from . . . the presumption of anticompetitive effects."), https://www.ftc.gov/system/files/attachments/press-releases/ftc-closes-its-investigation-genzyme-corporations-2001-acquisition-novazyme-pharmaceuticals-inc./thompsongenzymestmt.pdf [https://perma.cc/66D5-T5QZ]. Given the FTC's inconsistent views on the issue—and considering the strength of the FTC's other evidence establishing the Proposed Transaction's anticompetitive effects, detailed below—the Court deems it unnecessary to decide whether Dr. Wilson's market share and concentration evidence entitles the FTC to a presumption of illegality.

b. Elimination of Head-to-Head Competition

If the FTC is not entitled to a general presumption of illegality, it must instead "make a fact-specific showing that the proposed merger is likely to be anticompetitive." *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019) (citation modified). "The Supreme Court has adopted a totality-of-the-circumstances approach to [Section 7], weighing a variety of factors to determine the effects of particular transactions on competition." *Baker Hughes*, 908 F.2d at 984. Only "examination of the particular market—its structure, history and probable future—can provide the appropriate setting for judging the probable anticompetitive effect of the merger." *Gen. Dynamics*, 415 U.S. at 498 (quoting *Brown Shoe*, 370 U.S. at 322 n.38); *see also Arch Coal*, 329 F. Supp. 2d at 116 ("[A]ntitrust theory and speculation cannot trump facts . . . .").

The FTC maintains that Edwards and JenaValve "vigorously compete" in the market for TAVR-AR devices in the United States and that the elimination of direct competition between them is likely to harm consumers in that market, which include patients and physicians. *See* FTC's PFOF-PCOL ¶¶ 54, 86, 88. Indeed, courts have "recognized that a merger that eliminates head-to-head competition between close competitors can result in a substantial lessening of competition." *Sysco*, 113 F. Supp. 3d at 61. The effects that result directly from the elimination of competition between the merging parties are referred to as "unilateral effects." *See Bertelsmann*, 646 F. Supp. 3d at 39; *United States v. Anthem, Inc.* (*"Anthem I"*), 236 F. Supp. 3d 171, 216 (D.D.C. 2017). "The most obvious example of this phenomenon is a 'merger to monopoly'—*e.g.*, where a market has only two firms, which then merge into one." *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559, 569 (6th Cir. 2014) (quoting Merger Guidelines § 6).

The Court concurs with the FTC that the Proposed Transactions is likely to have extensive anticompetitive effects. First, Edwards and JenaValve are currently the only two competitors in the TAVR-AR market in the United States. Second, substantial evidence demonstrates that Edwards and JenaValve vigorously compete in that market. Third, the Proposed Transaction is likely to lessen that competition substantially.

i. Edwards and JenaValve Are the Only Competitors in the Relevant Market

Prior to Edwards's acquisition of JC Medical, JenaValve and JC Medical viewed each other as their closest competitors in the relevant market: TAVR-AR devices on the path toward FDA approval in the United States. JenaValve was the first TAVR developer to clinically test a TAVR-AR valve in the United States, completing enrollment of its ALIGN-AR pivotal trial for the Trilogy device in 2022. *See* Kesselheim Rep. ¶ 76. In 2023, Dr. Mark Turco became CEO of JC Medical and oversaw the company's receipt of an IDE to begin an EFS for its J-Valve

device. *See* Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 102:7–103:8; Kesselheim Reply Rep. ¶ 22. After JC Medical launched its EFS in late 2023, Dr. Turco commented, referencing the Trilogy valve, that JC Medical had an "opportunity to close the gap and be a very fast follower with a likely better valve," given J-Valve's superior "ease of use," among other advantages. PX-1038 at 1. In an internal presentation earlier that year, JC Medical referred to JenaValve as "[o]ur closest competitor" in the U.S. TAVR-AR market. PX-1037 at 16. JenaValve similarly viewed JC Medical as its "main competitor." PX-3057 at 2. JenaValve's CEO testified that as of the 2023 Cardiovascular Research Technologies ("CRT") conference, JenaValve took JC Medical seriously, as JC Medical "presented reasonably good data, [was] well capitalized, and . . . selected several strong [principal investigators]" to lead its EFS. Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 96:25–98:13.

Additionally, several Edwards executives testified that, if the Proposed Transaction is blocked, its SOJOURN valve (formerly J-Valve) would be competing with JenaValve's Trilogy valve. *See, e.g.*, Nov. 19 Hr'g PM Tr. (Zovighian (Edwards)) at 78:18–79:5. Edwards's CEO, Mr. Zovighian, testified that Edwards would need a strategy update if the FTC prevails in its merger challenge, as JenaValve would then become Edwards's competitor. *See id.* at 79:6–13; PX-1437 at 1. As part of that strategy update, Mr. Zovighian contemplated "[h]ow to make JC [Medical] the first and best," as well as how to "further slow down" JenaValve, including by limiting Edwards's provision of knowledge and funds to JenaValve beyond what is contractually required under the parties' Merger Agreement. PX-1437 at 1; *see also* Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 78:21–79:5. JenaValve, meanwhile, demanded a "firewall" blocking Edwards's access to JenaValve information once it found out about Edwards's acquisition of JC Medical. Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 112:2–7. An Edwards executive

observed that it was "fair enough" for JenaValve to make this demand, as "the deal hasn't closed and we have a competing AR technology." *Id.* at 112:12–113:16. Defendants' industry expert, Dennis McWilliams, agreed that for Edwards, "JenaValve's Trilogy device is the closest competitor for U.S. TAVR-AR." Nov. 25 AM Hr'g Tr. (McWilliams) at 107:8–11.

Although Defendants concede that the SOJOURN and Trilogy valves are close competitors, they insist that Edwards views other TAVR-AR devices as "potential innovation competitors," regardless of location or development stage. Defs.' PFOF-PCOL ¶ 300. As explained in Section IV.A.1.b, however, the FDA's regulatory approval process for high-risk medical devices is a significant barrier to entry for TAVR-AR valves in development abroad. Furthermore, although Defendants track the development of TAVR-AR valves in other countries, and other TAVR developers have published clinical trial data from abroad and presented at U.S. conferences, Defendants are generally unaware whether TAVR developers outside of the United States have concrete and imminent plans to initiate U.S. clinical trials. Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 16:6–18:4. The Court considers that Defendants' ordinary course documents and testimony more strongly suggest that other TAVR developers outside of the United States are not viewed as serious competitors. *See, e.g.*, PX-1048 at 20; Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 96:25–99:17.

In the United States, it is clear that Edwards and JenaValve are not only the closest competitors, but currently, the only two competitors in the TAVR-AR space. Defendants acknowledge that SOJOURN and Trilogy are the only two TAVR-AR devices in clinical trials in the United States and the only two to have been implanted in patients in the United States. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (Jenavalve)) at 18:7–15; Nov. 19 AM Hr'g Tr. (Wood

(Edwards)) at 32:2–8. Leading physicians—including Defendants' witnesses—agree. *See, e.g.*, Nov. 21 AM Hr'g Tr. (Vahl) at 62:1–23.

Other than Defendants, LagunaTech is the only TAVR-AR developer that is based in the United States. *See* FTC's PFOF-PCOL ¶ 73. [redacted] *See* Madrid Designation at 108:19–22; 111:25–113:24; *see also* Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 31:23–32:6. As for other TAVR developers abroad, the Court agrees with the FTC that "[s]imply publishing clinical data" and "attending conferences in the United States," without undertaking U.S. clinical testing for their TAVR-AR valves, is "insufficient to affect the behavior of U.S. TAVR-AR manufacturers," given that these other TAVR-AR valves are not yet available for implantation in U.S. patients. *See* FTC's PFOF-PCOL ¶ 75.

ii. Edwards and JenaValve Vigorously Compete in the Relevant Market

Defendants' ordinary course documents and testimony show that Edwards and JenaValve spur each other to increase the pace of innovation and bring a superior TAVR-AR valve to patients in the United States. Defendants compete in several areas, including valve sizes, patient indications, speed to market, clinical testing, clinical outcomes, and pricing.

Expanding Valve Sizes

Edwards/JC Medical and JenaValve compete to expand their valve size offerings to cover a broader range of patients. Currently, SOJOURN is designed to treat patients with aortic annular perimeters up to 104 millimeters, while Trilogy cannot treat patients with perimeters greater than 90 millimeters. *See* PX-6006 at 2–3; Defs.' PFOF-PCOL ¶ 142. In a March 2024 email to JenaValve's Board of Directors, JenaValve's CEO, Mr. Kilcoyne, observed that JC Medical was

using J-Valve's larger size offerings to their advantage, and that JenaValve "need[ed] to have one more additional large size to optimize market opportunity." PX-2139 at 3–4; Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 99:22–101:13. That same month, in a presentation to its Board, JenaValve made the case for a larger valve size, noting that "competitor J-Valve already has a large valve size" and concluding that it was "imperative that we accelerate the XL valve . . . to maintain our leadership position." PX-2186 at 24–25 (citation modified). And in an April 2023 presentation, JC Medical noted that J-Valve had an "advantage" over JenaValve with its larger valve sizes. PX-1037 at 16.

Around that time, a principal investigator for JenaValve's ALIGN-AR trial also pressured JenaValve to develop a larger valve size. JenaValve's CMO, Dr. Duane Pinto, told the principal investigator that it would take two or more years for JenaValve to develop the larger valve, to which the principal investigator responded that he was "worried J-Valve [wa]s gaining too much of a foothold" and did not want to wait that long for a larger valve size for Trilogy. PX-2132 at 1; *see also* Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 91:11–93:7. At the evidentiary hearing, Dr. Pinto testified that JenaValve is still in the process of developing a larger Trilogy valve, which is expected to launch in two or three years. *See* Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 93:8–19; *see also* Nov. 24 AM Hr'g Tr. (Keltjens (JenaValve)) at 123:8–25.

Expanding Patient Indications

Edwards/JC Medical and JenaValve also compete to cover a broader range of patient indications. JenaValve's pending PMA application, based on the ALIGN-AR trial, is for AR patients who are at high surgical risk. JenaValve's ARTIST trial seeks to expand Trilogy's indications to AR patients at low and intermediate surgical risk. *See* Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 151:7–152:5; Nov. 21 AM Hr'g Tr. (Vahl) at 65:25–66:7. If the ARTIST

trial is successful, Trilogy will thus be able to treat a larger portion of the AR population. *See* Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 74:9–12. This is of "huge strategic importance," JenaValve executives observed, because obtaining multiple indications for Trilogy will help JenaValve stay ahead of J-Valve and maintain market share dominance over J-Valve if both devices are commercialized. PX-2042 at 1; *see also* Nov. 20 PM Hr'g Tr. (Sun (JenaValve)) at 53:23–54:1. As JenaValve's Daniel Sun wrote in a corporate presentation, the ARTIST trial will allow JenaValve to "extend [its] head start on J-Valve by moving on to low and intermediate risk [patients] as [JC Medical] work[s] on their high-risk study." PX-2041 at 7. Another JenaValve presentation from March 2024 cited competitive pressure from J-Valve four times as a rationale for accelerating the launch of the ARTIST trial. *See* PX-2138 at 8.

Speed to Market

JenaValve and JC Medical competed to bring their respective TAVR-AR devices more quickly through the FDA approval process and to market. In March 2023, a JenaValve executive observed that "[a] major takeaway" from the CRT conference, at which JC Medical presented, was that "J-Valve is ramping up activities" and that, while JenaValve had the "lead," it "will need to maintain it." PX-2436 at 2. JC Medical, meanwhile, sought to catch up to Trilogy, noting in an April 2023 presentation that it "need[ed] to start [a] US pivotal trial before Trilogy is approved." PX-1037 at 16. A few months later, in August 2023, J-Valve obtained an IDE from the FDA, to which Daniel Sun, at JenaValve, commented, "Hopefully the leadership realizes it's time to get ready for launch." PX-2533 at 2. At the evidentiary hearing, Mr. Sun testified that he would often "bring up J-Valve" with others at JenaValve as a reason to "move faster" on projects like JenaValve's ARTIST trial and the program to develop larger Trilogy valves. Nov. 20 PM Hr'g Tr. (Sun (JenaValve)) at 50:1–21.

Since acquiring JC Medical, Edwards has continued to focus on accelerating J-Valve/SOJOURN. Upon learning the "disappointing news" that the FTC had brought a merger challenge, Edwards's CEO instructed the team responsible for J-Valve to go faster, considering it his "duty" as CEO to challenge the team "to do anything possible" with J-Valve. Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 45:2–46:6. Following through on their CEO's orders, Edwards leadership scheduled a meeting in August 2025 "specifically on how [to] accelerate SOJOURN." PX-1285 at 3; *see also* PX-1389 at 1; Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 86:23–87:8.

Clinical Testing

Dr. McCabe, a principal investigator for JenaValve's ALIGN-AR trial, explained that device manufacturers are "deliberate" in seeking out clinical sites and principal investigators that will enable them to enroll patients quickly and execute the trial expertly. *See* McCabe Dep. at 74:9–75:6. This has been the case for Defendants. In organizing clinical trials for their respective TAVR-AR devices, Edwards/JC Medical and JenaValve carefully selected clinical sites and principal investigators that, in the companies' views, would maximize the chances for successful clinical trials. In early 2023, for example, soon after JC Medical announced that it was contemplating an EFS for J-Valve, JenaValve's CEO reported that JC Medical was "literally chasing" down principal investigators who had participated in JenaValve's ALIGN-AR pivotal trial. PX-2181 at 2. In response to JC Medical "targeting all of our [clinical] sites," a JenaValve executive suggested communicating to JenaValve's current and prospective priority clinical sites "that involvement in J-Valve trials would preclude us [from] including them in the future." PX-2097 at 1. He wrote: "We need to . . . leverage our strength, leadership and relationships . . . to present the practical reality of multiple AR trials in one site." *Id.*

JenaValve's concern is not unfounded. As Dr. McCabe testified, given how "resource- and effort-intensive" it is to enroll patients in trials, his preference as a principal investigator is to avoid "competing trials for the same disease" in the same clinical site. McCabe Dep. at 70:11–71:8. Conducting competing trials in the same site can, in fact, hurt patients, Dr. McCabe explained, because the site has to split up eligible patients into two trials, which can slow down clinical testing for medical devices and ultimately postpone their commercialization. *See id.* at 71:2–22. Accordingly, Medtronic's Greg Larkin testified that "there is some competition" between device manufacturers with competing trials for placing their products in different sites and ensuring that physicians choose to enroll in their trials. Nov. 19 AM Hr'g Tr. (Larkin (Medtronic)) at 129:8–130:1.

Defendants disagree with Mr. Larkin. In their view, "[c]linical trials do not involve competition in the ordinary sense and are not a proper antitrust market." Defs.' PFOF-PCOL ¶¶ 235–42. Defendants explain that companies in clinical trials are not competing to implant as many devices as possible—to maximize output, so to speak—because to get a device to commercial approval as quickly as possible, companies aim to enroll the minimum number of patients needed to satisfy clinical protocols. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 60:10–21. Device manufacturers are also not attempting to maximize profits at the clinical stage, Defendants note. By law, companies cannot charge sites or investigators a price for the device greater than necessary to recover manufacturing and R&D costs. *See* Bailey Rep. ¶¶ 62, 63 (citing 21 C.F.R. § 812.7); Nov. 21 AM Hr'g Tr. (Vahl) at 30:16–31:1. Moreover, according to Defendants, Edwards and JenaValve do not face a scarcity of clinical sites or principal investigators. For example, only about five percent of clinical sites in the United States equipped to perform TAVR procedures are currently involved either in the JOURNEY trial for Edwards's

SOJOURN device or in the ARTIST trial for JenaValve's Trilogy device—and a handful of sites are involved in both trials. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 59:3–60:2; Bailey Rep. ¶ 58.

The Court agrees that, at the clinical stage, device manufacturers are not seeking to maximize output or profits, and that the total number of clinical sites and principal investigators available to conduct TAVR trials exceeds Defendants' current demands. Furthermore, to the extent the FTC is arguing that a reduction in the number of companies competing for available sites is itself an independent antitrust harm, the Court has already explained that it will not presume illegality based on Dr. Wilson's HHI calculations for clinical sites.

Nevertheless, as noted above, there is evidence that Defendants have competed for access to some of the same clinical sites and principal investigators, even though there are more sites and investigators than Defendants can use. *See, e.g.*, PX-2097 at 1; PX-2181 at 2. The Court is persuaded that such competition for clinical sites and investigators has benefitted patients, at least indirectly. JenaValve, for example, sought to accelerate its ARTIST trial because of competition from JC Medical at clinical sites, with Dr. Pinto writing in November 2023 that "it is time critical and mission critical to get our ARTIST Sites buttoned up ASAP (Concern about Jvalve)." PX-2104 at 1; Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 105:4–106:06. According to Dr. Pinto, JenaValve also streamlined its patient enrollment process in part because of concerns from principal investigators that patients would "jump to J-Valve." Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 93:20–97:3; *see also* PX-2132.

Clinical Outcomes

Edwards/JC Medical and JenaValve also compete on the quality of their respective TAVR-AR valves, as measured across several dimensions, including mortality, valve

embolization (when valve anchoring fails), and pacemaker rate (the rate at which a pacemaker must be implanted along with the valve). In a May 2023 email to JenaValve's CEO, Dr. Pinto provided eighteen bullets summarizing the "clinical outcomes" from J-Valve's EFS results. *See* PX-2195 at 1. In turn, JC Medical analyzed Trilogy's clinical data, concluding that J-Valve's "clinical performance ha[d] to match or be superior to Jena[V]alve's" and that JC Medical "need[ed] to start [a] US pivotal trial before Trilogy is approved." PX-1037 at 16.

After the 2023 TCT Conference, JC Medical's CEO wrote about "[g]reat excitement around our valve and the opportunity for improvement" from JenaValve's Trilogy valve, including J-Valve's better "pace[maker] rates, larger annular dimensions, ease of use, [and] no need for general anesthesia." PX-1036 at 1 (citation modified). Meanwhile, a JenaValve executive opined after analyzing JC Medical's compassionate use data that Trilogy beat J-Valve "on basically everything but pacemaker." PX-2056 at 1. Later, after Edwards acquired JC Medical, an Edwards executive wrote that J-Valve "may have [an] edge" on valve embolization rates compared to Trilogy. PX-1289 at 2. JenaValve has devoted resources to improving Trilogy's pacemaker rate, with Dr. Pinto vowing in an April 2025 email to PIs that JenaValve is "best positioned to figure this out and we will." PX-3078 at 2.

Pricing

The FTC's evidence shows that there is some price competition even at the clinical stage. The FTC highlighted Defendants' pricing strategies with respect to The Christ Hospital, a clinical site that participated in both JenaValve's ALIGN-AR trial and Edwards's/JC Medical's EFS and JOURNEY trial. When JC Medical began its EFS, it did not charge The Christ Hospital for the J-Valve device in clinical trial or compassionate use cases, at least initially. *See* Kereiakes Dep. at 33:11–34:1, 48:6–17. Around the time Edwards acquired JC Medical, The

Christ Hospital was being charged [redacted] for each J-Valve device, [redacted] after the JC Medical acquisition. *See id.* at 33:15–34:21. The Christ Hospital [redacted], after which it agreed to participate in the JOURNEY pivotal trial. *See id.* at 34:23–35:22.

JenaValve, meanwhile, initially charged The Christ Hospital [redacted] for the Trilogy valve in the ALIGN-AR trial. *See id.* at 32:7–18. In the latter half of 2024, though, JenaValve increased the price to [redacted] for its LVAD study, which examines Trilogy in AR patients who use left ventricular assist devices ("LVAD") to combat end-stage heart failure, and its ALIGN-AR continued access program, which permits clinical sites to continue implanting Trilogy devices even after enrollment in the ALIGN-AR trial has ended. *See* PX-2232 at 1–3. After JenaValve declined The Christ Hospital's request to maintain the lower price, The Christ Hospital decided to withdraw from these trials. *See id.* at 1–2. Although "unfortunate," The Christ Hospital communicated to JenaValve that "given the cost issue and other viable device options available to us"—namely, J-Valve—withdrawing was the "best decision" for the hospital. *Id.* at 2.

Defendants argue that this evidence is not indicative of pre-commercial price competition because the FTC did not establish that Edwards/JC Medical's lower price for J-Valve was driven by competition with JenaValve, as opposed to some other factor, or that this lower price exerted competitive pressure on JenaValve. *See* Defs.' PFOF-PCOL ¶ 241. And Defendants' economic expert, Dr. Bailey, performed economic analyses indicating that, at several clinical sites hosting trials for both the Trilogy and J-Valve devices, including The Christ Hospital, JenaValve did not lower Trilogy's price once JC Medical/Edwards began hosting a rival EFS or pivotal trial. *See* Bailey Rep. at Exs. 13–19.

The Court acknowledges that there is little evidence of JenaValve engaging in pre-commercial price competition. *See* Nov. 20 PM Hr'g Tr. (Sun (JenaValve)) at 66:24–67:1 ("Q: Has JenaValve ever used pricing or discounts to incentivize a physician to enroll Trilogy over J-Valve? A: No."). But JC Medical, at least, understood that J-Valve's lower price would incentivize enrollment of J-Valve over Trilogy. In late 2024, Dr. Kereiakes, a principal investigator at The Christ Hospital, informed JC Medical's CEO, Dr. Turco, that The Christ Hospital had decided to forego participation in JenaValve's LVAD study due to Trilogy's high price. *See* PX-1046 at 2. A large reason for this was that JC Medical had also agreed to conduct an LVAD study, for which it offered J-Valve to The Christ Hospital for free. *See id.* at 2–3. Dr. Kereiakes urged Dr. Turco to accelerate JC Medical's LVAD study, predicting that the price difference between the two valves would cause "everyone [to] want to use J-Valve and not [Trilogy]." *Id.* at 2. Dr. Turco responded that he "could not agree more" and asked Dr. Kereiakes to similarly urge Edwards, which had acquired JC Medical by that point, to initiate an LVAD study. *Id.* at 1.

In sum, the Court considers that the FTC's evidence shows a modest amount of pre-commercial price competition. That is, Defendants' pricing decisions for their TAVR-AR valves in clinical trials seem to be influenced primarily by manufacturing and R&D costs and secondarily by other considerations, such as accelerating enrollment in their clinical trials. The Court further accepts that the incentive to lower prices as a means of accelerating enrollment in trials is naturally strongest when there are multiple TAVR developers offering competing TAVR-AR devices and clinical trials. And lower prices indisputably benefit the patients and physicians who participate in clinical trials. As Dr. Kereiakes testified, The Christ Hospital can

afford to enroll more patients in a clinical trial when the price of a device is lower. *See* Kereiakes Dep. at 37:17–38:20.

Additionally, the Court finds that the FTC has established that Edwards and JenaValve would engage in price competition once one or both of their TAVR-AR devices are commercialized. For example, JenaValve's Daniel Sun proposed pricing rebates on a commercialized Trilogy device "in an effort to get [JOURNEY sites] to prioritize Trilogy implants over J-Valve." PX-2414 at 2. Furthermore, JenaValve planned to increase the list price of Trilogy upon launch because JenaValve would have the only TAVR-AR device approved commercially in the United States. *See* Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 93:15–94:6. But JenaValve estimates that J-Valve's entry into the commercial market would erode JenaValve's market share "15 to 20 percent." PX-2090 at 1. Edwards, similarly, anticipated setting a premium price for its AR platform if it acquired both JC Medical and JenaValve, recognizing that, in that scenario, it would be "first to market" and have "one shot at setting the bar on commercial price." PX-1390 at 2. Additionally, Edwards would not "have to deal with low-cost alternatives." *Id.*

iii. The Proposed Transaction Will Likely Lessen Competition Substantially

By eliminating head-to-head competition between Edwards and JenaValve, the Proposed Transaction is likely to lessen competition substantially. As shown above, current competition between Edwards and JenaValve—even at the clinical trial stage—has incentivized the firms to make decisions that have benefitted and will continue to benefit patients and physicians. JenaValve, for example, has responded to competitive pressure from Edwards/JC Medical by seeking to accelerate the development of a larger Trilogy valve and enrollment in the ARTIST pivotal trial—efforts that, if successful, will allow JenaValve to treat more AR patients.

Similarly, Edwards/JC Medical has sought to stay ahead of JenaValve by accelerating development and clinical testing of SOJOURN/J-Valve, including by offering the device for free to clinical sites. If the Proposed Transaction is consummated, Edwards will no longer face the threat of a rival TAVR-AR valve beating it to market and cannibalizing its sales, reducing its current incentive to accelerate the development of SOJOURN. Furthermore, if Edwards owns both Trilogy and SOJOURN, it anticipates setting a premium price for its AR platform, as it would not have to contend with competitor devices.

Edwards resists these conclusions. It argues that "Edwards has strong incentives to innovate regardless of competitive pressure from JenaValve." Defs.' PFOF-PCOL ¶ 203–212. The company's "biggest competitor," one Edwards executive testified, "is the disease" itself. Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 125:9. As another Edwards executive put it, the company's "north star" is to "get to zero percent mortality, zero percent stroke, [and] zero percent on other complications," and until that happens, Edwards's "job isn't done." Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 93:15–25. This guiding philosophy translates into an economic incentive to "unlock[] the market," "[drive] market growth," and treat more AR patients. Nov. 24 PM Hr'g Tr. (Sharma (Edwards)) at 125:11–15. And this, according to Edwards's CEO, is ultimately the reason for which Edwards wants both Trilogy and SOJOURN: to develop a TAVR-AR solution "able to treat a broad range of patients." Nov. 19 PM Hr'g Tr. (Zovighian (Edwards)) at 79:21–80:4.

While the Court does not doubt Edwards's bona fides, the central question here is not whether Edwards would have strong incentives to develop SOJOURN if JenaValve were out of the picture, but rather, whether Edwards would be meaningfully incentivized to develop both SOJOURN *and* Trilogy if it owns the two devices. Economic theory predicts that this would not

be the case. As the FTC's economic expert, Dr. Wilson, explained, "if two firms have products that will 'contest' with each other for sales," a merger would reduce the combined firm's "incentive to incur costs to develop [both] products." Wilson Rep. ¶ 89. This describes Trilogy and SOJOURN: although the two TAVR-AR devices have certain differentiated features, including sizing and frame design, their addressable populations overlap—so much so that JenaValve and JC Medical predicted that the two devices would compete for market share. *See* PX-2090 at 1 (estimating that J-Valve's entry into the commercial market would erode JenaValve's market share "15 to 20 percent"); PX-1049 at 10.

Economic theory aside, Edwards contends that its experience in the TAVR-AS space shows that it will have incentives to innovate in the TAVR-AR space even without commercial competition. *See* Defs.' PFOF-PCOL ¶ 209. Between 2011 and 2014, Edwards's TAVR-AS device, SAPIEN, was the only commercially approved TAVR-AS device in the United States. *See id.* Despite the lack of competition during this time, Edwards highlights that it did not stop innovating. *See id.* By the time a second TAVR-AS device entered the commercial market—Medtronic's CoreValve—Edwards "had already expanded [SAPIEN's addressable] patient population, developed a second-generation device, and was working on a third." *Id.*

Although Edwards lacked commercial competition, however, it overlooks the fact that it faced *non-commercial* competition even while SAPIEN was the only commercially approved TAVR-AS device. Medtronic, for example, began a U.S. pivotal trial for CoreValve a year before SAPIEN received commercial approval. *See* Kesselheim Rep. ¶ 117. Dr. Kesselheim, the FTC's FDA regulatory expert, noted that panel-track supplements—FDA submissions signaling innovations to approved devices, such as significant design changes or new indications—occurred most often after CoreValve and SAPIEN were approved. *Id.* ¶¶ 101, 120. In any event,

Edwards's record of developing SAPIEN despite a lack of commercial competition does not show that Edwards would be incentivized to continue developing both Trilogy and SOJOURN under similar circumstances.

Defendants next argue that the FTC did not *prove* that the Proposed Transaction would result in substantial harm to innovation. *See* Defs.' PFOF-PCOL ¶¶ 231–33. Dr. Wilson, for example, did not attempt to quantify the extent to which competition between Edwards and JenaValve is currently driving innovation or analyze whether the Proposed Transaction will reduce net R&D expenditure in the TAVR-AR market. *See id.* ¶ 231. In contrast, Defendants note that their economic expert, Dr. Bailey, did conduct an empirical analysis of Edwards's innovation incentives after the Proposed Transaction. *See id.* ¶ 232 Dr. Bailey explained at the evidentiary hearing that her analysis examined whether Edwards would find it profitable to continue developing only the larger SOJOURN valve sizes that Trilogy currently lacks. *See* Nov. 25 PM Hr'g Tr. (Bailey) at 17:17–19:20. Dr. Bailey concluded that even if Edwards owns both Trilogy and SOJOURN, it would have a $76 million incremental profit incentive to continue developing those additional SOJOURN valve sizes. *See id.*

Again, though, that analysis misses the point. If Edwards owns two TAVR-AR devices, one of which can treat patients with larger aortic annuli, and one of which cannot, Edwards would plainly find it profitable to continue developing the device that can treat more patients. But Dr. Bailey did not analyze the more relevant question of whether it would be profitable for Edwards to develop larger valve sizes for two TAVR-AR devices instead of one. *See id.* at 72:3–6. In fact, testimony from Edwards executives at the evidentiary hearing suggests that Edwards may not pursue development of larger Trilogy valve sizes if the Proposed Transaction is consummated. As discussed, JenaValve is developing a larger valve size for Trilogy, and if

the Proposed Transaction terminates, it plans to continue this effort, assuming it has the budget for it. *See* Nov. 18 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 113:22–114:12. However, because SOJOURN already has large valve sizes and because Edwards has doubts about whether Trilogy can support larger valve sizes, Edwards has yet to determine whether it would continue Trilogy's large valve program after the Proposed Transaction. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 32:20–33:23; Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 87:23–88:1.

Evidence at the hearing also indicates that Edwards has contemplated adopting J-Valve/SOJOURN as its long-run TAVR-AR platform. In May 2024, shortly before Edwards agreed to acquire JenaValve and JC Medical, Larry Wood, Edwards's former Corporate Vice President, suggested to other Edwards executives that an optimal "Gen 2" TAVR-AR product for Edwards might turn out to be a "combination" of Trilogy and J-Valve. DX-0116 at 2; *see also* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 99:10–100:23. But after Edwards agreed to the dual acquisition, Edwards's Vice President of Strategy circulated materials for a leadership meeting describing Trilogy as "Gen 1" and J-Valve as "Gen 2." PX-1394 at 3. A "key priority" discussed at this meeting—as reflected in notes taken by an Edwards employee—was launching Trilogy as "Gen 1" and "proceed[ing] with [J-Valve] Gen 2 over JenaValve." PX-1280 at 1; *see also* Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 9:18–20, 12:13–18. Furthermore, in May 2025, Mr. Wood wrote to Edwards's CEO that "[f]eedback from the doctors who have used Jena[Valve] and JC [Medical] is that JC is clearly the better platform" and that "[i]t is becoming increasingly clear we have a next generation AR platform." PX-1272 at 2.

The Court finds that in addition to reducing competition and the incentive to innovate in both the pre-commercial and commercial TAVR-AR markets, the Proposed Transaction is likely to produce anticompetitive unilateral effects once Trilogy and/or SOJOURN are commercialized.

"The extent of direct competition between the products sold by the merging parties is central to the evaluation of unilateral price effects." *H&R Block*, 833 F. Supp. 2d at 81 (quoting Merger Guidelines § 6.1). In a differentiated product market—or one in which products "are similar enough to compete in a relevant market, but different enough that some customers prefer one product over another"—unilateral effects are likely to be profitable under four conditions. *ProMedica Health*, 749 F.3d at 569; *see also FTC v. CCC Holdings Inc.*, 605 F. Supp. 2d 26, 68 (D.D.C. 2009). First, the products in the market must be differentiated. *CCC Holdings*, 605 F. Supp. 2d at 68. Second, "the products controlled by the *merging* firms must be close substitutes, *i.e.*, 'a substantial number of the customers of one firm would turn to the other in response to a price increase.'" *Id.* (quoting *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1117 (N.D. Cal. 2004)). Third, "other products must be sufficiently different from the products offered by the merging firms that a merger would make a small but significant and non-transitory price increase [SSNIP] profitable for the merging firm." *Id.* Fourth, repositioning—or, in other words, new entry by competitors—must be unlikely. *See id.*

A future market including commercialized TAVR-AR devices in the United States would meet these conditions. Although competing TAVR-AR devices, including Trilogy and SOJOURN, are viewed as close substitutes for AR patients, they also differ in certain features, as noted above. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 32:20–33:8. Furthermore, as Dr. Wilson found, a merger would likely make a SSNIP profitable for Edwards. *See* Wilson Rep. ¶ 50. And, as further explained below in Section IV.A.3.a, new entry by competitors into a commercialized market is unlikely in the short term because both Trilogy and SOJOURN are expected to receive commercial approval between [redacted] and 2029, but no other TAVR-AR device is likely to do so before 2034. Accordingly, in a world where Edwards owns both Trilogy

and SOJOURN and either is commercialized, the Court finds that unilateral anticompetitive effects are very likely to be profitable for Edwards.

As a final matter, the Court acknowledges that this scenario is not a certainty. It assumes that Trilogy and/or SOJOURN will obtain FDA approval—a nontrivial assumption, given the inherent uncertainties surrounding the FDA's premarket approval process. *See* Defs.' PFOF-PCOL ¶¶ 187–92. Nevertheless, a Section 7 analysis demands a "predictive judgment, necessarily probabilistic and judgmental rather than demonstrable." *Hosp. Corp. of Am.*, 807 F.3d at 1389; *see also Heinz*, 246 F.3d at 719 ("Section 7 is, after all, concerned with *probabilities*, not certainties."). As Defendants recognize, the Court "must compare the world with the merger against the world without" it to determine which one "is better for patients." Defs.' PFOF-PCOL ¶ 265.

Experts for the FTC and Defendants provided identical estimates of the average likelihood of obtaining FDA approval for therapeutic medical devices at each stage of the premarket approval process, drawn from the same academic publication. *See* Kesselheim Rep. ¶ 66; Bailey Rep. ¶ 13 & nn.20-21. According to that publication, the estimated probability of FDA approval is 14% from the nonclinical stage, 29% from a feasibility study, 61% from a pivotal study, and 81% from a PMA submission. *See* Kesselheim Rep. ¶ 66. Based on these statistics, Dr. Bailey calculated that the probability of both Trilogy and SOJOURN obtaining FDA approval is 49.1%.[5] *See* Bailey Rep. ¶ 54 & n.118. Given that "the probability of both devices being approved *is less than 50%*," Defendants argue that the prospect of anticompetitive

[5] Trilogy has a PMA submission pending (80.5% chance of FDA approval). SOJOURN is undergoing a pivotal trial (60.9% chance of approval). 80.5% multiplied by 60.9% is 49.1%. *See* DX-0289 (Bailey Rep.) ¶ 54 n.118. Despite this simple mathematic calculation, both devices are more likely than not to individually obtain FDA approval (80.5% and 60.9% respectively). And the evidence presented at the hearing corroborates these positive predictions.

harm in a future commercial TAVR-AR market is "too speculative" to support a Section 7 claim. Defs.' PFOF-PCOL ¶¶ 187–92.

However, the danger of anticompetitive harm associated with an Edwards monopoly in the commercial TAVR-AR market will materialize once either Trilogy or SOJOURN obtains FDA approval. If Edwards owns both Trilogy and SOJOURN, it would be entirely within Edwards's control whether to continue developing both devices or whether to focus on one of the devices and withdraw the other. Regardless, once either device obtains FDA approval, Edwards would control the entire commercial TAVR-AR market, assuming that Trilogy or SOJOURN is the first to market. The Court finds, in its "predictive judgment," that this scenario is likely. In other words, the Proposed Transaction would grant Edwards a total monopoly in the commercial TAVR-AR market because at least one of Trilogy or SOJOURN—or both—will likely obtain FDA approval at least several years before another TAVR-AR device manages to do so.

In the case of Trilogy, Defendants counter that JenaValve's recurring issues with [redacted] make its timeline for FDA approval [redacted] Defs.' PFOF-PCOL ¶ 188. JenaValve completed enrollment in the ALIGN-AR pivotal trial for Trilogy over three years ago, *see* Kesselheim Rep. ¶ 76, and until recently, anticipated obtaining FDA approval by 2025, *see* PX-0044 at 19. But, as explained above, in September 2025 it received a deficiency letter from the FDA [redacted]

Although JenaValve's [redacted] are not inconsequential, not even Defendants believe that they doom Trilogy's chances for FDA approval. *See, e.g.*, Nov. 24 AM Hr'g Tr. (Keltjens (JenaValve)) at 122:16–18 ("[I]f this transaction would have closed as we originally hoped for a year ago, I think we would have PMA approval by today."); [redacted] Defs.' PFOF-PCOL ¶¶ 79–92 (arguing that "Edwards can help Trilogy obtain FDA approval"). The Court will assume, however, that the FDA will require [redacted] the FTC provided no evidentiary basis on which to conclude that the FDA is likely to dispense with this request. A new test would push back JenaValve's expected timeline for approval by [redacted]. *See id.* at 119:10–13. Nevertheless, nothing in the record suggests that JenaValve is likely to fail the new test or fail to receive FDA approval. [redacted]. Therefore, the Court finds it reasonable to expect that JenaValve will [redacted] and receive FDA approval sometime in [redacted].

As for SOJOURN, Defendants offered little evidence to refute Edwards's current projections regarding its FDA approval timeline. Although Edwards anticipates receiving FDA approval in 2029, Defendants note that since initiating the JOURNEY pivotal trial, Edwards has twice opted to pause enrollment to address issues that could affect patient safety. *See* Defs.'

PFOF-PCOL ¶¶ 86, 319. However, Edwards resolved these unforeseen issues both times using its "resources, creativity, and expertise," and from the latest the Court heard at the evidentiary hearing, [redacted] *See id.* ¶ 92; Nov. 20 PM Hr'g Tr. (Concepcion (Edwards)) at 22:2–10. Furthermore, Edwards's current "best-case" 2029 projection presumably already factors in the delays from the recent enrollment pauses. *See* Defs.' PFOF-PCOL ¶ 190; Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 106:12–23.

In view of the above, the Court is not concerned that the FTC's alleged harms are based on mere "ephemeral possibilities." *See FTC v. Meta Platforms Inc.*, 654 F. Supp. 3d 892, 927 (N.D. Cal. 2023). The Court concludes that, in addition to the immediate harm to innovation and competition threatened by the Proposed Transaction, the FTC has also shown a "reasonable probability" that a merger between Edwards and JenaValve may lessen competition substantially by granting Edwards a monopoly in the U.S. TAVR-AR market.

3. Defendants' Rebuttal Arguments

Defendants advance three principal arguments in an attempt to rebut the FTC's prima facie showing that the Proposed Transaction is likely to be anticompetitive. First, they argue that numerous TAVR developers around the world could seek to enter the U.S. TAVR-AR market, which would offset the anticompetitive effects of the Proposed Transaction. Second, they contend that, given JenaValve's limited resources and capabilities, merging with Edwards would produce procompetitive "efficiencies." Third, they argue that JenaValve has no feasible alternatives outside of the Proposed Transaction. The Court finds that none of Defendants' rebuttal arguments is availing.

a. New Entry or Expansion

Defendants contend that numerous companies around the world are developing TAVR-AR devices today, any of which could begin U.S. clinical trials and seek FDA approval for their devices. *See* Defs.' PFOF-PCOL ¶ 214. In predicting the likely future effects of a merger, courts "consider the existence and significance of barriers to entry or expansion into the relevant market by new competitors." *Anthem I*, 236 F. Supp. 3d at 221. "In the absence of significant barriers, a company probably cannot maintain supracompetitive pricing for any length of time." *Baker Hughes*, 908 F.2d at 987.

"[D]efendants may meet their burden of rebuttal by demonstrating low barriers to entry in the relevant market." *Bertelsmann*, 646 F. Supp. 3d at 47. "[B]ecause the burden of persuasion ultimately lies with the [FTC], the burden to rebut must not be 'unduly onerous.'" *Anthem II*, 855 F.3d at 350 (quoting *Baker Hughes*, 908 F.2d at 991). Defendants can meet their burden by producing evidence showing that any entry by new firms, or expansion by existing firms, will be "timely, likely, and sufficient in its magnitude, character, and scope" to counteract the Proposed Transaction's anticompetitive effects. *Anthem I*, 236 F. Supp. 3d at 222 (quoting *H&R Block*, 833 F. Supp. 2d at 73). The "relevant time frame" for entry to be considered timely is "two to three years." *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 133 (D.D.C. 2016); *see also H&R Block*, 833 F. Supp. 2d at 73 n.28.

Defendants have not shown that low barriers to entry into the market for TAVR-AR devices in the United States offset the Proposed Transaction's anticompetitive effects. As the Court has explained, the FDA's premarket approval process for high-risk medical devices is a significant barrier to entry in this market. Defendants agree that the FDA sets a high clinical bar to protect U.S. patients from suboptimal technologies. *See, e.g.*, Nov. 19 PM Hr'g Tr.

(Zovighian (Edwards)) at 71:13–17. As JenaValve's Dr. Pinto put it, "you can't just have a new valve and then start putting it into people," because the FDA requires evidence of a device's safety and effectiveness before it can be implanted in humans or commercialized. Nov. 21 AM Hr'g Tr. (Pinto (JenaValve)) at 8:11–24.

In Edwards's view, though, the FDA's regulatory requirements offer little guarantee that the U.S. TAVR-AR market will remain unsaturated. Even if no other TAVR-AR devices besides Defendants' are in U.S. clinical trials today, Edwards insists that there are numerous competing TAVR-AR developers "whose mere potential entry" into the U.S. market "drives Edwards to constantly innovate." Defs.' PFOF-PCOL ¶ 213. Multiple TAVR-AR developers have presented at recent U.S. medical conferences, which, according to Defendants, "suggest[s] a strategic focus on the US market and possible entry." *Id.* ¶ 222. A U.S. strategic buyer could also acquire a foreign TAVR-AR valve at any time, Defendants observe. *See id.* ¶ 220. Considering these possibilities, Edwards's expert explained that it must "constantly be innovating, constantly looking over [its] shoulder," because "if [it] slow[s] down, the competitor can show up, and it will be hard to catch up," given the long development cycle of TAVR devices. Nov. 25 PM Hr'g Tr. (Bailey) at 20:9–19.

It is true that the D.C. Circuit has found that, "[i]f barriers to entry are insignificant," even "the *threat* of entry can stimulate competition in a concentrated market, regardless of whether entry ever occurs." *Baker Hughes*, 908 F.2d at 988. Nevertheless, as explained, the barriers to entry into the U.S. TAVR-AR market are not "insignificant." *See id.* Furthermore, Defendants offer little evidence suggesting an imminent threat of new entrants into the U.S. market. Participation in U.S. medical conferences, for example, does not strike the Court as a reliable indicator of a company's intent to enter the U.S. market imminently. *See* Kesselheim

Reply Rep. ¶ 32 (noting that "research at any stage may be presented" at such conferences, which are not specifically "intended for manufacturers with a plan to commercialize their devices imminently in the United States").

As far as the Court is aware, no other TAVR-AR developer has taken the first step toward FDA approval. *See* Nov. 21 PM Hr'g Tr. (Kesselheim) at 33:7–19. The closest in this regard appears to be Jenscare, a Chinese company with a transapical TAVR-AR device, Ken-Valve, that has been approved for commercial use in China. *See* PX-1292 at 1. Edwards's internal documents anticipate Ken-Valve's entry into the U.S. market, albeit without a specific timeframe. *See, e.g.*, DX-0197 at 15 (noting that Jenscare's anticipated entry is "TBD"). Part of the reason for Jenscare's predicted entry, according to Edwards's Jeremy Bierman, is that Jenscare has completed an EFS in the United States for another TAVR device used for treating a different heart valve. *See* Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 108:2–109:10. Given that Jenscare has already learned how to navigate the U.S. regulatory landscape, Mr. Bierman surmised that Jenscare should logically pursue U.S. clinical testing for Ken-Valve, too. *See id.* The Court agrees with this logic. However, other evidence suggests that Jenscare's entry may be delayed. Ken-Valve is a transapical device, which the U.S. market disfavors. *See, e.g.*, Nov. 21 AM Hr'g Tr. (Turco (JC Medical)) at 100:21–101:4, 122:8–17. Jenscare has recently announced that it is developing a transfemoral TAVR-AR device, *see id.* at 122:8–17, but this, too, is not a guarantee of imminent entry, *see* Kesselheim Reply Rep. ¶ 22 (noting that although early concept development of the transfemoral J-Valve system began in 2015, the first in-human transfemoral implantation did not occur until 2018).

Assuming, however, that Jenscare or another competitor enters the U.S. market in the next year or so—which the Court agrees is possible, *see* Defs.' PFOF-PCOL ¶¶ 243–49—

such potential entry would not be timely enough to offset some of the most significant anticompetitive effects likely to be caused by the Proposed Transaction. Currently, JenaValve and Edwards are finishing up pivotal trials or navigating premarket application submissions. The Proposed Transaction would grant Edwards ownership of the two TAVR-AR devices furthest along in the FDA approval pipeline. *See* Nov. 25 AM Hr'g Tr. (McWilliams) at 104:8–105:13. Although JenaValve projected receiving FDA approval in [redacted], the Court assumes for present purposes that JenaValve could be required to [redacted] pushing back Trilogy's approval timeline to [redacted]. Nov. 18 Hr'g PM Tr. (Kilcoyne (JenaValve)) at 85:3–8, 119:10–13. SOJOURN, meanwhile, is expected to be approved in 2029. *See* PX-1048-007; Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 94:24–95:5. If Trilogy and SOJOURN are commercialized consistent with these projections, Edwards would have a complete monopoly in commercialized TAVR-AR devices in the United States as soon as this year, and no later than 2029.

For new entry to be considered timely, it must break up this expected monopoly within two to three years of its formation. *See H&R Block*, 833 F. Supp. 2d at 73 n.28; *Staples*, 190 F. Supp. 3d at 133; Nov. 24 AM Hr'g Tr. (Wilson) at 52:14–21. In other words, a competing TAVR-AR valve should ideally obtain FDA approval by 2029, assuming the monopoly forms this year or next, and no later than 2031 or 2032 in any event. However, both Dr. Kesselheim, the FTC's FDA regulatory expert, and Dr. Bailey, Defendants' economic expert, agree that on average, starting from the feasibility study stage, it takes medical device manufacturers eight and a half years to complete the FDA's premarket approval ("PMA") process. *See* Kesselheim Rep. ¶ 60, Table 2; Bailey Rep. ¶ 82; Nov. 25 PM Hr'g Tr. (Bailey) at 28:25–29:14. If a medical device developer were to begin an EFS today for a new TAVR-AR valve, it would probably not obtain FDA approval for the valve until 2034, according to the parties' experts. This would

impermissibly leave Edwards as the sole supplier of commercialized TAVR-AR devices for at least five years, and likely longer. *See* Nov. 24 AM Hr'g Tr. (Wilson) at 53:3–18.

Defendants submit that some parts of the PMA process can be shortened if a TAVR-AR device has completed pre-clinical or clinical testing outside of the United States, *see* Nov. 21 AM Hr'g Tr. (Vahl) at 26:12–27:7, which is the case for several competitor devices, largely being developed in China, *see* DX-0197 at 15. Nevertheless, the Court heard from multiple witnesses that clinical data associated with foreign devices, particularly from China, is viewed skeptically by the FDA and frequently fails to meet the FDA's regulatory standards. *See* Nov. 19 PM Hr'g Tr. (Bobo (Edwards)) at 128:15–129:8; Nov. 21 PM Hr'g Tr. (Kesselheim) at 34:2–17. Accordingly, Dr. Kesselheim explained that "in nearly all cases, high-risk devices are approved based on U.S. data." Nov. 21 PM Tr. (Kesselheim) at 34:2–17. This conclusion is consistent with the history of the TAVR-AS market in the United States, where "no TAVR-AS device was approved solely on the basis of ex-U.S. data." *Id.* at 13:16–24. In view of the FDA's strong preference for U.S. clinical data, the Court accepts that any TAVR developer seeking to bring a foreign TAVR-AR valve to the U.S. market will need to conduct U.S. clinical testing as part of the FDA's premarket approval process.

Still, the experts' eight-and-a-half-year estimate for the PMA process assumes some degree of variation. *See id.* at 68:17–25. Defendants suggested during the hearing that if Medtronic, for example, acquired a foreign TAVR-AR device, got through a feasibility study on the same timeline that JC Medical did (nine months), then got through a pivotal trial and the PMA process on the same timeline that Medtronic did with its TAVR-AS device (three years), then Medtronic's TAVR-AR device could be commercially approved four years from now. *See id.* at 67:13–19. This is quite a rosy scenario, though. In fact, other evidence—including

testimony from Defendants and interventional cardiologists—suggests that the FDA's regulatory review process tends to take longer. *See, e.g.*, Kereiakes Dep. at 30:10-31:21 (estimating that it takes "five to seven years" to wind through the FDA approval process); PX-2413 at 15 (JenaValve presentation indicating that "[s]everal new dedicated AR TAVR devices [are] in development, but all are in early clinical stages and will not be available for 5+ years"); Kesselheim Rep. ¶ 95 (estimating that other TAVR-AR devices "still have five to ten years before they may obtain FDA approval").

In sum, contrary to Defendants' contentions, low barriers to entry do not characterize the TAVR-AR market in the United States. Given the high market barriers and the typical length of the FDA premarket review process, it is likely that any new entrants into the market will be several years behind in the FDA approval pipeline compared to both SOJOURN and Trilogy. Any new entry would therefore not be timely enough to offset the Proposed Transaction's expected anticompetitive effects. And considering Edwards's expectation that the first entrant to the market can "set[] the bar on commercial price," *see* PX-1390 at 2, the Court finds an elevated risk that, in the absence of competitors, the pricing for commercialized TAVR-AR products would be detrimental to the interests of patients, doctors, and hospitals.

b. Procompetitive Effects

Defendants next argue that, rather than causing a substantial lessening of competition, the Proposed Transaction would benefit competition and patients. *See* Defs.' PFOF-PCOL ¶¶ 306–15. Notwithstanding the fact that a merger between Edwards and JenaValve would reduce the number of firms in the U.S. TAVR space, Defendants suggest that the merger would increase JenaValve's chances of obtaining FDA approval for Trilogy, help it manufacture the device at scale, and therefore maximize the number of patients it can treat. *See id.* As Defendants explain,

the FTC assumes that, if independent from Edwards, JenaValve will be a robust firm capable of exerting meaningful competitive pressure on Edwards, both in the innovation market and a future commercial market. *See id.* ¶ 306. According to Defendants, though, this JenaValve does not and would not exist. *See id.* Without Edwards, Defendants maintain, JenaValve's "dire financial condition," "persistent manufacturing and quality issues," and inability to secure FDA premarket approval would seriously constrain its ability to compete in the U.S. TAVR-AR market. *See id.* ¶¶ 153, 306.

These arguments invoke two commonly asserted rebuttal grounds in Section 7 cases: the "weakened competitor" defense and the "efficiencies" defense. The weakened competitor defense requires the defendant to make "a substantial showing that the acquired firm's weakness, which cannot be resolved by any competitive means, would cause that firm's market share to reduce to a level that would undermine the government's prima facie case." *FTC v. Univ. Health, Inc.*, 938 F.2d 1206, 1221 (11th Cir. 1991). In other words, "a defendant may rebut the government's prima facie case by showing that the government's market share statistics"—or, in this case, the FTC's assumptions about JenaValve's finances and capabilities—"overstate the acquired firm's ability to compete in the future," such that a "merger would not substantially lessen competition." *See id*. The efficiencies defense, meanwhile, is premised on the argument that "efficiencies" resulting from a merger "will offset any potential anticompetitive effects of the merger." *CCC Holdings*, 605 F. Supp. 2d at 72; *see also Sysco*, 113 F. Supp. 3d at 81 ("[I]n some instances, efficiencies resulting from the merger may be considered in rebutting the government's *prima facie* case."); *Heinz*, 246 F.3d at 720. The Court reviews the weakened competitor and efficiencies defenses in turn.

i. Weakened Competitor Defense

Even if JenaValve receives FDA approval for the Trilogy device, Defendants assert that the company faces weaknesses and limitations that would prevent it from successfully commercializing the device. *See* Defs.' PFOF-PCOL ¶ 46. For example, Defendants argue that JenaValve does not have the manufacturing capacity to produce valves at the scale required to commercialize Trilogy. *Id.* ¶ 47. Each Trilogy valve is [redacted]. Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 113:6–114:25. JenaValve's CEO explained at the evidentiary hearing that the company has [redacted] for the valve and [redacted] *Id.* at 115:4–6. Furthermore, [redacted] *Id.* at 113:6–114:4. As a result, the cost of manufacturing each valve is "astronomical," as one Edwards executive put it. Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 102:24–103:2.

According to Defendants, JenaValve also lacks adequate financial resources. *See* Defs.' PFOF-PCOL ¶ 52. JenaValve's CEO testified that the company [redacted] *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 122:7–16. Moreover, JenaValve does not have enough clinical support staff to consistently meet the demand for Trilogy valves in clinical trials. *See* Nov. 21 AM Tr. (Pinto (JenaValve)) at 13:14–14:11. Interventional cardiologists serving as principal investigators at these sites described having to delay valve implantations due to the unavailability of valves or support staff. *See, e.g.*, Nov. 25 AM Hr'g Tr. (Chetcuti) at 11:22–12:13;[6] Nov. 21 AM Hr'g Tr. (Vahl) at

[6] Before the evidentiary hearing, the FTC moved to exclude the testimonies of Dr. Stanley Chetcuti and Dr. Vinod Thourani—both principal investigators for the Trilogy and/or SOJOURN pivotal trials—on the basis that the doctors had "inappropriately interfered with the

33:12–34:22. Due to resource and personnel constraints, JenaValve has delayed certain innovation efforts, including the development of larger Trilogy valve sizes. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 123:4–124:8; Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 152:11–15.

Furthermore, Defendants claim that JenaValve's limited resources undercut its ability to support a national commercial launch of the Trilogy valve, assuming it obtains FDA approval. According to Defendants, JenaValve's internal projections contemplate only a constrained launch at a limited number of sites if the Proposed Transaction does not go through. Specifically, 2023 projections show that in a base model, JenaValve contemplated activating [redacted] sites and implanting [redacted] valves in the first two years following Trilogy's commercialization, while an "accelerated" model that assumed a merger with Edwards projected the activation of [redacted] sites and the implantation of [redacted] valves during the same period. DX-0060 at 18; *see also* DX-0189 at 11 (noting that the 2025 budget does not cover "[c]omprehensive buildout of internal commercial infrastructure").

FTC's ability to take written and deposition discovery." FTC's Mot. Exclude Testimony at 1, ECF No. 108-1. Defendants opposed the motion, arguing that testimony from the doctors is directly relevant to several central issues in this case. *See* Defs.' Opp'n to FTC's Mot. Exclude Testimony, ECF No. 125. The FTC renewed its motion at the evidentiary hearing, and the Court informed the parties that it would take the matter under advisement. Having heard the testimony at the hearing and reviewed the papers, the Court finds that it can consider the doctors' testimonies without undue prejudice to the FTC. The Court shares some of the FTC's concerns about the circumstances surrounding the doctors' testimonies. For example, Dr. Chetcuti shared at the hearing that he was unaware that his counsel had failed to provide the FTC with certain documents responsive to its subpoena, including documents showing that his counsel was chosen and paid for by Edwards. *See* Nov. 25 AM Hr'g Tr. (Chetcuti) at 62:3–25. Nevertheless, the doctors' accounts of their experiences as principal investigators and their interactions with Edwards and JenaValve largely mirror those of other doctors whose testimonies the FTC has not moved to exclude. The Court has not relied on the testimonies of Drs. Chetcuti and Thourani to make any finding that is not otherwise supported in the record.

Although the Court does not doubt that JenaValve has experienced manufacturing limitations and financial constraints, the Court is not convinced that such weaknesses are so severe that, without the Proposed Transaction, JenaValve would be unable to compete effectively in the U.S. TAVR-AR market going forward. JenaValve's resources as a small startup plainly do not come close to matching Edwards's "thousands of R&D engineers, hundreds of field technicians, and over 9,000 manufacturing employees." Defs.' PFOF-PCOL ¶ 6. Nevertheless, as the FTC observes, JenaValve's singular focus on developing the Trilogy device has allowed it singlehandedly to advance the device to the brink of FDA approval. *See* FTC's PFOF-PCOL ¶ 181. Significantly, JenaValve's latest U.S. sales forecasts for Trilogy, which assume that the company remains independent, [redacted], before it signed the merger agreement with Edwards. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 83:1–86:3. In 2023, for example, JenaValve expected to sell [redacted] *See* DX-0060 at 19; Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 81:3–82:5. In 2025, its sales forecasts were [redacted], respectively, with [redacted] *See* PX-2461 at 3; Nov. 18 PM Tr. (Kilcoyne (JenaValve)) at 83:1–86:3. These numbers belie Defendants' suggestion that that the FTC has "overstate[d] [JenaValve's] ability to compete in the future" without the Proposed Transaction. *See Univ. Health*, 938 F.2d at 1221.

Regardless, even if JenaValve's weaknesses were to preclude it from effectively competing in the U.S. TAVR-AR market, Defendants have not shown that those weaknesses "cannot be resolved by any competitive means." *See id*. As detailed below, JenaValve likely has meaningful alternatives to the Proposed Transaction, including merging with another

competitor. The Eleventh Circuit has explained that because it is generally "not certain" that an acquired firm's weakness "cannot be resolved through new financing or acquisition by other than a leading competitor"—as is the case here—the weakened competitor defense is credited "only in rare cases." *Id.* (citation modified); *see also Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1339, 1341 (7th Cir. 1981) (noting that "[f]inancial weakness, while perhaps relevant in some cases, is probably the weakest ground of all for justifying a merger" and "certainly cannot be the primary justification" for permitting one). In view of the evidence reflecting JenaValve's ongoing plans to commercialize Trilogy with or without the Proposed Transaction, the Court is not convinced that this is one of those rare cases.

ii. Efficiencies Defense

As Defendants argue, a merger between two firms can sometimes generate efficiencies that counteract its anticompetitive effects. For example, a merger might lead to a "better utilization of existing assets, enabling the combined firm to achieve lower costs in producing a given quantity and quality than either firm could have achieved without the proposed transaction." *Heinz*, 246 F.3d at 720 (citation modified). "Although the Supreme Court has never recognized the 'efficiencies' defense in a Section 7 case, the [D.C. Circuit] as well as the Horizontal Merger Guidelines recognize that . . . efficiencies resulting from the merger may be considered in rebutting the government's *prima facie* case" of an anticompetitive merger. *Sysco*, 113 F. Supp. 3d at 81; *see also Heinz*, 246 F.3d at 720.

With its "superior resources and capabilities," Edwards argues that it can "resolve JenaValve's problems and provide the best chance to obtain approval for, and successful commercialization of, Trilogy." Defs.' PFOF-PCOL ¶ 21. If Edwards acquires Trilogy, it plans to "figure out" how to make the device "more manufacturable," "improve yields," and get it

commercially approved. *See* Nov. 19 AM Hr'g Tr. (Wood (Edwards)) at 98:12–23. For example, if the FDA requires JenaValve to redo [redacted] Edwards suggests it could conduct the new test in house. Defs.' PFOF-PCOL ¶¶ 81–83. If it turns out the [redacted] is due to a flaw in the design of the Trilogy valve, Edwards's engineers could help with that, too. *Id.* ¶ 83. Furthermore, Edwards could fix JenaValve's "persistently poor tissue yields." *Id.* ¶ 98.

Edwards also intends to "use its existing (and superior) TAVR field-support teams, relationships with TAVR centers, and TAVR training materials to commercialize Trilogy faster and more robustly than JenaValve could alone." Defs.' PFOF-PCOL ¶ 106. Edwards has a "fully-fledged TAVR-AS nationwide field team" that "could be easily retrained to focus on TAVR-AR." *Id.* ¶ 102 (quoting Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 54:9–12). Indeed, it plans to train its entire TAVR-AS team on TAVR-AR. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 52:3–6; 53:24–54:12. Moreover, according to Edwards, leading physicians agree that Edwards will be able to commercialize and scale Trilogy in a way that a standalone JenaValve cannot. *See, e.g.*, Nov. 21 AM Hr'g Tr. (Vahl) at 39:13–24 (explaining that Edwards "ha[s] a strong track record of" building out clinical specialist teams); Nov. 25 AM Hr'g Tr. (Chetcuti) at 16:4–17 (opining that post-merger, Edwards would have "a bigger field team that could allow more sites to be launched at a faster pace" and "a scale of manufacturing to have more devices available").

For Edwards, the Proposed Transaction ultimately represents the "merger of two heart-valve R&D streams whose combination provides the best chance to save thousands of lives." Defs.' PFOF-PCOL ¶ 337. Trilogy and SOJOURN are "complementary technologies," Edwards asserts, with design differences that make them better suited for distinct patient anatomies. Nov.

24 PM Hr'g Tr. (Sharma (Edwards)) at 139:9–16. Edwards thus seeks to develop both devices to be able to treat a broader patient population. *See* Defs.' PFOF-PCOL ¶ 25. In so doing, "Edwards also expects to combine the learnings from each to increase the chance of FDA approval and improve the likelihood of developing successful next generation devices." *Id.*

In considering the merging parties' claimed efficiencies, the Court must undertake a "rigorous analysis" of the arguments and evidence offered in support thereof so as "to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721. "Specifically, the court must determine whether the efficiencies are 'merger specific'—meaning they represent 'a type of cost saving that could not be achieved without the merger'—and 'verifiable'—meaning 'the estimate of the predicted saving must be reasonably verifiable by an independent party.'" *Sysco*, 113 F. Supp. 3d at 82 (quoting *H&R Block*, 833 F. Supp. 2d at 89). Because "efficiencies are inherently difficult to verify and quantify," it is "incumbent upon the merging firms to substantiate efficiency claims so that it is possible to verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firm's ability and incentive to compete, and why each would be merger-specific." *H&R Block*, 833 F. Supp. 2d at 89 (citation modified).

As the Court has already alluded to, there is no doubt in its mind that Edwards has more funds, experience, technical expertise, engineers, and clinical personnel than JenaValve does. The problem for Defendants, though, is that evidence bearing on Edwards's "superior resources and capabilities"—although plentiful—is merely the starting point for utilizing the efficiencies defense to rebut a prima facie case. *See* Defs.' PFOF-PCOL ¶ 21. What Defendants failed to do—and what they needed to do to prevail—was to demonstrate how Edwards's resources and

capabilities, when combined with JenaValve's, would produce specific and independently verifiable cost savings that could not be achieved outside of the merger and that would be passed on to consumers rather than kept by the merged firm. *See Sysco*, 113 F. Supp. 3d at 82; *CCC Holdings*, 605 F. Supp. 2d at 74.

Consider, for example, Defendants' claim that the Proposed Transaction will save thousands of lives by accelerating the development and commercialization of the Trilogy valve. As the FTC notes, Defendants did not attempt to calculate, verify, or perform a "lives saved" analysis. *See* Nov. 25 PM Hr'g Tr. (Bailey) at 71:25–72:2. This is not to say that Defendants needed to *prove* the number of lives that would be saved. But Defendants did not provide the Court with any models or assessments to ground this claim. *See Illumina*, 88 F.4th at 1059–61 (rejecting the defendant's contention "that a merger would lead to 'significant supply chain and operational efficiencies' of approximately $140 million" because it "presented no model" or assumptions "by which it calculated this number"). Defendants point to the JenaValve sales forecast discussed above, in which JenaValve estimated that as a standalone company, it could implant [redacted] valves in the two years following Trilogy's commercialization, whereas with Edwards, it could implant [redacted]. *See* DX-0060 at 18. But JenaValve's CEO, Mr. Kilcoyne, testified at the evidentiary hearing that this forecast was created by JenaValve based on assumptions it made about Edwards with no information provided by Edwards. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 76:5–77:13. In fact, Mr. Kilcoyne sent the same forecast to another potential buyer, Boston Scientific, because, as he later testified, he believed that Boston Scientific could accelerate production of Trilogy to a similar extent as Edwards. *See id.* at 77:22–79:12; PX-2144 at 6. Thus, at the very least, Defendants have not shown that the "lives

saved" efficiency "could not be achieved without the merger." *Sysco*, 113 F. Supp. 3d at 82 (quoting *H&R Block*, 833 F. Supp. 2d at 89).

As for Edwards's alleged expertise in [redacted], the Court has no reason to doubt that, if the FDA [redacted], Edwards would be able to conduct it in house. But the Court is not convinced that this claimed efficiency is "merger specific." On the one hand, Edwards has 45 years of experience conducting [redacted] and [redacted] "dedicated to in-house valve testing." Defs.' PFOF-PCOL ¶¶ 81–82; *see also* Nov. 24 PM Hr'g Tr. (Sirimanne (Edwards)) at 74:1–9. On the other hand, JenaValve did not think it needed help from Edwards to conduct [redacted] as a standalone company. *See* Nov. 19 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 10:7–19. In fact, JenaValve successfully [redacted] *See id.* at 11:17–12:4. [redacted] *See id.* at 12:5–14. If this is the case, it is not clear that JenaValve would need Edwards specifically to conduct a new test. If this is not the case—if [redacted] is instead due to a valve design flaw—Edwards asserts that it can help fix this. *See* Defs.' PFOF-PCOL ¶ 83. But Edwards does not have to do so. [redacted] *See* Nov. 19 AM Hr'g Tr. (Kilcoyne (JenaValve)) at 9:2–11. Accordingly, Edwards's "promise[] about post-merger behavior" cannot be recognized as an efficiency. *Heinz*, 246 F.3d at 721.

Edwards's claim that it can fix JenaValve's poor tissue yields is also not "merger specific." In support of this idea, Edwards explains that after it acquired JC Medical, it transferred manufacturing of J-Valve from China to Edwards's U.S. facilities, where Edwards has been able to integrate its own bovine pericardial tissue into J-Valve. *See* Nov. 24 PM Hr'g

Tr. (Sirimanne (Edwards)) at 53:9–17, 83:23–85:4. However, assuming it does the same for Trilogy, Edwards has not explained why it is uniquely positioned to improve JenaValve's tissue yields. While J-Valve used bovine tissue even in China, Trilogy uses porcine tissue. And Edwards's comparative advantage is in bovine tissue, not porcine tissue. In a 2022 presentation that JenaValve prepared for its investment committee, JenaValve highlighted that Medtronic, Boston Scientific, and Abbott Laboratories have "known" experience with porcine tissue, but Edwards does not. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 97:11–98:11; PX-2146 at 11. Additionally, Medtronic's Greg Larkin testified at the evidentiary hearing that Medtronic has "significant expertise" in "manufacturing valves that use porcine pericardial tissue" and "commercially scaling up valves that use porcine pericardial tissue." Nov. 19 AM Hr'g Tr. (Larkin (Medtronic)) at 138:12–18.

As a final matter, Defendants argue that the Court need not apply the efficiencies defense's "stringent standard" because, rather than mounting an affirmative defense, their evidence of procompetitive benefits is aimed at rebutting the FTC's prima facie case. *See* Defs.' PFOF-PCOL ¶ 310. However, of the several circuits to have recognized that efficiencies can serve as rebuttal evidence, most of them, including the D.C. Circuit, have applied the verifiability and merger-specificity requirements in evaluating alleged procompetitive benefits.[7] *See, e.g.*, *Anthem II*, 855 F.3d at 354–56; *Heinz*, 246 F.3d at 720–22; *Illumina*, 88 F.4th at 1059;

[7] Defendants cite one exception: *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999). In *Tenet Health Care*, the district court enjoined the merger of two hospitals in a small town in southeastern Missouri. 186 F.3d at 1051. In reversing the injunction, the Eighth Circuit found that, although the district court properly rejected the hospitals' efficiencies defense, it "nonetheless should have considered evidence of enhanced efficiency in the context of the competitive effects of the merger." *Id.* at 1054. Nevertheless, the Court is persuaded by the logic of the D.C. Circuit's binding opinion in *Anthem II* that courts should not dispense with the verifiability and merger-specificity requirements when evaluating evidence of procompetitive benefits. 855 F.3d at 354–56.

FTC v. Hackensack Meridian Health, Inc., 30 F.4th 160, 176 (3d Cir. 2022). In *Anthem II*, the D.C. Circuit explained the logic behind these requirements. There, Anthem, a health insurer, argued that a merger with another insurer would produce efficiencies, including by allowing Anthem to renegotiate customers' contracts and pass on the savings to them. *See Anthem II*, 855 F.3d at 352, 356. The D.C. Circuit reasoned that the downward pricing pressure flowing from this efficiency could very well offset the upward pricing pressure that would result from the merger, but that before the district court could reach this conclusion, it needed to verify that Anthem would indeed renegotiate the contracts. *See id.* at 356. As for merger specificity, the D.C. Circuit was persuaded that "consumers should not bear the loss of a competitor if the offsetting benefit could be achieved without a merger." *Id.*

Here, Defendants assert that evidence of procompetitive benefits refutes the FTC's theories that the Proposed Transaction will reduce output, harm innovation, eliminate competitors, and harm patients. *See* Defs.' PFOF-PCOL ¶ 310. But the FTC has offered substantial evidence that the Proposed Merger will eliminate competition in the U.S. TAVR-AR market and thereby reduce Edwards's incentives to develop two competing TAVR-AR devices. Although Defendants can counter this theory with evidence of efficiencies, requiring Defendants to verify those efficiencies and explain why they are achievable only through the "loss of a competitor" is ultimately to the benefit of consumers, who already face a considerable risk of harm from the merger itself. *Anthem II*, 855 F.3d at 356. This consideration is especially important in "highly concentrated market[s] characterized by high barriers to entry," including, at a minimum, the future commercial TAVR-AR market. *CCC Holdings Inc.*, 605 F. Supp. 2d at 72. Because the risk of anticompetitive harm is typically greater in such markets, courts require "'proof of extraordinary efficiencies' in order to rebut the presumption of anticompetitive

effects." *Id.* (quoting *Heinz*, 246 F.3d at 720); *see also id.* ("[C]ourts have rarely, if ever, denied a preliminary injunction solely based on the likely efficiencies.").

iii. Competitive Alternatives

The parties dispute whether JenaValve has meaningful alternatives to the Proposed Transaction, including a merger with a different company or new investments. The FTC argues that Defendants cannot show that JenaValve has no "options besides merging with [Edwards] that would . . . preserve[] competition" in the TAVR-AR market. *Steves & Sons, Inc. v. JELD-WEN, Inc.*, 988 F.3d 690, 715 (4th Cir. 2021); *see also* FTC's PFOF-PCOL ¶¶ 172–80. The FTC highlights that besides Edwards, other potential buyers, or "strategics," have expressed interest in JenaValve in the past and would be willing to purchase JenaValve today. *See* FTC's PFOF-PCOL ¶¶ 175–77. And even if JenaValve is unable to secure a different buyer, the FTC contends that it could raise private capital as a standalone company, which would carry JenaValve through a public offering. *See id.* ¶¶ 178–80. Accordingly, the FTC asserts, JenaValve's poor financial situation, even if accurate, could be "resolved by . . . competitive means." *Univ. Health*, 938 F.2d at 1221. Below, the Court discusses JenaValve's likelihood of successfully negotiating an acquisition by another strategic or obtaining additional financing from private markets.

Acquisition by Another Strategic

The record shows that in the early 2020s, around the time JenaValve was in negotiations with Edwards about a potential acquisition, JenaValve also reached out to several other leading companies in the structural heart device market to gauge their interest in JenaValve. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 19:2–11. These strategics included Medtronic, Boston Scientific, Abbott Laboratories, and Johnson & Johnson. *Id.* at 19:12–21; *see also* Nov. 24 PM

Hr'g Tr. (Keltjens (JenaValve)) at 8:24–9:10. The FTC argues that JenaValve remains an attractive acquisition target today and could therefore negotiate a merger with any one of these strategics in lieu of the Proposed Transaction. *See* FTC's PFOF-PCOL ¶¶ 176–77.

The parties dispute the level of interest that other strategics have expressed in JenaValve. Defendants insist that "[d]espite years of outreach . . . [to] potential acquirers, no other company was seriously interested in acquiring JenaValve." Defs.' PFOF-PCOL ¶ 22. Jan Keltjens, Chairman of JenaValve's Board of Directors, [redacted] Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 8:17–9:10. Mr. Keltjens noted that [redacted] *See id.* at 9:18–20. The FTC, on the other hand, maintains that other strategics have seriously considered acquiring JenaValve over the years. *See* FTC's PFOF-PCOL ¶ 175. The FTC cites an email from JenaValve's CEO, John Kilcoyne, to the Board of Directors in late 2023, in which Mr. Kilcoyne noted a "[h]igh degree of interest exhibited by Edwards followed by [redacted]" PX-2177 at 4. "Two interested parties create an auction opportunity," Mr. Kilcoyne observed. *Id.* The FTC further highlights that [redacted] *See* FTC's PFOF-PCOL ¶ 175.

Excluding Edwards, JenaValve advanced furthest in the sales process [redacted]

[redacted]

This disparity in valuation arose in part due to [redacted]. *See id.* at 8:8–22; PX-3003 at 7. In contrast, [redacted]. Another risk was that [redacted]. In other words, [redacted]

"[G]iven the [redacted]," [redacted] *Id.* at 15:10–13. The [redacted] presentation from December 2022 shows that the company intended to [redacted]. That is, [redacted] would continue monitoring JenaValve over that time, with the hope that, as JenaValve developed additional clinical data, [redacted] Even with these risks, however, [redacted] would have been comfortable pursuing an acquisition in 2022 if J[redacted]. *Id.* at 140:23–141:5. [redacted] also testified that he understood JenaValve to be [redacted] *Id.* at 142:2–8. Furthermore, he stated that if JenaValve were [redacted] *Id.*

According to Defendants, [redacted] purported interest in acquiring JenaValve today is not genuine, and no other strategic is going to be the "white knight" that purchases JenaValve if the Proposed Transaction is blocked. *See* Nov. 18 AM Hr'g Tr. (Defs.' Opening Statement) at 79:22–24. Defendants stress that although all U.S. strategics monitor the TAVR-AR space, only Edwards was willing to take the risk to acquire JenaValve. *See* Defs.' PFOF-PCOL ¶ 162. Moreover, nothing indicates to Defendants that other strategics have had a change of heart. According to Mr. Keltjens, while JenaValve assumes there is a market opportunity in TAVR-AR, "[redacted] doesn't believe it" and [redacted] don't believe it." [redacted]. Only Edwards believed it. *See id.*

The Court weighs two principal considerations in assessing the likelihood that [redacted] or another strategic would seriously consider acquiring JenaValve today. First, it considers

JenaValve's relative value today compared to what it was before JenaValve signed the merger agreement with Edwards, when it was still in talks with other strategics. As the parties agree, JenaValve's value hinges on a number of factors, including the strength of Trilogy's clinical results and the likelihood that the valve will receive FDA approval. *See* Defs.' PFOF-PCOL ¶ 165; FTC's PFOF-PCOL ¶ 176. Second, the Court considers the size of the U.S. TAVR-AR market and whether other strategics are likely to find that the market can support the entry of multiple TAVR-AR devices.

As to the first consideration, Defendants argue that [redacted] . . . stand[] in the way of any potential acquisition." Defs.' PFOF-PCOL ¶ 165. At the hearing, Mr. Keltjens explained that around mid-2025, before the FTC brought its merger challenge, JenaValve felt [redacted] No. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 13:4–11. Shortly thereafter, however, JenaValve received a deficiency letter outlining [redacted], which has raised uncertainties about Trilogy's approval timeline. *See generally* DX-0283. Without a "clear line of sight to PMA approval," Mr. Keltjens testified that an acquisition by another strategic was unlikely, as JenaValve needs access to the U.S. market to be profitable. Nov. 24 AM Hr'g Tr. (Keltjens (JenaValve)) at 121:22–122:11.

The Court is not convinced that the latest deficiency letter makes FDA approval so uncertain as to preclude serious merger negotiations between JenaValve and other strategics. *See* Nov. 21 PM Hr'g Tr. (Kesselheim) at 20:19–23 (noting that "70 to 90 percent of PMA applications each year receive deficiency letters"). As the Court previously explained, evidence suggests that JenaValve will be able to resolve [redacted] and obtain FDA approval by

[redacted] Furthermore, Edwards agreed to acquire JenaValve despite being aware of the company's [redacted]. Although Edwards [redacted] it returned to the negotiating table a few months later with a second offer that was [redacted]. *See id.* at 7:10–25. The second offer included an [redacted] giving Edwards the option to terminate the merger agreement if [redacted]. *See id.* at 8:19–9:11. The Court sees no reason why another strategic would not be able to reach a similar arrangement with JenaValve.

The Court also finds it probable that other strategics would currently view JenaValve as an attractive acquisition target, just as Edwards did. Mr. Keltjens testified that JenaValve's value as a company is built on [redacted] JenaValve has now implanted the Trilogy valve in close to 2,000 patients, including over 1,000 patients in Europe, where Trilogy is commercially approved, and 700 patients in the ALIGN-AR pivotal trial in the United States. *See id.* at 20:3–9; Nov. 20 PM Hr'g Tr. (Pinto (JenaValve)) at 75:25–76:3. Additionally, Trilogy has generated compelling safety and effectiveness data. *See* DX-0297 at 12-13 (medical article noting that the ALIGN-AR trial "overall showed high technical success and a marked reduction in aortic regurgitation"). As Mr. Keltjens put it, it is "very convincing" that the Trilogy device cures AR. *See* Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 20:3–9. [redacted], JenaValve has a TAVR-AR device that has been

proven safe and effective and that is likely to be the first to market—surely an appealing prospect for a potential acquiror. Even if JenaValve is not able to negotiate a deal with terms as favorable as those of the Proposed Transaction, the Court believes there is tangible opportunity for a deal to close. [redacted] (testifying that [redacted] would have pursued an acquisition with JenaValve in 2022 if JenaValve's counteroffer had been closer to [redacted] offer).

The Court next considers whether the size of the AR market in the United States could support multiple TAVR-AR devices. Defendants' industry expert, Mr. McWilliams, testified that other strategics appear less interested in investing in TAVR-AR because of the unknown size of the market relative to the TAVR-AS market. *See* Nov. 25 AM Hr'g Tr. (McWilliams) at 89:15–90:3. Testimony from Dr. Turco, JC Medical's former CEO, supports this notion. Dr. Turco testified that when Edwards made an offer to purchase JC Medical, JC Medical reached out to other strategics, including [redacted], to gauge their interest in submitting a competing offer. According to Dr. Turco, [redacted] "just really did not get comfortable with the size of the aortic regurgitation market." Nov. 21 AM Hr'g Tr. (Turco (JC Medical) at 124:17–23. [redacted] informed Dr. Turco that although JC Medical's "technology and early clinical results certainly look[ed] promising," [redacted] "ha[d] questions on the overall segment opportunity and market development lift required," and it was "not in a position to submit a competing offer" at that time. DX-0106 at 1.

Although the Court is not discounting this evidence, other considerations give it comfort that, as with JenaValve's value, the size of the AR market is not so small that all other strategics would refuse to seriously consider acquiring JenaValve. One relevant consideration is that Edwards, at least, seems to believe that the AR market is big enough to support two TAVR-AR

valves. Not only did it seek to acquire both JenaValve and JC Medical, but it maintains that its entry into the TAVR-AR market "will pave the way for fast followers"—other strategics who will seek to enter this market once its viability is established. *See* Defs.' PFOF-PCOL ¶¶ 120–28, 195. Given the market entry barriers described above, the Court is not convinced that multiple potential entrants will flood the U.S. TAVR-AR market once one TAVR-AR device receives commercial approval. Nevertheless, the Court finds that the U.S. TAVR-AR market could support more than one device.

Defendants' internal market analyses reinforce this conclusion. Edwards and JenaValve estimate that the number of treatable individuals with severe symptomatic AR in the United States is between 118,000 and 129,000. *See* PX-1394 at 3; PX-3003 at 7. For both companies, the addressable patient population represents a sizeable market opportunity, which Edwards calculates to be worth between [redacted] in 2030 and JenaValve calculates as [redacted] by 2033. *See* PX-1394 at 3; DX-0060 at 12. JC Medical's market share and revenue projections are instructive for putting these numbers in context. In early 2024, JC Medical projected that upon receiving FDA approval for J-Valve, it would capture 15% of the U.S. TAVR-AR market, increasing to 70% by 2035. *See* PX-1066 at 35. In other words, JC Medical calculated that it would share the market with other firms at least through 2035. JC Medical also projected that J-Valve's revenue would reach $269 million in 2030 and $803 million by 2033. *See id.* This is less than what Edwards and JenaValve calculate as the market opportunities in those years, suggesting that the AR market will be able to support more than one firm for the foreseeable future. Furthermore, JC Medical predicted low market penetration rates over the next decade—between 1.5% and 14%—implying a large untapped market of untreated AR patients who are nevertheless eligible for TAVR-AR. *See* PX-1066 at 35; *cf.* Nov. 18 PM Hr'g

Tr. (Kilcoyne (JenaValve)) at 131:6–16 (noting that of the 120,000 AR patients in the United States, JenaValve can currently treat [redacted]).

Additional Financing from Private Markets

As another alternative to the Proposed Transaction, the FTC argues that JenaValve could raise capital from private markets. *See* FTC's PFOF-PCOL ¶ 180. [redacted]. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 122:7–16; DX-0270 at 62. The company currently subsists on interim funding from Edwards pursuant to the parties' merger agreement. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 119:16–22. Upon termination of the Proposed Transaction, JenaValve would have around [redacted] of cash on hand, giving it a runway—the amount of time it can operate with current reserves—of about one to two months. *See* Nov. 24 AM Hr'g Tr. (Keltjens (JenaValve)) at 128:15–129:9; DX-0270 at 65. Additionally, JenaValve [redacted] *See* Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 27:10–20. [redacted]

Mr. Keltjens and JenaValve CEO John Kilcoyne testified that the company has planned several contingencies if the Proposed Transaction is blocked, including an immediate plan to raise emergency funding from existing investors [redacted] while it considers long-term options. *See* Nov. 18 PM Hr'g Tr. (Kilcoyne (JenaValve)) at 72:1–11; Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 4:15–5:7; 15:14–20. Defendants' industry expert, Dennis McWilliams, believes that current [redacted] "would be incentivized to give [JenaValve] additional [emergency] financing." Nov. 25 AM Hr'g Tr. (McWilliams) at 86:19–23. This is

supported in the record. [redacted]

Beyond [redacted], JenaValve would need to [redacted] Mr. Keltjens estimates that JenaValve needs roughly [redacted] in additional funding to [redacted]. *See* Nov. 24 PM Hr'g Tr. (Keltjens (JenaValve)) at 19:7–19. But Mr. Keltjens testified that [redacted]

In view of evidence indicating [redacted] the Court is not convinced that JenaValve does not have a "credible" line of sight to FDA approval. Although the Court acknowledges that an IPO, at least, seems less certain than securing another strategic acquiror or Series D funding, *see* Nov. 25 AM Hr'g Tr. (McWilliams) at 91:15–92:9 (testifying that non-revenue medical device companies rarely go public), the Court finds insufficient support in the record to conclude that JenaValve would have no other "options besides merging with [Edwards] that would . . . preserve[] competition" in the TAVR-AR market. *Steves & Sons*, 988 F.3d at 715.

* * *

In light of the above, the Court finds that the FTC has shown a "reasonable probability" that the Proposed Transaction will lessen competition substantially in the U.S. TAVR-AR market, in violation of Section 7 of the Clayton Act. *Arch Coal*, 329 F. Supp. 2d at 116 (quoting *Staples*, 970 F. Supp. at 1072). At the very least, the FTC's extensive evidence of the benefits that current competition in the TAVR-AR market has brought consumers, coupled with the harms to consumers threatened by the Proposed Transaction, "raise[s] questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance." *Heinz*, 246 F.3d at 714–15.

B. Weighing of the Equities

Because the Court has found that the FTC has shown a likelihood of success on the merits, "a presumption in favor of a preliminary injunction arises." *Staples*, 970 F. Supp. at 1091. Despite this presumption, however, the "public interest" standard of Section 13(b) of the FTC Act "still requires the court to weigh the public and private equities of enjoining the merge[r]." *Sysco*, 113 F. Supp. 3d at 86; *see also IQVIA*, 710 F. Supp. 3d at 400 (noting Section 13(b)'s command to "weigh the equities in order to decide whether enjoining the merger would be in the public interest" (citation modified)). "The public equities are the interests of the public, either in having the merger go through or in preventing the merger," as well as in "effectively enforcing antitrust laws" and "ensuring that the FTC has the ability to order effective relief if it succeeds at the merits trial." *Staples*, 970 F. Supp. at 1091; *Sysco*, 113 F. Supp. 3d at 86. As for the private equities, which "include the corporate interests" of the Defendants, "they are not to be afforded great weight." *See FTC v. Swedish Match*, 131 F. Supp. 2d 151, 172 (D.D.C. 2000); *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 352 (3d Cir. 2016); *see also Whole Foods*,

548 F.3d at 1035 ("[T]he 'private equities' alone cannot override the FTC's showing of likelihood of success.").

Defendants argue that the public equities weigh against granting a preliminary injunction because Edwards's and JenaValve's proposed merger will benefit the public. *See* Defs.' PFOF-PCOL ¶ 339. As with their efficiencies defense, Defendants contend that Edwards is best positioned to resolve [redacted] and help it obtain FDA approval. *See id*. Even if JenaValve manages to obtain FDA approval on its own, Defendants add, JenaValve lacks the resources and expertise to build the commercial TAVR-AR space. *See id*. In contrast, Defendants assert, Edwards can help JenaValve produce the Trilogy valve at scale, which will benefit thousands of patients with AR, and particularly the high-risk patients for whom there is currently no other treatment alternative. *See id.*

The Court agrees that the Proposed Transaction promises certain immediate benefits to the public. In particular, Edwards has enormous resources and experience that it could bring to bear to develop the Trilogy valve. *See* Nov. 20 AM Hr'g Tr. (Bierman (Edwards)) at 91:5–8 (noting that Edwards has "manufactured . . . more [TAVR valves] than any other TAVR manufacturer in the world"); Nov. 19 PM Tr. (Zovighian (Edwards)) at 103:2–17, 105:15–116:16 (noting that Edwards is prepared to allocate $100 million in support of Trilogy in 2026 alone). Additionally, if the Proposed Transaction is blocked, JenaValve could run out of funds in as little as a month if it is unable to secure another strategic acquiror or emergency funding from its investors. Obviously, the public interest favors a JenaValve with adequate resources to continue pushing Trilogy toward FDA approval.

Nevertheless, the public equities advanced by the FTC outweigh those claimed by Defendants. Because the FTC has shown a likelihood that the Proposed Transaction will

substantially lessen competition, "[t]here is a strong public interest in effective enforcement of the antitrust laws that weighs heavily in favor of an injunction." *Swedish Match*, 131 F. Supp. 2d at 173. In view of the FTC's showing, the Court finds that the public is at risk of serious anticompetitive harms if the Proposed Transaction is consummated. *See Staples*, 970 F. Supp. at 1091. As explained above, economic theory intuitively predicts that because Edwards's and JenaValve's TAVR-AR devices are likely to compete for sales, a merger between the firms would reduce Edwards's "incentive to incur costs to develop" both Trilogy and SOJOURN. Wilson Rep. ¶ 89. Certain evidence supports this theory bearing out: as detailed above, some Edwards documents reveal a hesitation to commit to developing larger valve sizes for Trilogy, and others suggest a possibility of proceeding with SOJOURN over JenaValve.

Another relevant consideration for the Court is that, in the short term, Defendants expect JenaValve [redacted], giving it several months' runway to seek alternative financing options. Of course, such alternatives are not guaranteed. Nevertheless, the Court believes the risk is low that an independent JenaValve would be unable to obtain FDA approval and commercialize Trilogy. And when Trilogy's strong clinical data is added to the mix, the Court considers that strategic acquirors and investors are likely to express genuine interest in JenaValve, especially given that its TAVR-AR device will likely be the first to market in the United States.

An additional public interest factor—"preserving the FTC's ability to order effective relief after the administrative hearing"—also weighs in favor of an injunction. *Sysco*, 113 F. Supp. 3d at 87. If this Court declines to enjoin the Proposed Transaction now but ensuing administrative proceedings determine that the merger violates Section 7 of the Clayton Act, the FTC "would face an especially daunting and potentially impossible task of 'unscrambling' the

eggs"—that is, "returning the merging companies to their pre-merger state." *Sysco*, 113 F. Supp. 3d at 87; *see also Staples*, 970 F. Supp. at 1091. As the D.C. Circuit has recognized, "Section 13(b) itself embodies congressional recognition of the fact that divestiture is an inadequate and unsatisfactory remedy in a merger case." *Heinz*, 246 F.3d at 726.

Here, testimony from Edwards's Corporate Vice President, Mr. Bobo, strongly supports that divestiture would not be a feasible option post-merger. During its review of the Proposed Transaction, the FTC asked Mr. Bobo whether Edwards would be willing to divest JC Medical in order to clear the JenaValve acquisition. *See* Nov. 20 AM Hr'g Tr. (Bobo (Edwards)) at 39:2–10. Mr. Bobo's response was a "hard no." *Id.* at 39:12. As he explained at the hearing, as soon as Edwards acquired JC Medical, it began developing J-Valve using its materials, trade secrets, and intellectual property. *See id.* at 39:14–40:3. Because Edwards's DNA is now intertwined with J-Valve, Mr. Bobo explained that it would be impossible for Edwards to sell J-Valve to a third party. *See id.* Similar considerations are present now. If the Court allows the Proposed Transaction to proceed, Edwards would gain immediate access to and be able to modify Trilogy, and unscrambling Edwards's and JenaValve's integrated assets later on—if the Proposed Transaction is found to be illegal—would become "difficult" and "disruptive." *FTC v. Lancaster Colony, Corp.*, 434 F. Supp. 1088, 1096 (S.D.N.Y. 1977).

Ultimately, the Court cannot discount the high likelihood—as demonstrated by the FTC—that the Proposed Transaction, if consummated, will lead to significant anticompetitive effects. The Court therefore finds it prudent to enjoin the Proposed Transaction pending adjudication of the FTC's challenge to the Proposed Transaction. Just as the public interest favors a financially capable JenaValve, so too does it favor a TAVR-AR market with multiple competitors vying to develop the safest and most effective treatment options for Americans with

severe AR. The FTC offered convincing evidence that, if Edwards acquires JenaValve, it would plan to discontinue several beneficial Trilogy initiatives, including the large valve program. Against this backdrop, the Court considers that the public equities favor enjoining the consummation of the Proposed Transaction.

V. CONCLUSION

For the foregoing reasons, Plaintiff's petition for a preliminary injunction (ECF Nos. 1, 104) is **GRANTED**. Edwards and JenaValve are preliminarily enjoined, pending the conclusion of the administrative trial that the FTC has initiated, from taking any further steps to consummate the Proposed Acquisition or any related transactions, stock assets, or acquisition of any other interests of one another either directly or indirectly; and from carrying out any other agreement, understanding, or plan by which Edwards would acquire control over JenaValve or any of its assets. The Court will retain jurisdiction and maintain the status quo until such administrative trial is concluded. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: January 9, 2026

RUDOLPH CONTRERAS
United States District Judge

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 22nd day of January 2026, I served the foregoing on the following counsel via email and the Court's CM/ECF system:

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