UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Andrew N. Ferguson, Chairman**
Melissa Holyoak
Mark R. Meador

In the Matter of **EDWARDS LIFESCIENCES CORP.,** **a corporation;** **and** **JENAVALVE TECHNOLOGY, INC.,** **a corporation.**	**Docket No. 9442** **PUBLIC VERSION**

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents Edwards Lifesciences Corp. ("Edwards" or "Edwards/JC Medical") and JenaValve Technology, Inc. ("JenaValve") (together with Edwards, "Respondents") have executed a merger agreement pursuant to which Edwards and its affiliates and subsidiaries will acquire substantially all the assets of JenaValve (the "Proposed Acquisition") in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and which if consummated would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

NATURE OF THE CASE

1. Edwards, a global supplier of medical devices for treating structural heart disease, proposes to acquire JenaValve, which is developing a transcatheter aortic valve replacement ("TAVR") device for the treatment of aortic regurgitation ("AR"), a potentially fatal heart condition. Through its subsidiary, JC Medical, Edwards is also developing a TAVR device for the treatment of AR ("TAVR-AR device"). Edwards and JenaValve are the only two companies that are currently conducting clinical trials on TAVR-AR devices in the United States. JenaValve expects to obtain approval from the U.S. Food and Drug Administration ("FDA") to commercialize its device by [redacted] and Edwards expects to obtain FDA approval for its TAVR-AR device by the [redacted] Thus, the Proposed Acquisition, if consummated, would consolidate the [redacted] TAVR-AR device [redacted] in the United

States, eliminate the close and ongoing head-to-head competition between Edwards and JenaValve, and give Edwards a TAVR-AR monopoly for at least the next [redacted].

2. [redacted]—in a bold bid to [redacted] Edwards executed agreements to acquire both JC Medical and JenaValve. [redacted] Edwards' gambit to acquire both companies, and their executives were [redacted] JenaValve's Chief Commercial Officer [redacted] and its Senior Director of Strategy and Operations [redacted] Another JenaValve [redacted] JC Medical's Chief Executive Officer [redacted] Edwards, having consummated its JC Medical acquisition, now seeks to close its acquisition of JenaValve.

3. At least 8 million Americans over age 50 suffer from AR. AR is a serious and often fatal condition in which the heart's aortic valve does not close properly, causing blood to backflow into the heart. AR can cause heart failure and sudden cardiac death. Approximately one in four people diagnosed with severe and symptomatic AR will die within a year if left untreated.

4. Currently, the only FDA-approved treatment for AR is surgical valve replacement via open heart surgery, or surgical aortic valve replacement ("SAVR"). This procedure is not recommended for high-risk patients, including patients who are older, frailer or have certain co-morbidities. Aside from open heart surgery, there is no suitable treatment option available for people with AR. TAVR-AR devices fulfill this unmet need. This revolutionary technology is significantly less invasive than open heart surgery and offers a safe and effective treatment for AR.

5. JenaValve is poised to become the [redacted] JenaValve has [redacted] clinical trials for its device, called Trilogy, [redacted] Edwards/JC Medical, which has an ongoing clinical trial for its J-Valve TAVR-AR system, is [redacted] and is expected to be [redacted]

6. JenaValve and JC Medical have [redacted] For example, to [redacted] Trilogy, JenaValve launched a large new pivotal trial called ARTIST aimed at showing that treatment with Trilogy is as effective as SAVR, which, if successful, would make Trilogy available to even more patients—those who are eligible for open heart surgery. JenaValve's Chief Marketing Officer [redacted] For its part, JC Medical sought to [redacted] to JenaValve. One doctor affiliated with JC Medical [redacted] to which JC Medical's founder and former CEO [redacted]

[redacted] In another conversation, the same doctor [redacted] JC Medical [redacted]

7. If Edwards controls both Trilogy and J-Valve, the pace of innovation in TAVR-AR devices is likely to slow and the risk of one of the valves being de-prioritized or abandoned rises.

8. For example, Edwards anticipated [redacted] after closing the Proposed Acquisition. Days after the agreement was signed, [redacted] and Edwards' Vice President of Clinical Affairs [redacted] The next day, an Edwards' Senior Vice President [redacted] JenaValve documents [redacted] if the Proposed Acquisition closes, while it [redacted] if the Proposed Acquisition fails to close. Should Edwards [redacted]

9. Edwards executives [redacted] and have not [redacted] Edwards' CEO [redacted]

10. Edwards also would have little business reason to maintain two valves that treat the same indication. Documents indicate that it is likely to [redacted] For example, [redacted] Alternatively, Edwards has [redacted]

11. The Proposed Acquisition would eliminate the vigorous head-to-head competition between Edwards/JC Medical and JenaValve, bringing under one roof the only two TAVR-AR companies conducting ongoing clinical trials with the FDA. The Proposed Acquisition therefore may substantially lessen competition or tend to create a monopoly in the TAVR-AR device market, resulting in reduced innovation, diminished product quality, and potentially increased prices for U.S. consumers.

12. There are no countervailing factors sufficient to offset the likelihood of competitive harm from the Proposed Acquisition. Respondents cannot demonstrate that new entry of TAVR-AR devices would be timely, likely, or sufficient to offset the anticompetitive effects of the

Proposed Acquisition. Nor will Respondents be able to show sufficient cognizable, verifiable, or merger-specific efficiencies that would offset the likely and substantial competitive harm from the Proposed Acquisition.

JURISDICTION

13. Respondents and each of their relevant operating affiliates and subsidiaries are, and at all relevant times have been, engaged in commerce or activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

14. The Proposed Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

RESPONDENTS AND THE PROPOSED ACQUISITION

15. Respondent Edwards is a Delaware corporation headquartered at One Edwards Way, Irvine, CA 92614. Edwards is a global structural heart medical device manufacturer. Edwards agreed to acquire JC Medical on [redacted] JC Medical owns J-Valve, a TAVR device designed to treat AR. Edwards/JC Medical is currently conducting a pivotal trial to support FDA approval of J-Valve (which Edwards [redacted] and anticipates receiving FDA approval in [redacted]

16. Prior to acquiring JC Medical and agreeing to acquire JenaValve, Edwards [redacted] Edwards [redacted] deciding to acquire the two companies.

17. Respondent JenaValve is a medical device company developing TAVR systems for the treatment of aortic valve disease. It is headquartered in Irvine, California. JenaValve's flagship product, Trilogy, is a TAVR device designed to treat AR.

18. JenaValve published the results of its pivotal trial for Trilogy, ALIGN-AR, in March 2024 and [redacted] It expects to receive FDA approval for Trilogy [redacted]

19. Pursuant to its Agreement and Plan of Merger with JenaValve, executed on [redacted] Edwards proposed [redacted] JenaValve for approximately [redacted]

20. The competitive harms in this case result from Edwards owning *both* JC medical *and* JenaValve. As early as November 2024, Commission staff asked whether Edwards would resolve the antitrust concerns with the JenaValve acquisition by divesting JC Medical. This proposal was renewed many times over the following eight months, including in meetings with staff, the Bureau of Competition leadership, and the Comission Chairman. Edwards repeatedly rejected the Commission's outreach to divest JC Medical in order to clear the path for Edwards to consummate its proposed acquisition of JenaValve.

21. JenaValve itself [redacted]

The JenaValve CEO's [redacted]

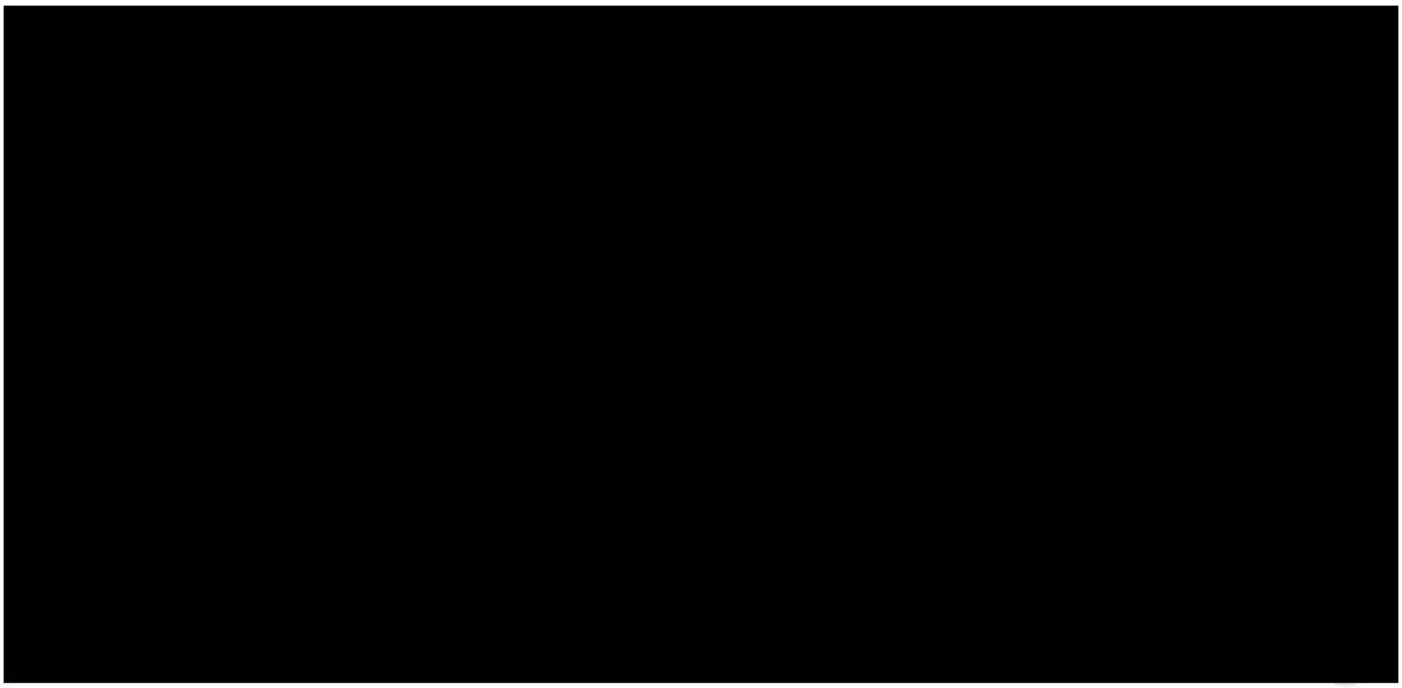
Although JenaValve [redacted]

INDUSTRY BACKGROUND

22. TAVR is a transformative technology that allows physicians to safely and effectively replace malfunctioning aortic valves without the need for SAVR, i.e. open heart surgery. TAVR allows a physician to use a catheter to guide an artificial valve through a patient's blood vessel, typically the femoral artery, and place the artificial valve in the position of the malfunctioning native valve. The replacement valve then expands and anchors securely, taking over the native aortic valve's task of regulating blood flow. Compared to SAVR, TAVR is a much less invasive procedure and only requires a small incision in the patient's groin. The physician does not need to stop the patient's heart or administer general anesthesia. Conversely, SAVR requires the use of general anesthesia, surgically opening the patient's chest, stopping the patient's heart, and replacing the patient's valve with a new mechanical or bioprosthetic valve. TAVR patients experience much shorter recovery times compared to SAVR. Most TAVR patients spend one day in the hospital after the procedure, compared to three to seven days following SAVR.

23. TAVR devices are already commercially available for other heart valve diseases. Most notably, Edwards commercialized the first TAVR device to treat aortic stenosis ("AS") ("TAVR-AS device") when it debuted its Sapien valve in 2011. AS is characterized by a buildup of calcium on the aortic valve, preventing it from fully opening after each heartbeat and impeding blood flow. Whereas AR is caused by the aortic valve's failure to close after each heartbeat, AS is caused by the aortic valve's failure to open fully due to calcification. Treatment with the use of TAVR-AS devices has become a multibillion-dollar market, and Edwards remains the overwhelming market leader, [redacted] of the TAVR-AS market.

24. The JenaValve and JC Medical TAVR-AR devices are designed specifically to adhere to AR patients' aortic annuli. The aortic annulus is the ringed juncture that acts as the foundation for the attachment of the aortic valve.



25. Trilogy and J-Valve use self-expanding frames that deploy in the heart and anchor to the aortic annulus. Once positioned, the TAVR-AR device takes over the task of regulating the patient's blood flow.

26. TAVR-AR devices are Class III medical devices. The FDA must grant the device PMA approval before the device may be sold commercially. PMA approval is based on the FDA's determination that the PMA application contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use. To generate this scientific evidence, medical device companies will first conduct early feasibility studies to assess the initial safety and functionality of a device. After a successful early feasibility study, the medical device company will conduct pivotal trials, typically involving hundreds of patients, which demonstrate the safety and efficacy of the device for its intended use in support of a PMA application. These clinical trials take years to complete and can cost tens of millions of dollars.

THE RELEVANT ANTITRUST MARKET

A. TAVR-AR Devices Is the Relevant Product Market

27. A relevant product market in which to assess the competitive impact of the Proposed Acquisition is TAVR-AR devices.

28. TAVR-AR devices are designed specifically to treat AR and have unique characteristics that afford them distinct safety and efficacy profiles compared to other medical

devices. Respondents, the medical community, and other industry participants recognize dedicated TAVR-AR devices as having unique uses for which there are no adequate alternatives. Only a small number of companies have created TAVR-AR devices for use in the United States, and [redacted] Competition between TAVR-AR device competitors that are in their clinical trial stages drives improvements in their research, development, and commercialization efforts—ultimately benefitting doctors and patients.

29. AR's unique anatomical characteristics require dedicated transcatheter treatment devices. TAVR-AS devices are unsuitable treatments for patients with AR. AS involves calcified aortic leaflets that do not fully open; AR involves uncalcified leaflets that do not close properly. TAVR-AS devices are designed to rely on the calcium deposits in stenotic valves to anchor themselves and therefore may not anchor securely to patients with AR if those patients do not have similar calcium buildup. Doctors have attempted off-label use of TAVR-AS devices to treat AR but have found there is significant risk the valve dislodges, resulting in a potentially fatal issue called "embolization." For this reason, Respondents [redacted] TAVR-AR devices, in contrast, are designed specifically for treating AR, affixing to non-stenotic aortic valves without calcium deposits. The structural heart industry and medical community similarly recognize that TAVR-AS devices are not viable substitutes for dedicated TAVR-AR devices.

30. TAVR-AR devices are designed to treat a distinct patient population—patients with AR—and they are the only available treatment for patients who are ineligible for SAVR due to age or other co-morbidities. Further, the interventional cardiologists who use TAVR-AR devices are often different than the cardiac surgeons who implant aortic valves through open heart surgery.

B. The United States Is the Relevant Geographic Market

31. The United States is the relevant geographic market to assess the competitive effects of the Proposed Acquisition. TAVR-AR customers cannot practically turn to a TAVR-AR device provided outside the United States.

32. TAVR-AR devices require approval by the FDA to receive reimbursement from healthcare payers in the United States. As such, TAVR-AR devices sold outside the United States, but not approved for sale in the United States, do not provide viable competitive alternatives for U.S. consumers.

C. Market Structure

33. Edwards/JC Medical and JenaValve are the only two competitive participants in the TAVR-AR device market. According to JC Medical, [redacted] For example, a JenaValve [redacted] Other party documents [redacted]

34. A third company, Laguna Tech, is a small developer [redacted] It has a [redacted] TAVR-AR product that is **{much farther behind}** Respondents' devices in development. Moreover, Laguna Tech [redacted] JenaValve, [redacted]

35. No TAVR-AR company other than Edwards/JC Medical and JenaValve is engaged in clinical trials in the United States. There are TAVR-AR companies in various stages of development outside the United States, but to enter the United States market those companies would have to satisfy the full slate of FDA clinical trials, a process that typically takes at least five years.

36. The merging parties combine to account for [redacted] of the TAVR-AR device market, which is currently in its clinical trial stage. Further, given Trilogy's [redacted] JenaValve is anticipated to maintain 100% of commercial sales of TAVR-AR devices until J-Valve's [redacted] at which point the companies will split the market for the [redacted]

37. Should the Proposed Acquisition be consummated, the number of competitors in the TAVR-AR device market would shrink from two to one.

ANTICOMPETITIVE EFFECTS OF THE PROPOSED ACQUISITION

38. The Proposed Acquisition would substantially lessen competition or tend to create a monopoly in the U.S. TAVR-AR device market in the United States by eliminating vigorous head-to-head competition between Edwards/JC Medical and JenaValve, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

39. Respondents do not [redacted] For example, [redacted]

[redacted]

40. Edwards/JC Medical and JenaValve consistently identify [redacted] In a [redacted] Likewise, JenaValve's Chief Commercial [redacted] In another instance, JenaValve's Director of Marketing [redacted] JenaValve similarly recognized [redacted] The current head-to-head competition between Edwards/JC Medical and JenaValve drives the companies to accelerate the advancement and improvement of their TAVR-AR devices more than they would

absent that competition. [redacted] industry participants identify Edwards/JC Medical and JenaValve as the only two companies with advanced TAVR-AR device programs that are in FDA clinical trials.

41. As direct competitors, Edwards/JC Medical and JenaValve have spurred each other to accelerate and advance their TAVR-AR devices. JC Medical emphasized that [redacted] and they [redacted] JenaValve [redacted] as one JenaValve employee [redacted] For example, due to competitive pressure from JC Medical, JenaValve [redacted] In [redacted] JenaValve's Chief Medical Officer [redacted] A few months later, in [redacted] JenaValve's Chief Commercial Officer reacted to [redacted] A few days later, JenaValve leadership evaluated [redacted] JenaValve's Director of Strategy and Field Operations wrote, [redacted] If JenaValve's ARTIST trial is successful, thousands more patients with AR will have access to Trilogy.

42. Additionally, [redacted] which will expand patient access to the Trilogy valve system. When JenaValve [redacted] As JenaValve was running its ALIGN pivotal trial, [redacted] Many of those patients received [redacted] JenaValve concluded that [redacted] It recognized that it [redacted] Soon after, JenaValve concluded [redacted] Contemporaneously, JenaValve's Chief Commercial Officer recognized that there would be [redacted]

43. After Edwards agreed to acquire JenaValve, however, JenaValve [redacted]

Thus, if the Proposed Acquisition closes, JenaValve anticipates [redacted] If the Proposed Acquisition terminates, however, JenaValve expects [redacted] Even more concerning, Edwards documents indicate that it would [redacted] Elsewhere, Edwards stated that [redacted]

44. Patients will suffer if ongoing competition between Edwards/JC Medical and JenaValve ceases, and [redacted] post-acquisition.

45. Edwards/JC Medical and JenaValve also compete head-to-head to place their TAVR-AR devices in clinical trial sites at major medical research institutions, where they generate quality clinical data for FDA approval. In addition, they compete for the best TAVR specialists

to serve as principal investigators for their clinical trials. For example, at an industry conference, JenaValve noted [redacted] JenaValve's Director of Marketing noted in [redacted] Around the same time, JenaValve's Chief Commercial Officer [redacted]

46. There is robust and ongoing competition between Edwards/JC Medical and JenaValve to improve the quality of their TAVR-AR devices and generate superior clinical outcomes. For example, one risk of TAVR-AR procedures is the potential to disrupt the heart's conduction system, requiring the implantation of a pacemaker in addition to the new valve. All else equal, a TAVR-AR device with a lower "pacemaker rate"—the percentage of TAVR-AR procedures requiring pacemaker implantation—is considered superior. Currently, [redacted] In part due to [redacted] and that it [redacted] JenaValve recognizes [redacted] JenaValve's Director of Marketing commented on an [redacted] Prior to an industry conference JenaValve's CEO predicted that [redacted] and directed employees to [redacted]

47. With both valves in its portfolio, Edwards may choose to mothball or phase out Trilogy or J-Valve. As one JenaValve employee remarked [redacted] An Edwards [redacted] Even if Edwards [redacted] and continues to offer both devices, it would have little incentive to maintain the current competitive interaction between the two devices.

COUNTERVAILING FACTORS DO NOT OFFSET THE PROPOSED ACQUISITION'S THREAT TO COMPETITION

48. Respondents cannot demonstrate that entry of other TAVR-AR device companies would be timely, likely, or sufficient to offset the anticompetitive effects of the Proposed Acquisition.

49. Respondents cannot demonstrate that the Proposed Acquisition would likely generate verifiable, cognizable, merger-specific efficiencies that would offset the likely and substantial competitive harm from the Proposed Acquisition.

VIOLATION

COUNT I – ILLEGAL ACQUISITION

50. The allegations of Paragraphs 1 through 49 above are incorporated by reference.

51. The Proposed Acquisition, if consummated, may substantially lessen competition or tend to create a monopoly in the TAVR-AR device market in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18 and Section 5 of the FTC Act, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the 7th day of January, 2026, at 10 a.m. EST, is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that this administrative proceeding shall be conducted as though the Commission, in an ancillary proceeding, has also filed a complaint in a United States District Court, seeking relief pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. 53(b), as provided by Commission Rule 3.11(b)(4), 16 CFR 3.11(b)(4). You are also notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint

and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the Respondents' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Proposed Acquisition challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Proposed Acquisition is consummated, full divestiture or reconstitution of all associated and necessary assets, in a manner that fully restores competition, eliminates the effects of the Proposed Acquisition, and replaces the lost competitive intensity.

2. A prohibition against any transaction between Respondents that combines their businesses in the relevant market, except as may be approved by the Commission.

3. A requirement that, for a period of time, Respondents provide prior notice to and obtain prior approval of the Commission before all acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant market.

4. A requirement to file periodic compliance reports with the Commission.

5. A requirement that Respondents' compliance with the order be monitored at Respondents expense and by an independent monitor for a term to be determined by the Commission.

6. Any other relief appropriate to correct or remedy the anticompetitive effects of the Proposed Acquisition or to restore JenaValve as a viable, independent competitor in the relevant market.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this 6th day of August, 2025.

By the Commission.

SEAL:

Joel Christie
Acting Secretary