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**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES**

In the Matter of

Edwards Lifesciences Corp.

and

JenaValve Technology, Inc.

Docket No. 9442

Public Version

**RESPONDENT EDWARDS LIFESCIENCES CORP.
ANSWER AND DEFENSES**

Pursuant to Rule 3.12, Respondent Edwards Lifesciences Corp. hereby answers the Commission's Complaint.

Introduction

Edwards' acquisition of JenaValve offers the best chance to develop and bring to market new, lifesaving treatments for a deadly, underdiagnosed, and undertreated heart disease—aortic regurgitation ("AR"). If successful, the Commission's misguided challenge to this acquisition will stifle both competition and innovation. And many patients will not receive a treatment that they desperately need, as only Edwards is positioned to develop the marketplace for this new treatment at scale, solve JenaValve's persistent manufacturing problems, and develop next-generation treatments. The antitrust laws do not support that perverse result.

The only option for AR patients in the US today is open-heart surgery, an invasive and difficult procedure for which many AR patients are too frail to endure or otherwise cannot qualify. Hundreds of thousands of Americans have untreated AR.

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An estimated one in four untreated patients with severe AR die each year, and about 70% will die within five years—a prognosis worse than most metastatic cancers. Edwards seeks to change that by combining complementary research-and-development efforts initiated by two struggling startup companies—JenaValve and JC Medical, which Edwards acquired last year to prevent it from being shut down. These two transactions will enable Edwards to expand treatment access to thousands of additional patients and accelerate the development of next-generation treatment that neither start-up has the capability to develop absent the transactions. In the short term, the merger will accelerate and expand the launch of the first non-surgical AR treatment. In the long term, the merger will enhance innovation, enable treatment solutions for a larger population of patients whose anatomy may require different devices, and pave the way for fast followers.

The but-for world if this merger is blocked is not a vibrant JenaValve with a rapid and robust entry reaching the maximum number of patients. Rather, without the merger, JenaValve will be left limping and financially insecure with, at best, a slow and weak launch, ultimately taking longer to reach fewer patients. Likewise, the but-for world if this merger is blocked is not one with numerous competitors and options. Rather, without the merger, there will likely be no one to quickly establish viability and clear the way for others. Blocking the transaction would also rob Edwards of the synergies and complementarities that the transaction will create, impairing Edwards' R&D efforts, slowing Edwards and others from providing this

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much-needed therapy, handicapping future innovation, and harming patients now and in the future.

In contrast, the merger will not harm competition. There is no current product competition—just R&D efforts in a highly uncertain and novel space. Several other companies are engaging in R&D in non-surgical AR treatments, and strong competitors are well-positioned to follow once Edwards incurs the substantial costs required to successfully launch a brand-new medical device and therapy option for AR patients. This will lower the barriers for others to enter—as has happened in the recent past in other structural heart treatments pioneered by Edwards. The Complaint’s speculation that Edwards might slow innovation in some unspecified way has it exactly backwards and is directly contradicted by the facts—including Edwards’ specific, ordinary-course business documents.

No court has ever blocked a pure R&D merger, least of all under facts like these, where there is powerful evidence of immediate and future procompetitive benefits and, at most, only speculative theories of anticompetitive harm to weigh against those benefits. This procompetitive merger should be cleared to proceed as quickly as possible; anything less will leave many patients with no treatment options.

Response to the Complaint’s Specific Allegations

All allegations not expressly admitted herein are denied. To the extent the Complaint defines TAVR-AR to include only those devices being developed by Defendants, that definition is expressly denied. Edwards does not interpret headings or subheadings in the Complaint as well-pleaded allegations to which any response

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is required. To the extent such a response is required, they are denied. Edwards reserves the right to amend and/or supplement this Answer.¹

Each paragraph below corresponds to the same-numbered paragraph in the Complaint:

1. Edwards admits the first and second sentences. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence related to JenaValve; Edwards otherwise denies the allegations in the fourth sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fifth sentence. Edwards denies the allegations in the sixth sentence.

2. As to the first sentence, Edwards admits that it executed agreements to acquire JC Medical and JenaValve on the dates listed; to the extent the first sentence purports to quote from a document, Edwards respectfully refers the Court to that document; Edwards otherwise denies the allegations of the first sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence; to the extent the third sentence purports to quote from a document, Edwards respectfully refers the Court to that document. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth

¹ For clarity, references to sentence numbering refer to quotes as single sentences even if the quote has multiple sentences within that quote.

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sentence; to the extent the fourth sentence purports to quote from a document, Edwards respectfully refers the Court to that document. The fifth sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. Edwards admits the sixth sentence.

3. As to the first sentence, Edwards admits that a significant population of patients suffer from AR but otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations. The second sentence purports to describe AR, but Edwards denies that it is a full description. Edwards admits the allegations in the third sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence.

4. Edwards admits the first and second sentences. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the third sentence. As to the fourth sentence, Edwards admits that TAVR-AR devices seek to provide a treatment alternative to SAVR for patients for whom invasive surgery is not recommended; Edwards otherwise denies the allegations. As to the fifth sentence, Edwards admits that TAVR-AR devices are significantly less invasive than—and may be an alternative to—SAVR.

5. As to the first sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the second sentence, Edwards admits that it understands that JenaValve has engaged in clinical trials for its TAVR-AR device; otherwise, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the third sentence, Edwards

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admits that Edwards/JC Medical has an ongoing clinical trial for its J-Valve TAVR-AR system; to the extent the third sentence purports to quote from a document, Edwards respectfully refers the Court to that document; Edwards otherwise denies the allegations.

6. As to the first sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding JenaValve; Edwards otherwise denies the allegations. As to the second sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations; to the extent the second sentence purports to quote from a document, Edwards respectfully refers the Court to that document. The third, fourth, fifth, and sixth sentences purports to quote from and describe documents, and Edwards respectfully refers the Court to those documents. As to the seventh sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

7. Denied.

8. Edwards denies the allegations in the first and second sentences. The second and third sentences purport to quote from documents, and Edwards respectfully refers the Court to those documents; further, Edwards denies the allegations as a mischaracterization of those documents. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fifth sentence and otherwise denies the allegations in the fifth sentence.

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9. Paragraph 9 purports to describe testimony, and Edwards respectfully refers the Court to the testimony; Edwards also denies the allegations as a mischaracterization of the testimony.

10. Edwards denies the allegations in the first and second sentences. The third and fourth sentences purport to quote from documents, and Edwards respectfully refers the Court to those documents; further, Edwards denies the allegations as a mischaracterization of the documents.

11. Denied.

12. Denied.

13. Paragraph 13 contains a legal conclusion that requires no response. To the extent a response is required, Edwards denies the allegations.

14. Paragraph 14 contains a legal conclusion that requires no response. To the extent a response is required, Edwards denies the allegations.

15. Edwards admits the allegations in the first, second, third, and fourth sentences. As to the fifth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations related to the timing of FDA approval; Edwards otherwise admits the allegations in the fifth sentence.

16. The first sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. As to the second sentence, Edwards admits that it did not pursue the referenced projects; it otherwise denies the allegations.

17. Admitted.

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18. As to the first sentence, Edwards admits that JenaValve published the results of its pivotal trial for Trilogy in March 2024; Edwards otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the second sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

19. Edwards admits that it entered an agreement to acquire JenaValve on the date listed.

20. Edwards denies the allegations in the first sentence. As to the second, third, and fourth sentences, Edwards admits that Commission staff has raised the possibility of divesting JC Medical and that Edwards has not agreed to divest JC Medical; Edwards otherwise denies the allegations.

21. Edwards denies the allegations of the first sentence. The remainder of Paragraph 21 purports to quote from documents and/or testimony, and Edwards respectfully refers the Court to those documents and/or that testimony; further, Edwards denies the allegations as a mischaracterization of the documents and/or testimony.

22. Paragraph 22 purports to compare TAVR and SAVR, but Edwards denies that it is a full comparison or description; Edwards otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

23. Edwards admits the allegations in the first and second sentences. The third and fourth sentences purport to compare AS and AR, but Edwards denies that it is a full comparison or description. As to the fifth sentence, Edwards admits that

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treatment with the use of TAVR-AS devices has become a multibillion-dollar market; to the extent the fifth sentence purports to describe testimony, Edwards respectfully refers the Court to that testimony. Edwards otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fifth sentence.

24. Edwards admits the allegations in the first and second sentences; the graphic purports to reflect a document, and Edwards respectfully refers the Court to that document.

25. As to the first sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations as to Trilogy; Edwards otherwise admits the allegations. As to the second sentence, Edwards denies that allegations are a full description of how a TAVR-AR device works.

26. Edwards admits the allegations in the first, second, and third sentences. As to the fourth sentence, Edwards admits that it understands that medical companies conduct early feasibility studies but otherwise denies that this is sufficient to generate sufficient scientific evidence. The fifth sentence purports to describe the FDA-approval process, but Edwards denies that it is a full description. As to the sixth sentence, Edwards denies these allegations on the grounds that duration and cost vary.

27. Denied.

28. As to the first sentence, Edwards admits that TAVR-AR devices are designed specifically to treat AR; it otherwise denies the allegations. As to the second

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sentence, Edwards lacks knowledge or information sufficient to form a belief as to the allegations related to other entities; it otherwise denies the allegations. As to the third sentence, Edwards lacks information sufficient to form a belief as to the truth of the allegations. As to the fourth sentence, Edwards denies the allegations.

29. Edwards denies the allegations in the first and second sentences on the grounds that treatments are based on case-by-case patient and physician considerations. The third sentence purports to compare AS and AR, but Edwards denies that it is a full comparison or description. As to the fourth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the fifth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. The sixth sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. As to the seventh sentence, Edwards admits that TAVR-AR devices are designed specifically for treating AR. As to the eighth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations regarding other entities; it otherwise denies the allegations.

30. Edwards denies the allegations in the first sentence. As to the second sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

31. Denied.

32. The first sentence reflects a description of the FDA-approval process, but Edwards denies that it is a complete description. Edwards also denies the

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allegation in the first sentence to the extent it suggests that TAVR-AR devices that receive FDA approval is a relevant product market as Edwards' TAVR-AR product has not received FDA approval. Edwards otherwise denies the allegations of Paragraph 32.

33. Edwards denies the allegations in the first sentence. The remainder of Paragraph 33 purports to describe and quote from documents, and Edwards respectfully refers the Court to those documents.

34. Edwards denies the allegations in the first sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the remainder of Paragraph 34.

35. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence. As to the second sentence, Edwards denies the statement that “companies would have to satisfy the full slate of FDA clinical trials” to enter the testing market alleged by the FTC and denies that the process of entering the FTC’s alleged testing market “typically takes at least five years.”

36. Denied.

37. Denied.

38. Denied.

39. Edwards denies the allegations in the first sentence. The rest of Paragraph 39 purports to describe and characterize a document, and Edwards respectfully refers the Court to that document.

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40. Edwards denies the allegations in the first sentence. The second, third, fourth, fifth, sixth, and seventh sentences purport to characterize and quote from documents, and Edwards respectfully refers the Court to those documents; further, Edwards denies the allegations as a mischaracterization of the documents. Edwards denies the allegations in the eighth sentence. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the ninth sentence.

41. Edwards denies the allegations in the first sentence. The second and third sentences purport to quote from documents, and Edwards respectfully refers the Court to those documents. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the fourth sentence. The fifth sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. The sixth sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. As to seventh, eighth, and ninth sentences, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

42. The first sentence purports to describe and quote from a document, and Edwards respectfully refers the Court to that document. As to the second sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the third sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the fourth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of

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the allegations. As to the fifth, sixth, seventh, and eighth sentences, to the extent they purport to quote from documents, Edwards respectfully refers the Court to those documents; otherwise, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

43. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first, second, and third sentences. Further, the entirety of Paragraph 43 purports to characterize and quote from documents, and Edwards respectfully refers the Court to those documents.

44. Denied.

45. Edwards denies the allegations in the first and second sentences. As to the remainder of Paragraph 45, to the extent it purports to quote from documents or testimony, Edwards respectfully refers the Court to those documents or that testimony; further, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations.

46. Edwards denies the allegations in the first sentence. Edwards admits the allegations in the second sentence. As to the third sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. As to the fourth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations. The fifth sentence purports to quote from a document, and Edwards respectfully refers the Court to that document. As to the sixth sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations; to the extent the sentence purports to quote from a

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document, Edwards respectfully refers the Court to the document. As to the seventh sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations; to the extent the sentence purports to quote from a document, Edwards respectfully refers the Court to the document. Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the eighth sentence; to the extent the sentence purports to quote from a document, Edwards respectfully refers the Court to the document.

47. Edwards denies the allegations in the first sentence. As to the second sentence, Edwards lacks knowledge or information sufficient to form a belief as to the truth of the allegations; to the extent the sentence purports to quote from a document, Edwards respectfully refers the Court to the document. The third sentence purports to quote from a document, and Edwards respectfully refers the Court to the document. Edwards denies the allegations in the fourth sentence.

48. Denied.

49. Denied.

50. Edwards incorporates by reference its responses to Paragraphs 1 through 49.

51. Denied.

* * *

The remainder of the Complaint reflects a notice and notice of contemplated relief. To the extent a response is required, Edwards denies that the Commission is entitled to any relief.

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Defenses

1. The Complaint fails to state a claim upon which relief can be granted, including because:
 - A. The Complaint fails to allege a valid product market or line of commerce, including because there are no commercial TAVR-AR devices in existence in the United States.
 - B. The Complaint fails to allege a valid geographic market, including because the Complaint's definition apparently fails to account for companies outside the United States likely to enter FDA clinical trials, *i.e.* companies that are in the same position JC Medical was in before Edwards' acquisition.
 - C. The Complaint fails to allege that the proposed transaction will plausibly harm consumers or competition, including because the Complaint fails to account for alternative means of innovation and the probability of fast entry after a TAVR-AR device receives approval.
2. This case must be dismissed because these proceedings violate the separation-of-powers doctrine and Article III.
3. This case must be dismissed because these administrative proceedings are unconstitutionally insulated from Presidential oversight in violation of the separation-of-powers doctrine and Article II.
4. This case must be dismissed because these administrative proceedings violate the Fifth Amendment's Due Process Clause.

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5. The case must be dismissed because Congress has unconstitutionally delegated legislative powers to the Commission.
6. The case must be dismissed because the Commission has failed to identify a line of commerce.

Notice of Contemplated Relief

Edwards requests that the Commission:

- A. Dismiss the Complaint with prejudice;
- B. Deny the Commission's requested relief;
- C. Award to Edwards the costs incurred in defending this action, including expert's fees and reasonable attorney's fees;
- D. All further relief as the Commission may deem just and proper.

Dated: August 18, 2025

Respectfully submitted,

/s/ Ryan A. Shores

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Certificate of Service

I hereby certify that, on August 18, 2025, I caused the foregoing to be electronically filed with the Secretary of the Commission using the Federal Trade Commission's e-filing system, causing the document to be served on the following registered participants.

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Certificate for Electronic Filing

I hereby certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 18, 2025

/s/ Ryan A. Shores
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