

IN THE SUPREME COURT OF THE STATE OF DELAWARE

JOHNSON & JOHNSON and)	
ETHICON, INC.,)	
)	
Defendants-Below,)	Case No. 490,2024
Appellants,)	
)	
v.)	Court Below: Court of Chancery of
)	the State of Delaware
)	
FORTIS ADVISORS LLC, solely in)	
its capacity as representative of)	C.A. No. 2020-0881-LWW
former stockholders of Auris Health,)	
Inc.,)	
)	
Plaintiff-Below,)	
Appellee.)	

**MOTION FOR LEAVE TO FILE BRIEF OF THE CHAMBER OF
COMMERCE OF THE UNITED STATES OF AMERICA
AS AMICUS CURIAE SUPPORTING APPELLANTS AND REVERSAL**

Pursuant to Delaware Supreme Court Rule 28, the Chamber of Commerce of the United States of America (the “Chamber”) requests leave to file a brief as *amicus curiae* in support of the Appellants and reversal of the Chancery Court’s decision below, and states as follows:

1. The Chamber is the world’s largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations.

2. The Chamber represents a wide range of businesses that share a common interest in the stability, regularity, fairness, and predictability of business practices.

3. Pursuant to Supreme Court Rule 28(b), the Chamber has attached to this motion a Disclosure of Corporate Affiliations, and Financial Interest.

4. The Chamber has no monetary interest in the outcome of this case or appeal. However, its members—many of which are incorporated in and do business in Delaware—have an interest in the correct application of Delaware law regarding implied contractual terms.

5. No party's counsel authored the brief in whole or in substantial part; no party or party's counsel contributed money that was intended to fund preparing or submitting the brief; and no person—other than the *amicus curiae*, its members, or its counsel—contributed money that was intended to fund preparing or submitting the brief.

6. The Chamber seeks leave to file a brief highlighting the salient differences between the 510(k) and De Novo pathways for FDA marketing authorization of new medical devices and how those significant differences affect the bargaining incentives of medical device manufacturers. The brief highlights these differences by marshaling FDA guidance documents, FDA performance data, market survey data, and case law that would benefit the Court.

7. The brief argues that it is not at all clear that a medical device manufacturer like Johnson & Johnson (J&J) would have agreed to pursue De Novo authorization as well as, or instead of, 510(k) clearance without changing any other term in its contract with Auris Health. The 510(k) pathway is much more streamlined and less burdensome than the De Novo pathway—roughly 3 times cheaper, 4 years faster, and over 2 times more successful. Because the De Novo pathway is far costlier and riskier than the 510(k) pathway, no medical device manufacturer would be agnostic about which pathway applies or agree to pursue the De Novo pathway on the same terms as the 510(k) pathway.

8. The Court of Chancery therefore erred in holding that, by agreeing to contractual terms premised on pursuing the 510(k) pathway, J&J obligated itself to pursue the De Novo pathway, with all the extra costs and delays that pathway entails.

9. This Court should take these arguments into account, reverse the decision below, and make clear that Delaware continues to promote certainty by holding sophisticated parties to the express terms in their contract.

10. Pursuant to Supreme Court Rule 28(b)(3), the Chamber inquired as to the position of the Parties. Appellants consent to this Motion. Appellee opposes the Motion.

11. For the foregoing reasons, the Chamber requests leave to file the *Amicus Curiae* Brief attached as **Exhibit A**. Pursuant to Rule 28(b), a Disclosure of Corporate Affiliations and Financial Interest is attached as **Exhibit B**.

Dated: February 7, 2025

MARGRAVE LAW LLC

Of Counsel:

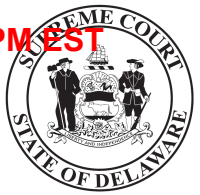
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**CERTIFICATE OF COMPLIANCE WITH TYPEFACE
REQUIREMENT AND TYPE-VOLUME LIMITATION**

1. This motion complies with the typeface requirement of Supreme Court Rule 13(a)(i) because it has been prepared in Times New Roman 14-point typeface using Microsoft Word.

2. This motion complies with the type-volume limitations of Supreme Court Rule 30(d) because it contains 535 words, which were counted by Microsoft Word.

Dated: February 7, 2025

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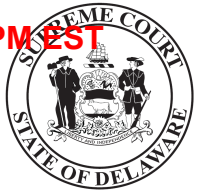
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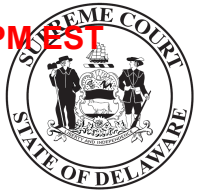
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[PROPOSED] ORDER

UPON CONSIDERATION of the *Motion for Leave to File Brief of The Chamber of Commerce of the United States of America as Amicus Curiae Supporting Appellants and Reversal*, it is hereby ORDERED AND DECREED that the Motion is Granted.

Dated: _____, 2025

J.



CERTIFICATE OF SERVICE

I, Anthony A. Rickey, hereby certify that on February 7, 2025, I caused true and correct copies of the foregoing *Motion for Leave to File Brief of The Chamber of Commerce of the United States of America as Amicus Curiae Supporting Appellants and Reversal*, and exhibits thereto, to be served through File & ServeXpress on the following counsel of record:

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