

Financial Interests in Public Comments for Medicare National Coverage Determinations of Therapeutic Medical Devices

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BACKGROUND

- The Centers of Medicare & Medicaid Services (CMS) utilizes public comments to inform its coverage of services and products through national coverage determinations (NCDs).
- The characteristics of commenters and their financial ties is unknown.

METHODS

Design: Cross-sectional study.

Setting: Public comments for therapeutic medical device NCDs from June 2019 to August 2022.

Outcomes and Measures:

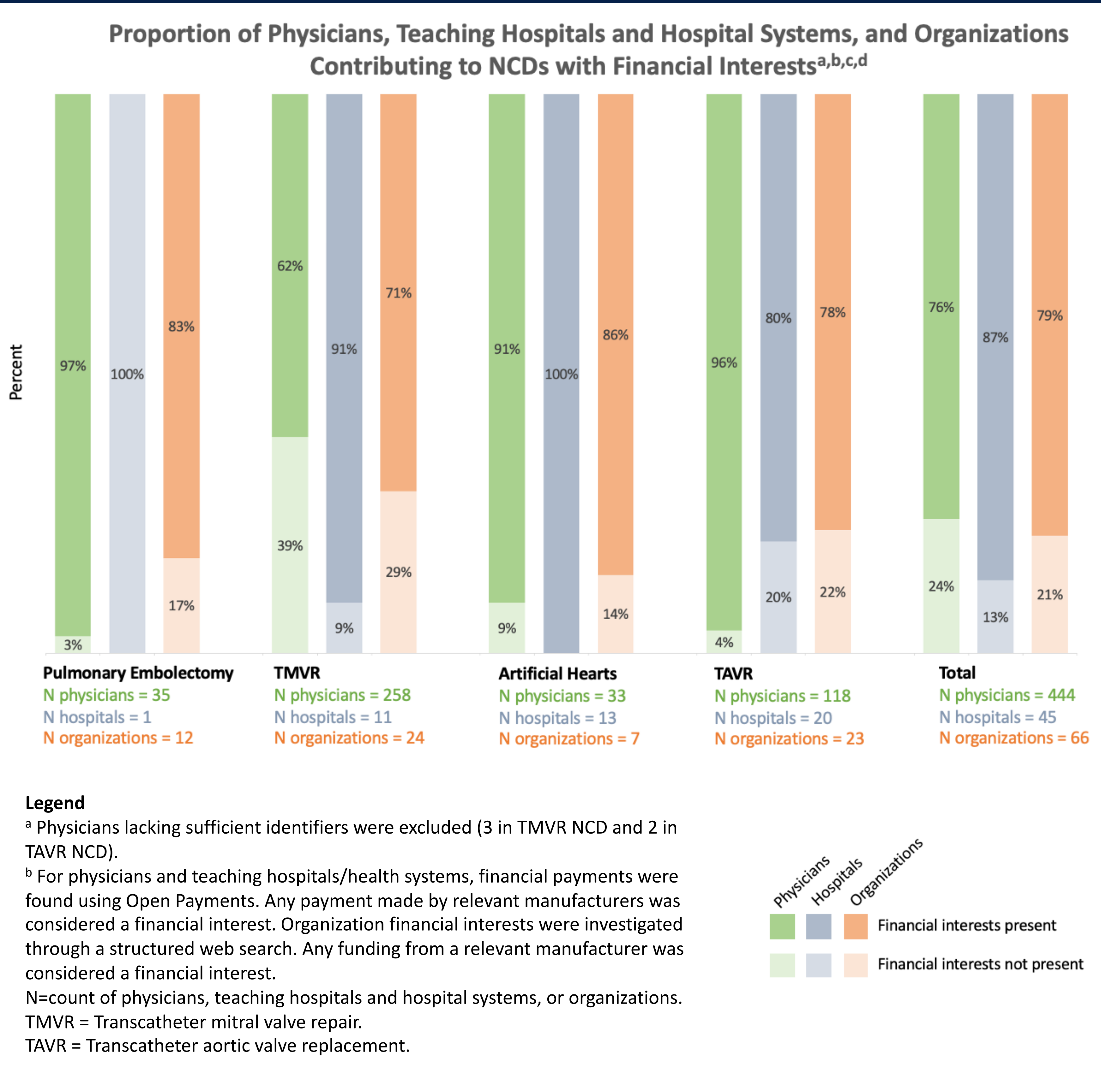
- Proportion of physicians, teaching hospitals, and organizations that commented and had financial ties to manufacturers that would benefit from expanded coverage, and their rates of disclosures.
- Proportion of evidence submitted by commenters with direct manufacturer funding or author financial relationships with relevant manufacturers.

RESULTS

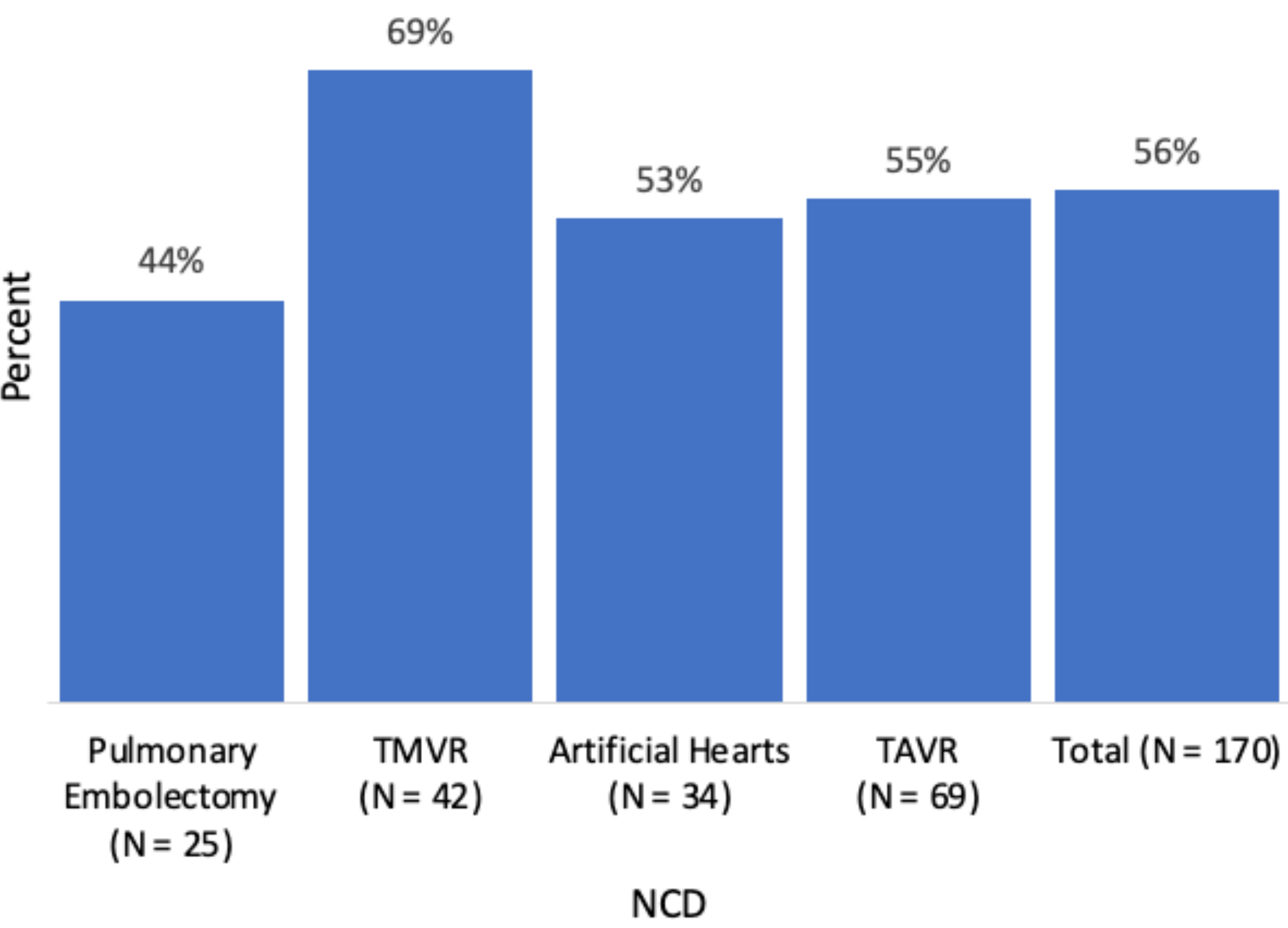
- 681 comments were manually reviewed.
- Most commenters were physicians, followed by non-physician healthcare professionals, teaching hospitals and health systems, and then patients and their families.
- 76% of all physician commenters, 87% of teaching hospitals, and 79% organizations had financial relationships with relevant device manufacturers (Central Figure).
- Median payment from these manufacturers to physicians was \$2,624 (interquartile range [IQR]: \$51 - \$ 51,226) and teaching hospitals was \$49,262 (IQR: \$5,211- \$339,330).
- Only one physician and one organization disclosed financial interests. No teaching hospital disclosed financial interests.

77% of physicians, teaching hospitals and organizations that submitted public comments had financial relationships with manufacturers.

56% of submitted evidence was funded by manufacturers or included authors who had received payments from manufacturers.



Proportion of Published Articles Cited in Public Comments that Received Manufacturer Funding or Author Financial Support Across National Coverage Determinations^a



- 56% of 170 research publications either had direct funding and/or an author with financial ties from relevant manufacturers.

DISCUSSION

- Most physicians and organizations submitting comments about CMS NCDs and evidence cited in comments had financial relationships with device manufacturers that would benefit from expanded coverage.
- Increasing transparency of financial disclosures and citations of independently (i.e., non-manufacturer-funded) generated data could help mitigate potential bias influencing NCDs.
- CMS could require financial disclosures and encourage participation of those without financial conflicts to submit public comments for NCDs.

FUNDING AND DISCLOSURES

This study was supported by Arnold Ventures. Drs. Ross and Dhruva serve on the Medicare Evidence Development & Coverage Advisory Committee.



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