Analysis of Potential Conflicts of Interest Among Otolaryngologic Patient Advocacy Organizations in 2016

Neil S. Kondamuri BA[1]; Vinay K. Rathi MD[2]; Matthew R. Naunheim, MD[2], MBA; Rosh V. Sethi, MD[2], MPH; Ashley L. Miller, MD[2]; Mark A. Varvares, MD[2]

[1]Warren Alpert Medical School of Brown University; [2]Massachusetts Eye and Ear Institute, Harvard Medical School

Introduction

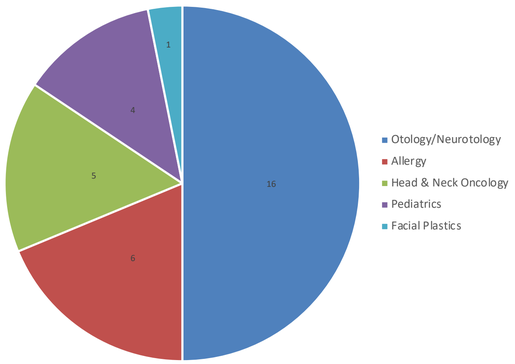
- Patient advocacy organizations (PAOs) are nonprofit groups dedicated to benefiting patients and their families through activities such as education and counseling, biomedical research funding, and political advocacy for therapeutic access.[1,2]
- Monetary support from drug and device companies may bias PAOs to serve the interests of industry donors over patients (e.g., by promoting the use of drugs with known harms or uncertain benefits).[2,3]
- For instance, an investigation by the U.S. Senate revealed that 14 PAOs receiving donations from opioid manufacturers subsequently promoted these medications despite growing concerns about potential for misuse.[4]

Methods

- Using previously described methods,[2,5] we identified all otolaryngologic PAOs listed within the Kaiser Health News (KHN) nonprofit database,[6] which defines PAOs as 501(c)(3) charities with medical National Taxonomy of Exempt Entities (NTEE) codes that assist patient populations through programs extending beyond the provision of services or care.[6]
- We classified disease area of focus and extracted (as available) total annual revenue and total annual donations between January 1st, 2016 and December 31st, 2016 from Form 990 tax filings and annual reports/websites, respectively. We then used PAO annual reports and websites to identify donor lists, quantify donations from industry (defined as medical drug or device companies), and establish conflicts of interest (COI) policies.

Results

Analyzed Otolaryngologic PAOs



Annual Revenue and Donations to Otolaryngologic PAOs

Annual Revenue in millions, $	
Greater than or Equal to 10	2 (6.3)
5 - 9.99	2 (6.3)
1 - 4.99	19 (59.4)
<1	9 (28.1)
Annual Total Donations in millions, $	
Greater than or Equal to 10	1 (3.1)
5 - 9.99	2 (6.3)
1 - 4.99	3 (9.4)
<1	8 (25.0)
Unclear	18 (56.3)

Characteristics of Otolaryngologic PAOs

Publicly Available Donor List	
Yes	15 (46.9)
No	17 (53.1)
Industry Donors	
Yes	10 (31.3)
No	5 (15.6)
Unclear	17 (53.1)
COI Policy Published on Website	
Yes	11 (34.4)
No	21 (65.6)
Annual Industry Reported Donations, $	
>1,000,000	0 (0.0)
500,000 - 999,999	2 (6.3)
100,000 - 499,999	1 (3.1)
<100,000	0 (0.0)
Unclear	29 (90.6)

Conclusions

1. Significant variation among PAOs with respect to both disease area and public disclosure of donations.
2. Half of all PAOs – including the highest-revenue organization (Starkey Hearing Foundation; total annual revenue exceeding $22 million) – were focused on patients with otologic/neurotologic conditions, which may be attributed to the high prevalence of hearing loss.
3. In contrast, other patient populations (e.g., individuals with obstructive sleep apnea) may lack such advocates, highlighting the importance of professional societies such as the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNSF) in promoting the interests of these patients.[7]

Solutions

1. PAOs may voluntarily implement rigorous internal policies to protect against financial COIs with donors. In a recent survey of PAOs, many organizations acknowledged the need for more robust self-governance mechanisms.[1,3] PAOs should publish these internal policies to promote transparency for the benefit of external stakeholders.
2. Lawmakers could require drug and device companies to publicly report donations to PAOs, as is currently required for industry payments to clinicians.[3,9]
3. Professional societies such as the AAO-HNSF could incentivize transparency by maintaining a publicly accessible online repository of PAOs and their disclosure practices.

References

1. Rose SL, Highland J, Karafa MT, Joffe S. Patient Advocacy Organizations, Industry Funding, and Conflicts of Interest. *JAMA Intern Med.* 2017;177(3):344-350.
2. McCoy MS, Carniol M, Chockley K, Urwin JW, Emanuel EJ, Schmidt H. Conflicts of interest for patient-advocacy organizations. *N Engl J Med.* 2017;376(9):880-885.
3. McCoy MS. Industry Support of Patient Advocacy Organizations: The Case for an Extension of the Sunshine Act Provisions of the Affordable Care Act. *Am J Public Health.* 2018;108(8):1026-1030.
4. McCaskill C. Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups. In: U.S. Senate Homeland Security & Governmental Affairs Committee, ed2018.
5. Li DG, Singer S, Mostaghimi A. Prevalence and Disclosure of Potential Conflicts of Interest in Dermatology Patient Advocacy Organizations. *JAMA Dermatol.* 2019.
6. Kopp EL, Elizabeth; Lupkin, Sydney; Knight, Victoria. Pre$cription for Power: Methodology and Sources. https://khn-data-projects.herokuapp.com/patient-advocacy/methodology. Published 2018. Accessed January 10, 2019.
7. AAO-HNSF. Advocacy. https://www.entnet.org/content/legislative-political-affairs. Published 2019. Accessed May 5, 2019.
8. Rose, S. L. Patient advocacy organizations: institutional conflicts of interest, trust, and trustworthiness. *J Law Med Ethics.* 2013;41(3): 680-687.
9. Rathi VK, Samuel AM, Mehra S. Industry ties in otolaryngology: initial insights from the physician payment sunshine act. *Otolaryng Head Neck Surg.* 2015;152(6):993-999.

Acknowledgments

This project was not supported by any external grants or funds. The authors assume full responsibility for the accuracy and completeness of the ideas presented.

Mr. Kondamuri and Dr. Rathi were responsible for the conception and design of this work, the acquisition of data, statistical analysis, manuscript drafting. All authors participated in the analysis and interpretation of the data and critically revised the manuscript for important intellectual content.