

SPECIAL REPORT

Conflicts of Interest for Patient-Advocacy Organizations

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Patient-advocacy organizations are nonprofit groups whose primary mission is to combat a particular disease or disability or to work toward improving the health and well-being of a particular patient population.¹ As political actors, such organizations play an influential role in shaping health policy, pursuing agendas that include expanding coverage for drugs, devices, and diagnostic procedures; increasing support for medical research; and streamlining approval of experimental therapies.²⁻⁵

Reports by media and watchdog groups have drawn critical attention to financial relationships between patient-advocacy organizations and drug, device, and biotechnology companies.⁶⁻¹¹ Industry support can be an important resource for patient-advocacy organizations but can also give rise to institutional conflicts of interest,^{2,12} which exist when “an institution’s own financial interests or the interests of its senior officials pose risks to the integrity of the institution’s primary interests and missions.”¹³ In the context of organization–industry relations, concerns have been raised that industry-supported patient-advocacy organizations have spoken out for access to drugs with questionable therapeutic benefit and remained silent on policy proposals, such as drug-pricing reforms, that might benefit their constituents.^{6,7}

Despite these concerns, there have been few systematic attempts to quantify the frequency and scope of industry financial support for patient-advocacy organizations, the extent to which such organizations voluntarily disclose this support, the frequency of other industry–organization relationships that may give rise to conflicts of interest, or the policies that patient-advocacy organizations have in place to manage conflicts of interest. The few studies that exist have limitations. Many have been published outside peer-

reviewed journals.^{9,14-16} Some are small, involving no more than 35 patient-advocacy organizations.^{14,16} Others examine samples of patient-advocacy organizations that include small organizations, rather than focusing on those likely to have the largest effect on the public.¹⁷ Others have restricted their focus to patient-advocacy organizations that are active in a particular disease area.¹⁸ Others are outdated.^{15,17} We are not aware of previous studies that have examined conflicts of interest arising from the presence of industry executives on the boards of patient-advocacy organizations.

We analyzed the Form 990 tax records, annual reports, and websites of 104 U.S.-based patient-advocacy organizations with annual revenues of at least \$7.5 million to answer three specific questions. First, to what extent do patient-advocacy organizations disclose information necessary for assessing possible financial and other conflicts of interest? Second, how frequently do patient-advocacy organizations have financial and other conflicts of interest? Third, do patient-advocacy organizations have policies to minimize and manage conflicts of interest?

METHODS

SAMPLE

To focus on organizations likely to have a major effect in terms of outreach and advocacy, we used a purposive sampling strategy that was designed to capture the largest patient-advocacy organizations, on the basis of annual revenue, that were operating at the national level in the United States. To construct the sample, we searched the GuideStar charity database for 501(c)(3) charities with annual revenues of at least \$7.5 million and National Taxonomy of Exempt Entities codes in groups G (Disease,

Disorders, Medical Disciplines) or H (Medical Research). The \$7.5 million cutoff was selected to ensure a sufficiently sizable sample of large organizations. This query returned 756 organizations, which included patient-advocacy organizations as well as other nonprofit organizations — such as hospitals and professional societies — that engaged in health-related activities. We excluded organizations that were not patient-advocacy organizations, as well as regional organizations (e.g., local chapters of national organizations) and internationally focused organizations, leaving 104 organizations for the final analysis. For a list of all organizations included in the study as well as detailed inclusion and exclusion criteria, see the Supplementary Appendix, available with the full text of this article at NEJM.org.

DATA COLLECTION

From January through June 2016, we reviewed the Form 990 tax records, annual reports, and websites of each organization included in the study. Data collection followed a standardized process for each organization. (For details, see the Supplementary Appendix.) We began by visiting the website of the organization and downloading the most current annual report and Form 990 available. Tax forms were reviewed to confirm the annual revenue of the organization in order to calculate the percentage of its annual revenue made up of industry donations. Annual reports were reviewed in four steps. First, we determined whether the annual report included a list of donors and, when donor lists were available, whether they included the amounts or uses of individual donations. Second, if an organization reported receiving donations from drug, device, or biotechnology companies, we recorded the names of the donors and, if available, the amounts and uses of the donations. Third, we searched the annual report for the names and employment information of the board members of the organization. Fourth, if any board members were employed by a drug, device, or biotechnology company, we recorded their names, employers, and positions on the board.

Websites were reviewed with the use of the same four-step process. In addition, we searched websites for conflict-of-interest policies or policies on accepting corporate donations and re-

corded the entire text of such policies when available.

STATISTICAL ANALYSIS

Descriptive statistics and frequencies were calculated with the use of Microsoft Excel. When patient-advocacy organizations reported the amounts of individual donations that they received, we summed donations from drug, device, and biotechnology companies to calculate the total revenue that each organization received from industry donations. Revenue from industry donations was then divided by the annual revenue of the organization to calculate the percentage of its revenue accounted for by industry donations. When organizations reported donation amounts using ranges (e.g., \$100,000 to \$249,999) rather than exact figures, we calculated the maximum and minimum values of industry donations. Maximum values were calculated under the assumption that all donations fell at the upper bound of reported ranges; minimum values were calculated under the assumption that all donations fell at the lower bound of reported ranges. Maximum and minimum donation values were then divided by the annual revenue of the organization to determine the maximum and minimum percentage of annual revenue from industry donations.

RESULTS

CHARACTERISTICS OF THE ORGANIZATIONS

Our analysis included 104 patient-advocacy organizations. More than a third of these organizations (37%) focused on a variety of cancer; more than half had annual revenues of \$7.5 million to \$24.9 million. For more on the characteristics of the organizations, see Table 1.

DISCLOSURE PRACTICES

Overall, 91 of the 104 patient-advocacy organizations (88%) published a list of donors either on the website of the organization or in the annual report (Table 2). Two of the 91 organizations stated explicitly that published donor lists included all corporate donors.

Of the 104 organizations, 57% published the amounts of received donations. Only 5% published the exact amounts of received donations, whereas 52% published donation amounts in

Table 1. Characteristics of Patient-Advocacy Organizations.

Characteristic	Organizations (N=104)
	no. (%)
Disease area	
Cancer	38 (37)
Neurologic	13 (12)
HIV–AIDS	7 (7)
Musculoskeletal	6 (6)
Heart or lung	5 (5)
Vision	4 (4)
Kidney	3 (3)
Diabetes	2 (2)
Mental health	2 (2)
Lupus	2 (2)
Other disease or condition*	11 (11)
General†	11 (11)
Annual revenue, in millions of \$‡	
7.5–24.9	60 (58)
25.0–49.9	18 (17)
50.0–74.9	5 (5)
75.0–99.9	5 (5)
100.0–124.9	2 (2)
125.0–149.9	4 (4)
150.0–174.9	1 (1)
175.0–199.9	2 (2)
200.0–224.9	1 (1)
225.0–249.9	0
≥250.0	6 (6)

* These organizations are active in a single disease area that is not captured by the categories in the table. Examples include the American Liver Foundation, Alpha-1 Foundation, and Crohn's and Colitis Foundation of America.

† These organizations claim to serve a broad group of patients rather than patients in a particular disease area. Examples include Community Health Charities, National Organization for Rare Disorders, and Patient Advocate Foundation.

‡ Annual revenues are reported on the basis of the most recent Form 990 tax records made available by the organization at the time of data collection.

ranges. The difference between the upper and lower bounds of reported ranges varied considerably, from less than \$250 to more than \$1 million. Nearly two thirds (31 of 54) of the organi-

zations that published donations using ranges included an unbounded upper range (e.g., >\$1 million). Of the 104 organizations, 18 specified the total amount of industry or corporate donations that they received; 10 provided information about how individual donations were used.

Almost all the organizations (97%) published the names of board members. A total of 74% of the 104 organizations provided board members' employment information.

FINANCIAL SUPPORT

Overall, 86 of the 104 patient-advocacy organizations (83%) reported receiving financial support from industry. Of the 18 organizations that did not report receiving industry support, 13 provided no donor information. Only 1 of the 104 organizations explicitly indicated that it does not accept industry support.

Given that donation amounts were typically reported in ranges, it is impossible in most cases to provide precise estimates of the amount of industry support that patient-advocacy organizations received. Of the 59 organizations that published the amounts of donations, 23 (39%) reported receiving at least \$1 million annually from industry donations; 13 (22%) reported receiving less than \$1 million; and 23 (39%) reported information that did not allow a determination of whether industry donations were less than \$1 million or at least \$1 million (Table 3). There are two reasons for this ambiguity. For some organizations, the minimum value of the reported donations was less than \$1 million and the maximum value was more than \$1 million. Other organizations did not definitively report industry donations of at least \$1 million but reported donations using unbounded upper ranges, thus making it impossible to cap the maximum value of the reported donations. With respect to the percentage of annual revenue, 11 of the 59 organizations (19%) that reported donation amounts reported receiving at least 10% of annual revenue from industry donations; 20 (34%) reported receiving less than 10% of annual revenue from industry donations; and 28 (47%) reported information that did not allow a determination of whether industry donations accounted for less than 10% or at least 10% of annual revenue.

Table 2. Information Disclosed by Patient-Advocacy Organizations on Websites or in Annual Reports.

Information Disclosed	Website (N = 104)	Annual Report (N = 104)	Website or Annual Report (N = 104)
	<i>number of organizations (percent)</i>		
Financial support			
Names of donors	60 (58)	67 (64)	91 (88)
Amount of individual donations	23 (22)	48 (46)	59 (57)
Range	19 (18)	47 (45)	54 (52)
Exact figure	4 (4)	1 (1)	5 (5)
Uses of individual donations	9 (9)	4 (4)	10 (10)
Total revenue received from industry or corporate donations*	8 (8)	12 (12)	18 (17)
Board membership			
Names of board members	101 (97)	84 (81)	101 (97)
Board members' employment information	76 (73)	35 (34)	77 (74)

* The organization made an explicit statement indicating the total amount of revenue that it received from drug, device, or biotechnology companies or from all corporate donors.

BOARD MEMBERSHIP

Of the 104 patient-advocacy organizations, 37 (36%) reported at least one current drug, device, or biotechnology company executive on the governing board. In addition, 4 organizations reported at least one former industry executive on the board. A total of 12 of the 104 organizations (12%) reported that a current drug, device, or biotechnology executive held a leadership position on the board, such as chair or vice-chair, with 1 additional organization reporting a former industry executive in a board leadership position. Roughly one quarter of patient-advocacy organizations (26%) provided no employment information for board members.

CONFLICT-OF-INTEREST POLICIES

Of the 104 patient-advocacy organizations, 27 published any policy pertaining to conflicts of interest on the website of the organization. We analyzed the content of these policies and found that 12 organizations had a policy that addressed institutional conflicts of interest — that is, conflicts of interest arising from the relationships between the organization and the corporate donors or other partners. Other conflict-of-interest policies dealt only with the individual

Table 3. Annual Revenue from Reported Industry Donations across Patient-Advocacy Organizations That Disclosed Donation Amounts.

Annual Revenue from Industry Donations	Organizations (N = 59)
	<i>no. (%)</i>
In total dollars	
≥\$1 million*	23 (39)
<\$1 million†	13 (22)
Unclear‡	23 (39)
As percentage of annual revenue	
≥10%*	11 (19)
<10%†	20 (34)
Unclear‡	28 (47)

* Shown are organizations that received at least \$1 million (or 10% of annual revenue) on the basis of the minimum value of industry donations.

† Shown are organizations that received less than \$1 million (or 10% of annual revenue) on the basis of the maximum value of industry donations. Included are two organizations — Child Mind Institute and Children's Cancer Recovery Foundation — that reported no donations from industry.

‡ Shown are organizations with a minimum value of industry donations of less than \$1 million (or 10% of annual revenue) and a maximum value of industry donations of at least \$1 million (or 10% of annual revenue) and organizations that did not definitively report industry donations of at least \$1 million (or 10% of annual revenue) but reported donations using unbounded ranges.

conduct of the employees and board members of the organization.

DISCUSSION

This study shows that among 104 of the largest U.S.-based patient-advocacy organizations, at least 83% received financial support from drug, device, and biotechnology companies, and at least 39% have a current or former industry executive on the governing board. Our results raise four points worth highlighting.

First, industry financial support of patient-advocacy organizations is widespread, with at least 83% of reviewed organizations receiving financial support from drug, device, and biotechnology companies. By comparison, a recent study showed that 41% of physicians across all specialties received industry payments in 2013–2014.¹⁹ Moreover, although there is considerable variation in the levels of declared industry support across patient-advocacy organizations, we found that the support was often substantial, with at least 39% of the organizations that disclosed donation amounts receiving at least \$1 million annually from industry.

Second, although existing studies of the relationships between patient-advocacy organizations and industry have focused almost exclusively on financial support from industry, it is important to recognize that conflicts of interest can also arise as a result of the competing interests of board members and senior officials. We found that ties between patient-advocacy organizations and industry are reflected in the governance structures of many organizations: at least 39% of patient-advocacy organizations have a current or former industry executive on the board, and at least 12% have a current or former industry executive in a leadership position on the board.

Third, current disclosure practices of patient-advocacy organizations are limited. Although we can conclude that industry support for such organizations is common, the full scope of this support and the severity of conflicts of interest remain difficult to determine given the disclosures of the organizations. Many of the organizations (88%) published the names of donors in the annual report or on the website of the organization. Although these donor lists are necessary for determining the existence of conflicts of

interest, they are insufficient for assessing the severity of such conflicts, which requires knowing — at a minimum — the amounts of donations and the uses to which donations were put. We found that full disclosure of this information was rare. Over half (57%) of the 104 organizations disclosed the amounts of the donations that they received. However, disclosure of donation amounts was typically done with the use of broad ranges rather than exact figures. Disclosure of donation uses was rarer, with only 10% of patient-advocacy organizations providing such information.

Fourth, we found little evidence of self-regulation of conflicts of interest among patient-advocacy organizations. Only 12% of such organizations have published policies in place for managing institutional conflicts of interest. Having conflict-of-interest policies in place does not ensure that they will be followed, nor does it eliminate conflicts of interest. However, sound, publicly accessible policies are generally thought to reduce the likelihood of harm resulting from conflicts of interest while fostering public trust.¹³

Our study has several limitations. First, because we relied on publicly disclosed data, we cannot determine the extent to which patient-advocacy organizations received unreported or underreported industry donations. Consequently, our findings are likely to underestimate the full scope of industry support for patient-advocacy organizations. Second, companies can channel donations to patient-advocacy organizations through nonprofit entities that they control or substantially fund but that are not readily identifiable with those companies. Any donations of this type are not captured by our findings. Third, we studied high-revenue patient-advocacy organizations and are thus unable to draw conclusions about the reporting practices and industry ties of smaller organizations with annual revenues of less than \$7.5 million. Larger organizations are likely to have more resources to devote to tracking donations and maintaining up-to-date websites and annual reports. Thus, our findings may overestimate the extent to which patient-advocacy organizations disclose industry support.

Taken together, the ubiquity of industry support for patient-advocacy organizations, the variation in levels of support, and the limitations of

the current disclosure practices of such organizations provide strong reasons in favor of creating a “sunshine” law to cover industry payments to patient-advocacy organizations. Although the 2009 Institute of Medicine report on conflict of interest¹³ recommended such a provision, it was not included in the Sunshine Act passed in 2010. However, other countries, such as France, have enacted requirements for companies to disclose payments to patient-advocacy organizations, which shows the feasibility of such measures.²⁰ Greater transparency would enable citizens, researchers, policymakers, and others to assess the possible conflicts of interest of patient-advocacy organizations in a way that is not currently possible. Greater transparency would also benefit organizations that receive only modest industry donations, by allowing third parties to differentiate them from patient-advocacy organizations that are highly dependent on industry funding. Short of legislative change, greater transparency could be achieved by strengthening disclosure requirements for patient-advocacy organizations that testify before federal advisory committees.²¹ Finally, patient-advocacy organizations should also consider strengthening their own reporting practices.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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1. National Health Council. Membership directory. 2016 (<http://www.nationalhealthcouncil.org/about-nhc/membership-directory>).
2. Rose SL. Patient advocacy organizations: institutional conflicts of interest, trust, and trustworthiness. *J Law Med Ethics* 2013;41:680-7.
3. Rothman SM, Raveis VH, Friedman A, Rothman DJ. Health advocacy organizations and the pharmaceutical industry: an analysis of disclosure practices. *Am J Public Health* 2011;101:602-9.
4. Dresser R. *When science offers salvation: patient advocacy and research ethics*. New York: Oxford University Press, 2001.

5. Davis C, Abraham J. *Unhealthy pharmaceutical regulation: innovation, politics and promissory science*. Basingstoke, United Kingdom: Palgrave Macmillan, 2013.
6. O'Donnell J. Patient groups funded by drugmakers are largely mum on high drug prices. *USA Today*. January 21, 2016 (<http://www.usatoday.com/story/news/nation/2016/01/21/patient-groups-drug-makers-high-drug-prices/79001722/>).
7. Rosenberg M. Bone associations funded by Big Pharma push questionable drugs on women. June 13, 2016 (<http://www.theepochtimes.com/n3/2089469-bone-associations-funded-by-big-pharma-push-questionable-drugs-on-women/>).
8. Meyer B. Fibromyalgia: drugmakers' push is boosting 'murky' ailment, influencing patients, doctors. February 8, 2009 (http://www.cleveland.com/nation/index.ssf/2009/02/fibromyalgia_drugmakers_push_i.html).
9. Claypool R. Patients' groups and big pharma. Washington, DC: Public Citizen, August 4, 2016.
10. Weisman R. Biotech leverage patient groups in drug development. *Boston Globe*. September 29, 2016.
11. Thomas K. Furor over drug prices puts patient advocacy groups in bind. *New York Times*. September 27, 2016.
12. Emanuel EJ, Steiner D. Institutional conflict of interest. *N Engl J Med* 1995;332:262-7.
13. Lo B, Field MJ, eds. *Conflict of interest in medical research, education, and practice*. Washington, DC: National Academies Press, 2009 (<http://nationalacademies.org/hmd/reports/2009/conflict-of-interest-in-medical-research-education-and-practice.aspx>).
14. Marshall J, Aldhous P. Patient groups special: swallowing the best advice? *New Scientist*. October 25, 2006 (<https://www.newscientist.com/article/mg19225755-100-patient-groups-special-swallowing-the-best-advice/>).
15. Jacobson ME. *Lifting the veil of secrecy: corporate support for health and environmental professional associations, charities, and industry front groups*. Washington, DC: Center for Science in the Public Interest, 2003 (<https://cspinet.org/resource/lifting-veil-secretary>).
16. Ethics and disclosure: how health nonprofits handle contributions from medical companies. *Chronicle of Philanthropy*. September 6, 2010 (<https://philanthropy.com/article/How-Health-Nonprofits-Handle/160015/>).
17. Ball DE, Tisocki K, Herxheimer A. Advertising and disclosure of funding on patient organisation websites: a cross-sectional survey. *BMC Public Health* 2006;6:201.
18. Abola MV, Prasad V. Industry funding of cancer patient advocacy organizations. *Mayo Clin Proc* 2016;91:1668-70.
19. Pham-Kanter G, Mello MM, Lehmann LS, Campbell EG, Carpenter DC. Public awareness of and contact with physicians who receive industry payments: a national survey. *J Gen Intern Med* (in press).
20. Kreis J, Schmidt H. Public engagement in health technology assessment and coverage decisions: a study of experiences in France, Germany, and the United Kingdom. *J Health Polit Policy Law* 2013;38:89-122.
21. McCoy MS, Emanuel EJ. Health policy: addressing conflicts of interest of public speakers at advisory committee meetings. *Nat Rev Clin Oncol* 2016;13:267-8.

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