



EDITORIALS

Patient organizations and conflict of interest

Voluntary disclosure isn't working

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As non-profit public charities, patient organizations seek to combat particular diseases or disabilities by increasing awareness through outreach and advocacy, providing education and support services for patients, and funding research focused on prevention or cure. Such organizations carry important lobbying power among national governments and often contribute to policy discussions on key matters such as drug approval and insurance coverage. However, given increasing financial pressures, many groups receive corporate funding from pharmaceutical and device companies, which poses a potential conflict of interest. In the linked paper (doi: 10.1136/bmj.k5300), Mandeville and colleagues provide a welcome perspective on this concern by examining the financial interests of patient organizations contributing to discussions of treatment coverage, known as health technology assessments, at England's National Institute for Health and Care Excellence (NICE).¹

To evaluate both the prevalence of financial interests among patient organizations and the extent to which NICE's current policy requires and ensures disclosure, Mandeville and colleagues did a thorough review relying not only on self disclosure but also on multiple outside sources. Through this innovative approach, the authors determined that more than two thirds of patient organizations contributing to appraisal of a technology received funding from that technology's manufacturer or the manufacturer of a competitor technology within the previous year. NICE's decision making committees were aware of less than a quarter of these potential financial conflicts of interests. For nearly two thirds of the interests of which committees were unaware, disclosure was not required by NICE's current policy.¹

These findings contribute substantively to the broader picture of the influence of industry in patient organizations. International studies echo the findings, suggesting that a substantial number of patient organizations have potential financial conflicts of interest but limited disclosure practices.²⁻⁶ Mandeville and colleagues add a valuable perspective to this discourse by illuminating the role these conflicts of interest may play in

government decision making on healthcare in England. Limited research on decision making by the US Food and Drug Administration and the European Medicines Agency suggests that this problem is unfortunately widespread.⁷⁻⁹

That most patient organizations did not voluntarily disclose their potential conflicts of interests on Disclosure UK, online, or through the researcher's follow-up inquiry is surprising and raises concerns about the policy of voluntary self disclosure as a realistic or effective method of appropriately managing these organizations' conflicts of interest. Reviews of Disclosure UK, the database recording payments from companies in the Association of the British Pharmaceutical Industry to healthcare professionals and organizations, have shown that the recipients most likely to opt out are those receiving the largest payments, and thus the most likely to have substantial financial conflicts of interest.^{10 11} Recognizing these concerns, the US and several European countries have moved towards mandatory disclosure through various "sunshine" acts meant to increase transparency,^{12 13} leaving some people clamoring for the UK to do the same.^{10 14} However, patient organizations are often not included in these disclosure laws, including those in the US.

Beyond disclosure to the general public through a national database, England and other countries must confront the critical question of how to manage disclosure of interests by patient organizations contributing to government decision making in health. When pharmaceutical and device companies lobby government leaders or participate in government decision making, their for-profit incentives are typically clearly visible; however, when patient organizations participate in similar activities, government leaders and members of the public may believe them to be unbiased and acting independently in the best interests of the patients they represent.¹⁵ For NICE (and its counterparts in other countries) to better judge and interpret recommendations made by patient organizations, its policies must require disclosure in all circumstances and not just in the nomination of patient and clinical experts. Furthermore, NICE

must ensure complete enforcement with compliance from all patient organizations.

Finally, once patient organizations achieve fully transparency, how should NICE and similar organizations interpret and respond to their declared conflicts of interest? According to Mandeville and colleagues, almost all of the nominated patient and clinical experts who declared financial conflicts of interest were selected to attend NICE committee meetings. Furthermore, similar proportions of those declaring and not declaring conflicts attended NICE meetings.¹ Disclosure alone does not provide a robust enough safeguard to ensure public trust, and additional legislation and organizational policies are needed for all stakeholders to react in a meaningful way to the information disclosed.¹⁵

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