

COI declarations and off-label drug use

August 7 2012

Conflict-of-interest statements made by physicians and scientists in their medical journal articles after they had been allegedly paid by pharmaceutical manufacturers as part of off-label marketing programs are often inadequate, highlighting the deficiencies in relying on author candidness and the weaknesses in some journal practices in ensuring proper disclosure, according to a study by international researchers published in this week's *PLoS Medicine*. Off-label marketing is the promotion by a manufacturer of a drug for use in a condition or age group, or in a dose or form of administration that has not been specifically approved by a drugs regulatory body; it is illegal in the United States.

In an analysis led by Aaron Kesselheim from Brigham and Women's Hospital in Boston, the authors from the US and Australia found that overall, only one in seven authors reported by whistleblowers to be involved in off-label marketing activities fully disclosed their [conflict of interest](#) in published articles.

The authors reached these conclusions by examining 26 whistleblower complaints of illegal off-label promotion and identified the 91 doctors and scientists recorded as being involved in this practice. The researchers found 39 (43%) of these 91 experts had authored 404 publications related to the drugs at issue in the complaints. However, only 62 (15%) of these articles had adequate disclosures. Among the articles without adequate disclosures, 43% (148) had no disclosure at all, 4% had statements denying any conflicts of interest, 40% had disclosures that did not mention the [drug manufacturer](#), and 13% had

disclosures that mentioned the manufacturer but inadequately conveyed the nature of the relationship between author and drug manufacturer reported in the complaint.

The authors argue that such failures in relation to off-label marketing schemes are especially troubling because off-label use is an area of clinical practice in which opinion is likely to be divided about appropriate care and there is no guidance from regulatory authorities. Therefore, high-profile "opinion leaders" may exert considerable influence on prescribing practices through their publications. The authors argue: "More adequate disclosure of financial ties in these situations would give readers an opportunity to weigh the potential for bias."

The authors conclude: "Our findings suggest that approaches to controlling the effects of [conflicts of interest](#) that rely on author candidness and variable policing by journals have fallen short of the mark. Readers are left with little choice but to be sceptical."

More information: Kesselheim AS, Wang B, Studdert DM, Avorn J (2012) Conflict of Interest Reporting by Authors Involved in Promotion of Off-Label Drug Use: An Analysis of Journal Disclosures. *PLoS Med* 9(8): e1001280. [doi:10.1371/journal.pmed.1001280](https://doi.org/10.1371/journal.pmed.1001280)

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