

Is lack of guidance on the Sunshine Act hampering publication of clinical trial results?

August 28 2015



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A research article, published today in *Postgraduate Medicine*, has concluded that a lack of professional guidance on how to interpret elements of The Physician Payments Sunshine Act (2010) may be having a "chilling effect" on physicians' desire to participate in clinical trials and publish results.

'The Sunshine Act and Medical Publications: Guidance from Professional Medical Associations' reviews the literature issued by professional associations, with the goal of identifying what guidance has been provided to physicians on the Act and, crucially, on any non-monetary support provided by the [pharmaceutical industry](#) to those who write medical publications on licensed drugs.

The Act, passed in 2010 and recently upheld by the US Supreme Court, legislated for the mandatory reporting of some financial transactions between [pharmaceutical companies](#) and licensed physicians, whether direct or indirect payments, also known as transfers of value (TOV). However, the Act was not specific on the interpretation and significance of non-monetary assistance for the development of medical publications. The research published today found only sparse information available from professional associations on this, raising questions such as 'is provision of editorial support by pharmaceutical companies reportable as TOV?'

Kim Pepitone, senior author of the paper said of their findings, "I believe we continue to raise more questions than provide answers as to

how to interpret the Sunshine Act with respect to reportability of non-monetary support to physician authors. Many companies believe that the support is actually in the other direction; that authors provide important help to companies to interpret and publish their clinical research."

The authors' conclude such lack of clarity may have led to confusion among physicians who publish, with publications asking for full disclosure but various interpretations of whether this non-monetary aid should be reported to regulatory bodies as a TOV. The authors shine a light on how this grey area may have implications for patients, [physicians](#) (whether author or reader) and journal editors alike, and once again raises the importance of financial and non-financial transparency between physician and pharma.

More information: "The sunshine act and medical publications: Guidance from professional medical associations," *Postgraduate Medicine*, www.tandfonline.com/doi/full/10.1080/0325481.2015.1084211

Provided by Taylor & Francis

Citation: Is lack of guidance on the Sunshine Act hampering publication of clinical trial results? (2015, August 28) retrieved 18 May 2024 from <https://medicalxpress.com/news/2015-08-lack-guidance-sunshine-hampering-clinical.html>

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