The sunshine act and medical publications: Guidance from professional medical associations

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The sunshine act and medical publications: Guidance from professional medical associations

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Abstract

Objective. To review guidance from professional medical associations to physicians on the Sunshine Act, with a focus on industry support for medical publications. Methods. Using ‘Sunshine Act’ as a search term, we searched PubMed (dates February 2013 to November 2014) and the ‘grey literature’ using Google and Google Scholar. Online information was extracted from websites of professional medical associations. Results. Some professional medical associations have published peer-reviewed recommendations, position statements or general advice on their websites and in journals around the Sunshine Act. Associations also provided broad online educational resources for physicians. There was universal agreement between peer-reviewed publications, including guidelines, for the need for full transparency and disclosure of industry support. Surveys by some professional associations showed variance in opinion on the forecasted impact of the Sunshine Act on physician–industry relationships. There was scarce information specifically related to reporting requirements for industry-supported medical publications. Conclusions. There is a shortage of guidance from professional associations regarding the Sunshine Act and support for medical publications. Due to the lack of clear guidance regarding support for publications, there are presently varying interpretations of the Sunshine Act. The literature debates the potential impact of the Sunshine Act and expresses some concerns that physician-enabled innovation in drug development may be hindered.

Keywords: Sunshine Act, professional associations, transparency

History

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Introduction

The relationships between the pharmaceutical industry (industry) and healthcare professionals (HCPs) are valuable not only for drug development and the medical publication process, but also for eventual improvements in patient care (Table 1). In many cases, these relationships include financial transactions between HCPs and industry, which are under intense scrutiny. The potential to influence physician prescribing patterns and other ethical considerations have led to demands for increased transparency around these financial relationships [1].

Part of the Patient Protection and Affordable Care Act (PPACA), the US Sunshine Act (the Act) is a landmark federal-level mandate to disclose certain financial relationships between industry and US physicians holding a current license to practice (covered recipients [CR]). The Centers for Medicare and Medicaid Services (CMS) Final Rules for Implementation (the Rules), which were published in February 2013 [2], defined CR as US physicians holding a current license to practice, and teaching hospitals. Employees of sponsoring companies who met the definition of CR were excluded [2]. The relationships cited in the Act include both direct and indirect payments and “transfers of value” (TOV), and cover such in-kind benefits as meals, travel expenses and/or educational materials in connection with medically relevant interactions. This information is made publicly available in the US CMS Open Payments database [2]. The Act has evoked a range of reactions, including concerns regarding the accuracy of the published data, potential subsequent misinterpretations of these data and potential downstream effects on innovative drug development [3].

Industry often provides nonmonetary assistance to authors to assist with the development of medical publications (including peer-reviewed journal articles and reviews, congress abstracts and oral and poster presentations). The support often is in the form of medical writing, copyediting and creating artwork for the publications, under the direction of the authors. The support provided is made transparent in the disclosures that accompany manuscripts upon journal submission, and is often included in the final publication. By

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Clinical Feature Review

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adhering to ICMJE guidelines, regardless of the study sponsorship or support provided, the authors are able to review the data, provide input into interpretation of the results and provide final approval of the submitted version. Since most medical journals follow the ICMJE criteria for authorship, medical writers can qualify for authorship as long as they fulfill the ICMJE criteria [4].

Although the rules mention support for medical publications related to research, it is unclear under the Rules how and to what extent the TOV reporting obligation should be applied [2]. In our review of the Rules, we found three mentions that could potentially be related to publications [2]. The first states that, “Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as part of the research contract.” The second speaks to ghostwriting, which is prohibited by the good publication practices that are followed by the industry [5]. The third addresses journal reprints, which is not relevant to author support for the development of publications. The query “medical writing support placed by the authors to the CMS open payments website produced a single FAQ response (FAQ8159) confirming that “medical research writing/publishing” could be included as part of research agreement [2].

Regarding company interpretation, many suggest that publication support should be reported as a TOV, while others suggest that the Rules are written too broadly to provide the required clarity [6]. Without clear guidance, companies have taken varied approaches, many regarding it as a TOV but with different interpretations of the specific reporting requirements [3,6].

Physicians often turn to their professional associations for guidance, not only for answers to clinical questions, but also for matters related to ethical and business-practice issues. This literature review covers the time period from 1 February 2013 (the date that CMS announced the release of the Rules) to 6 November 2014. It was undertaken to better understand how much and what type of information has been provided by professional associations regarding authorship and industry support, and whether the information was consistent with other interpretations of the Rules.

### Materials and methods

Peer-reviewed and “grey” literature

Using “Sunshine Act” as a search term, we reviewed peer-reviewed publications indexed in PubMed from 1 February 2013 (month of issue of the Rules) to 6 November 2014. The “grey literature,” defined as articles, in print or electronic form, not published in easily accessible journals and which may not be indexed in formal academic databases, was surveyed using the Google search engine and the Google Scholar database, applying the same search term. Publications were manually identified and confirmed from the predefined search strategy and downloaded for detailed review. Three medical publishing professionals with independent affiliations screened the publications list resulting from the searches. Publications were reviewed in detail and classified using the following six pre-specified criteria to confirm eligibility/inclusion and to aid data extraction: industry-supported/sponsored publications, industry-author relationships, industry-investigator relationships, guidance and/or recommendations related to industry HCP relationships, ethical considerations around the Act, and industry-sponsored research. Classifications were not mutually exclusive. Publications not fitting into the six inclusion/research criteria detailed above were excluded.
Once it was determined that a publication met at least one of the pre-specified criteria, data collected included publication type (whether peer reviewed, “grey,” industry, or academic), year, content type, theme and a structured summary of three salient findings/conclusions per publication.

Professional medical association websites

Websites of 11 pre-identified professional medical associations were manually searched and data extracted for publicly available information or statements regarding the Act, following the above data extraction criteria. The aim of the manual selection of professional associations was to obtain a sufficiently diverse sample (based on membership number, size and type, i.e. general medicine and specialty associations) to be representative of professional medical associations in the US.

Data extraction and analysis

Data from the literature searches were consolidated into a fact sheet/repository housed centrally at the International Society for Medical Publication Professionals (ISMPP). Articles were subsequently reviewed in-depth and key points were summarized; all discrepancies were resolved by agreement. Additional articles identified ad hoc during the review process were added to the repository.

Results

A total of 59 articles were reviewed, 28 of which were initially considered relevant (Figure 1). However, upon further review, we did not include the publication of PPACA in our analysis. The three themes into which the articles fell were ethics, guidelines/recommendations and industry/investigator relations. In cases of more than one theme represented in an article, the authors elected to assign the theme that covered the majority of content (Supplementary table).

Information from professional association publications and websites

Published information and position statements from professional associations focused on clarifying the reporting requirements to their readership in the peer-reviewed journals [7-9]. Results from our website searches are summarized in Table 2. Many HCP-specific association websites provide general information on the Act and/or Toolkits, FAQs and computer-based “apps” to track their data. The American Medical Association (AMA) posted a position statement advocating that transparency reporting should: not impose a “burden on physicians;” “protect physician rights and provide” meaningful, accurate data [10]. With respect to specialist medical associations, the American Society for Clinical Oncology (ASCO) and the American Academy of Dermatology (AAD) provide practical information and resources related to the Act. In addition, the National Comprehensive Cancer Network (NCCN) recommends various resources available on the CMS website, such as tutorial videos, fact sheets and a live help desk [11]. Although the literature from professional associations contained broad guidance, there was insufficient consistence or consensus from associations around specific concerns, including TOVs for research grants, trial participation and medical publications.

Of note is that ASCO updated its conflict of interest (COI) policy to promote transparency and independence in the development of scientific publications [8]. The 2013 ASCO
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Several published papers and guidelines note that payments to authors should be disclosed [7,8,13-22]. However, the Rules contain no clear direction on how to report industry support of authors, which is notably different from direct payment. Simcoe et al. noted that a lack of clear guidance exists, even when such guidance is formally sought [14]. Information from ISMPP, including surveys and meetings with pharmaceutical companies, demonstrates varying interpretation of the Rules with respect to reporting support for medical publications as a TOV. Surveys of ASCO members show variance in opinions among different membership cohorts as to the value and necessity of reporting TOVs [19]. Other authors question whether writing assistance should be disclosed or whether the information, once disclosed, will be helpful to journal editors [3,23]. Among publications that appeared after 1 February 2013, that mentioned the Act and authors, most lacked specific advice or opinions. Publications that do present opinions or advice suggest that the understanding of TOV by authors is generally poor in the medical community [6,8,13-16,18-21]. For example, in recent published surveys, many respondents disagree regarding the value of reporting TOV [19]. Additionally, the editors of the Journal of Clinical Psychopharmacology go so far as to suggest that in many cases writing assistance creates a qualification for authorship, removing it from the category of TOV altogether [24].
Discussion

Articles published between 1 February 2013 and 6 November 2014, contain only sparse information by professional associations regarding how to interpret the Rules in relation to industry-sponsored paid research for medical publications. Most of the information recapitulates the Rules and highlights the steps that covered recipients should take to prepare themselves and to check their data (Table 2). Of the 11 association sites reviewed, 9 failed to provide information on the Act in relation to publications. Also addressed were industry-sponsored research, a precursor to publication of results, and the importance of balancing industry – HCP relationships [25-27]. Interestingly, some reports highlighted possible unintended “reverse-direction” adverse consequences, such as biases that may be introduced in trying to overcompensate to avoid perception of bias [7]. The most frequent ethical concerns mentioned were COIs and inappropriate influence regarding HCPs’ prescribing of drugs and/or use of devices manufactured by companies with whom they have financial relationships, as well as the importance of transparency in those relationships [26,28,29].

Most authors of the reviewed publications suggest that transparency in industry–HCP financial relationships is important. However, a major concern is the potential for unintended negative perceptions of the reported data. Examples include equating the data with bias simply because physicians appear in the Open Payments database, and the assumption that research payments attributed to a single physician (lead investigator), which may be substantial, were actually received by that individual rather than the institution where the research was conducted [3,30,31]. Detailed context for all payments and TOVs would clarify these issues.

There is also the potential for a “chilling effect” on the participation of investigators in industry research and the subsequent publication of results. Some investigators may potentially decline to participate to avoid the perception of payment for authorship [3,6]. If authors decline the offer of publication support, there may be a negative effect on manuscripts development timelines, which may in turn affect industry’s ethical obligations to publish clinical trial results in a timely manner. Due to time constraints of busy practicing clinicians, manuscripts may likely take longer to be written [6]. In some cases, investigators may not possess the skills required to produce journal-ready manuscripts, which may also cause delays [24]. As Citrome observes, a mandate to report writing assistance as a TOV may adversely impact the participation of academic colleagues in the publication of industry-sponsored research; however, in the absence of either clear guidance or reporting experience, such concerns remain theoretical [6].

Equally concerning may be the potential for the loss of critical review and input provided through industry–HCP partnerships [26]. Although many companies have qualified physicians who can author clinical publications, they are usually not practicing clinicians. Thus, the clinical practice interpretation and real-world application of the data may be lost if practicing HCPs decline to participate. Finally, other HCPs may decide to not participate in industry-sponsored research at any level, which may impede continued advances in healthcare [30].

Of importance to all professionals affected by the Act, including the authors, is how the Open Payments data are reported, interpreted and perceived by both the medical community and the public [6]. Another viewpoint questions the meaning of all financial disclosures given the inconsistency and incompleteness of existing databases as well as the possibility that the public may misinterpret the significance of reported payments [32]. These publications remark on the complexity of the data reported and the difficulty of drawing meaningful conclusions from so many disconnected data points, even for those with expertise in managing clinical datasets. It has also been noted that key opinion leaders (KOLs) may be overrepresented in the clinical literature relative to other experts regardless of their financial relationships, which limits the value of disclosures under the Act [1,15,16,28]. Further clarifications and recommendations are needed.

There are several limitations to our study that are important when considering our findings. Since many of the results are from professional associations with documented publication policies, they may not be generalizable to all associations. As well, because of our pre-selection of association websites, we may well have missed some that do not include specific information on our research topic. In addition, since the Act is relatively new, the shortage of guidance from professional associations may simply be due to the expectation that there may be future amendments/changes to the Act.

Conclusion

Industry-funded research and publication of results is a critical component in the education of practitioners and in advancing patient care [25]. The lack of clear direction in the Rules has led to varied interpretations regarding reporting of industry-provided publication support as a TOV [33]. The Rules may need additional detail, specificity and guidance around subcategories of reporting for publication support that would constitute a TOV. In our opinion, without appropriate context, companies that report TOV for publication assistance may be erroneously perceived as paying authors for authorship rather than purely providing funding to support writing assistance, and companies that do not report may be perceived as lacking transparency.

What appears to be missing in the published literature regarding industry-funded publication support is an expert interpretation of the Final Rules or, ideally, more definitive guidance from CMS. Without this, the process of assigning a monetary value to publication support may continue to vary across companies. One consequence may be confusion among authors, particularly those working with several different companies, and the risk of disputed Open Payments records. Education among all stakeholders is key to ensure that the relationships between industry and CR, and the data reported in Open Payments, are placed in proper context [34].
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Disclaimer

The information and opinions presented here reflect those of the authors and do not represent the position of ISMPP, Amgen, Hofstra University, Ashfield Healthcare Communications, MedImmune, Excerpta Medica BV, or Cactus Communications.

Declaration of interest

D Toroser is an employee of Amgen Inc. K Pepitone is a contracted consultant for Cactus Communications. A Cairns is an employee of Ashfield Healthcare Communications. R Juneja is an employee of MedImmune. A Georgieva is an employee of Excerpta Medica BV. A Weigel is an employee of ISMPP. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Supplementary material available online