

The Sunshine Act and Authors

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The Physician Payment Sunshine Act, part of the Patient Protection and Affordable Care Act, requires applicable manufacturers of drugs, devices, and biological and medical supplies covered under Medicare (or a state plan under Medicaid or CHIP) to report annually to the secretary of the US Department of Health and Human Services some payments or other transfers of value to physicians and teaching hospitals. The secretary is required to publish the reported data on a public Web site. The law raises multiple issues for authors of medical publications; some of the most important issues are highlighted below.

Under the Sunshine Act—and accompanying regulations issued by the Centers for Medicare & Medicaid Services (CMS)—applicable manufacturers were required to begin collecting data on payments made as of 1 August 2013, and they were required to begin reporting to CMS on 31 March 2014. How the law and regulations are applied and how manufacturers and others proceed remain to be seen. But legal requirements and issues that they raise can be identified.

The purpose of the Sunshine Act is to promote transparency. As CMS has noted, although collaborations among physicians, teaching hospitals, and industry manufacturers contribute to the design and delivery of life-saving technologies, payments from manufacturers can also introduce conflicts of interest that may influence research, education, and clinical decision making in ways that compromise patient care and can lead to increased costs. Thus, the law and accompanying regulations require manufacturers to report. The law and accompanying regulations do *not* prohibit or restrict the activities being reported; that task is left to other laws and regulations.

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As a threshold matter, the law and regulations require (1) an “applicable manufacturer” of (2) a “covered product” to collect data and to submit reports regarding (3) “transfers of value” to (4) “covered recipients”. Generally speaking, an “applicable manufacturer” is a manufacturer that operates in the United States; a “covered product” is a drug, device, or biological or medical supply for which payment is available under Medicare, Medicaid, or CHIP *and* that requires a prescription (in the case of a drug or biological) or premarket approval by or notification to the Food and Drug Administration (in the case of a device or a medical supply that is a device); a “transfer of value” is anything of value; and a “covered recipient” is a licensed physician, other than a physician who is an employee of an applicable manufacturer, or an employee of a teaching hospital. CMS’s regulations identify numerous refinements, exceptions, and specific applications of those definitions, but the foregoing generalizations can serve as a guide in evaluating—at the outset—whether a particular situation may fall under the new reporting requirements.

With specific regard to publications, it appears that a manufacturer’s publication support could be considered a reportable transfer of value; CMS’s report accompanying its issuance of its final regulations specifically mentions payments for medical research writing and/or publication. There may be questions as to the appropriate category under which a manufacturer might report support; for example, depending on the circumstances, a manufacturer might report support as a research payment or as compensation for services other than consulting. Note that publication support might include any support provided to an author for any publication to be submitted to a scientific or medical journal or provided for submission or presentation to a professional congress, and it might be provided either *directly* by a manufacturer or *indirectly* by an agency hired by a manufacturer.

Assuming that there is a reportable transfer of value, a manufacturer and a covered recipient need to determine the amount of value; CMS’s report accompanying its final

regulations seems to indicate that reportable value is value that is received by a covered recipient *and* that is economically discernible. Thus, for example, there might be costs in developing a publication that are not borne by an author, such as legal expenses for drafting appropriate contracts, or that otherwise are not of discernible economic value. If those elements are parts of the total cost, it might be appropriate to subtract them from the reportable transfer of value.

There might also be a concern, with a multi-authored publication, of allocating value among the authors. CMS’s report accompanying its final regulations does not appear to address that in detail. But it appears that such allocation might be done in numerous ways, depending on the relative contributions of the authors and whether all authors constitute covered recipients.

In addition to those issues regarding the development of publication content, there might be questions regarding the distribution of content. As noted above, support for presentations might constitute a reportable transfer of value. Furthermore, distribution of written publications might constitute reportable transfers, depending on how and to whom distributions are made. For example, CMS’s regulations exclude from the definition of reportable transfer of value (1) transfers representing less than \$10 and (2) transfers that directly benefit patients and that are intended for patient use.

Even if a manufacturer has made a reportable transfer of value, for some transfers the law and regulations provide for delayed publication by the secretary on the public Web site. According to CMS’s report, such transfers include those made in connection with research that is pursuant to a written agreement for research related to new products. CMS’s report adds that for transfers of value related to research for new applications of products already on the market, publication can be delayed only if the research does not meet the definition of “clinical investigation”. CMS’s report states that “clinical investigation” includes phases 1 through 4 clinical research for drugs and

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biologicals and approved trials for devices (including medical supplies).

The Sunshine Act and accompanying regulations largely, *but not entirely*, preempt state and local laws and regula-

tions. Thus, manufacturers and recipients must determine whether any additional laws or regulations are relevant to specific situations. For most journals, authors must disclose conflicts of interest and funding

support. The Sunshine Act provides yet another mechanism for transparency in those relationships and adds the force of law behind the failure to make such a disclosure. 

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in a PPPR report may serve as a form of public shame among peers, it also serves the important function of a deterrent for scientists who wish to commit scientific fraud or for those who accidentally and carelessly undermine the importance of QC before submission of a manuscript to a journal. With PPPR, a decision made by an EIC or editors—usually on the basis of peer reviewers' reports—does not determine the final status of a published paper. PPPR would also help to eliminate actual or perceived bias inherent in the traditional peer-review process⁷. Finally, a PPPR report would lead to a public historical record of scientific misconduct or fraud or lack of QC and should thus not be subject to copyright.

When a PPPR report is received by an EIC or publisher who flatly refuses to examine it—because it is outdated, because it may overburden the review system, or because of professional pride or arrogance—how can it be made public to raise awareness? Revealing a scientist's identity in a PPPR may expose the scientist to professional abuse or bias, reveal COIs, and damage his or her reputation, even though, as Yong and colleagues⁶ indicate, “a person has the obligation to do the right thing if they can.” The adverse and unintended consequences of an EIC's or publisher's failure to act on a PPPR report that factually lists errors, fraud, or misconduct are that such a paper will continue to be referenced in the literature; that is, continued recognition will be given when it should no longer be. In such a case, who should be held accountable for intransigence and professional negligence?

PPPR is an important way—whether used anonymously or not—to raise awareness about and correct errors in the plant-science literature⁸. Even if somewhat controversial, PPPR is an effective tool.

Although still in a nascent stage, open-commentary tools used by such publishers as *Frontiers* (www.frontiers.org), open peer-review systems used by such journals as *F1000 Research* (<http://f1000research.com>), and such tools as *PubPeer* (<https://pubpeer.com/>) and *PubMed Commons* (www.ncbi.nlm.nih.gov/pubmedcommons/) are all evidence that PPPR is becoming established as a way to correct the scientific literature and expose scientific misconduct and fraud.

Summary

Errors in the plant-science literature can have fundamental adverse consequences for science and society. Incorrect findings and fraudulent data in scientific reports of research that cannot be reproduced may corrupt the literature, burden taxpayers, and diminish public trust in science. Inefficient, incomplete, and biased peer review aids that erosion, as does—to some extent—the rapidly evolving open-access movement. However, open access also provides a way to detect poor science, misconduct, and fraud. A spike in retractions in the biomedical sciences may reflect a rise in awareness of and action to correct research and publishing misconduct and improved methods for detecting such misconduct. An effective way to fortify the validity of data and to sustain trust among science peers and the public is required. Postpublication peer review (PPPR) is one concrete solution. PPPR complements traditional peer review and allows trust in the peer community to be regained. However, it will take an active effort by scientists, editors, peer reviewers, and publishers—the cornerstones of the publishing process, each with their own responsibilities, pre- and postpublication⁹—to improve and

correct the plant-science literature. PPPR will undoubtedly be embraced by some and skeptically shunned by others.

Conflict of Interest Statement

The author declares that the research for this paper was conducted in the absence of any commercial, financial, or other relationships that could be construed as a potential conflict of interest. 

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