April 18, 2018

Dear Dr. Shamoo:

On behalf of DePuy, I am writing to you in your role as Editor-in-Chief of the journal Accountability in Research to request a retraction of an article previously published in your journal (henceforth referenced as the AIR Article):


As set forth more fully below, the AIR Article contains numerous factual errors that undermine its conclusions. Moreover, the authors have omitted and failed to disclose substantial conflicts of interest. Thus, a retraction is warranted under Taylor & Francis policy. If you decline to retract the AIR Article, please consider this as a Letter to the Editor for publication. I am also copying Taylor & Francis editorial contacts as they are presumably familiar with the situation that led to the retraction of a prior article authored by David S. Egilman.

Contrary to the representation in the conflict of interest disclosure that ‘None of these authors were compensated for work on this paper and the lawyers for the injured plaintiffs did not review this paper and had no input into the content of the paper’, the article constitutes little more than an effort to cloak one-sided, non-scientific plaintiffs’ litigation arguments and characterizations with the appearance of scientific reliability through publication in your journal.

Although the senior author, Egilman, disclosed that he has served as an expert witness in litigation involving the DePuy Pinnacle Metal on Metal Hip System (Pinnacle MOM; no longer marketed), his disclosure is misleading. While he represents that he was not compensated “for work on this paper” and claims lawyers had no involvement in it, in truth, plaintiffs’ lawyers paid him at least $300,000 for his litigation-related work, which included writing a report in which they were involved and that they did review. The expert witness report forms the basis for the AIR Article and is cited as support for statements in the article 13 times. The remaining authors all were paid to assist Egilman with his expert report. Moreover, the AIR Article is largely a one-sided, uncritical presentation of the characterizations and arguments made by plaintiffs’ counsel in the last three Pinnacle MOM trials when addressing the study in question (PIN Study). A very subtle, but important, example of the litigation’s influence is the pervasive
reference to “J&J/DePuy” (113 times in the body of the article and 21 times in the references). There is no company by that name and never has been. Rather, the article adopts a litigation tactic employed by plaintiffs’ counsel in the lawsuits to try to conflate two separate entities into one. The authors provide no explanation or justification for using this terminology—which appears intended to advance the litigation agenda of the lawyers who have been paying them.

Although the authors have postured their criticisms of DePuy’s conduct in connection with the PIN Study as a research article with supporting scholarly references, it is not the product of an impartial scientific examination or discourse. The AIR Article is not a dispassionate narrative of scientific facts; rather, it is a biased summary of “cherry picked” courtroom exhibits and non-scholarly sources, many which have been taken out of context to advance the plaintiffs’ point of view. For example, 51 of the 132 references in the AIR Article consist of court testimony, exhibits, and documents, and a further 30 references are company brochures, advertisements, web articles, government websites, newspaper articles, and a LinkedIn account. The AIR Article liberally adopts plaintiffs’ litigation claims, but it makes no reference to or acknowledgement of DePuy’s response to these claims, which can also be found in the court testimony and exhibits.

Importantly, DePuy is not aware of a single patient who was injured as a result of his/her participation in the PIN Study. Nor is DePuy aware of any patients in the PIN Study who received medical treatment without consent. Further, the title (“grave fraudulence”) is highly misleading, perhaps causing some readers to conclude that DePuy fabricated patients and outcomes. To the contrary, the PIN Study was a DePuy sponsored post-market clinical study, in which patients received the same hip replacement components and substantially the same standard of care as they would have received if not enrolled in the study. The study consisted of real patients, treated by real physicians, and for whom real clinical outcomes were collected for scientific purposes, and Egilman does not show otherwise. As with almost any clinical study, variations from the protocol and incomplete data reporting from clinical sites occurred during the 10 year duration of the study. These issues were disclosed in an article published in Arthroplasty Today (ARTD Article); the on-line open access version of which may be found here (published online 26 August 2017):

https://www.sciencedirect.com/science/article/pii/S2352344117300717. The AIR Article authors fail to mention or discuss these facts, which are inconsistent with their claim of “fraudulence,” further undermining the lack of academic integrity in the article.

The following is a non-exhaustive list of factual inaccuracies within the AIR Article:

• The title states without qualification that “grave fraudulence” occurred within the PIN Study. It is astonishing that a peer-reviewed journal would publish an article with such a serious accusation without even giving the sponsor an opportunity to respond, let alone without independent verification of the assertion. Contrary to the message in the article’s title, there was no fraud in the PIN study. No data have been fabricated or falsified, and there was no intent to deceive or mislead when the interim or final results were reported.

• The PIN Study was not a seeding study. The sponsor implemented sound scientific research practices in conducting the PIN clinical study. The study had a clearly defined scientific objective,
which was to evaluate the survivorship of the Pinnacle Acetabular Cup System in primary THA at 5 years. To the extent that marketing functions perceived benefits from conducting the study, these marketing benefits did not impact the scientific integrity of the study.

- Contrary to the authors’ assertion, the PIN Study protocol did not “proscribe” any interim report or interim analysis. The study protocol stated that “No interim analysis is planned in this study other than standard monitoring of adverse event rates.” Stating that no interim analyses are planned is materially different from prohibiting interim analyses.

- Regarding the poster (PIN poster) which was presented by Kindsfater et al. at the 2007 AAOS conference, the AIR Article states that there were ‘false statements’ in the PIN poster, leading the reader to believe that there was a willful misrepresentation of the study and data in the poster. This is not true. The references to courtroom testimony from nine years later in which ‘the Worldwide Vice President of Clinical Research [Pam Plouhar] admitted [that the PIN poster] did “not accurately reflect the data that was at the [surgeon investigator] site”’ is a mischaracterization of the retrospective nature of Plouhar’s testimony. Plouhar was testifying that certain data were not reported to DePuy from clinical sites and that the poster therefore was not accurate to the extent data had not been reported by the clinical sites. The AIR Article ignores the remainder of Plouhar’s testimony, which confirms that when the analysis for the poster was conducted, only one cup revision had been reported to DePuy as part of the study. When Plouhar testified nine years later, DePuy had additional information. Newly acquired or clarified data over the passage of time does not make an earlier analysis of the then-existing data ‘false’, as the article claims.

- The AIR Article states that ‘the study was conceived, developed, funded, and ultimately terminated prematurely by the company’s marketing department’. This statement is not entirely true. The clinical research group, not the marketing department, conducted the PIN Study. DePuy’s clinical research department established the scientific objectives for the study; developed the clinical study protocol and case report forms; contracted with investigators; established the clinical database; maintained clinical files; terminated the study; analyzed the data; and published the results.

- In reference to a deferred prosecution agreement (DPA) between DePuy and the Department of Justice (DOJ), which does not even mention the PIN Study, the AIR Article states that DePuy ‘accepted responsibility for its illegal conduct and paid the government $84.7 million’. This simply is not true. First, the DPA says nothing about accepting “responsibility for illegal conduct,” and the criminal complaint was dismissed. Second, the payment to the government was to settle civil claims, not criminal claims.

- The AIR Article goes on to state that ‘mismanagement of the PIN Study seemingly violated [the requirements under the DPA]...the DPA monitor recognized the potential for kickback schemes in clinical research, the monitor either did not uncover or chose not to cite the company for this misconduct during an oversight period in 2008 and 2009’. This is speculation and conjecture. It also ignores the possibility that the monitor knew of the PIN Study and how investigators were selected and paid, and that the monitor concluded that it was entirely proper. It is concerning that such an obvious, speculative and biased advocacy survived AIR’s peer review process.
The AIR Article states that ‘none of the patients used to extend the survivorship curve to five years met study inclusion criteria, which included site IRB approval, a signed informed consent form, and prospective enrollment’, suggesting that data from some patients should not have been utilized in analysis (for the PIN poster or otherwise). This criticism is unsound. The conventional scientific practice regarding the analysis of safety outcomes (such as revisions) in a post-market study is to summarize safety outcomes on all patients who consent to participate in a clinical study regardless of whether there were protocol violations.

The AIR Article states that ‘The PIN poster reported only one cup failure, but there were actually cup and liner failures (8 cups, 12 liners) prior to January 2, 2007, the date when [DePuy] last updated the results that they presented at AAOS... After excluding the liner failures and failing to locate seven of the eight cup failures, [DePuy] reported that the five-year acetabular cup survival was 99.9% (by KM analysis)’. The tallies within this statement are wrong and the statement itself is misleading. Only 1 cup revision had been reported to DePuy as part of the PIN Study at the time of final data extraction for the PIN poster (October 19, 2006). The analysis undertaken on January 2, 2007 was only a re-analysis of the same October 19, 2006 data extract—not a new update. Lastly, even as of the date of this letter, DePuy is aware of only 5 cup revisions from the PIN Study that occurred before January 2, 2007.

Regarding the PIN poster, the AIR Article states ‘Furthermore, the same month [DePuy] submitted the AAOS abstract, they submitted another report on the PIN Study outcomes to the French regulatory authority... [DePuy] reported eleven failures to the French regulatory authority (although at this time there had been sixteen failures)... [DePuy] reported a survival estimate of 96.6% at four years, compared to the AAOS poster which claimed 99.9% survival at five years’. This statement is incorrect in several ways. There is no inconsistency; the 99.9% survival at 5 years that was reported in the PIN poster pertains to survivorship of the acetabular cup (no removal of the cup), whereas the 96.6% survival estimate at four years pertains to survivorship of both the acetabular cup and liner (no removal of either). Both of these survivorship parameters were clearly presented in the respective analyses. Moreover, of the 16 cup or liner removals that the AIR Article incorrectly claims had occurred by the time of analysis, only 11 were known to DePuy Clinical Research at the time of the report to the French regulatory authority. This AIR Article statement regarding 16 failures is also in conflict with other statements within the article itself (discussed in the preceding bulleted item regarding ‘cup and liner failures (8 cups, 12 liners) prior to January 2, 2007’). Specifically, according to tallies within the AIR Article (tallies with which we disagree), the total number of patients with cup and liner removals would be at most 12 since the cup cannot be removed without also removing the liner. The sufficiency of the peer review of this article is further called into question by the failure to catch even this internal inconsistency in the article.

Regarding IRB approval, the AIR Article states ‘In trial testimony, [DePuy’s] director and then vice president of clinical research originally claimed that the PIN Study did not require IRB approval because [DePuy] did not intend to submit the results to the FDA... During another trial six months later, she changed her testimony...’. This statement is incorrect in several ways. Most significantly, it is not correct to say that Plouhar changed her testimony with respect to whether
federal law required IRB approval of the PIN Study. There was no statutory or regulatory requirement for investigators in the PIN Study to have IRB approval at the time the study commenced.

- The AIR Article states that ‘Dr. Kindsfater, the first author and presenter of the [PIN poster] gave a presentation in 2014 that includes the PIN poster with the 99.9% in the title; this presentation is currently available online (Kindsfater 2014)’. This statement is simply false. Dr. Kindsfater’s 2014 presentation did not mention the PIN poster or the previous 99.9% survivorship estimate. Dr. Kindsfater’s 2014 presentation provided a KM analysis of PIN Study data with follow-up through December 2012.

These are only a small portion of the factual inaccuracies and biased analyses within the AIR Article. These alone, however, undermine the conclusions proffered in the AIR Article and are troubling given the misleading conflict disclosures provided by the authors.

The AIR Article also suffers from a lack of transparency regarding the authors’ affiliations and interests (financial or otherwise). Specifically, the authors do not disclose that their work related to the PIN study was specifically developed in their role as paid experts in the Pinnacle MOM litigation, working closely with the attorneys for plaintiffs suing DePuy. The affiliations which the authors have disclosed create the false impression that the AIR Article was drafted by multiple authors from varied backgrounds and institutions. In fact, all the authors are affiliated with the consulting firm Never Again Consulting, which only Steffen and Reardon mention. The senior author, Egilman, owns the firm (I have appended his letter to DePuy and J&J counsel regarding the AIR Article, which shows this in the header), which he fails to disclose in the AIR Article. Instead, he references only his affiliation with Brown University. Although Fassler has previously claimed affiliation with Never Again Consulting (https://alumnius.net/cornell_university-8947-324#), she fails to disclose this in the AIR Article conflict disclosure. Moreover, Fassler, Steffen, and Reardon do not appear to have any previous published research aside from what they have published in collaboration with Egilman. As stated previously, all of these authors were paid to assist Egilman with his expert witness work in the Pinnacle MOM litigation.

Egilman also understates his long-standing financial conflict of interest as a consultant to plaintiffs’ attorneys. He gives the following disclosure within the AIR Article:

‘David Egilman has served as an expert witness in litigation at the request of people who were injured as a result of having total hip replacements with the Pinnacle Metal on Metal Hip System’.

This understates his connection to the attorneys involved in the Pinnacle MOM litigation. Egilman has consulted for the same plaintiffs’ counsel in multiple previous “mass tort” cases (including Vioxx litigation against Merck, and Zyprexa litigation against Eli Lilly and Company). Egilman has had a relationship with plaintiffs’ counsel since at least 2002, at which time plaintiffs’ counsel was Egilman’s personal attorney in another court case (see the Washington Post article:
In 2005, Egilman claimed to have made between $2 and $2.5 million over a 20 year period as a litigation consultant (see the following article in 2009 *Mayo Clinic Proceedings*: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2735431/; and a correction in https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2800280/).

Taylor & Francis retracted a different peer-reviewed article of Egilman’s in another Journal, *International Journal of Occupational and Environmental Health*:

D. Egilman (2016) The production of corporate research to manufacture doubt about the health hazards of products: an overview of the Exponent Bakelite™ simulation study, IJOEH.

The original article can be found here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4894274/; the April 2016 retraction statement can be found here: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5728250/. Notably, this retracted article was also litigation-related.

As should be clear from the context of this letter, I am not a neutral, unbiased critic of the AIR Article. I am employed by Johnson & Johnson Medical Devices, which includes DePuy Orthopaedics, Inc. DePuy Orthopaedics, Inc. and Johnson & Johnson (a separate entity) are involved in ongoing litigation brought by parties who have retained Egilman and his co-authors as experts. I have been involved in the PIN Study as a statistician and co-authored the paper published in Arthroplasty Today reporting the final results of the PIN Study. Because the topics discussed in the AIR Article and in this response are all part of ongoing litigation involving the Pinnacle MOM device, I have consulted with DePuy’s attorneys in preparing this response.

In summary, the AIR Article contains multiple inaccuracies, is not scientific, but is biased advocacy written by authors deeply entrenched in Pinnacle MOM litigation where they have been paid by plaintiffs’ counsel to (among other things) review the study that they now claim to be evaluating objectively. The AIR Article is fraught with factual inaccuracies, and lacks a fair, reasoned, and balanced analysis; it simply restates wholesale and without critical analysis the one-sided litigation attacks by plaintiffs’ counsel. We would respectfully submit that this work has no place in a reputable scientific, peer-reviewed journal. According to the retraction policy of Taylor and Francis, the article should be withdrawn (https://authorservices.taylorandfrancis.com/wp-content/uploads/2016/01/Author-services-correction-policy.pdf).

Respectfully submitted, on behalf of DePuy,
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Attachment

Egilman’s letter to DePuy and J&J counsel regarding the AIR Article
November 13, 2017

Dear Mr. Quattlebaum:

I hope all is well with you and yours. I have attached a draft paper on the PIN study. It is intended for publication. I would normally send it to J&J/DePuy for comments but I have been told that this may be improper due to the litigation.

Therefore I am providing it to you and request that you and/or your clients comment on it and let me know if you think there are any errors.

Sincerely yours,

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