http://dx.doi.org/10.2106/JBJS.17.00184


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eLetter exchange between Quinn et al. of the American Academy of Orthopaedic Surgeons (AAOS) and Checketts et al., authors of a *JBJS* study titled "An Evaluation of Industry Relationships Among Contributors to AAOS Clinical Practice Guidelines and Appropriate Use Criteria" (http://dx.doi.org/10.2106/JBJS.17.00184).

http://dx.doi.org/10.2106/JBJS.17.00184


March 20, 2018

Marc Swiontkowski, MD
Editor-in-Chief, Journal of Bone and Joint Surgery

Dear Dr. Swiontkowski:

At AAOS, we take our conflict of interest policy seriously, particularly where our quality products are concerned. The Council of Research and Quality and the Committee of Evidence Based Quality and Value have created some of the most respected clinical practice guidelines (CPGs) and appropriate use criteria (AUC) in healthcare. We pride ourselves on being one of the organizations most compliant (and usually exceeding) IOM standards for the development of evidence-based guidelines and our management of financial conflict of interest (FCOI). We therefore read the recent Orthopaedic Forum article, *An Evaluation of Industry Relationships Among Contributors to AAOS Clinical Practice Guidelines and Appropriate Use Criteria,* with dismay.

We would expect a scientific article submitted to JBJS to undergo substantial scrutiny. Nevertheless, questions regarding methodology may often arise and be subject to scientific challenge. It is serious enough in those situations where analysis of scientific evidence results in inappropriately recommending for or against a particular treatment. It is another matter entirely when inappropriate methodology impugns the integrity and credibility of an entire organization. As we will point out, the statement that 85/120 participating physicians received industry payments and that 76% of these were relevant to the CPG-AUCs is untrue and is detrimental to the reputation AAOS has developed from rigorous attention to the IOM standards.

Regarding this particular manuscript, it is relatively easy to cross-check the data by simply searching the relevant databases by participant. Therefore, independent verification should reveal minor discrepancies at most. This would be true if the assumptions in inclusion and interpretation were reasonable. Although there are many errors in assumption here, the most questionable would be using the assumption that payments were included relevant if they were labeled as "knee." By our standards, a surgeon who is an expert in knee replacement, and has a FCOI in that regard, would not necessarily have a relevant conflict if he/she participated in an ACL-related project, or vice-versa. How was relevancy determined, particularly without an orthopaedic surgeon as an author or consultant?

AAOS policy (meets IOM and Guideline Clearing House standards) allows for FCOI in AUC writing and review panel work group members. This is accepted as recognition that many of our experts in each specific practice area are often conflicted related to their area of expertise. However, conflicted members are <u>not</u> able to participate in the AUC voting panel. Consistent with IOM standards, only a minority of CPG panel members may have FCOI and any of these with *relevant* FCOI should be managed (eg. recuse themselves from specific subtopic discussions). To date, the AAOS has exceeded this standard by not allowing any CPG panel members to have *relevant* FCOI. All potential members are required to submit detailed financial disclosure. Where possible FCOI is present, leadership of EBQV individually evaluates

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*each* conflict, often requesting additional supporting data from the candidate. In fact, our standards have been sufficiently strict to elicit the ire of some of our specialty societies as they expect participation yet often have difficulty providing us with candidates that meet our high standard with regard to *relevant* COI. Not only did the authors not sufficiently recognize this fact in their analysis, they have included unrelated committee and council chairs with the participating committee members and moderators in their analysis. Although these individuals serve in various oversight roles and approve the final products, they do not participate directly in the process and are not able to manipulate or otherwise change the recommendations.

We first performed a side-by-side analysis of the data using the same assumptions as the authors. This is shown in Table 1, corresponding to the data in Table II from the manuscript. Summary of findings follows:

- There is wide disparity in the number of individuals who should have been included in each CPG or AUC workgroup.
- The disparity in individuals and data resulted in a substantial discrepancy in the total amount disclosed ($1,766,640).
- Regarding the $8,263,113 total amount of FCOI, $6,814,892 was attributed to 5 individuals which are outlined in detail below. $3,897,770 of the total amount was from AUC writing panel members, where relevant FCOI is allowed. <u>It is completely misleading to use this number to generate any kind of mean comparison among all participants, particularly where many received minimal or no payments.</u>
- Regarding the top 5 financial recipients:
    - David Dalury received a total of $2,951,987 in the years 2013-2015. Only $50,700 was listed as "knee." $2,627,000 was related to intellectual property. Payments were related to surgical implants for hip and knee arthroplasty. He participated in the Nonarthroplasty Treatment of Osteoarthritis of the Knee AUC writing panel which did not address any surgical treatment options.
    - Peter Sharkey received a total of $2,416,100 in the years 2013-2015. $2,387,000 was related to intellectual property. All payments were related to surgical implants for hip and knee arthroplasty. He participated in the Nonarthroplasty Treatment of Osteoarthritis of the Knee AUC voting panel which did not address any surgical treatment options.
    - Robin Dore, a rheumatologist, received a total of $700,455 in the years 2013-2015. All were related to drugs not used to treat OA knee.
    - Frederick Buechel received a total of $430,897 in the years 2013-2015. The majority of payments were related to knee arthroplasty. However, he was a member of an AUC writing panel, where FCOI is allowed if the individual is felt to be an expert in the field.
    - Craig Della Valle received a total of $444,984 in the years 2013-2015. However, he was a member of an AUC writing panel, where FCOI is allowed if the individual is felt to be an expert in the field.

Regardless, the authors use time periods which were not relevant to the product timelines reviewed. The surgical management of osteoarthritis of the knee (SMOAK) AUC initially

convened in November, 2015 and was published in December, 2016. Therefore, data reported in 2013, 2014, and most of 2015 was not germane. Similarly, for the OA Knee CPG, publication date was May 18, 2013 therefore, by the authors' own criteria only 2014 should have been included in the analysis (under the appropriate premise that participants should remain unconflicted for one year after publication). The ACL AUC was published in October, 2015, therefore data from 2013 was not relevant. Table 2 shows how the analysis would look by removing SMOAK and including only 2014 for the OA knee CPG. This analysis still fails to recognize that we have insured that none of these participants (except AUC writing panel members) have *relevant* conflicts.

Table 3 shows the subanalysis data for the workgroup co-chairs and oversight chair for each product. Regarding the assumptions made on the basis of this subanalysis we are unable to draw the same conclusions as the authors. In this instance, and throughout the manuscript, the authors repeatedly fail to separate *relevant* COI from *non-relevant* COI. The IOM makes the following statement in this regard: "…conflicts of interest – for example, relevant clinical specialists who receive a *substantial portion of their incomes* from services *pertinent to* the guideline." (emphasis added).

Paragraph 5 on page e10(3) intentionally misrepresents both the IOM and AAOS policies on COI. See attachment for a detailed description of the AAOS policy relevant to our quality products. This document is readily available to the public on the AAOS website. The paragraph makes no reference to *relevancy* of FCOI.

Further, there is a significant discrepancy between N of members included in JBJS article and the N of actual work group members with voting privileges (Table 4). The JBJS analysis included far more members than those who actually had voting privileges (i.e. the ability to affect treatment recommendations). This, invariably, misrepresents the real disclosure findings in the JBJS article, especially for the AUCs.

We do agree with the recommendation that the AAOS should use Open Payments and Dollars for Docs to verify disclosure statement accuracy, and we plan on doing so as a result of discrepancies pointed out in this study. Three of the other four recommendations have been in place since the inception of our quality products and are consistent with IOM and AAOS standards, with the caveat (consistent with those same standards) that *relevant* FCOI's are the concern in question.

We met in person with one of the authors (Checketts), who admitted much of the above including the difficulties in determining relevancy from a lay perspective, misinterpretation of IOM standards (following a previously issued summary statement rather than the document cited), misinterpretation of various roles, misinterpretation of writing panel allowances for FCOI, and mistakes in the timeframes analyzed (paragraph 6 above). He expressed willingness to voluntarily retract the article given the errors and the gravity of the overall message relayed in the manuscript. However, further progress from the authors in this regard has not been forthcoming.

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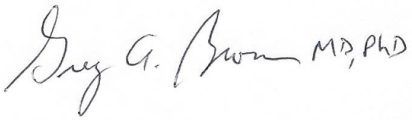
We would welcome the opportunity to officially respond to the assumptions and conclusions of the authors. However, given the methodologic flaws in the study, and the ethical allegations leveled at the AAOS through these flawed assumptions and errors, we respectfully request a full retraction of the article.

Sincerely,

Robert H. Quinn, MD
Chair, Council on Research and Quality

Kevin Shea, MD
Chair, Evidence Based Quality and Value Committee

Deborah S. Cummins, PhD
AAOS Director Research, Quality, and Scientific Affairs



Gregory A. Brown, MD, PhD
CPG Section Leader, Evidence Based Quality and Value Committee

CC:
JBJS Board of Trustees
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James Heckman, MD

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| Aim 1 | Panel | JBJS | | | | | | | | AAOS | | | | | | | | Notes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | # Physicians | Reporting Data | | | | | | | # Physicians | Reporting Data | | | | | | | |
| | | | >1 Reported pmt | >$1,000 | >$10,000 | >$50,000 | >$100,000 | Mean | Total | | >1 Reported pmt | >$1,000 | >$10,000 | >$50,000 | >$100,000 | Mean | Total | |
| Total | | 120 | 85 | 56 | 35 | 17 | 11 | $93,537 | $9,912,309 | 108 | 78 | 32 | 14 | 1 | 10 | | $8,263,113 | |
| OA CPG | | 11 | 9 | 7 | 3 | | | | | 8 | 6 | 3 | 1 | 0 | 0 | | $55,384 | individual > $10,000 rheumatologist, JBJS included CORQ chair and oversight chair (although only CORG chair reported, $115), one doc still not accounted for |
| OA AUC | Total | 34 | 29 | 17 | 13 | | | | | 34 | 24 | 5 | 3 | 1 | 5 | | $6,784,463 | |
| | Writing | | | | | | | | | 6 | 5 | 1 | 1 | 0 | 2 | | $3,402,775 | Per AAOS 5 reported >$100,000. One was the rep of the Arthritis Foundation. Only 2014 should be included (one year after publication). |
| | Review | | | | | | | | | 12 | 10 | 2 | 1 | 1 | 1 | | $807,418 | |
| | Voting | | | | | | | | | 16 | 9 | 2 | 1 | 0 | 2 | | $2,574,270 | |
| ACL CPG | | 15 | 14 | 7 | 3 | | | | | 12 | 10 | 6 | 2 | 0 | 0 | | $45,564 | JBJS may have included CORQ Chair and oversight chair; still one unaccounted for |
| ACL AUC | Total | 23 | 13 | 8 | 4 | | | | | 21 | 10 | 6 | 0 | 0 | 0 | | $16,255 | |
| | Writing | | | | | | | | | 12 | 6 | 3 | 0 | 0 | 0 | | $11,440 | |
| | Voting | | | | | | | | | 9 | 4 | 3 | 0 | 0 | 0 | | $4,815 | |
| SMOAK CPG | | 15 | 13 | 11 | 10 | | | | | 12 | 9 | 7 | 2 | 0 | 2 | | $512,841 | Of the 2 reporting >$100,000 the largest was from Hospital Medicine $322,776. |
| SMOAK AUC | Total | 22 | 20 | 13 | 6 | | | | | 21 | 19 | 5 | 6 | 0 | 3 | | $848,606 | |
| | Writing | | | | | | | | | 10 | 9 | 2 | 3 | 0 | 3 | | $837,526 | |
| | Voting | | | | | | | | | 11 | 10 | 3 | 0 | 0 | 0 | | $11,080 | |
| | | | | | | | | | | | | | | | $7,270,607 was from 10 individuals, leaving $992,506 for the remaining 98 ("mean" of $10,127) | | | |
| | | | | | | | | | | | | | | | $3,897,770 of that is from AUC writing panel members | | | |
| | | | | | | | | | | | | | | | $6,814,892 was from 5 individuals, leaving $1,448,221 for the remaining 103 ("mean" of $14,060) | | | |

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| Aim 1 | Panel | JBJS | | | | | | | | AAOS | | | | | | | | Notes |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | # Physicians | Reporting Data | | | | | | | # Physicians | Reporting Data | | | | | | | |
| | | | >1 Reported pmt | >$1,000 | >$10,000 | >$50,000 | >$100,000 | Mean | Total | | >1 Reported pmt | >$1,000 | >$10,000 | >$50,000 | >$100,000 | Mean | Total | |
| Total | | 120 | 85 | 56 | 35 | 17 | 11 | $93,537 | $9,912,309 | 87 | 59 | 27 | 8 | 1 | 7 | | $3,486,874 | |
| OA CPG | | 11 | 9 | 7 | 3 | | | | | 8 | 6 | 3 | 1 | 0 | 0 | | $55,384 | individual > $10,000 rheumatologist, JBJS included CORQ chair and oversight chair (although only CORG chair reported, $115), one doc still not accounted for |
| OA AUC | Total | 34 | 29 | 17 | 13 | | | | | 34 | 24 | 5 | 3 | 1 | 5 | | $2,856,830 | |
| | Writing | | | | | | | | | 6 | 5 | 1 | 1 | 0 | 2 | | $1,393,319 | Per AAOS 5 reported >$100,000. One was the rep of the Arthritis |
| | Review | | | | | | | | | 12 | 10 | 2 | 1 | 1 | 1 | | $350,926 | Foundation. Only 2014 should be included (one year after |
| | Voting | | | | | | | | | 16 | 9 | 2 | 1 | 0 | 2 | | $1,112,585 | publication). |
| ACL CPG | | 15 | 14 | 7 | 3 | | | | | 12 | 10 | 6 | 2 | 0 | 0 | | $45,564 | JBJS may have included CORQ Chair and oversight chair; still one unaccounted for |
| ACL AUC | Total | 23 | 13 | 8 | 4 | | | | | 21 | 10 | 6 | 0 | 0 | 0 | | $16,255 | |
| | Writing | | | | | | | | | 12 | 6 | 3 | 0 | 0 | 0 | | $11,440 | |
| | Voting | | | | | | | | | 9 | 4 | 3 | 0 | 0 | 0 | | $4,815 | |
| SMOAK CPG | | 15 | 13 | 11 | 10 | | | | | 12 | 9 | 7 | 2 | 0 | 2 | | $512,841 | Of the 2 reporting >$100,000 the largest was from Hospital Medicine $322,776. |
| | | | | | | | | | | | | | | | $3,266,632 was from 7 individuals, leaving $220,242 for the remaining 80 ("mean" of $2,753) $1,404,759 of that is from AUC writing panel members | | | |

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| Title | Dates | Position | Name | COI (Dollars for Docs) | Category |
|---|---|---|---|---|---|
| ACL CPG | Published 9/15, data from 2014 and 2015 | Oversight Chair | Jevsevar | $21,156 | Hips, Euflexxa, no relevant FCOI |
| | | Chair | Shea | $2,903 | $104.24 food/beverage, $2,902.66 unknown (Dr. Shea has no record of ever receiving this); no relevant FCOI |
| | | Vice-Chair | Carey | $224 | No relevant FCOI |
| ACL AUC | Published 10/15, data from 2014 and 2015 | Voting Panel Round Two Discussion Moderators | Sanders | $804 | No relevant FCOI |
| | | | Brown | $9,624 | $9,350 for hip trauma (Smith & Nephew), no relevant FCOI |
| SMOAK CPG | Published 12/15, data from 2014 and 2015 | Oversight Chair | Jevsevar | $21,156 | HIPS, Euflexxa, no relevant FCOI |
| | | Chair | McGrory | $32,973 | KNEES, HIPS. $30,000 received October, 2015* |
| | | Co-Chair | Weber | $21,290 | Research payments related to oncology, $0 to Weber directly or indirectly, no relevant FCOI |
| SMOAK AUC | Convened 11/15, published 12/16, data from 2016 and 2017 | Voting Panel Round Two Discussion Moderators | Quinn | $0 | |

*We are investigating the timing and relevancy of these payments

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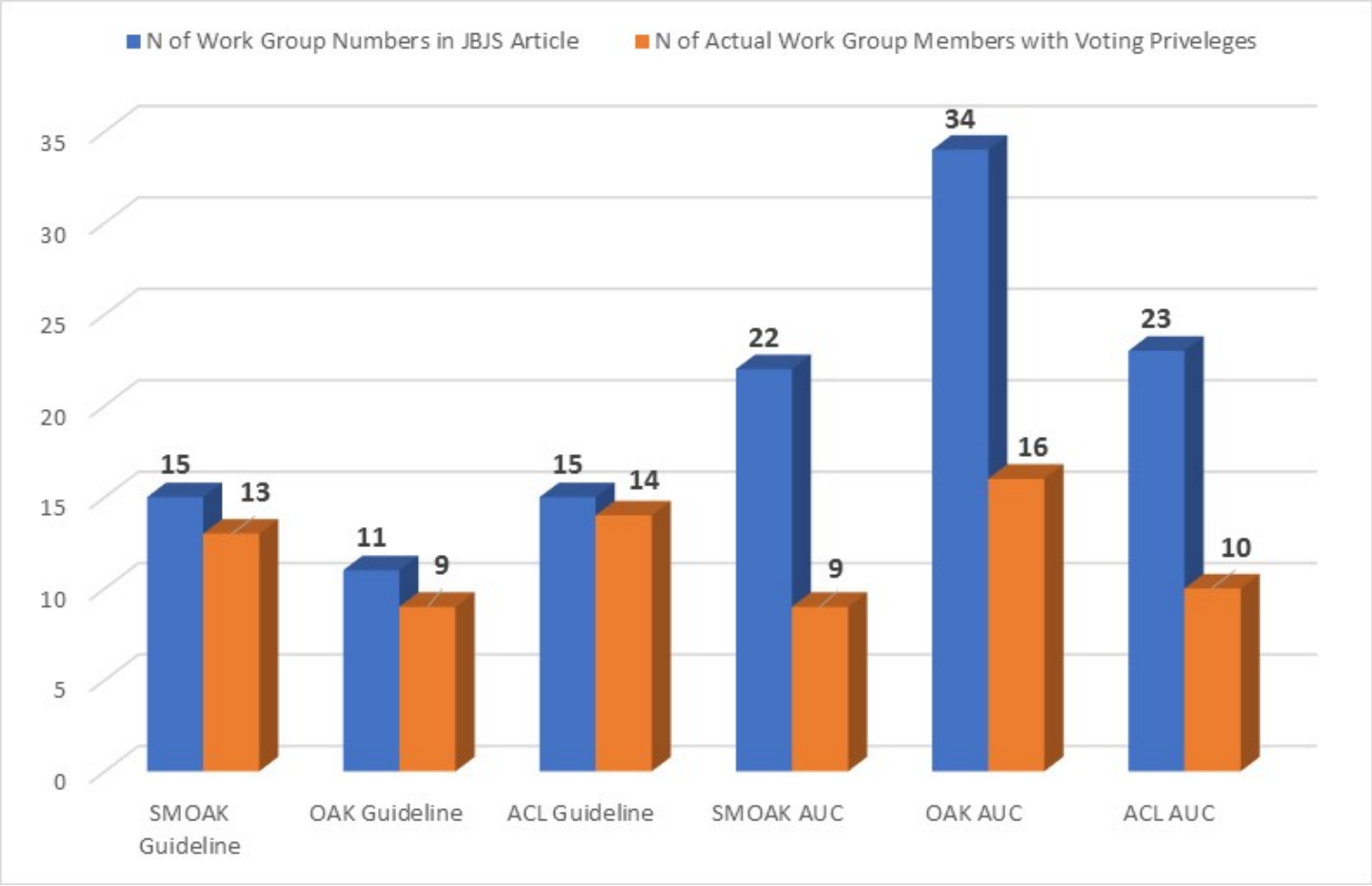
Table 4. Overinclusion of Disclosure Items in JBJS Article vs. Voting Members on Each Work Group



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# Chapter 2 - AAOS Orthopaedic Disclosure Program

## *Click Image to View Chapter*


**1. Why do I have to disclose?**
Pages 9-10


**2. How do I disclose?**
*Page 11*

**3. How is "conflict of interest" defined?**
*Pages 12-13*

**4. What are my options in the event that I am determined to have relevant conflicts?**
Page 14

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# AAOS Orthopaedic Disclosure Program

## Why Do I Have to Disclose? Part 1 of 2

- **To preserve the integrity** of the AAOS guideline development process, work group members must be free of relevant conflicts of interest since these types of external factors are often a major cause of bias on one's views. In addition, members are not permitted to engage in activities that might constitute relevant conflicts during development of the guideline and **for a minimum of one year following approval and publication.** Each work group member will be asked to sign an attestation indicating agreement with the above stipulations until the guideline is approved by the AAOS Board of Directors (please see Attestation Form ).
- **The AAOS holds** all guideline work group members to the same high standard of disclosing conflicts of interests as the AAOS Board of Directors. What does this mean? The disclosure form work group members are required to complete is more detailed than the general form Academy members are currently required to use and requires monetary disclosure of all financial conflicts of interest. A very limited number of individuals (necessary AAOS volunteers, leaders, and a few staff) will have access to the detailed information you provide while the majority of other individuals will see only whether a potential conflict of interest exists. Managing potential conflicts of interests of work group members follows the Institute of Medicine's standards for developing trustworthy clinical practice guidelines.

**Click Here To View Full AAOS Guidance Document on Service on Work Groups Developing CPGs and SRs**

http://dx.doi.org/10.2106/JBJS.17.00184


# AAOS Orthopaedic Disclosure Program

## Why do I have to disclose? - Part 2 of 2

*1.* **The Guidelines Section Leader, EBQV Committee Chair, and Oversight Chair will review** the enhanced disclosure information of applicants interested in serving as Chair or member of a work group charged with developing a Clinical Practice Guideline (CPG) prior to appointment. No member of the work group developing a clinical practice guideline may have any relevant financial conflicts of interest related to the respective CPG during development of the guideline and for at least one year post approval of the AAOS Board of Directors.

2. **When the AAOS publishes a CPG**, such document will list the disclosures of all work group members and note that they have signed an affidavit declaring they have no relevant conflicts of interests. (Please see section VII. Attestation).

3. **All future peer reviewers and public commentators** of AAOS CPGs must disclose their relevant conflicts of interest on the structured review form. The comments and AAOS responses to reviewers' comments will be posted on the website with their declared relevant financial conflicts of interest.

All AAOS conflict of interest policies are available on the Academy's website (www.aaos.org). Voluntary participation in the AAOS disclosure program is encouraged for the membership of orthopaedic surgeons at large.

**Click Here To View Full AAOS Guidance Document on Service on Work Groups Developing CPGs and SRs**

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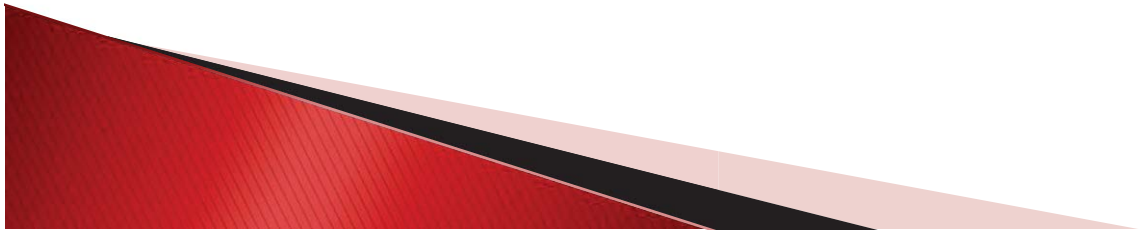
# AAOS Orthopaedic Disclosure Program

## How Do I Disclose?

- **You may disclose your conflicts** of interest via the **AAOS website** after staff has updated your disclosure status to requiring "*full disclosure*". Once you are in the system, you will be automatically prompted for updates every six months. Mandatory disclosure is required verbally at the start of the introductory meeting, where a general disclosure report of the entire work group is also circulated, and again online approximately one month prior to the final meeting.
- **Automating the disclosure program** online has streamlined the process and improved transparency in the Academy. If you have questions concerning how the information is collected or used , or about our retention and privacy policies, please visit the AAOS website.
- **If you are not a member of AAOS**, you will still be required to disclose your conflicts of interest. A customer identification number and password can be used to log in, access the system, and complete the disclosure form once staff has updated your disclosure status to "*full disclosure*." Even if your disclosure has been recently completed it may still need updating due to the greater detail required. If you do not have a customer identification number and password, you may contact AAOS Member Services to have one created for you (847-384-4307); and if you have any difficulties, you may contact the AAOS Evidence-Based Medicine Manager, Jayson Murray at jmurray@aaos.org for assistance.



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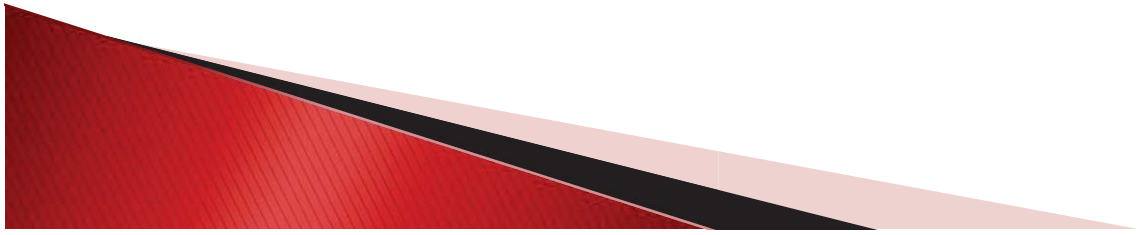
# AAOS Orthopaedic Disclosure Program
## Definition of "Conflict of Interest" Part 1 of 2

A **conflict of interest** exists when there is a current or past financial relationship with a business entity (e.g., drug or implant manufacturer) AND the use of the product(s) manufactured by this business entity may be directly affected by the guideline recommendations.

"Financial relationships" include:

- Research sponsored by the manufacturing company (For disclosure, list all grants, dates, and dollar amounts)
- Ownership of shares or stock options (For disclosure, list amount and if held by you or family members). Mutual fund holdings are exempt from this rule
- Seat on Board of Directors or Advisory Board (For disclosure, list stipend paid for board membership)
- Speaker fees (For disclosure, list frequency of speaking and total amounts received)
- Royalty payments (e.g., from patents or consultative agreements, etc.)
- Consulting agreements



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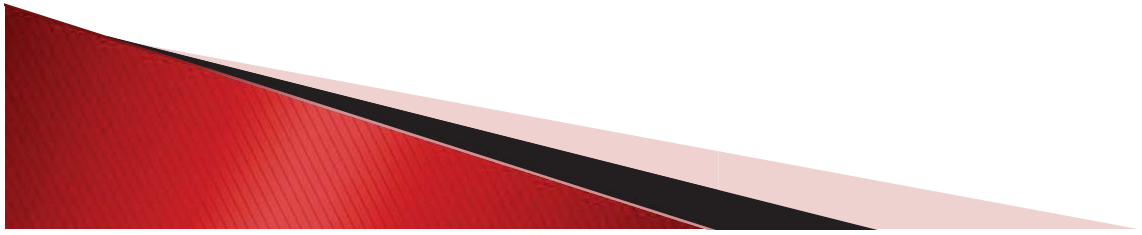
# AAOS Orthopaedic Disclosure Program

## Definition of "Conflict of Interest" Part 2 of 2

- **Guideline work group members cannot have any relevant or perceived conflict of interest, as determined by the AAOS Committee on Outside Interests.**

- **In order to clarify** a perceived relevant conflict, the AAOS Committee on Outside Interests will require a written clarification detailing pertinent facts. It is important to observe the requested deadlines in providing this information because this committee will review all disclosures for a given guideline during a single meeting. If you have not responded with clarification prior to the materials being sent to the Committee on Outside Interests, you will forfeit your opportunity to appeal and be ineligible to serve on the work group. Applicants will be notified as to the disposition of their disclosures.
- **We realize that members who are actively involved** in evidence-based medicine projects might perform numerous functions within the AAOS as well as other organizations. Any possibly conflicting incentives arising as a result of one's multiple-role participation that will jeopardize the integrity of the guideline development process must be declared and the work group member must recuse him/herself from the process at the point where the conflicting interest becomes apparent. All members of the approving bodies of a guideline [currently the AAOS Committee on Evidence-Based Quality and Value (EBQV) and the Council on Research and Quality (CORQ)] who participate in a guideline work group, are not permitted to vote during the approval process. These members can participate in discussions but must declare their COIs at the time the vote is taken.
- **Managing conflicts of interest** will be addressed throughout the development of clinical practice guidelines as a part of the AAOS' approach to explicitly limiting bias and increasing transparency.



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# AAOS Orthopaedic Disclosure Program

## What are my options if I am determined to have relevant conflicts?

1. **Divestment**: An applicant denied participation in a Guideline Development Group has the option of divesting himself/herself of the financial or nonfinancial conflict. Once the conflict is divested, the applicant should advise AAOS staff responsible for the CPG and request a reconsideration of his/her application.
2. **Appeal:** An applicant denied participation in a Guideline Development Group due to perceived relevant financial or nonfinancial conflict may appeal the decision. The CPG Oversight Chair and the Guideline Development Group Chair shall discuss the situation with the Chair of the Committee on EBQV and the Chair of the CORQ. If they cannot or elect not to make a determination, the matter will be referred to the Committee on Outside Interests, via the Office of General Counsel. The Committee on Outside Interest's decision regarding whether a relevant financial or nonfinancial conflict of interest exists and whether an individual is eligible to serve or remain a member of the Guideline Development Group shall be considered final.
3. **Consultant**: There may be an important role for a Consultant ("Consultant") in the CPG process. A Consultant is an individual who has unique knowledge about the topic of the CPG, but who has a relevant financial or nonfinancial conflict of interest. The addition of a Consultant to assist the Guideline Development Group shall be determined by the CPG Oversight Chair, the Guidelines Oversight Section Leader, Chair of the Committee on EBQV, and the Chair of the CORQ. For example, a Consultant might:
   - Act as a subject matter expert aiding the Guideline Development Group in generating topics of PICO (Population, Intervention, Comparison and Outcome) questions for the CPG as well as helping to determine outcomes of interest and search criteria restrictions;
   - Be invited, at the discretion of the CPG Oversight Chair, to contribute topic suggestions or provide input prior or during the first Guideline Development Group meeting, If participation by the Consultant during the first Guideline Development Group meeting is desired, the CPG Oversight Chair will determine whether the Consultant should attend in person or participate remotely via telephone or webinar; and
   - Be included in the discussion of development of PICO questions.

   However, the Consultant may not participate in the following: final selection of PICO topics; the systematic review of the literature; review of evidence; or drafting or rating recommendations. In addition, the Consultant will not be invited to participate in the final Guideline Development Group meeting.

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# Attestation form

## ATTESTATION

### Attestation Statement for Potential Clinical Practice Guideline (CPG) Work Group Members with No Relevant Conflicts

*If you wish to be considered as a candidate to serve on a Work Group that develops AAOS Clinical Practice Guidelines, please know that you will be required to disclose potential conflicts of interest at the same level as the AAOS Board of Directors prior to beginning work on any CPGs. This disclosure is more detailed than regular member disclosure and includes specific financial details.*

By signing this affidavit, I am stating that I have no relevant conflicts concerning the subject matter of the CPG titled:

_____

I attest that I will not enter into relationships that might create a conflict of interest situation (i.e. becoming a consultant to an orthopaedic or medical company, etc.) both during the time the CPGs are being developed and for one year after the AAOS Board of Directors approval of the CPGs.

Please Print:

Member Name _____

Member Signature _____

Date _____

http://dx.doi.org/10.2106/JBJS.17.00184


April 6, 2018

Marc Swiontkowski, M.D.
Editor-in-Chief, Journal of Bone and Joint Surgery
20 Pickering Street
Needham, MA 02492

Dear Dr. Swiontkowski:

Thank you for the opportunity to respond to the American Academy of Orthopaedic Surgeons' (AAOS) letter which calls for a retraction of our paper recently published in Journal of Bone and Joint Surgery (JBJS). We have carefully reviewed their response to our paper as well as the data and methodology used in our study. After such review, we remain confident in our methodology, analysis, and recommendations.

JBJS uses the Committee on Publication Ethics (COPE) guidelines to resolve disputes pertaining to retraction. According to these guidelines, a retraction should be considered if the Editor has "clear evidence that the findings are unreliable, either as a result of misconduct (e.g. data fabrication) or honest error (e.g. miscalculation or experimental error)"[1]. Conversely, The Office of Research Integrity defines integrity as, "the use of honest and verifiable methods in proposing, performing, and evaluating research and reporting research results with particular attention to adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms."[2] Thus, we emphasize *honest* and *verifiable* in the narrative that follows, presenting clear evidence from specific examples in our paper that indicate that our methods were developed, conducted, and reported in good faith.

We point to the following examples from our paper that indicate that we did not bias our methodology to misrepresent the AAOS.

1. We report our methodology clearly and in a way that fosters reproducibility.
2. In our data analysis, we reported both adjusted and unadjusted means. Failure to remove two outlying values would inflate the means, so we reported both for the sake of accuracy and transparency. Means have been used to summarize industry payments in other JBJS publications which used Open Payments Data [3] as well as the Mitchell study [4] upon which our methodology is based.
3. In Figure 1, we display a box plot containing medians (solid lines) and interquartile ranges (whiskers) as well as means (dotted lines) and standard deviations (diamonds). We presented the data this way to allow readers to interpret and compare these different measures of central tendency. We even took our analysis a step further by graphing every data point (excluding the outliers).
4. We did not selectively include Institute of Medicine (IOM) criteria that we knew the AAOS would fail to meet. As evidence, we evaluated compliance with Standard 1. In our results, we state the following "The AAOS did explicitly and publicly disclose the funding source of each CPG; therefore, the CPGs were in compliance with this standard."

The remainder of this letter is structured as follows: First, we respond to the AAOS letter point-by-point. With the exception of their introductory paragraph (which required no response from us), we have responded to all comments. Like comments have been grouped together and explained once. Following our point-by-point rebuttal, we report our findings from a carefully conducted re-examination of our data collection and analysis processes.

All scientific experiments are subject to a number of investigator decisions; these decisions have bearing on the study's outcomes. The narrative that follows provides a rationale for the decisions we made when planning and

conducting this study. We point out that our decisions are clearly articulated in our methodology section, and we submit that our methodology was carefully and honestly executed and developed in good faith. In the following narrative, we also establish that the AAOS misrepresented the true intention of the IOM standards for conflicts of interest in their letter, that the AAOS made inaccurate assumptions about verification of our study results, and that their own analysis contains errors. AAOS remarks are extracted verbatim and appear in red font. We have used blue font in our responses. Quotations from pertinent documents are in black font.

The AAOS states, "We would expect a scientific article submitted to JBJS to undergo substantial scrutiny. Nevertheless, questions regarding methodology may often arise and be subject to scientific challenge. It is serious enough in those situations where analysis of scientific evidence results in inappropriately recommending for or against a particular treatment. It is another matter entirely when inappropriate methodology impugns the integrity and credibility of an entire Organization.

Our response: Our study methodology was based on Mitchell et al.[4], which was published in *JAMA Oncology* after passing a rigorous JAMA peer review process. As a result of that process, we are confident that this paper and the methodology used therein received a careful, thoughtful, and critical review from both content and statistics experts. The JBJS peer review process is equally rigorous, and our paper had 3 peer reviewers and underwent 3 revisions prior to publication. When issued the first editorial decision on this paper, we were told the following: "Your manuscript entitled " Title: Evaluating Potential Financial Conflicts of Interest in Orthopaedic Knee Surgery Clinical Practice Guidelines" was reviewed by the JBJS Deputy Editor for Ethics and three consultant reviewers. All three reviewers have an academic interest in the field of ethics and/or are familiar with the process for developing clinical guidelines; I [Dr. Swiontkowski] also read the manuscript." This insight confirms our expectation and understanding that our paper and methodology used therein received substantial scrutiny from reviewers with knowledge of the topics addressed in our paper. Furthermore, our analysis was faithfully and honestly executed according to our methodology. Both the reviewers and editors found this methodology appropriate to address our research questions.

The AAOS states, "As we will point out, the statement that 85/120 participating physicians received industry payments and that 76% of these were relevant to the CPG-AUCs is untrue and is detrimental to the reputation AAOS has developed from rigorous attention to the IOM standards."

Our response: The first error in the AAOS's statements appears early in their letter. They state that we included 120 participating physicians in our first analysis; however, this statement is incorrect. In our abstract, we clearly stated, "Of the 106 physicians that were evaluated, 85 (80%) received at least 1 industry payment…" We further stated in the results, "[t]hree AAOS CPGs and their corresponding AUC were retrieved, including 120 physicians. After deleting duplicates, 106 were included in our sample." Therefore, the AAOS's error regarding our data — that 85/120 participating physicians received industry payments — can be refuted with a cursory review of the paper itself.

The AAOS states, "Regarding this particular manuscript, it is relatively easy to cross-check the data by simply searching the relevant databases by participant. Therefore, independent verification should reveal minor discrepancies at most. This would be true if the assumptions in inclusion and interpretation were reasonable."

Our response: The Center for Medicare and Medicaid Services' (CMS) Open Payment Database, the definitive data source for our investigation, refreshes the data at least annually. Their website reports, "On January 17, 2018 CMS refreshed the Open Payments dataset to reflect changes to the data that took place since the last publication on June 30, 2017."[5]. It is an erroneous assumption that an independent verification would reveal minor discrepancies at most. We extracted the data on March 20-21, 2018 and compared the data reported in the article

with the latest available Open Payments data. The dollar amounts of industry payments received by CPG-AUC contributors increased from $9,912,309 (reported in our paper) to $10,222,425 - an increase of $310,116.

The AAOS states, "Although there are many errors in assumption here, the most questionable would be using the assumption that payments were included relevant if they were labeled as "knee." By our standards, a surgeon who is an expert in knee replacement, and has a FCOI in that regard, would not necessarily have a relevant conflict if he/she participated in an ACL-related project, or vice-versa. How was relevancy determined, particularly without an orthopaedic surgeon as an author or consultant?"

Our response: First, we point out that we did not use the AAOS's standards as our benchmark; rather, we used the IOM standards. While the AAOS claims to adhere to all IOM standards for guideline development, they have their own regulations for clinical practice guideline development, which may or may not achieve the high standards of the IOM.

The examination of relevance in this paper was requested by Reviewer 3. In our second revision, this reviewer stated:

> "It is possible to establish from the available data what the sources of the payments are, and to some extent what the subject matter of the relationship with the payer involves. If it does not involve the knee, perhaps there is no conflict. I have not used the Open Payments database directly, but I have accessed the information through the ProPublica Dollars for Docs website (https://projects.propublica.org/docdollars/). On this website it is possible to identify whether the payments were for food and beverages, travel and lodging, promotional speaking, or royalty or license. It is also possible to identify the company making the payment and, to some extent, the subject matter (I do not know how the subject matter information is obtained.) For example, I find that hand surgeon Dr. Charles Carroll received $44 worth of food and beverages from the Stryker Corporation on December 16, 2014, as part of a presentation having to do with hips and knees. I can also find that Dr. Brian McGrory, one of the chairs of the AAOS knee guideline committees, received $32,579 in calendar year 2015. Of this amount, $11,861 was related to "Knees", and of this $10,000 was for Promotional Speaking / Other on October 7, 2015. This is likely to be related to the content of the guidelines, and would need to be reported."

We agreed with this reviewer, presumably an orthopedic surgeon (s/he referred to the AAOS as "our colleagues"), and included this as a subanalysis using the objective method s/he described. Including an orthopaedic surgeon on this manuscript would not have changed the interpretation of company name or subcategory information in Dollars for Docs. The authors of this manuscript were able to perform this task without an orthopedic surgeon (i.e., recording payments in various subcategories or researching whether a drug or device applied to osteoarthritis or ACL tears). We also point out that this process was at the suggestion of the reviewer, not the authors, which provides support that our methods were developed without the intention of bias. Furthermore, we used other categories such as "ACL", "osteoarthritis", and "joint implant" as well as the names of specific drugs/devices when we considered a payment as relevant. The products related to guideline topics are verifiable by examining the product listings on company websites.

Furthermore, our primary research question was presented in our paper as follows:

> "Herein, we investigate the value, frequency, and types of payments received by physician contributors to AAOS CPG-AUCs"

In their letter, the AAOS has attempted to frame the primary research question of our paper as something it was clearly not in order to meet their own objectives. We make no mention of relevance, or even conflicts of interest, here. We also specify that we examined physician contributors, not solely authors. Our methods were informed by Mitchell[4], a study of industry payments received by clinical guideline members of the National Comprehensive Cancer Network published in *JAMA Oncology*. In this paper, Mitchell summarized all industry payments, making no distinction between relevant and non-relevant payments.

There is no consensus in the literature regarding the degree to which a financial relationship with industry is problematic for guideline panels. On one hand, experts have advocated that "PMAs [Professional Medical Associations] must hold the individuals who write guidelines and outcome measures to the most stringent conflict of interest standards. Disclosure of industry relationships by committee members is not sufficient protection. Professional medical associations should be encouraged to appoint to these committees only individuals who have no ties to industry." (p. 1370)[6]. The IOM also gives preference to a more conservative approach stating, "given the important role that clinical practice guidelines play in many aspects of healthcare, it is important that these guidelines be free of industry influence" (p. 210)[7]. The IOM goes on to say that "Groups that develop clinical practice guidelines should generally exclude as panel members individuals with conflicts of interest" and only "in the exceptional situation in which avoidance of panel members with conflicts of interest is impossible"(p. 20)[7] should panelists with conflicts be included. On the other hand, some professional medical societies, such as the AAOS, apply a standard that only "relevant" conflicts of interest should limit the involvement of panel members. Conflicted panelists are allowed, provided that the number of conflicted panelists is limited and that conflicts are managed (such as through recusal during certain votes). We found no indication in official AAOS policy of how they ascribe a financial relationship as relevant; however, many other official documents found on the AAOS website acknowledge the importance of perceptions of conflicts of interest. For example, the Standards of Professionalism[8] state the following,

> "A collaborative relationship between orthopaedic surgeons and industry is necessary to improve patient care, but must be carefully scrutinized to avoid pitfalls of improper inducements, ***whether real or perceived.***" (p. 1)

Both the AAOS Mandatory Disclosure Policy[9] and the AAOS Failure to Disclose Policy[10] acknowledge the importance of *all potentially conflicting interests* by stating that,

> "Each Fellow or Member participating in an AAOS CME program, serving as an author of enduring materials, as a member of the AAOS Councils, Cabinets, Committees, Project Teams or other official AAOS groups, editors-in-chief and editorial boards or AAOS guideline development workgroups has the obligation to disclose ***all potentially conflicting interests*** through the AAOS Orthopaedic Disclosure Program. (Failure to Disclose)

> "Each participant in the AAOS CME program or author of enduring materials, member of the AAOS Board of Directors, Board of Councilors, Board of Specialty Societies, Councils, Cabinets, Committees, Project Teams or other official AAOS groups (collectively "AAOS governance groups"), editors-in-chief and editorial boards and AAOS clinical practice guidelines, appropriate use criteria and performance measures development workgroups, has the obligation to disclose ***all potentially conflicting interests***. Each participant in the AAOS CME program or author of enduring materials, AAOS governance groups, editors-in-chief and editorial boards and AAOS clinical practice guidelines, appropriate use criteria and performance measures development workgroups must disclose ***relevant activities or relationships*** through the AAOS Orthopaedic Disclosure Program." (Mandatory Disclosure Policy)

Restricting only those "relevant" industry payments that represent *actual* conflicts (e.g., ACL payments for ACL guideline) fails to account for several possible forms of bias that have potential to influence guideline decision making, do not align with IOM's intentions, and do little to protect the integrity of guideline development. Therefore, the use of industry payments with the *potential* to influence decision making (e.g., literature selection, topic discussions, voting, drafting recommendations, upgrading/downgrading a recommendation level, guideline approval) is a more comprehensive lens with which to study conflicts of interest and is in line with the IOM's position on the matter.

The AAOS also states, "Regarding the top 5 financial recipients: [Name redacted by us] received a total of $2,951,987 in the years 2013-2015. Only $50,700 was listed as "knee." $2,627,000 was related to intellectual property. Payments were related to surgical implants for hip and knee arthroplasty. He participated in the Nonarthroplasty Treatment of Osteoarthritis of the Knee AUC writing panel which did not address any surgical treatment options.

"[Name redacted by us] received a total of $2,416,100 in the years 2013-2015. $2,387,000 was related to intellectual property. All payments were related to surgical implants for hip and knee arthroplasty. He participated in the Nonarthroplasty Treatment of Osteoarthritis of the Knee AUC voting panel which did not address any surgical treatment options."

Our Response: Although AAOS notes that these contributors received "only" a small portion (relative to overall amount received) in knee payments, we submit that these payments represent substantial — not trivial — compensation. Furthermore, for the first contributor mentioned above, the majority of these knee payments were for "consulting" with Depuy Orthopaedics, which manufactures numerous options for the treatment of osteoarthritis of the knee. Though surgical treatment may not appear directly related to the non-arthroplasty guideline, these payments are relevant because a physician who is influenced by industry in a pro-surgery manner could alter his or her votes or writing (whether consciously or subconsciously) in a way that disfavors non-surgical options.

"[Name redacted by us], a rheumatologist, received a total of $700,455 in the years 2013-2015. All were related to drugs not used to treat OA knee.

Our response: Above, the AAOS failed to report that the contributor received over $25,000 for NSAID drugs such as Diclofenac and Indomethacin. Both drugs are thoroughly discussed by name in the guideline from which the AUC was based. Diclofenac was mentioned 535 times in the guideline and among the most evaluated drugs. Furthermore, there is a recommendation within the guideline dedicated to NSAID use for osteoarthritis of the knee, and the non-surgical AUC thoroughly discussed (mentioned 577 times) the use of NSAIDs, having been based on the non-surgical CPG. In addition, almost $14,000 of these payments, directly relevant to the guideline, were received during or within one year of guideline development. Receipt of such payments during this time interval violates the AAOS and IOM policies, and provides evidence that the AAOS disclosure process did not adequately protect against such violations.

The AAOS has criticized our study for not including an orthopedic surgeon as an author or consultant to determine the relevance of industry payments, yet a majority of authors of the letter to which we are responding are orthopedic surgeons, and these authors failed to identify Diclofenac and Indomethacin payments as relevant, even when these drugs were mentioned by name.

The AAOS states, "AAOS policy (meets IOM and Guideline Clearinghouse standards) allows for FCOI in AUC writing and review panel work group members. This is accepted as recognition that many of

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our experts in each specific practice area are often conflicted related to their area of expertise ". Later they state, "Paragraph 5 on page e10(3) intentionally misrepresents both the IOM and AAOS policies on COI. See attachment for a detailed description of the AAOS policy relevant to our quality products. This document is readily available to the public on the AAOS website. The paragraph makes no reference to relevancy of FCOI."

Our response: Although the AAOS has accused us of intentionally misrepresenting IOM, our understanding of their standards is accurate and not misrepresented in the paper. To support our paper's representation of the IOM standards, below we provide exact quotations from two IOM documents to support our case: 1) Chapter 7 of the IOM's *Conflicts of Interest in Medical Research, Education, and Practice* entitled "Conflicts of Interest and Development of Clinical Practice Guidelines"[7] and 2) *Clinical Practice Guidelines We Can Trust* [11]. We have extracted particular sections of these documents below and have provided some contextual narrative to allow the reader to fully understand the issue.

Second, we show that the AAOS selectively quoted only a small portion of an IOM document and used an ellipsis to omit an important portion of the narrative.

The following narrative summarizes the IOM position on COI in guideline development. We underlined and/or bolded portions of the text below for emphasis.

> "Given the important role that clinical practice guidelines play in many aspects of health care, it is important that these guidelines be free of industry influence and be viewed by clinicians, policy makers, patients, and others as objective and trustworthy. The committee found substantial variation in the extent to which different groups disclosed their conflict of interest policies and the financial ties to industry of the sponsoring group and the members of the guideline panel. It also found little systematic descriptions or assessments in the literature. On the basis of its judgment and experience (including experience with conflicting guidelines and guidelines not based on formal reviews of the evidence), the committee believes that the risk of undue industry influence on clinical practice guidelines is significant, and **that risk justifies that strong steps be taken** to strengthen conflict of interest policies governing the development of guidelines. Recommendation 7.1 proposes several such steps.
>
> Groups that develop clinical practice guidelines **should generally exclude** as panel members individuals with conflicts of interest and should not accept direct funding for clinical practice guideline development from medical product companies or company foundations. Groups should publicly disclose with each guideline their conflict of interest policies and procedures and the sources and amounts of indirect or direct funding received for development of the guideline. **In the exceptional situation in which avoidance of panel members with conflicts of interest is impossible** because of the critical need for their expertise, then groups should:
>
> - publicly document that they made a good-faith effort to find experts without conflicts of interest by issuing a public call for members and other recruitment measures;
> - appoint a chair without a conflict of interest;
> - limit members with conflicting interests to a distinct minority of the panel;
> - exclude individuals who have a fiduciary or promotional relationship with a company that makes a product that may be affected by the guidelines;
> - exclude panel members with conflicts from deliberating, drafting, or voting on specific recommendations; and
> - publicly disclose the relevant conflicts of interest of panel members." [7](p.210-211)

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*Clinical Practice Guidelines We Can Trust* states the following, "Optimally, GDGs [guideline development groups] are made up of members who lack COIs. Experts who have unique knowledge about the topic under consideration -- but who have COIs -- can share their expertise with the GDG as consultants and as reviewers of GDG products, but generally should not serve as members of the GDG."[11] (p.80-81).

Based on this narrative, we concluded that, according to IOM standards, the guideline panels should not include members with any conflicts of interest, except under extraordinary circumstances. Furthermore, groups must make a concerted effort to locate non-conflicted applicants to serve on guideline panels and publicly document these efforts.

The AAOS states, "The IOM makes the following statement in this regard: "…conflicts of interest – for example, relevant clinical specialists who receive a *substantial portion of their incomes* from services *pertinent* to the guideline. (emphasis added [AAOS added the emphasis here, not us])."

Our reply: Here, an ellipsis has been applied that obscures the intent of the paragraph. The full text reads:

> "Whenever possible, GDG [Guideline Development Group] members should not have COI. In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG"[11] (p.83).

The full context establishes that COIs are discouraged and may be allowed only as an exception if all other avenues fail. In contrast, by omitting the IOM declaration that COIs are to be avoided "whenever possible", the AAOS misleads the reader into assuming that the IOM is more accepting of including panel members with COIs. Further, even in such an exception, compliance with IOM standards requires public documentation of efforts to minimize COIs.

The AAOS states, "However, conflicted members are not able to participate in the AUC voting panel." Later they state, "We first performed a side-by-side analysis of the data using the same assumptions as the authors. This is shown in Table 1, corresponding to the data in Table II from the manuscript. Summary of findings follows: There is wide disparity in the number of individuals who should have been included in each CPG or AUC workgroup .The disparity in individuals and data resulted in a substantial discrepancy in the total amount disclosed ($1,766,640). Regarding the $8,263,113 total amount of FCOI, $6,814,892 was attributed to 5 individuals which are outlined in detail below. $3,897,770 of the total amount was from AUC writing panel members, where relevant FCOI is allowed. It is completely misleading to use this number to generate any kind of mean comparison among all participants, particularly where many received minimal or no payments." And later they state, "Further, there is a significant discrepancy between N of members included in JBJS article and the N of actual work group members with voting privileges (Table 4). The JBJS analysis included far more members than those who actually had voting privileges (i.e. the ability to affect treatment recommendations). This, invariably, misrepresents the real disclosure findings in the JBJS article, especially for the AUCs." Finally, they state, "[Name redacted by us] received a total of $430,897 in the years 2013-2015. The majority of payments were related to knee arthroplasty. However, he was a member of an AUC writing panel, where FCOI is allowed if the individual is felt to be an expert in the field. [Name redacted by us] received a total of $444,984 in the years 2013-2015. However, he was a member of an AUC writing panel, where FCOI is allowed if the individual is felt to be an expert in the field."

Our reply: The comments above all relate to the same issue, so we have included them together for this discussion. First, the AAOS has made an error in their analysis, presented above. The AAOS, according to their own standards, included too many contributors in Table 4. Table 4 shows 13 included contributors who comprise

the work group. While there were 13 contributors on the surgical management for osteoarthritis of the knee work group, 1 of these contributors was a Physical Therapist/Ph.D. The AAOS made this same mistake for the ACL and Non-Surgical guidelines, including 2 Ph.D. panelists for the ACL guideline and 1 Ph.D. for the nonsurgical guideline. This error was also made in calculations for the AUCs, as the authors included extra contributors for the ACL (n=1) and non-surgical (n=1) AUCs. In total, the AAOS included 5 extra contributors that they should have omitted (according to their own standards of only including work group members and voting panel members). Only physicians are catalogued in Open Payments Database; therefore, the inclusion of non-physician contributors in this analysis artificially reduces the number of contributors who received industry payments.

The AAOS' AUC development process divides the panel into two groups: the writing panel and the voting panel. According to the AAOS AUC Methodology document, the writing panel,

> "discusses methods described in this document, select[s] clinical indications, write[s] definitions and assumptions, approve[s] scenario matrix and literature review". (p. 5)

We chose to include the writing panel in the first research question (describe industry payments received by guideline and AUC contributors), because there is a risk that members of the writing panel have the potential to bias an AUC.

As one example, the AAOS AUC Methodology document states that,

> "Concurrent with the development of the criteria by the Writing Panel, the AAOS Evidence-Based Medicine Unit undertakes a literature review based on the results of the clinical practice guideline related to the selected topic. This literature review considers the relevant articles from the clinical practice guideline. The literature review informs the decisions relevant to the indications identified by the Writing Panel when articles are available and necessary. The literature review also considers lower quality evidence when the best available evidence (i.e. the evidence used in AAOS Clinical Practice Guidelines) does not contain information relevant to the clinical scenarios.
>
> AAOS staff "maps" the findings of the literature review to the criteria developed by the Writing Panel by referencing the relevant article(s) that the literature review identifies (or figures/tables developed by AAOS staff based on the relevant article(s)).
>
> The Writing Panel can suggest additional articles for consideration in the literature review or suggest removal of an article that does not correctly address the clinical scenario it is associated with. The addition or deletion of articles to/from the literature review is at the discretion of the entire Writing Panel (all panel members must agree that the article is relevant/not relevant to the clinical scenario). No article previously included in an AAOS Clinical Practice Guideline related to the selected topic can be removed from the literature review." (pp. 6-7).

Given the writing panel members' ability to influence the literature review (potential for selection bias or citation bias), it is imperative to include them in this first analysis. The contributor examples above showcase the magnitude of the industry payments allowed by the AAOS to serve on writing panels.

Of further note, according to the AAOS website (https://www.aaos.org/auc/?ssopc=1; accessed March 26, 2018), the organization "uses the RAND/UCLA Appropriateness Method to develop AUCs." According the RAND/UCLA Appropriateness Method User's Manual[12], "the main selection criteria to be considered are acknowledged leadership in the panel member's speciality, absence of conflicts of interest, geographic diversity, and diversity of practice setting." (p.24).

We also point out that following our first research question, we did evaluate the AUC voting panel members separately. In our methods, we state, "the AAOS AUC methodology mandates that all voting panel members be free from relevant FCOIs." In our results, we state, "Furthermore, of the AUC voting panel members, 58% had relevant FCOIs averaging $51,794 (SD=$298,256)."

The AAOS states, "Consistent with IOM standards, only a minority of CPG panel members may have FCOI and any of these with relevant FCOI should be managed (eg. recuse themselves from specific subtopic discussions). To date, the AAOS has exceeded this standard by not allowing any CPG panel members to have relevant FCOI. All potential members are required to submit detailed financial disclosure. Where possible FCOI is present, leadership of EBQV individually evaluates each conflict, often requesting additional supporting data from the candidate. In fact, our standards have been sufficiently strict to elicit the ire of some of our specialty societies as they expect participation yet often have difficulty providing us with candidates that meet our high standard with regard to relevant COI. Not only did the authors not sufficiently recognize this fact in their analysis,..."[we truncated here as this sentence bridges to the next thought which is discussed immediately following our reply here].

Our reply: The AAOS Clinical Practice Guideline and Systematic Review Methodology states,

> "Applicants with financial conflicts of interest (COI) related to the CPG or SR topic cannot participate if the conflict occurred within one year of the start date of the CPG or SR's development or if an immediate family member has, or has had, a relevant financial conflict. Additionally, all CPG or SR development group members sign an attestation form agreeing to remain free of relevant financial conflicts for one year following the publication of the CPG or SR." (p. 2).

This statement is the only one within the methodology document that provides guidance about conflicts of interest related to panel members (others exist for peer reviewers). It does not make reference to the AAOS's refusal to allow any individual with a relevant conflict from participating on guideline panels. Thus, many of the *high standards* the AAOS describes above were not available for us to *sufficiently recognize* them. We would like to point out that our study was not the only one that reported discrepancies with their disclosure statements. Andreatos et al.[13], referenced in our study, found that of the 4 AAOS guidelines they evaluated, all physicians serving on AAOS CPGs with significant payments had inaccurate disclosure statements.

The AAOS states, "[continued from previous quote]...they have included unrelated committee and council chairs with the participating committee members and moderators in their analysis. Although these individuals serve in various oversight roles and approve the final products, they do not participate directly in the process and are not able to manipulate or otherwise change the recommendations."

Our response: We evaluated contributors, not authors. We included individuals who hold positions with the authority to "approve the final products". Given the possibility that these leaders could fail to approve a guideline because of certain recommendations, it was necessary to include them in our first analysis.

The AAOS states, "Paragraph 5 on page e10(3) intentionally misrepresents both the IOM and AAOS policies on COI (we addressed this comment above). See attachment for a detailed description of the AAOS policy relevant to our quality products. This document is readily available to the public on the AAOS website. The paragraph makes no reference to relevancy of FCOI."

Our response: The AAOS provided a PowerPoint presentation containing clip art to JBJS to assist in understanding AAOS's policy relevant to their quality products. They further state that, "This document is readily available to the public on the AAOS website". First, as authors of a scientific paper, we refer to official,

professional policies that are published on the AAOS website where attestations of approval or reaffirmation are readily apparent on the documents. We would not cite a PowerPoint presentation as official policy. Second, we are unable to verify the claim that the PowerPoint presentation is readily available on the AAOS website. Two of us conducted searches lasting approximately 20 minutes each and were unable to locate the document on the AAOS website, even when we entered the exact name of the document in the website's search box.

The AAOS states, "Regardless, the authors use time periods which were not relevant to the product timelines reviewed. The surgical management of osteoarthritis of the knee (SMOAK) AUC initially convened in November, 2015 and was published in December, 2016. Therefore, data reported in 2013, 2014, and most of 2015 was not germane. Similarly, for the OA Knee CPG, publication date was May 18, 2013 therefore, by the authors' own criteria only 2014 should have been included in the analysis (under the appropriate premise that participants should remain unconflicted for one year after publication). The ACL AUC was published in October, 2015, therefore data from 2013 was not relevant. Table 2 shows how the analysis would look by removing SMOAK and including only 2014 for the OA knee CPG. This analysis still fails to recognize that we have insured that none of these participants (except AUC writing panel members) have relevant conflicts."

Our response: In our first analysis, we included all payment years available in the Open Payments Database (2 years and 4 months). We did so to describe the extent of industry payments occurring before, during, and after guideline development. Our time frame is well within the parameters of previous literature. Bindslev et al.[14] considered a conflict of interest to be present if a guideline author had an affiliation with a drug company up to 3 years prior to guideline publication, consistent with ICMJE standards. Cosgrove et al. [15] evaluated the financial relationships among the American Psychiatric Association's CPG authors. These authors were screened for any financial affiliations they had with the drug industry from up to 5 years before the publication of the guidelines. Cosgrove et al.[16] used 3 years on either side of the guidelines' publication dates. Neuman et al.[17] included payments made 2 years before guideline publication and year of publication. We point out that this comment applies only to our first analysis. For the evaluation of disclosure statement accuracy and for the evaluation of payments received by guideline chairs, we further limited the dates in which authors received payments.

The AAOS states, "Table 3 shows the subanalysis data for the workgroup co-chairs and oversight chair for each product. Regarding the assumptions made on the basis of this subanalysis we are unable to draw the same conclusions as the authors. In this instance, and throughout the manuscript, the authors repeatedly fail to separate relevant COI from non-relevant COI. The IOM makes the following statement in this regard: "…conflicts of interest – for example, relevant clinical specialists who receive a *substantial portion of their incomes* from services *pertinent* to the guideline." (emphasis added [AAOS added the emphasis here, not us]).

Our reply: We addressed the issue of relevance above. We also addressed the truncation of this sentence elsewhere in this letter.

The AAOS states, "We do agree with the recommendation that the AAOS should use Open Payments and Dollars for Docs to verify disclosure statement accuracy, and we plan on doing so as a result of discrepancies pointed out in this study. Three of the other four recommendations have been in place since the inception of our quality products and are consistent with IOM and AAOS standards, with the caveat (consistent with those same standards) that relevant FCOI's are the concern in question."

Our reply: We disagree that 3 of our 4 recommendations have been in place since the inception of the AAOS's quality products. In our discussion section, we state our recommendations as follows: "1) The chair and cochair not have any FCOIs; 2) Workgroup members with FCOIs be limited to one-third of the group; 3) Disclosure statements should include a broader range of years, and a higher degree of detail (e.g. the date of the FCOI, the amount of the FCOI, and whether the relationship is ongoing); and 4) the AAOS should use Open Payments and

Dollars for Docs to verify disclosure statement accuracy and ensure the workgroup are in compliance with IOM and AAOS standards."

The chairs and co-chairs analyzed in our study unequivocally received industry payments. Currently, the AAOS requires that work group members with FCOIs be limited to less than one-half the group, not less than one-third as we recommended. Published disclosure statements in the CPG-AUCs do not have the recommended degree of detail, and the AAOS did not cross-check these statements with the mentioned databases.

The AAOS states, "We met in person with one of the authors (Checketts), who admitted much of the above including the difficulties in determining relevancy from a lay perspective, misinterpretation of IOM standards (following a previously issued summary statement rather than the document cited), misinterpretation of various roles, misinterpretation of writing panel allowances for FCOI, and mistakes in the timeframes analyzed (paragraph 6 above). He expressed willingness to voluntarily retract the article given the errors and the gravity of the overall message relayed in the manuscript. However, further progress from the authors in this regard has not been forthcoming."

Our reply: The AAOS reached out to us on January 25, 2018 in response to the recent publication of our article in JBJS. In this email, they stated the following, "Please understand that this is NOT an attempt to refute your findings or your reporting. Rather, it is vitally important for us to understand where there are any misunderstandings, the magnitude of errors/discrepancies in the CMS database, and the significance of under-reporting by our member participants. All with the singular goal of trying to improve our processes, transparency, and the reliability of our quality products and efforts." Because of our goal to improve transparency and quality of guideline development in orthopaedic surgery, we reasonably interpreted this request as an opportunity to collaborate with the AAOS to improve future guidelines. We offered to meet with the AAOS committee at the March 2018 AAOS Annual Meeting as one of us (Checketts, a second year medical student) was already presenting other research there. This meeting occurred on Thursday, March 8, 2018. On the morning of Tuesday, March 13, 2018, Checketts and Vassar received an email from the Chair of the Council on Research and Quality with an attached letter written by the AAOS committee that stated that we [the authors] had admitted to serious methodological flaws and were requesting a voluntary retraction. After talking to Checketts about the tone and degree of professionalism of this meeting, the senior author (Vassar) became significantly concerned. Vassar emailed this Chair on March 13 to request a written transcript of the meeting but was told later that afternoon that none existed. On the afternoon of March 14, Checketts alone received an email from this Chair alerting him that if we [the authors] did not reach agreement on the retraction letter by March 20, the AAOS would submit a letter with a "much different tone" to JBJS requesting retraction. On March 19, Vassar emailed the Chair to request a 21 day extension to comprehensively evaluate the study methodology. The Chair quickly rejected this reasonable request.

The lack of a written transcript is concerning, especially in cases where formal accusations are being made that have far reaching consequences for the authors and JBJS. Without a written transcript, statements made — or not made — during the meeting remain a matter of perception and are subject to recall bias. Such statements are therefore unverifiable and unsubstantiated. Furthermore, Checketts, a second year medical student, is not an agent of the University and cannot speak on behalf of the other authors. The senior author was not present at the meeting, as we were unaware of the AAOS' intentions. Vassar's presence at such a meeting would likely have changed its tone, direction, and professionalism.

Having now responded to all comments from the AAOS, we report our findings from a carefully conducted re-evaluation of our data collection and analysis processes. In our re-evaluation, we found that the mean payments was listed in the abstract as $93,512 but in the results as $93,537, a difference of $25. Upon investigation, this difference in reporting came about through the JBJS copy editing process. $93,512 was the correct value. We

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also found that one data cell contained a blank instead of a zero (one contributor's associated research payments). The formula used to calculate the mean was correct, but a blank instead of a zero value caused listwise deletion (counting the cell as a missing value rather than zero dollars), and the mean was computed with the reduced denominator (105 instead of 106). Last, we found that one guideline contributor's name was listed differently in two guidelines. This contributor has a common name, and there are 21 physicians with his name in Open Payments Database. We removed duplicate authors for analysis, but this author was inadvertently included twice. This author received $55.81 in total general research payments and $12,800 in total associated research payments. When removing this duplicate, the sample size was reduced from 106 to 105 contributors, and resulted in changes to total payments (Rp=$9,912,309; Ac=$9,899,453; a 0.13% change), general payments (Rp=$8,717,756; Ac=$8,717,700; a 0.0006% change), and associated research payments (Rp=$1,114,303; Ac=$1,101,504; a 1.15% change), where Rp is the reported payment in the JBJS publication and Ac is the actual (corrected) payment. We noted the possibility for unintentional duplication of contributors in our discussion section as a limitation. We regret that these discrepancies occurred, but they do not change the conclusions of our paper or the magnitude of our findings.

In closing, we have provided sound justification for our decision making. We have shown that the AAOS made at least two different errors in their own data analysis and reporting and truncated a direct quotation from the IOM that alters the intended meaning of the narrative. We have also presented evidence of the IOM's preference that only non-conflicted authors be able serve on guideline panels unless reasonable efforts to find non-conflicted panelists have failed. Perhaps most important, we have made the case that our methodology was planned and conducted in good faith.

Sincerely,



Jake X. Checketts  Courtney Cook  Matt Vassar, Ph.D.

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17-00184 Checketts

Methodology Reviewer Comments (4/19/18):

I have reviewed the article, the AAOS response and the authors' response to the AAOS letter.

The article was carefully designed and well written. If I were reviewing it de novo, I would have asked the authors to not report mean payment amounts, because the few outliers receiving over 1 million dollars pulled up the mean. Median is a better choice here. In their defense, the authors do provide the payment information in categories, with box plots and also with the outliers removed, so they have handled the data sensibly.

The AAOS makes a number of reasonable points in their letter. In particular, they point out that their COI rules actually permit participation on guideline panels of some persons with COI. They further point out that the payments over a million dollars were primarily for intellectual property and a much smaller amount (50,000 dollars in one case) for work relating to the knee. The authors point out that 50,000 dollars is not trivial.

In sum, the authors have written a reasonable paper using careful methods. The AAOS takes issue with a number of the authors' assumption and statements. I think it would be perfectly reasonable for the AAOS to respond with a letter to the editor. I would put a word limit on the letter. I see no scientific justification for a retraction.