LITERATURE REVIEW

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Industry Sponsorship in Dentistry: An Ethics Scoping Review

Jeffrey Gruenglas, DHSc, MSc, MA, HEC-C, Roxana Menes, MPH, MA, Lori Rainchuso, DHSc, MS, RDH

jgruen@bu.edu rmene1@stu.mcphs.edu Lori.Rainchuso@mcphs.edu

Abstract: Evidence to guide dentistry on conflict of interest (COI) and professional-industry relationships is limited. To determine the breadth of literature regarding ethics in dentistry and COI relating to sponsorship. A scoping review following the PRISMA extension was performed. Medline/PubMed and Cochrane Library databases were used to identify peer-reviewed sources, published 2013-2023. Titles, abstracts, and full-text reviews were conducted by two independent reviewers. Disagreements were resolved by consensus. The remaining studies underwent critical appraisal. Key findings were extracted and analyzed. Adjusted for critical appraisal thresholds, we evaluated a total of (n=9) studies associated with dentistry, COI, and sponsorship (industry and non-profit research funding). The majority of evidence demonstrated a significant correlation with disclosure of COI and professional ethical conflict. More than 32% of publications demonstrated no clear disclosure or failed to report COI. Sponsored studies demonstrated significantly greater scrutiny of disclosure practices, whereas industry/dentist-reported payments were prevalent but varied widely (19% to 62%). Regardless of funding or influence, dental professionals are likely to disclose industry conflicts when presented with policies to guide transparency, thus strengthening patient trust and professional code of ethics.

Keywords: Dentistry, ethics, conflict of interest, sponsorship

*Address correspondence to: Lori Rainchuso, MCPHS University, School of Arts and Science, 179 Longwood Avenue, Boston, MA 02115. Email: Lori.Rainchuso@mcphs.edu

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INTRODUCTION

There are ethical standards and codes that guide all health professions relevant to the specific field of practice. Literature regarding professional ethics, healthcare, and the medical product industry is well published. ^{1–3} However, the dental profession is subject to far less scrutiny and oversight concerning professional ethics, particularly in the context of industry influence and product promotion. ^{4,5} Direct-to-consumer (DTC) advertising is a ubiquitous strategy for pharmaceutical and device manufacturers in the US. While the majority of advertisements are devoted to medical conditions, a smaller number promote the use of specific dental products, namely oral hygiene products. Although prescribed and investigational dental products are regulated under the Food and Drug Administration (FDA)⁶, DTC promotions, similar to their medical counterparts, are overseen by the Federal Trade Commission (FTC). ⁷ Such promotion often escapes the regulatory eye for misleading and false claims. ⁸ A more recent trend of manufacturers is to engage licensed dental professionals as spokespersons for their products (e.g., Sensodyne TV). Without a fair alliance to the endorsement, there is an ethical concern that such providers may be subject to conflict of interest (COI) and thereby betray their unbiased medical opinion while undermining the trust of patients. ^{1,9,10} Moreover, manufacturers who engage in such marketing practices fail to disclose any payment to advertised provider endorsers, which may bring into question the extent to which such endorsements are evidence-based or whether such payment influences prescribing and treatment behavior. ¹¹

The American Dental Association (ADA) Principles of Ethics and Code of Professional Conduct is an obligatory ethical guideline for dental members of the ADA and was recently revised in 2023. Section 5 concerns veracity and COI, highlighting the use of valid scientific evidence in the representation of products and/or procedures, compulsory disclosure of monetary gain and relationship between third party and dentist when endorsing a product. ADA censure for unethical behavior is limited to reprimand and/or suspension of professional membership. 12

Given the lack of regulatory oversight with company-sponsored DTC advertising, this review posited that, unlike the volume of research conducted on ethics in the medical profession, evidence to guide the dental professional on COI and professional-industry relationships, particularly concerning drug and device promotion is limited. This scoping review aimed to determine the current state of the literature regarding ethics in dentistry and COI as it relates to sponsorship. This review asked the following question: What is the breadth and degree of the research associated with ethics in dentistry and COI as it relates to industry sponsorship? To better understand the breadth of the diverse body of evidence relating to this inquiry, a scoping review was deemed most appropriate.

METHODS

An initial literature search was conducted in the PubMed/Medline database. Relating to the research inquiry, variations of the following terms were included: "dentistry," "ethics," "conflict," "sponsorship," "industry," "funding." The literature search excluded terms pertaining to "artificial intelligence", "technology," "COVID," "food," and "medical." Filters were applied using date range from 2013-2023, and English as the article language, generating 1,495 results. Additional refinements were made, searching for higher levels of evidence through systematic reviews and meta-analyses resulting in 89 studies. All potential sources were then skimmed by title and abstract for relevance to the research inquiry, producing 5 sources.

To identify an acceptable level of evidence saturation, Cochrane Library database was also employed in the literature search process. No additional sources were found. Additionally, four relevant sources were discovered via cross-referencing, for a total of 9 sources (Figure 1). The literature search was concluded in June 2023. However, one pertinent article was discovered as an incidental finding outside of the literature search. It was initially posited that journals outside of the US would not be relevant to the dynamics of industry influence on dental professionals in the United States, particularly because direct-to-consumer pharmaceutical or device advertising is permitted and thus regulated only in the United States and New Zealand. However, the scoping review expanded inquiry into industry funding of research separate from product promotion and was deemed relevant to the specific study objective, thus justifying inclusion.

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Identification of studies via databases and registers Identification of studies via other methods Sources identified initially through PubMed/Medline; followed by a secondary Cochrane Library Cross-referencing citation search database search (n=4)(n=1,495) Identification Additional refinements were Accidental finding of pertinent applied filtering for systematic articles reviews and meta-analysis (n=1) (n=89) All sources were skimmed by Additional sources identified by title and abstract for relevance to cross-referencing the 89 or 쥬 accidentally the research inquiry (n=5) (n=5) A total of n=10 studies were generated. To reduce bias and increase strength of article inclusion, two of the investigators independently conducted breadth and depth assessments, resulting in the exclusion of one study. Final studies included in the review (n=9)

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flowchart of included studies according to the search strategy

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Next, an independent assessment of the 10 sources was conducted among two of the investigators to reduce bias and increase reliability and strength of agreement. Each article underwent a full-text review and was evaluated and scored using a bi-level threshold of *breadth* and *depth* of relevance to the criteria of this review. Breadth was predefined as the degree of relevance to the topic of dentistry and professional ethics. Depth was assigned a degree of granularity and specificity to the research question and associated subquestions. Each article was measured on a scale of low, medium, or high. Disagreement among the investigators was discussed and resolved by consensus. As a result of the independent assessment, one source was omitted, yielding a total of 9.

The remaining sources underwent critical appraisal to assess quality. Due to the variety of study designs included in this scoping review, three critical appraisal tools were employed to discern the quality of studies: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), PRISMA-ScR (for a scoping review), and the Newcastle-Ottawa Assessment Scale for the remaining studies. PRISMA was employed to appraise four systemic reviews (Beyari et al., 2014; Dos Santos et al., 2019; Popelut et al., 2010; Reda et al., 2017), and three systematic reviews with meta-analyses (Brignardello-Peterson et al, 2013; Faggion et al. 2020; Schwendicke et al., 2016). The PRISMA checklist for systematic reviews with or without meta-analysis consists of 27 items. The PRISMA guidelines to discern the quality of journal articles are based on the following categories: (1) a score of < 19.0 indicates low-quality studies; (2) a score of ≥19.0-22.5 indicates moderate-quality studies, and (3) a score of ≥ 22.5 indicates high-quality studies. Therefore, based on the PRISMA guidelines, only studies with a score of 22.5 points or higher are considered to be high-quality studies and thus included in this scoping review. For the Holden et al study the PRISMA extension checklist for scoping reviews (PRISMA-ScR) was employed using the 22-item checklist. The study was deemed applicable and of overall good quality, and therefore included. Lastly, the Newcastle-Ottawa Quality Assessment Scale was used to appraise one retrospective, observation study (Lee & Chuang, 2020). The evaluation scale is as follows: (1) very good studies rate 9-10 points; (2) good studies rate 7-8 points; (3) satisfactory studies rate 5-6 points, and (4) unsatisfactory studies rate 0-4 points. Based on the Newcastle-Ottawa Quality Assessment Scale guidelines, study inclusion for this scoping review was deemed to be of good quality with a score of 7 or higher.

RESULTS

Based on the critical appraisal scores, a total of (n=9) studies published from 2010 to 2020, associated with dentistry, COI, and sponsorship (industry and non-profit research funding) were included in this review.

Beyari et al (n=66) found no association between funding source and disclosure of COI (p=0.387) and whether it was reported (p=0.120).¹³ Source of publication itself (i.e., journal) demonstrated a significant bearing on whether such COI was disclosed (p ≤ less than equal to 0.0001). Specifically, all of the articles reported on COI, whereas disclosure of sponsorship varied widely between *Community Dentistry* and *Oral Epidemiology* or *Journal of Dental Research* (25% and 72%, respectively). Geography itself was not a meaningful variable, as no relationship was demonstrated between the continent of source funding and declaration of COI. The review concluded that COI reporting lacks a standardized method of both reporting and identifying disclosures.¹³ Another study found likewise no association between positive study results and journal of publication or area of practice,¹⁴ yet investigators with more broadly characterized COIs were more likely to report positive findings compared to those studies with no COIs reported. This finding suggests that the presence of COIs alone may not be a contributing factor for sponsorship influence on reported outcomes. According to Faggion et al more than 32% of publications demonstrated no clear disclosure of COI or failed to report disclosures altogether. Approximately 16% of such studies reported no sponsorship, 37.2% reported support from non-profit organizations, and a mere 4.3% reported support from profit organizations. Disclosure of support from a combination of for-profit and non-profit organizations was even lower (2.0%).¹⁵

A significant predictor of reported sponsorship was the number of authors compared to such other variables as number of citations, altmetric scores, and impact factor. In a comprehensive scoping review, Holden et al evaluated the evolution of the influence of commercialism on the dental professional, particularly with respect to ethical conflicts.^{4,5} Researchers found that the degree of industry influence strongly indicated a compromise of values among dentists, thus threatening their professional objectivity.

With respect to documented reporting of industry sponsorship of devices or products, researchers found that the majority of the trials that did disclose such relationships with limited transparency and carrying a high risk of bias (66%). ¹⁶ The Popelut et al review found more than half of dental implant brands, for example, were dominated by one company source (59%). Additional bias was noted with respect to geography, where Sweden, the source funding company's original country, was the most common country represented

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among corresponding authors (24%). The review also noted that only two trials reported a COI statement. Of concern, compared to non-industry associated trials, those whose studies were funded by industry, or an unknown source were more likely to report positive trends or clinical outcomes, such as lower annual failure rates of dental caries. Such variables were strongly correlated with the intentional selection of publication age (p=0.002) and funding source (p=0.001). The correlation of industry funding and dental practice was further measured in clinical outcomes across bone loss, implants, and dental caries.¹⁷ One study found no statistically significant relationship in reporting of marginal bone loss/year and dental implants in industry funded research albeit a marked level of publication bias (p < 0.001), suggesting that partiality may be present across journal review processes and peer-review rigor and standard. ¹⁷ Conversely, Reda et al found that publications of funded trials trended toward fewer unsubstantiated claims, thus underscoring the strength and value of the publication itself to thwart or mitigate the effects of sponsorship on publication bias. 18 In an analysis of studies that tested the effect of fluoride varnish and fluoride gels (n=17,726 participants), only one-third contained unsubstantiated claims that otherwise weighted evidence toward a specific product. For example, studies that reported on fluoride gels presented clinical claims that were more balanced and impartial than even non-sponsored trials or trials with unclear sponsorship status. In a subgroup analysis older sponsored studies (prior to 1990) demonstrated a significantly greater benefit in caries prevention than non-sponsored or possibly sponsored trials, ¹⁸ an indication that journal standards themselves can play a role in ensuing partiality in funded research. Similar findings were noted in the Schwendicke et al¹⁹ meta-analysis, investigating industry sponsorship effects on research relating to dental restoration material study design, the choice for comparison material, and outcome of findings. Investigators found that disclosure of clinical outcomes were reported with greater frequency than non-sponsored trials even with an indicator of significantly increased risk of detection bias (n=15,321 restorations in n=5,232 patients). 19 It should be noted that the greater volume, frequency, and longer follow-ups of restoration procedures in the sponsored trials poses a concerning limitation of such evidence (p < 0.05).

From a dental professional specialty perspective, industry-sourced payments range widely, from 19% to 62%, with the highest rates of funding among orthodontists, followed by oral and maxillofacial surgeons, and periodontists, although no correlation was demonstrated between payment amount and degree of influence, or provider conflict.²⁰ The amount of funding or payment itself may be a separate variable in determining the level of influence on dental provider behavior and product preference. The evidence demonstrated that sponsored trials were more likely to disclose conflicts, but with little bearing on effect estimates.¹⁹

Regarding, reporting of funding, fewer than half (44%) of the studies in this scoping review disclosed funding from external and academic sources. Dos Santos et al noted partial investigator support by the Meridional Foundation (Passo FundoBrazil), Coordination for the Improvement of Higher Education Personnel (Capes—Brazil), and the National Council for Scientific and Technological Development (CNPq—Brazil), although none of these institutions were involved in study design, analysis, or the development of the output.¹⁷ Faggion et al received funding limited to the authors' institution (University Hospital Münster, Münster, Germany; University of Bern, Switzerland; and Federal University of Pelotas, Brazil), ¹⁵ similar to Popelut et al, ¹⁶ who received an academic research grant (University Paris Diderot, Paris, France). In contrast, Schwendicke et al ¹⁹ received support from institutions, whereas the lead investigator was funded by the German Research Foundation, and the second author was under by the Ministry of Science & Technology in Taiwan. Two sources of evidence stated no conflict or source of funding (Beyari et al ¹³ and Brignardello-Petersen ¹⁴) and three failed to provide any statements of disclosure altogether (Holden et al ⁴, Reda et al ¹⁸, and Lee & Chuang ²⁰). It is undetermined whether this is an omission of the authors or the publisher.

DISCUSSION

This review sought to quantify the scope and degree of reliable evidence associated with COI and sponsorship in dentistry. Post critical appraisal, our analysis revealed 9 peer-reviewed studies. In addition to the research that focused on the relationship between industry sponsorship and clinician behavior, nearly half revealed that dental professionals were more likely to disclose conflicts regardless of whether sponsorship existed. These data are reassuring and support the premise that dental professionals would welcome policies and ethical codes that guide transparency with industry disclosure. There is little to no variance across geographical, journal, or area of practice factors, which suggests that the profession itself may recognize its obligation for transparency given that mechanisms for doing so are put into practice. Indeed, as Beyari et al¹³ observed, COI reporting lacks standardization when reporting and identifying such conflicts. Others, such as Brignardello-Petersen et al¹⁴, found that a lack of a systematic and standardized definition of conflict, points to challenges with accurate reporting, which is no surprise why positive clinical patient outcomes are reported when a definition

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is far broader and less-well defined. The evidence further confirms that the source of funding itself demonstrated no significant correlation with the reporting of positive findings. This learning is particularly concerning given the ongoing practice of industry-funded direct-to-consumer advertising and product promotion that employs paid dental professionals. As Dos Santos et al¹⁷ found, the forprofit sponsorship itself increased the probability of a conflict. Publication bias was far less associated with conflict and perceived patient influence, suggesting that patients are more likely to be influenced by consumer-directed mechanisms than clinical journals. Publications that are sponsored by industry demonstrated reports of reduced failure rates with specific devices and interventions, which is not surprising considering a sponsor's strategic goal to increase clinician exposure and awareness of their product.

Similar to industry sponsored medical journals; dentistry clinical trials are less likely to avoid unsubstantiated claims than claims backed by poor evidence. Although the literature from this review concludes that industry sponsorship status itself is not a significant predictor of such effect estimates, it cannot be ruled out that journal guidelines and policies themselves dictate greater scrutiny during the peer-review process. The data on studies with fluoride gels and dental caries demonstrated a lower or no effect of publication influence with sponsored trials, ¹⁸ which further reinforces the precise that sponsorship had a lower degree of correlation on influence when such relationships are disclosed and made public. Indeed, trials that evaluated restorations of load-bearing cavities with greater frequency reported a lower risk of detection bias and had longer follow-up periods.¹⁹

With regard to the relationship between industry payments and dental professional influence, the effect is less clear as the degree of payment and the type of dental specialty may have a greater bearing on behavior and practice. In contrast to this variation, media that fails to discriminate among specialty and type of practice is more likely to carry a greater likelihood of false or misleading product promotion, which in turn may have a more deleterious effect on patient influence. These findings are consistent with similar ethical considerations in general pharmaceutical and device direct-to-consumer advertising practices in the medical profession.^{21,22}

LIMITATIONS

The limitations of this scoping review are as follows; while the authors methodically searched for pertinent studies related to the research question, it is possible that a relevant study may have been inadvertently excluded. Secondly, this review was restricted to publications in English only. Lastly, due to a lack of robust number of studies relating to the research inquiry, conducting a systematic review was beyond the breadth of this study. However, to ensure a rigorous process for this scoping review, the PRISMA-ScR was employed. The appraisal concluded that all applicable criteria items were met.

CONCLUSION

The findings of this critical appraisal and review of the literature expose a concerning gap of adherence to dental ethics and the threat of industry influence on patient outcomes and the profession itself. Although evidence does not demonstrate a strong correlation of industry influence on dental professional practice and behavior, findings suggest that such influence nevertheless has the potential to adversely impact professional trustworthiness among patients. Beyond the need for additional research to examine the effects and degree of such correlations, the authors hope this work encourages further discussion regarding the merits of advancing appropriate regulatory and policy reforms in dentistry.

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