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DISCLOSURE OF CONFLICTS OF INTEREST IN THE ORTHOPAEDIC FIELD
AND IN MEDICAL EDUCATION

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

By
Brian Lee Ju
2012

DISCLOSURE OF CONFLICTS OF INTEREST IN THE ORTHOPAEDIC FIELD AND IN MEDICAL EDUCATION. Brian L. Ju, Christopher P. Miller, Peter G.

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The purpose of this study was to determine the variability in disclosure information reported by authors at three annual orthopaedic conferences in the same year. Furthermore, we examined the number of medical schools with disclosure policies regarding educational activities and the acceptance of gifts from industry (law school policies were similarly analyzed for comparison). We hypothesize there will be significant variability in disclosure of conflicts of interest in both the professional and educational arena.

The author disclosure information published for the 2008 North American Spine Society (NASS), Cervical Spine Research Society (CSRS), and Scoliosis Research Society (SRS) conferences were compiled into a database and examined. Online disclosure policies for all 131 accredited medical schools and all 200 accredited law schools were evaluated during August/September 2009.

Disclosure records were available for 1,231 authors at NASS, 550 at CSRS, and 642 at SRS. Of the 153 authors who presented at the NASS and CSRS meetings, 51% exhibited discrepancies in their disclosure information. Of the 131 accredited medical schools, 98% (vs. 18% of law schools) had protocols in place requiring faculty to disclose their financial relationships to their institutions. Only a small percentage of both medical and law schools required lecturers to disclose these associations with students. 40% of medical schools (vs. 1% of law schools) had established policies limiting gifts from industry.

These findings emphasize the significant variability that currently exists in the reporting of financial conflicts of interest by authors who presented at three major spine conferences. We believe these discrepancies are likely due to confusion regarding what relationships should be acknowledged in certain situations and the clear lack of uniformity among the disclosure policies. Not only in the professional arena, but the widespread implementation of disclosure guidelines in medical schools emphasizes the acknowledged need to regulate physician-industry relationships. The varied policies addressing faculty disclosures and the acceptance of gifts demonstrate that the regulation to these relationships remains inconsistent.

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To Dr. Grauer and the entire Orthopaedic section for their help and continued support throughout my four years at Yale School of Medicine.

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INTRODUCTION

Conflicts of Interest in Orthopaedics

As the resources for scientific endeavors offered by traditional sources of funding such as the National Institutes of Health have continued to decline, private industry has taken on a greater role in providing financial support and other opportunities to physicians. These arrangements allow companies to take advantage of the knowledge and experience of clinicians while facilitating the completion of studies that are of interest to both parties. These physician-industry interactions may take on various forms, including research grants, consulting agreements, advisory board positions, royalties, or stock options; given their value to these companies, it is not unreasonable for these clinicians to expect to be fairly compensated for their time and effort on these projects.

Although these partnerships may in many cases foster advances in medical care and technology, there are growing concerns regarding the negative consequences of clinicians working closely with industry [1-5]. Many critics have suggested that these relationships may unduly influence the professional judgment of clinicians who are otherwise bound to place the welfare of their patients above all else. For instance, any investigators with a direct financial stake in the outcomes of a study are particularly susceptible to bias which may compromise the veracity of their research at any point from the conception of the experimental design [6] to the actual analysis and interpretation of results [7,8]. As a result, these associations have come under greater scrutiny in recent years as the prevalence of industry-sponsored studies has increased.

One initial strategy that has been widely implemented in an attempt to limit the effects of industry involvement on scientific inquiries is to establish an environment of transparency so that all of an individual physician's corporate ties are readily available to the public [9]. However, the goal of disclosure is not necessarily to eliminate all sources of bias but to inform the readership of the existence of possible conflicts of interest (COIs) and allow them to draw their own conclusions about the objectivity of the authors [10]. Some critics of mandatory disclosure insist that financial incentives represent only one of many factors that investigators take into consideration when performing a study and is therefore unlikely to alter the findings to a great extent [11]. Regardless, the scientific community has strongly advocated disclosure as a method for protecting the integrity of the research process, and the majority of journals and conferences have adopted some mechanism for the reporting of financial disclosure information [12].

There are generally two types of disclosure policies that are being implemented, one of which requires authors to simply reveal the relationships that are germane to the research being presented [13] while the other entails the comprehensive documentation of all of their financial dealings with industry regardless of whether they are relevant to the current investigation [14,15]. While both of these approaches are intended to maintain the transparency of clinician-scientists, the inconsistencies between these two sets of guidelines and their often ambiguous definitions of what constitutes a true conflict of interest (COI) has led to continuing confusion among physicians and may even yield inappropriate or inadequate disclosure of their industry ties. Nevertheless, the clarity and effectiveness of these two disclosure protocols have not been well characterized. The purpose of this part of the investigation was to compare the self-reported disclosure

information of authors attending three major spine conferences in the same calendar year (2008 annual meetings of the North American Spine Society, Cervical Spine Research Society, and Scoliosis Research Society) and to quantify the variability between their published data.

Conflicts of Interest in Medical Education

Much like their counterparts in the post-graduate stage, medical schools often rely on partnerships with commercial entities to ensure continuing progress in biomedical research and student education. However, such relationships have come under closer scrutiny in recent years, in part because of their potential to influence medical education [16-22].

The primary concern is that COIs arise when physicians in academia form relationships with industry which may affect both their clinical and research endeavors. Financial relationships that directly result in personal or monetary gain such as grant support, stocks, and consulting positions, clearly represent potential COIs, but even seemingly less significant patterns of interaction with industry exemplified by travel reimbursements, honoraria, office supplies, and other gifts have been shown to subtly bias physicians' judgments and possibly manipulate their perceptions over time [23-26].

In an effort to bolster public trust in our nation's medical institutions, as well as to ensure the continued integrity of medical education and biomedical research, the Association of American Medical Colleges (AAMC) and the Accreditation Council for Continuing Medical Education (ACCME) have published guidelines to assist members in managing industry collaborations in accord with higher standards of medical

professionalism. Aside from focusing on many aspects of the interactions that exist between industry and individuals in academia, these recommendations also underscore the importance of this issue [27,28].

The influence of commercial entities on the field of medicine may affect physicians at every level of training. In particular, the degree of interaction industry has had with medical professionals throughout all of the stages in their education raises questions about the overt or subtle effects of this presence in academic settings, including the classroom or laboratory. For example, a recent New York Times article describes a pharmacology professor at Harvard Medical School who touted the benefits of cholesterol-lowering drugs and inappropriately minimized their side-effects without acknowledging to his students that he was a consultant to several pharmaceutical companies that market these types of medications [29]. These and other similar incidents illustrate how industry affiliations may sway both practicing physicians and the next generation of healthcare providers.

One method that has been proposed for enhancing the transparency of individuals who educate medical students is the mandatory disclosure of their industry relationships to their students. This approach has been widely adopted by medical journals and professional societies which have proven this strategy to be reasonably effective for regulating these collaborations [9-12]. Similar policies requiring medical school faculty to disclose their COIs may be equally as beneficial for maintaining their transparency. This information may allow students to form their own judgments about the merits of lectures given by individuals with industry connections. By emphasizing the necessity of divulging these relationships, these protocols may also compel physicians-in-training to

be cognizant of the impact of commercial ties and hopefully serve as a framework to guide them during their subsequent interactions with corporate interests in the future.

While faculty disclosure has taken on increasing significance among medical practitioners, it is unclear how prevalent these policies are in other professions (that are often held to similar ethical benchmarks), such as the legal community. COIs inevitably arise between lawyers and third parties but the American Bar Association (ABA), which provides accreditation of law schools and is the legal analog to the AAMC, does not mandate disclosure at its educational programs or insist that its institutions address attorney-industry relationships in a certain fashion [30]. Thus, the manner in which this issue is discussed is solely determined by each individual law school.

The purpose of this part of the study was to quantify the number of medical schools with policies that specifically require faculty disclosure of financial relationships to their institutions and/or their students and to characterize their policies regarding the acceptance of gifts from industry. In addition, these guidelines were compared with any analogous protocols implemented by law schools in an attempt to assess the relative importance of reporting COIs within each respective field and to provide a larger perspective on this issue.

OBJECTIVES

The purpose of this study was to determine the variability in disclosure information reported by authors at three annual orthopaedic conferences in the same year. Furthermore, we examined the number of medical schools with disclosure policies regarding educational activities and the acceptance of gifts from industry (law school policies were similarly analyzed for comparison). We hypothesize there will be significant variability in disclosure of conflicts of interest in both the professional and educational arena.

METHODS

COI in Orthopaedics

We retrospectively reviewed the disclosure listings for all of the authors presenting at the 2008 North American Spine Society (NASS), Cervical Spine Research Society (CSRS), and Scoliosis Research Society (SRS) conferences which were printed in the final program for each meeting. Individuals submitting abstracts to these meetings were obliged to declare their potential conflicts of interest by February 2008 for NASS and SRS, whereas the corresponding deadline for CSRS was June 2008. Although it is possible that the disclosure status of a participant may have changed during the few months between these dates, we operated under the assumption that the incidence of any such modifications would be minimal.

The official disclosure policies for these meetings were obtained from the website of the sponsoring society and corroborated by the corresponding program brochures as well as by phone calls to the respective societies (see Appendix). According to these references, NASS and CSRS requested that surgeons report any and all financial relationships regardless of their relevance to the research being presented, while SRS only solicited disclosures that were directly connected to that particular study.

Since the guidelines established by NASS and CSRS were analogous, we were able to compare the industry affiliations of authors who attended these conferences because their disclosures would supposedly be identical. For example, a surgeon

acknowledging three industry associations to NASS who registered the same three entities with CSRS would be classified as displaying “no discrepancies.” However, another author who recorded three conflicts of interest to NASS but only revealed two to CSRS would be considered to have “1 discrepancy.”

In contrast, the project-specific policy implemented by SRS made it necessary to employ a different strategy to compare this data to that generated by NASS and CSRS. For those who presented their work at the SRS and either or both of the other meetings, it would be expected that all of the collaborations declared to SRS should also have been listed by NASS or CSRS under their global disclosure policies. If all of the industry entanglements that an author reported to SRS were also noted within the larger set of financial relationships supplied to NASS or CSRS, he or she was thought to possess “no discrepancies.” Similarly, individuals who had no conflicts of interest at SRS but were found to have one or more at NASS or CSRS were still deemed as having “no discrepancy” because these investigators may not have had any commercial ties related to their studies yet still possess other financial interests that did not have to be conveyed to SRS (but would still have to be shared with NASS and CSRS). Conversely, a disclosure that was published at the SRS conference but not at the NASS or CSRS conventions was categorized as “1 discrepancy”.

For the purpose of comparison, all of the researchers were segregated into 3 separate groups based upon which two of the three meetings they had attended: NASS/CSRS; SRS/NASS; and SRS/CSRS. In each cohort we identified the authors with no changes in their listings and those with discrepancies in the disclosures that they had divulged to the two societies, focusing on those who had apparently had no affiliations at

one convention but declared one or more financial interests at the other. Furthermore, we also recorded the number of different industry relationships each individual with consistent data had acknowledged, as well as the number of discrepancies that existed between the information submitted to the two conferences by participants who exhibited variability in their disclosure status.

COI in Medical Education

Medical School Review

A list of the 131 medical schools accredited by the Association of American Medical Colleges (AAMC) was obtained from its official website (www.aamc.org). The disclosure policies and physician-industry interaction protocols for all of these institutions are publically available and were acquired from each school's website during the month of August 2009.

Disclosure policy to students

Each disclosure policy was analyzed using several criteria. First, we noted which medical schools had established formal guidelines requiring classroom lecturers to disclose their industry affiliations to their students. We subsequently determined whether the institution had similar policies dictating that faculty members divulge their commercial ties to students with whom they would be performing research. Finally, we calculated the proportion of medical schools that were also accredited by the Accreditation Council for Continuing Medical Education (ACCME).

The rationale for characterizing the proportion of ACCME-accredited medical schools was that this organization issues specific guidelines to its member institutions regarding disclosure of industry relationships. [13] These ACCME directives apply to individuals who seek Continuing Medical Education (CME) credits or participate in these events. According to these regulations, lecturers at sanctioned speaking engagements must disclose any relevant commercial ties prior to the beginning of the educational activity. Even though the ACCME protocol is not necessarily part of medical schools' formal policies, the adherence to these principles reflects an increasing awareness of the importance of acknowledging COIs to those in attendance and maintaining full transparency.

Physician-industry interaction policy

Each medical school's policy regarding physician-industry interactions was also reviewed for statements that related to the acceptance of gifts by physicians or other academic faculty from commercial entities. We quantified the proportion of medical schools that explicitly prohibited the receipt of gifts and/or defined the types of items that were allowed.

Law School Review

A similar evaluation of law schools was performed for the purpose of comparison to the data collected for the medical schools. The 200 law schools accredited by the American Bar Association (ABA) were identified from its official website (www.aba.org). The disclosure guidelines and policies for attorney-industry interactions

of these institutions are all publicly available and were recorded from each school's website. All protocols were analyzed using the same methods that were described previously for the medical school policies during the month of September 2009.

While law schools are accredited by the American Bar Association, there is no national governing body equivalent to the ACCME that oversees legal education; in each state this responsibility is generally fulfilled by its supreme court or another designated committee. The American Academy of Law Schools (AALS) is a close analog of the AAMC that supports legal education, but it is not involved in the accreditation of law schools.

RESULTS

COI in Orthopaedics

Disclosure information was available for 1,231 authors at NASS, 550 at CSRS, and 642 at SRS; of these researchers, 278 (NASS), 129 (CSRS), and 181 (SRS) also presented at one of the other conferences with 40 having listings for all three conferences. The three data sets analyzed in this study were comprised of 153 individuals for NASS/CSRS, 205 for SRS/NASS, and 56 for SRS/CSRS which represents 334 out of the total of 2,049 possible author combinations derived from all three conferences (Figure 1). The mean (\pm standard deviation) and median number of disclosures for these authors were 1.8 ± 3.5 and 1, respectively.

Number of authors at annual 2008 spine meetings

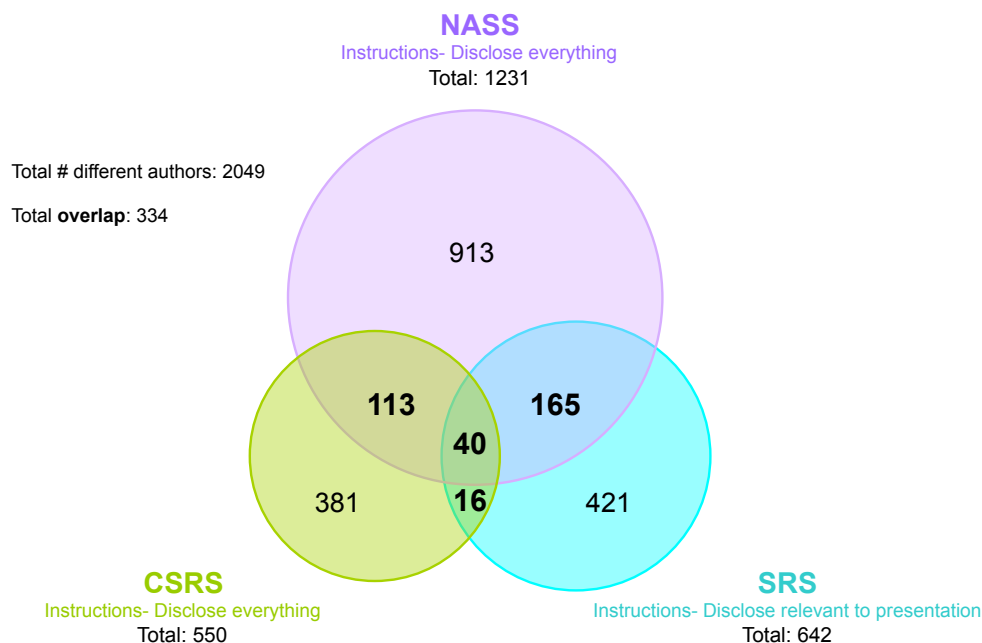


Figure 1. Venn diagram delineating the general disclosure policies of each organization and classifying the authors who attended the three conferences.

NASS and CSRS

153 authors presented at the NASS and CSRS meetings, both of which required disclosure of all industry collaborations regardless of their relevance. 51% of this group was noted to have contradictory information of which 32% had one discrepancy, 24% possessed two, and 44% demonstrated three or more. In addition, 45% of these individuals affirmed that they had “nothing to disclose” at one of the conferences yet informed the other society of at least one financial relationship (Figure 2a, 2b).

Discrepancies in disclosure reporting for authors who attended both NASS and CSRS

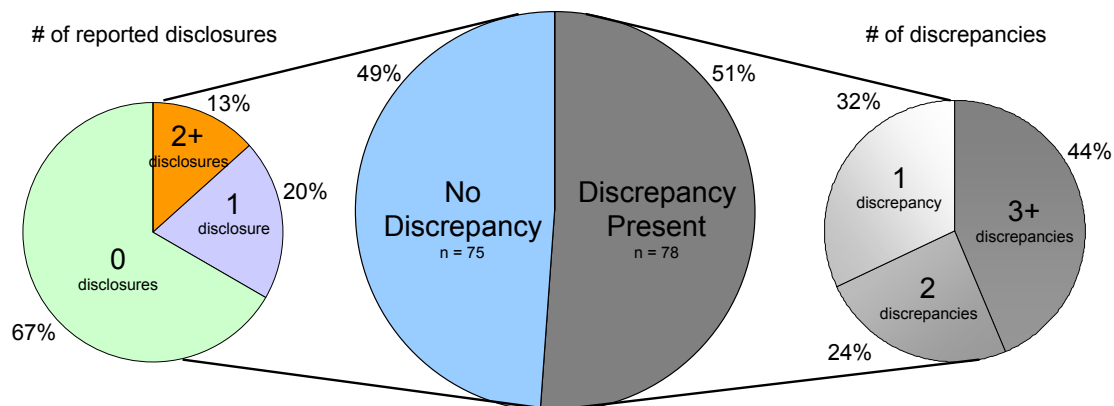


Figure 2a. Proportion of authors attending NASS and CSRS who were noted to have discrepancies in their disclosure information for the two conferences, including the number of discrepancies exhibited by individuals with inconsistencies as well as the number of industry relationships reported by those without any discrepancies.

Percentage of common NASS/CSRS authors who disclosed nothing at one conference vs. something at the other

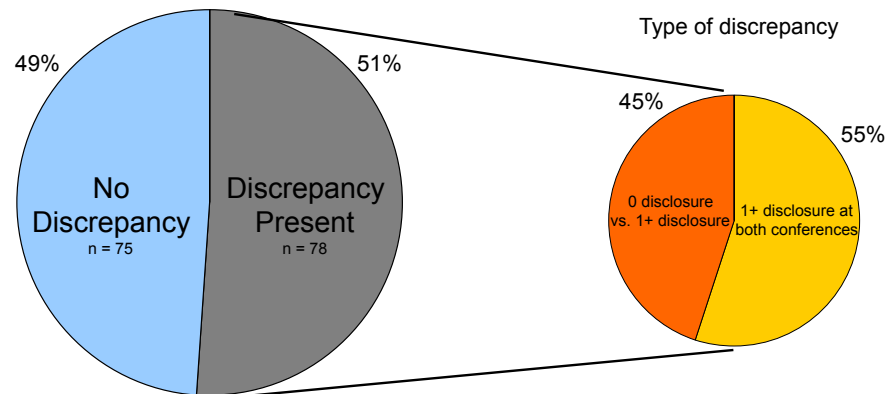


Figure 2b. Proportion of authors attending NASS and CSRS with documented discrepancies that identified no disclosures at one conference but declared at least one conflict of interest at the other.

The other 49% of authors attending NASS and SRS were completely consistent in their reporting with the majority (67%) having no industry associations while 20% and 13% named one versus two or more commercial entities, respectively (Figure 2a). This trend of researchers with accurate disclosure statements typically having no conflicts of interest was apparent for all three pairs of meetings (Figure 2a, 3a, 4a).

SRS and NASS

Unlike the global disclosure guidelines of NASS and CSRS, SRS utilized a more limited policy that involved the declaration of any financial ties that were specific to that

investigation. According to the results of this assessment, only 9% of the 205 authors presenting research at both SRS and NASS demonstrated irregularities in their information, with 95% having one discrepancy and 5% revealing two or more. Moreover, 42% of surgeons with disparities had indicated that they had “nothing to disclose” in response to the all-inclusive requirements of NASS while confirming the existence of at least one industry affiliation to SRS (Figure 3a, 3b).

Discrepancies in disclosure reporting for authors who attended both SRS and NASS

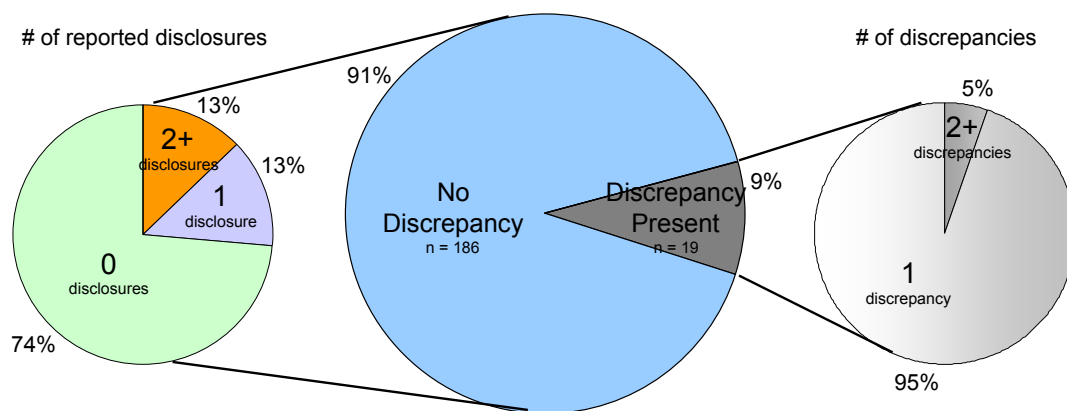


Figure 3a. Proportion of authors attending SRS and NASS who were noted to have discrepancies between their project-specific disclosures at SRS and their global disclosures at NASS, including the number of discrepancies exhibited by individuals with inconsistencies as well as the number of industry relationships reported by those without any discrepancies.

Percentage of common SRS/NASS authors who disclosed something at SRS vs. nothing at NASS

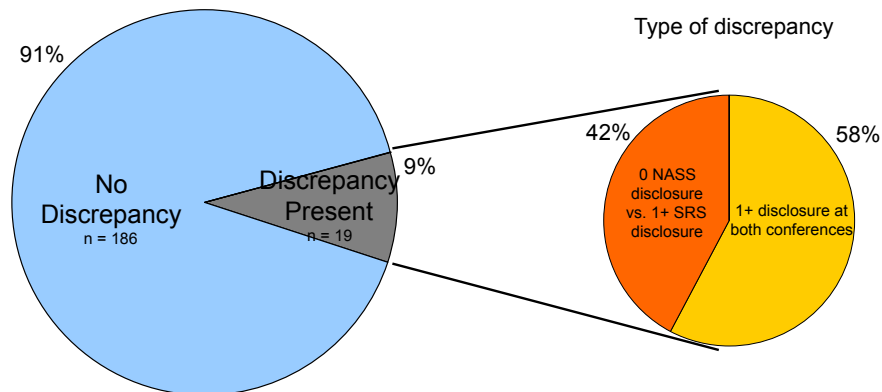


Figure 3b. Proportion of authors attending SRS and NASS with documented discrepancies that identified no disclosures at NASS but declared at least one conflict of interest at SRS.

The other 91% of authors with research investigations at both SRS and NASS were found to have uniform reporting of their conflicts of interest. Although the preponderance (74%) of these researchers had no disclosures, 13% listed one source of industry support and another 13% admitted to having two or more (Figure 3a).

SRS and CSRS

Of the 56 authors common to both the SRS and CSRS meetings, 18% were observed to have incongruous disclosure information. In this subset of individuals, 60% had one discrepancy and 40% had two or more. As with the other pairs of conferences,

50% of those with inconsistencies marked “nothing to disclose” as part of their global disclosures to CSRS but cited at least one financial relationship at the SRS convention (Figure 4a, 4b).

Discrepancies in disclosure reporting for authors who attended both SRS and CSRS

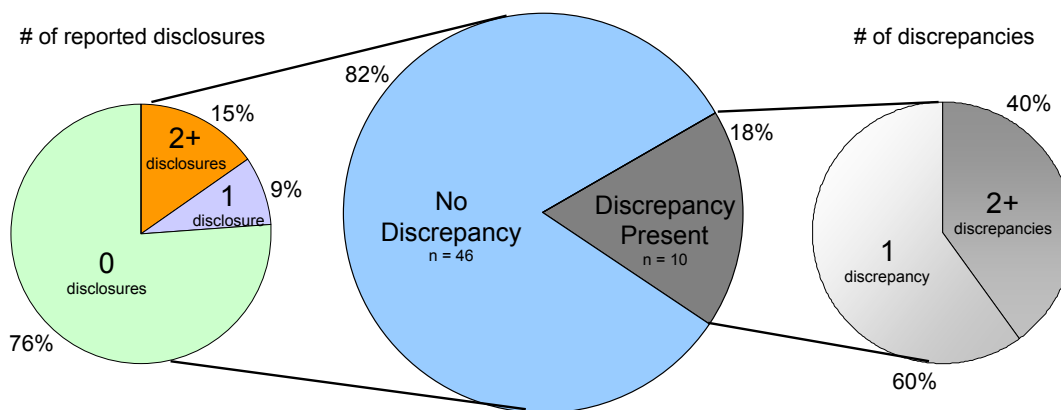


Figure 4a. Proportion of authors attending SRS and CSRS who were noted to have discrepancies between their project-specific disclosures at SRS and their global disclosures at CSRS, including the number of discrepancies exhibited by individuals with inconsistencies as well as the number of industry relationships reported by those without any discrepancies.

Percentage of common SRS/CSRS authors who disclosed something at SRS vs. nothing at CSRS

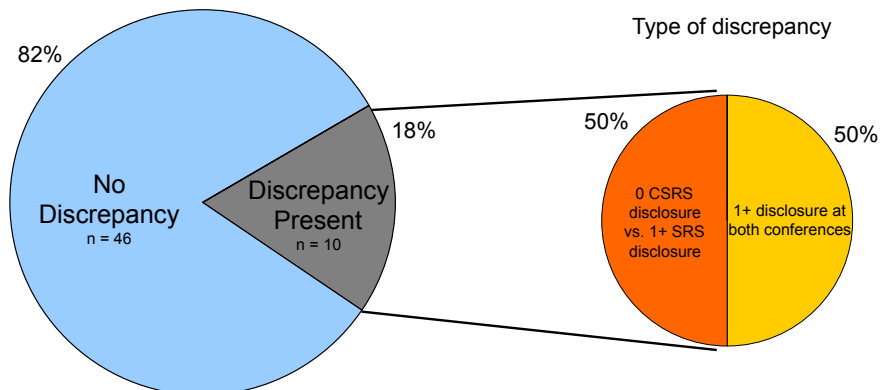


Figure 4b. Proportion of authors attending SRS and CSRS with documented discrepancies that identified no disclosures at CSRS but declared at least one conflict of interest at SRS.

The remaining 82% of this cohort displayed no discrepancies between what they had furnished to SRS and CSRS. A large proportion (76%) of these researchers maintained that they had no financial interests with 9% and 15% designating either one or more than one industry relationship, respectively (Figure 4a).

COI in Medical Education

Medical School Policies

Disclosure policies

Of the 131 AAMC-accredited medical schools, 98% had policies in place requiring faculty members to disclose their financial relationships to their institution, and 92% of the schools were accredited by the ACCME (Figure 5). However, just 4% of the medical schools were found to have formal guidelines obliging lecturers to divulge their commercial interests to students prior to the beginning of an educational activity, and 5% of these institutions expected faculty to convey their industry affiliations to those engaging in joint research projects. Only 2% of all medical schools expected disclosure information to be reported to individuals in both of these situations.

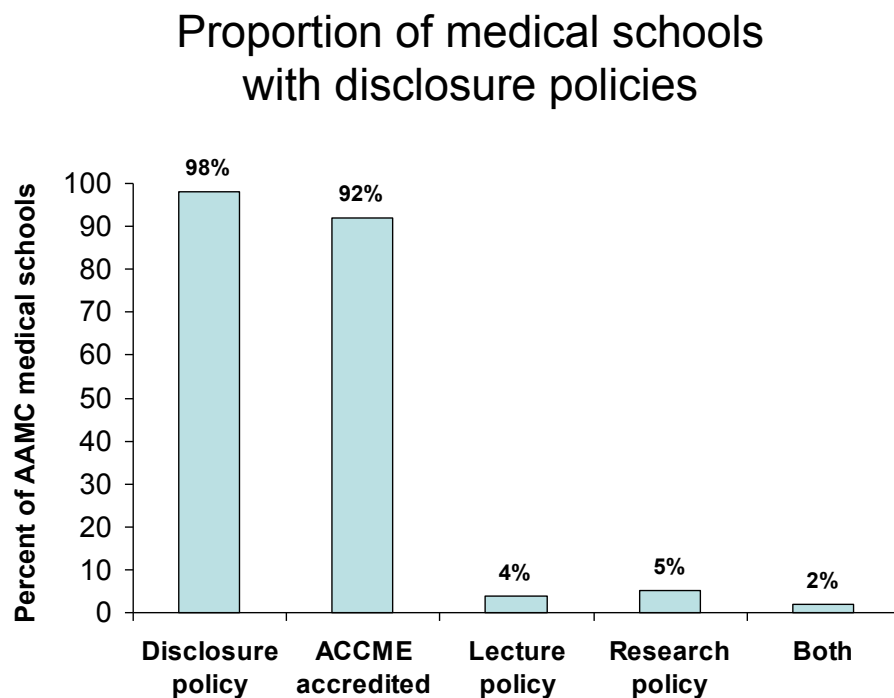


Figure 5. Proportion of AAMC-accredited medical schools that have policies requiring faculty disclosure to students.

Physician-industry interaction policies

Although 22% of medical schools prohibited the receipt of any item from an industry source regardless of its monetary value, more than half (60%) had no preemptive restrictions on the acceptance of gifts (Figure 6). The remaining 18% of institutions set specific limits for these gifts; of this cohort of schools, 15% allowed the acceptance of nominal benefits related to “academic pursuits” (i.e. office supplies, honoraria, or travel reimbursements) and 3% capped the total value of gifts accepted to less than \$300 annually.

Medical school policies on industry gifts

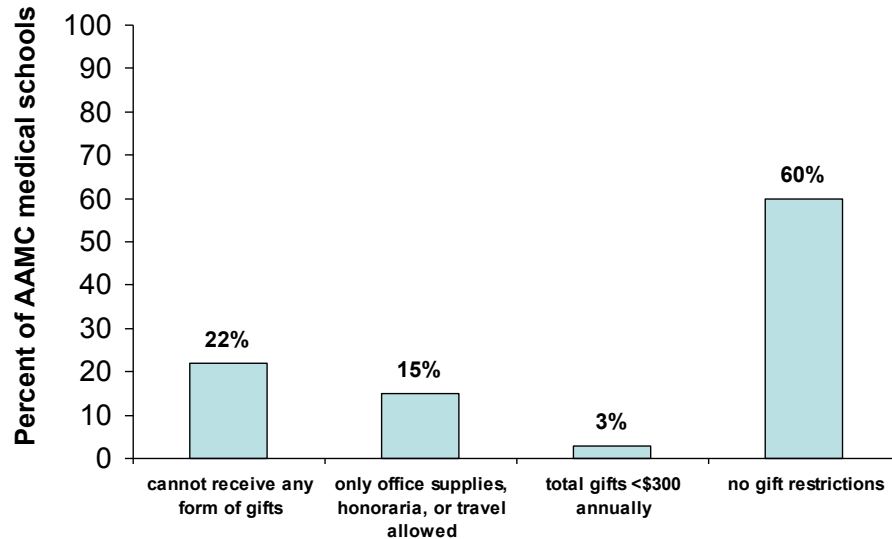


Figure 6. Medical school policies on the acceptance of industry gifts by faculty.

Law School Policies

Of the 200 law schools accredited by the ABA, 18% had adopted policies requiring faculty to disclose their financial relationships to their institution (Figure 7). However, none of these institutions stipulated that lecturers acknowledge their industry relationships to students prior to the beginning of an educational activity or embarking on research endeavors. Only 1% of law schools regulated the gifts that professors were able to accept from commercial interests; moreover, the protocols that did exist were vague and did not include actual dollar amounts or values.

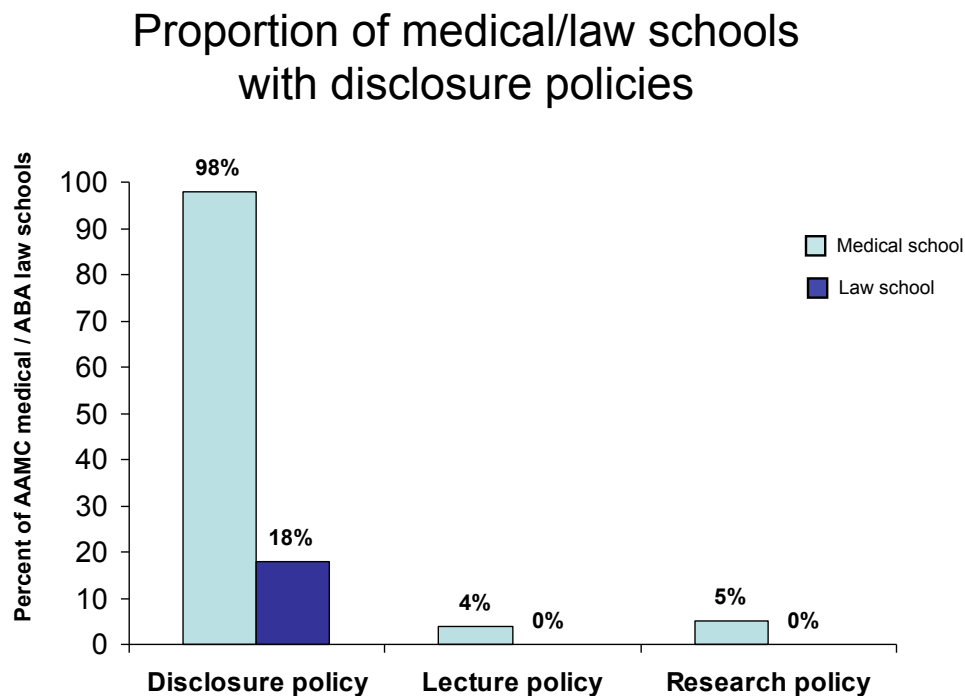


Figure 7. A comparison between medical and law school faculty disclosure policies during lectures and research activities.

DISCUSSION

The issue of physician-industry conflicts of interest has taken on greater significance in recent years such that most journals and medical societies have instituted some form of disclosure policy in order to uphold the fundamental integrity of scientific research. Nevertheless, the efficacy of these measures has not been elucidated and there is still very little data addressing the consistency of the disclosure information provided by authors performing investigations in the field of spine surgery. Similarly, in an attempt to address these concerns and maintain the transparency of their faculty, many medical schools are continuing to revise their guidelines on COI. The purpose of this review was to evaluate the variability in the self-reported disclosures of physicians both in the professional arena (who present at national conferences to other practicing physicians) and the academic arena (who educate the rising physicians of tomorrow).

COI in Orthopaedics

These comparisons revealed a higher than anticipated prevalence of inconsistencies among the disclosure records of researchers participating in these three meetings. Despite the fact that both NASS and CSRS had requested acknowledgement of all industry affiliations (i.e. global disclosure), one out of every two authors (51%) who had attended both meetings exhibited contradictory information in the final programs with nearly half of them (44%) having three or more discrepancies. Although it is

conceivable that the number or type of an investigator's financial relationships may have undergone some modification during the four months between the abstract submission deadlines for NASS (February 2008) and CSRS (June 2008), it certainly would not be expected for the disclosure status of so many of these individuals to change so dramatically within such a short period of time. In addition, 45% of this cohort declared no industry ties at one conference but identified at least one conflict of interest at the other, which suggests that the current guidelines are insufficient for establishing absolute transparency which is now more than ever necessary to maintain the public's trust in the medical community.

One possible explanation for these irregularities is that while authors were instructed to inform NASS and CSRS of all industry connections regardless of their relevance to the studies being presented, they may have misinterpreted these instructions and only cited those disclosures that were pertinent to their work. Alternatively, these findings may reflect the inadvertent omission of one or more commercial entities by physicians who are less diligent in keeping records of their industry relationships. Another possibility is that there is simply a lack of effective penalties, for both authors and their corresponding industry liaisons, to correct naiveties in attitude where accurate disclosure is concerned. In either case, this analysis serves to quantify the significant degree of variability that exists between the self-reported global disclosure listings documented for the 2008 NASS and CSRS conferences.

Of the remaining 49% of authors in the NASS/CSRS group who were not noted to have any discrepancies, a large majority (67%) indicated that they had nothing to disclose; similar percentages were also calculated for the SRS/NASS and SRS/CSRS data

sets as well (74% and 76%, respectively). Not surprisingly, it appears as if physicians are more likely to respond in a consistent fashion in the absence of any industry collaborations because they can presumably declare “no disclosures” across the board for all meetings.

Besides assessing the rate of inaccuracies between the information submitted to NASS and CSRS, we also evaluated the project-specific conflicts of interest collected by SRS with respect to the other societies with their global disclosure policies. The frequencies of irregularities in the SRS/NASS and SRS/CSRS cohorts were only 9% and 18%, respectively, with most of these individuals possessing only a single discrepancy. Interestingly, 42% of individuals with inconsistencies cited one or more financial relationships at SRS but nothing at NASS; this percentage was even higher (50%) among those with studies at both SRS and CSRS. Finally, the finding that a significant proportion of authors in each these groups (91% for SRS/NASS and 82% for SRS/CSRS) were consistent in their disclosures between these two conferences implies that authors may be more proficient at recognizing industry affiliations that are directly related to their investigations.

This review emphasizes the extensive variability that existed in the self-reported disclosure information of authors presenting at three major spine conferences within the past year. Yet these implications most probably extend outside the particular subspecialty of spine to the larger field of orthopaedics as well, since orthopaedics is an area that has traditionally and continues to deal heavily with industry. If such discrepancies occur in major spine conferences, it is likely to occur in other areas as well, and it would be interesting to see further such studies in comparison to this one. If nothing else, it

behooves the readership to use the lessons presented here as an educational insight into a not-so-clear disclosure system, so that they can protect both themselves and their integrity.

Rather than attributing these results to intentional duplicity, we believe that these disparities are most likely due to confusion regarding which financial relationships should be divulged in different situations given the lack of uniformity among the disclosure policies of these associations. It certainly appears as if authors are more proficient at identifying collaborations that are germane to their work than they are at imparting an accurate and comprehensive listing of every single one of their industry affiliations. Nevertheless, an inherent challenge associated with project-specific disclosure guidelines is that it may often be difficult for clinician-scientists to discern which financial ties are in fact relevant to their research. This risk of omission represents one of the primary reasons why many forums consider global disclosure to be the most effective strategy for establishing transparency.

Many organizations including NASS, CSRS, and SRS, have recognized the complex issues involved in the reporting of physician-industry relationships and are in the process of revising their disclosure policies so that they are better able to monitor these types of interactions and ensure that they are in accord with appropriate ethical benchmarks. Based on the relatively high frequency of inconsistencies evident in the disclosure information provided by spine surgeons at these meetings, we recommend that more explicit and standardized guidelines be elaborated by these societies in order to facilitate the accurate disclosure of financial relationships and to minimize their potential effects on scientific investigations. Be it a global disclosure policy or project-specific

disclosure policy that we ultimately implement, the policy should be a uniform one across all societies as a first step of many toward our goal of transparency. While it is true that the ultimate responsibility for reporting disclosures lies with the individual authors, the current protocols and policies regarding disclosure create an environment such that even the most diligent and forthcoming of authors may become labeled as “misreporters.”

COI in Medical Education

Based on our investigation, it is apparent that nearly all (98%) of the medical schools have some sort of policy requiring disclosure of industry ties to the institution itself. Furthermore, 92% of these institutions are also accredited by the ACCME and are therefore bound to their guidelines for CME activities. Conversely, a surprisingly small percentages of schools have formal policies insisting that faculty divulge their industry relationships to the students they teach or supervise in a laboratory setting (4% and 5%, respectively). The finding that only a small minority of medical schools mandates disclosure for student-directed activities may be indicative of the need for additional strategies to maximize transparency and further limit the influence of industry on academic pursuits. The concept of disclosure as a paradigm for managing possible COIs has been widely utilized by medical journals and societies, and it may be a viable option for medical schools as well. We expect the prevalence of these institution-driven regulatory policies to increase substantially during the coming years.

Although the training programs for medicine and other professions are not entirely analogous, law schools were selected as a benchmark for comparison. Among the

institutions accredited by the ABA, only 18% had published disclosure policies and none appeared to expect speakers to inform students of corporate support or other COIs in the classroom or any other situation. Although the Association of American Law Schools (AALS) has recognized the significance of disclosure-related issues, there are still no formal guidelines that have been mandated for the institutions under its auspices [31].

This analysis also confirms that less than half (40%) of the medical schools had definite policies limiting the acceptance of gifts from third parties. Only 22% of these institutions prohibited faculty from receiving any items from commercial sources, regardless of their monetary value. While 18% of medical schools allowed for the provision of certain gifts that were of benefit to “academic pursuits” such as office supplies, honoraria, and travel reimbursements, these policies were often vague and subject to interpretation. Of note, 60% of medical schools had no such restrictions at all at the time of this study. Nevertheless, this percentage is much lower relative to that observed for law schools, of which merely 1% had implemented any type of strategy to curb this practice.

We recognize that there are several limitations to this study. First, these findings are derived from the guidelines posted on the official internet website of each school so this review does not take into account internal documents that may exist regarding the management of industry relationships; because of delays in updating these websites, it is conceivable that these listings may not represent the most recent policies of these institutions. It is possible that a survey of these schools may have circumvented this problem but we elected not to send out questionnaires due to the potential for non-responder bias and an inability to monitor whether the individuals who furnished the

requested information were fully familiar with their institutions' complex disclosure protocols. As a result, we believe that the listings available on these schools' websites are a relatively accurate reflection of their official policies.

Given that virtually all medical schools have introduced some form of disclosure policy, it is obvious that the issue of COIs and their deleterious effects on faculty as well as the education of the next generation of practitioners has taken on greater importance. The significantly lower number of institutions requiring the reporting of financial relationships to students during educational activities and the variability in the degree to which they restrict the acceptance of gifts from commercial entities indicates that additional work needs to be done to develop more coherent guidelines to regulate these types of interactions. Over the coming years, the landscape of COIs and disclosure policies will continue to change significantly for both those in professional practice and those in education in the hopes that we not only maintain transparency throughout the entire process, but we also hold ourselves to the same standards we so often demand of others.

REFERENCES

1. Okike K, Kocher MS, Mehlman CT, Bhandari M. Industry-sponsored research. *Injury*. 2008 Jun;39(6):666-80.
2. Okike K, Kocher MS, Mehlman CT, Bhandari M. Conflict of interest in orthopaedic research. An association between findings and funding in scientific presentations. *J Bone Joint Surg Am*. 2007 Mar;89(3):608-13.
3. Kubiak EN, Park SS, Egol K, Zuckerman JD, Koval KJ. Increasingly conflicted: an analysis of conflicts of interest reported at the annual meetings of the Orthopaedic Trauma Association. *Bull Hosp Jt Dis*. 2006;63(3-4):83-7.
4. Warner TD, Gluck JP. What do we really know about conflicts of interest in biomedical research? *Psychopharmacology (Berl)*. 2003 Dec;171(1):36-46.
5. Boyd EA, Bero LA. Assessing faculty financial relationships with industry: A case study. *JAMA*. 2000 Nov 1;284(17):2209-14.
6. Shah RV, Albert TJ, Bruegel-Sanchez V, Vaccaro AR, Hilibrand AS, Grauer JN. Industry support and correlation to study outcome for papers published in *Spine*. *Spine (Phila Pa 1976)*. 2005 May 1;30(9):1099-104; discussion 105.

7. Lu-Yao G, Albertsen P, Shih W, Yao SL. Failure to report financial disclosure information. JAMA. 2009 Jan 7;301(1):35-6.
8. Tomaszewski C. Conflicts of interest: bias or boon? J Med Toxicol. 2006 Jun;2(2):51-4.
9. Weinfurt KP, Friedman JY, Dinan MA, Allsbrook JS, Hall MA, Dhillon JK, et al. Disclosing conflicts of interest in clinical research: views of institutional review boards, conflict of interest committees, and investigators. J Law Med Ethics. 2006 Fall;34(3):581-91, 481.
10. Go RS. Issues behind disclosure of conflicts of interest. JAMA. 2008 Nov 12;300(18):2120.
11. Krinsky S, Rothenberg LS. Financial interest and its disclosure in scientific publications. JAMA. 1998 Jul 15;280(3):225-6.
12. Rowan-Legg A, Weijer C, Gao J, Fernandez C. A comparison of journal instructions regarding institutional review board approval and conflict-of-interest disclosure between 1995 and 2005. J Med Ethics. 2009 Jan;35(1):74-8.

13. American Academy of Orthopaedic Surgeons. AAOS Mandatory Disclosure Policy. [updated March 2008; cited 2009 March 23]; Available from: <http://www.aaos.org/about/policies/DisclosurePolicy.asp>.
14. North American Spine Society. NASS Disclosure Policy. [updated February 2009; cited 2009 March 23]; Available from: <http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/NASSDisclosurePolicy.aspx>.
15. Cervical Spine Research Society. Proposed Bylaws Amendment: Article II, Section 1, Membership. [updated August 2008; cited 2009 March 23]; Available from: <http://www.csr.org/web/about/bylaws.htm>.
16. Harris, S., Conflicts of Interest Targeted in Research, Medical Education. 2007, AAMC: Chicago.
17. Brennan, T.A., et al., Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. JAMA, 2006. 295(4): p. 429-33.
18. Campbell, E.G., et al., A national survey of physician-industry relationships. N Engl J Med, 2007. 356(17): p. 1742-50.

19. Carlat, D., *Diagnosis: Conflict of Interest*, in *New York Times*. 2007: New York City.
20. Christie, C.J., *Five Companies in Hip and Knee Replacement Industry Avoid Prosecution by Agreeing to Compliance Rules and Monitoring*, U.S.D.o. Justice, Editor. 2007: Newark.
21. Kling, J., *Academia and the company coin*. *Nat Biotechnol*, 2009. 27(5): p. 411-4.
22. Armstrong, D., *Surgeon Faces Probe of Research*, in *Wall Street Journal*. 2009: New York City.
23. Marco, C.A., et al., *Gifts to physicians from the pharmaceutical industry: an ethical analysis*. *Ann Emerg Med*, 2006. 48(5): p. 513-21.
24. Wazana, A., *Physicians and the pharmaceutical industry: is a gift ever just a gift?* *JAMA*, 2000. 283(3): p. 373-80.
25. Association of American Medical Colleges and Baylor College of Medicine, D.o.N.a.C.P.U. *The Scientific Basis of Influence and Reciprocity: A Symposium*. 2007. Washington, D.C.: AAMC.

26. Dana, J. and G. Loewenstein, A social science perspective on gifts to physicians from industry. JAMA, 2003. 290(2): p. 252-5.
27. Colleges, A.o.A.M., Industry Funding of Medical Education- Report of an AAMC Task Force. 2008, AAMC: Washington, D.C.
28. Education, A.C.f.C.M., ACCME Standards for Commercial Support- Standards to Ensure the Independence of CME Activities. 2007, ACCME: Chicago.
29. Wilson, D., Harvard Medical School in Ethics Quandary, in New York Times. 2009: New York City.
30. American Bar Association. Available: <http://www.aba.org>. Accessed 2009 September 1.
31. Association of American Law Schools. Handbook. Statement of Good Practices by Law Professors in the Discharge of their Ethical and Professional Responsibilities.

APPENDIX

NASS disclosure instructions-

“Financial relationships that have taken place within the last year are to be held to a robust disclosure standard. NASS members participating in an activity should disclose all financial relationships that have occurred within the last 12 months...”

CSRS disclosure instructions-

“All members shall disclose any personal or financial interest of conflicting fiduciary obligation that may introduce or be perceived to introduce bias. Disclosure information shall be updated annually.”

SRS disclosure instructions-

“It is the policy of Medical Education Resources (MER) and Scoliosis Research Society to ensure balance, independence, objectivity, and scientific rigor in all its educational activities. All faculty participating in our programs are expected to disclose any relationships they may have with commercial companies whose products or services may be mentioned so that participants may evaluate the objectivity of the presentations.”