

A Discussion of Conflicts of Interest in Plastic Surgery and Possible Remedies

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THE PROBLEM

Conflict of interest (COI) is a subject of intense interest, to the extent that an entire issue of the *Journal of the American Medical Association* was devoted to this subject last year.¹ In 2014, the American Society of Plastic Surgeons created a task force to address this problem.² Conflict of interest was the lead story of a recent issue of *Plastic Surgery News*.² Remarkably, about half of U.S. physicians, and 61% of surgeons, received payments from the pharmaceutical and medical device industries in 2015, amounting to \$2.4 billion, including 136 plastic surgeons who received >\$10,000 each.³

Before the early 1980s, there was little intersection between medicine and industry. Collaboration between the medical profession and the corporate world has increased.⁴ The link between commercial funding and study conclusions is undeniable in plastic surgery.^{5,6} When industry-supported Continuing Medical Education programs are conducted at resort hotels and upscale restaurants, the boundary between education and industry marketing is blurred.⁷

At meetings, plastic surgeons often declare, “I have no relevant conflict of interest” or “I have no conflicts that would affect the content of my presentation.” Luce laments that sometimes the duration of the disclosure slide presentation could be measured in nanoseconds, as reported in *Plastic Surgery News*.² The speaker usually decides whether a conflict is relevant. Presenters sometimes comment, wryly, “I have no conflict of interest, unfortunately,” recognizing, and trivializing, the financial benefit of a COI. Some speakers display a long list of conflicts and suggest that because they have so many, they are at least “equal opportunity conflicters.” Some investigators believe that if they previously received money but no longer receive payments, they are no longer conflicted. Is there an expiry date for financial conflicts? Although some journals specify a 3-year period before submission, full disclosure is preferred, allowing the reader to decide on the merits.⁸

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DEFINITION

Luce⁶ defines COI: “Conflicts in ethically problematic situations are those in which the practitioner participates in clinical investigation of new devices/technology, publishes that experience, and, in parallel, is paid a consultant’s fee by the manufacturer.” Fineberg⁹ believes that a COI exists when a reasonable person would interpret the financial circumstances as sufficient to influence a physician’s judgment. When the reasonable person standard is used, the “appearance of” a COI is redundant.⁹ Proof of patient harm is not a requisite for COI; there are no “potential” COIs.¹⁰

INDUSTRY PAYMENTS TO INDIVIDUALS

The American Society of Plastic Surgeons recently introduced dollar ranges for reporting financial conflicts.² However, no data are available regarding a monetary threshold for a COI.¹¹ Using Open Payments data, a 2016 study found that receipt of industry-sponsored meals, even just a single meal, was associated with an increase in the rate of prescribing the promoted brand-name drug.¹² The more money doctors receive, on average, the more brand-name medications they prescribe.¹³ The evidence shows that even small gifts induce unconscious feelings of gratitude and reciprocity. Gifts to physicians can perpetuate a mindset of entitlement.¹⁴

INDIRECT CONFLICTS OF INTEREST

Incentives that are not directly financial but have financial implications such as career advancement may also represent potent COIs.¹⁵ Academic COIs may contribute to the disturbing prevalence of research irreproducibility.¹⁵

Preset convictions can cause investigators to overlook or selectively interpret data. The investigator who is so certain that the concept is correct may, even subconsciously, alter the eligibility criteria, or the number of subjects, to fit the data to the hypothesis, and reach the desired level of significance, a practice known as *p* hacking.¹⁶ A *t* test may be conducted on a tiny number of patients using data that are not normally distributed. The sample size may be kept small to ensure that adverse outcomes do not reach statistical significance.

INDUSTRY PAYMENTS TO PROFESSIONAL SOCIETIES AND JOURNALS

Many professional societies, including plastic surgery societies, accept large payments from industry (ie, >\$1

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million annually). A key recommendation of a 2009 consensus report was a preliminary reduction in industry support to <25% of the operating budget of the professional medical association, with an ultimate goal of complete freedom from industry funding.¹⁷

Companies partner with our societies and fund journal supplements, compromising the separation of science and advertising. Industry involvement may extend to writing the manuscript, called “writing support.” Many medical journals derive a substantial proportion of their operating revenue from advertising.¹⁸ Sponsored supplements are typically written to support the marketing goals of the sponsor,¹⁸ and lack counterpoint discussions written by nonconflicted plastic surgeons. Brand names are featured in the titles. Editors may argue that supplements are treated with the same degree of scrutiny as regular publications,¹⁹ but the potential for inappropriate influence cannot be excluded.

Publication bias is a well-known problem.⁵ Researchers who are consultants, hold stock options, or receive royalties from companies, are much more likely to report positive results.^{5,20} Not surprisingly, industry is notoriously reluctant to publish negative findings.^{5,21} Some trial protocols include a provision for review of the manuscript by the funder before submission for publication, and the right to delay or even veto its publication.^{5,22} The timeline is pertinent. Plastic surgeons reporting on new products (eg, breast implants, implantable mesh, cryolipolysis, radiofrequency) may hold changing, often increasing, ownership stakes in successive publications, begging the question, when was this investment decision made and did it influence the research?

EXAMPLES OF CONFLICT OF INTEREST IN PLASTIC SURGERY

Breast Implants

The promotion of shaped, textured breast implants reflects the *quid pro quo* between the industry and surgeons.²³ The highly praised gummy bear implant was always an inferior product. Shaped implants malrotate in 42% of patients.²⁴ These devices are firm, may have palpable edges, can cause double capsules and seromas²⁵ and are much more costly than smooth round alternatives. Most importantly, textured implants are linked to breast implant-associated anaplastic large-cell lymphoma.²⁶ Hidalgo and Weinstein²⁷ and others^{28,29} report no aesthetic advantage. Yet for decades now, textured, shaped implants have been promoted as superior to less expensive alternatives. Hall-Findlay³⁰ writes: “We listen to the manufacturer’s claims and then years later we find that we have been misled – both by the manufacturers themselves and by those surgeons who are burdened by a conflict of interest.”

A study of nano-textured and micro-textured breast implants was recently published in a corporate-funded journal supplement.³¹ The authors report a complication rate of 0.3%, with 1 hematoma, no cases of implant malposition, no pain, no rippling, no ruptures, no redness, and no capsular contractures among 4,103 breast augmentations. The reoperation rate was <1%. The lead author

reported no COI regarding this study, but accepted a position on the company’s medical advisory board immediately after submitting the article.³¹

Implantable Mesh

The problem is not limited to breast implants. The COI regarding acellular dermal matrix is well documented.³² A recent article advocating the off-label use of implantable mesh in breast surgery was published by 2 authors who have a financial stake in the company that manufactures the mesh.³³ A third author is a paid consultant and speaker. Galatea Surgical, a subsidiary of Tepha Inc. (Lexington, Ma.) financed the study, including medical writing, and referenced supplemental publications.³³ Galatea is a corporate sponsor of the American Society for Aesthetic Plastic Surgery.³⁴ The authors report that 100% of participating surgeons preferred to use mesh in all patients and the 1-year result was satisfactory in 100% of women.³³ Such publications encourage plastic surgeons to adopt commercially driven practice patterns. A recent Continuing Medical Education article suggests that mesh support represents a paradigm shift.³⁵ However, a nonconflicted analysis of mesh, and of the dated internal bra concept, finds no advantage.³⁶

Radiofrequency Treatments

A recent corporate-funded supplemental article, written by surgeons who are also shareholders, claims that radiofrequency-assisted liposuction (BodyTite, InMode Corp., Toronto, Canada) provides effective soft-tissue contraction, even creating an “internal brachioplasty scar.”³⁷ This claim is based on a greater reduction in linear measurements than area measurements after radiofrequency-assisted liposuction compared with standard liposuction, a finding that is impossible to reconcile with basic geometry (the difference in area measurements must exceed linear changes).³⁸ The authors offer a favorable return on investment analysis to justify the \$205,000 purchase price, based on a \$7,000 treatment fee.³⁷

Conflicted author/investors frequently publish photographs that are not standardized in an effort to demonstrate a therapeutic benefit.^{33,36,39,40} A recent corporate-funded study on facial radiofrequency treatments with micro-needles was co-authored by a shareholder.³⁹ The authors magnified the preoperative photograph of a nasolabial crease 58% to make it appear larger before treatment.⁴⁰ Statistical errors included using a *t* test to compare nonparametric data, citing a *P*value of 1.00 for a comparison of nonidentical data, and a maximum range within 1 SD of the mean.⁴⁰

DISCOUNTS TO INVESTIGATORS

New transparency regulations help to inform the public about payments made to physicians.⁴¹ Unfortunately, it is not difficult to sidestep such reporting requirements. A well-known investigator may be given a device (eg, an ultrasonic liposuction machine) at a heavily discounted price. A breast implant manufacturer may provide its researchers with complimentary or discounted implants. There are

many ways to reimburse surgeons indirectly. These considerations are substitutes for reportable cash payments, and they undermine the integrity of our research.

COMPANY OFFICERS

Investigators who are not only passive investors but company officers and shareholders⁴² have a financial obligation to the company. A fiduciary responsibility makes it impossible to remain objective.⁴³

CLEARANCE BY U.S. FOOD AND DRUG ADMINISTRATION

When a device receives clearance by the U.S. Food and Drug Administration, it is labeled with a stamp of authority that is reassuring to the public. This label also serves as a powerful marketing tool. Unfortunately, the approval process is not protected from commercial influence. For example, Coolsculpting (Allergan plc, Dublin, Ireland) gained Food and Drug Administration clearance for treatment of the thighs based on studies performed by investigators that received major financial reimbursement.⁴⁴ The company itself was allowed to conduct vital ultrasound and photographic imaging.⁴⁴ The lead investigator was at one time a Zeltiq Aesthetics Inc. (Pleasanton, Calif.) paid consultant and shareholder.⁴⁴ Zeltiq was purchased in 2017 by Allergan plc (Dublin, Ireland) for \$2.48 billion.⁴⁵

HONEST REPORTING

Corporate-funded studies consistently report unusually low complication rates, speedy recoveries, high rates of patient satisfaction, high “conversion rates,” and even the prospects for cross-selling.⁴⁶ These sales-oriented characteristics undermine hard-won gains in honest reporting and the recognition of the importance of evidence-based medicine in our scientific journals.

Adoption of unsound treatments and devices based on biased studies can have harmful long-term ramifications through a “rippling effect.”⁷⁵ Biased studies may be referenced in practice guidelines.⁵ Physician disillusionment, especially after the purchase of an expensive yet underperforming device, may be a factor in physician burnout.

CONSULTANTS

Although physicians may consider themselves to be ethical professionals, many doctors remain unaware of the subconscious bias that industry relationships create.⁴⁷ The practice of doctors accepting payments from companies has gone on for decades without a critical review. Are plastic surgeons truly acting as consultants, or is “consultant” a euphemism for receipt of a payment to shape one’s opinion in favor of the product and confer loyalty? Industry payments, which may be viewed as kickbacks, have created serious legal difficulties for physicians.² Lopez et al.²⁰ found that self-reported COIs have declined in recent years, but the proportion of consultantships has increased.

In proposing an end to industry influence and regaining the public trust, a committee formed by the Institute

of Medicine finds that continuing medical education “has become far too reliant on industry funding,” which “tends to promote a narrow focus on products.”⁴⁸ The committee recommends restricting consultantships to the provision of objective technical advice paid at fair market value, documented in written contracts. Moreover, companies “should not involve physicians and patients in marketing projects that are presented as clinical research.”⁴⁸

RECOMMENDATIONS

The International Committee of Medical Journal Editors disclosure form insists that contributors disclose relevant financial relationships.⁴⁹ In 2010, the Council of Medical Specialty Societies published a code for interactions with companies, with a provision that prohibits society officers and journal editors from accepting any compensation from industry.⁵⁰

To facilitate transparency of disclosure, Congress passed the Physician Payments Sunshine Act, which requires commercial companies to report any “transfer of value” to any physician, with a \$10 threshold.⁵¹ In October 2010, ProPublica introduced Dollars for Docs, a central search engine for physician payments.⁴¹

Luce⁶ proposes that plastic surgeons with conflicts be excused as manuscript discussants and reviewers. Lichter⁵⁰ recommends that a presentation with a COI should be balanced by a nonconflicted counterpoint discussant. The American Society of Plastic Surgeons has adopted a requirement for disclosure of financial conflicts in dollar ranges (ie, \$100–\$1,000, \$1,001–\$5,000, \$5,001–\$10,000, etc.).² These are reasonable first steps.

Device evaluation does not necessarily require industry funding, as evidenced by the research efforts of investigators without financial conflicts.^{25,27} Publication of independent research in a highly respected peer-reviewed journal and the accolades that come with it provide more than adequate compensation, and potential for practice building and career advancement.

It is impossible to reconcile corporate sponsorship with unbiased research. Physician investigators should consider declining any paid consultantcies and all forms of indirect corporate reimbursement. Study design and implementation, and manuscript preparation should not be outsourced.

RELINQUISHING INDUSTRY FINANCIAL SUPPORT

Asking attendees to visit the exhibits, “without which none of this [i.e., the meeting] would be possible” is a familiar refrain at meetings. The physician-industry complex has gone on for so long that plastic surgeons may find it difficult to imagine an arms-length relationship. Without industry sponsorship, plastic surgeons can expect to pay more to attend meetings and Continuing Medical Education activities, but the prices of devices and implants are likely to fall as companies are relieved of the tremendous financial burden⁶ of payments to physicians and societies. The net overall financial effect to physicians is zero,

but medical integrity is restored. Relinquishing industry financial support represents a bold step, but recent examples of the influence of financial conflicts underscore the magnitude of the problem.

As reported by Rohrich et al.,⁵² when Goldwyn stepped down as the longtime former editor of *Plastic and Reconstructive Surgery*, he worried most about commercial influence and keeping the specialty “pure.” He cautioned the incoming managing editor that he would need a strong sense of ethics because “you’ll need them in this business.” Goldwyn,⁵³ quoting his father, wrote: “It is amazing how easy it is to be truthful if one wants to be.”

CONCLUSIONS

It is impossible for investigators to function as highly paid consultants and remain unbiased. Disclosure, including the amount of money paid, allows the audience to determine the importance of the conflict. Separation of commerce and science in our journal publications is vital so that scientific publications do not become marketing tools. Plastic surgeons must be better advocates for our patients and their pocketbooks. Part of the privilege of caring for patients is to be mindful of their finances and their health.¹⁴ Most importantly, our societies need to reconsider corporate partnership. Editors are already aware of the professional positions of reviewers and the need to protect the article that upsets the apple cart. As Descartes famously observed, “doubt is the origin of wisdom.”⁵⁴ Progress is only made possible by challenging the status quo.

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