Perspectives
When money talks
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Despite the explicit and detailed reports of extensive financial ties between physicians and researchers on the one hand and device and drug companies on the other hand and notwithstanding a proliferation of conflict of interest policies by academic medical centers (AMCs) and professional medical societies, some recipients of industry largess continue to deny that these relationships are in any way problematic. No matter how sizable the payments or personally advantageous the association, some heavily conflicted authors insist that neither patient welfare nor scientific integrity is undermined [1–3]. Their arguments take several forms and have been so insistently reiterated as to warrant thorough rebuttal.

First, and most often heard, is blanket denial: Professional obligations are not compromised by considerations of income or grants. Some authors and researchers doggedly deny that generous speaking honoraria, lavish entertainment, or substantial consulting retainers exert any influence whatsoever over their prescriptions, endorsements, or promotions [4]. By the same token, funding has purportedly no effect on research design or published findings. In the vernacular, physicians and investigators cannot be bought for a steak dinner or, for that matter, the equivalent of a million steak dinners.

Second, some recipients of industry largess offer what they believe is a more nuanced distinction. Conceding that there may be a potential conflict of interest in promoting or investigating a specific company’s drug or device in which they have a substantial financial interest, these proponents insist that the conflict does not extend to any of that company’s other products. Conflict of interest, in this paradigm, is entirely commodity specific, linked only to a particular item and not to the company and its interests in general. Accordingly, recipients believe that they need not report financial relationships with a company if their income derives from its Product A, but they are reviewing or promoting its Product B.

Third, although recipients do not specify the exact durations of time, there is an implied statute of limitations. Recipients who has received industry funding for or consulted on a product in the past may assert that they need not disclose that funding 2, 4, or 6 years later when submitting an article about this same product or when promoting it for the company. So too, some physicians or researchers who were intimately associated with, and handsomely reimbursed for, causing or promoting a company’s product may insist that this fact becomes irrelevant within a short period of time after these monies were received and hence need not be disclosed.

Finally, recipients of company grants to investigate one of its products maintain that the source of research funds has no impact on the outcome of the studies. Methods and outcomes are ostensibly unaffected when the company is paying for the work.

To analyze these interlinked propositions, it is useful to step back and consider the fundamental concepts underlying the concern with conflict of interest. The core principle can be stated succinctly: gifts, payments, reimbursements, honoraria, and grants to a physician or researcher, just like gifts and exchanges between neighbors, stimulates a felt need to reciprocate, regardless of the value of the compensation itself. As anthropologists, sociologists and now neurologists (with the help of brain scans) have concluded gifts beget gifts [5]. Physicians who have received payments and grants, substantial or minimal, are disposed to prescribe and promote that company’s product. Investigators funded by...
industry are disposed to adopt methods and tailor findings to put a company product in the most favorable light [6].

Although the impact of company grants on research findings has long been considered problematic (eg, company-funded studies are more likely to report positive results than National Institutes of Health–funded studies), the concern is now even more intense [7,8]. One outstanding case in point involves Medtronic-funded studies on BMP-2, as examined in 2011 in this journal. As many readers will know, critics found the results of the Medtronic studies so self-serving and incomplete that the company funded and released all its BMP-2 research data to the Yale University Open Data Access Project. In June 2013, the findings of two independent research teams were published, and one of them (Fu et al.) was particularly troubled by the effects of company-sponsored research. “No trials were truly independent of industry sponsorship,” its author concluded. “Earlier disclosure of all relevant data would have better informed clinicians and the public than the initial published trial reports did” [9]. So too, the editors of the *Annals of Internal Medicine* concluded that “Early journal publications misrepresented the effectiveness and harms through selective reporting, duplicate publication and underreporting.” In other words, just as gifts bias the recipient, so apparently do research grants and consulting [10].

None of this is new to marketing division managers, many of whom also have a say in grant making. When companies dispense payments to physicians, they are attempting to attract and reward “market drivers,” those they consider to be “Key Opinion Leaders.” They are not being kindhearted or gracious—in private, they may be both; rather, in calculating fashion, they seek to promote sales and strengthen the bottom line. If gifts, honoraria, and grants did not bring material gains, companies would have dispensed with them a long time ago.

In most cases, recipients of company largess are not being “bribed”—they are being “gifted.” The standard response of “you can’t buy me for …” misses the point. The problem is not patent illegality but deliberate and shrewd company inducements to promote products. Some recipients try to dodge these arguments by accusing their critics of demonizing industry and impeding medical progress. But such inflated rhetoric diverts attention from the substance of the problem. A heavy reliance on biased publications or podium spins best serves the inferior product and not the innovative one with excellent outcomes.

At the same time, personal economic interests negate the contention that conflict of interest is specific to a product. A physician or researcher who is handsomely reimbursed, funded, or feted by a company has an obvious stake in that company’s overall financial well-being. Endorsing or promoting any or all its products helps to ensure that their own benefits will keep coming. At the same time, the psychological impact of a gift is not product specific. There is a company halo effect, biasing recipients to be more positive in their evaluations of its various products.

Finally, the impact of financial relationships with industry is not bound by a specific timetable, expiring immediately after the last check is cashed. A gift may still have an impact a year or two later; memories are not so short. Moreover, a significant association with a surgical device manufacturer may remain relevant to a surgeon’s career even decades later. One’s reputation can often hinge on the validity of that original company-sponsored research: The Yale University Open Data Access Project groups critical assessment of decade-old research was not only relevant to the company but also reflected back in stark terms on the original authors, many of whom had moved along in academic careers but remained intellectually if no longer financially vested in the criticized publications.

So obvious and widespread is the recognition of the power of the gift that we are now witnessing an extraordinary and novel commitment to transparency. At the governmental level, a number of states including Vermont, Massachusetts, and Minnesota require company disclosure of payments to physicians [11]. Even more notably, the new federal Sunshine Act mandates that drug and device companies must report to Health and Human Services payments made to all physicians and teaching hospitals; the data will appear on a searchable government Web site. So too, many drug and device companies have been releasing payment data on their Web sites, either as part of a legal settlement with the Department of Justice or in preparation for the Sunshine Act itself. To be sure, Sunshine has shortcomings. Payments to physicians through third-party vendors, such as medical communication companies that organize Continuing Medical Education offerings, need not be reported. Nevertheless, we are about to learn more than we ever knew before about company-physicians financial relationships [12].

Almost most American AMCs require faculty to submit an annual conflict of interest statement that includes the number and size of outside payments, and some AMCs are checking individual responses against the data on company Web sites [13,14]. When Sunshine data becomes available, the practice is certain to increase. Professional medical societies, none more effectively than North American Spine Society, require their officers to disclose company-physicians financial relationships; presenters at annual meetings are held to the same standard. Last but certainly not least, medical journals, like *The Spine Journal*, require that authors who submit articles for publication report personal income, investment, and research funding from industry, an obligation that is being enforced more diligently than ever before.

The pervasiveness of disclosure requirements testifies to the growing consensus that physician-industry relations must, at the least, be carefully managed and as appropriate lead to disqualification. Patient welfare and scientific integrity are too important to allow bias to affect the research reports in journal articles, the prescribing habits of physicians, the content of lectures, the decisions of professional associations’ guideline committees, and the choices made...
by formularies for drugs and devices. The better part of wisdom is to select individuals for these assignments who are free of entanglements. The claim that all “real” experts in a field are financial bond to industry, and limiting their participation would undercut the quality of decision making, is rightfully fading as a believable argument. More than 75% of presenters at the North American Spine Society 2011 Annual Meeting report no financial associations whatsoever. Obviously, the pool of talented but nonconflicted physicians and investigators is large and available for unbiased input. Advice from heavily conflicted researchers can certainly be solicited, but these individuals should not be among the final decision makers.

In sum, managing and eliminating conflict of interest now has unprecedented prominence on the health care agenda. Those denying or qualifying the reality and scope of the problem are in a losing position. To be sure, scandals will inevitably recur. The drive for income and profit, no matter what the cost, cannot be completely contained. But the policy changes taking place are having a positive influence on current physicians and investigators. Perhaps more important that influence will be even more compelling for the next generation.

References