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THE MORAL EDUCATION OF JOURNAL EDITORS

BY SHELDON KRIMSKY

Most scientific and medical journals now have conflict-of-interest policies in place, but disclosure alone does not ensure scientific integrity.

Refereed journals in science and medicine are the gatekeepers and repositories of knowledge in their respective fields. Research reported in peer-reviewed journals builds professional careers, determines which drugs and medical devices are licensed, influences what medical treatments become standards of care, and establishes the veracity of scientific theories. Maintaining the reliability, integrity, and objectivity of journal content is

paramount, particularly in an era of increasingly common university-industry partnerships. Journal editors have become attentive to the need to preserve the credibility of their publications to colleagues within their disciplines and to the general public.

These relatively new university-industry partnerships, largely fostered by federal policies put in place in the early 1980s, have required government funding agencies and journal editors

alike to rethink how to ensure publication integrity. Yet despite the best efforts of editors to set standards of research integrity, the escalation in conflicts of interest in academic science and medicine that has occurred over the past three decades has cast a shadow over many publications.

Stories of multivested scientists and physicians abound in the media. The details vary, but they follow a common pattern: An article written by authors from top-ranked medical schools is published in a prestigious medical journal describing a clinical trial that supports the efficacy or safety of a drug formulation. Major media outlets report the results as a promising potential drug therapy. A short time after the first wave of media reports occurs, an investigative reporter publishes a story disclosing that one of the study's co-authors holds an equity interest in a company poised to benefit from the study. Based on the author's conflict of interest, questions are raised about whether the public can trust the study's results. Because a journalist (rather than the journal editor or the authors themselves) exposed the conflictual relationship, the level of mistrust increases.

Disclosure of Conflicts of Interest

Before the mid-1980s, the only disclosures found in scientific or medical journals were related to the direct sources of funding for a study. Such conflicts as speakers' fees, positions on advisory boards, royalties, stock ownership, and equipment donation were not subject to disclosure. That changed in 1984, when the *New England Journal of Medicine's* editor-in-chief, Arnold Relman, announced to his readers in an editorial titled "Dealing with Conflict of Interest" that the journal was adopting a conflict-of-interest policy for authors. Relman wrote, "Now, it is not only possible for medical investigators to have their research subsidized by businesses whose products they are studying, or act as paid consultants for them, but they are sometimes also principals in the businesses or hold equity interest in them."

A year after the *New England Journal of Medicine* changed its policy, *JAMA* established similar disclosure rules. These decisions set new standards for author disclosure in journal publication, and by the mid-1990s, many other journals had followed as editors began to understand the potential effects of conflicts of interest on their publications' integrity.

By passing legislation like the Bayh-Dole and the Stevenson-Wydler Technology Innovation Acts of 1980, enacted to make America more competitive in cutting-edge technology, Congress encouraged new forms of cooperation among industry, government, and academia. However, the now-defunct Office of Technology Assessment acknowledged in its 1988 report "New Developments in Biotechnology" that "it is possible that the university-industry relationships could adversely affect the academic environment of

universities by inhibiting free exchange of scientific information, undermining interdepartmental cooperation, creating conflict among peers, or delaying or impeding publications of research results." With time, the report's authors were proven correct about the unintended consequences of academic-industry partnerships: those partnerships have fostered a system of higher education and scientific scholarship replete with conflicts of interest.

I was among a handful of people who predicted the negative effects of the new corporate partnerships with American universities. In January 1980, *Nature* published an edited debate between David Baltimore, then a virologist at the Massachusetts Institute of Technology, and me on the new academic-business alliances, in which I was quoted as saying, "Just as war-related research compromised a generation of scientists, we must anticipate a demise in scientific integrity when corporate funds have an undue influence on academic research." Now, with thirty years' perspective, I know that I didn't overstate the case.

In 1982, Al Gore, then a young congressman, co-chaired hearings that described growing problems with policies enacted to provide incentives for corporations to develop partnerships with universities: increasing conflicts of interest, shifting research priorities, and growing interference with the free and transparent exchange of ideas and research data. By the early 1990s, a series of congressional hearings were raising important questions such as, "Can Conflicts of Interest Be Dangerous to Your Health?" The idea that conflicts of interest could adversely affect health outcomes prompted congressional leadership to address some of the unintended consequences of the policies passed a decade earlier.

In 1995, the U.S. Public Health Service (which includes the National Institutes of Health) and the National Science Foundation, responding to congressional oversight, issued a new set of regulations on conflicts of interest to grantees and their institutions. These new guidelines required each institution that received funding to develop a management plan for its faculty. The management plan required faculty members to report their conflicts of interest—defined as annual income from private companies of more than \$10,000 in areas related to their research activities—to a university administrator. There were no reporting mechanisms beyond the institution itself, no generalized norms or prohibitions, and no sanctions for noncompliance.

By this point, it had become clear that the primary impetus for academic scientists to make public disclosures of their conflicts of interest came from academic journals that required financial disclosures in published articles. Journal editors faced two challenges: (1) journals had to adopt meaningful and effective conflict-of-interest policies, and (2) authors had to comply with those policies.

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Compliance and Transparency of Reporting

In a 2001 article in *Science and Engineering Ethics*, L. S. Rothenberg and I reported our findings that a mere 16 percent of general science and medical journals had adopted some type of conflict-of-interest disclosure policy (although medical journals by themselves were faster at accepting these policies). But eight years later, in a survey of medical journals published in *Accountability in Research*, Erin Sweet and I reported that 84 percent had adopted such disclosure policies.

Despite the growth of journal adoption of conflict-of-interest regulations, compliance remained a serious problem. Many editors had little incentive to police their authors. In our 2001 study, Rothenberg and I examined more than 60,000 articles in 181 refereed journals with conflict-of-interest policies and found that only 0.5 percent of the articles had any conflict-of-interest disclosures. We also learned that a majority of the journal editors never rejected a paper based on conflicts of interest. On September 14, 2010, the *New York Times* reported that twenty-five out of thirty-two highly paid consultants to medical-device companies in 2007 failed to reveal their financial ties in journal articles.

By contrast, in 2009, another group of investigators studied physicians who had given talks at professional meetings and been asked to file conflict-of-interest disclosures. That research group, whose study was published in the *New England Journal of Medicine*, found an overall compliance rate of 71 percent for disclosing payments of external income related directly or indirectly to the physician's presentation.

Even as compliance may have increased in some areas, the journals have much to do to make transparency meaningful. In our 2009 study of 47 toxicology and 187 medical journals, Sweet and I found that only 15 percent and 28 percent of the toxicology and medical journals, respectively, were explicit about the type of content covered by their policies (for example, what specific activities or financial relationships constituted a conflict of interest), and only 20 percent and 29 percent, respectively, included a monetary threshold for reporting purposes. The discretion of authors in how they interpreted their disclosure obligations under a journal's policy of whether and what to report was quite high (46 percent in toxicology journals and 41 percent in medical journals), while the level of specificity in the policies about what had to be reported was quite low. When a journal does not provide specifics about what to report while simultaneously giving authors considerable discretion on whether to report, it is impossible to assess the effect of disclosure across journals and fields accurately.

Consistency across Policies

Harmonizing journal disclosure policies has addressed some of the problems. Some professional societies, such as the American

Chemical Society, have developed unified conflict-of-interest policies for their journals. Similarly, the International Committee of Medical Journal Editors issued a unified format for conflict-of-interest disclosures in the dozen journals their members publish.

Of the two entities that require disclosure, universities (through government mandate) and journals (through editorial policies), much of the media attention had focused on the latter. That changed in 2007–08, however, when Iowa senator Charles Grassley investigated whether multivested academic scientists were fully and accurately reporting their external incomes to their institutions. A June 8, 2008, headline in the *New York Times* read, "Researchers Fail to Reveal Full Drug Pay." The *Times* reported that Grassley found egregious violations in federal conflict-of-interest reporting requirements, citing the case of a Harvard University child psychologist who promoted the use of anti-psychotic medicines in children while earning at least \$1.6 million over a period of seven years consulting for drug makers.

"We all rely on the advice of doctors, and leading researchers influence the practice of medicine," Grassley notes on his Web site. "Taxpayers spend billions each year on prescription drugs and devices through Medicare and Medicaid. The National Institutes of Health distributes \$24 billion annually in federal research grants. So the public has a right to know about financial relationships between doctors and drug companies."

The discovery of noncompliance with federal disclosure requirements in the context of growing evidence about bias in published studies has had several effects. In 2007, Grassley and Wisconsin senator Herb Kohl had introduced the Physician Payments Sunshine Act, which would require drug and medical-device manufacturers to report payments to physicians annually. That act finally made its way into law in March 2010 as part of a larger health-care reform bill. Some states, including Colorado, Connecticut, Massachusetts, Minnesota, and Vermont, have enacted their own physician payment freedom-of-information ("sunshine") laws. And in May, the U.S. Public Health Service issued new proposed regulations on conflict-of-interest disclosure for all grant recipients and their institutions. The proposed rules increase institutional reporting requirements, lower the threshold for reportable annual external payments from \$10,000 to \$5,000, and require that universities establish a publicly accessible database that lists external income of faculty members related to their grant activities.

Under the 1995 rules, faculty members must report external income to their institutions. That information is typically unavailable to the public, researchers, or the media, but it can be requested by federal funding agencies. The 2010 proposed policy also recommends, as an option in a university conflict-of-interest management plan, that institutions require authors to disclose significant financial conflicts of interest to journals. If such a

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practice became mandatory for federal grantees, the journals would have an inducement for improving their own conflict-of-interest policies.

Concern about Privacy and Bias

Full public disclosure of financial conflicts of interest is being advanced at the expense of privacy for scientific and medical researchers who receive federal funding. We may refer to this trend as “Conflict of Interest in the Sunshine.” While the regulations are not yet final, based on the proposal, income to an investigator or his or her immediate family members from certain sources would have to be reported in a publicly accessible database. Many people would view this as an intrusion into privacy even if they felt that it was justified on transparency grounds.

And even while government and the academic journals raise the bar for conflict-of-interest transparency, existing solutions apparently do not address the problems of bias resulting from linkage between the outcome of research and the source of consulting, gifts, and equity income. This was the finding of the Institute of Medicine, a part of the National Academy of Sciences and the nation’s preeminent medical advisory group. In 2009, the institute asked medical schools and physicians to refrain from accepting gifts from drug and medical-device companies.

The Institute of Medicine’s request brought attention to drug companies’ funding of continuing medical education for medical professionals. Continuing-education courses have become platforms for drug companies to market new drugs directly to physicians by using selected speakers in academic medicine. The same practices that have given rise to conflicts of interest

also have provided lucrative income streams for medical schools. Those institutions that have had the moral courage to wean themselves from drug company support have replaced it with new creative financing.

Another reason that conflict-of-interest disclosure may not be effective is that it hasn’t changed the influence of drug companies on the prescribing behavior of physicians. A 2010 study published in the *Journal of Medical Ethics* found that most physicians do not discount the quality of drug-company-funded studies when they make prescribing decisions.

Transparency, by itself, will do little to reduce the “funding effect” in science. Nonetheless, it will have some positive effects. It will give journal editors information to determine whether they want to publish articles by authors who have substantial conflicts of interest. It will afford federal granting agencies the opportunity to decide whether or not they want to fund heavily conflicted scientists. It also may elevate the reviewing standards used by journal referees. And it will be useful to social scientists who are inclined to study the correlation of funding with scientists’ views and their research findings, as well as to investigative reporters who, more than ever, believe they owe the public information about the commercial interests of those making knowledge claims.

In the quarter century since journal editors began addressing authors’ conflicts of interest, we have learned that scientific research, with its important public outcomes, cannot be separated from social context. The financial interest of authors in the subject matter of their publications has ethical implications, and the integrity of (and public trust in) the gatekeepers of certified knowledge is held in the balance. ■