

THOMAS P. STOSSEL, MD

Professor of Medicine,
Harvard Medical School,
Boston, MA

Overregulation of conflicts hinders medical progress

■ ABSTRACT

The revolution in medicine and technology over the past few decades is largely the result of partnerships—or a “harmony of interests”—between private companies and entrepreneurial scientists and clinicians. Regulations to prevent conflicts of interest by restricting medical education, medical research, expert advisory functions, or researcher ownership of inventions may have the unintended consequence of slowing medical progress.

This conference was convened because of a prevalent perception that we are not doing the right thing when it comes to interactions between clinicians and researchers and the companies that develop biomedical products. The code words for this perceived wrongdoing are “financial conflicts of interest.” Only the imagination limits the extent to which financial conflicts allegedly compromise medical practice, medical education, and medical research, and this compromise is illustrated in the imagery of corruption and greed that accompanies the accusations.

■ DISCLOSURE RUN AMOK

This apocalyptic message has led to action. One action, euphemized as disclosure or transparency, has become an invasion of privacy. In the past, we named sponsors of our research and education efforts as a way to honor them. Now, we must itemize them so that others can discount our words and our work. Attempts to process this burden of information have given rise to bureaucracies charged with censorship. For example, the Accreditation Council for Continuing Medical Education (ACCME), which accredits CME providers for permission to confer CME credits on attendees (and charge them for it), imposes elaborate disclosure

Dr. Stossel reported that he has ownership interests in ZymeQuest, Inc., and in Critical Biologics Corp.; has intellectual property rights in Critical Biologics Corp.; has received consulting/advisory fees from Merck, Inc.; has received honoraria from Pfizer, Inc.; and has received royalties from Lippincott Williams & Wilkins.

demands on speakers, replete with “attestations” of independence from commercial influence. To maintain this accreditation, CME providers assign censors to sanitize presentations, in advance, of commercial content. We now live in an informant culture in which conflict-of-interest vigilantes, either activists or persons with grievances against us, scan for opportunities to embarrass us.

Nothing better illustrates the fact that what we disclose demeans us than the vigorous call to remove the best and brightest with commercial interests from useful advisory roles. Worse, the idea that commercial relationships drive us from objectivity to the moral low ground provides the media with license to abuse us.

■ ‘RED-LIGHT REGULATION’ STIFLES INNOVATION

The second major action is prophylactic law, or what I call “red-light regulation.” My university, for example, severely restricts researchers’ ownership of their inventions, and these rules have prevented companies from licensing Harvard Medical School technologies. Similarly, the National Institutes of Health forbids all corporate consulting by intramural investigators, and the result is that companies suffer from a shortage of expert advice. Red-light regulations are akin to preventing speeding by forbidding ownership of fast cars.

Some research institutions restrain themselves to “yellow-light regulations” by overseeing corporate interactions on a discretionary basis, as we heard about at Stanford University, but activists criticize them for their leniency.

■ MEDICAL ADVANCES SPEAK TO A HARMONY OF INTERESTS

None of these supposed solutions is solving problems.

Among my supervisors during my medical residency nearly 40 years ago were Mike Brown and Joe Goldstein, future Nobel laureates and contributors to the spectacular decline we have seen in mortality from heart disease. Moreover, many of my colleagues from residency are today in prominent positions in American medicine. Despite this intellectual fire-

power, we practiced terrible medicine by today's standards. Heart attack victims languished on our wards for a month; imagine what that would cost today.

While far from perfect, today's medicine is nearly miraculous when compared with medicine from even the recent past. Today's much more effective, innovative, and safe medicine resulted entirely from technologies developed by private companies abetted by entrepreneurial physicians and scientists, a partnership spectacularly epitomized by the biotechnology revolution. Having had the privilege to participate in that revolution, I see a harmony, not a conflict, of interests.

■ ATTITUDES ABOUT CONFLICT ARE UNFOUNDED

In a recent article in the *New England Journal of Medicine*,¹ I laid out how facts do not justify the attitudes or rules concerning conflicts. The accusations that such conflicts have compromised research are untrue and violate the very standards of scientific rigor they purport to protect. The allegations of harm arise from conjecture and very few anecdotes, certainly when compared with the full extent of academia-industry interaction. They provide no evidence that more adverse outcomes arise in the presence, as opposed to the absence, of commercial influence, or that institutions with more lenient (yellow-light) regulations have more research or education misconduct than those with stricter (red-light) rules.

■ WHERE DO THESE ATTITUDES COME FROM?

Why do we see such a glaring discrepancy between objective analysis and the prevailing mindset? One reason is that the immediacy of scandals and the inevitability of temporary failure overshadow the high risks, drudgery, and boredom underlying technological advances, which emerge inexorably but far too slowly to suit the attention span of the media and the public.

Another reason is that the scandals and mistakes that entrance the media and endanger academic administrators encourage protective overregulation.

I believe the most important reason, however, is ideological. As we have heard, authorities can see that we need interactions between companies, academic researchers, and clinicians, but they harbor a conceit that the scientific and promotional elements of private enterprise are separable. They demand that we wall ourselves off from the "commercial aspects" of companies. Curiously, they ignore the principal source of money exchange in medicine—clinical practice—even though promotion of clinical services is routine. For instance, is Cleveland Clinic's rating as one of the top three hospitals in America by *U.S. News & World Report* evidence-based?

A recent article in the *Journal of the American Medical Association* epitomizes this ideology,² and I will mention four notable points about it:

- Citation of relevant literature is generally considered good research practice, but although this paper appeared 4 months after my article in the *New England Journal of Medicine*,¹ it did not refer to it or address any of my arguments.
- It illustrates the definition creep that morphs conflict of interest from a conflict to any situation that certain persons do not approve of.
- It calls for the collectivization of corporate-sponsored research, a recommendation that, together with factual errors in the paper, undermines its credibility.
- Nevertheless, its call to separate science and business by banning pharmaceutical gifts and sales personnel from the academic medical center is being put into practice. Nowhere is the contempt for the market more apparent than the expressed disdain toward company sales forces, and I am disappointed that leading academic centers such as Stanford have accommodated such discriminatory recommendations.

■ FOCUS ON ACTIONS, NOT MOTIVES

Trust comes from a track record, not from who pays you or how much. The growing interaction between doctors and companies is an evolutionary adaptation to opportunity for all, not a diabolical commercial conspiracy. Let's celebrate the commercialism that has so improved medicine and shift our energies from bashing it to making it work better.

As for specific rules, academic institutions already require disclosures of faculty members' outside activities, which should be sufficient. Problems should be addressed when they arise, which is how we handle problems in most aspects of life. Give practitioners a little more credit for their ability to process information. For quality control, we should focus on what people say and do, not on their motives. In research, we operate with a narrow definition of misconduct, and we tolerate a lot of behavior that some people do not like because we progress best with freedom. That's a good model for medicine in general.

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Address: Thomas P. Stossel, MD, Professor of Medicine, Harvard Medical School, Brigham and Women's Hospital, 1 Blackfan Circle, Karp 6, Boston, MA 02115; tstossel@partners.org.