

To Print: Click your browser's PRINT button.

NOTE: To view the article with Web enhancements, go to:
<http://www.medscape.com/viewarticle/575760>

Commentaries

Response to AMA's Council on Ethical and Judicial Affairs Draft Report on "Ethical Guidance for Physicians and the Profession With Respect to Industry Support for Professional Education in Medicine"

Thomas P. Stossel, MD

Medscape J Med. 2008;10(6):137. ©2008 Medscape
Posted 06/12/2008

Introduction

In late May, the Council on Ethical and Judicial Affairs (CEJA) of the American Medical Association (AMA) released a draft report (henceforth "The Report") to provide "ethical guidance for physicians and the profession with respect to industry support for professional education in medicine."^[1] The report concluded that because "*industry support of professional education has raised concerns that threaten the integrity of medicine's educational function....individual physicians and institutions of medicine...must not accept industry funding to support professional educational activities.*"^[1]

Enactment of these regulations will have profound practical consequences for medical education, and stakeholders concerned about these effects should address them in detail. My intention here, however, is to challenge the fundamental beliefs underlying The Report that transcend medical education to affect medical practice and medical research in general. These beliefs are that commerce in general is detrimental to medical professionalism and that "medicine" and "commerce" have sufficiently misaligned interests to justifying their segregation from one another. Such segregation is increasingly becoming policy in academic medical centers in the form of severe prophylactic laws impinging on physicians' freedom of association and action, and similar rules are under consideration in state legislatures and in the Congress.

An article by Brennan and colleagues^[2] in *JAMA*, and prominently cited by The Report, frames the basis of the CEJA's Report and of emerging academic health center regulations. This article has been the most influential example of a burgeoning literature emerging in the late 1980s declaring any situation involving healthcare providers receiving payment in money or kind from private companies a "conflict of interest." The Brennan article broke new ground not only in the severity of its anticommmercial sentiments, but also in its insistence that disclosure of financial conflicts of interest is insufficient to control their adverse effects and that therefore these conflicts must be eliminated. The eliminative mechanisms recommended were to channel all corporate support for research and education through academic health center administrations to allocate at their discretion and to curtail at such centers all corporate detailing, gifting, and provision to physicians of product samples. The Report reiterates this reasoning and goes beyond Brennan and colleagues' recommendations to demand eradication of corporate support for *all* medical education.

I first show that Brennan and colleagues and the derivative Report failed to place their "concerns" in terms of a balanced risk-benefit assessment, and that such an analysis does not support their assumptions or the recommendations. I then argue that Brennan and colleagues and The Report based their conclusions on an arbitrary, obsolete, and frankly untenable definition of professionalism.

[Reader Comments on: Response to AMA's Council on Ethical and Judicial Affairs Draft Report on "Ethical Guidance for Physicians and the Profession With Respect to Industry Support for Professional Education in Medicine"](#)

See reader comments on this article and provide your own.

Readers are encouraged to respond to the authors at Tstossel@partners.org or to George Lundberg, MD, Editor in Chief of *The Medscape Journal of Medicine*, for the editor's eyes only or for possible publication as an actual Letter in the Medscape Journal via email: glundberg@medscape.net

Origin and Resistance to Commerce in Medicine

The growth in size and scope of the American healthcare enterprise since the middle of the last century challenged the control that physicians exercised over their activities and income. Although predictions that corporations would completely dominate medical practice^[3] did not materialize,^[4] healthcare providers today struggle "*to be competent to help and to help with the patient's best interests in mind*"^[5] and sustain their "*privilege of autonomy...self-regulation, public esteem, and a rewarding and well-compensated career*"^[6] (both statements cited in The Report^[1]). These challenges occur amidst the competing interests of government healthcare budgeters, private insurers, a demanding and litigious public, and the business community. All of these groups are complicit in and resentful of rising healthcare costs, but it is corporate producers of medical products that have become the major scapegoats for the resentments.

Industrial investment in biomedical research began to increase steadily in the 1970s, rose faster thereafter, surpassed public research funding in the late 1980s, and now exceeds it by nearly 2-fold.^[7] As the number of products available to more specialized providers in progressively diverse work settings grew, product marketing, especially by pharmaceutical companies, also became much more prevalent. Such marketing through promotion to physicians (detailing) or to the public (direct-to-consumer advertising) is US Food and Drug Administration (FDA)-regulated. As noted in The Report, private companies now provide half of the total costs of continuing medical education (CME) activities.^[1] Although codes of ethics promulgated by medical product manufacturers and accreditation requirements for CME limit companies' control of educational content, The Report concluded that these safeguards are insufficient to legitimize industry support of this activity.

Benefits of Commerce in Medicine and Medical Education

Prevalent political pronouncements that our healthcare system is "broken" belie the fact that longevity and quality of life have steadily improved since the 1960s when medicine began to become increasingly "commercial." The death rate from cardiovascular disease, for example, the number one killer, has steadily decreased and is currently half of what it was at that time.^[8] Because the overall death rate remains 1 per person, this spectacular improvement might have resulted in higher fatalities due to other major diseases, but deaths inflicted by cancer, the number two killer, remained relatively constant as heart disease deaths declined, and, for the last few years, have also decreased.^[9] Many factors have contributed to these trends, but economic analyses have concluded that the principal reason for them has been the introduction, and marketing, of new technologies by private companies -- drugs, biologics, devices, and information systems.^[10-13] Publicly funded research, primarily from the National Institutes of Health (NIH), has been essential for medical innovation, but the investments of private companies are the major mechanisms for the development and delivery of useful products on the basis of such innovation to patients.^[14,15] Other important examples of value derived from commercial medical technology include medications enabling prolonged symptom-free survival of HIV-infected patients and the introduction of diagnostic methods that render our blood supply increasingly safe.

If the purpose of medical "professionalism" is better patient care, the manifestly positive outcomes of corporate investments in research, development, and promotion -- outcomes ignored by Brennan and colleagues -- contradict The Report's remarkable distortion that corporate support of education somehow renders "*the wide array of diagnostic and therapeutic options available today*"^[1] a threat rather than a boon to patients. Such variety is precisely what providers wishing "*to be competent to help and to help with the patient's best interest in mind*"^[1] should have at their disposal. Brennan and The Report also failed to acknowledge the evidence that many patients frequently do not receive appropriate products, not because of access problems, but because their physicians do not recommend them.^[16-18] Because a major reason for deficient prescribing is lack of physician awareness, potentially curtailing information transfer by constraining its funding will increase this deficiency. In summary, this

context of manifest benefits from commercialism in medicine mandates serious caution before dismantling a system that delivered them.

Risks Imputed to Commerce in Medicine and Medical Education

The Brennan paper begins with the following statement:

The current influence of market incentives in the USA is posing extraordinary challenges to medical professionalism. Physicians commitment to altruism, putting the interests of patients first, scientific integrity and an absence of bias in medical decision making now regularly come up against financial conflicts of interest.^[2]

This paragraph merits close inspection because of its severe claims. What supporting evidence do Brennan and colleagues bring to bear on these strong statements?

Citing both sides of controversial issues is a requirement of serious scholarship. Violating this mandate, Brennan and colleagues not only ignored the benefits of commercial contributions to medicine, but exercised confirmation bias by referring only to publications critical of industry influences on medicine, although others rebutting these criticisms existed when the Brennan paper appeared.^[19-23] All of the references that Brennan and colleagues cited were to books, medical journal articles, and newspaper reports supportive of the authors' claims. These references were compilations of anecdotes, purportedly exemplifying industrial corruption of medical research. Not only has follow-up due diligence challenged the interpretation of some of these stories (eg, Shuchman^[24]), but, more importantly, considering the enormous expansion of corporate interactions with medicine, the paucity of examples is striking and their frequent repetition is not legitimate evidence. Like the Brennan paper, The Report only cited literature supportive of its conclusions and treated the benefits of commercialism in medicine cursorily.

Brennan and colleagues quoted a review article that summarized studies analyzing effects of corporate marketing on healthcare professionals to justify a claim that "*the systematic review of the medical literature on (industry) gifting by Wazana found that an overwhelming number of interactions had negative results on patient care.*^[25]"

Ashley Wazana, the author of the paper referred to, however, explicitly stated that no patient care data exist concerning this topic. According to Wazana's literature survey, product marketing enables the "*improved ability to identify the treatment for complicated illnesses*" -- a clearly desirable effect. The "negative" consequences alleged are "*inability to identify wrong claims,*" which would increase with cutbacks in CME funding; "*formulary requests for new medications with no advantages over old ones,*" which begs the question of what requests to censor; "*rapid prescribing of new products,*" which could be appropriate; and "*a positive attitude toward company representatives,*" which has no clear relation to medical practice.^[25] The favorable effects of promotion are arguably clear and the unfavorable ones ambiguous or trivial. Hence, the net effect of industry interaction with medicine as compiled by Wazana is, on balance, strongly *positive*, although the author did not come to that conclusion.

Unable to marshal evidence that corporate promotion adversely affects patient outcomes, The Report resorted to indirect arguments intended to convey that industry influence adversely biases physicians' judgment. In one, it mentions 2 notorious cases in which drug companies accused of promoting off-label drug use paid settlement fines to prosecutorial authorities. The obvious intention of mentioning such anecdotes is to imply that all corporations are fundamentally unethical. Considering the vast scope of corporate-sponsored medical education compiled by The Report, such extrapolation from isolated incidents -- meant to insinuate that such conduct is typical -- is grossly extravagant, bordering on slander.

In another indirect argument, Brennan and colleagues and The Report embraced the conclusion, derived from psychological experiments and embellished by neuroimaging studies, that physicians lack discriminatory powers to resist subtle persuasion tactics skillfully imbedded in educational activities by commercial marketers. A corollary of this viewpoint is that disclosure ("mitigation") is inadequate to control conflicts of interest, because in the face of the predetermined outcomes of the brainwashing sales pitch, disclosure is useless or even enabling because it imparts a false sense of security. The research behind these ideas is limited in extent and of questionable relevance. The behavior of college students engaged in experimental games may not apply to that of well-trained physicians in clinical practice. Even if the brain scans of a judge offered a large bribe and of a physician given a company pen look the same, neither scan predicts how the subjects will respond. To make such "evidence" the basis of policy is irresponsible.

Commercial Support and Educational Content

The Report made the pretentious assertion that eliminating commercial support of CME is necessary to preserve the gains in medical education initiated by the Flexner Report of 1908 that revolutionized medical education. To compare the alleged risks for commercial educational subsidy in today's highly technical medicine, based increasingly on the use of products minutely vetted by the FDA, with the documented chaos of unscientific pre-Flexnerian medical apprenticeship, training is hardly in the Flexnerian tradition of demanding scientific rigor.

Similarly, both The Report and Brennan and colleagues misrepresented science in their indictments of bias. Conceding that freedom from bias is incompatible with human existence, The Report nonetheless, resonating with Brennan and colleagues' assertion that "absence of bias in medical decision making" defines professionalism,^[2] set up as an ideal that "*professional education in medicine is fundamentally grounded in the ideal of scientific objectivity -- in other words, education that is free of all bias,*" and concluded that eliminating commercial support of medical education is necessary to approach this ideal.^[1] However, "scientific objectivity" is an oxymoron. Scientists passionately pursue their research driven by strong competing biases, but they subject their treasured ideas to rigorous tests designed to delineate their reproducibility and validity. From these tests a consensus may evolve, but in the end, except in mathematics, subjective interpretations come into play.^[26,27] Ultimately the track record of the science, not the motives -- or the profits -- of the scientists, determines the durability and utility of the scientific claims. The misrepresentation of objectivity in science fuels sterile quibbling over whether information is "educational" or "promotional." Because nearly all information, including -- indeed especially -- the content of the Brennan paper and The Report, has promotional elements, the contrast is false. The important issue is the strength of the evidence on which the information is based. Brennan and colleagues and The Report concluded without rigorous documentation that commercial information is by definition inferior to nonproprietary information.

To believe that some repository of nonpromotional or otherwise unbiased information exists that is superior to what physicians obtain from the competing universe of proprietary, or in part commercially supporting educational, offerings -- or could exist in some utopia where we could afford to subject all medical interventions to randomized controlled trials and find "disinterested" experts to perform and analyze them -- is a conceit. We rely on transparency in medicine not to eliminate all bias or even fraud but to ensure competition and inquiry that over time reveal and eliminate them. Proponents of "academic," "unbiased" medical education brand their education products by promoting the alleged unreliability of commercial information.

Commerce in Medical Education and the Definitions of Professionalism

According to Brennan and colleagues, "*altruism, putting the interests of patients first, scientific integrity and an absence of bias*" define "professionalism," and therefore physicians receiving any fee or gift from a private concern for any reason are potentially unprofessional. As a result, the imposition of bright lines preventing such transactions guarantee "professionalism." The Report parroted the mantra often offered up to justify such segregation, namely: "*Commercial entities have a responsibility to their shareholders and other vested stakeholders to thrive as businesses and maximize returns on investment. Medicine has a responsibility to put the needs of patients first.*"^[1]

This definition of professionalism, echoed by The Report, represents force feeding of one ethical framework for medicine when other, equally or more valid reference points exist.^[28] The definition resonates with the contempt for trade embedded in primitive cognition, religious traditions, and feudal aristocracies and most recently promoted by socialism and interventionism.^[29,30] When for millennia physicians had nothing substantive to offer patients, a high-minded aura of religious and learned authority was necessary for their social status. As "the youngest science," this requirement persisted until relatively recently.^[31] However, this need to declare medicine a secular religion is no longer relevant and potentially damaging, and the mantra quoted above reflects muddled thinking about both commerce and medicine. First, companies maximize profitability by coming up with products that benefit patients, and to conclude that industry has no interest in social responsibility is an enormous leap. Second, if corporate support of educational activities enables physicians to sustain their patient care activities, it is in the interests of patients. At a time when public support of biomedical research is not meeting research opportunities, when medical students are laden with debts and when organized medicine must desperately fight to sustain physician reimbursement rates, the wisdom -- indeed the ethics -- of arbitrarily discarding a major source of revenue for medical education is questionable. Third, scholars have explicitly articulated that medicine and commerce are *not* residents of parallel universes; practicing doctors are commercial. They are not government; they are not judges; and they are not news reporters, all of which are held to standards of apparent freedom from conflict of interest.^[32-34]

The Report's assertion that private companies' support of education corrupts educational quality is oddly selective because it neglects the obvious fact that academic health centers and medical journals are also "commercial," engaged in vigorous competition with rivals, and they exhibit the same promotional behavior deemed unattractive when exhibited by private companies.

As discussed above, "*absence of bias*," is impossible and therefore inappropriate as a criterion for professionalism. Although frequently invoked, the meaning of "*putting interests of patients first*" is totally vague and never specifically defined. Defensive medicine, fee-for-service reimbursement, and prepaid care -- all highly prevalent phenomena -- work at cross-purposes against "putting the patient first." Abundant historical evidence that stated good intentions disguise self-dealing and tyranny and do not guarantee good outcomes or prosperity mandate that we not mindlessly accept "*altruism*" as a central tenet of medical professionalism. The moral life of a practicing physician is a balancing act between multiple competing values and incentives -- not the abstract worship of absolute altruism.

[35-37]

Conclusions

Medical institutions have recently addressed the large interface between medicine and business as a reaction to accusations from critics echoed by the news media and by politicians that medicine is in a crisis state that demands correction of defective ethical norms by sanitizing medicine of its commercialism through imposition of bureaucratic management or elimination of commercial subsidies. In contrast, I argue that the medical-business frontier is a practical matter involving thousands of minute details that defy minute regulation. The key questions, therefore, are whether these interactions help physicians deliver the most effective medical care and relentlessly increase that effectiveness through innovation, minimizing inevitable risks associated with both care delivery and innovation. Only if an objective risk-benefit analysis confirms that corruption is prevalent leading to an answer in the negative should we engage in radical ethical reforms, and if we do, we must clearly define the ethical framework. I believe that the risk assessment answers the question in the affirmative and that individuals bent on altering our behavior base their recommendations on their own narrow ethical platform.

The challenges of medical care, medical innovation, and medical education are not well served by recrimination and sanctimony and certainly not by the poor scholarship represented by Brennan and colleagues. I recommend rejection of The Draft Report, which epitomizes these characteristics. Instead, I suggest that as recommended by the Association of American Medical Colleges Task Force on Industry Funding of Medical Education, we work in a spirit of mutual respect with our industry colleagues to improve physicians' and physicians-in-training's understanding of medical product development.^[38] This effort can yield a more sophisticated physician workforce better equipped to address the growing menu of medical product choices. By working together with industry colleagues, we can explain to the public that the contributions of corporations to medicine are on balance more beneficial than harmful and that both medicine and the industries that provide it with its technologies are worthy of public support. Cooperation, instead of antagonism, can help industry market its products with the highest integrity, keep physicians current on the best available evidence, and provide excellent patient care. This plan, not woolly ethical generalities, is the proper model of medical professionalism.

References

1. Report 1 of the council on ethical and judicial affairs (CEJA Report 1A-08). Industry support of professional education in medicine (Reference committee on amendments to constitution and bylaws). American Medical Association; 2008. Available at: <http://www.ama-assn.org/meetings/public/annual04/cejacme.doc> Accessed June 9, 2008.
2. Brennan T, Rothman D, Blank L, et al. Health industry practices that create conflict of interest. A policy proposal for academic medical centers. *JAMA*. 2006;295:429-433. [Abstract](#)
3. Starr P. *The Social Transformation of American Medicine*. New York: Harper; 1982.
4. Casalino L. Physicians and corporations: a corporate transformation of American medicine? *J Health Polit Policy Law*. 2004;29:869-883.
5. Pellegrino E. Professionalism, profession and the virtues of the good physician. *Mt Sinai J Med*. 2002;69:378-384. [Abstract](#)
6. Stern D, Papadakis M. The developing physician -- becoming a professional. *N Engl J Med*. 2006;35:1794-1799.
7. Moses H III, Dorsey E, Matheson D, Thier S. Financial anatomy of biomedical research. *JAMA*. 2005;294:1333-1342. [Abstract](#)
8. Wood A. A proposal for radical changes in the drug-approval process. *N Engl J Med*. 2006;355:618-623.

Abstract

9. American Cancer Society. Statistics for 2008. Available at: http://www.cancer.org/docroot/STT/STT_0.asp Accessed June 9, 2008.
10. Cutler D, Rosen A, Vijan S. The value of medical spending in the United States, 1960-2000. *N Engl J Med.* 2006;355:920-927. [Abstract](#)
11. Ford E, Ajani U, Croft J, et al. Explaining the decrease in US deaths from coronary disease, 1980-2000. *N Engl J Med.* 2007;356:2388-2398. [Abstract](#)
12. Fox K, Steg P, Eagle K, et al. Decline in rates of death and heart failure in acute coronary syndromes, 1999-2006. *JAMA.* 2007;297:1892-1900. [Abstract](#)
13. Lichtenberg F. Why has longevity increased more in some states than in others? The role of medical innovation and other factors. New York: Manhattan Institute for Policy Research; July 2007. Available at: http://www.manhattan-institute.org/html/mpr_04.htm Accessed June 9, 2008.
14. US Department of Health and Human Services, National Institutes of Health (NIH). NIH response to the Conference Report request for a plan to ensure taxpayers' interests are protected. July 2001. NIH Office of Technology Transfer (OTT) Web site. Available at: http://www.ott.nih.gov/policy/policy_protect_text.html Accessed June 9, 2008: 1-18.
15. Schacht WH. The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology. Congressional Research Service (CRS) Report for Congress. Document RL32076. Washington, DC: CRS, The Library of Congress. 2006:1-14. Available at: http://www.ncura.edu/content/educational_programs/sites/49/handouts/docs/Monday130/M130F11.pdf Accessed June 9, 2008.
16. Cutler D, Long G, Berndt E, et al. The value of antihypertensive drugs: a perspective on medical innovation. Why don't Americans do better at controlling hypertension, if the societal return on investment is so high? *Health Aff.* 2007;26:97-110.
17. Phillips L, Branch W Jr, Cook C, et al. Clinical inertia. *Ann Intern Med.* 2001;135:825-834. [Abstract](#)
18. Safford M, Shewchuk R, Qu H, et al. Reasons for not intensifying medications: differentiating "clinical inertia" from appropriate care. *J Gen Intern Med.* 2007;22:1648-1655. [Abstract](#)
19. Rothman K. Conflict of interest: the new McCarthyism in science. *JAMA.* 1993;269:2782-2784. [Abstract](#)
20. Stell L. Against the flow: why physicians should listen to drug reps. *ASBH Exchange.* 2005;8:1-5.
21. Stossel T. Regulating academic-industry research relationships -- solving problems or stifling progress. *N Engl J Med.* 2005;353:1060-1065. [Abstract](#)
22. Rothman K, Evans S. Extra scrutiny for industry funded trials. JAMA's demand for an additional hurdle is unfair-and absurd. *BMJ.* 2005;331:1350-1351. [Abstract](#)
23. Epstein R. Pharma furor. Why two high-profile attacks on big drug companies flunk the test of basic economics. *Legal Aff.* 2005:60-63.
24. Shuchman M. The Drug Trial. Nancy Olivieri and the Science Scandal That Rocked the Hospital for Sick Children. Toronto, Ontario, Canada: Random House of Canada; 2005.
25. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift. *JAMA.* 2000;283:373-380. [Abstract](#)
26. Polanyi M. *Personal Knowledge. Towards a Post-Critical Philosophy.* Chicago: University of Chicago Press; 1958.
27. Popper K. *The Logic of Scientific Discovery.* Chicago: University of Chicago Press; 1996.
28. Wear D, Altman J, eds. *Professionalism in Medicine: Critical Perspectives.* New York: Springer; 2006.
29. Tawney R. *Religion and the Rise of Capitalism With a New Introduction by Adam B. Seligman.* Edison, NJ: Transaction Publishers; 2005.
30. Friedman J. Popper, Weber, and Hayek: the epistemology and politics of ignorance. *Crit Rev.* 2005;17:1-42.
31. Thomas L. *The Youngest Science. Notes of a Medicine Watcher.* New York: Penguin Books; 1983.
32. Schumpeter J. *Capitalism, Socialism and Democracy.* 3rd ed. New York: Harper Torchbooks; 1950.
33. Nozick R. *Anarchy, State, and Utopia.* New York: Basic Books; 1974.
34. Jacobs J. *Systems of Survival.* New York: Vintage; 1992.
35. Smith A. *The Wealth of Nations.* New York: Modern Library; 1983.
36. Constant B. *Usurpation (1814).* In: Fontana B, ed. *Constant: Political Writings.* Cambridge, United Kingdom: Cambridge University Press; 1988:85-148.
37. Berlin I. Two concepts of liberty. In: H H, Hausheer R, eds. *The Proper Study of Mankind.* New York: Farrar, Straus, Geroux; 1997:191-242.
38. Association of American Medical Colleges (AAMC). Report of the AAMC Task Force on Industry Funding of Medical Education to the AAMC Executive Council. Washington, DC: Association of American Medical Colleges; 2008. Available at: <http://www.aamc.org/research/coi/industryfunding.pdf> Accessed June 9, 2008.

Acknowledgements

The author thanks Dr. Lance Stell and Thomas Brownlie for their very helpful suggestions. The author has and

continues to consult for private industry, and his employer Brigham and Women's Hospital has licensed his inventions to companies for commercial development. He receives no industry support for lectures or other educational activities directed at noncommercial audiences.

Thomas P. Stossel, MD, American Cancer Society Professor of Medicine, Harvard Medical School, Boston, Massachusetts; Director, Translational Medicine Division and Senior Physician, Hematology Division, Brigham and Women's Hospital, Boston, Massachusetts; Senior Fellow, Manhattan Institute for Policy Research, New York, NY; Member, American Medical Association
Author's email: Tstossel@partners.org

Disclosure: Thomas P. Stossel, MD, has disclosed that he is on the Board of Directors for ZymeQuest, Inc. and Critical Biologics Corporation. Dr. Stossel has also disclosed that he owns stock options in ZymeQuest, Inc. and stock options and stock in Critical Biologics Corporation. Dr. Stossel has also disclosed that he has received a consulting fee from Critical Biologics Corporation and that he is a paid lecturer at corporations.
