President’s Page: Relations With Industry: Thoughts on Claims of a Broken System

In April 2009, an article written by a number of well-respected physicians appeared in the Journal of the American Medical Association (1). In the article, the authors recommended sweeping changes in how professional medical associations (PMAs), such as the American College of Cardiology (ACC), should interact with pharmaceutical and medical device industries.

Their recommendations included totally removing industry support of PMAs and holding officers of the PMAs accountable for avoiding any industry support. Their definition of industry support included participation in Speakers’ Bureaus, industry-funded clinical trials, or investigator-initiated research while serving as an officer of the society. The authors felt that advertising in medical journals was appropriate and did not require consideration, and industry grants to academic institutions were also considered acceptable. However, trainees receiving awards from foundations should not be allowed to acknowledge or even know the source of their funding, according to the authors.

The authors proposed that the sole source for support of PMAs could only come from government or foundation grants and that no society member who had any relationship with industry could be appointed to a guideline committee. They also supported full disclosure and transparency regarding funding, and they called on the government to fund any clinical trials needed to provide evidence-based guidelines for care.

These recommendations assume that we all are easily influenced by relations with industry and need to be regulated; there is no comment about trust or virtue as a characteristic of the medical profession. The article implies that all physicians who receive support from industry will forever be biased to support the products of the related pharmaceutical or device company. It also implies that industry does not work for the best interests of patients or the better public good, but only for profit.

Faulty Assumptions-Guided Recommendations

The assumptions that led to these conclusions can be challenged on many fronts. First, to assume that physicians would not be responsible for providing the best care for their patients after being associated with an industry study or consultation is inappropriate. The authors cited isolated examples of errant physicians who received large sums of money from industry and then promoted their products. They presume that all physicians are represented by these few—that we all have a price. The authors’ assumption that the worst behavior is the average behavior of all physicians insults the profession. We are not to be bribed by a cheap pen or a free lunch. How could we expect patients to trust us with their lives if they thought we were swayed by a free dinner? On the other hand, we must act responsibly to eliminate doubt about our level of responsibility for our patients, and we should not accept funds for the purpose of supporting a commercial product. The authors’ assumptions imply that physicians as a group are not responsible people, yet physicians are among the most responsible professionals.

Any proposal to create proper relations with industry must be based on the assumption that we are personally responsible for the best interest of our patients and can work responsibly.
with industry while maintaining that goal. Responsibility is the key word. To assume that all physicians would act irresponsibly in relation to industry gifts or payments is inappropriate.

Our Goal: To Provide the Best Care

As a physician, my goal—and that of most of my colleagues—is to improve overall public health in the U.S. I accomplish this by providing the best care possible to individual patients and groups of patients, by doing research, by teaching, and by participating in public discussions about health policy whenever possible. I believe there is a moral right to good health, and that a healthy nation offers a better chance of long-term survival for a civilization.

To improve health, I have set 2 goals: prevention of disease and treatment of disease. These goals are best achieved through a well-defined process of research to understand disease and develop new treatments. The process begins with basic research, moves through the translational stage to clinical research, and then continues through application to large populations (clinical trials) to determine efficacy of a new therapy. The final step needs to be a production process that includes large-scale manufacture and distribution to make the new therapy available.

Funding for these various steps can come from public or private sources. In most of the developed world, public funds go primarily toward basic and translational research and some clinical research, while private funds generally support large clinical trials and manufacture and distribution of the new therapies. This system, which has evolved over several centuries, seems to be highly efficient. Total public funding (i.e., government-run industry) has not worked in the past, and total private funding reduces the basic science needed to develop new ideas because much of basic research provides no evident reward.

Society understands that reward drives innovation, so expecting a financial gain from a commercial medical enterprise is not wrong. In fact, it is the only way that new ideas will move from the laboratory to the public good. Using public funds for manufacture and distribution would add an enormous burden to government costs and, based on past experience, would be unproductive.

One may challenge these points philosophically; however, this approach, which is the foundation of our economic system, demonstrates the need for appropriate collaboration between industry and the medical community. Many of the advances in medicine in the past century would not have been possible without this collaboration.

A System That Works

So many examples validate my points. As a learned community of physicians, surgeons, and clinical and basic scientists, we hold a critical core of knowledge that should be disseminated widely for the betterment of our patients. If one of us has an idea for a new device and needs industry to help refine its design, fund its development and manufacture, and establish its value by animal and clinical studies, this process should be honored, not condemned. Will the government fund the development of the next new drug? Would the government have funded the development and manufacture of an implantable pacemaker? These are ventures that require large high-risk investments, and very few of us could do this on our own.

Governments have not shown an interest in funding the development of new drugs and devices. Industry raises the funds, takes the risks, and should reap the rewards for its role in creating a better life for our patients. How could industry develop new drugs or devices without input from the clinical and basic scientists among us? Total separation between the profession of medicine and the drug and device industry would cause irreparable harm to our patients by the lack of new therapies in the future—much more harm than the assumed bias produced by prohibiting industry funding of an education program.

There must be a middle ground. Industry must be able to call on the expertise of the medical community to develop new drugs and devices. This should not be viewed as a conflict. Industry should be able to support unbiased programs aimed at educating physicians and other health care providers about the therapies available for the care of their patients. Professional societies should be able to receive unconditional educational grants to provide up-to-date information to their members on medical therapies. Physicians should be able to conduct industry-funded clinical trials or consult with industry without being tainted with an assumption of lifelong misbehavior.

The recent Institute of Medicine report (2) describes a middle ground that recognizes the value of collaboration between medicine and industry and asks for systems that allow collaboration but prevent industry influence in education, clinical practice, and particularly in production of guidelines and practice standards.

When Marquis De Tocqueville visited the U.S. in 1830 to learn why our form of democracy worked so well, he was impressed by the spirit of independence and the entrepreneurs in the U.S. (3). He also noted a strong sense of responsibility that made the majority of people feel that they had a stake in the public good. New ideas were developed and new products were manufactured because of the sharing of ideas and the ability to create new enterprises. This is the way we achieve new therapies and new devices for the future. Let’s not destroy the best of what we have in our science and our industry.

The proper relationships should allow us to work with industry and allow our professional societies to receive undesignated funds from industry to foster better patient care. Society should and always has expected professionalism (i.e., that we always work for the best interest of our patients) from the medical profession. We do not need a
world of total disengagement; we need a world where responsibility and professionalism set the standards of relationships with industry, and the rules that we create to support this behavior are based on the best interest of our patients. I encourage you to read a statement on this issue that reflects the position of several professional organizations, including the ACC, at http://www.acc.org/PMA-JointLetterFinal.pdf.

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REFERENCES