Reforms Proposed to Limit Conflicts of Interest

Existing guidelines 'are not sufficiently stringent' and let professionalism and patient care be undermined.

BY MARY ANN MOON
Contributing Writer

The relationship between physicians and the makers of pharmaceuticals and medical devices now is so fraught with conflicts of interest that broad reforms regulating their interactions are essential, according to a group of medical ethics experts.

Industry-sponsored events, the dispensing of free samples and other "gifts" by detail people and drug reps, and lucrative "consultation" agreements are unmistakable ploys by drug and device makers to promote the use of their products. These practices have intensified in recent years to the point that they pose a "serious threat" to both physician integrity and patient welfare, Dr. Troyen A. Brennan of Harvard Medical School, Boston, and his 10 coauthors noted.

Existing guidelines of such groups as the American Medical Association, the American College of Physicians, and the Accreditation Council for Continuing Medical Education "are not sufficiently stringent" and allow both professionalism and patient care to be undermined. "The profession itself must exert much tighter control over the relationships between manufacturers and physicians," Dr. Brennan and his associates said (JAMA 2006;295:429-33).

The group, whose work was sponsored by the American Board of Internal Medicine Foundation and the Institute on Medicine as a Profession, called for academic medical centers to take the lead in:

- ▶ Prohibiting all gifts to physicians including free samples, meals, payment for travel, and payment for time spent at meetings.
- ▶ Strictly regulating industry support of continuing medical education and prohibiting direct funding of CME meetings.
- ▶ Strictly regulating industry support of research.
- ▶ Strictly regulating hospital purchases of drugs and medical devices.
- ▶ Prohibiting faculty from serving on manufacturers' speakers' bureaus and from publishing material ghostwritten by industry employees.

Of the proposed reforms, the prohibition of gifts such as drug and device samples may have the greatest effect on physicians in private practice, if it is enacted.

Most physicians believe that detailers' gifts don't influence their prescribing behavior. But pharmaceutical companies would hardly spend some 90% of their $21 billion marketing budget on these and other practices if the strategies weren't successful in promoting their products, Dr. Brennan and his associates said.

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"An overwhelming majority of interactions [with drug and device makers] had negative results on clinical care" in a recent review of the literature, the authors wrote. Prohibiting detailers' visits to physicians' offices will deprive manufacturers of "foot in the door" access that unduly influences physicians' choices of treatment, they added.

Two prominent cardiologists editorialized last year that, unquestionably, there is a powerful and well-organized effort by the pharmaceutical and device industries to co-opt vulnerable physicians (Circulation 2005;111:2552-4).

Dr. Thomas J. Ryan, senior consultant, emeritus chief of cardiology, and professor of medicine at Boston University, and Dr. Roman DeSanctis, emeritus director of clinical cardiology and Evelyn and James Jenks and Paul Dudley White Professor of Medicine, Harvard Medical School, said the resulting egregious professional behavior in medicine is unpardonable, but they also pointed out this behavior did not come about in isolation and has only paralleled changes in the culture and norms of society.

They recommended taking the billions of dollars spent on influencing doctor's prescribing habits and redirecting them to develop new rules of engagement between academic institutions and commercial entities that would undertake to translate policy into practice. They concluded that full disclosure and transparency in medical-industrial relationships should be the rule, not the exception.

But regardless of whether sampling should be eliminated, what goes on in a private practice is beyond the control of academic medical centers and the AMA, said Dr. Prakash Deedwania, professor of medicine at the University of California, San Francisco, and chief of the cardiology section at the Veterans Affairs Medical Center in Fresno. And the practice simply doesn't exist in many academic institutions, such as UCSF, which neither accepts samples nor allows pharmaceutical representatives in the offices, he added.

Regarding pay for physicians' travel expenses to medical meetings, the editorial writers are ignoring the fact that trainees don't get financial support from their institutions as they once did, and that those institutions don't have the money to send them, said Dr. Deedwania.

Also unrealistic is the notion that CME can survive without industry support, said Dr. John Flack, professor and interim chair of the department of medicine and chief of the division of clinical epidemiology and translational research at Wayne State University, Detroit. "Without industry support, CME will become a thing of the past, because few entities can afford to pay for it."

Nonetheless, many in the academic community have had a more positive response to the proposals, said Dr. Jordan J. Cohen, one of the JAMA report's coauthors and president of the Association of American Medical Colleges, Washington. The reforms will, of course, meet with resistance because they "represent a big change in practices that have been very widely accepted over a significant time, and frankly there's a significant amount of money in play here. I won't suggest that it would be at all easy to implement these changes, but it is looking possible," he said.

Dr. David L. Coleman, interim chair of internal medicine at Yale University, New Haven, Conn., applauded Dr. Brennan's group for "stepping forward with a very bold set of recommendations." Yale has already implemented strict guidelines prohibiting any gifts from industry representatives, any meals funded by industry, and any payment for attending CME meetings. The Yale guidelines are detailed in a report published in February (Acad. Med. 2006;81:154-60).

"I think banning food and gifts makes things a lot easier, frankly," he said. "It's so nice to walk into a conference and not have to have that awkward conversation with a drug rep, and not have to feel squeamish about possible conflicts of interest."

Most physicians interviewed agreed heartily with one proposed reform: ghostwriting. This should be controlled or eliminated, because some companies do influence the wording in research manuscripts, and busy investigators may go along with it, said Dr. Deedwania. ■

Health Care Industry Is Exhorted to Lean Toward Green

BY DOUG BRUNK
San Diego Bureau

LA JOLLA, CALIF. — The link between environmental toxins and cancer and other diseases is so suggestive that health care professionals must do all they can to diminish the risks to public health, Dr. Mitchell L. Gaynor declared at a meeting on natural supplements in evidence-based practice sponsored by the Scripps Clinic.

Such an effort, he said, should be based on what Lancet editor Richard Horton termed "the precautionary principle." This notion holds that "we must act on facts and on the most accurate interpretation of them, using the best scientific information," Dr. Horton wrote (Lancet 1998; 352:251-2). "That does not mean we must sit back until we have 100% evidence about everything. Where the … health of the people is at stake … we should be prepared to take action to diminish those risks, even when the scientific knowledge is not conclusive."

'Hospitals are huge releasers of a lot of pollutants, but this is starting to change.'

DR. GAYNOR

"We should demand that this principle become part of public policy" in the treatment and prevention of environmental causes of disease, said Dr. Gaynor, of the Weill Medical College of Cornell University, New York.

"I gave a lecture at the United Nations in 2003 on water pollution as it related to all the countries on earth and the fact that very soon, clean drinking water is going to become a scarce commodity," he said. "It's important that we become advocates for our own health."

While evidence on the adverse health effects of chemical exposure continues to mount, steps toward more environmentally friendly policies are under way at many health care organizations around the globe. For example, Health Care Without Harm is an organization of almost 450 member groups in 52 countries that are working to reduce pollution in the health care industry (www.noharm.org). Members include the American Nurses Association, Kaiser Permanente, Catholic Health Association, Stockholm County Council, and the Vienna Hospital Association.

"Hospitals are huge releasers of a lot of pollutants, but this is starting to change," Dr. Gaynor said at the meeting, which was cosponsored by the University of California, San Diego.

For example, more than 1,400 health care facilities in the United States have pledged to become mercury free, and 91% of chain pharmacies and the top 10 largest pharmacy chains have stopped selling mercury fever thermometers.

Consorta Inc., the large national health care group purchasing organization, supports the notion of greener and safer product innovation.

The decline of medical waste incinerators in the United States is an additional sign of a lean toward green. In 1998, there were 6,200 medical waste incinerators nationwide. By 2003, that number had dropped to 115. "Hopefully, there will be less need for even those," said Dr. Gaynor, who is also the author of "Nurture Nature, Nurture Health: Your Health and the Environment" (New York: Nurture Nature Press, 2005).

An effort is also underway to phase out polyvinyl chloride IV tubing; when PVC products are produced or burned, they emit dioxins, which are associated with cancer and damage to the immune system. ■