Ethics and their direct corollary—conflicts of interest (COI)—are again dominating medical discussions. Entities of all stripes, from the National Institutes of Health (NIH) to GlaxoSmithKline to our peer Journal of the American Medical Association, are being attacked for being less than forthcoming (1). There is an endless stream of allegations from the media that research organizations and health care professionals are intentionally “hiding” influential connections or negative results, culminating in destruction of the public trust and a pervasive perception of physician self-interest (2).

Even prominent medical professionals are pointing fingers, claiming in editorials that the use of “heavily conflicted experts” by medical organizations to make clinical policy “erodes the confidence of the public” (3). Although such accusations are most often not grounded in fact but in supposition, the American College of Cardiology (ACC) still must take such attitudes seriously. We must uphold the sanctity of the health care professionals’ role, which requires the public’s trust in order to be effective in our work.

The trust-based doctor-patient relationship is sacrosanct in our society. Not only is it the hallmark of good medicine but it is also legally protected. Patients must intentionally waive their inalienable doctor-patient privacy rights under the Health Insurance Portability and Accountability Act (HIPAA) so as to empower their physicians to breach this trust. Today’s rapidly evolving medical environment, however, can create illusory Hobson’s choices where the interests of the physician and the patient can appear to be contradictory. In fact, there is little room for choice. Ethical decisions keeping the patient primary must be made in all instances, and the physician must be prepared to understand and manage the repercussions of those actions.

Clinician-scientists and the medical industry continually develop new methods to support patients living with cardiovascular disease. Society has benefited from this methodical effort, with remarkable strides being made in pharmaceutical and medical device solutions. We also have witnessed—and driven—a change in culture that encourages heart-healthy habits, such as reduced smoking and weight consciousness. Patient-care protocols have improved worldwide through global cooperation, and lives are being saved.

As we know all too well, however, more—and better—treatment options can lead to thorny ethical issues. Access to cutting-edge care for certain populations can create perceived inequities in treatment. Patient-participants in research pose a peculiar dilemma for doctor-investigators seeking to treat disease yet advance knowledge. Researchers may engage in relationships with industry that they consider perfectly harmless but that can appear to present inescapable COI. Any of these circumstances can result in perceived harm to our primary concern, the patient. Harm, in this sense, may manifest as a physical detriment, or it may be a deterioration—or destruction—of the patient’s faith. Such a situation automatically breaches the hallowed physician-patient trust relationship that is fundamental to an effective health care environment.

Perception, however, should not be automatically inferred as reality. In our ACC members’ daily practices, protecting patients’ rights and trust is de rigueur. Cardiovascular specialists are renowned, with very few exceptions, for keeping their patients’ best interests at heart when creating care protocols or recommending life-management strategies. Rather than assuming the worst about physicians when it comes to potential COI, we submit it is far more accurate to assume the best.

High-profile cases in the media, however, have negatively trained the spotlight on ethics and the issue of COI. The NIH, through its subsidiary National Heart, Lung, and Blood Institute, released the National Cholesterol Education Program Update in July of this year, and unintentionally created a furor by failing to publish author disclosure of ties to affected industry (4). This contretemps came on the heels of an ongoing media frenzy that erupted in the spring over GlaxoSmithKline’s management of its Paxil antidepressant studies related to children and adolescents (5).
enough to address virtually any situation we may encounter. We are using COI management in the broadest sense here, encompassing clinical trial procedures, patient-participant procurement, industry and physician-investigator financial dealings, efficacy of findings in industry-sponsored tests, disclosure of all physician benefits derived from dealings with industry, and self-made patient testing referrals.

The first step toward providing advice and direction for all cardiovascular care professionals is to identify problem-prone situations and to expose them to vigorous, open, and solution-focused dialogue. Although frankly discussing our professional ethical challenges may generate anxiety among the lay public and the press, we firmly believe the first step to setting strong standards for uniform and optimal behavior for ourselves and our colleagues is to thoroughly examine areas we consider cause for concern.

As a major thought leader for cardiovascular care, the ACC is compelled to offer direction and guidance to its 31,500 members worldwide. We take this responsibility very seriously, as we hold ourselves before the mirror before others feel empowered to control our actions through legislation or regulation (6). Establishing acceptable choices is our charge, and we must all have the courage to challenge ourselves and each other to attain and maintain unassailable ethical reputations through bullet-proof behavior.

To this end, the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) convened a June 2004 Bethesda Consensus Conference on Professionalism and Ethics. Since the last Bethesda conference on ethics in 1999, significant advances have occurred in cardiovascular medicine. Although consensus recommendations from this joint ACCF/AHA conference do not constitute organizational policy, we sincerely hope they will be adopted by both organizations, resulting in common principles for cardiovascular specialists.

Six task forces tackled tough topics ranging from procuring patients for human-subjects research to prescribing tests to be performed by the same physician. These task forces did not shy away from confronting difficult discussions. Rather, they embraced the issues and debated their merits and demerits. The resulting document, which is published in toto in this issue of the *Journal of the American College of Cardiology (JACC)*, touches on research methodology, COI disclosure, and fiduciary duty.

When physicians deal with human subjects in research, there are basic ethical principles, articulated in the Belmont Report of 1979 (7), stemming from the Tuskegee Syphilis Study. Human participant research is a crucial element in the development and approval of new drugs, biologies, devices, and procedures that seek to improve patient care. Participation in clinical research is an important professional obligation for cardiovascular practitioners. This involvement ranges from study design and implementation as investigators to the critical role of subject enrollment for all cardiovascular practitioners:

- Underrepresented groups in clinical trials (elderly, women, ethnic minorities) need to be actively recruited and included in studies
- Investigators must fully disclose financial and any other type of COI to potential subjects
- Institutional review boards should have two processes, one to monitor patient safety and another to deal with COI
- Physician-investigators should be fully involved in the design and conduct of the trial, including maintaining responsibility for reporting results
- *All* trial results should be reported without undue delay, not just trials that are positive
- A publications committee should be established for multicenter studies prior to the start of the study and should prevent control of the publication process either by the sponsor or by a single investigator

Pharmaceutical clinical trials can create a difficult dichotomy for physician-investigators. When the world's best researcher-physicians are recruited to perform and analyze important drug trials, they are damned if they do and damned if they do not. This conundrum has been eased somewhat by the laudable actions of several pharmaceutical companies to publicly disclose results from all clinical trials (8). In the interest of corporate responsibility and transparency, such a free registry is the only sound option.

Disclosure of potential COI should be made for all ACC and AHA activities, without exception. Specific financial criteria are proposed by the Conference Task Force, in addition to documenting other non-tangible benefits doctors may derive from interactions with industry. Both the ACC and the AHA should adopt a single COI policy and form, and both organizations should maintain a secure and uniform database of COI, one that is updated regularly.

In practice, we reaffirm our stringent *JACC* disclosure requirements. Our basic policy is to offer all relevant relationships to readers, then let readers interpret the data in this light. All submissions must be accompanied by full-disclosure documents, which are formally attested to by the investigators. Likewise, peer reviewers must supply a complete list of industry relationships (9). This cross-check serves to ensure that evaluation of the study is not subjected to bias. While not every reviewer who carries a potential COI is omitted, we do seriously consider each such circumstance. Although *JACC* occasionally publishes manuscripts authored by individuals from industry, we never accept such pieces as state-of-the-art reviews.

In addition, *JACC*’s policy has been to publish important negative research results. Although we recognize a negative result often is considered less important and less likely to be cited in future studies, we believe making such results public is a valuable professional and public service. In a similar vein, we sometimes will ask contributors to provide additional data that we have determined should be available, even if it has been omitted from the initial manuscript.
Regarding research protocols and patient-participant informed consent, JACC again assumes a tough stand. Editors take note of how each manuscript fulfills the general requirements of institutional approval for protocol and informed consent. Occasionally, we have declined to publish manuscripts that did not provide evidence that these fundamental processes were appropriately conducted.

These strong policies also hold true for presenters of abstracts and posters at our renowned Annual Scientific Session and also for those who participate in the clinical guidelines for working groups. Participating professionals must meet an exceptional standard of disclosure, both in writing and verbally, during the presentations (10). Our Annual Scientific Session draws more than 400 media from around the world, creating fast-paced delivery of data to both the lay and trade press. Such quick dissemination demands a cadre of presenters who meet our ethics standards, and it requires the ACC to be diligent in credentialing them.

Another sticky potential COI is the practice of the same physician ordering and then performing in-office tests on his or her patients. Such circumstances are becoming increasingly common as well-trained cardiovascular practices appropriately incorporate emerging technology in their facilities. Although this decision typically is made to provide the most efficient and effective medical management of each patient, it poses a potential perception of COI and requires our close vigilance. The ACCF/AHA guidelines are an especially important mechanism to assure accepted evidence-based “best practices” standards of care and avoid inappropriate self-referral (11).

Heart hospitals, for example, may offer attractive advantages for consolidated patient care, but they also can open the door to charges of COI. Cardiologists must be exceedingly careful when it comes to investing in such facilities. The ACC and the AHA, as well as governmental agencies, should continue to collect data and monitor activity and outcomes in free-standing cardiovascular care centers that have close ties to cardiovascular practice groups.

Likewise, direct-to-consumer advertising is totally unregulated when applied to cardiovascular services. Misinformation, intentional or otherwise, can be deadly for our vulnerable and often-fragile patients. Methods should be devised to examine and control the veracity of information given to consumers, and consequences must be established for practitioners who violate the public trust with misleading or untruthful materials.

Cardiovascular specialists, in fact, have an obligation to serve as objective, third-party experts to the public, be it through the lay press or in the courtroom. Malpractice litigation poses special challenges for cardiovascular specialists who are requested to testify. Each of us bears the burden of responding to this call because expert witness testimony is, effectively, part of medical practice. Our goal on the stand should be to objectively educate those individuals in the case and should be independent of the attorneys paying for our opinion. The physician expert also should be board certified in areas in which he or she is asked to testify, erasing any question about preparation or ability to represent the very best in cardiovascular care.

These many issues, in congregate, may appear to hopelessly muddle our pursuit of a guiding “bright line” for making ethical choices. The “grays” may appear to overwhelm the black-and-white of clear choice. Quite the contrary, professional ethics requires our moral obligation to do what is good and honorable for our patients, for each other, and for society. When patients are the first consideration in all things, ethical dilemmas shrink precipitously and physician self-interest cannot be a deciding factor. After all, patients come to us for care “without fear or misgiving.” They rely upon us to be providers of sound medicine on their behalf, and they believe we will shelter them. As always, our Hippocratic Oath is our ethical guide. First, do no harm.

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REFERENCES

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