

## INTRODUCTION

# Cardiovascular Professionalism and Ethics in the Modern Era

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The health care professions have always enjoyed special trust and position in our society. Patients trust health care professionals (HCPs) to guard their health, inform them, and put a patient's interests above any other consideration. This is one definition of "professionalism." When HCPs deal with human subjects in research there are basic ethical principles, articulated in the classic Belmont Report of 1979, that have been accepted by all (1).

We believe from our experience that the members and staff of the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) strive to do "good" for society in general and for patients specifically. They put patients' interests first, above their own, in an overwhelming majority of situations. There are virtually hundreds of thousands of patient-HCP encounters daily in the U.S. It is assumed that HCPs are trying their utmost to benefit their patients even when the outcome is not optimal or when disease progression cannot be effectively treated. Complications of therapy occur despite the best of intentions. Clinician-scientists and the medical industry develop new therapies to improve the lives of patients living with cardiovascular disease, and society has seen the benefits of this effort over the past several years. Everything in this system works well until or unless a conflict between the HCP's interests and those of the patient results in actions that harm the patient. Then it is assumed that there has been a breach of that respected patient-HCP trust.

Many modern situations exist in which the personal interest of the HCP may not be aligned with that of the patient. Ethical choices must be made by the HCP in these situations. Examples include:

- A physician is awakened and gets out of bed in the middle of the night to assess a patient with chest pain.
- A procedure is done or an antibiotic is given with marginal indication by the HCP to satisfy the patient's wishes rather than the HCP providing a long or detailed explanation of why the action need not be taken.
- Procedures produce income for HCPs and provide experience and prestige that are valuable for the HCP in ways beyond those only for the individual patient's direct benefit.
- Medical scientists have a deep interest in developing new methods or therapies requiring testing in humans despite the initial imperfection of the agents being tested.
- HCPs continue to devote precious time to help patients make important behavioral changes (smoking and substance abuse cessation, dietary counseling, and so on), despite a lack of reimbursement or support from health care delivery systems and payers.
- An HCP advocates for a product or procedure because of his or her role as an adviser or consultant to a company profiting from the product or procedure while trying to differentiate this role from that of an impartial physician or other HCP educator.
- The HCPs are chosen for their opinions to serve as paid experts in legal actions, de facto taking "sides" in cases related to patient care or product liability issues.
- A physician prescribes a new statin drug for secondary prevention because he or she heard about it at a recent meeting hosted by a drug representative, although this drug is less proven to prevent subsequent events than older medications.

Specific high-profile cases in recent years have brought great attention to the issues of conflict of interest among those dealing with patients and with subjects of clinical trials (2,3). There has been sensationalism in the press addressing some of those cases. In many instances, the important issue centers around the lack of disclosure to all concerned of a potential conflict of interest in the HCP's relationship with the patient. Although these cases are rare, they are very important in our profession.

We must ask ourselves, as members of responsible professional organizations, "what are the issues in modern cardiovascular care that create real or potential problems of conflict of interest for our members and for the organizations themselves?" We believe the first steps toward providing advice and direction for HCPs are to identify such situations and to bring them to an open discussion. We recognize that publication of some of the specific issues addressed in this conference may have the effect of increasing the anxiety of the general public and of the media regarding the extent to which some of the negative situations occur. However, we believe the initial step on the path to setting standards for uniform and optimal behavior for HCPs and the protection of patients is to discuss fully those areas in which we see cause for concern.

The ACCF and the AHA decided to convene this conference in order to highlight the potential conflict of interest in major defined areas and to offer comments about

their management and resolution. We believe it is our responsibility to examine ourselves carefully because the nature of our work and developments in our own specialty of cardiovascular disease allow us to understand the complexities of many of these issues in 2004 perhaps as well as, or better than, others.

This conference, which was held in Bethesda, Maryland, was different from the prior ACCF conferences with "Ethics" in their titles (4,5). With this conference, we have taken a fresh approach since many of the issues to be addressed are "new" in light of the social, economic, and political environment in which we now find ourselves. The participants in the conference were widely experienced and brought both "real-world" and varied perspectives to these issues. They were actively involved in many areas of cardiovascular subspecialty practice, teaching, and research. Some of the cardiovascular specialist participants were employees of industry whose perspectives were seen as important to the discussions. Nevertheless, they were invited as colleagues and not as representatives of industry (nor was their participation sponsored by their companies). Participants did not uniformly agree on every point, but they were able to reach consensus on the issues as expressed in the following Task Force reports.

The Co-Chairs initially did not request a disclosure from attendees regarding their individual relationships with industry as none of the groups addressed or discussed specific companies or products. During the conference and afterward, it was appreciated that having a relationship with

industry might be seen as a factor informing or affecting one's opinion about the general issues discussed and the recommendations made. For this reason, we subsequently asked all participants to disclose such relationships; this disclosure is published as Appendix 1 to these conference reports so those reading the reports may be aware of these relationships with industries.

We believe these reports will be useful for many constituencies. However, the ongoing discussions of the topics covered here are truly the responsibility of the cardiovascular HCPs we represent. A responsible profession must police itself. We hope that this particular function is assisted by this conference. The decision regarding whether to adopt the recommendations from this conference as official policy of the organizations will be the responsibility of the leadership of the ACCF and the AHA.

## **INTRODUCTION REFERENCES**

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