Viewpoint

Not For Sale, Not Even For Rent: Just Say No. Thoughts About the American College of Rheumatology Adopting a Code of Ethics

There can be no high civility without a deep morality.
— Ralph Waldo Emerson

Medicine is, in essence, a moral enterprise, and its professional associations should therefore be built on ethically sound foundations[1].

Take this quiz. (1) Imagine that the biologic-response modifying antirheumatic drugs and selective cyclooxygenase 2 inhibitors are not available. Only several nonsteroidal anti-inflammatory drugs (NSAID) are on the market. A new NSAID is about to be introduced. The manufacturer invites you and your spouse (or guest) to a week-long meeting to learn about the new drug. All expenses will be paid and an honorarium will be provided. In addition the company will defray all costs of your attendance at an International League Against Rheumatism (ILAR) meeting the following week. The symposium will be on Tahiti and the ILAR meeting in Australia. Which of the following will you do?
(a) Respond to the company with an expression of indignation that they would dare insult you with such an ethically objectionable proposal.
(b) Attend these valuable educational events but at your own expense.
(c) Discard the letter of invitation, thinking it was from a sweepstakes promotion.
(d) Ask your son to reschedule his bar mitzvah planned for 6 weeks away, which conflicts with the Tahiti dates, so you and your spouse can attend.

(2) You, together with your spouse (guest) have accepted an invitation to participate in a symposium in Monte Carlo, Monaco. The event will introduce a(nother) new NSAID to the rheumatologic community. Your presentation will be on aspects of rheumatic diseases and their management which have nothing to do with the product. You are provided generous travel expenses and an honorarium, not inconsistent with other similar events and circumstances. The attendance of members of the audience, brought from the United States, is fully supported by the sponsor. Upon arrival your luggage cannot be found and your presentation, in the Royal Auditorium, is hours away. The sponsor does not wish you to appear on the podium in the jeans and sweatshirt you wore on the plane and offers to take you to the nearest clothing store (which happens to be the Royal Tailor) and buy you suitable clothes. Which of the following will you do?
(a) Realize the ethical inappropriateness of the entire event and return home, despite your spouse's disappointment at missing this opportunity to enjoy the French and Italian Rivieras.
(b) Buy your own new clothes, preserving your independence and integrity.
(c) Speak in your jeans and sweatshirt, preserving your independence and integrity.
(d) Allow yourself to be treated to a lovely new wardrobe.

(3) You are a member of the American College of Rheumatology (ACR) Board of Directors. The makers of IncreduMax, a new biologically-derived product capable of inducing remissions in inflammatory and degenerative arthritis by transcutaneous administration without reported toxicity and at very low cost, offer the American College of Rheumatology a munificent longterm endowment if the ACR changes its name to the IncreduMax American College of Rheumatology.... No, that's not right, if the ACR allows them to co-sponsor a major educational campaign on the value of early diagnosis and treatment of arthritis. Which of the following will you do?
(a) Argue and vote against the proposal, believing that the ACR's activities should narrowly focus on educational meetings and on the publication of a high quality journal, and believing that when the ACR ventures into enterprises of promotion or advocacy it cannot avoid being ethically tainted by the inevitable conflicts with commercial and industrial associations.
(b) Accept the proposal with stipulations that the ACR retain absolute and final control of the content of all material, of all aspects of the process, and that there be full disclosure of the ACR's relationship with the makers of IncreduMax.
(c) Advise your spouse/family to buy more stock in the company.
(d) Ask the company representatives how you can participate in their clinical trials and be on their speaker and advisor/boards.

(4) The makers of IncreduMax approach you, an ACR

Board of Directors Member, to seek your advice, distinguished rheumatologist that you are. They invite you to serve as a member of the advisory board, for substantial remuneration and possible stock options, of IncreduNet, a new internet-based enterprise that offers unique services broadly across all of medicine, not just rheumatology, and for which IncreduMax is a major sponsor. Which of the following do you do?

(a) Decline, viewing this as at least creating a perception of conflict of interest.

(b) Accept, but resign from the ACR Board of Directors.

(c) Accept, considering that the web-based company is independent of the makers of IncreduMax, that its business is not really rheumatology, and knowing that you will fully disclose this relationship and contribute any income realized to your academic division.

(d) Ask them what else they can do for you.

Score 10 for each (a) answer, 5 for each (b) answer, 2 for each (c) answer, and none for each (d) answer. If you scored 30 or more, let us know so that you can be considered for membership on the ACR Ethics Subcommittee; if you scored 10 to 29, read the rest of this article carefully; if you scored less than 10, do not despair — I myself answered (d) to questions (1) and (2) and here I am having served on the Food and Drug Administration Arthritis Advisory Committee and chairing the ACR Ethics Subcommittee.

MEDICAL ETHICS MADE EASY

These examples illustrate some of the seemingly vexing issues of professional and organizational ethics. I now think these are not particularly arcane nor difficult, but rather simple. Medicine is humane science inextricably bound to an ethical lattice. It is a moral enterprise[1-3]. As individual physicians we are committed to promoting the welfare of those we serve. So too must our professional association(s) affirm the moral imperatives from which derive our authenticity and integrity by demanding the highest possible standards. There are tensions, and there are surely temptations. Just say no.

Individually we are confronted with the allure of Tahitis, or Monte Carlos (and of course others). These challenge our ability to recognize moral dilemmas and to subordinate self-interest to that of our patients. As a professional association the opportunities for the ACR and ACR members to accept monetary support and/or gifts, to generate income, and to "partner" with industry in order to promote our own interests, privileges, and sense of entitlement are seductive indeed. I certainly succumbed, as have colleagues, as has the College at times, and I now regret this. It really is simple. Just say no. Medicine is not about us, our practices, our institutions, our organizations, our needs, our research, our careers, our perquisites, our prerogatives, our agendas, or our perceived entitlements. It is about our dedication and devotion to our patients and to their welfare even at personal and professional risk to profit, pride, and position[1-10]. Just say no.

Public trust in physicians and their associations has eroded[1]. There was a telling series of relatively recent articles in *The New York Times*, beginning with a front page feature about "hidden interests" in medicine[11]. The piece detailed physicians' and institutions' conflicts of interest with industry. One physician commented "the conflicts are just overwhelming... if you can't trust the opinion leaders, and the so-called experts, and even worse, in some cases, the studies themselves, what happens to the profession and what happens to the patients?" Another said "the science has been lost in the rush for money... we've lost our way. We've terribly, terribly lost our way."

ABOUT GIFTS

"It is not the office of man to accept gifts... How dare you give them. We wish to be self sufficient..." — Ralph Waldo Emerson. Just say no. It is necessary to understand "gifts" and "gift" giving in order to derive individual and professional ethics for these and related activities[2]. Gift giving and receiving exemplify the potentially problematic individual and professional relationships with industry. I use "gifts" in this context to reflect relationships from which personal or organizational benefit may accrue.

There is now a growing literature pertaining to "gifts." There is general recognition that professional and personal gift giving and receiving pose ethical conflicts to physicians and organizations and that there must be codes of conduct to govern this. Indeed the ACR was one of the first professional societies to realize this, and developed and has long had a set of standards higher than many other professional organizations[2,12]. There is less guidance relating to broader relationships with industry and other commercial sources, but the professional and ethical issues are essentially the same as for gifts." "Gifts" and industry/commercial relationships are pervasive.

HISTORICAL BACKGROUND

There has long been a special, close, but conflicted relationship between medicine and the pharmaceutical industry[13]. Industry develops and markets drugs (products) and physicians use them to benefit patients. During drug development industry depends on independent, impartial physician evaluation. However, as drugs are developed and brought to market the relationship changes. Companies in a competitive industry try to persuade physicians to prescribe their products while seeking information about safety and efficacy. This creates interactions that require awareness of the ethical and professional issues.

Readers of the *Journal of Rheumatology* will be familiar with the explosion of new pharmaceuticals, particularly NSAID, as well as antihypertensives, antibiotics, and others, beginning in the 1970s, and their increasingly aggressive

marketing to a receptive physician audience. Growing subspecialty professional societies welcomed the influx of funds from industry to support their activities. Academicians, competing for increasingly scarce research dollars, looked to drug company monies to fund investigation. Pharmaceutical dollars became a staple of continuing medical education (CME) programs and indeed many activities throughout organized medicine. As drug industry funding became pervasive so did its logos, symbols, products, representatives, gifts, and other tokens of its generosity. For the most part, medicine perceived this as part partnerships and perhaps part entitlement. It was only a distinct minority of physicians who rejected this relationship. Few cautioned about excesses, about ethical issues, or about perceptions of conflicts of interest[2,4,14].

It wasn't until the mid-1980s that physician and professional attitudes began to change. This was largely due to the powerful external influences of the media and the government. A forgettable and unremarkable NSAID, Opren (benoxaprofen), was introduced to the British market with an unusually lavish marketing campaign; physicians were invited to ride the Orient Express from England to Venice while "learning" about the drug, at the expense of the manufacturer. The drug was withdrawn from the market not long after its introduction, and the "Opren Scandal" was headlined in the English press and "exposed" by the British Broadcasting Company. Editorials followed in the *Lancet, British Medical Journal,* and *New England Journal of Medicine*[15-19]. Many will recall similar activities by US companies. These included the establishment of drug company-sponsored "speaker bureaus," certain "clinical trials," "CME" programs at exotic locations, and sponsorship of "social" events at professional meetings[17]. Some of these can only be described as obscene in their extravagance. One of the most notable marketing efforts was the offer of frequent flyer miles and other equivalent gifts to physicians by Ayerst as rewards for prescribing Inderal LA[20].

The resulting adverse and embarrassing publicity from articles in the press, including *The New York Times*[21], *Consumer Reports*[22], and others, as well as the threat of government intervention from hearings conducted by Senator Ted Kennedy[23-26], led to the development of position statements by professional organizations[17-31].

THE SEDUCTION OF PHYSICIANS

This begins early. First-year medical students were offered reference books from the pharmaceutical industry. Second-year students were given black bags, stethoscopes, hammers, and other items. By third year, students had obtained pens, notepads, paper clips, other "trinkets", books, and free medication samples for themselves and families and friends. Fourth-year students often enjoyed drug company-sponsored trips. Residents came to expect food, sponsored programs, social affairs, and parties. Fellows were offered travel grants, research funds, and clinical trials. In practice physicians were given gifts, opportunities to attend "educational" activities, golf/fishing/skiing trips, travel, and tickets to events. Academicians received grants, consulting and speaking opportunities, and support for CME and GME (graduate medical education)[21,22,32-35]. Physicians came to expect these.

MARKETING DRUGS

This is a big, sophisticated business. Pharmaceutical companies have spent over $10 billion each year on drug promotion in the US. This is more than is spent on research and development, more than is spent on the raw materials for products, several billion dollars more than the wholesale cost of all antihypertensives prescribed in the US, and more than is spent on medical school and residency training combined[2,21,22,36]. For example, in 1998 promotional spending reached $7 billion. Spending on detailing increased by 15% to $5.7 billion. Detailing increased by 12%. The pharmaceutical sales force grew to 56,000, up from 35,000 in 1994. There was nearly one drug representative and almost $100,000 for every 11 practicing physicians in the US. The top 10 drug companies analyzed averaged 16% profit, triple that of the average Fortune 500 company[2,21,22,36]. This is a big, sophisticated business. Companies are motivated by profit, not altruism. Representatives often have quotas, are schooled in selling, are not always accurate in the information they present, and collect detailed marketing information on their clients for their companies[2,36]. "When there are 8 drugs that are equally good, the doctor makes a choice based on non-science. If he has samples, or pens, or other devices, the doctor will write for my product and not the other guy's"[21]. "I can get any drug on a university hospital formulary. I just find some fertile soil — the right person who is hungry for research money. It doesn't matter what the side effects are or if it's four times the price of an equally good drug. I know the researcher would help me get it on my formulary in exchange for research money"[21]. "If market research by large industrial companies had suggested that the returns were not adequate, these activities would not take place... doctors were either unwilling to admit to the powerful influence of commercial pressure or unconscious of it... some of the venue participants declared that they would retain virgin intellectual purity... such a belief may preserve self-respect, but it is a delusion"[15]. "The degree to which the profession, mainly composed of honorable and decent men, can practice such self-deceit is quite extraordinary. No big company gives away its shareholders' money in an act of disinterested generosity"[16,17]. And a recent editorial included a strong call for more stringent, not softer, conflict-of-interest guidelines, emphasizing grave concern that "...close and remunerative collaboration...naturally breeds goodwill...and the hope that

the [beneficial relationship] will continue. This attitude can subtly influence...judgment... Can we really believe that clinical researchers [editorial addition: or organizational leadership or organizations/institutions] are more immune to self interest than other people?"[6]

POSITIONS OF PROFESSIONAL ORGANIZATIONS

The Royal College of Physicians, in 1986[31], wrote that physicians should not accept excessive or inordinate hospitality, that hospitality should not extend to spouses, and that the criterion of acceptability may be, "would you be willing to have these arrangements generally known?" The American Surgical Association (ASA) in 1989 was among the first professional societies to develop a position statement. The ASA stated, "that it is unethical for a surgeon to accept remuneration or material reward for participating in the advertising or other product promotional activity of a health care related industry with no relationship to professional service rendered..."[26]. They did not object to small gifts, sponsorship of educational lunches, or complimentary coffee and donuts for operating room teams. The ACR, also in 1989, established stringent policies for corporate sponsorship at its meetings, limited the value of gifts distributed, prohibited brand names at meeting venues, banned social and competing events from scientific meetings, and supported social events with members' fees[12,29]. In 1990 the American College of Physicians published its policies[27]. "Gifts, hospitality, or subsidies...ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgment. A useful criterion in determining acceptable activities and relationships is: "would you be willing to have these arrangements generally known?" Those who accept industry sponsorship for CME should have and enforce explicit policies to maintain programmatic control. Professional societies should have similar guidelines and discourage excessive gifts, amenities, and hospitality. Clinical trials should conform with scientific methodology. The AMA's policy, from its council and from its ethical and judicial affairs committee, followed in 1991[37]. This stated that gifts should not be of substantial value, that education subsidies should be funneled through sponsors, that gifts not be conditional, and that travel, lodging, and expenses should not be accepted to attend conferences and meetings. The Canadian Medical Association's policies were the most restrictive[26]. Among their 33 principles were recommendations to accept no gifts except patient teaching aids and those with no product logos. There is an extensive array of additional opinions in the literature regarding this. They are interesting reading[38-44].

GIFTS

Gifts are powerful symbols throughout cultures, used to initiate and sustain relationships[1,2,45-57]. This must be understood to appreciate discussion of their potential influence. Gifts are used ubiquitously to seduce and influence physicians. Companies are motivated by profit, not altruism. Gifts cost money. Costs are ultimately passed on to patients without their explicit knowledge or consent. Accepting a gift may contribute to erosion of the perception that the medical profession serves patients' best interests. Acceptance of a gift establishes a relationship between the donor and recipient with a vague but real obligation[1,2,45-57].

Contemporary society has lost sight of the importance of a gift as regulators of human relationships. Offering a gift proffers friendship. Acceptance of a gift initiates or reinforces a relationship. Acceptance of a gift assumes social obligations of grateful conduct, grateful use, reciprocation, and response. While gift-giving is an act of apparent generosity it serves the self-interest of the giver. A special relationship is formed between people who share a fine meal in an atmosphere of conviviality and agreement. Formal contracts can be dissolved, but gift relationships are subtle and less well defined. Remember, companies' ultimate goals are to increase profit to shareholders[1,2,45-57].

Three ethical problems arise for individual physicians with regard to gifts. One is "unjust" practices — spending patients' money without their knowledge to benefit physicians and industry. Another threatens the physician-patient relationship, eroding physicians' fiduciary role of trustee of patients' welfare above all. And the last is the potential to affect physicians' character, disturbing the delicate balance between self-interest and altruism[1,45-57].

A particularly strong editorial was penned in the *New England Journal of Medicine*[40]: "Gifts! I read bribes... I find the statement 'any gift...must leave the doctor's independence...manifestly unimpaired' to be nonsense... from the press, one can get an idea of what it costs to buy a judge or senator — generally thousands of dollars. But you can buy a physician for a pen or pizza and beer...the idea seems to be to stick to bribes that are small enough to be swept under the rug if someone asks...the point is simple. Just as you cannot be a little bit pregnant, you cannot be a partial bribe taker.... I suggest that we simply not be in the take, whatever the amount of context.... I also don't buy that argument that asks, would you be willing to have these arrangements generally known? My motivation comes from within.... The Hippocratic oath states 'in every house where I come I will enter only for the good of my patients'"[11]. Others have agreed[38,39,46].

CAN PHYSICIANS BE BOUGHT, RENTED, OR INFLUENCED?

Many dissenting physicians wrote impassioned responses to the notion that they are susceptible to influence by industry. They are worth noting, as some readers will undoubtedly have similar sentiments. Sample statements have been, "I'm tired of organizations that purport to represent physicians...treating us like we are gullible at best and unethical

at worst. We must be among the 'best and brightest' yet...once we enter practice, we are not bright enough to differentiate between a pharmaceutical sales pitch and a well written and researched journal article.... Professors should spend less time worrying about physicians being brainwashed...and more time getting...accurate information to us so that we can make appropriate, intelligent clinical decisions"[41].

Another similar view was anger at the "underlying (sometimes not so subtle) hypothesis that physicians are mindless idiots who cannot think for themselves and are easily swayed by material incentives into prescribing certain brands of medications to hapless, unsuspecting patients. I recently turned 41 years of age. I can dress myself, go to the toilet without assistance and feed myself without spilling things, and I have a very good idea of what is right and what is wrong.... I resent and am offended that any one person or body of self-professed wise people feel that it is in their mandate to tell me how to run my life, what is ethical and what is unethical. I am quite capable of making decisions related to these matters completely on my own. I am really fed up with pompous know-it-alls painting all physicians with a brush which colors them as...immoral and unethical doughheads who can't think for themselves or act responsibly. For the most part we are well-educated, highly ethical, well-mannered, literate, and worldly human beings. Some of us are actually quite charming as well[42]."

However, considerable evidence is now available that generally and convincingly documents that drug company support, gifts, hospitality, generosity, representatives, and detailing importantly influence physicians' activities[48-69].

WHAT IS THE EVIDENCE?

These data will be briefly summarized (Table 1). A classic study in 1982[65] examined physicians' perceptions of 2 drugs selected for minimal efficacy/uselessness in the scientific literature but which were heavily promoted as being effective for cerebral/peripheral vasodilatation (Vasodilan) and pain (propoxyphene). While 68% of physicians reported that drug advertising was of minimal importance to them in shaping judgments, 71% believed that vasodilators and 49% that propoxyphene were effective. The authors concluded that there was a preponderance of commercial influence over scientific data as a source of drug information.

A nested, case control study investigated physician requests to add drugs to a university hospital formulary[54]. Physicians requesting formulary additions had more drug company interactions (accepted money to attend or speak at symposia or to perform research) than others. These physicians were more likely than others to have requested drugs manufactured by specific companies to be added if they had met with representatives from or accepted money from the companies. Physicians were more likely to request additions from companies with which they interacted. These authors concluded that requests by physicians to add drugs to formularies were strongly and specifically associated with physicians' interactions with companies manufacturing the drugs. Of articles published in the literature, more with drug company support than without drug company support were likely to favor the drug of interest[55].

During the recent calcium channel antagonist controversy, authors supporting calcium channel blockers (96%) were significantly more likely than neutral authors (60%) or critical authors (37%) to have financial relationships with manufacturers. Supportive authors (100%) were also significantly more likely than neutral (67%) or critical (43%) authors to have financial relationships with any pharmaceutical manufacturer[64].

Other studies have shown that significant increases in physicians' prescribing drugs followed all-expenses paid "educational" meetings to luxurious resorts[60]; that physicians who received samples of drugs were more likely to recommend those drugs than physicians not receiving samples[66], that 25% of faculty and 32% of residents reported changing their practices in the preceding year on account of contacts with pharmaceutical representatives and that 20% of faculty and 4% of residents recommended formulary additions at the suggestion of drug representatives[51]; that 30% of chief medical residents said drug representatives were more likely to get access to house staff if they left gifts, 27% asked for gifts, one in 4 never asked for references when discussing products, and one in 10 ranked drug reps as superior to the medical literature, their attendings, and their peers as sources of information[67]; and funding sources introduced bias in CME activities favoring sponsors' products[57]. Other studies have documented that 11% of drug representatives' statements were inaccurate and that 42% of promotional material failed to comply with FDA requirements[61,63].

Table 1. Can physicians be bought, rented, or influenced?[2,47-69]

- Physicians' prescribing habits reflected a preponderance of commercial over scientific influence
- Physicians' requests to add drugs to formularies were strongly and specifically associated with physicians' interactions with companies manufacturing the drugs
- Of articles published in the literature, more with drug company support than without were likely to favor drug of interest
- Authors supporting calcium channel blockers, during a recent controversy, were much more likely to have financial relationships to the manufacturers than other authors
- Significant increases in physicians' prescribing followed all-expenses paid "educational" meetings at luxurious resorts
- Faculty and residents who were surveyed changed their prescribing habits and recommended formulary additions based on contacts with drug representatives
- Funding sources introduced bias into CME programs favoring sponsors
- Some chief residents considered reliability of drug representatives superior to the medical literature
- Not all drug representatives' statements were accurate nor complied with FDA requirements

A recent study[68], accompanied by a provocative editorial[69], suggested that policies designed to limit access of drug representatives during residency did not affect subsequent likelihood of physicians' seeing sales representatives.

WHAT THEN IS THE PROBLEM?

The problem for physicians is considered to be the following: (1) We may be learning much about drug (product) prescribing — our most common activity — from sources that stand to profit from our choices. (2) We may be abdicating our responsibility to educate ourselves impartially. (3) We may be selling access to our young (students, residents, and fellows) when they are most impressionable in exchange for institutional and personal perquisites. (4) We may risk losing the trust of society and our patients through ethically inappropriate relationships that other fiduciaries (i.e., bankers, judges, journalists, or purchasing agents) would not accept. And (5) we may risk inviting outside regulation to curb perceived excesses and costs if we don't do this ourselves[69].

ORGANIZATIONAL ETHICS

Let us briefly examine the moral responsibilities of professional associations. While there is a growing literature about ethical behavior of individual physicians[2], there is substantially less pertaining to the ethics of professional societies. Guidelines for medical organizations have been suggested[1]. These include the following. (1) The organization's mission should be consonant with that of the medical profession generally and should be responsive to patients' welfare, public needs, and high standards of professionalism. Associations should be aware of the dangers of focusing unduly on the economic concerns of members to the detriment of transcendent obligations to our patients and the public. (2) Associations should not be unions. Unions become self-serving and subordinate patients' interests to those of union members. They are probably incompatible with a true professional association. (3) Professional organizations should derive financial support from members' dues. Support from or deals with the health care industry inevitably risk and create unacceptable conflicts of interest. (4) Associations must assure the editorial independence of their publications and journals. (5) Scientific meetings sponsored by professional associations should abide by the preceding guidelines and be free of industry sponsorship, even if offered as unrestricted and for general education purposes. And (6) associations should be governed by bylaws adopted by members, association leaderships should be fully accountable to members. And all association activities and policies should be publicly disclosed. If this were a quiz, the ACR would not score well.

DEVELOPMENT OF AN ACR CODE OF ETHICS

Rationale and Goal

The ACR has been keenly aware of and concerned about these important issues — the pervasiveness of individual physicians' relationships with industry, availability of "gifts," and their threat to (perceptions of) the organization's integrity. The ACR therefore wished to act decisively to affirm its integrity by developing and promulgating a code of ethics. In doing so the ACR has tried to take a leadership position for medicine, certainly rheumatology.

Process

In early 2000, the ACR executive committee, consisting of the officers, charged its ethics subcommittee with addressing issues pertaining to conflicts of interest and with the process of disclosure. The ethics committee readily agreed that relationships with industry were prevalent among ACR physician leadership, that the extant disclosure form needed revision, that the ACR had no definitions of real or perceived "conflicts of interest," that there were no organizational procedures to address real or perceived problems, that the ACR had no code of conduct or ethics, that there were no guidelines for permissible or proscribed activities for physician leadership and staff, and that there were no recommendations to the membership at large regarding ethical issues.

The ethics committee's task was to redress this. We began by assembling and then summarizing and comparing information from a number of other professional societies and organizations. We sought advice from current and past presidents, board of directors members, and journal editors about these matters. The committee members — including Diana Anderson and Karen Kerr, and Drs. Sidney Block, David Hellmann, Ronald Kaufman, Arthur Kavanaugh, Joel Kremer, Nancy Olsen, Paul Romain, Shaun Ruddy, Benjamin Schwartz, and Elizabeth Tindall, all of whom were invaluable contributors to the effort — then deliberated over the course of several conference calls and meetings.

Ethical Approaches

The committee considered differing ethical approaches. These ranged from the position that any real of perceived conflict of interest should absolutely disqualify a member from any leadership position in the ACR to the opposite ethical pole that any relationship was permissible so long as it was disclosed[2,45]. Committee members invested appreciable effort into trying to develop a specific list of acceptable thresholds for relationships of individuals with varying levels of responsibility within the ACR for a variety of potential activities. The paper copies of that broad template filled a large wall, and we quickly realized that we could neither agree on details nor anticipate all possibilities; even were we to reach consensus we would have created a nightmarish document akin to the US tax code or the NCAA rule book, whose implementation would have been overwhelming.

Ten Principles and an Ethical Code

The committee then reached agreement on 10 principles, which follow (please note the heavy biblical symbolism in adopting 10 principles), and from which were derived a code of ethics. These were: (1) The ACR would concede the inevitability of real and potential and perceptions of conflicts of interest and tolerate the resultant discomfort. (2) All physicians and staff in ACR leadership positions must fully and openly disclose all relationships, as must the organization itself. (3) Disclosure information, in a qualitative fashion, must be made available to membership and the public. (4) It was not now — and may not ever be — possible to reach the consensus necessary to prepare a detailed "rule book" of behavior. (5) Adjudication of disclosure information must be made dispassionately. (6) At present this will be done by legal counsel and, if additional perspective is needed, by the immediate past president of the ACR. (7) There should be discussion of real and potential and perceived conflicts of interest on the agendas of meetings. (8) A code of ethics should be developed. (9) The ACR leadership should use case-study exercises for their education, and to facilitate agreement where possible on more specific guidelines. (10) And this entire process should be considered as an evolving one; we anticipate modifications and refinements in the code of ethics and its implementation.

Perhaps the most important initiative was the commitment to prepare a code of ethics for the ACR. Therein are contained the many specifics for which there was ready agreement, including details of the disclosure process. The code was heavily derived from one developed by the American Academy of Allergy, Asthma and Immunology (we plagiarized shamelessly, with permission, of course). Our code consists of several sections — general principles and aspirational model standards of professional conduct; specific, mandatory, enforceable rules of conduct for ACR members; our disclosure policy; a policy for industry gifts; and administrative procedures governing ethical issues. The code may be found on the ACR website (Rheumatology.org). The appended "exhibits" A through E contain those forms used for disclosure processes. This code was adopted by the Board of Directors on March 1, 2001.

Have We Done Enough?

These ethical issues obviously affect not only individuals but also professional organizations and institutions. There is no ethically intrinsically "right" or "correct" course of conduct regarding acceptance of "gifts" or other industry related largesse, their disclosure, and conflicts of interest. As with virtually all ethical decisions, individuals and organizations must make choices based on their own belief systems, character, integrity, sense of morality, and professionalism. Gifts create or enhance social relationships and obligate the recipient. Physicians, however, have duties of nonmalfeasance, fidelity, justice, and self-improvement[2]. Physicians should adhere to professional standards of altruism, accountability, excellence, duty, honor and integrity, and respect for others[70-72]. Organizational behavior should mirror that of its member physicians[1-10,70-72]. The ACR, and its member rheumatologists, have long prided themselves on their exemplary commitment to professionalism, honor, and integrity. Indeed, these have been themes of recent ACR presidential addresses[12,70,71].

The ACR has taken a significant step by initiating the process and the resultant dialogue and reflection leading to the development of a code of ethics. I am proud of the ACR for doing this and proud to have had a part in this. But I think we should do more. The ACR, and its members, should aspire to the highest standards of professionalism. Consistent with this, therefore, it is my personal view that the ACR staff and leadership should be expected to have no relationships, however trivial, with any industrial, commercial, political, or other sources. This would preclude any real, potential, or perceived conflict of interest. I believe this is the most ethically appropriate position. The ethics committee and the ACR should espouse that the ACR and its leadership follow a "higher standard," like Hebrew National Food products, which "answers to a higher authority." As a recent ACR board member stated, should not ACR leadership serve as a moral compass for the organization and its members?

There are rationalizations advanced that such a course may be more than is done in other professional organizations, will be difficult, will be problematic for leadership, will make it harder to identify organizational leaders, will be naively impractical or unrealistic, and that therefore such a proposed ethical standard should be compromised. In fact this was the reality in the development and adoption of the ACR Code of Ethics. I consider, however, that a policy of "just say no" would be a relatively clear and easy approach to adopt and utilize, and would be the most acceptable ethically. Problems would indeed result from a stricter standard but they could be surmounted, perhaps not always simply, but they would be amenable to solutions and the ACR would be stronger for it.

What about the ACR as an organization? I have thought about this at length, discussed this with past and present ACR (and other) leaders, and stared at these pages for many hours. I would like to be able to rationalize the ACR's policies for industry relationships from an ethical perspective, but I cannot, even though most are intended to promote effects we believe will benefit our patients. It is therefore also my view that ideally and in conformity with highest ethical and professional standards the ACR too, as its leadership, should have no relationships with industrial, commercial, or political sources. Having served the ACR in many leadership capacities over the years I appreciate keenly how difficult it would be for the ACR to function in

the manner I suggest. But from the prism of ethics I really see no other acceptable position. Perhaps others can. And perhaps others will consider that other issues — not necessarily a rather strict ethical position — are more important or expedient ACR priorities, that there may be a greater ACR "good" that trumps or transcends pure ethics.

The alternative to a simple, strict standard, it seems, may be a complex patchwork of guidelines, that will require careful, time-consuming documentation, interpretation, and monitoring; this would not ultimately eliminate potential conflicts of interest, only reduce their magnitude, and would not really satisfactorily resolve the ethical dilemma the ACR confronts. And such a compromise response misses the point. There really should not be degrees of relationships, or gift acceptance, or ethical behavior. As Kassirer exhorted us to meaningful professional accountability[10] so too should we be truly high principled, not "pseudo"-ethical. Sustaining high standards[1] is not necessarily easy, as we know from personal experience. The arguments against a higher standard are reminiscent of the story of the Hollywood mogul who could not entice Tallulah Bankhead to bed for $100 but piqued her interest when offering a considerably larger sum; he then remarked "We have already established what you are; the only thing we are quibbling about is your price." A philosopher in Bertolt Brecht's *Galileo* asks, "Why should we go out of our way to look for things that can only strike a discord in the ineffable harmony?" The answer is, sometimes we must, in order to affirm and uphold those values we cherish. Just say no.

SUMMARY

Medicine and industry have a special relationship. In many instances our interests are concordant and our interactions mutually beneficial. There are areas, however, where potential ethical and professional conflicts arise. Such an area is industry gifts and relationships. Gifts and relationships obligate. Acceptance of "gifts" or industry/commercial benefit(s) assumes obligations of grateful conduct, grateful use, reciprocation, and response. Increasing and compelling data document that industry support, gifts, hospitality, generosity, and other contributions clearly influence physicians. Physicians aspiring to the highest standards of professionalism will consider these issues in their personal conduct. Physicians with leadership responsibilities, and the organizations they serve, will eschew gifts and relationships and their inevitable conflicts. While these issues may seem difficult, I suggest they are really rather simple. As this is a time when so much is commercialized, when so much is for sale, when so little public confidence is left in our once noble profession, there is before us an opportunity to not compromise our ethics or our integrity, but rather assert the highest possible standards of professionalism, to remember that we serve our patients, and to champion their welfare. We should certainly not be for sale, not even for rent. We should say an emphatic "no." We should affirm our honor and integrity.

The sages wrote "there are three 'crowns' (symbols of earthly accomplishment, stature, dignity, and respect): that of learning, that of priesthood, and that of royalty; but the 'crown' of a good name is the most exalted of all" (Talmud. Avot 4: 17). Let us individually and together, as the ACR, have a good name. Just say no.

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