

MEDICAL ETHICAL CONSIDERATIONS IN COLLABORATIVE RESEARCH

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I. INTRODUCTION

The purpose of research should be to generate new knowledge that has potential to benefit society. Thus, there will be many views of what constitutes a benefit. A scientist would probably be satisfied with the discovery of a new bit of information that helped explain something. That “something” may be perceived by existing science as insignificant, in the same way the formula for relativity was once thought to be insignificant. Of course, this formula led to the scientific understanding of atomic energy. A benefit of research to a patient might be a cure for a fatal disease or a pill that treats a disease but has fewer side effects. A drug company may look at research as that which leads to any new information allowing for increased sales and greater profit for the company and its stockholders.

In a free society that has as one of its fundamental concerns the creation of new knowledge, the scientist should be allowed to explore ideas and to labor in an environment that facilitates the effort. It is obvious that not all of the work of scientists will lead to the creation of new knowledge, nor to a product that makes money. Thus, a fundamental conflict exists between society, with its desire for new knowledge, and the responsibility of a drug company to make a profit. Not all medical research leads to a profitable outcome. If profit determines the research projects that will be funded, it is likely that the research that leads to discovery will be jeopardized. This is because most research does not lead to discovery. In our present predicament of a decrease in new molecules—otherwise known as a “drying up” of the pipeline—a very likely cause is the control of university and government laboratories by industry. Industry does not have a social covenant with society to create new knowledge that does not yield a profit; its responsibility is to its stockholders. On the other hand, government does have a responsibility to society, which is abjured when business interests take control.

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No individual player in this complex game is looking to do something wrong; the problem is that there are too many conflicts of interest that have emerged with the commercialization of medical research. This Article will explore the bases of these conflicts and the problems that have been created for society. Conflicts of interest exist between scientists, both medical and non-medical, physicians, the medical profession, the pharmaceutical industry (as one example of business), and government.

Defining medical science and the profession of medicine will facilitate a clearer understanding of the bases for the conflicts of interest and the consequential changes that are occurring that may not benefit society.

II. MEDICAL SCIENCE

Let us start with medical science and the questions that relate to how new scientific knowledge is created.¹ This Article will not discuss in detail the various theories and divergent views regarding the history or philosophy of science, discovery or creativity.² However, some observations seem pertinent. For science to progress there needs to be freedom to discover new truths that replace old truths. New knowledge may come in small increments or with major discovery. A scientist working in pursuit of new knowledge will rarely, if ever, be able to predict the certainty of discovery, nor the time that the labor will take. Some believe that it was Einstein's genius that led to the formulae for relativity, while others point out the base of knowledge discovered by others before him that allowed for his incremental addition to knowledge.

An important question to answer in order to understand the impact that industry has had on medical science is: What has been the effect of

1. See generally GEORGE SARTON, A HISTORY OF SCIENCE (1952) (discussing historical advances in scientific history); 2 HENRY E. SIGERIST, A HISTORY OF MEDICINE (1961) (studying the "development of Greek and Indian medicine").

2. See, e.g., FRANCIS BACON, ADVANCEMENT OF LEARNING 21-23 (Joseph Devey ed., Am. Home Library Co. 1902) (1605) (rejecting the use of induction, rather than syllogism, in pursuing scientific thought); J.B. BURY, THE IDEA OF PROGRESS: AN INQUIRY INTO ITS ORIGIN AND GROWTH 1-2 (1932) (presenting the theory of "Progress of humanity" as the basis for human advancement); 2 THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS 6 (2d ed. enlarged 1970) (proposing that scientific advancement takes place in the form of "scientific revolutions"); LAURENCE B. MCCULLOUGH, JOHN GREGORY AND THE INVENTION OF PROFESSIONAL MEDICAL ETHICS AND THE PROFESSION OF MEDICINE 4 (1998) (discussing John Gregory's contribution of the "concept of medicine as a fiduciary profession"); KARL R. POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 27 (Routledge 1980) (1952) (discussing the problems of the "methods of empirical sciences").

its control of the medical science environment and of its financial reward structure? Has it created a negative impact? If it has, then this would be a possible explanation for the decline in creativity—though not necessarily productivity, at least with respect to quantity—at our university and government laboratories. The incremental increase in knowledge continues, but the quality declines. We produce more “me-too” drugs and fewer “breakthrough” drugs.³ The pipeline is dry.

The need for business, government and the profession of medicine is that they each do their own job and not try to assume control of another's. As separate entities serving society we have social balance; as merged entities we have societal dysfunction.⁴

III. THE PROFESSION OF MEDICINE

The profession of medicine has been a dynamic entity that has changed throughout history. It is important to understand the relevant history as it relates to those values and characteristics that are essential elements of medicine as a profession. These values are those that created trust between physician, patient and society.⁵ Guild members with knowledge and skill were needed by the vulnerable and were to be trusted only if they used that knowledge and skill in a manner that was in the best interest of the patient. Also, society expected that guild members establish standards or codes for their group to govern both technical and ethical behavior. And finally, a guild would be considered a profession if it served the needs of society.⁶ Over many hundreds of years, these relationships—physician and patient, physician and society and physician and physician—have changed.⁷ It is imperative that any discussion of the profession of medicine elucidates those values and characteristics that are fundamental.⁸ Technical and ethical competencies

3. U.S. GOV'T ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 2 (2006).

4. See ELLIOTT A. KRAUSE, DEATH OF THE GUILDS: PROFESSIONS, STATES, AND THE ADVANCE OF CAPITALISM, 1930 TO THE PRESENT 280-84 (1996).

5. See, e.g., *id.* at 12-14 (stating that university guilds, including doctors' guilds, “held onto their power over membership, training, and workplace” because capitalism did not interfere with the profession and “the cultural prestige of knowledge itself helped keep the [university guild] alive while all other guilds failed”); see also Everett C. Hughes, *Professions*, in ETHICAL ISSUES IN PROFESSIONAL LIFE 31, 31 (Joan C. Callahan ed., 1988) [hereinafter ETHICAL ISSUES].

6. Bernard Barber, *Professions and Emerging Professions*, in ETHICAL ISSUES, *supra* note 5, at 35, 36; Michael D. Bayles, *The Professions*, in ETHICAL ISSUES, *supra* note 5, at 27, 28.

7. See KRAUSE, *supra* note 4, at 12-13, 36-49, 281.

8. See, e.g., ELIOT FREIDSON, PROFESSION OF MEDICINE: A STUDY OF THE SOCIOLOGY OF APPLIED KNOWLEDGE 5, 71-73 (1970) (theorizing that major characteristics of medicine as a profession include a kind of unquestioned expert authority, as well as autonomy—the right to self-

are at the base of any foundation for a profession of medicine. Technical competence requires establishment of standards through training, continued education and evaluation of competence. Our task here is to make clear the ethical imperatives that exist as a result of the relationship between society and medicine,⁹ and that require continued attention. Without the specific ethical competencies that have enabled medicine to become a profession, the tenuous relationship between medicine and society could result in the return of medicine to being a craft guild. Professionalism will exist if all interactions by a profession, its professionals, its patients and society are consistent with the accepted values of a profession.

The essential characteristics of the medical profession include: 1) “a calling requiring specialized knowledge and often long and intensive academic preparation”;¹⁰ 2) “a collectivity or service orientation”;¹¹ and 3) professional autonomy, derived from societal needs.¹² Michael Bayles gives a more detailed definition of a profession. The three necessary features are:

First, a rather extensive training is required to practice a profession.

Second, the training involves a significant intellectual component[;] . . . providing advice rather than things is a characteristic feature of the professions.

regulation, made possible by the profession’s “relationship to the knowledge and values of its society”); Hughes, *supra* note 5, at 31-32 (emphasizing the “exclusive right to practice” and a “claim to esoteric knowledge and high skill”); EDMUND D. PELLEGRINO, *The Medical Profession as a Moral Community*, 66 J. URB. HEALTH 221 (1990), *reprinted in* PHYSICIAN AND PHILOSOPHER 205, 205, 209 (2001) (asserting that the medical profession has a moral obligation to the sick, rooted in basic aspects of medicine that distinguish it from other professions, including “the inequality of the medical relationship, the nature of medical decisions, the nature of medical knowledge, and the eradicable moral complicity of the physician in whatever happens to his patient”).

9. *See id.* at 210 (discussing the unique ethical obligations of the medical profession, which exist in part as a consequence of the fact that “physicians are granted a monopoly over medical knowledge”).

10. MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 991 (11th ed. 2003); SIGERIST, *supra* note 1, at 305; William J. Goode, *The Profession: Reports and Opinion—Encroachment, Charlatanism, and the Emerging Profession: Psychology, Sociology, and Medicine*, 25 AM. SOC. REV. 902, 903 (1960).

11. *Id.*; *see also* BACON, *supra* note 2, at 193 (asserting that physicians are “honored [not] only for necessity, but [also] as dispensers of the greatest earthly happiness that could well be conferred on mortals”); Barber, *supra* note 6, at 36.

12. FREIDSON, *supra* note 8, at 23-25, 72-73; Edmund Pellegrino, *Beneficence, Scientific Autonomy, and Self-interest: Ethical Dilemmas in Clinical Research*, 4 CAMBRIDGE Q. HEALTHCARE ETHICS 361, 361-69 (1992), *reprinted in* PHYSICIAN AND PHILOSOPHER, *supra* note 8, at 197 (discussing the need for adherence to the principle of “autonomy in trust” with regard to clinical research).

Third, the trained ability provides an important service in society[.] . . . important to the organized functioning of society.¹³

Other important characteristics of a profession that are considered to be less essential include: licensing by society, acting in the best interest of patients rather than self, and adherence to a code of ethical behavior, which is a requirement for membership in a voluntary organization that represents the profession.¹⁴

Medicine continued to separate itself from other knowledge-based crafts when religious groups in the Middle Ages took responsibility for the education of the clergy, lawyers and physicians.¹⁵ These became the “learned” professions. Subsequently, society became more secular with the emergence of universities. Medicine became integrated within the university structure and became a profession with a religious and educational foundation. “Among the traditional professions established in the European universities of the Middle Ages, [medicine] alone has developed a systematic connection with science and technology.”¹⁶

As societies formed into more complex political entities, laws were enacted that established the medical profession as a legal entity with special privileges. Throughout history, medicine was defining itself as a profession. Edmund Pellegrino notes:

Non-Christian physicians in the ancient world and middle ages—Egyptian, Hebrew, Moslem, Indian, and Chinese—were also members of moral communities each with its own religious or quasireligious binding force. What is remarkable is the congruence of ethical precepts among physicians who held widely disparate world-views. This suggests something intrinsic to the morality of medicine as a human activity that in some way transcends culture, religion, and historical era.¹⁷

Professionals during the Middle Ages were mostly members of craft guilds, and it was the rise of the university that enabled medicine and law to become “scholarly” guilds and thereafter to separate from the craft guilds.¹⁸ This fortuitous association led to legal and political protection from the economic forces of capitalism. Most of medical care rested in small towns and it was the growth of cities, the growth of hospitals and the explosion of technological advances that changed

13. Bayles, *supra* note 6, at 28.

14. *See id.*; *see also* Barber, *supra* note 6, at 36; Hughes, *supra* note 5, at 31.

15. *See* VERN L. BULLOUGH, THE DEVELOPMENT OF MEDICINE AS A PROFESSION: THE CONTRIBUTION OF MEDIEVAL MEDICINE TO MODERN MEDICINE 36-39 (1966).

16. FREIDSON, *supra* note 8, at xviii.

17. PELLEGRINO, *supra* note 8, at 207.

18. *See* BULLOUGH, *supra* note 15, at 46-48.

medicine, such that it required more sophisticated and detailed social arrangements.¹⁹

The balance of power between the professions, business and government remained favorable for the medical profession until the mid-twentieth century. The ethical basis of the profession of medicine remained the same throughout this period of seismic social change.²⁰ Being part of a learned profession, a physician had to act in the best interest of the patient and maintain technical competence.

In part, the segue to the present is the change from a profession comprised of individuals to a profession comprised of a group. As noted by Everett Hughes, it was the collective nature of the promise that set the stage for social value.²¹ The collective nature required that the group take a collective oath:

Oaths embody a distinctive form of ethics. They are activated by the performative utterance “I swear” and are couched in the first person singular. All these features make them inherently personal. Codes, by contrast, are collaborative. The transition from the personal ethics of oaths to the professional ethics of codes thus marks a radical transition from personally interpreted “gentlemanly” ethics to collaboratively interpreted professional ethics [This radical transition] was conceived in Britain and born in America.²²

John Gregory, Samuel Bard and Benjamin Rush clarified the responsibilities that physicians have had to patients.²³ Thomas Percival took these responsibilities from the purview of individual physicians and placed them onto the shoulders of a profession.²⁴ The British physicians opposed the move away from personal responsibility and it remained for physicians in the United States to embrace Percival’s ideas. Physicians in New Jersey and Boston accepted this changing view about medical ethics, indicating:

[P]rofessional conduct was not a function of personal character; it was rather a set of “laws” stipulated by the society to which practitioners were bound by “tacit compact . . . to submit.” The move from an ethics

19. *See id.* at 108; PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 71-72 (1982).

20. Eliot Freidson, *Professionalism and Institutional Ethics*, in *THE AMERICAN MEDICAL ETHICS REVOLUTION: HOW THE AMA’S CODE OF ETHICS HAS TRANSFORMED PHYSICIANS’ RELATIONSHIPS TO PATIENTS, PROFESSIONALS, AND SOCIETY* 124, 129-30 (Robert B. Baker et al. eds., 1999) [hereinafter *ETHICS REVOLUTION*].

21. Hughes, *supra* note 5, at 32.

22. *ETHICS REVOLUTION*, *supra* note 20, at xiii-xiv.

23. *See id.* at xv (observing that these roles of the physician and surgeon in light of their fiduciary relationship to patients were “standard eighteenth-century medical school material”).

24. *See id.* at xv-xvi.

of character to one of conduct was thus an extension, in the social sphere of medicine, of the American ideological commitment to egalitarian democracy; for it meant that all persons were treated as moral equals.²⁵

The early twentieth century saw the medical profession gain status through improved education²⁶ and the advent of state licensing that improved the industry's social position and autonomy.²⁷ Two other forces came into play beginning in the 1930s: One was the increased presence of hospitals and the other was the intrusion of corporate thinking into medicine. In addition, several laws were passed that altered medicine in many unforeseen ways. These include antitrust laws,²⁸ the Medicare Act,²⁹ and the HMO laws.³⁰ It has been argued that these types of changes to the organization and management of the medical profession contributed to the deprofessionalization, proletarianization and corporatization of American medicine.³¹ Another force that engendered the marginalization of the medical profession was the increased use of insurance to pay for healthcare. Since many healthcare costs can be controlled, either by the insured, or by physicians and hospitals, "which may profit from additional services and raise prices as the patient's ability to pay increases," there has been "difficulty in

25. *Id.* at xxiii.

26. See Rosemary A. Stevens, *The Challenge of Specialism in the 1900s*, in *ETHICS REVOLUTION*, *supra* note 20, at 70, 71 ("[I]n 1910 . . . Abraham Flexner published his devastating critique of [medical] schools, thus affirming and strengthening the AMA at a critical stage of its development.") (citing ABRAHAM FLEXNER, *MEDICAL EDUCATION IN THE UNITED STATES AND CANADA: A REPORT TO THE CARNEGIE FOUNDATION FOR THE ADVANCEMENT OF TEACHING* (1910) (criticizing medical education and recommending improvements)).

27. See FREIDSON, *supra* note 8, at 21.

28. See STARR, *supra* note 19, at 305 (discussing the negative impact of the Sherman Antitrust Act on "cooperative medicine"); see also *Am. Med. Ass'n v. United States*, 317 U.S. 519, 526, 536 (1943) (affirming the conviction against the AMA for violating section 3 of the Sherman Act by attempting to obstruct a nonprofit medical care organization that utilized a "risk-sharing prepayment" business model).

29. Health Insurance for the Aged Act (Medicare Act), Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at scattered sections of 42 U.S.C.); see also KRAUSE, *supra* note 4, at 43-44.

30. Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (codified as amended at 42 U.S.C. §§ 300e to 300e-14 (2000)).

31. See Donald Light & Sol Levine, *The Changing Character of the Medical Profession: A Theoretical Overview*, 66 *MILBANK Q.* 10, 11-19 (Supp. 2, 1988) (explaining deprofessionalization argument that as "professionals' decisions are subject to lay questioning, . . . challenges to expert authority and autonomy can be expected to occur with increasing frequency;" discussing proletarianization concept that the market power of physicians declines as "physicians take salaried positions in bureaucratic organizations where regulatory norms and administrative hierarchy shape the delivery of medical care"; and defining corporatization as "the experience of being subjected to forms of corporate control—such as utilization and quality review, incentive pay structures, restrictions on practice patterns and the organization of practice").

controlling costs in health insurance,” and consequently, “insurers cannot estimate their probable costs and the insurance itself may increase the losses—a problem known as . . . ‘moral hazard.’”³² All of these social and legal occurrences placed constraints on the doctor-patient relationship and reduced a physician’s ability to act as an agent of the patient. Elliott Krause notes the balance that is desirable between government, capitalism and the professions.³³ With the social changes noted above, one might conclude that medicine, as a profession, was the loser. However, the patient may be the real loser in this struggle.³⁴

IV. THE PRESENT STATE OF THE PROFESSION OF MEDICINE: THE CHALLENGES

The present challenges are due to the noted changes in the laws that govern us, the economic basis of medicine—healthcare insurance—and the advances in medical technology—cost. We now face the high cost of medicine due to technological advances; increased cost and utilization of drugs and technology; and profit-driven elements of healthcare, in which hospitals, both for-profit and not-for-profit, and private corporations control the insurance products made available to the public. Additionally, a growth in the aged population and the higher cost of federally controlled programs such as Medicaid and Medicare have caused an increase in the utilization of healthcare services.³⁵ The increased cost of medical care has led to new laws that authorize the development of “managed” healthcare entities that are profit-based, and has created enormous profits for insurance companies that entered this field early. The failure of “managed” care has been well-documented.³⁶ We now see further potential markets for profiteering with private stand-alone drug plan (Part D) benefits for Medicare beneficiaries.³⁷ The

32. STARR, *supra* note 19, at 290-91.

33. KRAUSE, *supra* note 4, at 46-49, 285-86.

34. *See id.* at 285-86.

35. *See, e.g.,* SHEILA DELANEY MORONEY, NAT’L INST. OF HEALTH POLICY, UNDERSTANDING HEALTH CARE COST DRIVERS (2003), available at http://www.bluecrossmn.com/bc/wcs/groups/bcbsmn/@mbc_bluecrossmn/documents/public/mbe1_healthcare_cost_drivers.pdf. Moroney cites evidence, for example, that (i) “the more providers there are in a given area, the higher the use of medical services and technology”; (ii) technological advances lead to increased utilization; (iii) technology is a cause of growing hospital costs; and (iv) “[m]edical costs will continue to rise because of [a] new cohort of aging patients.” *Id.* Part II(A)-(E). *See also* NAT’L COAL. ON HEALTH CARE, BUILDING A BETTER HEALTH CARE SYSTEM: SPECIFICATIONS FOR REFORM 5-7 (2004) [hereinafter BETTER HEALTH CARE].

36. *See, e.g.,* *What Could Have Saved John Worthy? Case Study Analyzing Decision Making in Managed Care Health Plans*, HASTINGS CENTER REP. (Supp.), July 1, 1998, at S1 (analyzing a case that illustrates some of the shortcomings of the managed care system).

37. *See* Joseph P. Newhouse, *How Much Should Medicare Pay for Drugs?*, 23 HEALTH AFF.

intrusion of business—Wall Street—and government into healthcare has not solved the major problems that our society now faces. The increased “out-of-pocket” expenses for, and the decreased access to, healthcare remain vexing issues in a democratic society.³⁸

The Accreditation Council of Graduate Medical Education (“ACGME”) has made professionalism a major component of the new core competencies for resident education.³⁹ The values enumerated include being respectful, altruism, and sensitivity to cultural, age, gender and disability issues. The American Board of Internal Medicine (“ABIM”) defines the “core of professionalism” as “constituting those attitudes and behavior[s] that serve to maintain patient interest above physician self-interest.”⁴⁰ The ABIM lists the elements of professionalism as “altruism, accountability, excellence, duty, service, honor, integrity, and respect for others.”⁴¹ And the new Charter on Medical Professionalism has three principles and ten commitments.⁴² These commitments could be fit into the classic triad of fiduciary responsibilities that physicians have had for more than a thousand years; they are the covenants with patients, with society and with colleagues. The changes in healthcare also force us to consider alternate views of “new concepts of professionalism” where it is encouraged that physicians “recognize constraints and include patient advocacy within a framework of procedural justice, responsibility for population health, new patient partnerships, and participation in an evidence-based culture.”⁴³ What is being asked is that physicians deal with the dilemma of either being advocates for particular patients or being advocates for all patients.⁴⁴

89, 89, 93 (2004) (noting that because prices for Medicare drugs on patent are typically well above marginal production costs, manufacturers have powerful incentives to spend money on marketing and to sell additional quantities of drugs, but cautioning that such incentives may invite abuse).

38. See BETTER HEALTH CARE, *supra* note 35, at 8-10; National Coalition on Health Care, Facts on Health Care Costs 1-3, <http://www.nhc.org/facts/2007%20updates/cost.pdf> (last visited Mar. 27, 2007).

39. See ACGME: Mission, Vision and Values, http://www.acgme.org/acWebsite/about/ab_mission.asp (last visited Mar. 12, 2007) (explaining that the mission of the ACGME is to “improve health care by assessing and advancing the quality of resident physicians’ education through accreditation” and that “ACGME [v]alues are manifest” through, *inter alia*, professionalism).

40. AM. BD. OF INTERNAL MED., PROJECT PROFESSIONALISM 2 (7th prtg. 2001).

41. *Id.* at 5.

42. See Harold C. Sox, *Introduction to Medical Professionalism in the New Millennium: A Physician Charter*, 136 ANNALS OF INTERNAL MED. 243, 243 (2002).

43. David Mechanic, *Managed Care and the Imperative for a New Professional Ethic*, 19 HEALTH AFF. 100, 101 (2000).

44. *Id.* at 104 (noting the dilemma faced by physicians is “how to fairly represent patients’ interests while distributing care equitably to a population”).

Many authors have moved the discussion of physician competence beyond being ethical to being professional.

V. PROFESSIONALISM IN MEDICINE

It is necessary to appreciate the environment in which physicians deliver healthcare to understand the difficulties in maintaining professionalism in medicine. Is medicine just a business? Should medicine yield to social forces and not be a profession? Why do we need a profession? Is it of any benefit to society for medicine to be a profession?

Alignment must exist between society (government), medicine (all healthcare providers) and professional organizations and patients in order to achieve an effective profession. All must act in the best interest of those who are vulnerable and seek healthcare.

A professional medical organization must present itself as aligned with the fundamental ethical tenets of the profession of medicine and not aligned with the commercial interests of corporations. They must be perceived as facilitating physicians' roles as agents of patients and regulating the technical and ethical behavior of its members. It also must help form the "moral community" as described by Pellegrino and recently by Arnold Relman.⁴⁵ The enticements of industry must be resisted so that the profession is not seen as working for industry. John Abramson, Marcia Angell, and others have detailed the depth of the loss of academic and professional freedom.⁴⁶ The loss of academic freedom is a loss to society. We no longer are creating knowledge; we are participating in creating a profit for a corporation. The profession of medicine has become party to the corporatization of medicine and the loss of professional freedom means that we can no longer act as the agent of our patients.⁴⁷ We, physicians, become de facto employees of industry. Our professional organizations need to be stewards of the promise that was made and safeguard our primary obligations to the

45. See Edmund D. Pellegrino & Arnold S. Relman, Commentary, *Professional Medical Associations: Ethical and Practical Guidelines*, 282 JAMA 984, 984 (1999).

46. See JOHN ABRAMSON, OVERDOSED AMERICA: THE BROKEN PROMISE OF AMERICAN MEDICINE 93-110 (2004); Marcia Angell, Editorial, *Is Academic Medicine for Sale?*, 342 NEW ENG. J. MED. 1516, 1516-18 (2000); David Blumenthal, *Academic-Industry Relationships in the Life Sciences: Extent, Consequences, and Management*, 268 JAMA 3344, 3344-46 (1992); Howard Brody, *A Matter of Influence: Changing Times Call for Changing Policies on the Presence of Drug Company Reps in the Residency Programs*, 21 HEALTH AFF. 232, 232-33 (2002).

47. See Blumenthal, *supra* note 46, at 3344, 3346; Brody, *supra* note 46, at 232-34; see also Financial Disclosure: American Academy of Ophthalmology ("AAO"), <http://www.aao.org/aao/member/financialdisclosure.cfm> (last visited Mar. 27, 2007) (stating that the AAO requests financial disclosure from "meeting presenters, authors, contributors or reviewers").

patient and to society.

The organizations that represent physicians have many responsibilities that are specific to the issues of the times. One recent example is physicians' conflicts of interest.⁴⁸ Thus it is imperative that the behavior of physician organizations adheres to the same ethical standards by which it asks its members to abide. Another is the concern over academic freedom. The pervasive influence by the biotech and pharmaceutical industries on educational and research programs is a potential source of social distrust of the medical profession.⁴⁹ Finally, professional organizations must represent the interests of both physicians and patients before the government. This requires active participation in the political process.⁵⁰

The importance of physicians' participation in their professional organizations cannot be overemphasized. The effectiveness of any organization can be determined by knowing whether members are merely "check-writing" members or members who actually attend meetings and are an active voice.⁵¹ Whether efforts are local, national or international, the impact on the ability to be seen by society as part of a "moral community" cannot occur in absentia. Also, inherent in the concept of social capital is participation. Couch potatoes do not help organizations. Ethics is not achieved without human interactions.

The place of a physician in healthcare has changed over millennia, from priest to scientist to partner. The changing complexities of healthcare (technical, economic and political) have created circumstances that appropriately forced changes within the profession of medicine. Physicians must adapt to the needs of society and, importantly, do so in a manner that allows it to maintain the essential standards and values of a profession. Recently, the increasing focus on

48. See generally Jerome P. Kassirer & Marcia Angell, Editorial, *Financial Conflicts of Interest in Biomedical Research*, 329 NEW ENG. J. MED. 570 (1993) (analyzing the effects of financial conflicts of interest on biomedical research and critiquing the policies used to handle disclosure of such conflicts); see also Catherine D. DeAngelis, Editorial, *Conflict of Interest and the Public Trust*, 284 JAMA 2237 (2000) (introducing articles addressing the prevalence of conflicts of interest between physicians and companies that financially support teaching and research, along with the effects of this relationship on public trust of physicians); David Korn, Commentary, *Conflicts of Interest in Biomedical Research*, 284 JAMA 2234 (2000) (discussing the ramifications of financial conflicts of interest in biomedical research on research participants and the credibility of academic institutions, and proposing initiatives for managing such conflicts of interest).

49. See Angell, *supra* note 46, at 1518; Blumenthal, *supra* note 46, at 3344, 3346; Brody, *supra* note 46, at 233-34.

50. See THE PROFESSION OF OPHTHALMOLOGY: PRACTICE MANAGEMENT, ETHICS, AN ADVOCACY 277-79 (David W. Parke II et al. eds., 2005); PELLEGRINO, *supra* note 8, at 212-13.

51. ROBERT D. PUTNAM, BOWLING ALONE: THE COLLAPSE AND REVIVAL OF AMERICAN COMMUNITY 52 (2000).

technical competence has threatened the importance of ethical competence. The medical profession has achieved significant improvements in curing, but not in caring. Unethical behavior by some physicians (certainly not a large percentage) has threatened the trust that is required for medicine to remain a profession.⁵² Unethical behavior has always been a burden to medicine and society. Examples include false advertising,⁵³ conflicts of interest,⁵⁴ and inadequate informed consent.⁵⁵ Disclosure, albeit necessary, is frequently an appropriate legal answer, but often an inadequate answer to the ethical mandates of a profession. The patient is vulnerable and seeks an agent who will act in his best interest. Expecting patients to understand the nuances of financial relationships between physicians and industry is naïve; patients expect honesty and not “dual agency.”⁵⁶ Industry has permeated the medical world—doctors’ offices, academic medical centers and government research laboratories.⁵⁷ If all of these groups are directly or indirectly “agents” of industry, not only will patients suffer, but patients will get only that care that supports the “bottom line” of industry. Corporations are fiduciaries of their stockholders. Universities and government research laboratories are supposed to create new knowledge that will benefit society. Physicians must act as professionals within these

52. See, e.g., Blumenthal, *supra* note 46, at 3346. Blumenthal describes a case involving a research fellow at Harvard’s Massachusetts Eye and Ear Infirmary who “benefited substantially from selling his holdings in a private company established to market a new drug he was testing in clinical trials” and whose later unpublished work showed the drug to be ineffective and raised questions about whether the investigator’s patients had suffered any adverse effects as a consequence of his conflicts of interest. *Id.* He was “found to have violated university procedures, including those governing protection of human subjects,” and it was noted that such “real or apparent conflicts of interest . . . can be damaging to public reputation of the health sciences, even when no evidence of misconduct or even any bias can be documented.” *Id.*

53. See Pilar Villanueva et al., *Accuracy of Pharmaceutical Advertisements in Medical Journals*, 361 LANCET 27, 27 (2003).

54. See *supra* notes 47-48 and accompanying text.

55. See, e.g., James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants’ Understanding in Informed Consent for Research: A Systematic Review*, 292 JAMA 1593, 1593 (2004) (pointing to studies that have revealed instances of shortfalls in informed consent, including a randomized trial of a drug to prolong the lives of patients with a history of myocardial infarction in which forty-four percent of research participants were not informed that they were assigned by chance to placebo or treatment).

56. See ABRAMSON, *supra* note 46, at xiv (“[M]any of the mechanisms that Americans trust to protect their health . . . have been dismantled by political pressure from doctors and medical industry lobbyists, while others have become absurdly dominated by people with financial ties to the pharmaceutical companies—a situation that no impartial observer would ever conclude was designed to represent anything other than corporate interests.”); see also MARCIA ANGELL, *THE TRUTH ABOUT DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* 127 (2004); E. HAAVI MORREIM, *BALANCING ACT: THE NEW MEDICAL ETHICS OF MEDICINE’S NEW ECONOMICS* 2, 47, 77 (1991).

57. See Angell, *supra* note 46, at 1516-18.

environments and not abjure the professional obligations that they profess.

Pellegrino would have our future center around the formation of a moral community “whose members are bound to each other by a set of commonly held ethical commitments and whose purpose is something other than mere self-interest.”⁵⁸ The antithesis of acting in the patient’s best interest is acting in one’s own best interest when the patient’s interests are conflicted.⁵⁹

The role of the patient is an oft forgotten key component to any solution to problems in healthcare and professional medicine cannot be sustained without the participation of patients. The classic dyad of patient and physician has been altered by government and business interests becoming incorporated into the delivery of healthcare. A basic ethical concern relates to foundational social concepts of how people are to live together and a major precept has been that with every right given by society comes corresponding individual responsibility. If patients do not accept responsibilities for their care then the other players in healthcare will be ineffective or less effective and, most certainly, care will be more costly. Patients must be their own advocates and work with physicians who are to act as agents for providing care. This includes patient responsibility and physician agency for economic issues. Neither should game the system.⁶⁰

VI. THE FUTURE OF PROFESSIONALISM IN MEDICINE

It is always too early to predict the future. Participation by physicians in three areas will be necessary: with patients, with society and with colleagues through professional organizations. “The concept of a profession is a slippery one that is not entirely fixed in our conceptual geography.”⁶¹ Michael Bayles, Everett Hughes and Bernard Barber “suggest that we understand professions as occupations which have certain shared characteristics, and that whether or not an occupation is more or less professionalized depends on how thoroughly it manifests these characteristics.”⁶² Also, Hughes points out “that genuine professionalism often involves a sense of having a ‘calling’ or vocation and being part of a community.”⁶³ Moreover, some commentators note: “Professionalism does indeed go beyond ethical principles, accounting

58. PELLEGRINO, *supra* note 8, at 208.

59. *See infra* Part VII.

60. *See* MORREIM, *supra* note 56, at 3, 72, 76-87.

61. ETHICAL ISSUES, *supra* note 5, at 26.

62. *Id.*

63. *Id.* at 27.

for competency and commitment to excellence and, most of all, implying a virtue ethics account of medical practice.”⁶⁴ The underlying concepts of how society is to function and the political nature of decision-making in a democracy create layers of complexity in the arguments regarding healthcare. Simple appeal to a basic ethical tenet, such as autonomy, will not suffice. Nor is it hoped that decisions regarding important social issues will turn on a politician’s prospect of personal gain. The need for the incorporation of ethical dialogue seems intuitive when dealing with healthcare issues.⁶⁵ The value of medicine to society hinges on the efforts by physicians, by government and by business to maintain medicine as a profession. After all, “[h]ealing is something more than a commodity transfer.”⁶⁶

The professionalism effort advanced by organized medicine must be augmented by a similar effort by all those involved in healthcare. Physicians and other healthcare providers will need to be able to function in an ethical and virtue-driven environment. Thus, organizations that represent physicians need to understand their obligations to the profession of medicine. As an example, Julia Connelly points out that “the continued dependence . . . on financial support from pharmaceutical companies” makes it difficult to be a “good doctor.”⁶⁷ Therefore, the burden to move the medical profession forward in its effort to have physicians be more professional will be vacuous without a coordinated effort by industry and government.

VII. CONFLICTS OF INTEREST

Physicians have had conflicts of interest from that point in the history of medicine when it became the responsibility of a physician to act in the best interest of the patient.⁶⁸ In other words, conflicts of interest have always been a problem for the profession. Examples are many and include the unwillingness of the Chamberlen brothers to share

64. David J. Doukas, *Where Is the Virtue in Professionalism?*, 12 CAMBRIDGE Q. HEALTHCARE ETHICS 147, 147 (2003).

65. See, e.g., Madison Powers, *Bioethics as Politics: The Limits of Moral Expertise*, 15 KENNEDY INST. ETHICS J. 305, 319-20 (2005) (asserting that there is great dissension among bioethicists, and proposing a universal approach to bioethical reasoning, but cautioning that disagreement at some level may be inevitable, and that private morality is underwritten by political obligations, which might realistically prevent consensus in the bioethical community).

66. Edmund D. Pellegrino, *What Is a Profession?: The Ethical Implications of the FTC Order and Some Supreme Court Decisions*, 29 SURV. OPHTHALMOLOGY 221, 224 (1984).

67. Julia E. Connelly, *The Other Side of Professionalism: Doctor-to-Doctor*, 12 CAMBRIDGE Q. HEALTHCARE ETHICS 178, 182 (2003).

68. See, e.g., Pellegrino & Relman, *supra* note 45, at 984.

their discovery of the benefits of using forceps for delivering children,⁶⁹ or of physicians' inappropriate desire to use patents for financial gain. The final responsibility is the physician's. The subtleties and nuances of more recent financial involvements of physicians with industry are but a thin veil to the underlying conflicts of interest that undermine the trust requisite for medicine to exist as a profession. Can a physician be a consultant to a Wall Street investment firm, a researcher for a drug company, and a recipient of National Eye Institute grants, while also being the trusted agent of a patient? The complexity of conflicts of interest has increased with the new relationships that physicians are encountering. These include relationships with other doctors in financial circumstances that may compromise their promise to act as their patients' fiduciaries. Other relationships that may create conflicts include: those with hospitals; ambulatory surgical facilities; the pharmaceutical industry; the biotech industry; research relationships (supported by peer-review grants such as those from the National Institutes of Health, or from industry); and consulting and investment relationships with financial or other commercial entities.⁷⁰

Commercial interests may conflict with a professional promise. Companies that are for-profit are fiduciaries of stockholders and must act to maximize profits. Professional interests center primarily on doing what is in the best interest of the patient and secondarily on relationships between medicine, as a profession, and society.⁷¹ If physicians wish to avoid conflicts of interest, a simple answer is that a contract and disclosure of that contract defines the relationship with the patient and society. This would mean that any patient coming into a relationship with such a physician would realize that the physician was working for a

69. See Peter M. Dunn, *The Chamberlen Family (1560-1728) and Obstetric Forceps*, 81 ARCHIVES DISEASE CHILDHOOD: FETAL & NEONATAL EDITION F232, F232-34 (1999).

70. See Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993) (noting "a wide range of conflicts involving physicians, medical researchers, and medical institutions"); see also DeAngelis, *supra* note 48, at 2237-38; Jerome P. Kassirer, *Financial Indigestion*, 284 JAMA 2156, 2157 (2000); Kassirer & Angell, *supra* note 48, at 570; Korn, *supra* note 48, at 2236; Robert M. Tenery, Jr., Commentary, *Interactions Between Physicians and the Health Care Technology Industry*, 283 JAMA 391, 391-92 (2000); Michael D. Witt & Lawrence O. Gostin, *Conflict of Interest Dilemmas in Biomedical Research*, 271 JAMA 547, 547-48 (1994).

71. See Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, HASTINGS CENTER REP., Apr. 1987, at 20, 22 (contrasting research with practice on the notion that a physician's "first obligation is solely to the patient's well-being," whereas research may be "a tool . . . for promoting the interests of others, including the researcher and society as a whole"); see also Freidson, *supra* note 20, at 124 (noting that "practice ethics" focus on the interpersonal relationship between doctor and patient, but also noting that "institutional ethics," which focus more directly on institutional relationships, are necessary for medical progress).

company as an employee and was not acting as a physician in that she was not able to act only as the patient's advocate. This begs the questions: What constitutes employment? Does being a consultant constitute employment? Does disclosure to the patient of a financial relationship with a company adequately protect a patient?

The essential covenants of medicine as a profession would seem to preclude physicians from entering into any of these relationships. However, social mandates in the present environment help to create dilemmas for physicians.⁷² Thus, simple answers are not possible and basic social philosophy often is required to understand different responsive resolutions to conflicts of interest. Some would view physicians as just one group among many healthcare agents and government as the final agent and decision-maker.⁷³ Others would perceive physicians as at the center of healthcare and agents of vulnerable patients, taking care of patients one at a time.⁷⁴ Clearly, medicine has accepted circumstances where concerns other than those of the individual patient emerge as primary. These include natural disasters, wars, and so forth. The value to society of having physicians and other healthcare providers who can be trusted to act in the best interest of

72. See Angell, *supra* note 46, at 1516-18 (discussing the interwoven relationship between academic medicine, industry, and government); Freidson, *supra* note 20, at 131-33 (illustrating how the medical profession as it exists in today's society has changed significantly from the time of the 1847 Code, and that the 1847 Code is "no longer adequate for the task of coping with the political and economic environment in which medicine finds itself today"); see also Blumenthal, *supra* note 46, at 3348 (recommending the federal government's role in the regulation of academic-industry relations, while preserving the benefits that accrue from these relationships); Susan L. Coyle, *Physician-Industry Relations, Part 1: Individual Physicians*, 136 ANNALS INTERNAL MED. 396, 396-97 (2002) (discussing the current environment of medical practice in which "industry's influence on medical practice, research, and education has continued to emerge, and physician-industry relationships have multiplied"); Ezekiel J. Emanuel & Daniel Steiner, *Institutional Conflict of Interest*, 332 NEW ENG. J. MED. 262, 263 (1995); Christopher G.A. McGregor, *Academia and Industry*, 1 GRAFT 161, 161 (1998). *But see* FREIDSON, *supra* note 8, at 33, 137-57 (observing that the litmus test for autonomy is self-regulation, that "[p]rofessional people have the special privilege of freedom from the control of outsiders" and that "in the United States, the medical professional association has represented a position of fairly important control over the quality and the terms of medical practice").

73. See, e.g., ROBERT M. VEATCH, *THE PATIENT-PHYSICIAN RELATION: THE PATIENT AS PARTNER, PART 2*, at 94-97 (1991) (suggesting that the patient—not only the physician—must be involved in decisions about the use of generic drugs over patented drugs, and portraying the government as arbiter in decision-making).

74. See, e.g., EDMUND D. PELLEGRINO & DAVID C. THOMASMA, *FOR THE PATIENT'S GOOD: THE RESTORATION OF BENEFICENCE IN HEALTH CARE*, at vii-ix; EDMUND D. PELLEGRINO & DAVID C. THOMASMA, *A PHILOSOPHICAL BASIS OF MEDICAL PRACTICE: TOWARD A PHILOSOPHY AND ETHIC OF THE HEALING PROFESSIONS* 199-200 (1981) (noting that the "historically dominant notion" of the physician-patient relationship "is the one derived from the Hippocratic authors," whose principles relied on the theory that "the cooperation required of the patient is that of the child or servant following the order of the master").

patients has been addressed. It is relevant to understand that conflicts of interest undermine the basic core values of the doctor-patient moral dyad.

Of tantamount importance is to understand the social forces at work that have influenced how medicine is expected to work. A specific example is the impact of the Bayh-Dole Act.⁷⁵ The intent was to make the results of research performed with government financial support more available to corporations, facilitating commercialization of the discoveries of research.

Financial support of medicine has seen an enormous increase from industry.⁷⁶ This has come in different areas, including financial support of physicians' own research with regard to support for consultants, advisors and researchers. Corporations have also supported continuing medical education ("CME"), medical education (students and residents) and direct support to various departments, as well as other medical organizations. In addition, they have been legally allowed to give gifts to physicians. Specific rules governing conflicts of interest are further delineated in the Appendix to this Article.

VIII. RESEARCH

Physicians who are involved in clinical research face several areas of ethical concern that are unique due to related potential conflicts of interest. Informed consent represents a particularly sensitive area and impacts any discussion on potential conflicts of interest for physicians. Specifically, the increased vulnerability that is common in a clinical trial is a concern.⁷⁷ Here, as in most research, the vulnerability of the patient is due to having a disease that is not responding to traditional treatment, and diminishing hope for cure. Thus, entering a clinical trial creates

75. See Robert P. Kelch, *Maintaining the Public Trust in Clinical Research*, 346 NEW ENG. J. MED. 285, 285 (2002) (citing Bayh-Dole Act of 1980, Pub. L. No. 96-517, § 202(c), 94 Stat. 3015, 3021 (codified as amended at 35 U.S.C. § 202(c) (2000))).

76. Eric G. Campbell et al., *Looking a Gift Horse in the Mouth: Corporate Gifts Supporting Life Sciences Research*, 279 JAMA 995, 996 (1998); Annetine C. Gelijns & Samuel O. Thier, *Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections*, 287 JAMA 72, 73 (2002); Alan F. Holmer, *Industry Strongly Supports Continuing Medical Education*, 285 JAMA 2012, 2012 (2001); Thomas J. Liesegang et al., Editorial, *Pharmaceutical Companies and Ophthalmic Research*, 112 OPHTHALMOLOGY 363, 363 (2005); Light & Levine, *supra* note 31, at 24; Hamilton Moses III & Joseph B. Martin, Commentary, *Academic Relationships with Industry: A New Model for Biomedical Research*, 285 JAMA 933, 933 (2001); Arnold S. Relman, *Separating Continuing Medical Education from Pharmaceutical Marketing*, 285 JAMA 2009, 2009 (2001).

77. See Flory & Emanuel, *supra* note 55, at 1593, 1598 (highlighting studies that found only a minority of research participants understood the information disclosed to them, and exploring the effectiveness of interventions to improve research patients' understanding).

hope for the patient. The problem of therapeutic misconception represents an important challenge for the clinical researcher in that acting as the agent of the patient is made more difficult.⁷⁸

Add to the above the need to disclose to the patient a conflict of interest and then imagine yourself as the patient, who wants to trust the researcher—perceived as another healthcare agent—to be an agent for her care and now that relationship, real or perceived, may be threatened. Will the doctor do what is in the best interest of the research participant or is she more concerned about her own benefits, financial or otherwise? Physicians can obtain rewards for performing research that are non-remunerative, such as recognition, fame, and promotion.

IX. CONTINUING MEDICAL EDUCATION

The presence of the pharmaceutical industry at CME events creates possible conflicts of interest for the physician, for the entity responsible for the event and for society.⁷⁹ The information being presented to the audience is supposed to be for the benefit of patients. This is especially so when the entity responsible is a university where society has the expectation of academic freedom from commercial interests. The purpose of industry support is to increase profits to stockholders and establish relationships with potential customers. To accomplish this they often create bonding relationships with academic medical centers and their academic leadership. Thus, they directly benefit from the imprimatur of academia. Payment for this marketing advantage is a wise business decision if the behavior of the audience responds by increasing purchases of their products. If this did not occur, the company could not afford to financially support these “academic” events. Academic medical centers, physicians and society have much at risk; academic freedom helps create information and disseminates it with social benefit as its goal. The involvement of corporate goals creates the potential for conflicts in purpose and in outcome. An “arms-length” arrangement is needed at the very least to preserve a major element that creates the profession of medicine. Organized medicine through the Accreditation Council of Continuing Medical Education (“ACCME”) has enumerated criteria to facilitate a relationship between academic medicine and industry.⁸⁰ The key is control of content of events, which includes

78. Appelbaum et al., *supra* note 71, at 20.

79. Accreditation Council for Continuing Med. Educ., ACCME’s Essential Areas, Elements, and Decision-Making Criteria, July 1999, at 6-10 [hereinafter ACCME]; Angell, *supra* note 46, at 1517; Brody, *supra* note 46, at 234; Holmer, *supra* note 76, at 2012; Relman, *supra* note 76, at 2009.

80. See ACCME, *supra* note 79, at 6-10.

speaker selection. However, the emergence of Medical Education and Communication Companies (“MECC”) threatens academia in the following way. These organizations are accredited by the ACCME and control content and speakers for the sole purpose of selling a company’s products. MECCs work closely with industry and obscure conflicts of interest. They organize “academic” events, often in conjunction with an academic entity and therein emerge the problems for society and for those who attend. With “opinion” leaders as the hired speakers and the venue being very attractive and subsidized (making attendance less costly or free), physicians are attracted like lemmings.⁸¹ The opposing view of this as presented by industry is the desire to educate and be helpful.⁸² Clearly, the need is for a new détente in the relationship between industry and the profession of medicine. This will require that industry respect the basic values of the profession of medicine as opposed to the basic values of business. If medicine is completely commercialized, society and its citizens will lose providers of healthcare who have promised to do what is in a patient’s best interest.⁸³

X. CONCLUSION

An understanding of the risks involved when physicians enter into commercial relationships will enable a dialogue that is respectful of the profession of medicine, and to the needs of society. The goal would be for both non-commercial research, in universities and national laboratories, and for-profit research to co-exist and not to have one overwhelm the other. For-profit research is where there is a convergence of the views of physicians, scientists and business interests.

A cross-fertilization of ideas, concepts that will hopefully lead to compromises that will benefit society. This will require a consensus between medicine, business and government that leads to socially responsible action.⁸⁴

81. See Brody, *supra* note 46, at 233-34; Moses & Martin, *supra* note 76, at 933; Relman, *supra* note 76, at 2009; see also Am. Med. Ass’n Council on Ethical & Judicial Affairs, Ethical Ops. 8.061, 9.011 (2005), available at http://www.ama-assn.org/apps/pf_new/pf_online?category=CEJA&assn=AMA&f_n=mSearch&s_t=&st_p=&nth=1&.

82. See Holmer, *supra* note 76, at 2012-14.

83. See KRAUSE, *supra* note 4, at 46-49; Light & Levine, *supra* note 31, at 11, 25.

84. Cf. JOHN RAWLS, A THEORY OF JUSTICE 508-10 (rev. ed. 1999) (discussing the importance of finding consensus, asserting that “one of the aims of moral philosophy is to look for possible bases of agreement where none seem to exist”).

APPENDIX

Potential Conflicts of Interest and Relevant Comments

	AAO Code of Ethics ⁸⁵	AMA Code of Medical Ethics ⁸⁶	Office of the Inspector General	PhRMA Code
Consultant, Advisor, or Researcher	<p>Principle 5: Fees must not be exploitive;</p> <p>Rule 10: Unnecessary procedures, devices, or drugs must not be ordered;</p> <p>Rule 11: Judgment must not be clouded by economic interest in, or benefit from industry</p>	<p>Opinion 8.031: Appropriate compensation and disclosure for researchers comports with researchers' efforts and all potential financial conflicts must be investigated</p>	<p>Five elements for being a bona fide consultant, including that compensation must be based on fair market value and be for providing needed services⁸⁷</p>	<p>"Token" consultant or advisor arrangements should not be made. Lists six required factors:</p> <ol style="list-style-type: none"> 1) written contract, 2) legitimate need, 3) legitimate consultant, 4) limited number, 5) document use, 6) appropriate venues⁸⁸

85. CODE OF ETHICS (Am. Acad. of Ophthalmology 2007), http://www.aao.org/aao/member/ethics/code_ethics.cfm (outlining Principles and Rules); American Academy of Ophthalmology, Policy Statement: Gifts to Physicians from Industry 1, <http://www.aao.org/aao/member/policy/upload/Gifts-to-Physicians-from-Industry.pdf> (Nov. 2003).

86. Am. Med. Ass'n Council on Ethical & Judicial Affairs, Ethical Ops. 6.02, 8.03, 8.06, 8.031, 8.061 (2005), available at http://www.ama-assn.org/apps/pf_new/pf_online?category=CEJA&assn=AMA&f_n=mSearch&s_t=&st_p=&nth=1&.

87. OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Compliance Program"), 68 Fed. Reg. 23,731, 23,738 (May 5, 2003).

88. PHARM. RESEARCH & MFR. OF AM., PHRMA CODE ON THE INTERACTIONS WITH HEALTHCARE PROFESSIONALS 11 (2004) [hereinafter PHRMA CODE].

	AAO Code of Ethics	AMA Code of Medical Ethics	Office of the Inspector General	PhRMA Code
Drug Samples	Rule 10	Opinion 8.061: Should primarily benefit patients and should be of minimal value	Must comply with the Prescription Drug Marketing Act ("PDMA"), which forbids the sale of samples ⁸⁹	Must comply with the PDMA ⁹⁰
Gifts	Rules 11; Rule 15: Conflict of interest exists where there is a reasonable chance physician will be influenced by other interests; Policy Statement: Gifts to physicians should follow certain guidelines	Opinion 8.061	Must not violate anti-kickback statutes ⁹¹	Gifts must be of minimal value and not be for the personal benefit of the physician ⁹²
CME	Rule 15	Opinion 8.061 (also includes disclosure requirement)	Must not violate anti-kickback statutes ⁹³	All financial support should go to the sponsor and not directly to the physician ⁹⁴

	AAO Code of	AMA Code of	Office of the	PhRMA
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89. OIG Compliance Program, 68 Fed. Reg. at 23,739 (citing Prescription Drug Marketing Act of 1987, 21 U.S.C. § 353(c)(1) (2000 & Supp. 2006)).

90. PhRMA CODE, *supra* note 88, at 17.

91. OIG Compliance Program, 68 Fed. Reg. at 23,738.

92. PhRMA CODE, *supra* note 88, at 17.

93. OIG Compliance Program, 68 Fed. Reg. at 23,738.

94. PhRMA CODE, *supra* note 88, at 9.

	Ethics	Medical Ethics	Inspector General	Code
Independence of Decision Making	Rules 12 and 13: Communications to colleagues and the public must be accurate and truthful	Opinion 8.03: Welfare of the patient is primary concern; Opinion 8.061: Provides seven guidelines on accepting gifts	Three areas of concern: 1) integrity of data, 2) kick-backs, 3) compliance with PDMA and other laws ⁹⁵	Nothing is to be given to a physician in exchange for prescribing ⁹⁶
Co-management	Rules 1, 2, 6, 7, 8, 9, 11, and 14: General guidelines for ophthalmologists to practice	Opinion 6.02: Physicians may never accept payment for prescribing or referring a patient to a particular source	Must not violate anti-kickback statutes ⁹⁷	Not relevant

95. OIG Compliance Program, 68 Fed. Reg. at 23,733.

96. PHRMA CODE, *supra* note 88, at 19.

97. OIG Compliance Program, 68 Fed. Reg. at 23,738.