Conflicts of interest in science and medicine: the physician's perspective*

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ABSTRACT: *The various statements and declarations of the World Medical Association that address conflicts of interest on the part of physicians as (1) researchers, and (2) practitioners, are examined, with particular reference to the October 2000 revision of the Declaration of Helsinki. Recent contributions to the literature, notably on conflicts of interest in medical research, are noted. Finally, key provisions of the American Medical Association's Code of Medical Ethics (2000-2001 Edition) that address the various forms of conflict of interest that can arise in the practice of medicine are outlined.*

I am deeply honoured by the invitation to address this distinguished audience on an important topic, namely the physician's perspective in regard to conflicts of interest in science and medicine. The theme selected for this Conference is both original and important. I can recall no previous international meeting on this topic, which is relevant to the practice of medicine in the consulting room, in clinics and hospitals, and in other settings. It is of course also highly relevant to physicians engaging in medical research. I see from the excellent programme that several of the presentations deal precisely with conflicts of interest in research. We in the World Medical Association have a profound interest in the latter issue, not least because of certain provisions that appear in the

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** The World Medical Association (WMA) is a global federation of National Medical Associations representing the millions of physicians worldwide. Acting on behalf of patients and physicians, the WMA endeavours to achieve the highest possible standards of medical care, ethics, education and health-related human rights for all people.

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latest, October 2000 version of the Declaration of Helsinki, a Declaration with which I am sure you are all familiar.[1]

What do these provisions say that is germane to the subject-matter of this Conference? Let me give some examples. First of all, paragraph 13 of Section B, which deals with "Basic principles for all medical research"; that paragraph lays down that the information to be provided by medical researchers to ethical review committees must include "information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects".

This information must be reviewed by the committee in conjunction with its review of the experimental protocol. Under the terms of paragraph 22, potential subjects of research must be adequately informed about the sources of funding of the research and any possible conflicts of interest. There are of course many other matters to be communicated to subjects in the informed consent process. Finally, let me mention paragraph 27, concerning the publication of the results of research. It is specified that sources of funding, institutional affiliations and any possible conflicts of interest must be declared in the publication. I have noted in this connection that the presentation of this kind of information is now a feature in relevant papers in the *Journal of the American Medical Association*, better known as *JAMA*. In this context, we are aware of the inclusion of a major section on conflicts of interest in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, formulated by the International Committee of Medical Journal Editors (fifth edition, 1997).[2]

The Lancet, another distinguished journal, poses the following question to all contributors in its editorial discussion of conflicts of interest and funding. Is there anything that would embarrass you if it were to emerge after publication and you had not declared it? Examples are cited of possible conflicts of interest.[3]

For those wishing to pursue this matter further, I should mention the excellent paper on "Managing conflicts of interest in the conduct of clinical trials", by Morin and her colleagues published in the 2 January 2002 issue of *JAMA*.[4] That paper is based on a report of the American Medical Association's Council on Ethical and Judicial Affairs, adopted in December 2000. Also of substantial interest are an article by Montaner and his colleagues in the 1 December 2001 issue of *The Lancet,*[5] and a guidance document issued just a few weeks ago by the General Medical Council in the United Kingdom.[6] The document is entitled "Research: The Role and Responsibilities of Doctors" and it has this to say on conflicts of interest.

> "You must always act in the participants' best interests when carrying out research. You must ensure that your judgement about the research is not influenced, or seen by others to be influenced, by financial, personal, political or other external interests at any stage of the process. You should always declare any conflicts that may arise to an appropriate person, authority or organisation, as well as to the participants."[7]

Up to now I have dealt—even if only briefly—with the physician as scientist—or, more precisely—as investigator engaging in human experimentation. In the remainder of this presentation, I propose to concentrate on the physician as practitioner. Initially,

I will examine some Declarations, Statements, etc. that have been adopted by the WMA General Assembly in the course of its annual meetings.[8] Let me mention that the WMA membership now includes more than 70 national medical associations and thus speaks for a very significant proportion of the world's physicians.

The International Code of Medical Ethics, adopted in 1949 and amended in 1968 and 1983, proclaims—in its second paragraph—that a physician must "not permit motives of profit to influence the free and independent exercise of professional judgement on behalf of patients". The Declaration of Geneva, adopted in 1948 and amended on three occasions, does not deal directly with conflicts of interest. But it does require the physician to acknowledge unambiguously that "The health of my patient will be my first consideration". It is obvious that certain types of financial arrangements may run counter to this statement and may constitute conflicts of interest.

The 1996 Statement on Professional Responsibility for Standards of Medical Care, adopted during a General Assembly held in South Africa, recognizes that the patient has the right to be cared for by a physician whom he or she knows to be free to make clinical and ethical judgements without inappropriate outside interference – this provision is derived from the WMA's Declaration of Lisbon on the Rights of the Patient. That Declaration was first adopted in 1981 and was amended in 1995.

I do not wish to cite every one of our Declarations and Statements that deal with real and potential conflicts of interest. But I must mention the 1986 Declaration on Physician Independence and Professional Freedom.

> "Within the context of their medical practice and the care of their patients, physicians should not be expected to administer governmental or social priorities in the allocation of scarce health resources. To do so would be to create a conflict of interest with the physician's obligation to his patients, and would effectively destroy the physician's professional independence, upon which the patient relies."

To what extent is this provision relevant in our societies? Only those of you in this hall familiar with health care policies and practices in individual countries can answer that question.

Potential conflicts of interest are also addressed in our 1993 Statement on Patient Advocacy and Confidentiality, the 1995 Statement on Ethical Issues Concerning Patients with Mental Illness and the 1999 Statement on Medical Process Patents. That Statement includes a paragraph which lays down that physicians have an ethical obligation not to permit profit motives to influence their free and independent medical judgement. "For physicians to pursue, obtain, or enforce medical process patents could violate this requirement."

I thought that I might briefly examine how a modern national Code of Medical Ethics addresses conflict-of-interest issues. As an example, obviously not necessarily typical of such codes, I selected the Code of Medical Ethics of one of our largest members, the American Medical Association. The WMA had access to the 2000-2001 Edition and it is that Code to which I will refer.[9]

The first issue I will deal with is fee-splitting. The AMA Code provides that payment by or to a physician solely for the referral of a patient is unethical as is the

acceptance by a physician of payment of any kind, and in any form, from any source such as a pharmaceutical company or pharmacist or a manufacturer of medical appliances and devices, for referring a patient to that source. Another section specifies that clinics, laboratories, hospitals or other health care facilities which compensate physicians for referral of patients are engaged in fee-splitting, which is unethical. Also unethical are offering or accepting payment for referring patients to research studies, known as "finder's fees". Moreover, a physician may not accept any kind of payment or compensation from a drug company or medical device manufacturer for prescribing its products.

The Code also draws attention to other situations in which conflicts of interest may arise, such as in the case of health facility ownership by a physician, and in the context of home health care. It is stated furthermore that the sale of non-health-related goods from physicians' offices presents a conflict of interest and, to quote the Code, "threatens to erode the primary obligation of physicians to serve the interests of their patients before their own".

Although other real or potential conflicts of interest are identified in the AMA Code, I cannot close without mentioning a particularly long though very clear section entitled "Gifts to physicians from industry". All the medical practitioners in this hall will be very familiar with the issues involved and the kinds of temptations to which physicians are all too often exposed.

Let me conclude by quoting one of the seven paragraphs of which the relevant section of the Code consists:

> "No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences and lectures."

REFERENCES

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