



Presidenza del Consiglio dei Ministri

NATIONAL BIOETHICS COMMITTEE

CONFLICT OF INTEREST IN BIOMEDICAL RESEARCH AND CLINICAL PRACTICE

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abstract

The doctors who are involved in applied research and the real problems of patients, today find themselves working in a context in which economic interest is increasingly important. Hence they are strongly exposed to possible conflicts of interest. This is the bioethical issue dealt with by this opinion.

The NCB has coined a definition of 'conflict of interest' which is today widely accepted: "There is a conflict of interest when a condition is created in which the professional judgement regarding something of primary interest (a patient's health or the truthfulness of the results of research) tends to be unduly influenced by an ulterior interest (economic gain, personal advantage)".

The document examines some of the problems such as the "fakes" in science, the methodological distortions in medicine, ethics in research, the relationship between contemporary clinical research and industrial groups, the conflict of interest of the doctor doing research and the clinical doctor.

The NBC recognises that the conflict of interest constitutes a condition and not a kind of behaviour. Therefore, it is to be morally condemned only when it determines reprehensible behaviour. What bioethics can do is to indicate a limit which makes reprehensible behaviour difficult or which establishes where a status of conflict generates reprehensible behaviour.

Both in scientific research and clinical practice, the methodological and ethical correctness with which scientific data are produced is considered fundamental. In the first case, the general interests of the patients must above all be evaluated. In the case of clinical activity, the solution is only to be found in the reference to a principle superior to the one resulting from a conflict of interest: the patient's well-being.

Having recalled some of the most frequent situations in which the objectivity of research and scientific information can be jeopardised, the NBC highlights the role of the ethics Committees in its final recommendations. They must assess the experimental protocols submitted for their approval, always evaluating the risks and benefits. Furthermore, they must promote the diffusion of the knowledge originating from clinical research and do everything to make sure that any news which may concern negative results is published. It is to be hoped that the ethics committees themselves carry out the task of being "guarantors", which implies that their independence from and extraneousness to any form of conflict of interest is guaranteed. By virtue of a principle of transparency, any sponsorship and link existing between industry and the single researcher or institution in which they work, must be publicly declared. The sponsors must furthermore declare all the data obtained.

Lastly the NBC discourages the divulgation of the results of an experiment before they have been examined and evaluated by the scientific committee, so as to avoid creating false hopes or dangerous alarmism in public opinion.