# FINANCIAL EQUIVALENT, INDUSTRY SPONSORED RESEARCH AND CONFLICT OF INTEREST

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# FINANČNÝ EKVIVALENT, SPONZOROVANÝ VÝSKUM A KONFLIKT ZÁUJMOV

**Conflicts of interest for the clinician(physician)-researcher are not limited only to direct and clear financial support by manufacturers of the pharmaceutical and medical device industry, but rather include delicate indirect monetary and research support.**
**Today professionals face an inevitable choice between two opposing moral orders, one based in the primacy of ethical obligations to the sick, the other in the primacy of self-interest and the marketplace. Some medical ethicists urge, reshape ethical codes to conform to the ethos of the marketplace, which legitimates self-interest over beneficence and makes vices out of most of traditional virtues. Second opinion represents the ethicists who recommend a firm stand in belief that being a physician imposes certain specific obligations. Medicine is at heart a moral enterprise and those who practice it are de facto members of a moral community. The market introduces an alien-till this time unknown-set of economic values into an institution (medicine) whose inherent ends are altruistic, but in countries under health care reform it brings a complex of special ethical issues in connection with deficient legislation and not firm ethical rules adopted. *(Ref. 17.)***
**Key words: ethics, biomedical research, conflict of interest, sponsored research, financial equivalent.**

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**Konflikt záujmov klinického lekára—výskumníka nie je limitovaný iba priamou a jednoznačnou finančnou podporou poskytovanou rôznymi výrobcami medicínskych zariadení a farmaceutického priemyslu, ale skôr zahŕňa delikátnu nepriamu finančnú podporu a podporu výskumu.**
**Dnešný profesionál je vystavený nevyhnutnému rozhodnutiu medzi dvoma vzájomne si odporujúcimi morálnymi postojmi, z ktorých jeden je založený na etickom záväzku k chorému a druhý na priorite vlastného záujmu a na finančnom ekvivalente. Niektorí medicínski etici nabádajú prispôsobovať etické kódy etike materiálneho sveta, ktorá povyšuje vlastné záujmy nad dobrodinstvo a tradičné cnosti pretvára na necnosti. Druhý názor predstavujú etici, ktorí požadujú vytrvať vo viere, že byť lekárom znamená dodržovať určité zvláštne záväzky. Medicína je z mnohých hľadísk morálna činnosť a tí, ktorí ju vykonávajú, sú de facto členmi morálneho spoločenstva. Dnešný svet vnáša do medicíny, ktorá je vo svojej podstate altruistická, cudzí súbor ekonomických faktorov. V krajinách s reformujúcim sa systémom zdravotníckej starostlivosti prináša aj komplex etických problémov v spojení s legislatívou a etickými pravidlami. *(Lit. 17.)***
**Kľúčové slová: etika, biomedicínsky výskum, konflikt záujmov, sponzorovaný výskum, finančný ekvivalent.**

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The market poses great possibilities for medicine and health care. The opportunities are expansion of individual choices, the possibility of partial economic efficiency, the satisfaction of a wider range of personal desire.

The hazzards are no less obvious. They include an introduction of an alien set of economic values into an institution-medicine-whose inherent ends are altruistic, not commercial. Market is directed by satisfying individual choice, it does not determine important medical priorities. One of the ethical issues, more or less ulteriorly attributed to the market, represents a conflict of interest in connection with research activities (Callahan, 1995).

Conflict of interest in question, as a part of group of different ethical conflicts, is commonly recognized when financial support and reimbursement are at issue.

Allocation of health care resources is clearly a moral dilemma, with a potential conflict between the interest of society and the interest of individual patients. The medical and pharmaceutical industries play an important role in this situation. There are various degrees of scarcity of resources and therefore many clinician and laboratory workers are involved in sponsored clinical trials. Some choose to do so from professional and academic reasons, others from psychological-social-economic purposes, others because they may have particular expertise, still others because they

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are the only resource available at a university, hospital, or as in case of Slovakia, in a country. Many times all mentioned purpose are taken into consideration. Specific issues arise when this clinical research is sponsored by medical and pharmaceutical industry (Thompson, 1993). Costing in Slovak health care institutions mostly had been rudimentary and unsophisticated.

In fact, conflict of interest for the clinician(physician)-researcher are not limited to direct and clear financial support by various manufacturers of the pharmaceutical and medical device industry, but rather include subtler indirect monetary and research support. Many guidelines and memoranda for addressing conflict of interest focus on issues of financial support by the companies. There are many areas mainly for a physician working with human subjects, that need to be considered and elucidated. These include indirect financial benefit, career benefit and conflict in the role of clinician-researcher as patient's advocate. The relationship between industry and investigators has been strenghtened and has become increasingly complex. This has proved to be beneficial for industry and clinics, after all for public. The changing relationship between industry and medical practice has created many situations which have the potential of leading to ethical conflicts and compromises. Clinical researchers have to consider also the code of providing medical care and the code of scientific research (Sámel, 1995; Council on Scientific Affairs, 1990).

Three categories of behaviour have been of the primary concern. The first involves scientific misconduct, which has been defined by fabrication, falsification of data and plagiarism. The second involves conflict of interest i.e. conflict between the private interest and the official responsibilities of a person in a position of trust. Third, a quite new category, called inappropriate behaviour includes activities, which in other contexts may not be particularly unacceptable, but which in the context of the relationship between industry and clinics may be inappropriate and preclude any further work by a company with a given investigator (Barnett, 1995).

When a research project is to be evaluated from the ethical point of view, three basic issues are in question: does the project ask an important question, are the risks to the research subject acceptable, will the research subject's autonomy be respected? Where research proposals cannot fulfill all those criteria a delicate balancing has to be used. The research support offered by pharmaceutical and medical device companies can influence this very delicate process of ethical consideration already on that level. This ethical consideration and its outcome depends also on different kinds of research project: therapeutic or non-therapeutic research on competent or non-competent subjects (Spagnolo, 1992; Foster, 1995).

Obviously, drugs, reagents, kits, consumables and devices must be well evaluated and tested before their approval for use. Although the researcher as independent investigator is not dependent on the company in a direct manner, the pressure to obtain data supporting the distribution and prescription of a given device or drug may be quite clear. In well defined multicenter trials this danger is partially limited. The funding source is a well — recognized potential conflict and most serious journals require the identification of the monetary support (Barnett, 1995). The potential to profit personally from the prescribing!and marketing of the drugs, reagents or devices under clinical testing and also in a post-trial period (money for prescribing) is also recognized as serious conflict. This situation is dangerous now in our country, in this time, on this level of the reform of the health care. In laboratory medicine there are additional questions concerning the involvement to relationship between manufacturers and laboratory professionals (McQueen, 1990; Pullmann, 1994).

A special issues represents a group of tests conducted away from the laboratory, nearer to patient. Professional organisations, including those of biochemists, haematologists, but also diabetologists and others, have identified many of the issues.

Many laboratories are involved in clinical trials on different levels. The first phase of the trials involves exploring the toxicity, routes of administration, methods of treatment. Many clinical biochemistry, clinical immunology and haematology laboratories provide the test that often may play an important part in assessment of toxicity. More often they take part in the second phase, when drug is administered to the specific group of patients and in the third phase when a randomized control studies are undertaken. Unfortunately, laboratory professionals know the details of the studies inadequately, and sometimes laboratory support is based on non-certified methods without external quality control procedures (Pullmann, 1992; Niederland, 1993).

It is an ethical obligation to be familiar with the details of the study. The ethical committees on many occasions do not watch this issue. Unless they have that information before providing the services, then they are unable to give an informed consent to participate. In its absence they are not meeting their own ethical standard.

Firstly a question should be answered it there is consensus as to the responsibility of the profession. Many clinical trials indeclude also selfmonitoring of patients. The question is if it ethical to sell instruments without including education and training as part of deal. Professional societies have made significant contributions in this area through various reports that have been produced, but only very limited consensus could be found among them and there is still no identification of the underlying ethical positions justifying the recommendation. This situation is sometimes utilised/abused by manufacturers to produce ethically questionable publications and leaflets. Manufacturers on the base of this results do stress selfmonitoring and selftreatment of patients and overemphasise the autonomy of patients (McQueen, 1990).

Motivation for mentioned pattern of behaviour are monetary gain, publications and citations practice and also new possibilities for additional grant and research funds. The criteria for funding have to be re-evaluated. Insufficient information of medical public about name of grant, money of funding, the applicants and terms is often still kept in secrecy.

In this context there are also potential sources of economic conflict of interest which are indirect. When clinical care is given in connection to manufacturer-sponsored research, the level of care very probably is higher than that which is in common. The investigator is not under pressure from insurance limitations. The researcher personally, a head of clinic, department, and institution all are receiving greater financial benefit those from participating in that funded research than from patients receiving „off-study" care by the same physicians. This attitude now results in competition between universities, clinics and institutes, hospitals to obtain this industry sponsored research. The advantage of the facilitated possibility to present results of testing by different ways in the country or/and abroad, often in manufacturers' indirectly sponsored journals, (and service trips) represents the base for ob-

taining other state grants. The citation practice and acceptation of papers for publication are sometimes adopted to those goals. Funds and resulting publications are of benefit not only to the researcher, but also to the institution. Special issue represents funding of the researchers, institutions located in a capital. These conflicts raise a lesser concern for their effect on the validity of the scientific results but a greater concern for their potential effect on patient welfare and as a "by-result" they influence research possibilities of other institutions in competition. Because of different legislation in European Community countries and Central/Eastern European ones (some of clinical trials ethically not allowed in EU countries) are running (exceptionally) in our countries. It should be stressed that the more existence of conflict of interest does not imply unethical behaviour (Editorial, 1991).

The physician in clinical practice plays many roles as scientist, teacher, healer, protector, public health manager and patient advocate (Barnett, 1995; Elks, 1995). The role of physician as scientist may not be in harmony with the role of the physician as healer or with other roles. As a scientist and often clinician, the researcher has not only the goal to seek truth but also the need to generate reliable data and research papers for constructing his own scientific career. If the results of the sponsored research are reliable and useful for patients there is a dilemma between the physician as researcher and the physician as the patients' advocate. This is a central ethical issues in all clinical research. The ways for evaluation of activities of academic clinician favour the physician-researcher. These conflicts intrinsic to the roles of the physician as patient advocate and as physician-researcher (academic clinician) also relate to certain hidden and indirect financial support (Engelhardt, 1989).

Today professionals face an unevitable choice between two opposing moral orders, one based in the primary of ethical obligations to the sick, the other in the primacy of self-interest and the marketplace. These two orders are not fundamentally reconcilable and, like it or not, clinicians and the profession will be forced to choose between them. In that choice the conscience of clinicians may play a central and indispensable role. Some medical ethicists urge that, reshaped ethical codes should be to conform to the ethos of the marketplace, which legitimates self-interest over beneficence and makes vices out of most of traditional virtues. Second opinion represents the ethicists who recommend a firm stand in the belief that being a physician imposes certain specific obligations that forbid turning professionals primarily into entepreneurs, businessmen, or agents of fiscal, social, or economic policy (Pellegrino, 1989). This attitudes can be observed now in freshly graduated physicians, and represents a challenge to the teachers of bioethics and medical ethics at universities.

It is still questionable how the medical profession will respond to this dilemma. Some clinicians and laboratory workers want to remain faithful to the primacy of the patients' welfare and the idea of a profession. Others see no reason why physicians should be held to a higher standard of ethical conduct than that which prevails in other professions or society. A typical example represents hard discussions concerning salaries in medical care workers running now in our country. In both groups prevails the pervasive conviction that the question has been already answered and that the ancient fortress has already fallen. Many believe it is no longer possible to be an ethical physician in situations when the incomes of health care workers in comparison to other professionals are significantly lower. Medicine is at heart a moral enterprise and those who practice it are de facto members of a moral community (Pellegrino, 1989). Medical professionals can accept or repudiate that fact, but they can no more ignore it. The care of the sick is increasingly treated as a commodity where participation in sponsored research is considered as representing a strong opposition to the idea of medical profession as a moral community.*

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