Principles of ethics

The principles of doing "good" and not doing "harm" are the essence of every code of medical ethics. It is the duty of the medical doctors to their patients to exercise their professional skills in an ethical manner and to observe the laws of the community. The essential purpose is to ensure that patients' trust in the medical profession is deserved. This is achieved by protecting patients and ensuring that they are able to obtain the maximum benefits available from medicine. At the same time, medical ethics aim to protect patients from the abuse that can occur when one person is in a position of power (in this case, based on superior medical knowledge and, often, status) *vis-à-vis* another.

Medical ethics are generally considered to be derived from the teachings of the Greek physician Hippocrates (460–377 BC), commonly known as the Father of Medicine. The ethical principles he taught survive today in the form of an oath (the Hippocratic Oath) traditionally (if not actually) taken by those entering medical practice. While the exact wording has changed to reflect more modern thinking and practice, the essential principle remains the same: the patient's interests are paramount. Codes of ethics have been enriched by the influence of religion and culture. Arabic and Islamic oaths have been developed and are used in medical schools in most of the Eastern Mediterranean Region.

The best known modern version is the Declaration of Geneva, adopted by the World Medical Association (WMA) in 1948 and subsequently amended in 1968, 1983 and 1994 (see Annex 1). The International Code of Medical Ethics of the World Medical Association—1949 was adopted by the WMA at London in October 1949 and has been used as the basis for various codes of ethical practice adopted by different national medical associations (see Annex 2).

In recent times, as an aid to decision-making in medicine and as a starting point for discussions on medical ethics, four principles have been generally agreed as fundamental. These are:

- *Autonomy*
  The right of patients to make decisions on their own behalf.
- *Beneficence*
  The duty or obligation to act in the best interests of the patient.

- *Non-maleficence*
  The duty or obligation to avoid harm to the patient.

- *Justice*
  This embodies concepts of fairness and giving what is rightfully due. It applies not only to the individual but also in the wider medical context and it incorporates notions of equity and fair distribution. This is important when medical services are distributed, as they usually are, in an environment of limited resources. In forensic medicine, justice is the goal that is being pursued.

While concern for safeguarding patients' privacy, as manifest by the duty to maintain confidentiality, can be derived from the first two principles above, some have regarded the concern as so important as to list "privacy" as a fifth principle.

The ethical standards of those working in medical laboratories and forensic medical institutions are derived from medical ethics and other codes and incorporate the same principles. Therefore public expectations of them will reflect, with regard to ethical standards, those expected of the medical profession generally. It is the responsibility of the professionals, whether medically qualified or not, working in those institutions, to ensure that these expectations are realized and that they are worthy of the same level of trust that the medical profession has come to enjoy.

After introducing some concepts common to both areas, we have divided this publication into two parts. This reflects the fact that, while the practice of forensic medicine has many health-related aspects and consequences, there is a duality of purpose: the interests of the patients (in clinical forensic medicine) on the one hand, and the proper administration of justice on the other. Working in this different environment carries with it a different, although allied, set of values and ethics to the patient-oriented service of laboratory medicine.

Definitions

- *Doctor*
  "Doctor" is used in the general sense of "registered medical practitioner". In some parts of the world the term "physician" would normally be used in this way, whereas in other places the term "physician" is restricted to a specialist in internal medicine.
- *Ethical practice*
  Ethical practice can be regarded as good technical practice accompanied by proper attitudes and behaviour. In deciding what is proper, reference is often made to moral values voluntarily adhered to within the community and to standards espoused in various codes of professional practice.
- *Forensic medicine*
  Forensic medicine is the application of the principles and practice of medicine to the proper administration of justice. For the purposes of this document, it includes the discipline of forensic pathology and clinical forensic medicine. In many parts of the world, these two disciplines are practised jointly, in others separately.

1.1 General application of ethical principles

Medical laboratories have responsibilities to others. There are three main groups to whom responsibility is owed:

- *Patients*
  Medical laboratory professionals are accountable for the quality and integrity of the services they provide. This obligation includes maintaining individual competence and endeavouring to protect the patient from incompetent or illegal practices by others.
- *Colleagues and the profession*
  Medical laboratory professionals should strive to uphold the dignity and respect of their professions and maintain a reputation for honesty, integrity and reliability. They should aim to contribute to the advancement of the profession by improving the body of scientific knowledge, promoting high standards of education and practice and collaborating with colleagues and other health professionals where practicable.
- *Society*
  Professionals working in a medical laboratory also have a responsibility to contribute to the general well being of society. This may be within their sphere of professional competence or simply as members of the community.

  Medical professionals should comply with relevant laws and regulations pertaining to their professional activities. The medical profession is committed to a high standard of care and practice, and professionals should endeavour to influence those that do not meet this standard.

1.2 Collection of information

Laboratories must collect sufficient information to identify adequately patients and specimens. They also should collect sufficient information for other legitimate purposes, but unnecessary information should not be collected. If possible, there should be sufficient clinical information to enable the test to be correctly performed and interpreted. Other legitimate purposes may involve information relevant to the safety of other patients and staff as well as information required for billing purposes and resource management, including utilization reviews. The patient should be aware of the information collected and the purpose for which it is collected.

1.3 Collection of specimens

All procedures carried out on competent patients require their informed consent. Where the patient is incompetent by reason, for example, of age or mental state, consent may be given by a parent or other properly authorized person. In exceptional circumstances when this is not possible, necessity may justify the procedure when it is clearly in the best interests of the patient that the procedure be performed. For most routine laboratory procedures, consent can be inferred when a patient presents at a laboratory and willingly submits to the usual collecting procedures, such as venepuncture. However, certain procedures, especially the more invasive procedures (such as bone marrow aspiration), will require a more detailed explanation of their risks prior to consent being given. Some tests, such as certain genetic testing, will require special pre-test counselling to ensure that the patient fully understands the implications of the test result.

Adequate privacy for the patient must be made available. It should be appropriate for the type of specimen (or information) being collected, and the cultural expectations of the patient and the resources available should be borne in mind.

1.4 Performance of tests

All tests must be carried out to an appropriate standard which should be determined in detail by professional organizations or regulatory authorities. Accreditation programmes designed to promote standards and ensure compliance are to be encouraged. Where no such guidance is available the patient's interests will prevail. In some situations, this may mean that a laboratory should refuse to attempt a test rather than produce an unreliable result which could result in harm being done to the patient. All laboratory work must be carried out with the high level of skill and competence expected of the medical, scientific and allied health professions.

1.5 Reporting of results

Test results are confidential unless disclosure is authorized. They will normally be reported to the clinician who requested the tests and may be reported to other parties with the patient's consent or as required by law. Decisions concerning implied consent for the reporting of results to other practitioners involved (such as consultant practitioners to whom the patient has been referred) should be made

carefully taking into account local customs. The laboratory should have written procedures detailing how various requests are to be handled, and this information should be made available to patients on request. The laboratory is also responsible for taking all reasonable precautions to ensure that the method of transmitting results to requesting clinicians, or other authorized persons, is secure and reliable. This applies whether transmission is by courier, public post or electronic means. The laboratory is also responsible for ensuring that the turnaround time for results is reasonable, taking into account the type of test and the patient's condition. There should be the facility to report urgent results as soon as they are available.

In addition to the accurate and timely reporting of test results, the laboratory is also responsible for ensuring that, as far as possible, the results are correctly interpreted and applied in the patient's best interests. Care must be given to the construction and format of the test report so as to facilitate correct interpretation and diagnosis. When appropriate a pathologist or some other competent professional should be available to discuss results. Consultation with regard to the selection and interpretation of tests is part of a medical laboratory service.

1.6 Storage and retention of medical records

The laboratory must ensure that information is stored so that there are reasonable safeguards against loss, unauthorized access, tampering or other misuse. Test results must never be altered or corrected, *except by properly authorized persons in accordance with established procedures*. The retention of medical records may be defined by various statutory requirements, and these need to be considered together with any guidelines issued by relevant professional bodies. Laboratories should develop their own protocols indicating how long different results, specimens and slides will be kept for. Test results should be physically available for ready authorized access. When the time comes for medical records to be destroyed this should be carried out in a way which minimizes the risk of unintentional disclosure.

1.7 Access to medical records

Access to medical laboratory records should normally be available only to the following:

- the clinician requesting the test
- the patient

- laboratory and hospital staff if required for the management of the patient
- other authorized individuals.

Incompetent patients such as children and intellectually impaired individuals have the same right of access as competent adults, although this right may be expressed through a parent or authorized agent. Parents, on the other hand, do not always have *automatic* right of access to their children's medical information, and different countries have different laws and customs in this respect. The laboratory should develop protocols on how to handle different requests taking into account local laws and customs. In exceptional circumstances the withholding of health information from individuals normally authorized to receive it may be justified (the top management of the laboratory would make such a decision). An example of such a circumstance is when disclosure may be contrary to a patient's best interests.

Where a request is made for access to test results by an authorized person the laboratory must first satisfy itself as to the identity of the person making the request. The way in which this is done, and the degree of certainty associated with the process, will vary with different situations.

Different methods may exist in the same laboratory for different tests. For example a degree of certainty associated with the identity of an authorized person seeking an HIV test result may be much greater than that required of one asking for the results of a routine haemoglobin test. Laboratories need to establish appropriate procedures for each situation.

1.8 Financial arrangements and organizational matters

Medical laboratories must be able to function with professional independence. They should not be subject to non-medical control where this has the potential to interfere with their ability to act freely in the best interests of the patient. They may not enter into financial arrangements with referring practitioners or funding agencies where that arrangement acts as an inducement or an impediment for the referral of tests or patients, or interferes with the doctor's independent assessment of what is best for the patient. This assessment, however, will usually be made in an environment of limited resources and so excessive application of these resources to any one individual may not be acceptable, particularly if it results in a failure to deliver a fair share of required services to another individual.

It is desirable that private laboratory collecting rooms be completely separate and independent from the referring practitioner's rooms but where this is not practicable, any financial arrangements must not include any element of inducement.

Laboratories should also be aware of situations which could give rise to conflicts of interest and take particular care. Such situations may arise where pathologists in private practice can self-refer work. Any such self-referred work must be justifiable.

The medical laboratory has a difficult ethical responsibility when operating in an environment of limited resources provided by a third party such as the state. On the one hand there is an obligation to ensure that patients receive all the necessary services to which they are entitled but, on the other hand, there is an obligation to see that resources are not wasted so that other patients are consequentially deprived of their fair share, and the tax payer (or other funding agent) is not unreasonably burdened. The practical implications of this will vary in different situations and particularly from country to country. There will also be different pressures on a laboratory depending upon whether funding is on a "budget" or a "fee-for-service" basis, and the extent to which those resources are under the control of the requesting clinician rather than the laboratory. Nevertheless, there is a responsibility on the laboratory to be involved, to the extent that is reasonable and practicable in the equitable allocation of resources.

1.9 Some special applications

1.9.1 Clinical pathology (clinical chemistry, haematology, microbiology, immunology)

Most of the issues are covered under general principles. As with histopathology and cytology, the results of tests in these areas can have a life-altering impact upon patients. Information provided about the results, and the manner of its provision, must assist the treating doctor to properly advise the patient about the diagnosis and its consequences.

1.9.2 Anatomical pathology

Autopsies[1]

Generally speaking, there are two types of autopsy: the "hospital" autopsy, which requires the voluntary consent of a properly authorized person (often the senior next of kin) and the "forensic", which is autopsy performed at the request or

[1] This section is complementary to Part 2, on forensic pathology, and should be read in conjunction with it.

direction of a coroner or other authority to meet statutory death investigation requirements. This section deals with the former.

An autopsy is the post-mortem examination of a body to provide information of medical or scientific use, including the cause of death, or for other relevant purposes such as the resolution of legal issues. The autopsy is an investigation which can have significant public and private consequences. The latter may be lost if the autopsy is limited to merely establishing the cause of death. The community, including the next of kin, has a right to expect that systems are developed to ensure that all the potential benefits are realized (these benefits are set out in the section on forensic pathology).

It can be difficult for families to cope with issues related to autopsies at the time of bereavement. Hospitals and forensic pathology institutions should have adequate facilities to advise, counsel and support bereaved relatives. Sudden or traumatic circumstances leading to death are particularly recognized as leading to much psychological stress, and the pathologist and other staff should not add to this by insensitivity. The body of the deceased person must at all times be handled with respect, and the relatives must be able to rely on this occurring.

Consent for autopsies

Many religions and cultures do not accept the need for or the desirability of autopsies, and this must be accepted. Procedures relating to consent for autopsies will usually be governed by law and these must be followed meticulously. In most countries, the non-forensic or hospital autopsy requires prior consent from the next of kin. This means that the nature and outcomes of the autopsy must be properly and sensitively explained. This will include an explanation of any need to retain tissues for the purpose of the autopsy or the possibility that tissues may be used for research or teaching purposes. In some cultures the removal of the brain and the heart, particularly if they are retained after the rest of the body is released for burial, is particularly sensitive. The interaction with the next of kin should be conducted in a manner that promotes discussion and encourages them to ask questions. The laboratory should have a clear understanding of the procedures for authorization of an autopsy in the absence of any next of kin or if they cannot be contacted.

1.9.3 Histopathology and cytology

In the course of a histopathological or cytological examination certain observations may be made (such as the presence of spermatozoa) which are not related to the purpose of the examination. Careful thought should be given as to

whether or not such observations should be reported as there could be significant social implications. As in clinical pathology, tissue diagnosis must provide information to assist the treating doctor to properly advise the patient about the diagnosis and its consequences.

1.9.4 Reproductive technology

Issues raised by discussions of reproductive technology may touch on deeply held convictions and religious beliefs, as well as on perceptions about what constitutes a human being or a person, about identity, about the family and about the sense of one's own characteristics living on in some form after death. Just as these convictions and perceptions vary, so does the way different societies and religions treat these issues. Consequently it is not possible to arrive at a universally accepted ethical view on this subject. The different and strongly held views on abortion, artificial insemination by donor, *in vitro* fertilization, gamete intrafallopian transfer, and other procedures and techniques are examples of this concern. Detailed discussion of these important areas is beyond the scope of this document.

1.9.5 Transfusion medicine

The code of ethics for blood donation and transfusion, which was unanimously approved by the general assembly of the International Society of Blood Transfusion during the Society's 16th Congress (Montreal, 16–22 August 1980) is given in Annex 6. The statement on the ethics of voluntary, non-remunerated blood donation of the Third International Colloquium on Recruitment of Voluntary Blood Donors, which was endorsed by the International Group of Red Cross Blood Transfusion Experts, is given in Annex 7.

Voluntary donation

Blood donors should give their blood voluntarily and without expectation of payment. No pressure to donate should be exerted on a potential donor. Volunteer blood donors give blood of their own free will and without coercion. This is in line with the right to self-determination and rights to protection of physical integrity and privacy. In this connection family donor or replacement donor systems have been shown not to meet the criteria of a volunteer system and are therefore undesirable and to be discouraged.

Non-remunerated donation

Blood is regarded in the same light as any other body tissue, so blood donation should be on a non-remunerated basis. There should be no rewarding of the donor with money, merchandise or services.

Protection of the donor

No coercion or pressure should be exerted on potential donors, who should be provided with adequate information about the process to properly consent to donation. Blood should be collected under the overall supervision of a physician. Confidentiality concerning all personal donor details, including laboratory results, should be ensured.

Protection of the recipient

The patient in need of a blood transfusion should, where clinically possible, be provided with reliable information of the risks, benefits and any available alternatives to blood transfusion.

A proper application of the principle of autonomy means that patients needing blood (provided they retain the capacity to understand and assess the information provided) are free to accept or refuse blood transfusion.

Quality assurance is paramount throughout all the stages of blood transfusion starting with the detailed criteria for donor selection or deferral. This also includes the complete range of management and operational systems needed to ensure the safety of blood, blood components or blood products, to prevent adverse reactions and transfusion-transmitted infections.

Self-sufficiency

Blood transfusion does not exist in isolation. It is an integral and indispensable part of a health care system. The public authorities have a responsibility to protect the health of the population and to ensure the availability of services, equity of access to those services and their quality and safety. Inherent in these values is the promotion of national self-sufficiency in blood. Self-sufficiency means that a country provides all the blood it needs from its own resources. If it is not attainable on a national level, then self-sufficiency of a slightly different kind can be achieved through collaboration with other countries in a similar position. Self-sufficiency applies to the source of blood, but not necessarily to the source of essential supplies, equipment, technology and plasma fractionation.

Optimal use of blood and blood products

Taking into account the scarcity of blood and the dangers inherent in its use, transfusion medicine should be properly practised. The risks of blood transfusion mean that blood should not be given to patients who do not need it. Patients who need blood, blood components, or blood products must receive what they need. There are three general types of misuse in transfusion therapy: use of blood products when not clinically justified, use of too little or too much in patients who require transfusion, and use of the wrong component or product in patients requiring transfusion. All these should be avoided.

1.9.6 Molecular biology/genetics

Issues raised by discussions of molecular biology and genetic testing touch upon deeply held convictions about what constitutes a human being or a person, about identity and about the family. Just as these convictions and perceptions vary, so does the way different societies and religions treat these issues. Detailed discussion of these complex areas are beyond the scope of this document.

1.9.7 Research

Biomedical research aimed at understanding and preventing disease or at improving the diagnosis or treatment of disease is highly desirable and is often conducted solely with altruistic motives. Many medical laboratories initiate research themselves and, knowingly or unknowingly, are involved in clinical trials. Unfortunately, there are too many examples where biomedical research has been conducted inappropriately and patients or research subjects have suffered. It is for this reason that medical laboratories should understand the implications of research projects with which they are involved to avoid complicity in unethical research. In many countries a system of institutional ethics committees has added a level of formal oversight to medical research. Even this is not a guarantee that the research is ethical in every respect, and a laboratory should be satisfied that the proposed research meets its own standards. Recommendations and guidelines on biomedical research involving humans are given in Annexes 3 and 4.

The involvement of medical laboratories in biomedical research will usually centre on analysis of tissue or fluids. Some of the issues associated with this are dealt in Section 1.9.9 on human tissues, the major one being that proper consent has been obtained, or proper authority has been given, for the analysis. The following

principles may act as a guide to laboratories initiating their own research or participating in other biomedical research:

- Potential benefits of the research should outweigh the risks.
- The risks of the research should be predictable.
- The patient or research subject should be well informed about proposed treatments, procedures, risks, costs, inconvenience, discomforts and relevant alternatives.
- Consent to participate should preferably not be sought by a doctor in a treating relationship with the patient.
- Due regard should be given to issues of privacy and confidentiality.
- The progress of the research should be regularly reviewed, especially in trials of therapeutic agents.
- In randomized clinical trials, control subjects must receive the best currently available means of prevention, diagnosis or treatment.

Volunteers may be used for non-clinical, non-therapeutic biomedical research, but participation must be free of any coercion or inducement. The pharmaceutical industry has contributed enormously to biomedical research in partnership with the medical profession, research institutions and hospitals. This partnership, however, provides opportunities for questionable practices and flagrant abuses of the ethical principles of biomedical research. Codes of conduct regarding the relationship between doctors and the pharmaceutical industry have been developed. National medical associations should be aware of those most relevant to a particular laboratory. In the absence of this awareness, the following may be of assistance:

- *Ethical guidelines in the relationship between physicians and the pharmaceutical industry*. Sydney, Royal Australian College of Physicians, 1994.
- Physicians and the pharmaceutical industry. Position paper of the American College of Physicians. *Annals of internal medicine*, 1990, 112: 624–6.

1.9.8 HIV/AIDS

Testing for HIV requires special consideration. Tests should normally be performed only on patients who are fully informed of the implications of a positive result. This may require special counselling. Confidentiality is especially important, and it is generally accepted that greater public health gains can be made in preventing the spread of AIDS by ensuring that individuals can be tested and treated with the assurance of confidentiality and sensitivity than by more punitive systems, which often have the effect of driving the whole problem "underground".

In some countries, compulsory testing of certain groups, such as intravenous drug users or prisoners, is required by law. While the wisdom of some programmes may be debated, it is reasonable for a laboratory to participate in the testing even though informed consent may not have been given. In these cases the burden of responsibility for the patient usually rests with the authority organizing the programme, but in some situations, such as testing for visa requirements, where the authorities may have little interest other then the requirement for a negative result, a laboratory could find itself with an obligation to provide counselling and support in the case of an unexpected positive result. The laboratory should ensure that facilities exist for these services to be provided. Screening programmes for epidemiological purposes are acceptable, but if patients with positive results can be identified (and notified) then prior informed consent is required.

Doctors with a dual responsibility both for an affected patient (including specimens from such patients) and for the health and safety of others, such as laboratory staff who may receive needle stick injuries, have a special responsibility. In those situations a doctor may consider that obligations to the new patient (that is, the staff member) supersedes obligations of confidentiality to the first patient. For example, in case of a needle stick injury to a staff member, a doctor may arrange for, say, HIV testing on the "donor" blood (that is, the blood of the first patient) in order that appropriate treatment of the new patient can be determined. Where possible any testing to be carried out on the "donor" blood should be done with the consent of the patient, but there will be situations when this is not possible. Under such circumstances the identity of the patient with the positive test result should be protected as far as possible.

1.9.9 Human tissues and fluids

At any one time, a medical laboratory is the repository of quantities of human tissues and fluids. Such tissues and fluids have many potential uses, including therapeutic purposes, teaching, research or even commercial development. Such tissues and fluids include:

- blood
- urine
- faeces
- biopsy specimens
- surgical or autopsy specimens
- histopathology blocks and slides.

The property status of these tissues and fluids has changed in recent times in some parts of the world. The predominant view is that, the tissue or fluid having been provided, the patient had no continuing right to determine how that tissue or fluid would be used subsequently. The analysis or test having been performed, the tissues or fluid had little more status than abandoned goods and could therefore be dealt with at the discretion of the person in effective control of them (the person in charge of the laboratory). Thus, blood specimens were readily available for research purposes, surgical specimens were "potted" for educational purposes (or even public display), and cell lines even appropriated for commercial purposes[1]. Among the earlier manifestations of changing attitudes was a developing concern with how laboratories dealt with the remains of fetuses, the stillborn, and extremely premature neonates dying within minutes of birth. If the birth was not one that needed to be registered (and sometimes even if it was) the remains were often sent to the hospital incinerator with other laboratory waste or buried, along with other unnamed neonatal deaths, in mass unmarked graves. Mothers (and fathers) began to take exception to this, and were supported by psychologists who pointed out the importance of more formal procedures for dealing with the remains and of helping the parents and other members of the family deal with the bereavement. Such procedures now exist in many laboratories.

The practice of storing and testing blood samples for epidemiological purposes also focused attention on important ethical issues for laboratories. For example, testing batches or large numbers of such samples for HIV antibodies raised issues about contacting patients found to be positive. These patients had not contemplated such a test at the time of providing the blood sample let alone consented to its performance. These and other similar examples have led to formal statements such as that of the Council of Europe:

> When in the course of an intervention any part of the human body is removed, it may be stored and used for a purpose other than that for which it was removed only if this is done in conformity with appropriate information and consent procedures[2].

This means that a surgical specimen, for example, should be "potted" for educational purposes only if the patient has agreed to this use. Properly approached,

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[1] See *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990), rev'g 249 Cal. Rptr. 494 (Ct. App. 1988).

[2] Council of Europe. *Convention on human rights and biomedicine. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine.* Article 22. Adopted by the Committee of Ministers on 19 November 1996.

few patients are likely to have any difficulty with this and most are likely to be pleased that some general benefit can be derived from preserving their specimen.

It also means that femoral heads and other skeletal tissue, for example, which can be processed, banked and later used as allograft material may only be so used if the donor patient has properly given prior consent. This will have the added practical advantage, without which the use of the tissue as allograft is potentially dangerous, of allowing a proper history to be taken and the appropriate extra tests to be performed to minimize the risk of transmitting an infectious disease to the recipient.

Chapter 1: The ethical basis of RCRH

The recent course of history in the Western world has been in the direction of greater freedom and self-determination of individuals. A logical result of that has been the movement from paternalism to autonomy in medical care and by extension in medical research. Great impetus to that movement was provided by the atrocities carried out in the name of research by the Nazi German physicians, as described in the reports of the Nuremberg trials. That led directly to the first clear statement of the relationship of research subjects to the investigator and to the research being proposed. ( ). However, a statement of principle, as ethically powerful and persuasive as it was, did not result in uniformly unimpeachable research performance. As a result of considerable consternation over several specific programs of human research in the United States, a national commission was convened under the direction of Kenneth Ryan that issued a report, (The Belmont Report) outlining appropriate research behavior. The commission proposed government control through Institutional Review Boards at research institutions. The report was enacted by Congress to encompass human research carried out under the auspices of a number of Federal agencies, hence The Common Rule. Subsequently the World Health Organization produced the Declaration of Helsinki that supported similar international rules and systems and provided special consideration for the populations of developing countries. That code has been modified and strengthened a number of times.

A. Nature of Science

Science can be thought of as the system of reasoning and communication that has, from the beginning provided our species with increasing control over its environment. Science is derived from the practical knowledge of craftsmanship that has been transferred within and between generations from prehistory. In the last 400 years scientific knowledge has distinguished itself by being observation-driven, cumulative and always tentative. Even its most hallowed theories remain in thrall to the next set of experiments for confirmation or denial. In the past hundred years, the sophistication of experiment and analysis has grown astonishingly deep so that only relatively small numbers of experts really understand the bases for far-reaching explanations of nature including cosmology, quantum mechanics, molecular structure, cellular systems and evolution. We benefit by that sophistication in every electronic gadget we employ, in every recombinant molecule with which we are treated, in new structural materials for medicine and everyday life, in improved weather prediction capacity, and in more efficient and pleasant housing and environs. We know that science works because technology works. We know that evolution is true because of its great explanatory power in all biological fields.

The general public remains puzzled by the conditional reasoning and probabilistic thinking that underlie the power of science. Nevertheless, research studies have come underlie legislation, nutritional recommendations environmental assessments and understanding of diesease. To the extent that studies are done scientifically and marketed honestly, they contribute greatly to the general lawfulness and openness to change that characterizes Western Society. Societal dependence on science conveys on scientists a great ethical responsibility to conduct research with integrity. Improving research integrity was the charge of a NAS commission and the following paraphrases parts of the report ( ).

A. <u>Research Integrity</u>

Research integrity may be defined as active adherence to the ethical principles and professional standards essential for the responsible practice of research.

By active adherence we mean adoption of the principles and practices as a personal credo, not simply accepting them as impositions by rulemakers.

By ethical principles we mean honesty, the golden rule, trustworthiness, and high regard for the scientific record.

> **NAS report definition: "For individuals research integrity is an aspect of moral character and experience. It involves above all a commitment to intellectual honesty and personal responsibility for ones actions and to a range of practices that characterize responsible research conduct." These practices include:**
>
> > **"1. Honesty and fairness in proposing, performing, and reporting research;**
> > **2. Accuracy and fairness in representing contributions to research proposals and reports;**
> > **3. Proficiency and fairness in peer review;**
> > **4. Collegiality in scientific interactions, communications and sharing of resources;**
> > **5. Disclosure of conflicts of interest;**
> > **6. Protection of human subjects in the conduct of research;**
> > **7. Humane care of animals in the conduct of research;**
> > **8. Adherence to the mutual responsibilities of mentors and trainees."**

While science encourages (no, requires) vigorous defense of one's ideas and work, ultimately research integrity means examining the data with objectivity and being guided by the results rather than by preconceived notions.

We will return to the importance of preserving the integrity of the scientific record in the section on misconduct.

B. Professionalism in Science

Professionalism in science denotes a pattern of behavior identified with scientific integrity that, in turn provides certain privileges. Like other professionals, scientists are expected to behave with intellectual honesty and excellence in thinking and doing. In many respects they perform their professional activities as a monopoly, licensed by society similar to doctors, nurses, lawyers, hairdressers, accountants, and real estate brokers. Besides providing their expertise, professionals are supposed to behave collegially and teach the skills to others, and put society's needs first in their professional activity. In response, society gives them a great deal of autonomy in conducting their professional lives. With scientists, that means selection of one's own research problems and methods of procedure. They also are given the responsibilities to allocate funding, and review of their output in publications. Like other professions they are given responsibility for discipline in the event of poor performance or malfeasance. When self-regulation fails to sustain honesty and high quality, society imposes rules and laws to maintain its interests in professional quality.

Table: Elements of Professionalism

Intellectual honesty **Excellence in thinking and doing** **Collegiality and openness** **Autonomy and responsibility** **Self-regulation**

C. Practical Elements of Responsible Research Conduct

1) Conducting and reporting research
- **Role of the hypothesis**
- **Critical nature of experimental design**
- **The tentativeness of conclusions**
- **Skepticism and humility tempered with conviction**
- **Dealing with surprises - serendipity**
- **Communicating with colleagues**
- **Communicating with the community- media**

2) Social responsibility of scientists

Is it appropriate to consider the broader consequences of the pursuit of a scientific question?
"I just make discoveries about nature, others use my discoveries for better or worse (nuclear energy, synthesis of viruses, very toxic compounds)."

"I must consider the predictable consequences of my research and decide in advance if I will create serious ethical problems as a result of its outcomes."

"It matters not that others might discover what I avoid seeking because of its consequences. I do not have to contribute to the misfortune of humanity in my research."

"The true consequences of a research effort are impossible to predict and it is the height of arrogance not to pursue a promising avenue of science just because of qualms about its misuse."

"How do I design and interpret my work not to bias the conclusions?"

"Do scientists have the responsibility to make every effort to enter their work into the scientific record whether it is positive or negative?"

3) Collegiality, sharing

This aspect of professional behavior has always been a core value of science. There is an NIH policy on sharing reagents, databases and transgenic animals. Materials Transfer Agreements (MTAs) routinely monitor the transfer of resources between labs and between institutions. On the other hand, science is so competitive that sharing may reduce credit to the lab and diminish the scientific achievement associated with the effort of the trainees in the lab, two of the major signs of research success. How to balance the two mandates is a serious challenge.

Patent and licensure are highly desired by research institutions and accrue benefit to investigators as well. They may require secrecy in research and sometimes result in closed laboratories where the trainees cannot discuss their work. This is incompatible with collegiality and sharing.

A major element of scientific integrity is the proper assignment of credit for past work of others and current work within the research group. Scrupulous adherence to this practice will help greatly but not eliminate dissatisfaction. Is there a process to ensure understanding and appropriate assignment of authorship and credit?

4) Mentorship

What is the essence of mentorship? Is it taking on a fiduciary responsibility for the trainee and putting her needs first? That too is one of the practices of research integrity. Questions arise such as, Is it appropriate for a PI to refuse to mentor the trainees in the lab? Is one mentor enough for a trainee or are they better off looking at least for a professional mentor and a research mentor? What are the responsibilities of mentors toward trainees? What are

the characteristics of good mentors? What are the responsibilities of trainees toward mentors?

5) Reviewing and monitoring research

This includes reviewing grants and research reports and serving on Data and Safety Monitoring Boards, Research Ethics Committees (IRBs) and other research oversight committees.
In all of these functions the individual involved must:

- **Provide an objective review**
- **Maintain confidentiality**
- **Avoid conflicts of interest by recusal when appropriate**
- **Avoid taking advantage of inside information**
- **Maintain integrity of the scientific record**

6) Conflicts of interest and commitment

Who is the scientist working for?
Definition of a conflict of interest – it's the situation
Managing conflicts of interest

- **Disclosure**
- **Limited financial involvement**
- **Transactional transparency**
- **Oversight – monitoring, auditing,**

7) Scientific Malfeasance and Misconduct

Fabrication Falsification and Plagiarism – definitions and distinction from error

- **Impact on the research record**
- **Risk of litigation**
- **Whistleblowing**
- **Mandated institutional responses**
- **Bad research manners- interpersonal relations – exploitation of subordinates, exploitation of inside knowledge,**

CASES Chapter 1

Immunology Graduate Student, Dubious Data

Darlene Campion, a PhD candidate in immunology gave her regular presentation of research progress when her PI said that her data looked great and that she should put together an abstract for the spring meeting with herself as first author. After the session Darlene basked in the pleasure of her success. However, nagging doubts about the solidity of her data resurfaced after the next set of experiments. She wanted to do more experiments but the abstract deadline was now only two weeks

away and she knew that she would not be able to complete further experiments before the deadline. She went to her PI Gabriella Corral.

"Darlene, she was told, you need to go out on a limb a little to be recognized. After all, the system runs on getting credit for doing something first and the innovation can provide recognition for years. Let's put in the abstract and you can keep doing experiments until the meeting. In fact, by then you might have the paper written and submitted. This is a very competitive world, so compete girl, compete!"

Darlene, still dubious, sends in the abstract and redoubles her efforts to provide a solid base of experimental evidence to support the novel hypothesis. Meanwhile Dr. Corral heard from the Immunology society that the abstract was selected for a plenary presentation as one of the most significant developments of the year. Elated, she relates the honor to Darlene. Rather than the expected elation, Darlene turns very pale.

"As I said before, she states, the data don't seem to be so great to me and I have not been able to substantiate the results."

"Well, you still have a little time but if you get no further, we will just present the original material in the abstract," says Dr. Corral.

Darlene hurriedly left the room.

Questions:

1. **Is there any questionable behavior here?**
2. **Elaborate on the underlying theme in research ethics?**
3. **What are the options for each of the players if the data remain the same?**

Case: Transhumans

It's a short time in the future, say 2020. You have been studying brain processing in hopes of enhancing the cognitive capacities of patients with Alzheimer's disease and those who are mentally retarded. You have just discovered a way of increasing the brain's memory capacity by 100% and it's processing speed two fold using the daily administration of 2 pills. You are overjoyed except for the fact that you know what happened when lesser improvements in cognitive function were introduced early in the 21st century. People started taking them to improve memory even though there was no evidence that they worked in normal persons. It was a reminder of what happened with steroids and growth hormone on physical performance in the 20th century. They became essential for every truly competitive athlete.

Your finding is so central to thought that those taking the drug will thoroughly outstrip everyone else that we might consider them to be transhuman. As you think about your discovery, you can visualize a situation in which the transhumans begin to take over the resources of the earth, and ultimately have no use for the "plain humans" they supplanted.

Questions:

1) **What do you think as a scientist of this potential state of affairs?**
2) **Do you have any responsibility as a scientist to consider the consequences of your work when you think of what to do with your findings?**
3) **Science as a discipline deals with major technological developments including:**
    a. **Nuclear power and bombs**
    b. **Recombinant DNA technology**

c. **Totipotential embryonic stem cells**
d. **Reproductive technologies using genetic manipulation**
e. **The Internet**

Is it appropriate to allow the political process to determine who will make the critical decisions about the use of scientific advances?

Case: The Real Thing

Eckhard and Wimmer demonstrated the complete synthesis from oligonucleotides of the cDNA of poliovirus, from which infectious virus could be produced. They published these results in Science. Cello et al demonstrated that the production of the active virus could be carried out from scratch – one could say that a form of life was created. This received a lot of press play.

There was considerable criticism of both the authors and Science for publishing material that might be of use to terrorists. A number of congresspersons filed a resolution criticizing the publication. Although, in this case the virus is tiny and available, the method expensive and unwieldy, and the infectiousness quite limited, there is no doubt that by appropriate genetic manipulation, with enough money, agents like smallpox and anthrax could be produced by scientists and their results published.

Scientists have social as well as individual responsibilities.

Questions: 1. How can we handle the inevitably increasing capacity to create dangerous life forms?

As individual scientists?

As a society?

As an international scientific community?

Case: Sloppy Lab work

Background: During the first year of graduate school, Tom has been taking courses and doing laboratory rotations. While in Professor Allen's laboratory, Tom makes several exciting observations. Professor Allen tells Tom that the results will be publishable in a major journal.

Part 1: When Professor Allen goes to write the manuscript a month later, she finds that Tom did not record in his notebook the incubation medium and times for one group of experiments. Also, the computer files where Tom thinks he saved the information were accidentally erased.

Questions:

1. Can Professor Allen still write the paper?
2. Would it make a difference if Tom said he could remember the details even though he didn't write them down?
3. Would it make a difference if a technician working on the project said that he remembered even though Tom could not?

Part 2: Professor Allen writes the paper, which is accepted for publication. Tom finishes his first year and returns to Professor Allen's laboratory. He begins where he left off, but in two attempts he cannot repeat the original finding.

Questions:

1. What should he and Professor Allen do about the paper assuming it has not yet been published?

2. What should they do if the paper has been published?

Part 3: Professor Allen receives a manuscript to review that contains experiments whose results make clear why Tom has been unable to make further progress with his experiments.

Questions:

1. Can Professor Alan share this information with Tom?
2. What if the information was contained in a grant proposal?

Derived from Fred Grinnel

Case: Research Integrity

Jones is a highly successful entrepreneurial academic scientist. He occupies an endowed chair that allows him to avoid teaching. His research team performs brilliantly conceived studies with precision and completeness. His lab has made many important contributions and he is consistently very well funded.

A graduate student is considering Jones' lab for his Ph.D. and speaks to the current trainees. They say that Jones is merciless, requiring 15-hour days for months before the annual meeting abstract due date. He assigns projects without regard to the trainee's interests, has trainees compete with each other, unilaterally determines authorship and first authorship in what appears to be an arbitrary manner and deals with staff and trainees in a paternalistic and demeaning manner. He personally spends little time with his trainees and shows little interest in their lives. His usual comment is that research is extremely competitive and they had better learn how to fend for themselves. His trainees almost invariably get excellent positions after completing their degrees with him.

QUESTIONS:

1. Does the investigator have research integrity? Intellectual honesty? Defend your answer.

2. If you were the student, would you select his lab? Defend your answer.

3. The department chair and dean know all about this lab chief's behavior and have never discussed it with him. What responsibilities does the administration have in relation to Jones' behavior? Defend your answer.

Case: Sharing in the Laboratory Setting

Al Glantz has recently completed a successful thesis defense and is planning for his move across the country to his new laboratory. He arranged a meeting with his mentor and lab chief, Calvin Jones.

Al: I'm really grateful for your support over these five years. I learned a great deal. The lab environment was terrific and your recommendation, I'm sure, was instrumental in my obtaining such a promising post-doctorial fellowship.

Prof. Jones: Well, you're one of my best trainees ever and I'm proud of your accomplishments and have great expectations for you as a scientist.

Al: That's great. I thought that this would be a good time to review some housekeeping details so that I can use my remaining time in the lab most productively.

Prof. Jones: That's a great idea. What do you have in mind?

Al: Well, I need to write a new investigator proposal to the NIH and I want to continue the work I've been doing here. I have some new ideas to pursue. In order to do that, I would like to utilize all our unpublished results as background and preliminary results for the fellowship application and get a letter from you supporting me and indicating that I will have access to all the DNA probes and monoclonal antibodies I prepared for our projects here. Then I'll really be able to get a good start. I want to start on the grant right away. When I get that done, I will get back to completing the papers describing our most recent results.

Prof. Jones: I'm glad we had this chance to get together on this, because we must make plans for your last three months. I would be happy to write you a good letter with regard to your grant proposal. You have a right to describe anything you personally did as preliminary work but you must not use other unpublished results from the laboratory unless they are accepted for publication and you are a co-author.

If I were you, I would write up the papers first because as you know, the data belongs to the lab and when you're gone, if the papers aren't submitted, I'll ask Fred to write them up and he'll be first author.

You will be able to take the monoclonals, cell lines and C-DNA probes that we send out but you will not be able to take any irreplaceable materials. Finally, you are going to a competing lab that shares materials poorly, so your ability to receive material from us will depend on reciprocity. We have others here whose careers need to be built, you know.

Questions:

1. **Was Prof. Jones being unfair?**
2. **Was Al expecting too much?**
3. **Was Jones statement consistent with NIH rules on sharing?**
4. **Who owns the data?**

Case: Genetics of Psychopathic Behavior

Dr. Brain discovered that a combination of 3 genetic polymorphisms was present in 86% of people who were criminally psychopathic. This combination of traits was present in 6% of the general population. Utilizing PET scanning, he discovered responses to specific scenarios that correlated very highly with criminal behavior. When the data were published, the investigators surmised that the 3 polymorphisms participated in brain development and when they were fully expressed they altered brain structure and function so that distinction of right from wrong was impossible. They thought that the combination of genetic testing and PET to elucidate the expression pattern attributable to the genes might make it possible to determine in advance the chance of recidivism in convicted criminals, that is to predict criminal behavior.

Shortly after publication Dr. Brain and team began to receive requests from prosecutors and defense attorneys to work up their clients to prove that they did or did not have the career criminal trait. Judges requested an evaluation before sentencing and parole boards also expressed interest.

Faced with fixed budgets, child services organizations wanted to screen troubled youths for the recidivist tendency so they could spend less money on these "incorrigibles" and focus their attention on those they might be able to help.

Questions:

1. **Is there a problem with the research?**
2. **Is there a problem with the reporting of the research?**
3. **The societal responses to the research could have been anticipated. What implications did that have for Dr. Brain and his team?**
4. **What should Dr. Brain do now?**
5. **If there were a medication that could reverse the impetus toward antisocial behavior, would that change the answers to any of these questions?**

"The use of flawed or incomplete science, and the reliance on scientific predictions beyond what the science is prepared to support, are exactly the kinds of concerns that should be foremost in the public mind when contemplating the potential social impact of predictive technologies or techniques. It is not just in courtrooms that prediction would have an impact, but also in schools, employment, healthcare systems, government investigations, and in other ways that would dwarf usage by the court system. The potential to pigeonhole, to discriminate, and to judge on the basis of test results could result in substantially negative consequences, including the development of a "neuroscientific underclass" denied access to education and other societal benefits on the basis of their neuroscience test results. These concerns parallel the current dialogue around genetics, and some feel the public dialogue around genetics may illuminate some of the promises and pitfalls that could accompany and greater understanding of the brain.

Though a host of possible predications might be desirable (e.g. tendency to be honest, willingness to follow authority, etc.), the potential for violence is of particular interest and significance. Prediction of violence has already been the subject of neuroscience research, and it will probably continue to interest science as well as the legal system. It is a predictive measure likely both to have tremendous utility and to carry great risk of misuse; and it is likely to cut both ways in criminal law – in mitigation and in marking someone as being predisposed to violence. While violent behavior will probably never be predicted with complete certainty, the likelihood that techniques will be developed

to distinguish those more likely or even very likely to react with violence seems quite enough that those techniques be considered for future research and public discussion."

("Neuroscience and the Law," Professional Ethics Report. 2004: 17, p.2)

BIBLIOGRAPHY – Chapter 1

Alpert, J. S., K. I. Shine, et al. (2004). "Task Force 1: The ACCF and AHA codes of conduct in human subjects research." Journal of the American College of Cardiology **44**(8): 1724.

A set of guidelines for cardiologist-investigators regarding clinical research.

.Annas, G. J. (2005). "Family Privacy and Death -- Antigone, War, and Medical Research." N Engl J Med 352(5): 501-505.

The article examines the issue of family privacy and death through three distinct cases -- the ban on filming of US casualties in war, Vincent Foster's suicide photos, and Iceland's Health Sector Database. It is applicable to investigators in that it highlights the importance of patient privacy after death. The deceased patient's family rather than the investigator has the right of disclosure if the patient participated in a medical study; this fact makes consent forms and other pre-experiment contracts especially important for research participants.
http://content.nejm.org/cgi/content/extract/352/5/501

Bates, B. R., J. A. Lynch, et al. (2005). "Warranted Concerns, Warranted Outlooks: A Focus Group Study Of Public Understandings Of Genetic Research." Social Science & Medicine **60**(2): 331.

This paper does focus groups on public attitudes toward genetic research and its clinical consequences. It concludes that the public has a reasonable understanding of these in its own terms.
http://www.sciencedirect.com/science/article/B6VBF-4CSYKDG-2/2/5fe206aeb8afd9dcff74ae19fec7ee9f

Beckwith, J. (2001). "On the Social Responsibility of Scientists." Ann Ist Super Sanita. 37(2):189-94

The author deals with the social responsibility of genetic researchers using the discredited eugenics movement in the early 20th century as the model to show that destructive results can be due to scientific developments. Few geneticists are fully aware of the eugenics movement, which led to labeling some humans as genetically inferior. Many geneticists became proponents of eugenics between 1906 and 1915 (scholarly articles and textbook influences). This paper reviews the horrific history and allows us to project the future. It also goes into the ELSI process in the human genome project and the failures of communication between scientists and those involved in the humanities.

Beecher, H. K. (1966). "Ethics and clinical research." Bulletin of the World Health Organization 79(4): 367-72.

This is one of the classics in the field of RCRH in that it points a finger at the unethical aspects of research as carried out at the time.

Benditt, J., et al. (1995). "Conduct in science." Science 268(5218): 1705-18.

This is the introduction to a number of papers on the culture of science and the methods for teaching responsible conduct of research. The whole sequence should be required reading of teachers of RCR.

Berry, R. S. (2003). "Validity and Ethics in Science." Science 300(5624): 1341-.

The author indicates that in science there are experiments and concepts that can be shown to be wrong by further research and experiments and concepts that are fraudulent, and known by their authors to

be so from the beginning. In dealing with misconduct, science is proposed to distinguish between the two poorly, and that is unsatisfactory.
http://www.sciencemag.org/cgi/content/summary/300/5624/1341

Bird, S. J. (1998). "The Role of Professional Societies: Codes of Conduct and Their Enforcement." Sci Eng Ethics 4(3): 315-320.

In discussions of professional standards and ethical values it is reasonable to consider who will develop the codes of conduct and guidelines for behavior that will reflect the standards and values of the community. Also worthy of consideration is whether the standards or guidelines are enforceable, and how and to what extent they will be enforced. The development of guidelines or professional codes of conduct is a responsibility that has been adopted by many professional societies. Useful to this discussion is an examination of the rationale behind the development of ethical codes by professional societies. The Ethics in Science Committee of the Council of Scientific Society Presidents (CSSP) has examined the codes of some of its member societies and some observations regarding them are pertinent. The nature and uses of ethical statements, codes and guidelines developed by professional societies are multiple and diverse. Their enforcement raises both practical and ethical concerns.

Block, S. (2002). "A Not-So-Cheap Stunt." Science 297(5582): 769-70.

This brief paper describes the de novo synthesis of the polio virus, an exercise in the creation of life from precursors. The article generated considerable concern as a potential blueprint for terrorists and raised questions about the social responsibility of scientists regarding publishing material that could be misused in that way.
http://www.sciencemag.org/cgi/content/full/297/5582/769b

Bloom, F. (1995). "Scientific conduct: contrasts on a gray scale." Science 268(5218): 1679.

Intense competition for funding and commercial influences on science have made it more difficult for scientists to live up to ethical standards. This is especially true when subtle ethical choices are involved such as deciding whose name will be listed first on a research report.

Blumenthal, D., E. G. Campbell, et al. (1997). "Withholding research results in academic life science. Evidence from a national survey of faculty." JAMA 277(15): 1224-1228.

This empirical study of scientists' behavior and the consequences for the progress of science focuses attention on secrecy as a mechanism of enhancing a laboratory's relative position and its consequences for society as a whole. A good study.

Bramstedt, K. and K. Kassimatis (2004). "A study of warning letters issued to institutional review boards by the United States Food and Drug Administration." Clin Invest Med 27(6): 316-23.

The author analyzed FDA warning letters to IRBs and found that the most common cause of a letter was failure to follow written procedures as to monitoring research after it was initiated.

Brody, J., D. Scherer, et al. (2003). "Voluntary assent in biomedical research with adolescents: a comparison of parent and adolescent views." Ethics and Behavior **13**(1): 79-95.

This study tests the relationship between perception of risk/aversion between adolescents with asthma and their parents in relation to an asthma protocol set to test agreement. There was about 75% concordance between the two and each felt that they were in control.

Brown, S. K., M. (1998). "Effects of Training in the Responsible Conduct of Research: A Survey of Graduate Students in Experimental Sciences." Sci Eng Ethics 4(4): 487-498.

Do all these courses have an impact? And what is it? Tune in and see.

Campbell, E. G., B. R. Clarridge, et al. (2002). "Data Withholding in Academic Genetics: Evidence From a National Survey." JAMA 287(4): 473-480.

The free and open sharing of information, data, and materials regarding published research is vital to the replication of published results, the efficient advancement of science, and the education of students. Yet in daily practice, the ideal of free sharing is often breached. The authors mailed a survey to geneticists and other life scientists in the 100 US universities that received the most funding from the National

Institutes of Health in 1998 with a response rate of 64%. They compared 1240 geneticists with 600 self-identified nongeneticists. There was substantial withholding of data even after publication and loss of scientific efficiency. Those who withheld had various reasons including further need to publish from the data and lack of resources to comply with requests. This illustrates the weakness of collegiality as a value in certain areas of modern science.
http://jama.ama-assn.org/cgi/content/full/287/4/473

Caplan, A. (2003). "Is Biomedical Research Too Dangerous to Pursue?" Science 303: 1142.
After the problems, often serious associated with biomedical research, the author concludes that it is worthwhile after all. Whew! The arguments in this brief paper are worth a read.
http://www.sciencemag.org/cgi/content/full/303/5661/1142

Chalmers, D. P., P. (1998). "Towards a Consensual Culture in the Ethical Review of Research." Medical Journal of Australia 168(2): 79-82.
The authors point out that research rules commonly follow some kind of ethical crisis and that this may not be the best way to develop and maintain regulations. They suggest an alternative method derived from the notion of consent of the governed. They also deplore the propensity of review organizations to increase the standards and therefore continually make it harder for investigators. As Australians they use Australia as the example.

Chen, D. and B. Worrall (2006). "Practice-based clinical research and ethical decision making--Part I: deciding whether to incorporate practice-based research into your clinical practice." Semin Neurol **26**(1): 131-39.
This paper reviews for neurologist practitioners what clinical research is and the pros and cons of incorporating research into their practices. It also points out, with the expansion of clinical research, that they might have to advise their patients about research participation even if they don't do research themselves.
http://www.thieme-connect.com/DOI/DOI?10.1055/s-2006-933317

Chen, D. and B. Worrall (2006). "Practice-based clinical research and ethical decision making--Part II: deciding whether to host a particular research study in your practice." Semin Neurol **26**(1): 140-7.
The second component of the previous article.

Cohen, J. (1995). "Share and Share Alike Isn't Always the Rule in Science." Science 268(5218): 1715-8.
This is a component of a series of articles on sharing in science, generally asking whether the hallowed principle of collegiality has lost its force and left us in a dog-eat-dog scientific world.

Cohen, J. (1995). "The culture of credit." Science 268(5218): 1706-11.
Scientific ideals call for collaboration and sharing. But in today's competitive scientific enterprise, a tremendous premium is placed on individual credit, setting the stage for conflict.

Cottingham, K. (2001). "University-Industry Collaborations: Whose Data?" Science 11(27).
This ethics case discussion relates to a PhD candidate who participated in a clinical trial as part of her research and found that she could not publish the data as part of her thesis. Because the results were not favorable, she was forbidden to use the data. Three “experts” discussed the scenario.

Cournand, A. (1977). "The Code of the Scientist and Its Relationship to Ethics." Science 198(4318): 699-705.
Scientist's norms (principally honesty, objectivity, tolerance, doubt of certitude, and unselfish engagement) are in danger of serious distortion unless broadened to apply to the relations between scientists and nonscientists. Also needing supplementation is an ethic of development appropriate to a fast-changing society and advanced as an approach to the more effective and humane regulation of cultural and technological development. Taken together, furthermore, they indicate the possibility of a humane world order based on the cooperation of a community of scientists and its public. See the date. This nobelist visualized a world that hasn’t arrived and may never arrive, considering what humans are. This is a classic.

Couzin, J. (2002). "BIOTERRORISM: A Call for Restraint on Biological Data." Science 297(5582): 749-751.

This response to the increasing power of biological sciences suggests that information that might be of use to terrorists not be published in usable form. Others argued that the development of counter weapons depends on knowing what can be done. Needless to say, journals are watching what they print.

Curfman, G. D. and J. M. Drazen (2001). "Too Close to Call." N Engl J Med 345(11): 832.

In response to criticism, the NEJM developed a new process for editorial review of papers derived from their own editorial board.
http://content.nejm.org/cgi/content/extract/345/11/832

Davidoff, F. (2001). "Sponsorship, Authorship, and Accountability." N Engl J Med 345(11): 825-7.
Davidoff, F., C. D. DeAngelis, et al. (2001). "Sponsorship, Authorship, and Accountability." Ann Intern Med 135(6): 463-466.

This article, which was published simultaneously in the agreeing journals began the process of improving the status of articles derived from clinical trials sponsored by pharmaceutical companies by making the listed authors understand they are accountable for the contents and should see the underlying data and actually write the paper. Changes in journal review practices as well as entering clinical trials at the beginning in a database as a criterion for publishability are all derived from the meeting of publishers that led to this paper.
http://jama.ama-assn.org/cgi/content/full/286/10/1232

Davis, L. L., M. S. Little, et al. (1997). "The Art and Angst of the Mentoring Relationship." Acad. Psychiatry 21(2): 61-71.

The authors review the ancient mentoring relationship in Homer's Odyssey and the mentoring discourse of Socrates. These relationships illustrate the art of inspiring a searching quality in the subject and the angst of the struggle that accompanies perplexity and unknowing. The developmental stages of the mentor and resident in psychiatric training are reviewed. A number of teaching interventions are discussed as they might be perceived by the student. Finally, Plato's "Allegory of the Cave" is used as a metaphor for the art of enlightenment and angst of learning and teaching in the mentoring relationship.

Dickenson, D. and J. Ferguson (2005). “Advisory Document for Retained Organs Commission.” University of Birmingham, UK: Centre for Global Ethics.

This document addresses the burning issue of retained organs and the rights of donors. They suggest a modified property rights approach to regulation of the practice.
http://www.globalethics.bham.ac.uk/consultancy/Retained_organs.htm

Easterbrook, G. (1997). "SCIENTIFIC COMMUNITY: Science and God: A Warming Trend?" Science 277(5328): 890-893.

This is a thoughtful discussion of the relationships or the lack thereof between religion and science. Both approaches to the world seek truth in different ways and both exert great power. The question is whether they can be reconciled. Lots of ideas are presented in a vigorous format.

Eastwood, S. D., P; Leash, E; Odrway, S. (1996). "Ethical Issues in Biomedical Research: Perception and Practices of Postdoctoral Research Fellows Responding to a Survey." Sci Eng Ethics 2(1): 89-114.

This empirical study surveyed 1005 trainees and got 1/3 to respond. Their ethics were not very strong and it didn’t matter whether they had taken training in research ethics during their training. This is well worth reading.

Emanuel, E. J., D. Wendler, et al. (2000). "What Makes Clinical Research Ethical?" JAMA 283(20): 2701-2711.

The authors point out that just getting informed consent does not make clinical research ethical. They propose 7 requirements for ethical clinical studies: “(1) value--enhancements of health or knowledge must be derived from the research; (2) scientific validity--the research must be methodologically rigorous; (3) fair subject selection--scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion

criteria for individual subjects; (4) favorable risk-benefit ratio--within the context of standard clinical practice and the research protocol, risks must be minimized, potential benefits enhanced, and the potential benefits to individuals and knowledge gained for society must outweigh the risks; (5) independent review--unaffiliated individuals must review the research and approve, amend, or terminate it; (6) informed consent--individuals should be informed about the research and provide their voluntary consent; and (7) respect for enrolled subjects--subjects should have their privacy protected, the opportunity to withdraw, and their well-being monitored." They claim that fulfilling all 7 is necessary and sufficient to make clinical research ethical. While studies must be adapted to the environment in which they are conducted, the 7 standards are broad enough to encompass them all. The latter may be questionable but the paper has become an instant classic and clinical research proposals are being evaluated on the basis of the seven points. A must read.
http://jama.ama-assn.org/cgi/content/full/283/20/2701

Endocrine Society. (2005). Ethical Guidelines for Research, found on their web site.

An important guide for understanding the basic requirements of publication in an accredited journal. Also a good source for authors looking for a guide to complying with standards of publication.
www.endocrinesocietyy.org

Evans, M., M. Robling, et al. (2002). "It Doesn't Cost Anything Just To Ask, Does It? The Ethics Of Questionnaire-Based Research." J Med Ethics **28**(1): 41-44.

This paper presents an analysis of potential psychological forms associated with questionnaire research, using as the example a study of attitudes toward breast disease in English women. They point out the possibility of harm both to researchers and to the practicing physicians cooperating in the study.
http://jme.bmjjournals.com/cgi/content/full/28/1/41

Faigman, D. L. (2002). "SCIENCE AND THE LAW: Is Science Different for Lawyers?" Science 297(5580): 339-340.

The author argues that the law is suspicious of the scientific method as a source of expertise. One of the reasons is that in contentious cases the science may not be there, but there is also the underlying theme that probabilistic thinking is difficult for the law. They discuss criteria for credibility of scientific information.

Ferber, D. (2004). "Occupational health. Beset by lawsuits, IBM blocks a study that used its data." Science 304(5673): 937-9.

This article deals with internal IBM data that might show an increased mortality rate in certain IBM work categories. The data were not part of a systematic study and, as they were the subject of numerous torts, they refused to allow the data to be utilized and promised a new, proper study.

Fine, M. K., L. (1993). "Reflections on Determining Authorship Credit and Authorship Order on Faculty-Student Collaborations." American Psychologist 48(11): 1141-1147.

This think piece focusing on psychology, reviews various kinds of trainee-faculty relationships in performing and reporting research. They indicate that beneficence, justice and paternalism should apply in making the decisions.

Flanagin, A., P. B. Fontanarosa, et al. (2002). "Authorship for Research Groups." JAMA 288(24): 3166-3168.

This editorial tries to adopt fair policies for the listing of authors in large multicenter clinical trials. They recognize that it's a tricky matter both to determine who meets authorship criteria and to properly credit those who are not lead authors.
http://jama.ama-assn.org/cgi/content/full/288/24/3166

Francke, U. (1999). Response to National Bioethics Advisory Commission on the Ethical Issues and Policy Concerns Surrounding Research Using Human Biological Materials. H. T. M. Shapiro, Eric. Meslin.

These authors, officers of the Am. Soc. For Human Genetics comment very negatively on the proposals of the NBAC regarding the use of human biological materials. The most powerful objections are

to the absolute requirement for anonymization and for revisiting donors to get permission to use their materials for new projects. They claim it will bring certain types of science to a halt.

Garland, B. (2004). "Neuroscience and the Law." Professional Ethics Report 17(1).

This reports on a conference that eventually became a book relating primarily to 4 questions. How will ability to predict behavior alter the law? How will scientific lie detection affect testifying witnesses? How could new neurological knowledge affect discrimination? What are the risks and benefits of brain modification for enhancement? These questions address key ethical issues including “free will” and responsibility for behavior.

Goodman, Ellen (2001). Medicine needs more "chumps". Boston Globe. Boston, MA. March 1, 2001.

In her way she points out that those who did not benefit financially from their discoveries were, perhaps, better off and more respected than those who struggle to make the last entrepreneurial dollar from their scientific achievements.

Goodwin, F. M., A. (1999). "Scientists in Bunkers: How Appeasement of "Animal Rights" Acitivism Has Failed." The Dana Forum on Brain Science 1(2): 50-62.

These investigators argue that appeasing animal rights activists only encourages them to demand more and more. They will never be satisfied. The suggestion is pushing back.

Gray, M. L. and J. V. Bonventre (2002). "Training PhD researchers to translate science to clinical medicine: Closing the gap from the other side." Nat Med 8(5): 433.

The authors suggest that training basic scientists to have a more practical bent and become interested in translational medicine will more discoveries to the pharmacopiea

Grinnell, F. (1999). "Ambiguity, trust, and the responsible conduct of research." Sci Eng Ethics 5(2): 205-14.

Ambiguity associated with everyday practice of science has made it difficult to reach a consensus on how to define misconduct in science. This essay outlines some of the important ambiguities of practice such as distinguishing data from noise, deciding whether results falsify a hypothesis, and converting research into research publications. The problem of ambiguity is further compounded by the prior intellectual commitments inherent in choosing problems and in dealing with the skepticism of one’s colleagues. To do this responsibly, the underlying theme had to be trust. However, in today’s environment trust had to be earned by being a responsible investigator. This paper raises lots of issues distinguishing the reality of scientific endeavor from the theoretical.

Grunberg, S. M. and W. T. Cefalu (2003). "The Integral Role of Clinical Research in Clinical Care." N Engl J Med 348(14): 1386-1388.

This article analyzes the relationship between clinical care and research in the performance of therapeutic clinical research. They argue that the role of the physician cannot be abrogated during the course of research and that individual subject improvement is the goal. This paper is very well worth reading in the face of contrary arguments indicating that researchers cannot put themselves in the position of clinicians if they are to conduct the research properly.

Gupta, M. (2003). "A Critical Appraisal Of Evidence-Based Medicine: Some Ethical Considerations." Journal of Evaluation in Clinical Practice **9**(2): 111-121.

This paper analyzes the philosophical support for "evidence-based medicine" as the route to better health care, focusing on the intrinsic weaknesses of the data and biases in the research.
http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2753.2003.00382.x

Gwynne, P. (1999). "Corporate Collaborations." The Scientist 13(11): 1, 6.

The reporter discusses cases in which a scientist under a confidentiality clause was prevented from reporting on adverse events associated with the research. This occurred under conditions under which the institution did not insist on academic freedom. The importance of writing the right kind of contract with industry was emphasized.

Helmuth, L. (2001). "COGNITIVE NEUROSCIENCE: Moral Reasoning Relies on Emotion." Science 293(5537): 1971a-1972.

This short paper demonstrates that what we consider to be moral reasoning is not fixed in the rational brain but is associated with feeling developed by the manner in which the information is presented to us.

Hensley, S. and L. Abboud (2004). Medical Research Has 'Black Hole.' Negative Results Often Fail to Get Published in Journals; Some blame Drug Industry. Wall St J. New York: B3. June 5, 2004.

This well-written article brings into focus the problems associated with failure to publish negative reports, something that has since gotten a great deal of attention.

Hoeyer, K., L. Dahlager, et al. (2005). "Conflicting notions of research ethics: The mutually challenging traditions of social scientists and medical researchers." Social Science & Medicine **61**(8): 1741.

When anthropologists and sociologists try to study health services in medical institutions, serious problems arise that are proposed in this paper to be due to cultural differences that might be ameliorated by dialogue. Good luck!
http://www.sciencedirect.com/science/article/B6VBF-4G1GFK2-1/2/3b6968c880005504c1256540aafff920

Inouye, S. K. and D. A. Fiellin (2005). "An Evidence-Based Guide to Writing Grant Proposals for Clinical Research." Ann Intern Med 142(4): 274-282.

The competition for research funding is intense. Patient-oriented research lags in support behind that allocated for basic science research. Much of the time that is due to poor experimental design and poor grant-writing, neither of which are taught to M.D.s. This article gives an outline for the grant-writing process for clinical researchers. It focuses on those components of the grant proposal that are most likely to be criticized. They recommend methods to improve the quality of areas commonly cited as deficient. This is a really neat paper for anyone in the early phases of a career who has to write and write in hopes of getting funded.

Institute of Medicine. (2002). Responsible Research: A Systems Approach to Protecting Research Participants.

This book attempts to describe improvements to the entire process of clinical research, emphasizing the protection of vulnerable participants. It makes numerous recommendations to institutions and government to improve the research process and better prepare all the team members for their roles. It should be required reading for those who have institutional responsibility for research.

Kaiser, J. (2005). "SCIENTIFIC PUBLISHING: NIH Wants Public Access to Papers 'As Soon As Possible'." Science 307(5711): 825-.

The NIH has pushed for early online access to research papers and manuscripts in order to increase public awareness and knowledge about science. However, publishers have battled against early release, since giving free access would significantly decrease revenues from scientific journals and reduce funds available to scientific organizations. The article contrasts pressure to make new research studies available with the pressure to produce sufficient revenues to preserve vital scientific organizations. It is significant in addressing both of these issues in an objective way.

Kempner, J., C. S. Perlis, et al. (2005). "ETHICS: Forbidden Knowledge." Science 307(5711): 854-.

A discussion of new social and political constraints placed on certain research subject areas. The article focuses on studies that seek to find out how research limitations affect the performance and opinion of scientists. Although most agreed that social constraints offered important protection for patients, many scientists felt uncomfortable with policy-makers setting limitations on their research. The article addresses the responsibility of investigators to maintain social norms while attempting to produce novel research.

Kennedy, D. (2001). "Editorial: "Accepted Community Standards"." Science 291(5505): 789.

This editorial deals with the concept that readership should have access to all the materials necessary to replicate a paper should they be skilled enough to do it. However, as science has become more proprietary and complex there has been movement away from this standard. He reiterates the standard and discusses exceptions.

Kennedy, D. (2003). "Multiple Authors, Multiple Problems." Science 301(5634): 733.
The author of this editorial deals with the problem of identifying the person among many authors who was responsible for problems in a paper and with the problem of promotion committees deciding whether an author made a critical contribution or otherwise. He suggests that authors be asked to identify their role in each paper.

Korenman, S. G., R. Berk, et al. (1998). "Evaluation of the Research Norms of Scientists and Administrators Responsible for Academic Research Integrity." JAMA 279(1): 41-47.
This study used a sophisticated scenario matrix method with 12 scenarios in four domains of research ethics to examine the professional norms of basic molecular and cellular biologists and institutional representatives to whom the were responsible. There was a 69% response rate. The investigators found that both groups expressed a high degree of research integrity and there was a hierarchy of research malfeasance with fabrication and plagiarism on the top. While scientists and institutional representatives expressed similar normative values, they differed significantly in their approaches to an unethical act.

Leshner, A. I. (2005). "Where Science Meets Society." Science 307(5711): 815-.
This article examines the clash between social/moral value-systems and advances in research. It attempts to examine ethical boundaries to scientific research within the framework of modern society; however, the article does not make a decisive conclusion on the value of ethical limitations on research.

Madsen, S. M., M. R. Mirza, et al. (2002). "Attitudes Towards Clinical Research Amongst Participants And Nonparticipants." Journal of Internal Medicine **251**(2): 156-168.
This Danish study showed that subjects and potential subjects have a positive attitude toward research. Those entering studies do it for both personal and altruistic reasons and those who refuse to participate were concerned about the unknown and about randomization.
http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2796.2002.00949.x

Marshall, E. (2002). "DATA SHARING: Clear-Cut Publication Rules Prove Elusive." Science 295(5560): 1625.
This comments on problems associated with producing a uniform code on the ethics of publishing as discovered at a meeting for that purpose. Again it was associated with the issues surrounding data sharing.

May, R. M. (2001). "Science and Society." Science 292(5519): 1021.
He discusses a number of ways in which society is puzzled and disappointed by science, especially since science usually has many voices with different agendas in issues of interest to the public. An example is how to handle bovine spongioform encephalopathy in England.

Merton, R. (1942). "A note on Science and Democracy." J Legal and Political Sociol 1: 115-126.
This little classic laid out the underlying responsibilities of scientists, to seek the truth with objectivity, to share, and to self-govern.

Michels, R. (1999). "Are Research Ethics Bad for Our Mental Health?" N Engl J Med 340(18): 1427-1430.
The author argues that many important mental health studies cannot be done because of the rules requiring informed consent. He points out the importance of studying the most serious psychiatric illnesses and the difficulty getting approval for the research. This continues to be a minority viewpoint.

Miller, F. G. and D. L. Rosenstein (2003). "The Therapeutic Orientation to Clinical Trials." N Engl J Med 348(14): 1383-1386.
Considers the ethical differences between clinical care and clinical research and argues that they should be more separated. Discusses in relation to the “Therapeutic misconception.” Excellent Bibliography.

Miller, F. G., D. L. Rosenstein, et al. (1998). "Professional Integrity in Clinical Research." JAMA 280(16): 1449-1454.

This excellent paper considers the dilemmas inherent in the physician carrying out clinical research. Although it notes the importance of regulation it focuses on the role of professional integrity in both halves of the clinical investigator role. They perform a critical examination of the moral identity of physicians as practitioners and as scientists and points out that they are indeed different. They show that you can't give up your responsibility as a physician completely when you carry out research. Nicely done arguments.

Miller, F. G. (2002). "Ethical Significance of Ethics-Related Empirical Research." J Natl Cancer Inst **94**(24): 1821-1822.

This editorial comments on an empirical study of oncologists' understanding of trials in which they participate. The author supports the idea of empirical ethics research and points out that it too can be excellent on trivial, well or poorly done.

http://jncicancerspectrum.oxfordjournals.org/cgi/content/full/jnci;94/24/1821

Miller, H. I. (2003). "Trickle-Down R&D and the Public Good." The Scientist 17(10): 18.

Curing the public-health ills of less-developed countries might be delivered most efficiently by the work that trickles down from the wealthier countries' high-powered research machines.

Morgan, J. P. (2002). "Lessons From a Horse Named Jim: A Clinical Trials Manual From the Duke Clinical Research Institute." JAMA 288(8): 1017-1018.

This review of Liu and Davis' clinical trials manual indicates that the book is very readable. It gives an excellent history of the sad story that led to today's clinical research environment and provides useful materials for anyone who wants to engage in clinical investigation.

N.I.H. (2003). Final NIH Statement on Sharing Research Data. N.I.H.

The NIH comes down on the side of data sharing and has the capability to make it happen.

Nathan, D. G. (2002). "Careers in translational clinical research-historical perspectives, future challenges." JAMA 287(18): 2424-7.

The author lays out the problems with developing a career in translational research under the funding mechanisms as they exist and the promotion policies of academic medical centers.

Petrelli, N. J. (2002). "Clinical Trials Are Mandatory for Improving Surgical Cancer Care." JAMA 287(3): 377-378.

The author notes that many advances in surgery have not gone through a formal clinical research process to their detriment. He argues that formal clinical trials are needed in surgical oncology.

Phillips, R. L., C. Jim, et al. (2004). "Intellectual Property Rights and the Public Good. Universities have Obligations To Developing Countries." The Scientist 18(14): 8.

Is there a fiduciary responsibility of academic institutions to provide patented materials to poor countries? They use the example of Golden rice, which would save many from blindness but is hung up in private hands and beyond the ability of the poor to pay.

Porter, R. and V. Tech (2003). "Facilitating Proposal Development: Helping Faculty Avoid Common Pitfalls." The Journal of Research Administration XXXIV(1): 28-32.

With increasing pressure to obtain extramural funding, success in proposal writing becomes ever more important to colleges and universities. Though the characteristics of good proposal writing are well understood, success ratios remain low and most proposals are rejected on first reading. This paper discusses the dimensions of the problems, identifies some common proposal errors and pitfalls, and suggests techniques to avert them. It concludes that grants specialists can employ intervention strategies centered around internal competitors, early career award workshops, funding search workshops and acceptance of pre-proposals to help faculty improve their grant writing skills.

Price, J., J. Dake, et al. (2001). "Selected ethical issues in research and publication: perceptions of health education faculty." Health Education & Behavior 28(1): 51-64.

This paper surveys a random sample of health education faculty with regard to their perceptions of ethical issues in research and publishing. Most of the respondents were academically mature. They were asked to rate whether each of 21 scenarios was ethical, unethical, questionable or not an ethical issue. The responses were overall quite variable but this did not relate to rank, gender or other demographic factors..

Reinhardt, U. E. (2004). "MEDICINE: Health Care in the Service of Science?" Science 303(5664): 1613-1614.

This review of Daniel Callahan's book "What Price Better Health", that argues that hell- bent scientific development is not the most effective way to optimize health in the population. He feels that scientists have a social responsibility to direct their research where they could reasonably think it will do the most medical good. Reinhardt believes that the way we do medicine reflects societal values and that Callahan is a little off track. Very good reading.

Rennie, D. (2004). "Trial Registration: A Great Idea Switches From Ignored to Irresistible." JAMA 292(11): 1359-1362.

The author reviews the recent history leading to clinical trial registration. Required reading.

Rensberger, B. (2000). "ESSAYS ON SCIENCE AND SOCIETY: The Nature of Evidence." Science 289(5476): 6.

The author, a science writer, responds to criticisms of his profession that they do not teach Americans about science and that opposition to science is based on their giving equal space to quacks as to real science, by indicating that the quality of scientific evidence is often very weak, generating doubt on its own. A very good short paper about the weakness of scientific communication.

Roberts, L. W., T. Warner, et al. (2003). "What is ethically important in clinical research? A preliminary study of attitudes of 73 psychiatric faculty and residents." Schizophrenia Bulletin **29**(3): 607-13.

This survey of psychiatric faculty and residents at one facility identified scientific quality and safeguards followed by trust in the integrity of the PI as the most important ethical aspects of clinical research. As might be expected, the residents are more ethically sensitive than the faculty.

Rodbard, D., P. O'Shea, et al. (2003). Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories. American Institutes for Research.

This private survery conducted for the NIH identified methods that scientists think preserve research integrity and the kinds and duration of training activity in research integrity.

Rosenberg, L. E. (1999). "Physician-Scientist- Endangered and Essential." Science 283: 331-332.

The author raises the alarm about the declining number of physicians preparing themselves as scientists and doing clinically related research. This argument was heard, finally in 2006.

Sa Couto Md, J. (2003). "An Objectivist's View On The Ethics Of Evidence-Based Medicine: Commentary On 'A Critical Appraisal Of Evidence-Based Medicine: Some Ethical Considerations' (Gupta 2003; Journal of Evaluation in Clinical Practice 9, 111-121)." Journal of Evaluation in Clinical Practice **9**(2): 137-139.

The author constructs a strong argument that "evidence-based medicine" and reason based on medical theory are incompatible. This "evidence based medicine" is opposed to objective reason. http://www.blackwell-synergy.com/doi/abs/10.1046/j.1365-2753.2003.00401.x

Saletan, W. (2001) The Ethicist's New Clothes. Slate Volume, DOI:

This article points out that drug and device companies were hiring ethicists as consultants, and compromising them. The ethicists seemed to them to be blind to how bad their conflicts of interests were in their field of endeavor.

Schacter, B. (2002). "Partners in Research, Competitors in Pay." The Scientist (March 4, 2002): 44-45.

The author sheds light on the fact that while scientists collaborate broadly in research, they are really competitors for the same relatively few good positions and pay. He points out the irony in this. But, is this so different from the real world where leadership teams both collaborate and compete?

Sideris, L., C. McCarthy, et al. (1999). "Roots of Concern with Nonhuman Animals in Biomedical Ethics." ILAR Journal 40(1): 3-14.

This paper reviews the history of concern for research animals and the impact of passionate anti animal research groups in getting more humane treatment of research animals on the regulatory agenda.

Silbergeld, E., S. Lerman, et al. (2004). "ETHICS: Human Health Research Ethics." Science 305(5686): 949-.

This is a strong argument for the use the "common rule" in designing and carrying out studies related to environmental protection. Distinctions between internal EPA studies and non-governmental studies that exist are proposed for change.

Steinbrook, R. (2000). "Medical Journals and Medical Reporting." N Engl J Med 342(22): 1668-167.

The author defends the role of the NEJM in reporting materials to the media. They claim purity because they only send out an advance copy of each issue to the press. Of course, we subscribers believe we are paying for the first look at the information. A very self-serving article, I think.

Steinbrook, R. (2004). "Public Registration of Clinical Trials." N Engl J Med 351(4): 315-317.

This is one of the articles from leading journals that publish clinical trials arguing the importance of registration. Subsequently, registration has become essentially required.

Swazey, J. P., M. S. Anderson, et al. (1993). "Ethical Problems in Academic Research: A survey of doctoral candidates and faculty raises important questions about the ethical environment of graduate education and research." American Scientist 81: 542-553.

This empirical study of faculty and trainees indicated that ethical lapses were both commonly admitted and commonly noted in others. The authors argued for better ethical education.

Tunis, S. R., D. B. Stryer, et al. (2003). "Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy." JAMA **290**(12): 1624-1632.

This policy proposal argues that we need much greater emphasis in research on practical clinical trials to help medical decisions makers make rational choices or offer rational choices to their patients. Almost all current clinical trials are designed for different purposes and are not helpful in real decisions http://jama.ama-assn.org/cgi/content/full/290/12/1624

Vandenbroucke, J. P. (2001). "In Defense of Case Reports and Case Series." Ann Intern Med 134(4): 330-334.

The author argues that case reports and case series have their own role in the progress of medical science. They permit reporting of new diseases and unexpected effects (adverse or beneficial) as well as the study of mechanisms, and they play an important role in medical education. He claims that case reports and series have a high sensitivity for detecting novelty and therefore remain one of the cornerstones of medical progress. Good case reporting demands a clear focus to make explicit to the audience why a particular observation is important in the context of existing knowledge.

Varki, A. and L. E. Rosenberg (2002). "Emerging opportunities and career paths for the young physician-scientist." Nat Med 8(5): 437.

The authors trumpet careers in translational medicine for scientifically trained physicians.

Wallerstein, M. B. (2002). "Science in an Age of Terrorism." Science 297(5590): 2169.

The author suggests that to thwart the use of biological agents by terrorists, we have to be careful in specific sensitive areas and try to teach our foreign students and other trainees to use what they learned for good. Sounds good but …

Wenger, N. S., S. Korenman, et al. (1997). "The ethics of scientific research: an analysis of focus groups of scientists and institutional representatives." J Investigative Med 45(6): 371-80.

The authors report on the range and depth of perceptions of scientists and institutional representatives on what is unethical in science.

Wolpert, L. (1989). "The social responsibility of scientists: moonshine and morals." BMJ 298(6678): 941-3.

A very compelling article that contrasts research for the Manhattan project with the eugenics movement leading to 1930s Nazi policy of discrimination and genocide. While the designers of the atomic bomb are praised for their insight, the eugenics movement is now seen as one of science's greatest evils. The author concludes that scientists must have the capacity to research all fields, but also bear the responsibility of disclosing the ramifications of their research.

Yarborough, M. and R. Sharp (2002). "Restoring and preserving trust in biomedical research." Acad Med 77(1): 8-14.

This significant position paper describes the diminution of trust in clinical research associated with recent events and the media characterization of them. The authors argue that if these institutions are to preserve the trust that the public has historically bestowed upon them, they must go beyond mere compliance with regulatory mandates. Several steps are suggested that the authors believe will bolster the public's confidence in academic research institutions. These steps grow out of the authors' analysis of three key components of institutional trustworthiness: (1) shared goals between research institutions and the communities they serve, (2) robust institutional oversight of research activities, and (3) training programs that build professional character. The authors' recommendations include the use of research advisory councils to assure the public that research goals reflect community interests, more collaborative relationships between institutional review boards and members of investigative teams, and educational programs that emphasize the importance of professional integrity in biomedical research.

Zigmond, M. (1999). "Promoting responsible conduct: striving for change rather than consensus. Commentary on "Ambiguity, trust, and the responsible conduct of research" (F. Grinnell)." Sci Eng Ethics 5(2): 219-28.

In this paper the author duels with Fred Grinnel about promoting the responsible conduct of research. He points out that "aspirational codes depend too much on the individual. He thinks that discussion and controversy play a role in buy in and clarification of issues and , unlike Grinnel, the scientific societies and investigators should play an important role in defining the rules of behavior. This is a very worthwhile read for those interested in teaching the responsible conduct of research.

Chapter 4: CONFLICTS OF INTEREST (COI)

A. Definitions

Interest

An interest may be defined as a commitment, goal, or value held by an individual or an institution.

Examples include a research project to be completed, gaining status through promotion or recognition, and protecting the environment. Interests are pursued in the setting of social interactions.

Conflict of Interest (COI)

A conflict of interest exists when two or more contradictory interests relate to an activity by an individual or an institution. The conflict lies in the situation, not in any behavior or lack of behavior of the individual. That means that a conflict of interest is not intrinsically a bad thing.

Examples include a conflict between financial gain and meticulous completion and reporting of a research study or between responsibilities as an investigator and as a treating physician for the same trial participant.

Institutional examples include the unbalancing of the institutional mission by acceding to the space requests of a large donor for an idiosyncratic program.

Other definitions include:

Conflicts of interest are "situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgement in conducting or reporting research." AAMC, 1990

"A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might therefore, in actuality or appearance compromise the integrity of the research." NAS, Integrity in Scientific Research

B. Consequences of a COI

When an individual COI exists, then independent of the behavior of the investigator, those knowledgeable about the study must take the COI into account when judging the validity of the study.

Beyond that, in clinical research, the well being of the subjects may also be compromised by a COI and this has become an overarching factor in the

regulation of financial COIs in clinical research. As noted above, the well being of the participants is paramount and trumps the completion of the research.

C. Government intervention

The Bayh-Dole act of 1980 made it possible for institutions and individuals to recover substantial financial rewards for their intellectual property as royalties and as equity. Furthermore, the reliance of research sponsors on the expertise of faculty to support a trial agent encouraged substantial payments to accrue to faculty as consultants, often on a continuing basis. Optimizing these financial interests produces a COI situation in relation both to the conduct of the research and to the welfare of trial subjects. Responding to these realities, the NIH, FDA and individual institutions developed rules for investigators to limit the impact of investigator COIs under Federal rules. A reminder follows
http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-05-013.html

The actual rules can be found at this URL
http://grants.nih.gov/grants/guide/notice-files/not95-179.html

The key provisions are, redacted:

"Investigators are required to disclose to an official(s) designated by the institution a listing of Significant Financial Interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding by the PHS. The institutional official(s) will review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research and, if so, the institution must, prior to any expenditure of awarded funds, report the existence of such conflicting interests to the PHS Awarding Component and act to protect PHS-funded research from bias due to the conflict of interest.

The definition of "Significant Financial Interest" in 50.603 has been changed in several respects. The exception for financial interests in business enterprises includes salary, royalties or other payments not reasonably expected to exceed $10,000 per annum. Alternative measures of $10,000 in value include stock or no more than five percent ownership interest."

In my view, $10,000 or an ownership position even if it has no cash value constitutes a significant COI and should be at least disclosed. Disclosure requirements are very poor in that the statute limits them to the institutional administrators and the COI committee. They should be required to disclose every time they present or publish research.

D. Industry Sponsorship

Studies of industry sponsorship reveal profound influence over study design, analysis and interpretation of data (bias). They also engage in suppression of results (negative, AEs). They promulgate secrecy among researchers by negotiating confidentiality clauses in contracts.

Sometimes results are made public while bypassing the peer review system.

"Drug company money and investigator COIs have so corrupted clinical trials research that drug companies control what clinicians and patients know and don't know about the $200,000,000 worth of drugs and devices they are consuming."

"This is all about bypassing science. Medicine is becoming a sort of Cloud Cuckoo Land, where doctors don't know what papers they can trust in the journals." Drummond Rennie of JAMA

E. Professional Societies

Professional societies take huge amounts of pharmaceutical money to support their annual meetings and other activities. The funding may unbalance the science presented at the meeting. They permit highly biased Continuing Medical Education segments.
Professional societies do not carefully control the listing of COIs in the scientific presentations. They foster over-the –top media presentations of advances. They permit biased articles and supplements in their journals.

F. <u>Clinical Practice Guidelines</u>

The practice of "evidence based medicine" has led to the development of guideline for the treatment for many medical conditions, based on meetings of "experts, " often from professional societies. Treatment guidelines generally support the use of more procedures and medications. It was recently shown that
33% of guideline authors have financial interests in the drug
50% guidelines had no COI documentation
34% of guidelines stated no COIs
50% had at least one author receiving research support
43% had at least one author who had been a paid speaker for the company
Derived from National Guideline Database

Nature, Oct 20,2005

G. Other initiatives

The people who need to know about the COI are those who learn about the results of a study and have to interpret it.

The decision about disclosure of a COI should never be left to the possessors of the COI because they are susceptible to self-deception or worse about the influence of the COI on their research behavior.

Thus, NIH and other funding agencies, Professional Societies sponsoring research meetings, and the leading journals now require disclosure of COIs as a precondition for reviewing, editing, presenting and publishing research and research proposals but there is no means of enforcing the requirement. Voluntary revelation of a COI precludes the reviewing, of a grant or paper. A COI must be disclosed in presenting science.

The Appearance of a COI must be avoided or disclosed. Consider the NY Times test. "Would you want the relationship published in the NY Times?" The presence of Conflicts of Interest tends to diminish the credibility of a study.

The most common conflicts of interest in research are between financial or career rewards and the integrity of a research study, report, presentation, or review.
It's necessary to manage outside income,
for consultations
for lectures,
for courses,
for research
when conducting a clinical trial.

Full disclosure of conflicts of interest should be required in consent forms, papers, lectures and presentations. COIs may result in:

1. **Loss of objectivity**
2. **Reordering of priorities towards applied research**
3. **Degradation of the *nature of science* as an open and collegial enterprise**
4. **Exploitation of trainees**
5. **Transfer of time and interest to Commercial ventures**

H. COIs in Financial Consulting

A new kind of COI has just come to light as the practice has become much more widespread through investigative reporting of the Seattle Times. Many investigators are recruited to consult for financial entities including venture capital firms, hedge funds and investment houses to inform them of the latest developments in their field. The pay is good and the investigators feel quite

flattered. Sometimes, the investigators have provided privileged information about an ongoing clinical trial about which both they and their institutions signed confidentiality statements. In all instances, the goal of the consulting groups is to learn information of investment value before the competition. After the initial concern, apparently this area of concern has lost immediacy.

Cases: Chapter 4

Case: Remembra

Dr. Zhivago, in NIH supported research, made remarkable progress in memory studies by identifying a new receptor "C" responsible for instilling and preserving memories. In mice and rats substantial improvements in memory were produced in a short time as demonstrated by performance studies. Activating C in monkeys permitted substantial acceleration in achieving cognitive skills and great enhancement in cognitive capability. Zhivago approached her institution's Office of Technology to arrange for patent and licensing.

The University had just established a research incubator to carry its inventions to a more advanced stage so that it would be able to retain a greater portion of the financial benefits to come from the products of discovery.

The Office of Technology suggested that Zhivago establish a company with the university to exploit her discovery and develop small molecule receptor agonists for use in treating certain forms of mental retardation as well as Alzheimer's and other disorders. Neither Zhivago, nor the university officials were unaware of the fact that once approved, the agonists would most likely be taken by normal persons to augment their intellectual capabilities.

Zhivago was told that the university would advance up to 1 million dollars of its endowment on this company and that as funding requirements grew, depending on the situation, either more new funds would be allocated or venture capitalists would be invited to invest.

Zhivago, figuring that if she reduced her clinical burden and got out of teaching, which were easily arranged, she could spare 30% of time for this project and suggested to her senior technician Anna Karenina that she take a job at the new company, LEARN, with a significant salary increase, and manage the practical details of creating C-receptor agonists under Zhivago's direction. When the time came, Zhivago would test her drug first in mentally retarded children, her specialty.

Dr. Zhivago delayed publication of her discovery for four months in order to accomplish the patent and license work.

Upon learning of the discovery, a couple of very large drug companies with an interest in mental health volunteered financial support for priority in the bidding for the new agent when it was developed.

The entire university leadership was highly attuned to this activity as the result of their big stake in the outcome.

Zhivago found that it was very difficult to recruit someone as effective as Anna to run her lab where she was expected to continue to perform at a high intellectual level.

Zhivago found that she needed a lot of assistance with designing, synthesizing and testing CR agonists. Pharmacologists from the university were asked to help and they asked for equity in return. The Pharmacologists were knowledgeable but unwilling to commit enough time to oversee the effort.

Three and one half million dollars and two years later, a potent CR agonist was available for testing. It was called Remembra.

The IRB, with an inquiry from the university President urging expediency, approved the Phase I and II trials. In a total of 25 subjects the pharmacokinetics and acute toxicity studies were completed satisfactorily.

As Dr. Zhivago gears up for the clinical test of Remembra, she learns that her NIH renewal was not going to make the grade because of poor recent productivity. She thinks, "If this works, I won't need to keep applying for grants."

While the IRB was initially reluctant to approve Dr. Zhivago's role in both managing and carrying out he Phase III placebo controlled double blinded trial, with a little institutional encouragement the protocol was approved and Zhivago began testing Remembra on mentally retarded adolescents who required special schooling. Even though the study was double-blinded, the progress on Remembra was so dramatic that everyone thought they knew who was taking the real drug. Treated students were able to learn and retain much more rapidly than ever before.

Enthusiasm at the school got out and reached university administration, which reveled in the possibility that one of their investments might pay off.

About 3 months into the six-month trial it was noted that some of the participants began to have episodes of sweating and confusion that came and went. The teachers and investigators reported these events and when the Data and Safety monitoring Board was informed, one of the investigators suggested measuring the blood sugar during episodes and sure enough, the symptoms were found to be due to hypoglycemia (very low blood sugar).

Since there were no severe episodes and the episodes were treatable with orange juice, the DSMB suggested providing frequent meals and teaching the families and teachers of the students how to treat hypoglycemia. The IRB required an amendment to both the protocol and the consent form recognizing the adverse event.

By the fifth month the adolescents were gaining a lot of weight and on one occasion a participant went into hypoglycemic coma and had to be treated in the E.R.

The DSMB decided to stop the trial for safety reasons even though the participants on Remembra were learning at an impressive rate and the teachers wanted it continued. The DSMB heard an appeal from the university president for the sake of the mentally retarded to continue the study but they did not budge.

One of the teachers told the story of Remembra to the N.Y. Times, which published a long article on the story. Shortly thereafter Dr. Zhivago received a call from a major drug company about the possibility of developing Remembra as a treatment for diabetes.

1. **What conflicts of interest exist in this scenario?**

2. **Remembra has potential. How can the ethical issues surrounding its testing be resolved?**

3. **How does the idea of improving on human intelligence strike you ethically?**

4. **If you were the CEO of LEARN what actions would you take now?**

Case: Conflict of Interest Committee

You are a member of your institution's conflict of interest committee charged with the responsibility of determining the significance of Eric Jensen's conflicts of interest (COI) and to manage it. You are the primary reviewer for Jensen's proposal. He has invented an electrical device that markedly accelerates the fracture-healing rate. This was brought to the intellectual property office where a patent was requested. Jensen also formed a company to exploit the patent with the University. They induced a large medical apparatus company to manufacture and market the device. The university and Jensen' company would receive equity and royalties.

Jensen receives a prototype of the commercial version of the device and decides to conduct a clinical trial on healing rates comparing the device with conventional treatment. He will carry out a blinded study using the device appropriately or in an inactive mode.

1. **Please comment on the proposed arrangement as primary reviewer for the COI committee.**

2. **What are the limits on a faculty member's interest in his/her company's ownership and function?**

3. **What does "conflict of commitment mean in this setting."**

Case: Expert consultant

Going through your E-mails you find the following:

Hansen and Question, a commercial analysis company, is conducting in depth 30 minute interviews with thought leaders in your field about dilational cardiomyopathy for which a new molecular mechanism was just uncovered.

The E-mail indicates that they have been commissioned by a pharmaceutical company to get a further understanding of approaches to the management of this condition. They are willing to pay you $500 for a 30 minute, one on one interview. The E-mail indicates that all your opinions will be reported anonymously in the final report.

As an expert on cardiomyopathy with definite views, you feel that might have a lot to offer the company; after all, you are the PI on a sophisticated study of cardiomyopathy at this very moment.

1) **Should you respond to the E-mail?**
2) **What questions should you ask if you chose to respond?**
3) **Are there any constraints in relation to giving your opinion?**
4) **What is the university's involvement in this kind of activity and what should it be?**

Chapter 4 Bibliography

Cohen, J. J. (2001). "Trust Us to Make a Difference: Ensuring Public Confidence in the Integrity of Clinical Research." Acad Med 76(2): 209-214.

Investigators' and institutions' financial conflicts of interest in clinical research raise serious questions about the objectivity of such research, the safety of human subjects, and the threat to public trust in the integrity of clinical research. Yet the author makes clear that a conflict of interest is a state of affairs, not a behavior, and therefore not automatically a manifestation of improper actions. But it is clear that both non-financial conflicts of interest and financial ones are double-edged: they can motivate individuals to do their best work but also can compromise judgment and undermine objectivity. The author offers eight suggestions for what academic medicine's leaders might do in this regard (comply with existing full-disclosure requirements; establish principles governing institutional conflicts of interest; etc.). He closes by reiterating that the pursuit of clinical research depends entirely on the ability and willingness of the research community to merit public trust.

(2003). "Protecting Subjects, Preserving Trust, Promoting Progress I: Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research." Acad Med 78(2): 225-236.

(**From the Executive Summary**) In December 2001, the AAMC Task Force on Financial Conflicts of Interest in Clinical Research released this report, the first of two (both published in this issue of Academic Medicine). This report focuses on gaps in existing federal financial disclosure regulations of individual conflicts of interests, finding that additional scrutiny is recommended in two areas: human subjects research and privately sponsored research. The task force suggests that when potential conflicts exist, a conflicts of interest committee should apply a rebuttable presumption against engaging in human subjects research. The task force recommends that the circumstances giving rise to the presumption against the proposed activity be balanced against compelling circumstances in favor of the conduct of the research. The AAMC task force delineates core principles to guide institutional policy development. First, an institution should regard all significant financial interests in human subjects research as requiring close scrutiny. Second, in the event of compelling circumstances, an individual holding a significant financial interest may be permitted to conduct the research. Whether circumstances are deemed compelling will depend in each case upon the nature of the science, the nature of the interest, how closely the interest is related to the research, and the degree to which the interest may be affected by the research. Four other core principles for development of institutional policies are identified in the report, pertaining to reporting, monitoring, management of conflicts, and accountability.

(2003). "Protecting Subjects, Preserving Trust, Promoting Progress II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research." Acad Med 78(2): 237-245.

(**From the Executive Summary)** The AAMC Task Force on Financial Conflicts of Interest in Clinical Research issued this report, the second of two, in October 2002. (The first report is also published in this issue of Academic Medicine.) This report offers a unique perspective on the new phenomenon of "institutional" conflicts of interest. The task force acknowledges the diverse obligations of academic institutions that conduct research and also invest in--and accept the philanthropy of--commercial research sponsors. The task force emphasizes the importance of disclosing institutional financial interests as an integral part of the research process, critical to allaying public concerns, and to strengthening the trust relationship between research subjects, the public and the scientific community. The task force found that the safety and welfare of research subjects and the objectivity of the research could be--or could appear to be--compromised whenever an institution holds a significant financial interest that may be affected by the outcome of the research. Thus, the task force recommends separating the functional and administrative responsibilities related to human subjects research from those related to investment managing and

technology licensing, and encourages the establishment of institutional conflicts-of-interest committees. As in the first report, the task force recommends that institutions should develop policies establishing a rebuttable presumption against the conduct of research at or under the auspices of an institution where potential conflicts in human subjects research are identified. This presumption against engaging in the research is to be balanced against compelling circumstances in favor of the conduct of the proposed research activity.

Kelch, R. (2002). "Maintaining the public trust in clinical research." N Engl J Med 346(4): 285-7.

This is a laudatory commentary on the AAMCs report on individual conflicts of interest.

(2003). Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. Federal Register. 68: 15456-15460.

The Office of Public Health and Science (OPHS), Department of Health and Human Services (HHS) announces a final guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. This guidance document raises points to consider in determining whether specific financial interests in research could affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by
HHS or regulated by the Food and Drug Administration.

Angell, M. (2000). "Is Academic Medicine for Sale?" N Engl J Med 342(20): 1516-1518.

This position paper uses evidence mostly from publications to argue that conflicts of interest are so pervasive so as to compromise the integrity of much medical publication.

Bekelman, J. E., Y. Li, et al. (2003). "Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review." JAMA 289(4): 454-465.

This was a meta-analysis of the quantitative analytic literature on conflicts of interest in biomedical research from 1980 to 2002 using a variety of search techniques for materials. In 34 studies meeting all their criteria they show that about ¼ of the investigators had industry affiliations and 2/3 of academic institutions hold equity in start-ups that sponsor research. They claimed a relationship between industry sponsorship and positive conclusions. Industry sponsorship was also associated with restrictions on publication and data sharing. They concluded that conflicts of interest can have a powerful effect on biomedical research reports.

Bentley, J. P. and P. G. Thacker (2004). "The influence of risk and monetary payment on the research participation decision making process." J Med Ethics 30(3): 293-298.

This study used pharmacy students' reactions to scenarios varied by risk and payment to determine the extent to which they affected decisions to participate in a clinical trial. They found that money did help enlist subjects but they were not blinded to the risks.

Blumenthal, D. (2003). "Academic-Industrial Relationships in the Life Sciences." N Engl J Med 349(25): 2452-2459.

The author describes the evolving set of relationships between academic institutions and industry as it pertains to biological developments. He points out the rapid progress of biotechnology and the significant support of research by industry. He also points out the influences on scientific integrity and diminished quality of treatment of research subjects. A very important paper.

Blumenthal, D. (2004). "Doctors and Drug Companies." N Engl J Med 351(18): 1885-1890.

The author describes the evolving nature of the relationships between doctors and drug companies over the 20th century and the influences that the companies have come to exert over medical practice and research. He also discusses efforts to manage these relationships. Conflicts of interest pervade. This is a very powerful statement and uncomfortable reading for physicians.

Blumenthal, D., N. Causino, et al. (1996). "Relationships between Academic Institutions and Industry in the Life Sciences -- An Industry Survey." N Engl J Med 334(6): 368-374.

Despite growing acceptance of relationships between academia and industry in the life sciences, systematic, up-to-date information about their extent and the consequences for the parties involved remains scarce. They surveyed a representative sample of life-science companies in the United States to determine their relationships with academic institutions by telephone from senior executives of 210 life-science companies (69%). Ninety percent of the companies had relationships with an academic institution in 1994. Fifty-nine percent supported research, providing approximately 11.7 percent of their research-and-development funding. Over 60 percent of those companies had received patents, products, and sales as a result. The companies also reported that they often had agreements to keep the results of research secret beyond the time needed to file a patent. These relationships need greater scrutiny.

Bodenheimer, T. (2000). "Uneasy Alliance -- Clinical Investigators and the Pharmaceutical Industry." N Engl J Med 342(20): 1539-1544.

The author details the uncomfortable relationship between clinical investigators who carry out research on new drugs and industry that has a powerful vested interest in the success of their products. Conflicts of interest are widespread with adverse consequences for the science.

Boyd, E. A. and L. A. Bero (2000). "Assessing Faculty Financial Relationships With Industry: A Case Study." JAMA 284(17): 2209-2214.

The authors reviewed disclosure forms at UCSF to determine more about clinical and basic science faculty relationships with industry. By 1999, almost 7.6% of faculty investigators reported personal financial ties with sponsors of their research, including paid speaking engagements 34%. 33% had consulting agreements, and 32% involved the investigator holding a position on a scientific advisory board or board of directors. 14% involved equity ownership, and 12% involved multiple relationships. The advisory panel recommended managing perceived conflicts of interest in 26% of the cases. They considered this to be a growing problem that required management.

Boyd, E. A., M. K. Cho, et al. (2003). "Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators." Acad Med 78(8): 769-774.

They questioned faculty at UCSF and Stanford who conducted clinical research about their knowledge of and attitudes towards conflict of interest policies. The campus COI policies were a mystery to more than half of those interviewed. Many investigators felt that, rather than the university, monitoring COIs was the job of professional societies, (who have no clout) the public (that understands nothing about this) and, individual investigators (who routinely engage in self-deception) should monitor conflicts of interest. Administrators and policymakers is have to find a way to convince investigators, both clinical and nonclinical, of the serious problems of bias and co-option associated with financial relationships with industry.

Brainard, J. (2001). Federal Rules on Conflicts of Interest in Biomedical Research Are Inadequate, GAO Finds. The Chronicle of Higher Education. Washington.

The GAO pointed out what everyone knew and was glad of, namely that COI regulations were weak and unenforceable.

Bramstedt, K. (2003). "Research subject advocates: to whom are they loyal?" Clin Invest Med 26(2): 64-9.

The author deals with the issue of conflicts of interest in the activities of Research Subject Advocates. This is based largely on who is paying them. Of course, the main issue is what are they paying them for. GCRC RSAs, for example are paid to support the subjects and they should normally operate in that manner. She deals with the Abiomed artificial heart case in which the subject advocate was sued as wrongly representing the institution. How hard is it for subjects to get the kind of support they need in difficult studies with considerable risk?

Brownlee, S. (2004). Doctors Without Borders: Why you can't trust medical journals anymore. Washington Monthly.

This reporter discusses the Nemaroff case in which a physician wrote a review article for Nature Neuroscience in which he failed to reveal his many and profitable conflicts of interest in recommending

drug treatments for psychiatric illness. She goes on to discuss in vivid terms the insidious downside of these conflicts and the great efforts made by industry to involve prominent physicians in supporting their drugs.

Calfee, J. E. (2001). "Pharmaceutical Price Controls and Patient Welfare." Ann Intern Med 134(11): 1060-1064.

He argues forcefully against price controls for drugs as inhibiting innovation and eliminating the risk capitol necessary to bring new ideas to market by killing incentive.

Campbell, E. G., J. S. Weissman, et al. (2001). "Market Competition and Patient-oriented Research: The Results of a National Survey of Medical School Faculty." Acad Med 76(11): 1119-1126.

They tried to determine the impact of carrying out clinical care in a competitive environment on research productivity by surveying research faculty (2336 responses). They found that both basic and clinical research productivity was adversely affected by the need to do more clinical care in the most competitive markets. Good study demonstrating the impact of changing priorities for survival.

Cech, T. and J. Leonard (2001). "Science and business. Conflicts of interest--moving beyond disclosure." Science 291(5506): 989.

As director of the Howard Hughes Institute the author makes his point about conflicts of interest in research and indicates a strong position in avoiding them.

Cho, M., R. Shohara, et al. (2000). "Policies on faculty conflicts of interest at US universities." JAMA 284(17): 2203-8.

This excellent study has become somewhat dated because of the impacts of studies and changing policies secondary to various forces acting on universities. It reviewed COI policies of 89/100 polled Institutions. They found that there was great variability in types of relationships that were controlled, the financial limits, and the disclosures required. They recommended much more specific and consistent rules throughout the country.

Coyle, S. L. (2002). "Physician-Industry Relations. Part 1: Individual Physicians." Ann Intern Med 136(5): 396-402.

This is part 1 of a 2-part paper on ethics in physician-industry relationships. Part 1 offers advice to individual physicians; gives recommendations to medical education providers and medical professional societies. While physicians and commerce share an interest in advancing medical knowledge they diverge in that the former is a fiduciary for the patient and the latter has responsibility primarily toward its investors. This can lead to conflicts of interest, biased reporting and issues with appropriate experimental design. While physicians and trainees think they are impervious to Drug Company blandishments, the companies know better. So physicians have to decide for themselves what gifts raise no problems and which do. A general guideline is inexpensive and no strings attached. But, in our society, the very act of accepting a gift creates an obligation. Other financial ties between physicians and industry include honorariums for speaking or writing and payment for doing clinical research. These also can influence a physician's beliefs and practices. The paper goes into considerable detail.

Coyle, S. L. (2002). "Physician-Industry Relations. Part 2: Organizational Issues." Ann Intern Med 136(5): 403-406.

This is part 2 of a 2-part paper on ethics and physician-industry relationsips. Part 1 offers advice to individual physicians; part 2 considers medical education providers and medical professional societies. While industry develops advances in medicine it also plays a key role in disseminating up-to-date medical information. The problem is bias and providers of the education must protect against that bias by presenting objective and balanced information. To do that, they must be careful of conditions under which money is collected to carry out their programs. They should insist on control of the content and conditions of the learning process Disclosure of industry sponsorship to students, faculty, and continuing medical education trainees is mandatory. This also applies to medical societies.

Dana, J and G. Lowenstein (2003). "A social science perspective on gifts to physicians from industry." JAMA 290(2): 252-5.

The article uses behavioral science to examine the nature of conflicts of interest. It examines the "self-service bias" in our perceptions of fairness, indicating an individual's notion of fairness is inherently biased toward his/her own self-interest. This makes the article very good in uniting cross-arguments into one inherent principle: human nature.

DeAngelis, C., P. Fontanarosa, et al. (2001). "Reporting financial conflicts of interest and relationships between investigators and research sponsors." JAMA 286(1): 89-91.

JAMA was one of the first journals to insist on disclosure of COIs in all papers, editorials, etc coming out of their shop.

Drazen, J. M. and G. D. Curfman (2002). "Financial Associations of Authors." N Engl J Med 346(24): 1901-1902.

Having come upon scathing criticism for publishing review articles written by persons with substantial conflicts of interest without identifying those interests, the authors (editors of NEJM) reiterate past policies and frame a new policy. They ended up, eventually, requiring disclosure of all conflicts of interes, but not in this article.

Drazen, J. M. and G. Koski (2000). "To Protect Those Who Serve." N Engl J Med 343(22): 1643-1645.

Patients submitting themselves to a clinical trial are inherently vulnerable; they understand the risk associated with their reward. When these clinical trials are industry-sponsored and may contain ambiguous COIs, they are in direct conflict with the patients' interests and therefore violate the physician-patient bond. This article calls for physicians to consider this when enrolling patients in clinical trials.

Duyk, G. (2003). "Attrition and Translation." Science 302(5645): 603-605.

The recently published NIH Roadmap proposes that public-sector science should place increased emphasis on the development of new therapeutics and diagnostics based on the fruits of fundamental research. Such "translational research" activities, traditionally the province of the private sector, have long been compromised by high rates of attrition (failure during the course of preclinical or clinical development of therapeutics). Attrition has led to growing financial costs, as well as opportunity costs. The new focus offers a way to reverse these trends, especially if the scientific community can improve on its ability to reconcile molecular genetic research with integrative organ- and organism-based research.

Eichenwald, K. and G. Kolata (1999). When physicians double as entrepreneurs. Hidden interests: a special report. NY Times (Print). New York City: A1, C16-17. November 30, 1999.

A very important report worth noting and reading. It chronicles not only COI's in medicine, but also the culture around them, questioning whether physician-inventors can ethically promote their products. Although there is much to be gained from new technology and increased competition, much is lost when physicians ignore patient interests and focus on profits.
http://query.nytimes.com/gst/fullpage.html?sec=health&res=9D07E6D6103FF933A05752C1A96F958260

Elliott, C. (2001). "Pharma Buys a Conscience. Bioethicists increasingly find their work underwritten by pharmaceutical companies. Who passes on the ethics of ethicists?" The American Prospect 12(17): 16-20.

Do as I say, not as I do. Does that apply to bioethicists? Unfortunately developing a center on bioethics requires lots of money and the usual deep pockets, drug and other companies seen to be the most willing sources of funding. This article bears some of the funding sources of prominent bioethics programs and questions bioethicists' behavior in the face of drug company dependence. He also indicates support of IRB members, of the FDA and of bioethics consultants tends to build favorable reviews.

Field, K. (2004). Medical School Reaches Agreement with Cancer Survivors in Suit over Canceled Study. The Chronicle of Higher Education.

If a study promises a therapeutic regimen and the company decides that the agent is not worth pursuing from the preliminary data, it can cancel the study. The participants argued that they were promised a full course of treatment by the university and sued.

Friedberg, M., B. Saffran, et al. (1999). "Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology." JAMA 282(15): 1453-1457.

Recent studies have found that when investigators have financial relationships with pharmaceutical or product manufacturers, they are less likely to criticize the safety or efficacy of these agents. In this study of a number of oncology drugs of different kinds, when comparing company vs non-profit supported studies, it was found that overstatement of positive results were less of a problem than a reduced likelihood of reporting unfavorable qualitative conclusions.

Friedman, P. J. (2002). "The Impact of Conflict of Interest on Trust in Science." Sci Eng Ethics 8(3): 413-420.

This paper is a deep analysis of the corrosive effects of conflicts of interest on trust in schience, with the public and even among investigators. This lack of trust can have an adverse effect on the scientific record as well. Disclosure, our major method of dealing with COIs is really inadequate even if it were well- and completely carried out. We need new rules and new approaches and the author discusses some possibilities. He points out that managing COIs is not institutions of learning's best suite and that institutions can get into COI problems themselves.

Gelijns, A. C. and S. O. Thier (2002). "Medical Innovation and Institutional Interdependence: Rethinking University-Industry Connections." JAMA 287(1): 72-77.

The authors attempt to present a balanced account of the great benefits associated with Industry-Academic collaborations in research and development and the negative impacts of the relationships. This paper reviews institutional patterns of innovations and suggests organizational and public policy implications. This is important reading because many of the papers in this area deal with the negative aspects of university-industry relations and do not deal with the importance of these collaborations for advances.

Hahn, R. (2002). "Conflicts of Interest and the False Comfort of "Full Disclosure"." Professional Ethics Report 15(4).

The concept that revealing conflicts of interest in all presentations and publications eliminates their insidious effects on research. Not true, this article claims. The problem is that other mechanisms of control severely limit the incomes of successful scientists.

Hall, S. S. (2001). Claritin and Schering-Plough: A Prescription for Profit. The New York Times. New York. March 11, 2001.

This article purports to show that Schering used inadequate science to demonstrate that a mediocre antihistamine was less soporific than the older variety and therefore supplanted the older versions at great cost to society. Ironically, branded clariton sells well as an over-the –counter antihistamine even though it is expensive.

Hart, D. (2002). "The "Corporatization" of Science." Science 295: 439.

This letter reviews the history of the support of basic research after WWII and reviews the changes in the scientific community that supported Bayh-Dole and indicated the importance of continuing attention to the new relationships developing as a result.

Horton, R. (2004). "The Dawn of McScience." The New York Review.

This review of Seldon Krimsky's book Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research? The reviewer indicates that Krimsky produced a polemic indicating that declaring conflicts of interest will not solve the problems but that the separation of science from industry never truly existed and that, to some extent, the moral requirement to tell the truth in science was always blemished when it related to practical products. The Nancy Oliveri case, as well as the purchase of investigators and physicians by gift giving of pharmaceutical houses, are thoroughly discussed. I think that we are moving in the direction of balance by now, but my naivete may be showing.

Johns, M. M. E., M. Barnes, et al. (2003). "Restoring Balance to Industry-Academia Relationships in an Era of Institutional Financial Conflicts of Interest: Promoting Research While Maintaining Trust." JAMA 289(6): 741-746.

This paper deals with University-Industry relationships from the point of view of the research managers and other leaders at academic institutions. The authors discuss divestiture, firewalls and other methods to ensure that industrial affiliations do not corrupt the activities of the university and adversely affect the public trust.

Johnston, J. (2004). "Outing the Conflicted: Et Tu, NIH?" Science 303(5664): 1610b-.

This report outlines the findings on NIH senior investigator and administrator conflicts of interest and their potentially serious consequences.

Kaiser, J. (2004). "BIOMEDICAL RESEARCH: Feeling the Heat, NIH Tightens Conflict-of-Interest Rules." Science 305(5680): 25-26.

This news article describes the first responses of NIH administration to revelations about intramural conflicts of interest.

Kaiser, J. (2004). "NATIONAL INSTITUTES OF HEALTH: Paid Consulting: Good for the Staff, Not for the Chiefs." Science 304(5673): 936a-937.

A news report on the extent of NIH staff involvement in conflicts of interest.

Kaiser, J. (2005). "CONFLICT OF INTEREST: NIH Chief Clamps Down on Consulting and Stock Ownership." Science 307(5711): 824-825.

A news report on the NIH ruling on conflicts of interest among its employees.

Kassirer, J. P. and M. Angell (1993). "Financial Conflicts of Interest in Biomedical Research." N Engl J Med 329(8): 570-571.

An early voice indicating the growing involvement of with industry and the conflicts of interest and of commitment they engender. Worthwhile reading.

Kassirer, J. P. and M. Angell (1997). "The High Price of Product Endorsement." N Engl J Med 337(10): 700-.

Product endorsement by a professional or scientific organization raises serious ethical problems. The endorsement is worth a lot to the product’s company and it is willing to pay well for it. The question is whether the organization has done the comparative testing to determine whether this is a superior product worth endorsing. Organizations take risks to their credibility and financial risks when they endorse a product.

Kjaergard, L. L. and B. Als-Nielsen (2002). "Association between competing interests zand authors' conclusions: epidemiological study of randomized clinical trials published in the BMJ." BMJ 325(7358): 249-.

To assess the association between competing interests and authors' conclusions in randomized clinical trials the authors conducted an epidemiological study of randomized clinical trials published in the BMJ from January 1997 to June 2001. Financial competing interests were defined as funding by for profit organizations and other competing interests as personal, academic, or political. They reviewed159 trials from 12 medical specialties.. Authors' conclusions were significantly more positive towards the experimental intervention in trials funded by for profit organizations alone compared with trials without competing interests, trials funded by both for profit and non-profit organizations, and trials with other competing interests. The authors' conclusions were that randomized clinical trials significantly favored

experimental interventions if financial competing interests were declared. Other competing interests were not significantly associated with authors' conclusions.

Krimsky, S. and L. Rothenberg (1998). "Financial interest and its disclosure in scientific publications." JAMA 280(3): 225-6.

Journal policies and requirements of funding agencies on financial disclosure of authors and grant applicants have divided editors and scientists who disagree on whether such policies can improve the integrity of science or manage conflicts of interest. Those opposed to such disclosure policies argue that financial interest is one of many interests held by scientists, is the least scientifically dangerous, and should not be singled out. Those who favor open reporting of financial interests argue that full disclosure removes the suspicion that something of relevance to objectivity is being hidden and allows readers to form their own opinions on whether a conflict of interest exists and what relevance that has to the study. The authors believe that the scientific community and the public will be best served by open publication of financial disclosures for readers and reviewers to evaluate.

Lawler, A. (2003). "UNIVERSITY-INDUSTRY COLLABORATION: Last of the Big-Time Spenders?" Science 299(5605): 330-333.

This review of the fate of large corporate gifts for research to universities suggests that the universities continued to do their thing but that the yield of marketable products to the dopanies was small. He concludes that on balance the agreements were win-win.

Levinsky, N. G. (2002). "Nonfinancial Conflicts of Interest in Research." N Engl J Med 347(10): 759-761.

The author considers his longstanding interest in his career and how that might have affected his objectivity in research. A worthwhile read.

Lo, B., L. Wolf, et al. (2000). "Conflict-of-interest policies for investigators in clinical trials." N Engl J Med 343(22): 1616-20.

There is substantial concern that financial conflicts of interest on the part of investigators conducting clinical trials may compromise the well being of research subjects. They analyzed policies governing conflicts of interest at the 10 medical schools in the United States that receive the largest amount of research funding from the National Institutes of Health. All 10 universities required that faculty members disclose financial interests to university officials. They conclude that policies governing conflicts of interest at leading medical schools in the United States vary widely. We suggest that university-based investigators and research staff be prohibited from holding stock, stock options, or decision-making positions in a company that may reasonably appear to be affected by the results of their clinical research. Of the 10 medical schools we studied, only 1 had a policy that was close to this standard.

Martin, J. B. and D. L. Kasper (2000). "In Whose Best Interest? Breaching the Academic-Industrial Wall." N Engl J Med 343(22): 1646-1649.

McCarthy, M. (2000). "Conflict of interest taints vaccine approval process, charges US report." The Lancet 356(9232): 838.

McCrary, S., C. Anderson, et al. (2000). "A national survey of policies on disclosure of conflicts of interest in biomedical research." N Engl J Med 343(22): 1621-6.

Conflicts of interest pose a threat to the integrity of scientific research. The current regulations of the U.S. Public Health Service and the National Science Foundation require that medical schools and other research institutions report the existence of conflicts of interest to the funding agency but allow the institutions to manage conflicts internally. They surveyed all medical schools (127) and other research institutions (170) that received more than $5 million in total grants annually from the National Institutes of Health or the National Science Foundation; 48 journals in basic science and clinical medicine; and 17

federal agencies in order to analyze their policies on conflicts of interest. There was a very high response rate.. Fifteen of the 250 institutions (6 percent)--5 medical schools and 10 other research institutions--reported that they had no policy on conflicts of interest. Among the institutions that had policies, there was marked variation in the definition and management of conflicts. They concluded that there is substantial variation among policies on conflicts of interest at medical schools and other research institutions. This variation, combined with the fact that many scientific journals and funding agencies do not require disclosure of conflicts of interest, suggests that the current standards may not be adequate to maintain a high level of scientific integrity.

Moses, H., III, E. Braunwald, et al. (2002). "Collaborating with Industry -- Choices for the Academic Medical Center." N Engl J Med 347(17): 1371-1375.

This is a core paper that defines the issues in the various relationships between industry and academic medical centers. They take a drastic step in outlawing (at Harvard) most conflicts of interest with industry.

U. S. G AO (2003). University Research: Most Federal Agencies Need to Better Protect against Financial Conflicts of Interest. G. A. Office.

This extensive study of Federal agencies and universities indicated that at the time of the report protection against conflicts of interest was inadequate. Among Federal agencies only the NIH and NSF had policies requiring review and reporting of conflicts of interest related to research support.

Orlowski, J. and L. Wateska (1992). "The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch."Chest 102(1): 270-3.

They examined the impact on physician prescribing patterns of pharmaceutical firms offering all-expenses-paid trips to popular sunbelt vacation sites to attend symposia sponsored by a pharmaceutical company. Drug usage patterns were tracked for 22 months preceding each symposium and for 17 months after each symposium. Ten physicians invited to each symposium were interviewed about the likelihood that such an enticement would affect their prescribing patterns. A significant increase in the prescribing pattern of both drugs occurred following the symposia. These changed prescribing patterns were also significantly different from the national usage patterns of the two drugs by hospitals with more than 500 beds and major medical centers over the same period of time. These alterations in prescribing patterns occurred even though the majority of physicians who attended the symposia believed that such enticements would not alter their prescribing patterns.

Patricia, B., D. Jocelyn, et al. (2002). "MEDICINE: Clinical Trials and Industry." Science 297(5590): 2211-.

Royal Australasian College of Physicians (2000). Ethical Guidelines in the Relationship Between Physicians and the Pharmaceutical Industry.

The Australians were able to agree on a set of ethical guidelines related to physicians and the pharmaceutical industry. They were opposed to most forms of gifts and proposed a skeptical position. It was not clear the extent to which these guidelines penetrated the profession..

Psaty, B. M., C. D. Furberg, et al. (2004). "Potential for Conflict of Interest in the Evaluation of Suspected Adverse Drug Reactions: Use of Cerivastatin and Risk of Rhabdomyolysis." JAMA 292(21): 2622-2631.

In recent years, US patients have increasingly been the first to receive new medications, some of which are subsequently discovered to have suspected adverse drug reactions (SADRs). As a result, the challenge of early detection has largely shifted to the US postmarketing systems. They sought to review the association between the use of cerivastatin sodium and the risk of rhabdomyolysis in an effort to illustrate the operation and limitations of the current US postmarketing safety-surveillance system. In the published literature, cerivastatin was associated with much larger risks of rhabdomyolysis than other statins. Analyses suggested that compared with atorvastatin calcium, cerivastatin monotherapy substantially increased the risk of rhabdomyolysis. To our knowledge, these findings were not disseminated or published. The company continued to conduct safety studies, some of them inadequately designed to assess the risk of rhabdomyolysis, until cerivastatin was removed from the market in August 2001. They concluded that

despite limitations of the available data, the asymmetry between the information available to the company and the information available to patients and physicians seems striking. A subjective element is present in the effort to infer whether or not the occurrence of untoward outcomes in users of a particular drug was actually the consequence of the use of that drug, and, under the current system, a pharmaceutical company's appraisal of SADRs may be influenced by economic considerations. Such an appraisal would best be made by an independent group. They claim US Congress should mandate and provide adequate support for independent reviews and analysis of postmarketing data.

Psaty, B. M. and D. Rennie (2003). "Stopping Medical Research to Save Money: A Broken Pact With Researchers and Patients." JAMA 289(16): 2128-2131.

This report documents a case in which a drug company decided that its cancer drug was no longer worth developing and stopped a trial even though they had promised a longer trial in writing. Both the company and the institution were sued.

Ramsay, S. (2001). "Online database reveals researchers' industry ties." The Lancet 357(9269): 1977.

This neat idea reveals the great extent to which those conducting clinical research have industry income associated with that activity. The list proceeds apace.

Roberts, T. G., Jr. and B. A. Chabner (2004). "Beyond Fast Track for Drug Approvals." N Engl J Med 351(5): 501-505.

Clinical Trials. Deals with fast track mechanism and the importance of selecting probable responses to each new drug. Proposes "selective approval mechanism."

Scherer, F. M. (2004). "The Pharmaceutical Industry -- Prices and Progress." N Engl J Med 351(9): 927-932.

This report examines the cost and pricing structures of pharmaceutical companies and tries to deal constructively with the demands for lower prices while at the same time supporting costly research. It is a very wor thwhile read.

Schulman, K. A., D. M. Seils, et al. (2002). "A National Survey of Provisions in Clinical-Trial Agreements between Medical Schools and Industry Sponsors." N Engl J Med 347(17): 1335-1341.

Concerned about threats to the integrity of clinical trials in a research environment increasingly controlled by private interests, the International Committee of Medical Journal Editors (ICMJE) has issued revised guidelines for investigators' participation in the study design, access to data, and control over publication. It is unclear whether research conducted at academic institutions adheres to these new standards. From November 2001 through January 2002, they interviewed officials at U.S. medical schools about provisions in their institutions' agreements with industry sponsors of multicenter clinical trials. The results demonstrated limited adherence to the standards embodied in the new ICMJE guidelines. Scores for coordinating-center agreements were somewhat higher for most survey items. They suggest that a reevaluation of the process of contracting for clinical research is urgently needed.

Univ. of California Senate. (2004). Report of the University Committee on Research Policy: Problematic Restrictive Clauses in Contracts, Grants and Gifts for Research, University Committee on Research Policy.

Steinbrook, R. (2004). "Conflicts of Interest at the NIH -- Resolving the Problem." N Engl J Med 351(10): 955-957.

This intermediate report discusses the various ideas that were considered at the NIH in an attempt to silence criticism while maintaining leeway for extra income for investigators.

The, Editor. (2004). "Publishing Commentary by Authors with Potential Conflicts of Interest: When, Why, and How." Ann Intern Med 141(1): 73-74.

This describes their policies at the time.

Weiss, R. (2004). NIH Bans Collaboration With Outside Companies. Washington Post. September 24, 2004.

This was the first response to the revelations of the extent of conflicts of interest at the NIH.

Williams, S. (2002). "Handle With Care: Avoiding Financial Conflict of Interest in Clinical Research." Academic Physician and Scientist January/February: 1, 10-12.

This paper begins by discussion the plight of the Fred Hutchison Cancer Research Center when sued by research subjects' families. The issue of the Center or its physicians derving financial benefit from the research put the organization in a weak position. This has led to the two AAMC reports on individual and institutional conflicts of interest that are referred to elsewhere in this bibliography.

Willman, D. (2001). Risk Was Known as FDA OKed Fatal Drug. Los Angeles Times. Los Angeles, CA. March 11, 2001.

The article chronicles Warner-Lambert's push and subsequent approval of the kidney drug Rezulin. Although liver damage was apparent in the clinical trial, Warner-Lambert's "partnership" with the FDA allowed for swift authorization. This should be a warning to all regulatory bodies about attaching themselves too closely to studies.

Willman, D. (2003). Stealth Merger: Drug Companies and Government Medical Research. Los Angeles Times. Los Angeles: A1, A32. December 7, 2003.

Some of the National Institutes of Health's top scientists are also collecting paychecks and stock options from biomedical firms. Increasingly, such deals are kept secret.

Willman, D. (2004). The National Institutes of Health: Public Servant or Private Marketer? Los Angeles Times. Los Angeles, CA: A29. December 22, 2004.

Another in a series of Willman's articles that deals with conflicts of interest. This one points out key scientists in the NIH with blatant COIs and the effect this has on research.

Willman, D. (2005). NIH to Ban Deals With Drug Firms. Los Angeles Times. LA, CA: A1, A17. February 1, 2005.

After initially breaking the COIs at the NIH, Willman announced the ban placed on industry-physician consulting relationships as well as other financial interests. These two Willman pieces on the NIH were monumentally influential in bringing to light gross inconsistencies in policy and their negative effects on the public.

Ziegler, M., P. Lew, et al. (1995). "The accuracy of drug information from pharmaceutical sales representatives." JAMA 273(16): 1296-8.

To provide quantitative data about the accuracy of the information about drugs presented to physicians by pharmaceutical sales representatives the authors investigated. one hundred six statements about drugs made during 13 presentations by pharmaceutical representatives. Statements were rated inaccurate if they contradicted the 1993 Physicians' Desk Reference or material quoted or handed out by the sales representative. They found that twelve (11%) of 106 statements about drugs were inaccurate. All 12 inaccurate statements were favorable toward the promoted drug, whereas 39 (49%) of 79 accurate statements were favorable. None of 15 statements about competitors' drugs were favorable, but all were accurate, significantly differing from statements about promoted drugs. In a survey of 27 physicians who attended these presentations, seven recalled a false statement made by a pharmaceutical representative, and 10 said information from the representatives influenced the way they prescribed drugs. They claim that eleven percent of the statements made by pharmaceutical representatives about drugs contradicted information readily available to them. Physicians generally failed to recognize the inaccurate statements.

Brennan, T. A., D. J. Rothman, et al. (2006). "Health Industry Practices That Create the physician's roles Conflicts of Interest: A Policy Proposal for Academic Medical Centers." JAMA 295(4): 429-433.

Conflicts of interest between physicians' commitment to patient care and the blandishments that pharmaceutical companies and their representatives lavish on them impair professionalism in medicine. Although the involved groups, including the Federal government have instituted self-regulation of marketing, research into gift receipt and giving indicates that current controls will not satisfactorily protect the interests of patients. More stringent regulation is necessary, including the elimination or modification of

common practices. They propose a policy for academic medical centers to take the lead in eliminating these conflicts of interest that impair patient care.

Stossel, T. (2005). Mere Magazines. The Wall Street Journal. Washington, DC: A16. December 30, 2005.

In this brief article Dr. Stossel raises important questions about the arrogance of major medical journals and their persistent negative attitude towards the companies that are responsible for all the advances in medicine that we have seen over the past half-century. Whether or not you end up agreeing with the arguments, this is a refreshing contrast with the uniformity of the beating big Pharma has been taking in the medical literature and the media.

(2004). Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. DHHS. Services, Federal Register. 69 (92): 26393-7.

This federal guideline asks IRBs and institutions to consider a variety of means to eliminate, document, disclose, and manage conflicts of interest. It is not overly prescriptive but it expects institutions to actively and effectively deal with conflicts of interest both of individual investigators and of IRB members. Conflict of interest committees distinct from IRBs are expected to be developed. Required reading for research administrators.

Brody, B., C. Anderson, et al. (2003). "Expanding Disclosure of Conflicts of Interest: Views of Stakeholders." IRB Ethics and Human Research **25**(1): 1-8.

Kim, S. Y. H., R. W. Millard, et al. (2004). "Potential research participants' views regarding researcher and institutional financial conflicts of interest." J Med Ethics **30**(1): 73-79.

This empirical study of the attitudes of potential research subjects towards the revelation of financial conflicts of interest and their existence gave strong evidence that subjects wanted to know. Some would be less inclined to participate in the proposed study knowing of the conflicts of interest. A very nice study.

http://jme.bmjjournals.com/cgi/content/full/30/1/73

Taylor, R. and J. Giles (2005). "Cash interests taint drug advice." Nature **437**(7062): 1070.

This paper and the accompanying editorial deal with groups empanelled by professional societies primarily to write "evidence based" clinical practice guidelines. A study by Materal found that substantial number of the panel members receive income or own stock in companies whose products are under consideration. The influence of these companies may be indirect in promoting drug use in the filed or to encourage use of a specific product. Better methods of developing guidelines are suggested.

http://www.nature.com/nature/journal/v437/n7062/full/4371070a.html

Brody, H. and F. G. Miller (2003). "The clinician-investigator: unavoidable but manageable tension." Kennedy Institute of Ethics J **13**(4): 329-46.

This paper addresses the two roles of the Clinician-Investigator as scientist and caregiver. The authors indicate that research is very different from care and thus there is ethical tension in doing both (the difference position). Those that argue that the physician's role is similar in both circumstances (similarity position) are claimed to be in error because the position denies the ethical tension. A very worthwhile read.

Mello, M. M., B. R. Clarridge, et al. (2005). "Academic Medical Centers' Standards for Clinical-Trial Agreements with Industry." N Engl J Med **352**(21): 2202-2210.

This critical paper delineates the weaknesses of academic institutions in writing contracts that protect data and investigators from bias. This is very important reading.

http://content.nejm.org/cgi/content/abstract/352/21/2202

(2003). "American Society of Clinical Oncology: Background for Update of Conflict of Interest Policy." J Clin Oncol **21**(12): 2387-2393.

The new version of their conflict of interest policy that is based on complete disclosure and a number of prohibitions. A good set of rules that others could emulate.
http://www.jco.org/cgi/content/full/21/12/2387

Bentley, J. P. and P. G. Thacker (2004). "The influence of risk and monetary payment on the research participation decision making process." J Med Ethics **30**(3): 293-298.
This questionnaire study attempted to determine the impact of various levels of payment on willingness to participate in a trial. Knowledge of the characteristics of a trial and whether it would lead to behavior damaging the quality of the study. Money was an incentive. The other effects did not seem to be present.
http://jme.bmjjournals.com/cgi/content/full/30/3/293

Miller, F. G. and A. F. Shorr (2002). "Ethical Assessment of Industry-Sponsored Clinical Trials*: A Case Analysis." Chest **121**(4): 1337-1342.
These authors review a single randomized control trial of asthma therapy in children for its ethical characteristics and find it faulty. This is worthwhile reading.
http://www.chestjournal.org/cgi/content/abstract/121/4/1337

Schroter, S., J. Morris, et al. (2004). "Does the type of competing interest statement affect readers' perceptions of the credibility of research? Randomised trial." BMJ **328**(7442): 742-743.
http://bmj.bmjjournals.com/cgi/content/full/328/7442/742
An empirical study noting a competing financial interest on receiving research support on various aspects of a study. Believability and relevance were both significantly reduced in the presence of a financial conflict. All in all, a weak paper, but provocative.
Resnik, D. (2004). "Disclosing conflicts of interest to research subjects: an ethical and legal analysis." Accountability in Research **11**(2): 141-59.
The author makes the case that investigators have an ethical and now a legal obligation to disclose their conflicts of interest in a manner such that the study participants will have enough information to sign an informed consent. He argues that disclosure of conflicts of interest should be required in informed consent documents.
Campbell, E., B. Moy, et al. (2004). "Institutional academic industry relationships: results of interviews with university leaders." Accountability in Research **11**(2): 103-18.
The investigators conducted interviews of university leaders to get their viewpoints on academic-industry relationships. Generally, there were many such relationships and these were generally thought to be constructive. There was understanding that conflicts of interest were pervasive and sometimes risky.
Holmes, D. R., B. G. Firth, et al. (2004). "Conflict of interest." American Heart Journal **147**(2): 228.
This report of an expert meeting reviews conflict of interest issues from the level of the investigator on to the FDA. It has become somewhat dated because of the recent NIH revelations and rule development and progress in registering clinical trials.

Bernstein, M. (2003). "Conflict of interest: It is ethical for an investigator to also be the primary care-giver in a clinical trial." Journal of Neuro-Oncology **63**(2): 107.
The author addresses one of the issues of the day. He comes down in opposition to the AAME report on individual conflicts of interest in clinical research, as supporting such research in many instances.
http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1023/A:1023959021758

Komesaroff, P. (2005). "Ethical issues in the relationships with industry: an ongoing challenge. New Guidelines open for public comment." J Paediatr Child Health **41**(11): 558-60.
In this paper the author explains the extent to which medical decision-making in Australia is influenced by industry. He provides guidelines to Australian physicians as to their behaviors, including the rejection of gifts, subsidized attendance at meeting, and samples. They should not endorse specific products. Clinicians should also avoid recruiting their patients into studies in which they are investigators, as well as only doing studies in which there is a commitment to make the results public. This should be followed by an empirical study on compliance.

http://www.blackwell-synergy.com/doi/abs/10.1111/j.1440-1754.2005.00719.x

Topol, E. J. and D. Blumenthal (2005). "Physicians and the Investment Industry." JAMA **293**(21): 2654-2657.
http://jama.ama-assn.org/cgi/content/full/293/21/2654

In this excellent paper the authors identify and discuss the new practice of clinical researchers providing information to investment groups as consultants. In a number of instances it appears that confidential information was leaked that gave investors significant advantages. The questions as to the ethical standing of this activity versus the right of professors to communicate about what they know was introduced. How can we be sure that the information is in the public domain before discussing it?

Weiss, R. (2004). NIH to Set Stiff Restrictions on Outside Consulting. Washington Post. Washington, D.C.: A01. August 4, 2004.

After a scandal revealed by the LA Times in which many NIH personnel including investigators and those with responsibilities for dispensing grants and contracts received substantial sums from drug and biotech companies the NIH took. Head of investigations by congress, internal reviews, and the report of an independent expert committee developed rules for NIH personnel. Familiar rules once being adopted by most major research institutions.

11

Science, context and professional ethics

Ruth Chadwick[#]

"There is a central core of universal values that any truly modern society must possess, and that science promotes. These are rationality, creativity, the search for truth, adherence to codes of behavior, and a certain constructive subversiveness" (Serageldin 2002)

Science and the ethics of distrust

In the last decade ethical issues relevant to scientists as professionals have come very much to the fore, although they have not, typically, been considered under the guise of *professional* ethics as such. Rather, appeal has been made to problems that have arisen in the context of, for example, genetically modified foods and the BSE case. These cases involved both public concerns over the profit motive prevailing in the research and policy agenda; and anxieties about the unpredictability of long-term consequences. Can the framework of professional ethics shed any light on these issues?

It might be relevant to consider the wider context of distrust in the professions (Pellegrino 1991). Both sociological and philosophical criticism (cf. Koehn 1994) have constituted aspects of this phenomenon, apparent in the late 1980s and early 1990s. An ethic of distrust proceeds by attempting to regulate more closely the activities of professionals, by increased external monitoring and demands for accountability. According to one view (Veatch 1991) this approach wins the day by default because the notion of an ethics of trust is not only difficult to sustain: it is actually incoherent.

Robert Veatch attacks what he sees as the three arguments supporting an ethic of trust: (1) that professionals serve the client's interest; (2) that professionals can present value-free facts to the client; (3) that professionals should act on a set of virtues inherent in the profession. Veatch argues that modern professionals ought not to know what the client's interests really are – the most they can know is what the client's interests are in one particular area of life. Whereas medical professionals might be primarily concerned with promoting health, for example, health might not be the top priority for a patient (Goldman 1992). Veatch further argues that professionals cannot present value-free facts; and that it is a serious mistake to think that any given profession is associated with one particular conception of virtue. These points are very apposite for a consideration of the ways in which ethical considerations enter debates about science, in the light of, for example: the questioning about the extent to which science serves society; debates about value neutrality in science; and the extent to which scientific 'truth' is an unquestionable good. But does science constitute a 'profession' in the relevant sense to make it worthwhile looking at it through the lens of professional ethics?

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Science as a profession?

There are different approaches to giving an account of what it means to be a profession: the 'defining characteristics' approach and the 'process' approach. The 'defining characteristics' approach, again, has a narrow and a wide version – in a wide sense 'profession' simply means someone's occupation; in a narrower (more interesting) sense it refers to a certain kind of activity, one carrying with it a certain status and associated with a particular ethic. Traditionally a profession has been marked out by a body of knowledge, mastery of which (at least partly) regulated entrance to its ranks; and by an ideal of service (Airaksinen 1994). Since the body of knowledge has the potential to confer power, money and status, professionals are expected to use their skills for the benefit of the community. Those groups which have long been secure in their recognition as professions, the so-called liberal or 'learned' professions such as medicine, divinity and the law, have also been characterized by a considerable degree of authority and autonomy in their practice. Along with the autonomy of the individual professional, professional bodies have also been accorded a significant degree of autonomy in controlling both accesses to the profession and professional conduct.

Taking into account the provisional nature of scientific knowledge, science as a profession can apparently satisfy the 'body of knowledge' criterion: the ideal of service, however, is less clear. Service to whom? This point may depend on the context in which the scientist works, and this is a very important consideration with regard to a discussion of the ethical issues. One of the problems, arguably, with current scientific practice is the rival claim of academia, industry and government as the context in which scientific research takes place.

If we look at a process account of profession, in terms of how an occupational group achieved a certain status (cf. Freidson 1994), rather than the set of characteristics approach, it is arguable that scientists have achieved a position of power, not only in having far-reaching effects on society through scientific advance itself but also in having considerable influence as government advisers and being able to command the highest salaries among academics.

Traditional classifications of professions have been subject to two contrasting trends: first, the attempt by some groups for recognition as professions or neo-professions; and second, challenges to the notion of professionalism either because of its conceptual inadequacy, or on the grounds of its social consequences. I shall set aside the former for present purposes, but I do want to say something about the second. One reason for the challenge to the concepts of profession and professionalism is that critical, reflective professionals, with autonomy over their practice, may be seen as a threat (Williams 1996). A second reason is connected with the potential for professions to become self-serving elite's (Freidson 1994; Illich 1997). In response to this situation there has been an attempt to replace the focus on professionalism with a focus on competencies. It may not be so easy, however, to dispense with the notions of 'profession' and 'professionalism'. J.K. Davis, for example, has argued that for the professional it would not be sufficient that a client was satisfied, if the professional him- or herself felt that the service was below standard. For the professional, however, it is more than simply doing a competent job: a worker becomes a professional by professing reasons for doing their work in a certain way (Davis 1991a).

We cannot assume, however, that the area of 'competence' is ethically neutral, while values come into the realm of 'reasons for action'. Certainly in the case of science, while there may be dispute about what we mean by calling science a profession, it is increasingly recognized that while *scientific* competence may be necessary it is not sufficient for the 'good' scientist. A recent article in *The Daily Herald* (2003??) said:
"Here are three biology terms: endoskeleton, enzyme, epidermis. If you're serious about a career in biology, add one more item to the list: ethics". Here ethics appears among the basic *competencies* for a biological career.

What I want to suggest is that it may be enlightening to consider science as a profession and to look at it through the lens of professional ethics. It enables us to put aside the specific 'scandals' that have, supposedly, given rise to the distrust of science and to look at the wider context of the distrust of professional power, the reasons for it, and the proposed solutions, such as the approach to grounding trust in the professions anew. Koehn (1994) has argued that to do this is important because professions represent the mechanism chosen by Anglo-American morality for providing people with goods such as health and justice, and if professionals are not trustworthy, where are we to turn for help? For health and justice are not goods that are readily dispensed with. Does the same apply in the case of science? This depends on identifying the relevant good. For Koehn, the challenge is to show not only that there are grounds for trust in the professions because they provide people with such goods, when they lack them, but also that they do not violate the requirements of ordinary morality (Koehn 1994). There is a connection here with current policies of trying to re-establish trust in science by, for example, the developments we have seen starting from public understanding of science, moving through public consultation, to public 'engagement'. At what stage in the process should the public be engaged? There has been debate about the limitations of involving the public only at the 'downstream' stage of the impact, implications or applications of science, rather than at the 'upstream' stage of debating what scientific research should be carried out. It would be possible to move even further back, however, to consider what the 'good' of science is: is that for scientists themselves to determine?

Although it seems that there are close connections between the debates in professional ethics as a whole and those concerned with the ethics of science, it is clear that *context*, as we have already noted, is important. In so far as scientists are academics, the relevant questions of professional ethics will be common to other academic disciplines – I am thinking here of the avoidance of plagiarism, for example. In this paper however I want to consider whether and to what extent there are issues that are specific to science and the relevance of context in addressing them. With that in mind I shall move on to the problems of professional ethics.

Professional ethics and science

Problems of professional ethics typically fall into two broad categories, but both arise essentially from professional power. The first is concerned with the professional–client relationship, while the second relates to the role of professions and professionals in society as a whole.

The professional–client relationship

Although an ideal of service is supposed to provide a safeguard to promote the use of professional expertise to help rather than harm, specialist knowledge, to which

professionals have access and clients do not, does give the professional power, and the client is thus placed in a vulnerable position. One caveat however (Langan 1991) is that the paradigm of a relationship between two individuals is inadequate because it overlooks those professions which do not, or not substantially, conform to this pattern, such as teaching, which may be but commonly is not done on a one-to-one basis. Although there are ethical issues arising in relation to science concerning treatment by researchers of individuals, e.g. in human subjects research, science *per se* also does not conform to this pattern, having as it does an impact on society as a whole.

The second category of problems is more concerned with the role and image of professionals in society. While it may be true (Pellegrino 1991) that there has always been a tendency towards distrust of professionals, this has been exacerbated by social and political developments. The trend towards client autonomy; attempts by government to curb the independence and privilege of professionals; media criticism have all had their effect.

Professions and science in society

Sociological critique has suggested that professions, rather than being essentially moral enterprises, are in fact effective monopolistic institutions and that the professed commitment to ethical ideals, rather than conferring legitimacy on the profession, is nothing more than ideology. Ivan Illich (1997) famously termed the mid-twentieth century the age of 'disabling' professions: far from using their knowledge to serve, they had become forms of control, claiming the authority to determine human needs. This critique is one that has been levelled against science, leading to calls for the democratization of science.

There are several aspects to this criticism of science:

(a) the belief that scientific progress is inevitable is under challenge, and indeed, that there is such a thing as progress
(b) the attempt to draw a distinction between the pursuit of knowledge and questions about its use has been undermined – it is no longer adequate for the scientist to say 'I just do the science: it is for society to decide what to do with the knowledge'
(c) perceived undesirable consequences of scientific developments 'going too far' have led people to fall back on ideas about the natural and familiar.

What I want to suggest is that while the tendency has been to address these questions by trying to make science and scientists more accountable, this has been inadequate. We have seen in the last ten years moves in many countries to do this in a number of ways, for example by allowing other forms of expertise, such as ethical and lay expertise, to influence debates in the policy area. This has had the effect of opening up the whole notion of expertise and what counts as a relevant 'body of knowledge' for particular purposes. The approach, however, has been what I call 'external' and again I think here the discussion that has taken place in professional ethics about internal and external ethical approaches might offer some useful insights.

Theoretical perspectives: internal and external

A self-derived ethic?

Some critics have taken issue with a self-derived ethic which permits professionals to be guided by standards other than those of ordinary morality. "Problems in professional ethics typically arise when the values dominant within particular professions come into conflict with other values in the course of practice.

Professionals are likely to perceive these values as dominant where others may not" (Goldman 1992, p. 1018). While few might subscribe to the view that nothing else can compete with the value of a new fact (quoted in Vyvyan 1971), a self-derived ethic might take a number of forms. In one form it is associated with the idea that there are certain ways of behaving appropriate to different roles, which diverge from those suited to people who do not fill that role. For example, it might be argued that a lawyer is under an obligation, arising out of the lawyer's role, to achieve the best result for a client even if that conflicts with what he or she believes as a private individual.

Another form which a self-derived ethic might find expression in is a code of professional conduct or code of ethics. The possession of a code of professional conduct has been pivotal in debates about what constitutes a profession. Such a code can fulfil a variety of functions: offering a public statement of ideals and values; providing a disciplinary mechanism for a professional body; reassuring the public that the profession upholds certain standards; and educating members of the profession to 'think like' others in the group (Davis 1991b).

The standards incorporated in a code may be either higher or lower than the standards of ordinary morality. Professionals have traditionally been prevented from doing things which people in other spheres of activity are permitted to do e.g., advertising. This arises out of the purported commitment to serve first the interests of clients, rather than their own profit. On the other hand this same commitment can act as a shield to protect professionals from the criticism that they do things which would be frowned on in terms of ordinary morality e.g., lying to clients or physically hurting them in order to promote some further end identifiable as being in the client's interests (Häyry and Häyry 1994).

Criticism of a self-derived professional ethic, whether in the form of role ethics or a code of conduct, is based on arguments that if an action is morally right it should be susceptible of justification by the same moral arguments that apply to the behaviour of any other member of society - professionals should not require special ethical norms to be determined by themselves. For it is not clear how such norms could be justified if not by common moral principles (Goldman 1992).

How would these considerations be applicable to science? There have been attempts to outline sets of ethical principles for scientists. One example is the HUGO Ethics Committee Statement on the Principled Conduct of Genetics Research (1996). Drawn up as it was by the Ethics Committee of the Human Genome Organisation, it is not entirely self-derived because the Ethics Committee members are not all members of HUGO, but its primary audience is scientists who are members of that organization, and who are engaged in genetic research. (It is worth mentioning however, that it is to a large extent in the context of genetics that recent debates about the ethical conduct of science have been situated). This statement is sometimes described as a 'Ten Commandments' or the 'Ten C's'. I shall not enumerate all the principles. As the statement relates to human genetic research, several of the principles relate to treatment of research participants, and I want to confine myself to science *per se*. The first principle concerns competence, which is said to be an essential prerequisite for research, and which has been mentioned above. Others which I think are relevant to the present discussion relate to *communication*, *collaboration* and *conflict of interest*.

Communication is relevant to being 'accountable' (cf. Holdsworth 1994) but the HUGO Ethics Committee states that "Communication is a reciprocal process; researchers must strive to understand as well as to be understood". It is stated that

"[C]ollaboration … in the free flow, access, and exchange of information is essential not only to scientific progress but also for the present or future benefit of all participants". It is this principle of ethical science that is held to be under threat from scientists' loyalty to particular organizations, and this explains the importance of the principle stating that "any actual or potential conflict of interest be revealed at the time information is communicated and before agreement is reached".

Internal goods

A more interesting distinction between internal and external perspectives is that between internal and external goods. The internal approach might attempt to derive values internal to specific professions by examining the *point* of those professions, or the relevant *good* they produce, as outlined above. Rather than accepting them as Illich's 'dominant' professions that take it upon themselves to define human need, the question to ask is: what pre-existing human need or value do and should they serve? This quest might take different forms. The identification of health and justice as goods that cannot readily be dispensed with, because they may be needed by vulnerable people, has been mentioned (Koehn 1994). Or there might be an argument for some intrinsic or 'transcendent' values embedded in a professional activity (Tur 1994). Thirdly, knowing the point of a practice such as a professional activity might point the way to virtues internal to the practice of that activity.

Does this sort of analysis make sense in relation to science? What might qualify as the 'internal good' of science in this sense? The European Group of Advisers to the European Commission in its 1997 Opinion (Group of Advisers on the Ethical Implications of Biotechnology GAEIB 1997) referred to "the fundamental principle of freedom of research, which flows from freedom of thought". It is difficult to accept that freedom of thought can be the relevant internal good, however. Even if there are grounds for thinking that this is a good in itself, it surely cannot be the relevant good in terms of professional ethics. It is not specific to science, and it is not clear, without more, why it should be a service to the community. The relevant internal good must be something that is provided for those *affected* by the profession rather than a good *to members* of the profession.

The internal good that science provides must be in some way connected with the purported benefits to society that science can provide. If the matter is looked at in this way, it becomes clear why there are demands for the public to be engaged at a more 'upstream' stage, rather than only after the event, because arguably there are some categories of research that, for social reasons, should not be done. The European Group of Advisers (Group of Advisers on the Ethical Implications of Biotechnology GAEIB 1997) argued that the freedom of thought had to be reconciled with the protection of European citizens and human responsibilities towards animals and the environment, but this is far from being confined to the conduct of research. The very *decision to undertake* certain research might express discriminatory attitudes, for example, as in research on the genetic basis of homosexuality.

Context

My argument is that this dimension of the debates about the ethics of science has been overlooked, and that an investigation of it could help us in addressing specific problems about the context in which science is practised. The issues of context, it seems to me, are two, related to money and power. Now clearly money and power have been issues in professional ethics generally, especially in the 'process' account

of professions and the sociological critique of professionalism. In science however they take on a particular character. First there is the debate about commercialization, which concerns scientists working for profit-making organizations and the pressures to which that might lead. The second concerns power, and the role of scientists on 'expert' committees.

Attempts have been made to address these issues via the external approach. For example, the profit-making issue has been addressed using concepts such as benefit-sharing, as in the HUGO Ethics Committee Statement on Benefit-Sharing (2000). This statement made the fundamental point that there are issues of justice to be addressed here, partly in so far as benefits accruing from scientific research are frequently relying on publicly funded resources to make private profits. As already mentioned, the power issue has been addressed through various mechanisms of public involvement.

However, what needs to be examined is the extent to which different institutional contexts are at variance with the 'internal good' of science, the very point or rationale of the activity. The quotation at the beginning of this paper suggests some universal values that science *promotes* and which are said to be essential to any truly modern society. To take one of these, constructive subversiveness, it is easy to see that some institutional contexts which require loyalty to the institution would be incompatible with this and which can lead to disaster (cf. Davis, M.K. 1991??).

Conclusion

I have argued that current debates on the distrust of science have missed what might be an enlightening dimension, that is to set the debate within the context of professional ethics as a whole. Reference to this context shows that it might be helpful to contrast the internal and external approach. Present day debates about the ethics of science, while trying to incorporate public engagement 'upstream' could usefully be informed by discussions about what constitutes the 'internal good' of science. This should not be understood purely in terms of freedom of thought. Analysing this good would also provide a framework for analysing the problems arising from scientific research in particular institutional contexts which might by their very nature undermine the pursuit of the internal good.

References

Airaksinen, T., 1994. Service and science in professional life. *In:* Chadwick, R.F. ed. *Ethics and the professions*. Aldershot, Avebury, 1-3.

Davis, J.K., 1991a. Professions, trades and the obligation to inform. *Journal of Applied Philosophy,* 8 (2), 167-176.

Davis, M., 1991b. Thinking like an engineer: the place of a code of ethics in the practice of a profession. *Philosophy and Public Affairs,* 20 (2), 150-167.

Freidson, E., 1994. *Professionalism reborn: theory, prophecy and policy*. Polity Press, Cambridge.

Goldman, A., 1992. Professional ethics. *In:* Becker, L.C. ed. *Encyclopedia of ethics*. St. James Press, Chicago, 1018-1020.

Group of Advisers on the Ethical Implications of Biotechnology GAEIB, 1997. *The ethical aspects of the 5th research framework programme*. Office for Official Publications of the European Communities, Luxembourg. European Group on

Ethics Opinions no. 10. [http://europa.eu.int/comm/european_group_ethics/gaieb/en/opinion10.pdf]

Häyry, H. and Häyry, M., 1994. The nature and role of professional codes in modern society. *In:* Chadwick, R.F. ed. *Ethics and the professions*. Aldershot, Avebury, 136-144.

Holdsworth, D., 1994. Accountability: the obligation to lay oneself open to criticism. *In:* Chadwick, R.F. ed. *Ethics and the professions*. Aldershot, Avebury, 58-87.

HUGO Ethics Committee, 1996. *Statement on the principled conduct of genetic research*. Human Genome Organization HUGO, London. [http://www.gene.ucl.ac.uk/hugo/conduct.htm]

HUGO Ethics Committee, 2000. *Statement on benefit-sharing*. Human Genome Organization HUGO, London. [http://www.gene.ucl.ac.uk/hugo/benefit.html]

Illich, I., 1997. *Disabling professions*. Boyars, London.

Koehn, D., 1994. *The ground of professional ethics*. Routledge, London.

Langan, J.P., 1991. Professional paradigms. *In:* Pellegrino, E.D., Veatch, R.M. and Langan, J.P. eds. *Ethics, trust, and the professions: philosophical and cultural aspects*. Georgetown University Press, Washington DC, 221-235.

Pellegrino, E.D., 1991. Trust and distrust in professional ethics. *In:* Pellegrino, E.D., Veatch, R.M. and Langan, J.P. eds. *Ethics, trust, and the professions: philosophical and cultural aspects*. Georgetown University Press, Washington DC, 69-85.

Serageldin, I., 2002. The rice genome: world poverty and hunger - the challenge for science. *Science,* 296 (5565), 54-57.

Tur, R.H.S., 1994. Accountability and lawyers. *In:* Chadwick, R.F. ed. *Ethics and the professions*. Aldershot, Avebury, 58-87.

Veatch, R.M., 1991. Is trust of professional a coherent concept? *In:* Pellegrino, E.D., Veatch, R.M. and Langan, J.P. eds. *Ethics, trust, and the professions: philosophical and cultural aspects*. Georgetown University Press, Washington DC, 159-169.

Vyvyan, J., 1971. *The dark face of science*. Joseph, London.

Williams, B., 1996. *Freedom on probation: a case study of the Home Office enforced changes to the University education and training of probation officers (pamphlet)*. Association of University Teachers.

ETHICS IN RADIATION PROTECTION

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A DEFINITION OF ETHICS

Ethics is a branch of philosophy. Its object is the study of both moral and immoral behaviour in order to make well founded judgements and to arrive at adequate recommendations.

The Collins English Dictionary provides the following definitions of the word 'ethic':
Ethic: a moral principle or set of moral values held by an individual or group
Ethics(singular): the philosophical study of the moral value of human conduct and of the rules and principles that ought to govern it
Ethics(pleural): a social, religious or civil code of behaviour considered correct, especially that of a particular group, profession or individual
Ethics(pleural): the moral fitness of a decision, course of action, etc.

Ethics has a two-fold objective:
Firstly it evaluates human practices by calling upon moral standards; it may give prescriptive advice on how to act morally in a specific kind of situation
This implies analysis and evaluation. Sometimes this is known as Normative ethics.
The second is to provide therapeutic advice, suggesting solutions and policies. It must be based on well-informed opinions and requires a clear understanding of the vital issues.
In the medical world, we are governed by the Hippocratic Oath. Essentially this requires medical practitioners (doctors) to do good, not harm.

There is great interest and even furore regarding ethics in radiation protection.
You will know that IRPA has become interested, with discussion on the creation of a code of ethics at the Executive Council Meeting in Southport in June 1999, the publication of a discussion paper on enhancing the role of IRPA in November 1999 and the matter was discussed at the Associate Societies Forum in Hiroshima in 2000. At that time, it was felt any code should be for individuals and indeed be a code of conduct rather than ethics. Papers have been given at recent national meetings in the United Kingdom and Romania.

An Ethics discussion web site: www.srp-uk.org/irpaethics/ has been set up by the UK Society for Radiological Protection for all to contribute to the debate. Readers of this paper are strongly advised to consult the work of Lars Persson for greater analysis of the issues.

In this short paper, I cannot hope to cover the issues in radiation protection in any depth, but will outline the issues.

There appear to be 2 main points.

The first concerns codes of conduct. The Health Physics Society in USA and the Australian SRP have both produced codes of conduct. These deal with the moral issues such as maintaining good work standards, etc.
The other concerns the actual issues involved. There are a number of major issues, and here I am very grateful for Lars Persson and his colleagues for setting out these issues so clearly. It appears there are 8:
Equity v. Efficiency: the justification principle
Health v. Economics: the optimisation principle
Individual rights v. Societal benefits: the dose limitation principle
Due process v. Necessary sacrifice: liability principles
Stakeholder consent v. Management decisions: controlling exposures
Psychology: fear of radiation more harmful than radiation
Psychology: fear of radiation as a contribution to genocide
Science: the question of truth

Two other topics can also be mentioned:
Communication: the need to communicate with the public v. lack of will to seek public consent
Standards for workers v public

Equity v efficiency. The benefits to society of radiation outweigh the detriment to individuals. But it could also be said that this must not be achieved by the misery of a minority or even future generations. With current radiation protection practice today, the risks are considerably less than in many other walks of life.

Health v economics. Large amounts of cash are needed to further improve RP in the Western world. The improvements would be minor, but only a relatively small amount of cash in the underdeveloped world would have a much greater effect on the population generally.

Individual rights v societal benefits. We have to consider minimal risk v any risk. Zero risk does not exist. A 1% risk may be low, but for the person affected, it is 100%. An interesting example is in the UK. Efforts to stop illegal immigrants are being hampered by an inability to check trucks and trains. A new xgamma machine is being proposed to irradiate trucks, trains to see if illegals are hiding inside. There are major issues here.

Due process v necessary sacrifice. This applies to the previous example. Illegals will not show themselves, so will be irradiated for the general public good. No consent will be given, even if sought, though how it could be sought is unclear.

Stakeholder consent v management decisions. Some say that the public should have a right to know and consent. Others say that a general consent is enough. anything else would be too costly in terms of time and money. Fear of radiation is more harmful than radiation itself .All persons have different knowledge and experiences. Radiation cannot be seen, hence it is to be

feared. Risks that one person will accept have little or no bearing of the true nature of the risk. This applies in all areas of life. Example, sailing v diving.

Fear of radiation as a contribution to genocide. This fear may mean that a nation may reject a cost effective tool, e.g. nuclear power generation of electricity, in favour of a much more costly alternative. Costly may mean financial, but may also include other deleterious effects.

Science: the question of truth What is the truth? The public generally does not trust scientists. What is the truth about low dose and the non linear threshold hypothesis? Is there in fact an answer?

Communication. Medical staff have to communicate with patients daily, but this is on an individual basis. The concern here is of general public communication. It is just not done well enough. In the western world, gloom and disaster make good press for the papers. Improvements in RP receive scant if any attention. This is a reflection of the society we live in. It makes things very difficult for those of us in areas of safety and protection generally, not just radiation.

Workers standards. Why should workers be exposed to a greater risk than the public? This applies to all areas of risk, not just radiation. However, with current safety standards and dose levels, radiation dose to workers is low and has shown little deleterious effect, except where rules have been broken or ignored. We tend to accept a little risk for more benefit ourselves. But do not forget, good training, regularly updated, is essential and must not be ignored. The fact that no incidents have occurred does not mean that training can be forgotten. Safety records are only as good as the last incident. Recent world events are an all too sad example of poor safety procedures.

REFERENCES

Persson L, Shrader-Frechette K
An evaluation of the ethical principles of the ICRP's radiation protection standards for workers
Health Physics. 2001 Mar; 80(3): 225-234

Lakey J.
Informing the public about radiation – the messenger and the message: I Morgan Lecture
Health Physics. 1998 Oct: 75(4): 367-374

Schwarz D
Ethical issues in radiation protection, continued
Health Physics 1998 Aug: 75(2) 183-186

Shrader-Frechette K, Persson L
Ethical issues in radiation protection
Health Physics.1997 Aug; 73(2): 378-382

Silini G
Ethical issues in radiation protection – the 1992 Sievert Lecture.
Health Physics 1992 Aug; 63(2); 139-148

Wiedis D, Jose DE, Komer K
An overview of the current state of radiation litigation
Health Physics 2001.Sept: 81(3); 253-259

Jose DE, Wiedis D, Komer K
A radiation litigation causation analysis which achieves fairness to both litigants
Health Physics 2001 Sept81 (3); 260-264

Rysavy CF, Shaw RP, Cehn JI
A litigation primer for the health physicist
Health Physicist. 2001 Sept81 (3); 246-252

Persson L
Ethical issues in radiation protection
Radiation Protection Dosimetry. 1999 Vol86 (2) 83-85

Persson L
Effects of low-dose ionizing radiation. Ethical considerations
Health Physics Society Newsletter September 1997

Persson L
Modern environmental ethics and the possible implications for radiation protection
In Proceedings, International symposium on ionizing radiation, Stockholm 1996

Ethical issues in radiation protection – an international workshop.
SSI Report 2000:08

Shrader-Frechette K and Persson L
Ethical problems in radiation protection
SSI Report 2001:11

Rijlaarsdam J
Ethical and legal aspects of medical exposure to ionizing radiation in the Netherlands in the year 2000.
In Proceedings, IAEA Symposium, Malaga March 2001. IAEA-CN-85-218

Bridging Radiation Policy and Science.
An international conference. Virginia, December 1999

CHAPTER 1

GEOETHICS – THE MODERN PHILOSOPHICAL BRANCH IN GEOSCIENCE

1.1 HISTORY OF GEOETHICS

Different categories as differentiation principles can be considered in development of models of promotion of geoethical awareness. As a form of social conscious, morality is traditionally considered a complex of norms that determine the responsibilities of humans in relation to the society, other people for a person (individual) is a member of the society. At each stage of its development, morality has been expanding the categories, which it belonged. For instance, the ethical rules of Ancient Greece did not apply to the slaves who were treated as human animals. By abolition of slavery, ethical categories were applied to a human being and society.

During the era of Enlightenment, the idea of the "kingdom of intelligence" – a hypothetic future of the conditions of the society and its interaction with the nature, where human intelligence would take the priority role, was first introduced. While nobody would have thought of any global environmental problems, the Enlighteners gave the world an idea, penetrated by the belief in human brain that is intended to ensure the progress of the society. However, the "brains of the Enlighteners" appeared to be neglected and development of capitalism has lead, in its sense, to formation of industrial-consumer values.

In 1915, German theologian, philosopher, Nobel Prize winner Albert Schweitzer, expanded the boundaries of the use of moral relations. Once, when at sunset, he slowly floated in a small boat in the Ogove River in Africa and watched a majestic scene of bathing of hippopotamuses, he imagined a slim system of ethics, whereby the animals had their own positions like humans and the basics of such system was the thought of "Piety in front of life" that struck him. According to the philosophic concept that Schweitzer defined, ethical treatment of all living creatures would end the duty of humans

in relation to the surrounding world. He wrote: “The mistake of all previous ethics variations was that one had to consider relation of a human to another human being, while in reality, we are talking about how a human treats everything that surrounds him” and “He (human being) will become ethical only when life as it is, lives of animals and plants will be sacred to him like the life of a human being, and when he will devote himself to life that is in disaster. The universal ethics of ruefulness only, the responsibility for which has no boundaries in relation to all living, can give an opportunity to reason ourselves in brain/thought”[152, 153].

The shortfalls of A. Schweitzer’s ethics were limitation of the morally important objects by higher animals and lack of any rules of solution of ethical situations, ethical problems and ethical dilemmas.

In 1920, Russian biologist V.I. Skuchaev developed the theory of biogeocenose, according to which biogeocenose is a homogenous area of the earth surface with certain composition of living (biocenose) and inorganic (near Earth atmospheric layer, solar energy, and soils) natural components, united by substance and energy exchange into a single natural complex. The complex of biogeocenoses forms the biosphere of the Earth [166, 167].

In 1922-1923, the scholar from remote and mysterious Soviet Russia Vladimir Vernadsky gave lectures in geochemistry at Sorbonne. At Sorbonne, it was the first time when he formulated the thesis on geological role of humans and humanity, which was later published in his works [173, 174, 175]. V.I. Vernadsky’s firm belief was that our planet has stepped into a new era of development, where homo sapiens plays the determinant role, both because of its unprecedented scale and his impact to the planet of Earth like the effects of geological forces, any of his actions and inaction is reflected on the condition of the natural environment. The geological activity of humans is obvious and indubitable. What happens if a little part of the fantastic strength destructive forces that humans have is initiated? Now humans are capable of destroying the Earth, but the reality puts a great challenge in front of him: can humans turn the Earth into a blossoming garden? [174].

Two young Frenchmen E. Le Roy* и and P. Teilhard de Chardin** were among the listeners. In 1927, preparing his own lecture course in philosophy at College de France in Paris, E. Le Roy was first to introduce the notion "noosphere", as a qualitatively new state of the biosphere, qualitative new driving force of evolution. Noosphere (Greek. νόος – brain/intellect, σφαῖρα – sphere) – an area of the planet, covered by sensible human activity. In his lectures and in his works "The need for idealism and fact of evolution" (1927), "Origin of humanity and evolution of intellect" (1931), E. Le Roy noted that the idea of noosphere developed under the influence of V.I. Vernadsky's lectures, where the occurrence of life was considered as a single entity. "The great geological literature lacks a related article of biosphere, which is considered as a single entity, as a naturally determined occurrence of the mechanism of the planet, its upper region – the sphere of the Earth". The very idea of the entirety of all living creatures, and all inorganic substances, and complex interrelation of living and inorganic and "sluggish" gave real revolutionary colour to V.I.Vernadsky's conclusions. This idea – of the entirety – triggered in Le Roy the conclusion on combination of the intellects of all people, represented by individuals, who are different, sometimes contradictory to each other, but nevertheless, can also be a single entirety, alongside with the lithosphere – complex of sluggish/fossil mother and biosphere – combination of living creatures – act as a separate factor of evolution, as a component of life on planet Earth.

During the second half of 1930's, after reviewing the works of E. Le Roy, V.I. Vernadsky wrote: "I accept Le Roy's idea of noosphere. He has further developed my biosphere. Noosphere was formed in post-Pliocene era – human thought covered the biosphere and is changing all processes from a new angle, and as a result the

* E. Le Roy (1870-1954), French philosopher, representative of catholic modernism. From 1921 to 1941 headed faculty of philosophy at College de France. Member of Academy of moral and political sciences from 1919, member of French Academy of Sciences from 1945. Introduce the term "noosphere", together with P. Teilhard de Chardin developed the concept of noosphere, trying to agree catholic dogmas with new data, accumulated by biology, anthropology, palaeontology. Catholic church included his works in the "List of banned books", and his ideas were criticised by Pope Pie X in encyclical Pascendi in 1907.

** P. Teilhard de Chardin (1881-1955) – French scholar-palaeontologist, philosopher and theologian, one of the discoverers of sinanthrope (ape man). Created philosophic concept of "Christian evolutionism", together with E.Le Roy developed the concept of noosphere.

biosphere energy increases." [175]. Actively developing the concept of E. Le Roy and P. Teilhard de Chardin on increasing of the role of intellect in development of civilisation, V.I. Vernadsky proposed an idea of noosphere becoming the main direction of development of humanity as a base of its future survival. He believed in human sense (intellect), which obliges us moving to very different relationships with the Nature. Not to fight it, as we had been doing until recently, no to melt over to be "pious" pre-civilisation balance of humans with the nature, not to idealise him, but to systematically even our relationships with the environment, to assist in improvement of the mechanism of single gigantic living system thus making possible the transfer from biosphere to noosphere.

It was not a simple step to take for human society to think about human relation to other life forms in the way of ethics. For all the time of their existence (this is about 2 million years, according to contemporary information), the humanity really thought that exploitation of biological resources was right for it supplies the vital needs of Homo sapiens, and lies outside the boundaries of morals. And only for the last hundred years, there has been some two-way traffic: development of Schweitzer's "piety with life" in social conscious thus its rights for existence and preservation of all biological forms of life, on one hand and awareness of human species as an element of ecosystems on the other.

In late 1930's the Benthamites and conservatives of USA initiated a burning discussion on the methods of preservation of the nature. The Benthamite approach supporters proposed a concept of preservation that assumed temporary preservation of selected areas of wild life, which would be reused for economic needs after rehabilitation. While the supporters of anti-Benthamite concept proposed complete conservation of most vulnerable and valuable areas of wildlife. American environmental scientist Oldo Leopold was a representative of conservatism. In his assays collection "A Sandy County Almanac", published after his death, explained the Land Ethics ideas. "The initial ethics assumed relationship between individuals; further additions are associated with relationships of an individual and the society. But there still does not exist the ethics that regulates the relationships be-

tween humans with the Earth, with animals and plants that live on the Earth. Like Odyssey's bond-maids, the Earth is still considered as a property and all relationships with it are still based on consumer point of view that assume only rights without any obligations", – wrote Leopold [90].

As opposed to A. Schweitzer, A. Leopold did not apply ethics to individual species, but to species and societies, and to the Earth as well* (an inorganic object in general understanding). According to the Land Ethics, humans should not abolish or contribute to dying off species, heedlessly mix local and exotic species, extract endless energy from subsoil and liberate it at household, dam up or contaminate rivers. This, ethics was applied to the third element in surroundings of humans. Such expansion radically changes moral approach of humans to the Earth: Land Ethics turns Homo sapiens from conqueror of the land community into a simple member and citizen of such community. The economic system of values that dominates our relationship with the Earth does not yet help understanding non-economic types of value: the nature protection system, based on economic egoistic interests, is hopelessly unilateral. It tends to ignore and this gradually abolish many earth community components, which do not have any commercial value, but which (as far as we are aware) are extremely important for unimpaired functioning". Leopold states that such polarisation in economic and environmental paradigms exists in all sciences, in whatever way related with study of the planet – wild life biology, forestry or agronomy. In the economic model, the value of the Earth is reasoned by its resource or instrumental value.

According to statement by the English philosopher J. Locke in his theory of occurrence of private property, the nature itself does not have any internal value, and using their labour humans can transform the concealed resource value of the Earth into useful products. By way of cultivation, people must "liberate" as much values from the Earth as possible. While A. Leopold approached the issue of preservation of nature as "a moral issue". He treated the Earth not only as stores of re-

* Here A. Leopold took the ideas of Russian philosopher P.D. Uspensky (1878-1947) as bases, who stated that everything in nature owns its own intellect: "there is nothing dead or mechanical in nature… the life and feelings should exist in everything"; "a mountain, tree, fish, a drop of water, rain, plane, fire – each in isolation should own its own conscious"

sources for humanity, but he looked at it as a living matter, which humans are closely connected to. And in his ecological model, the value of the Earth is higher and wider than the economic model. A. Leopold called this "the philosophic value" [50].

He took the Earth as some "collective organism". It feeds humans and forms their culture. People are responsible for preservation of the Earth's health. Not only the lives of existing, but also future generations of all living creatures who live on the planet are dependent on her health. Humans must cardinally review their approach to the nature. Humans must change from the conqueror and parasite into "citizens of biosphere". Humans must realise the fact the Earth is a collective organism, and they are part of it themselves. Parts of this organism not only compete with each other but also cooperate and work together. As the higher creature, humans are capable of regulating the competition and cooperation processes, but they have no rights to abolish such. For humans, wild nature must become a laboratory for studies of the health of the Earth. This science about the health of the earth is at its initial stage of formation. The land ethics is also forming in parallel. It "expands the boundaries of commonness/generality to include soils, water, plants and animals (collectively we call them the Earth)". According to A. Leopold, it is necessary to understand the fact that everything that exists in Nature is good irrespective of whether we understand it or not. All creatures, living and inorganic (in common understanding of such), have the right for existence and self-fulfilment. A. Leopold proposed a concept of commonness/generality, which is an integral part of the Land ethics. He clearly understood that "of course, the Land Ethics cannot prevent changes, management and use of these "resources", but it asserts their rights for continuous existence in the natural condition". Leopold's idea served the base for such independent trend of studies as ecological ethics (Figure 1) that deals with the norms of interrelations between humans and the nature and moral bases of use of nature.

In 1940's and 1950's Americans could not treat A. Leopold's proposals with any enthusiasm. The calamities of the Great Depression grew into the World War tragedy. The post war decade was the time for active construction of houses and families. Maintaining the integ-

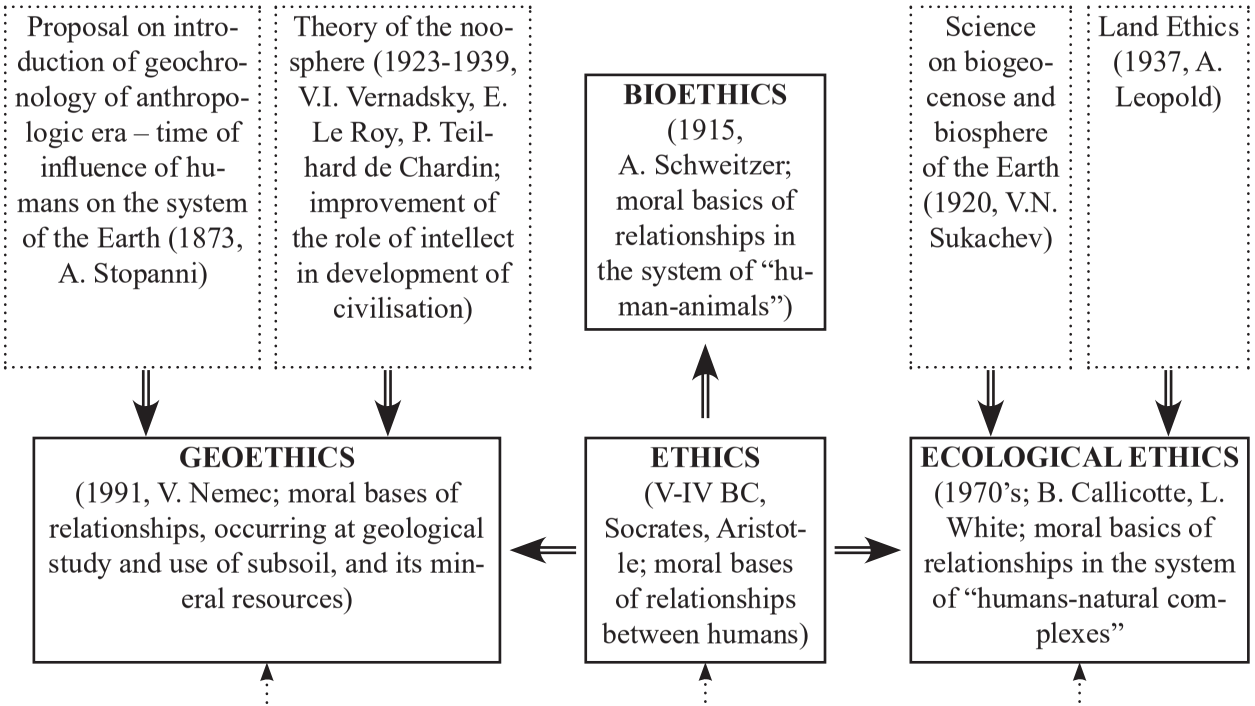

Figure 1. **Basics and history of formation of geoethics**

rity, stability and beauty of ecosystems, offering basic rights even to useful species was almost a meaningless phrase for the first generation of flourishing Americans; ecology was an abstract science to such people. A. Leopold's ideas did not even get the support by majority of ecologists. A. Leopold himself realised that accepting his Land Ethics would depend on changes of far ago established positions and did not express any optimism in relation to the potential of possible changes in social conscious.

Nevertheless, in the following 20 years, a sharp growth of ecological reality awareness created a favourable climate for formation and improvement of positions of the ecological ethics. Should A. Leopold continue to live after 1948, he would probably be surprised and satisfied by occurrence of the ecological ethics, growth of eco-philosophy and even occurrence of such journals like "Environmental Ethics" and "Ecology Law Quarterly", would eagerly read Christopher Stone's assay "Should trees have standing? Toward legal rights for natural objects", he would welcome introduction of environmental protection legislation in various countries, laws on protection of subsoil and preservation of geological objects that are guarantors of the case the some representatives of living nature have rights for living and freedom, while some cliffs and landscapes would be preserved for future generations. Though A. Leopold died in doubt in any possibility of expanding the ethical boundaries, the following generation of environmentalist scholars and philosophers made the ideas of the rights of natural objects more and more popular and try to expand the altruism field.

Being an active supporter of ecocentric ideas of O. Leopold, B. Callicott developed them into his own ecocentric ethics model. According to B. Callicott [27-30], ecosystems are more important than living species, and the basics for moral thinking must be assessment of natural sense for their sake irrespectively of any specific characteristics, which they may have (for instance, internal value, ownership, divine value, etc.).

The "deep ecology"*, a movement that was formed in 1972 that proposed not an integral philosophy of nature, but some philosophic

* This term was first proposed by Norwegian philosopher Arne Naeiss.

way to create its own ecosophic version, was based on eight ecobiocentric ethic theses:

1. The benefit and flourishing of life on the Earth has its value as it is (synonyms: its own internal value, true dignity, self-value). These values do not depend on their usefulness to people.
2. Abundance and diversity of life forms helps implement these values and are valuable on their own.
3. People have no rights to reduce the abundance and diversity of life, with the exception of satisfaction of vital needs.
4. Flourishing of human life and culture, as well as flourishing of life of other creatures, requires significant reduction of population of people.
5. Current interference of humans into nature is excessive and the situation is getting worse rapidly.
6. Changes are required in the policy and efficient impact on basic political, technological and ideological structures.
7. Ideological changes – the essence is mainly in the changes in assessment of the quality of life – life with feeling of internal value of the entire nature, but not the tendency to higher consumer standards.
8. Those who are prepared to accept these principles, should directly and indirectly try to implement such into life [107, 108].

According to A. Naeiss, nature cannot be treated simply as a source of resources for existence of people, "deep ecology" must promote the striving for identification with nature so that the damage done to it is perceived as damage to humans themselves; it is necessary to respect the right of all life forms for living and flourishing, emphasise with other substances, aspire to maximum diversity of life of people and other species.

Commenting general thesis of "deep ecology", A. Naeiss explains that in para 1 he means not only about biological forms of life, but also all components of the ecosystem – rivers, mountains, seas, etc.

This means that in 1970's, due to aggravation of global ecological crisis, some worldview basics of ecocentrism and ecothinking were formulated. The dominating role is now played by the principle

of ecologism, reorientation of processes of development of scientific awareness and activity of the society towards their ecologisation, in other words - taking into account the laws of wild nature, and expanding the traditional boundaries of ethics to biological and non-biological objects (water, air, landscapes).

In early 1990's, while enumerating the categories, which the moral approaches should be applied to, the philosophers to some extent mentioned such systems of the earth (geosphere) like biosphere, hydrosphere, atmosphere and soil cover. There was only one step left to apply the use of moral norms to interrelations of humans with the last system of abiotic nature system – subsoil and mineral resources contained in them. And this step was taken in 1991 at the symposium in Krakow (Poland), dedicated to the 70th anniversary of professor Adam Trembetsky, well known Check scholar and organiser of science, doctor Vaclav Nemec made a speech with his report "Technical and ethical problems of computer modelling of open pit mining activities", where he was first to declare the ideas of development of ethical principles of reproduction and use of mineral resources, which should have international nature*, calling such scientific trend "Geoethics". "My inspiration of geoethics was not associated with the ideas of Aldo Leopold, who called them Land Ethics and which he compared with animate nature. My inspirations are business ethics and an idea to formulate a special ethics for geologists and miners; Geoethics should mean the same for inanimate nature as the bioethics does for animate life. In addition, I would love to formulate Geoethics that is independent from Ecoethics, though efforts of these two sciences coincide in certain situations, but Ecoethics is indubitably closer to A. Leopold's ideas" (quotation from a private letter from Vaclav Nemec to the author; we kept the style unchanged).

There had been attempts to date formulation of Geoethics in 1973, when Antonio Stoppani, Italian geologist and palaeontologist proposed an idea of introducing the anthropologic era into the geochronological scale - an era of domination of Homo sapiens that significantly affected to the natural environment. In 1980's, this idea was

* The report was published in "The materials of the symposium" No 4, pages 99-104 ISBN 83-900110-1-8)

captured by Eugene Stoermer, American ecologist, and in 2000, it was popularised by Paul Crutzen, Nobel Prize winner for chemistry as a proposal of the Commission for Stratigraphy of the Geological Survey of London to use the term "anthropocene" that indicates the geological epoch with the level of human activity that plays a significant role in the Earth ecosystem [40]. We should note that these and similar statements did not mean formulation of Geoethics in the rank of a scientific discipline. This was more occurrence of ecological way of thinking. While formulation of ecological ethics was based on awareness of significance of the impact of human activity to natural systems and crust of the planet, together with this awareness, Geoethics was originated by the following assumptions:

– accumulation of geological knowledge that has facilitated understanding of geographic irregularity of distribution of mineral deposits, their limitation in volume/size, exhaustibility, non-renewability, potential for high economic, environmental and social risks that are associated with mining;
– occurrence of ethical problems like fair distribution of income from mining of minerals, the minerals belonging not to contemporary, but also future generations, responsible (irresponsible) subsoil use, acceptability (unacceptability) of destruction and disappearance of geological objects and systems that are classified as non-renewable resources, ethical collisions that arise in prognosticating geological calamity processes (eruptions, earthquakes, landslides, floods) etc.

Thus, determination of Geoethics as a science, classification of Geoethics into an independent philosophic discipline owes to Vaclav Nemec. He and his associated and followers from different countries – G.S. Gold, M.A. Komarov, N.K. Nikitina (Russia), L. Nemcova (Check Republic), N. Nishivaki (Japan), A. Trembetsky (Poland), J.-M. Frias (Spain) etc. specified the objectives of Geoethics, objects and targets of its studies.

The geoethical situation, problems, dilemmas, the results of theoretical studies and their practical application are regularly discussed at meetings on the Geoethical section of biennial international symposiums "Mining Pribram" (Check Republic) since 1992 (Table 1).

Since 1997, an independent Geoethics section has been active within the framework of biennial international conference "New ideas in Earth sciences", which is organised by the Russian State Geological Exploration University (Moscow).

Since 1996, at the international geological congresses held once in four years, there is an independent Geoethics section under the chair of the Geoethics founder Vaclav Nemec (Table 2).

From 2009, the geography of conferences expanded. Discussions of Geoethics issues are included in the agenda of annual Assembly of European Federation of Geologists – AFG), forums of some national geological societies (Italy, Columbia, Mozambique, Spain, and etc.)

In 2012, according to the results of the symposium "Geoethics", held within the framework of the 34 International geological congress (Brisbane, Australia), a decision was made on foundation of two international associations: International Association for Geoethics – IAGETH) and International Association for Promotion of Geoethics – IAPG), which are affiliated members of the International Union of Geological Sciences – IUGS) since 2014.

As at January 1st 2016, IAGETH has 44 national societies of professionals in the field of Earth sciences of the following countries: Algeria, Argentine, Australia, Belgium, Botswana, Brazil, Canada, Cape-Verde, China, Columbia, Costa-Rika, Cuba, Ethiopia, Greece, Egypt, Hungary, India, Iceland, Italy, Japan, Kazakhstan, Kenya, Libya, Malawi, Mexico, Mongolia, Morocco, Mozambique, Niger, Nigeria, New Zealand, Namibia, Portugal, Romania, Russia, Sri-Lanka, Spain, South Africa, Tajikistan, Tanzania, United Kingdom, USA, Venezuela, Yemen, Zimbabwe.

The results of these conferences, symposiums, and congresses where the Geoethics sectors run their activity, is significant growth of both theoretical knowledge and the results of applied research work.

However, despite the fact that more and more scientists have to some extent considered geoethical issues in their research works, Geoethics still looked a little-known scientific discipline. Partly this was associated with lack of foundational monographs. Prior to publication of First Edition of this book in July 2012, where it was the first time to show a systemic explanation of the fundamental principles of Geo-

Table 1

Reports, published in collections of geological symposiums in Pribram (Check Republic)

(*According to Vaclav Nemec*)

Parameters	1992	1994	1996	1998	1999*	2001	2003	2005	2007	2009	2011	2013	2015
No of participating countries	5	7	13	7	9	9	11	10	10	6	18	16	18
No of participants	5	9	13	16	16	18	18	20	21	18	60	30	28
No of reports	9	33	38	24	27	30	25	26	27	19	24	29	39
Accumulating No of reports	9	42	80	104	131	161	186	212	239	258	282	311	350

Table 2

Reports, submitted at international geological congresses

No of international congress	Year	Town (country)	No of reports		No of special symposium on Geoethics
			Total	Including, No of verbal reports	
29	1992	Kyoto (Japan)	3	2	–
30	1996	Beijing (China)	5	4	21.3.1
31	2000	Rio-de-Janeiro (Brazil)	10	6	26.1
32	2004	Florence (Italy)	24	7	8.03 8.04
33	2008	Oslo (Norway)	18	12	IEE-007 IEE-008
34	2012	Brisbane (Australia)	19	16	2.4

* In 1999 the symposium was held in Prague

ethics, there had been some reports only (thesis of reports) on various trends of geoethics, represented at conferences and congresses.

At its initial stage of development of Geoethics as a new scientific trend, it was important to formulate the notion "Geoethics" itself. During the many discussions, several different definitions have been proposed. M.A. Komarov understands "relation/approach of humans and society to the geological environment in different aspects of its occurrence" as the object of Geoethics. G.S. Gold considered Geoethics as a trend that studies "the possibilities of use of ethical principles with regard to the activity in the field of mineral resources" [54].

N.L. Shilin formulated a definition of Geoethics from the point of view of contemporary global problems. Based on the ideas of V.I. Vernadsky, E. Le Roy, P. Teilhard de Chardin, who separated a new planetary crust of noosphere (sphere of intellect/brain), he managed to make a compelling proof that noospheric thinking allows understanding the geological and ethical role of humanity in transformation of all other spheres of the Earth. From this point of view, according to N.L. Shilin, Geoethics combines a complex of ethical problems, associated with geological scientific studies, practical geological exploration works, mining and use of mineral-raw resources, being one of the most important components of the natural environment, by preserving the geo-diversity and geo-heritage, by development and implementation into practice of professional codes of conduct. One way or another, but today all researchers agree with the fact that Geoethics is a notion that includes moral principalities in relation to the Earth as a geological body, and to social and economic objects in all their diversity [50].

1.2 SPIRITUAL BASICS OF GEOETHICS

At all times, the Church had been the preserver of ethical norms. Even most of our contemporaries belong to this or that religion to obtain answers to those questions, related with understanding of the right (godly/righteous) and wrong (vicious) conduct and way of life. Often, moral behaviour of statesmen, political leaders take their origin from that world perception, which, though not directly associated with official Church, but are very close to religious.

In 1967, in his work Lynn White [176] made an attempt to answer the question "about historical roots of our ecological crisis" and came to a conclusion of existence e of dualistic ethical system in Judaism and Christianity traditions, according to which exploitation of people is not desirable, while exploitation of nature is not only acceptable, it is mandatory: "And in completion God created Adam, and after some thinking – he created Eve for the man not to be alone. The man gave names to all animals thus establishing his reign over them. God envisaged and planned all this exclusively for the benefit of the man and that he managed the world: no natural creature has other mission other than to serve the purposes of the man. Though the body of the man has been created from the Earth ash, he not simply is a part of nature – he had been created after the image and likeness of God… By contradicting completely and irreconcilably to Greek paganism and Asian religions, with the possible exception of Zoroastrianism, Christianity not only established dualism of the man and nature, but also insisted on the proposition that God's will definitely means that the man exploits the nature for the sake of his purposes. For a common person all this turned into very interesting consequences. In the antique epoch, each tree, each stream, each water flow, each hill had their own genius loci, their own protector-soul. These souls were accessible by the man though they did not resemble him at all: centaurs, fauns, Naiads (river-nymphs) – all of them had double faces. Before cutting a tree, digging a shaft, building a dam at a river it was important to tune the soul that owned certain situation into his favour and take care not to get deprived of his mercy in future. By abolishing the pagan animism, Christianity opened a psychological possibility to exploit the nature in the manner of indifference to self-feeling of natural objects".

However, there exist other readings and interpretation of Bible. For instance, according to G.S. Senatskaya [155, 156], Bible stresses on the uniqueness of our mission: "And God took the man and put him in the Garden of Eden (that obviously represented the Earth at that moment), to cultivate it and preserve it". In addition, the reason of the ecological crisis is that the man did not fulfil the instructions imposed on him. The Biblical ascertaining that God created the man "after his image and likeness" assumes that the man was created as a sensible,

free and thinking creature. Obedience was to be voluntary, no violence was assumed on the personality. The "tree of recognising the evil and good", to which the people had free access – is the proof of this. Had the man chosen obedience, he would have been granted the good eternal life. Otherwise, this was the choice of immorality and fall. If the first people on Erath, as opposed to the people living in our days, the harmonic life in integrity with God and creations (in the meaning both humans and the natural environment that surrounds him) would have been quite natural, but after the Fallal of Adam and Eve, a rapture had occurred between God and the man, which lead to damages in relations of the man with the nature. "Cursed is the Earth because of you, thy shall be eating from it with grief… It shall grow thorns and thistle for thy", - such were the consequences of the human disobedience.

There are commandments in Bible on protective care of flora and fauna, caring use of subsoil: "… thou shall not damage trees, from which one can find food and thy shall not exhaust surroundings", "thou shall crop your land thy land for six years and collect its produces, and in year seven leave it alone". Bible not only calls humans to reasonably manage the natural resources, but also suggests principles of sensible management [156]:

- Rental relationships principle. The Holy Writ stresses that everything that surrounds people is owned by God. Bible clearly explains the thought: "The land and everything that fills it belongs to God" (Genesis, 9:29; To Corinthians: 10:26). It is also written in it that all wealth in subsoil also belongs to God: "For all the land is mine" (Genesis 19:5), "silver is mine and gold is mine and jewellery is mine" (Book of Joel 3:5, Haggadah 3:8). This means that humans are more tenants (let it be a long-term rent) than being the owner. "The rent" means obedience to God's commandments, which call for sparing and adding to God's gifts.
- The principle of necessity and sufficiency. From the days of genesis of Jews from Egypt, God taught his people not to rush for excessive things and get satisfaction from what is available. By sending the manna from heaven, He warned the people: "Collect each of thou in the amount the he can eat" (Genesis 16:16). In addition, those, who did not believe in God's saying and collected

the excess manna, found the manna spoilt in the following day (Genesis 16:20). The Book of Proverbs says: "Have you found honey? Eat from it the amount you require not to be repleted with it…" (The Book of Proverbs 25:16), in other words, any excessive amount that is taken from nature will not bring benefit.

- The sparing principle. Contemporary aspiration to maximum utilisation of wastes has biblical justification. Gospel tells the story that Jesus, having fed thousands of people with a few bread, told his disciples: "Collect the remaining pieces to avoid loss of anything", and they "filled twelve boxes with pieces…, left from those who ate" (In: 6:12, 13; comp. from Matthew 6;34-43; 8:1-8,19).

All the previously mentioned tells us that moral norms, including in relation to nature, established in the Holy Writ, are the source and basics of modern Geoethics. High professionalism in subsoil use issues assumes both Geoethical and moral fundamentals, if one of these is not in place, it will lead to irreparable errors [155].

Catholic Church, who took the moral obligations for expressing their own point of view on vital social problems of humanity, periodically publishes Pope's social Encyclical Letters)*. The most important of these are *Rerum novarum* (On the basis of new events, 1891), *Quadragesimo Anno* (Year forty, 1931), Mater et Magistra (Mother and preceptress, 1961), *Centesimus Annus* (Year one hundred, 1991), were combined in Compendium** in 2004 along with formation and clarification of Christian social doctrine that contain ecological elements and ideas, called for stressing on the necessity of preservation of the surrounding natural environment as a fundamental ethic value (Part 10 "Preservation of the environment") [37]. These documents do not contain any concentrated instructions how to behave in this or that situation, they propose the main opinions on various issues of contemporary word.

* Encyclical texts (Latin encyclical, from Greek. ενκυκλιος – circular) is main Pope document on various issues, addressed to the believers or bishops or archbishops of an individual country, second importance document after the apostolic constitution.

** Because social studies of catholic Church is represented in many different scattered documents, often unavailable to common public, in 2000-2004, on the order by Pope Joan Paul II, the Pope's Council "Justice and peace" prepared a Compendium of Social Studies of the Church that systematised and unifies the main ideas of these documents.

Limila Nemcova completed a detailed analysis of the Compendium from the point of view of Geoethics and ecology [113]. As opposed to any ideology, social doctrine of the Church is not a doctrine of political order, but of religious and moral order.

The basics of Part 10 mentioned above is primarily the following postulate of Catholic Church – God gave the Earth to all people without exceptions and any preferences. As a result of Divine creation, the Earth is not an enemy to people. On the contrary, relationships between humans and surrounding world - nature are a significant determinant part of its human identity. These relationships, in their turn, are the result of another, deeper relationship between humans and God. In his dialogue with God, a man finds the truth, which he takes inspiration, ideas and norms for planning of the future of the world from. This world was, is and must be a garden, which God had given to people for them to preserve and cultivate (paras 451-453 of Compendium). Thus, the key point that Compendium proposes is the following: the activity of people in relation to the Nature must be ethically oriented. However, such orientation is impossible if Nature is treated as an object of worship/cult only or as an unlimited field for technical activities. During the entire period of their existence, people had only one purpose – to achieve more and more favourable conditions of life, by investing huge amounts of individual and collective effort. With the help of science and equipment, today people have significantly expanded their reign over nature. But humans are not competitors of the Creator. By positively assessing the achievements of science and equipment as a whole, Catholic Church is confident that the achieved triumph of human race in his way of constant interaction of nature and people – is a sign of the beauty of Divine Providence and apotheosis of God's secret project [37]. At the same time, Compendium gives Christians a warning – technical achievement of humanity that gave them power over the Nature, may lead not only to prominence of humans, but also to their degradation.

1.3 FOUNDATIONS OF GEOETHICS. OBJECTS, SUBJECT AND OBJECTIVES OF STUDY

The etymology of the term "ethics" originates from the notion that indicates joint dwellings, living in which, according to the logic of things, required adherence to certain rules. The term was introduced by Aristotle to indicate the final part of his doctrine, which considers the orientation and methods of regulation of human behaviour. Aristotle determined ethics as a practical study of ways of achieving the desired targets by humans [8].

Ethics is a metascience discipline and has its own certain sphere of influence. Theoretically, in the world of geological processes and occurrences there should be no ethics at all: it is impossible to say that a lava flow (geosyncline, fault, megablock etc.) may behave amorally. However, ethics steps in in problem definition of axiological (practical) geosciences associated with analysis of value contents of deeds of humans that, as a rule, contradict and are ambivalent in their content.

Geoethics is a theory about ethical relations of humans with inorganic nature, based on the perception of this nature as a member of moral community, moral partner (subject), based on the principles of equality and equivalence of inorganic matter and on limitation of the rights and needs of humans in relation with inorganic nature. The mission of Geoethics is in implementation of the values approach, values criteria in practice of geological exploration and mining activities, use of mineral resources and preservation of objects of inorganic nature (geo-heritage) as opposed to self-interest and (individual, corporate, state) mercantilism.

The object of study of Geoethics is morals in the field of study of subsoil of the Earth and other planets that contain mineral-raw resources, in the field of reproduction of the mineral-raw base, mining and use of mineral-raw resources and useful properties of subsoil, while the subject of its study are pragmatic sciences for starting from and surpassing the latter, Geoethics can fulfil the noble role of regulating the behaviour of people in the system of "human - inanimate nature". As a science about morals, Geoethics studies the process of motivation of behaviour, general orientation of relationships in the

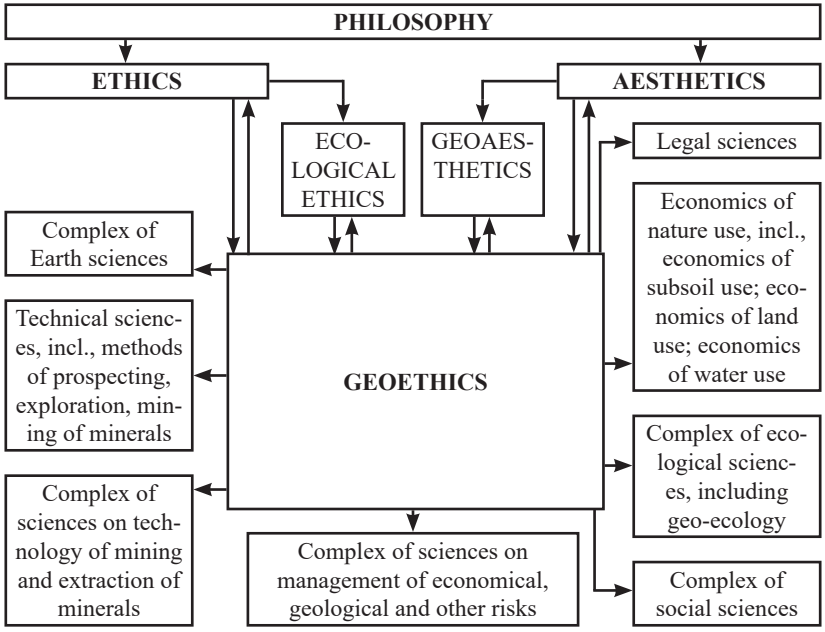

Figure 2. **Interrelation of Geoethics with other sciences**

said system, justifies the necessity and most expedient form of the rules of joint existence of this system, which humans are prepared to accept and fulfil based on voluntary intention.

Position and relation of Geoethics with other sciences is shown in Figure 2.

Morals in the field of study of subsoil of the Earth and other planets, reproduction of mineral resources and their use as it is, occurs in the history of the society when there is a freedom of choice, possibility of fulfilling these processes in a different way, by preferring this or that system of valuables. Such choice is only possible in accordance with some ideas, on the basis of contrapositioning of "true" and false targets owing to establishing of understanding of the true mission of the man by way of realising the position and role of humans in the nature system of the planet Earth.

For the period of its existence, being a short time for a science, there are several practical justifications for expansion of the moral

field to all objects of inorganic nature and all spheres of the Earth and other celestial bodies: lithosphere, hydrosphere, atmosphere, relief, landscapes, and the circumplanetary space. The subject of study of Geoethics is morals in the field of study and use of maximum large conglomerate of geological and geographical environments and their systems that cover any planet (and not only the Earth) as a single unit and that are combination of various of parameters of inorganic nature, which are in close indissoluble connection, while on the Earth they are involved in the globalisation process.

At the initial stage of formation of Geoethics as a scientific discipline (1992-2012), in the process of formulation of definitions, specification of objectives, purpose, objects and subjects of these categories, many scientists tried to maximise the extent of the list of each category, often, possibly, by incidentally including some objects and subjects of studies, purpose and objectives of ecological ethics.

There existed another extremity. Some philosophers did not see any problems that could be resolved using already existing ecological ethics* and directly refused Geoethics in its right for existence.

It is possible that in near future all applied ethical disciplines, related with study and use of organic and inorganic systems of the earth, will be combined into a single science – something like the Ethics of the Earth.

Jamais Caascio, American futurologist, known for his works on prognostics and development of moral norms of future life, defines the ethics of the Earth as "*a set of guideline principles, which should determine human behaviour and deeds that deal with large planetary systems, including atmospheric, oceanic, geological and ecosystems of flora and fauna. These guideline principles are especially necessary, if human behaviour and deeds may lead to long lasting, large scale and/or difficult to repair changes in planetary systems; but even local and surface changes should be considered through the prism of the Ethics of the Earth. The principles of the Ethics of the earth do not ban long term, large scale transformations, but require mandatory*

* It is indubitable that both geo-studies and more over geo-developments could be the subject of ethical regulation, but here there is nothing that could be studied in ethics of the researcher (science) or in ecological ethics, or in ethics of sustainable development" – from a private letter to the author (we have kept the style of the letter intact).

prognostication and accounting of consequences, including so called "secondary order effects", in other words undeliberate consequences, that are the results of interaction of the changed system with other connected systems" [31].

We should note another extremity, which represents attempts of breaking Geoethics into more isolate disciplines on names of minerals: ethics of hydrocarbons, ethics of ground waters, etc., which, the author thinks, has no potential for in such cases, there really is not any necessity in isolation of any new ethical regulators, while the objectives of such micro-disciplines may be resolved within Geoethics.

Geoethics is primarily based on perception of the planet Earth, its geological spheres, its subsoil, and all geological objects as the base of the life of humanity, on acknowledgement of equality and equivalence of inorganic matters, and on limitation of the rights of people in relation to inorganic nature. Within the framework of these new global ethical assumptions, humanity is trying to rethink the main issues of the entire complex of earth sciences. Combination of geoscientific problems (geographic unevenness of distribution of mineral deposits on the planet, exhaustion of mineral resources, constant growth of costs for discovery of such, natural and commercial risks for development, increase of the coverage area of protected natural territories etc.), main ethical achievement (responsibilities, rights and justice, responsibility of generation, religious beliefs in secular societies, etc.) and possibilities of such practical instruments like local and global geological knowledge, prognostics, scientific expertise of various projects and participation of citizens in decision making, allow formulating the following main geoethical postulates:

- natural, including mineral resources have specific internal properties that do not allow reflecting certain elements of their value in market prices or in any other similar utilitarian units of measure of value [178];
- geographic unevenness of distribution of mineral deposits on the planet requires using principally new global approaches to management and use of mineral resources, and to distribution of waste from development of such;
- exhaustion of mineral resources, limited volume and finiteness

of such cause the issue of access, rights of currently living and future generations for mineral resources; the decisions to be taken by national and regional governments may be initial cause for wars; at this stage of life it is necessary to develop international instruments of regulation of use of mineral resources, scientific expertise, including ethical expertise of decisions to be taken, wide public awareness of consequences of such decisions;

- the geography of world mineral resource mining is expanding: it at least depends on availability of mineable mineral deposits in a given territory, and it to larger extent is determined by social conditions and requirement of nature protection legislation of the given territory; moving mining centres to poorly developed counties has become a tendency;
- sustainable development assumes priority use of secondary resources, re-processing of which does not cause a destructive effect to all spheres of the Earth, which happens at initial (primary) extraction and processing of minerals.
- The nature, landscapes, biological diversity of species, subsoil should be treated not simply as objects of protection in the territory of mining and processing of minerals, they are primarily the objects of heritage for future generations [1].

The subject of study of Geoethics includes geoethical situations, geoethical problems and geoethical dilemmas.

Geoethical situations occur when there are two different points of view in relation to the issue of what is acceptable or inacceptable in a specific situation. For instance, as a whole, geoethical situations occur every time when a decision has to be made on commercial developing of a mineral deposit, if there are two equivalent objects, there are two (or more) options of its development methods. A fair decision in such a case would be based on a complex analysis of existing geological, economic, environmental and other information, on assessment of the objectiveness, reliability and completeness of information, drawing of conclusions on the basis of the above to facilitate a correct choice.

Geoethcal problems are more sophisticated than geoethical situations for they assume the presence of several possible ethical decisions. For determination of content and decision of the problem, it

is necessary to have time and collective common sense to determine the best option out of all available decisions for all interested parties.

For instance, the issue of acceptability of mining of offshore hydrocarbon resources. Annually growing needs in hydrocarbons cannot be satisfied from mining of continental hydrocarbon deposits only. But the accident at the Mexican Gulf Deepwater Horizon oil platform on April 20th 2010, when it cost lives of 11 people, sinking of the platform itself, and according to different estimates from 2.9 to 4.9 million barrels of oil was let go to the waters of the Gulf for four months resulting in a big environmental catastrophe in USA and neighbouring countries.

Less than one month before the accident, President of USA published the programme of developing the continental offshore shield area, which gave access to oil miners to significantly wide territories along the Southeast coast. USA banned mining at most parts of the offshore zone in 1981, and since American oil companies had spent much effort to try to persuade the government in the necessity of developing new resources.

The consequences of this accident will affect all participants of oil-and-gas industry, including the producers and consumers, local communities and government structures. These events remind us again that the oil-and-gas industry is a complex in its nature, and running business in this industry is associated with significant risks, and that, unfortunately, the risks can be brought to zero only by stopping all work in exploration and development of continental offshore area, and the needs of economy in energy sources would be covered by, for instance, alternative energy sources. According to a number of scientists, the mid-term potential does not have any reliable alternative to hydrocarbons anywhere in the world.

Exploration and development of offshore deposits can be continued only by keeping in mind the fact that from time to time, some problems will inevitably happen, cause damage to people, and have negative impact to the environment. In this case, the consequences would be increasing of oil mining costs due to additional costs for risks and expenses to be envisaged in developing hydrocarbon deposits in offshore areas, and delays of implementation of many projects,

which, in similar conditions, would be commercially not profitable or inacceptable for social or political reasons.

Subject to the territorial significance, different levels of geoethical problems can be differentiated: global, regional, local and private.

Geoethical dilemmas occur when, in any case, upon making any decision one of the sides incurs losses. For instance, for various reasons, when local population acts against mining of mineral resources in the territory of their habitat. In this case, it is necessary to choose the least of several evils, for no decision would be good for all. Often, dilemmas are caused in crisis situations, for instance, during natural calamities. So, during unprecedented fires in abandoned peat mines in Moscow oblast in the summer of 2010, when it caused serious contamination to the atmosphere (Maximum Admissible Concentrations were exceeded dozens of times), significant losses of forestry, human deaths, the Government of Russian Federation took a decision on emergency installation of dozens of kilometres of water lines from the Ob River to flood the peats. In addition, the old peat drainage systems, installed prior to mining activities, were not dismantled, while large amounts of water were pumped from the Ob River, which was already shallow due to the anomalous hot summer.

Even after complete control of fires, the abandoned peat mines are still potential causes of fires. In such conditions, a serious decision was taken on the necessity of rehabilitation of swamps in these territories to their initial state. The consequences are easily prognosticated (changes of flora and fauna, water sites and their circulation regime, and their positive consequences are not obvious, for under the motto of rehabilitation of the initial natural balance, the natural balance that has been established for the past decades would be changed.

Code of Ethics for Biomedical Laboratory Scientists

This code of Ethics applies to Biomedical Laboratory Scientists worldwide.

As practitioners of an autonomous profession, Biomedical Laboratory Scientists have the responsibility to contribute from their sphere of professional competence to the general well being of the community.

The Code of Ethics is a resource for the profession and a support for the individual in everyday practice and in challenging situations. At the same time they are society's guarantee that the Biomedical Laboratory Scientist (BLS) practises the profession in an ethically sound manner.

Duty to the global society

- **Biomedical Laboratory Scientists shall:**
  - Be dedicated to the use of biomedical laboratory science to benefit humanity
  - Perform biomedical research to improve and develop public health globally
  - Be responsible for establishing new standards and develop existing standards for improved laboratory practice and patient safety
  - Take responsibility and play a leading role towards issues regarding the global and local environment

Duty to the client

- **Biomedical Laboratory Scientists shall:**
  - Be responsible for the logical process from the acquisition of the specimen to the production of data and the final report of the test result
  - Be accountable for the quality and integrity of biomedical laboratory services
  - Exercise professional judgment, skill and care while meeting international standards
  - Maintain strict confidentiality of patient/client information and results of laboratory analysis
  - Safeguard the dignity and privacy of patients/clients
  - Implement scientific advances that benefit the patient/client and improve the delivery of results of laboratory analysis

Duty to colleagues, the profession and other members of the health team

- **Biomedical Laboratory Scientists shall:**
  - Uphold and maintain the dignity and respect of the profession and maintain a reputation of honesty, integrity and reliability
  - Continuously improve professional skills and knowledge
  - Actively seek to establish cooperative and harmonious working relationships with other health professionals
  - Provide expertise and advise, teach and counsel students, colleagues and other health professionals
  - Be loyal to the policies, laws and legislations which apply to the workplace, as long as they do not conflict with the professional ethical guidelines

Code of ethics for Biomedical Laboratory Scientists were first adopted by IAMLT in Dublin 1992, and revised by IFBLS in Nairobi 2010.