NATIONAL COMMISSION OF BIOETHICS

OPINION

ON RESEARCH ETHICS IN THE BIOLOGICAL SCIENCES

The National Bioethics Commission has considered the issue of the respect of moral values by contemporary biological research in repeated meetings. In several of its earlier opinions the Commission dealt with the issue of ethics in specific research areas (stem cells, clinical trials, use of animals in research) identifying the serious implications of the development of biological applications on the values of modern society. The present opinion emphasizes a dimension that cuts across all fields of biological research: the ethics of "procedure" of research.

The Commission believes that this dimension is crucial and requires consideration both by the scientific community and by the authorities, in particular in the light of the implementation of the new national legal framework for research (Act 3653/2008).

I. General remarks

A. Identifying the issues

Generally speaking, the terms and conditions of contemporary research are significantly different from the past. The main characteristics of research during the last decades are the following: a) it is conducted by research teams in large-scale facilities and international networks of co-operation and b) it is closely linked to the economy.

- 1. Nowadays research does not rely on the individual activity of isolated scientists. The production of new knowledge requires complex organization and co-ordination of collective effort, a research environment that ensures high quality infrastructure and the corresponding funds as well as international co-operation.
- 2. Modern economy is particularly interested in innovation; therefore, it is closely connected to research, especially in the area of new technologies. As a result research is usually orientated to the market, it becomes familiar with the workings of competition

and, to a large extent, adjusts its priorities accordingly. Modern research institutions often operate as independent economic entities that do not depend on public funding and are primarily interested in applied research in accordance with the needs of the market.

This "industrial" organization of present research directly affects the way in which research is carried out and developed and often restricts the freedom of researchers in the following ways:

- Moving away from basic research in favour of prioritized commercially exploitable applications,
- intense competition between research units,
- overdependence on sponsors,
- preoccupation with fund raising and the management of the research institutions, often at the expense of scientific endeavour.

B. Research in the biological sciences

The Commission considers that these general remarks on the conditions of current research are particularly relevant to research in the biological sciences. And this because, a) a major part of the related investment is met by private funds on an international scale, and, b) they have direct implications on fundamental principles (protection of human value, the environment, health, privacy).

Situations that are seen at times, such as the exclusion of useful research for rare diseases or diseases that affect mainly the Third World, concealment of negative findings, "fabrication" of results likeable to sponsors, demonstrate the absolute need to safeguard the independence of research, especially biological research.

C. Research as a public good – Safeguarding its independence

In the Commission's view scientific research constitutes a public good because it promotes the understanding of the surrounding world and contributes to the "well-being" of society as a whole. At the same time, however, it is also a fundamental right, an indispensable component of freedom for the person performing research. These two dimensions are inextricably linked.

Based on the above, the Commission concludes that there are mainly two safeguards for the independence of research:

- 1. The self-regulation of research ethics by the community of scientists, since researchers are the first ones who have an interest in protecting the credibility of their work. "Outside" regulation must take into account this margin of autonomy in order to avoid bureaucracy.
- 2. The State must provide adequate public funding for independent research so that not every research initiative is necessarily linked to opportunistic economic priorities, which often operates not to the benefit of but at the cost of innovation.

These safeguards need to be adopted with specific initiatives.

II. Proposals

Based on the above, and in view of the new national legal framework for research, the Commission suggests the following:

To the Administration

a) To lay down specific rules to safeguard research ethics in publicly financed research projects.

These rules must oblige the scientist awarded the research grant to verify the accuracy of and to publish all the results, to report the actual contribution of each researcher (in related publications in scientific journals, in papers presented in conferences and in the activity reports of research institutions) and to control compliance with ethical principles.

b) To support basic research in the allocation of national grants by the responsible bodies.

To the academic research community

a) Research institutions of biological sciences should compile a code of research ethics. Basic issues to be dealt with by such a code (which must also provide for disciplinary sanctions) must include, by way of indication, fabrication of results, plagiarism, violation of ethical principles (e.g. independence, principle of "beneficence or no harm", ethical treatment of experimental animals, etc.). The Commission intends to present a model of principles.

- b) To adopt initiatives to familiarize researchers with research ethics in their field of activity.
- c) To ensure transparency as to the source of the direct and indirect financial funding of research projects and, generally, of the operation of research institutions.