

Change of science policy

A condition for European integration of Romanian medical research

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1 Gates are just beginning to open

The Sixth Framework Program for Research and Technology Development is one of the most ambitious programs ever coordinated by the European Union: sixteen billion Euro allocated and a broad range of activities from Nanosciences & Nanotechnologies to Global Change and Ecosystems. The section for Life Sciences, Genomics and Biotechnology for Health occupies an important second place on the list of priorities. Not casually, the first place is occupied by Informatics and Communication Sciences. The intricate interplay between the two is expected to play a major role in the future of biosciences. Possibly not far in the future, bioinformatics will become synonymous with biotechnology. "The analyses of biotechnology research would be conducted *in silico* and would involve the exchange of information among sophisticated computer databases. In electronics, the use of the specificity of proteins in biochips is underway".¹

Recent breakthroughs in the mapping of the human genome, stem cell research, and gene therapy are reinforcing the belief that we are moving towards an "age of biology". The human genome will continue to have a powerful impact on research and development of human diseases and healthcare. Discoveries in genetics and pharmacogenomics will have great impact on drug development and will allow the prediction of the patient's response to various drugs as well as the possibility of individualized or "designer-made" drugs. Knowledge of human stem cells biology may enhance opportunities to grow young cells, tissues and organs for therapeutic purposes. This poses however many ethical, financial and institutional problems that have made science policy a pivotal concern for developed countries. "In the beginning, the infrastructure that supported these efforts - intellectual property, venture capital, streamlined technology transfer - was less widely dispersed and the world's brightest biotech researchers clustered in only half a dozen scientific centers. Nowadays, biotechnology's global diaspora seems inevitable, especially since governments are promoting it".²

Romanian biomedical research was supported by locally successful National Programs in 1992-2002, supervised by the Ministry of Education and Research: grants of the Romanian Academy (Medical Section), the "Orizont 2000" Program, and recently (since 2001) the "Viasan" National Program. Medical researchers at the "Carol Davila" University of Medicine and Pharmacy, Bucharest, conducted research in basic and clinical areas, by fulfilling more than 200 grant contracts with the financing institutions.

¹ Chang, S. K. *Biotechnology – updates and new developments*, Biomed. Environ. Sci., 14: 32-39, 2001.

² Feldbaum, C. *Biotechnology's foreign policy*, World Hosp. Health Serv., 38:42-45, 2002.

However, the researchers encountered many challenges, not always related to medical science, but rather to administrative and financial issues. Ten years of experimenting science in the “transitional” economy taught some lessons about how to reshape science policy. It is a need for major changes in both Romanian legislation related to research, and the mindset regarding the statute of research and researchers.

2 Changing legislation

Besides the explosions in research efforts, regulatory issues, legislation and intellectual property rights have to evolve for the climate of discovery and innovation to flourish. In their dialogue with the Government project leaders should always address their concerns related to science funding and the conflicts of interest generated by exclusive for-profit enterprise.³

Presently, Romanian legislation is opposing the true sense and finality of research due to excessive centralization and high level of bureaucracy, inflexibility and lack of adaptation to research needs, administrative and financial inadvertencies. The unwanted consequence is waste of funds (already insufficient), time, and capabilities! Romanian financing institutions have now the unique opportunity to set the basis for a good model of funds administration.

What should the ideal situation be? Throughout the world, biotechnology is an increasingly visible and important item on the national science policies agenda. With growing corporate and government funding, basic research in biomedicine and related technologies are expanding rapidly. Romania cannot afford to be left out of this trend. It is conceivable that a bigger slice of tax-derived funds should go *directly* to medical research. Romanian laws should also encourage private investment in research that potentially cures diseases. An articulate local framework has to adjust rationally to the new opportunity of the Sixth Framework Program of the European Union.

The primary researcher should acquire more independence in order to freely choose his team, administer the available funds at will, directly negotiate with the customer (usually an export/import enterprise), and adequately manage international cooperation. An effort for changing legislation should be done to achieve flexibility and clarity of the financial regulation, facilitation of grants management, that will *serve* research itself, rather than the bureaucratic apparatus.

At this stage of development, Romanian science is paradoxically confronted with either asset-less hyper-competence, or competence-less lay-off nearby high-tech assets. Coherent plans for development should match the right level of trained competence with adequate material and technical resources. Bilateral recognition of diplomas by Romania and countries with prestigious educational systems would very much help Romanian young researchers find their way back to their native country. Ways should be found to stimulate young researchers, by setting rules and criteria for promotion based on the true merit and capabilities.

The research team might become an institution with juridical personality, clear responsibilities, obligations and rights, stipulated by a specific law. The recent Romanian Government Urgency Ordinances (57 and 65/2002) represent a step forward but insufficient at meeting specific issues of research administration. An organism made of competent members of the scientific community, aware of the research culture from the inside should be instituted. This organism will sustain a permanent dialogue with the policy leaders. Finally, they should conceive and promote an improved law project that could be submitted to the Parliament for approval.

3 Changing frames of mind

We can say with a smile that mindsets in some prominent parts of Romanian society are impregnated with gerontocracy and paternalism and aggravated by male chauvinism. Disrespect for value-based hierarchy, combined with obedience in front of power-based hierarchy are also visible at various social levels. The feeling that problems are insurmountable and irregularities cannot be sanctioned cause for apathy. Such a gloomy climate does not encourage young doctors to pursue research in their home country. Naturally, we have to fight for self-regeneration. Remedies would come from fresh opinions about values and their

³ Brennan, T. A. *Government and Science: stimulation of inhibition*, Bull. N.Y. Acad. Med., 68:151-161, 1992.

recognition. As mentioned above, age of merit recognition and assigning responsibility should be lowered. Hopefully, human value would take care of itself. Scientific value has to be quantified by scientometric parameters. Methods for evaluating scientific work, based on the Medline and the Science Citation Index databases, should be defined and applied by specialized evaluators. Accordingly, the judgment of competent referees should become the main basis of grants, awards, and other forms of funding. A beginning has been made by founding the National Centre for Science Policy and Scientometry ("Cenaposs"), in Bucharest, but apparently the activity of this centre does not have yet practical effects on research evaluation.

We are confronted with an atomization of research due to lack of confidence, and therefore absence of coherent plans and inter-cooperation. Undoubtedly, these are remnants of the communist mentalities. Romanian researchers should re-learn solidarity and cooperation in order to efficiently use resources. Programs of rehabilitation of Romanian laboratories and scientific centers should involve young researchers trained to meet specific needs in coherent research plans and, naturally, invited prestigious scientists from abroad.

On the other hand scientists should "make peace" with society. The public and politicians should be reminded that science if not the "most important" thing in the world it is a bare necessity and not luxury! For instance, a 1979 American study⁴ found that only seven percent of American adults met a minimal definition of scientific literacy. Recently, public attitudes towards biotechnology in the European Union have been characterized as negative, using "Eurobarometer" data.⁵ To our knowledge, a study, such as the above, was never been done in Romania. This would include identifying the affected populations and estimating the costs for society, develop a set of basic indicators of health science literacy to allow assessment of the extent of the problem at the individual, community, and national levels. A more recent study performed in the US lead to the following conclusion: "Probably the current levels of public awareness and knowledge about biotechnology will not allow a public policy debate similar to those associated with controversies involving Social Security or gasoline prices".⁴ Obviously, such an opinion cannot preclude the crucial role of civil society in determining policy design.⁶ New metric and analysis are proposed to explore the level of awareness and knowledge of biotechnology in Europe, in order to shape public attitude towards science.⁵ In any country, civil society should initiate thoughtful and informed discussions on science policy. This may help create honest and fair-minded debates that will lead to positive, socially responsible outcomes for society. Public education will have to be continually improved as awareness could negate any fear resulting from novel and innovative improvements from biotechnology. Media coverage of this type of debate will also heighten awareness and influence the level of public awareness for biotechnology.

The debate over the benefits and risks of stem cell research could be initiated by a working group of scientists, ethicists, patients and theologians. Thus a set of policy recommendations on stem cell research, based on an ethical approach may be developed followed by acknowledgement by the legislation.

Breakthroughs in biology need to be used for the benefit of society in an ethical and responsible fashion. Ethical rules should be observed in all respects by researchers and monitored by assigned Ethical Boards. Special interests should not dominate the debate but scientific fact and reason.

The experience acquired in developed countries over 50 years lead to opinions such as this: "To understand the formulation of public policy toward biotechnology, it is necessary to focus on the role of the policy leaders in a stratified model. In general, when there is agreement on a given policy between the decision-makers and the policy leaders, the policy is implemented and there is no wider involvement in the policy formulation process. A large number of science and technology policy issues have been handled in this manner in the decades since the Second World War and it is likely that most science policy matters will continue to be resolved directly between policy leaders and decision-makers".⁴ Nevertheless we incline to think that common sense of an informed civil society should take an important part in making decisions. Moreover, in countries undergoing a transition, a vital issue is that most competent professionals must become decision-makers in their field of expertise and establish a permanent dialogue with policy leaders.

⁴ Miller, J. D., *The attitudes of religious, environmental, and science policy leaders toward biotechnology*, *Recomb. DNA Tech. Bull.*, 8:141-164, 1985.

⁵ Pardo, R.; Midden, C.; Miller, J. D., *Attitudes toward biotechnology in the European Union*, *J. Biotechnol.*, 98:9-24, 2002.

⁶ Munoz, E., *Social perception of biotechnology: a new tool for decision making*, *Law Hum. Genome Rev.*, 10:195-208, 1999.

Medical research and other basic health issues should find their place on today's agenda of policy leaders thus helping ease the suffering of many people.