Bioethics, Science Ethos, and Regulatory Science

Biotechnology development as an agent of ethical change and a challenge to ethical regulation

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Abstract

In this paper I shall briefly survey the main domains of ethical engagement relevant to biotechnological development. I shall start with bioethics, describing its approach, subject matter, and deficiencies. I shall then turn to the scientists engaged in ethical issues, outlining their contemporary situation and proceed to analyse this in the important terms of science ethos and science ethics. Finally, the rise of 'regulatory science' and of ethical committees will be described. The aim is to provide a concise account of the domain as it stands today, and to sketch, however briefly, a few perspectives for future research.

The development of modern science and technology, especially biosciences and biotechnologies, presents a challenge to modern society that has never been encountered at any previous time. Biotechnology is a rapidly expanding sector, and nowadays its applications are found in scientific and clinical research, agriculture, industry, environmental research and medicine. Biotechnological techniques, providing an opportunity for the manipulation of living matter, appear to be of a great benefit to society, in medical diagnosis, manufacturing of medicine and vaccines, developing of original therapeutic techniques, innovatory crops and breeding techniques, and in new energy production and pollution control processes. On the other hand, there are risks in this development, arising from the possibility of unexpected damage to human beings, the living world, and the whole environment due to biotechnological applications, which are also unprecedented. The dangers of human cloning, genetically modified crops, or new bio-weaponry are just a few well-known examples, amongst many others. Consequently, there is a pressing social need for finding a subtle and sustainable equilibrium between the interests in technological progress and that of reducing its potential harmful side effects.

There are moral questions and ethical difficulties at the core of this situation, which challenge contemporary social capabilities for rational and open discourse, understanding, and decision-making. These problems are made even more complex by the fact that in the biotechnology sector experiments go beyond the laboratory stage and often are extended to a global scale. Society as a whole is involved in a 'collective experiment', and all of its strata have stakes in finding out solutions to the biotechnological ethical dilemmas. This is why the ethical situation of biotechnology is incredibly complicated by the multitude of interests involved and by the urgent need for an interdisciplinary dialogue, which would involve all the actors concerned. Needless to say, in these settings the issues of regulation and control loom larger than ever before.

In this paper I shall briefly survey the main domains of ethical engagement relevant to biotechnological development. I shall start with bioethics, describing its approach, subject matter, and deficiencies. I shall then turn to the scientists engaged in ethical issues, outlining their contemporary situation, and proceed to analyse this in the important terms of science ethos and science ethics. Finally, the rise of 'regulatory science' and of ethical committees will be described. The aim is to provide a concise account of the domain as it stands today, and to sketch, however briefly, a few perspectives for future research.

When it comes to modern biotechnology, there are two kinds of moral questions. The first type concerns the context of a given application, while the second is connected with moral questions concerning technology *per se*. In view of the global ethical problems described, discussion ought to concentrate on the way biotechnology is used (and on the regulation of its use), insofar as biotechnology already exists and its applications are widespread.[1]

Bioethics

The issues arising from modern biotechnology research have social, ethical and legal implications. The newly emerged field of bioethics claims to be a place where the discourse between science, philosophy and law could be situated in order to deal with ethical issues arising from the progress in biosciences and biotechnologies. Bioethics crashes disciplinary boundaries and appears as a cross-cultural movement toward global reasoning about the future of humanity.

The academic discipline of bioethics emerged during the 1970s (Institute of Medicine of the National Academies 1995, 67). The term refers to the activities of scholars trained in academic disciplines dealing with ethical matters, such as theology, philosophy, or law, who began to study and write about the ethical issues of modern medical science and health care, applying the methods of their basic training. The object of investigation of academic bioethics is the professional activity of physicians, nurses, and scientists involved in ethical problem solving.

Preoccupation with the moral dimensions of medical practice does not, however, restrict bioethics to medical ethics, which is an ethics of physician-patient relationships, including all general obligations and duties for patient welfare, as well as specific rules of conduct, such as confidentiality. Bioethics—literally 'life ethics'—is increasingly regarded by some authors as including medical ethics as a subset (Kuczewski 2002). According to this view, it is a more general category that comprises additional issues of research ethics, as well as ethical issues related to new techniques—cloning, human genetics, environmental policy. This already suggests a more general and philosophical approach in contrast to the strictly clinical case-oriented approach used in medical ethics. As an applied ethics dealing with practical problems arising in biosciences and technology, bioethics employs various ethical theories, which can be useful for the analysis of those problems. Accordingly, traditional normative ethics, such as utilitarianism and deontology, are supplemented by virtue ethics, ethics of care, and casuistry (Beauchamp & Walters 1999, 1–17).

Having noted this, it should be stressed that the main objects of bioethical analysis are still the ethical and legal issues arising from biomedical research and research involving human subjects, such as genetic testing, gene therapy, stem cell research, etc. Bioethical research is mainly oriented towards studying gene technology and its applications in medical treatment, a reason for the often-interchangeable use of bioethics and medical ethics in the available literature. An entire area is still lacking in the bioethics field in terms of focusing on biotechnology as genetic engineering on a production scale and on 'new' biotechnology as the industrial use of rDNA. In this respect bioethics is a still developing field of inquiry, not only in regard to methodology, but also to the subject matter.

The involvement of bio-scientists in ethical regulation

The ethical constraints imposed on the science-based technology advance also draw attention to the role of bio-scientists as a community, as well as to their contribution to the ethical discourse about the impact of their research practice. To begin with, the modern regulatory process applied to biotechnological research practice, in which ethical constraints take an important part, requires the decision-making process to be opened up to a range of interested parties. Accordingly, the representatives of the scientific community sit side by side with the representatives of the public, government, and industry on various ethical committees, which have emerged during the last two decades. Moreover, we are witnesses of a curious process of the splitting up of scientists' activities. Scientists today perform two distinctive roles from two distinctive, but not always separate positions: the role of researcher and the role of regulator. Insofar as the advance of biotechnology represents a challenge toward genuine regulation, enforcing prohibitions and restrictions upon research in science, the two levels of scientists' activities are bound to produce tension. On the other hand, it is felt that the two functional levels, if they are properly co-ordinated, could assign, at least in principle, a better method for harmless regulation that would at the same time, preserve the autonomy and freedom of scientific endeavour.

The scientists involved in the regulatory process are experts assuming advisory functions, but they are also performers of specific behaviour patterns peculiar to the research community. Their technical expertise is grounded on relevant knowledge, codified and tacit, whose bearer is the scientific community. Their ethical sensitivity is rooted in the traditional science 'ethos', maintaining the communal moral authority. Only awareness of this ethos, constituting the heart of scientific self-regulation enables scientists' evaluation from a meta-position, and further could be a stable ground for good ethical regulatory practice, which is currently being developed and applied to biotechnology. The scientific community has long acted as a self-regulatory agent; i.e. the two positions discerned above have been an amalgam and rarely an object of reasoning; moreover, it has been sequestered behind academic walls. The newly emerged conditions provoke their explicit formulation in terms of science ethics.

Science ethics

The notion of 'science ethics' refers to two distinctive phenomena: on the one hand, an ethos built in scientific activity itself, prescribing a conduct, discernable from 'unacceptable misconduct', and on the other, theoretical conceptualization of this phenomenon, intended to understand and explain its role, origins, past and current performance. The first phenomenon is, in fact, an ethos-in-practice, while the second sets a conceptual branch of the domain. The two branches, though related, are nevertheless disparate; they demonstrate different rates of progress too: the conceptual one (ethics) lags behind the recent boom of its practical counterpart (ethos).

This discrepancy is due to some basic factors inherited through the history of science. The professional institution of science was organized on the basis of 'rational objectivity' of scientific endeavour. The objectivity of science presumes value-neutrality and autonomy of the scientific community. Recently, in opposition to the ethical reflection in science, an anthropological movement has introduced a sense of pluralism in human affairs leading to moral relativism and subjectivism. This move has been marked by an attempt to put the very foundations of ethics in doubt but this was a trend that ran counter to the scientists' even stronger emphasis on objectivity. A distinction between objective science and subjective ethics was thus created (Toulmin 1979, 27–28). In a separate but linked line of development, the trust in scientific claims has evolved from the notion of scientists' personality based on the idea of their integrity as devoted truth seekers. The special reliability and objectivity of the scientists' testimony have been associated with the special virtue of scientists' celebrity. Great scientists have been endowed with 'simplicity, righteousness, modesty, candor, frankness and sincerity' (Shapin 1995, 399).

A different perspective to the scientists' character, however, was set by the tradition investigating science as a social institution and scientists' behaviour as a collective conduct of the scientific profession. Robert Merton, the unquestionable founder of the sociology of science, programmed a new research trend. His object of study was institutionalized science with its important social function and independent set of norms and values, the so-called 'science ethos'.

The ethos of academic science

Robert Merton conceptualized a 'science ethos' in terms of openness, universality, communality, and, finally, self-correction and self-criticism (Merton 1973, 268–278). The 'ethos' of science was shown as a complex body of principles and norms, legitimized as institutional values. Those values were treated as spontaneously imposed within the scientific community, probably engendered by the main goal of modern science—the growth of 'certified knowledge', and performed as a supporting mechanism in pursuit of that goal. Their interdependence, it seemed, proved that their roots were in specifically scientific endeavour and that they were naturally built up within scientific practice.

The four isolated 'moral imperatives'[2] of modern institutionalized science, however, are far from being codified rules, they are transmitted by precepts and examples and through patterns of behaviour from teacher to disciple; their expression takes the form of prescriptions, proscriptions, preferences, and permissions. The institutional imperatives (mores), appearing as recommendations rather than laws, are not written and rarely explicitly verbalized; they have been entirely institutionalized by scientists' moral consensus and moral indignation toward deviations from the ethos. In such cases only did the scientific community formulate the hidden, taken-for-granted rules in a negative mode—as 'what not to do' or from what behaviour a scientist must abstain. The deviation from the norms actually presupposed the legitimacy of the norms, their reaffirmation.

The ethos conceptualized by Merton was but a first, tentative approximation to the institutionalized values or norms guiding scientists in their research practice in their academic setting, i.e. the scope of activity of the scientific community as a self-regulatory agent is an academic science—the traditional disciplines and fields of pure research. The institutionalized ethos of science justifies the existence of science as a social institution, with a 'distinctive body of norms exerting moral authority'.

The scientific communities can serve as an example of an extreme case of effective social control by a minimum of informal sanctions. They compromise one of the interesting instances where a group of people is held together by a common purpose and shared norms without the need of reinforcement by familial, ecological or political ties (Ben-David 1971).

It is significant, however, that in Merton's formulae the nature of various norms is hard to be discerned, because they have diverse expressions and diverse regulatory functions as well. It was no accident that Merton called them 'mores'; these norms unified in their ethical, methodological and institutional functions. They could be considered simultaneously as norms of personal behaviour, norms of relationships in the community of scholars, norms of professional conduct, and norms of knowledge production; all of them favouring the advance of certified knowledge. As long as academic science performs in a quasi self-contained cycle, where transition from a problem to another problem is driven by a requirement for an original contribution, one finds science norms embodied in every stage of that process—research, communication or evaluation.

Merton's first attempt to describe the science ethos prepared the ground for further examination by successors as well as for criticism. The criticism was especially vocal and prominent; some latter sociologist of science tried to deny the existence of any scientific norms whatsoever and there was a robust opposition to Merton's paradigm in particular. According to Michael J. Mulkay, for example, Merton's approach has a very tenuous empirical foundation and involves considerable theoretical difficulties (Mulkay 1969, 22–31). He claims there is a lack of empirical studies able to demonstrate that these norms are characteristic of the scientific community. Mulkay suggests that it is the body of established knowledge that provides the strongest influence upon the scientific community, and not the social norms. Furthermore, in the case of 'revolutionary science' in Kuhn's terms, the Mertonian norms do not appear to operate effectively. Mulkay provides evidence for cases of non-conformity to the Mertonian norms within the scientific community that does not make the non-conformists less productive than conformists. His most compelling example is the resistance to innovations as a form of violation of all formulated principles of 'science ethos'. Moreover, resistance to innovation does not occur in isolated cases, on the contrary, the annals of science provide evidence that this is almost a general rule or common practice. Therefore, the marked deviation from the Mertonian norms and radical theoretical innovation occur together.

Nevertheless, the cases of deviation from the norms hardly contest or deny the availability of self-regulation in science. On the contrary, the practical ethos could scarcely be neglected, for it is becoming more and more visible in the newly emerging conditions of knowledge production.

The change

An impetus for the disclosure of the hidden science ethos and the revealing of the gap between ethos and ethics, i.e. practice and its theoretical conceptualization, have been provoked by some fundamental events in science history: the professionalization of science entailed by increasingly close links created between basic research and its practical applications having changed the research environment.

The appearance of applied science has induced a process of the slow transformation of research from a vocation to a profession. Even after Ben-David's effort (1971), this historical transformation remains still vague on a conceptual level. There are real consequences stemming from it, however, which are visible today. Research activity is no longer a vocation; it has become a profession, practiced in specialized settings. Researchers go through a long period of education and training, governed by special scientific bodies, ensuring the upholding of professional standards. The ethical standard becomes a subset of the professional one. The knowledge created in the context of application makes scientists more exposed to ethical problems and public accountability and entirely transforms the former research environment. Since the new research environment has a strong influence on the research process and the behaviour of the scientific community, various external and internal factors have come into play (Alberts & Shine 1994, 1660–1661), stimulating the advancement of science, but also, at the same time, providing incentives for scientific misconduct (Goodstein 1996), i.e. deviation from ethically 'good' scientific practice. Consequently, the new mode of knowledge production (Gibbons et al. 1994), performed in an already changed research environment with high standards of accountability and intensified competition for resources and recognition, provides conditions for evading or violating the traditional norms of science.

The practice of the ethical regulation of science is obviously far richer than its generalization into four norms as suggested by Merton; and this remains true, however much his followers tried to extend the list of norms, and to make sure that it is complete.[3] The recent revival of Merton's concept of science ethos in the form of a 'standard of ethical conduct in science' (Resnik 1998, 53–73) only shows once more the difficulties of this approach. In the light of the newly emerged conditions of knowledge production mentioned above, the institutional and professional norms of science appear more and more visible, but they also look more complicated than ever.

In contrast to the theory, the ethical practice of science more intensively verbalized the norms (in forms of ethical codes, for instance) even though it did not give any explanation whatsoever for them.

Ethics in regulatory action

Following the epoch making discovery of the DNA molecule by Watson and Crick in 1953, scientists felt uneasy with the possibilities of the technology based on the newly obtained knowledge. They decided to gather and discuss the relevant issues, and so a unique event in the annals of science—the Asilomar conference of 1975—took place. The conference could be marked as the first step toward ethical reasoning in connection to rDNA and further on to genetic engineering and biotechnology. It was intended as a 'strategic conference' amongst scientists, whose aim was to discuss safety measures necessary to continue rDNA research, but it became a step in public-policy formation and focused more on control, instead of on the safety of the technology. Nevertheless, the event marked the importance of those issues, and opened a door for serious public debate (Hong Lim Oei 1997).

In fact, the history of regulation started a year earlier with the so-called NIH guideline issued by the Recombinant DNA Advisory Committee on 7 October 1974. The guideline was grounded mainly upon the scientific expertise or so-called technocratic approach, which granted autonomy to scientists as overseers of their research. But in the years following the Asilomar conference, the internal community debates eroded the credibility of scientists as decision-makers and provided ground for the application of a more democratic approach in the decision-making process. This process was reinforced by the fact that a 'new generation' of ethical issues have been given birth by modern biotechnology development, many of them calling for the examination of science ethos in a broad social context.

This process put pressure on scientists, and they had to take up a new role in which ethical considerations have increasingly become an important part of their professional life. There are at present various initiatives which serve as a clear expression of this process. Special regulatory bodies, such as the Office of Scientific Integrity Review (OSIR) or the Office of Inspector General (OIG), are being created in order to monitor whether the research process is conducted according to the accepted standards for integrity and responsibility in the conduct of research (PSRCR 1992, 109–110). Some universities and research institutions are developing educational programs, whose purpose is to inform the participating students and young researchers of ethical problems.[4] An increasing awareness of the ethical rules, their conversion from tacit to explicit, from negative to positive formulation, is finding a manifestation in multiplying ethical codes.[5] The scientific community is undertaking more organized regulatory action, replacing the former spontaneous reaction; and it is taking responsibility for determining which practices are serious enough to warrant institutional or professional responses and what forms these responses should take.

A good example of this is the American Society for Microbiology. Its members are concerned with issues of research integrity at several levels: a Code of Ethics for the Society's members; editorial oversight of ethical issues involved in publications; involvement in ethical issues and controversies at a national level by the Public and Scientific Affairs Board; and the use of meetings and publications to inform and educate members about research integrity (The Role and Activities of Scientific Societies, 2000).

Apparently, unlike in the 1940s of the 20th century, when the Mertonian 'moral imperatives' were first formulated, the practical ethos of science is now more explicit and broader in scope, and the already enriched science ethos is being vigorously implanted into a modern regulatory practice.

However, the conceptual knowledge used in the regulatory process is different from biotechnological research proper, which is liable to regulation. Being more than knowledge and skill, regulatory practice is taking shape as a scientific domain—so-called regulatory science—'the new branch of science' (Jasanoff 1990)—with its own institutional structure and methodology for evaluation and prediction, and with a clear aim: to determine how serious and significant the risks created by the new technologies really are. Research in science and science used in policy making perform in different institutional structures, with diverse goals, end products, and time frames. They are accountable to different institutions, have no similar procedures for evaluation, and have their own special standards of conduct (Jasanoff 1990).

What seems especially characteristic of contemporary biotechnology is the fact that the regulatory process is performed in interdisciplinary settings. Scientific, ethical, and legal approaches are unified for the purpose of common problem solving. Consensual interaction between the parties involved finds expression in the established bioethics committees. They are independent bodies providing advice to the executive level about the ethical issues arising in the biotechnology sector (EGE 2003). They are established as a result of growing public attention to issues related to the application of biotechnology. These bodies are independent, interdisciplinary associations with representatives from different fields of science, medicine, theology, philosophy, law, ecology, economy as well as a number of lay members. They have been established as forums for dialogue about ethical issues in the life sciences. The ethical committees embrace the advisory function as technical expertise; they also provide a meaning of ethically oriented technology.

Regulatory science and the ethical committees are the last stages in a very intensive development of the ethical issues associated with modern biotechnology. In these phenomena the traditions of bioethics, the increasingly more explicit science ethos and broader social agendas are converging, creating new perspectives of knowledge and action. Perhaps more than anything else, research on them and their interactions with the executive, the lay public, and academic and applied scientific research would reveal the true ethical significance of contemporary biotechnological development.

Notes

1 Nowadays the boundary between science and technology is wearing thin and they appear in the form of a new research culture—Mode 2 in Gibbons' terms (Gibbons et al. 1994). Since technological research is steeped in the academic practice, an examination of the academic ethos could provide a ground for ethically sound technology regulation as well.

2 Universalism, communalism, disinterestedness and organized skepticism (Merton 1973).

3 Honesty, carefulness, openness, freedom, education, social responsibility etc. (Resnik 1998, 53–68).

4 For example, the session of ethics, entitled 'Etiquette and Ethics in Science' at the University of California, San Francisco, is organized largely around real cases of ethically difficult situations that researchers have encountered in the course of a scientific career. At the University of California, Los Angeles, interest in the issue of scientific ethics has led to the creation of a Center on Scientific Ethics. Central work of the center has been the preparation of an extensive bibliography and the collection of case studies.

5 An information and an alphabetical list of ethical codes in science can be found in the Center for the Study of Ethics in the Professions, Illinois Institute of Technology, Hub Mezzanine, Room 204, 3241 S. Federal Street, Chicago, IL 60616–3793, e-mail: csep@iit.edu, Codes of Ethics Online Science.

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