The control and regulation of scientific and medical research

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Clin Med JRCPL 2001;**1**:261–3

Lurking in the minds of many scientists and others in what is sometimes referred to as the 'Knowledge Industry' (but which I prefer to think of as the academic world), there is an ideal of freedom to pursue research wherever it may lead, to publish results, and perhaps to open up new pathways to the goals of medicine or other useful activities without restriction. We may call this the ideal of the Enlightenment. In the eighteenth century natural philosophers, if they could find a patron, could carry out what research they wanted, in their own homes or that of their patron, could present their findings to the Royal Society, and sometimes put them to practical use, rejoicing in at last being free from the kind of restrictions imposed by the church on Galileo and Descartes. It is a noble ideal, and one not to be lightly abandoned.

On the other hand, among people who are not scientists or who have no particular interest in the pursuit of knowledge, there is a fear that science goes too fast; that new knowledge and new technologies may be misused. Any skill, as Plato knew, could be used for good or ill: the clever doctor may also be a clever poisoner. This cannot, however, in itself constitute grounds for prohibiting the development of the skill in question. Instead, Plato held, one had to try to find out how best to educate a man so that he could be relied on to use his skill for beneficent ends.

Today we cannot be so individualistic as either the scientists of the Enlightenment, or Plato's imagined doctors. As soon as the question is raised of applying largely publicly funded research for medical or other purposes the issues become issues of public policy, in which not only parliament but society at large may be thought to have a proper interest. Moreover, questions may be raised not only about the ends to which research may be put, but about the actual methods and procedures of the research itself. For scientific research is no longer the hobby, or even the professional interest of certain individuals, but is a corporate activity, inevitably something in which government has to invest, and for which those who undertake it must therefore be accountable.

There is a further difference between our society and that of the eighteenth century. At that time, the sciences were not subdivided; all scientists were natural philosophers. A man like the anglophile Dutch medical practitioner, Ingen Housz, friend of Benjamin Franklin and Joseph Priestly, not only practised vaccination against smallpox, but also conducted experiments with electricity and discovered the theory of photosynthesis. The inevitable fragmentation of the sciences has made them unintelligible, sometimes to other professional scientists, and certainly to non-specialists.

To what extent, then, must scientists expect to submit to regulation and controls imposed on them by sources of authority outside their own discipline, who cannot be expected to know much, if anything, about the matter in hand? After all, if historians or those engaged in the social sciences were told what research they might or might not pursue by people less well qualified than themselves, we should be outraged and call all the forces we could muster in defence of academic freedom to aid us. We should remind ourselves of the absurdities of civil servants in Stalinist Russia, pronouncing judgment on the music of Shostakovich. Why should scientific or medical research be different?

The question of control and regulation arises most acutely in the biological sciences. Here there are two different matters on which society is generally thought to have an entitlement to control what scientists may do, by regulation and inspection or even by force of the criminal law. The first is the matter of the methods of research, the second the ends to which the research is put. Both these are seen to be potentially moral matters, and therefore to lie within the province of everyone, scientist and lay alike. There are no experts or specialists in morality; everyone is entitled to his or her own view. The reason why the biological sciences are so open to (some would say vulnerable to) the criticisms and opinions of the lay is obvious enough: not only are the ends for which the sciences may be applied concerned with living creatures, but the methods of research themselves often involve living animals, including human beings. How they are to be treated by research scientists, as well as what is proposed for their lives in the future, and the long-term goals of the research, are questions of immediate interest to us all, and are manifestly moral questions.

To consider the morality of methods of research, perhaps the longest-standing moral objection to biological research has been its use of live animals. As early as the eighteenth century there were those who deplored 'vivisection' and there were biological scientists who could not bring themselves to use live animals in experiments, let alone to encourage fellow members of the Royal Society to come along to witness such experiments. In 1876 a law was introduced to control the experimental use of animals (The Cruelty to Animals Act 1876), as well as to criminalise some ill-treatment of domestic animals, especially horses. The 'experiments' in question at the time were mostly surgical; the Act was left on the statute book, but its scope widened by a comprehensive Act criminalising cruelty to animals which became law in 1911. In 1986, after deliberation by a House of Lords Select Committee and by a Home Office Advisory Committee, a new Act became law, specifically to protect and regulate the uses of laboratory animals, and to establish a new procedure for the granting of licences for the use of animals in research. This was the Animals (Scientific Procedures) Act, which still governs the use of animals. Currently there is a new House of Lords Select Committee, which has met only once at the time of writing, to examine the working of the 1986 Act and to consider afresh 'the effectiveness of and justification for' animal procedures, and the possible development of alternatives. This committee has been set up because of the considerable changes in biotechnology since 1986, and also in response to the increasingly vociferous, and sometimes violent, moral protests against the use of animals in laboratories. The Animal Rights movement, largely inspired by Peter Singer's book, *Animal Liberation**, has become a terrorist movement, requiring both physical control and up to date, reasoned argument.

Nevertheless, those who object as a matter of moral principle to the use of animals for research (even when the use is subject to licence and inspection) are still a small minority. The moral objections to the use of live human embryos are, if not more strongly held, perhaps more widespread and more understandable. Once again, it is the manifest moral nature of the issues that have necessitated legislative regulation of the work of biological scientists. The recent decision in Parliament to widen the scope of research using early human embryos is a good example of how a quite general moral sentiment among the public at large can be rationally discussed, and by means of a 'free' or 'conscience' vote, can be translated into legislation. Research using human embryos is no longer restricted to research into infertility or the development of contraceptives, as was laid down the 1990 Human Embryology and Fertilisation Act, but has been extended to research using embryonic stem cells, to discover more about the way in which stem cells differentiate into one or other of the 216 types of cell that make up the human body, and how differentiation may be controlled, so that cells of a specific kind may be developed. The time limit, laying down that no embryo may be kept alive in the laboratory for more than fourteen days from fertilisation, remains part of the law.

There are other areas where the methods of research scientists, whether biological or specifically medical, may be held to be morally contentious, and where it is therefore necessary to control or regulate the research. These include the use for research purposes of children, or adults who through disability are not in a position to give informed consent to being part of a research procedure. They also include the use of people as controls in all sorts of blind or double-blind research projects. Probably no one doubts that such uses of other human beings are necessary for the advancement of medical knowledge; but they are not in accordance with how most people think that humans beings should be used, and therefore scientists must, on moral grounds, be subject to restrictions on what they may do. It is not simply that public money generally supports research, and therefore scientists must be accountable. It is rather that, despite what we are often told, we live in a society within which there is a considerable degree of moral consensus about what is or is not a decent way to treat people. The law (or lesser regulative instruments) is deployed to safeguard and strengthen such consensus.

The second matter about which biological scientists may be subjected to criticism and perhaps control is far more contentious. This is the matter of how their research will ultimately be used. The issue of embryonic stem cell research provides a good example of this kind of case. There were those who, though satisfied by (or resigned to) the use of human embryos for the purposes of remedying infertility, were horrified by the possibility of cultivating human cells in the laboratory. The less rational among these objectors were, perhaps influenced by the use of the expression 'therapeutic cloning', certain that since the procedures to be used were the same as the first steps in the cloning of whole animals (the removal of the nucleus of an egg and its exchange for another) the cloning of whole humans would inevitably follow. The very thought of the cloning of whole human beings causes a powerful revulsion. This cannot be because the idea of two people with a virtually identical genome is intrinsically revolting (we do not object to identical twins), but because of a deep fear that somehow the human race could be manipulated. At any rate it is generally agreed that to produce human clones would be a moral outrage, and the HFEA has undertaken that a licence for such an attempt would never be granted.

My own view about human cloning is that it would certainly be morally wrong to attempt it at present, when the procedure to produce a cloned sheep was so precarious and wasteful; but that if the techniques were improved, there might be cases of infertility where a clone would be the best solution.

Of course there is no logical connection between carrying out the first steps of a procedure and going on to carry out all the rest. However, the so-called slippery slope argument does not rely on logic but upon a general mistrust of human nature, and especially of scientific human nature – if the first step is permitted, scientists will demand to be allowed to take the next steps, or will take them without permission.

* For further details see Roger Scruton, *Animal rights and wrongs*. 2nd edn. Demos, 1998.

Leaving cloning aside, there are still those who have moral scruples about the possibility of cultivating human cells in the laboratory and using them for cell-transplant, to replace damaged or diseased cells in a human patient. At first sight this seems nothing but benign. What could be better than to allow the brain of someone suffering from Alzheimer's disease to develop new and healthy cells; or to allow the skin of someone with extensive burns to renew itself? It would surely be contrary to all the principles of medicine to legislate against such novel and dramatic therapies. But if some of the cells of the human body can be renewed, might not all be renewed in turn? Would not there then arise the possibility of causing people to live for ever? And this, surely, would be a disaster.

There are many other goals sometimes proposed for the new biotechnology, such as changing people's characters or abilities by changing their genes. All are at present more or less fanciful, but all capable of abuse. However, the possibility of abuse in the future cannot be a sufficient reason for trying to bring advances to a halt. It is better to continue as we are, with regulation and, if necessary, legislation in line with or deriving from a moral consensus, broadly shared, and shared for the most part with scientists themselves.

Of course it may be argued that if regulation becomes too stringent, if the whole elaborate business of licensing and inspection becomes too bureaucratic, then scientists will simply leave, and take their work abroad. And there is much sense in this argument. After all, all we can do in setting up regulation is to say 'Not in my back yard'. It is true that we must try to balance the views of the optimists, who look to a golden future for medical science, with those of the pessimists. But even the pessimists and those with deep moral anxieties may, I believe, take comfort from the regulation that we have, and the way it works. If one considers, for example, the case of IVF: in this country every clinic where IVF is carried out must be licensed, and all related research procedures are likewise licensed and inspected. The HFEA is a powerful and robust body, with powers to refuse or remove licences, or in extreme cases to prosecute offenders. And this goes for all clinics and hospitals, private and public. In contrast, in the United States, though there is no federal funding for IVF, nor for related research, there is no regulation whatsoever to control what happens in the private sector. The morally nervous have far greater cause for alarm there.

I believe we should be glad of the framework of the law that we have, and accept it as a necessity. That is not to say, of course, that as science moves on, we may not wish to change the laws that control it. But this can be done, albeit slowly, by clear argument, and the processes of democracy.

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