...A heightened awareness by experimenters of the responsibilities associated with the use of animals and increased sensitivity to their needs and their capacity to suffer will achieve much more for laboratory animal welfare than new legislative measures ...

But this heightened awareness requires Committee that take their educational role seriously. They must be more than a group of the experimenters' buddies plus a ' tame ' outside member. As Senator Georges rightly commented, the matter of selecting the outside member is fairly crucial to public confidence in this system. There have been problems in Sweden where confirmed anti-vivisectionists found their way on to the large committees set up under a system designed to give advice and quick decisions. But the animal interest is not properly protected if the outside member is not of independent views. One has said that it is not an easy role: if you are too such outside member has said that it is not an easy role: if you are too strident, as an obstructionist. One is led to wonder whether, if it is to remain on the committee, this appointment or appointments should not be initiative of the institution, this appointment or appointments should not be made by the institution from a list provided by some outside organisations involved in animal welfare, or subject to confirmation by a senior government official after considering any comments by such organisations.

It is only a short step from this to the system now proposed for New South Wales, where there is a Committee responsible to the Minister which supervises a licensing system for institutions, but not for individuals or for projects. The difficult decisions about projects are to be made by the ethics committees. The case made above for small inspectorate provides for some monitoring and for an independent investigation of complaints. This certainly provides a way of accountability. In view of the case made above for protecting animal interests, I do not believe that it unduly restricts freedom.

References


REGULATORY STRATEGY AND ANIMAL EXPERIMENTATION

John Braithwaite

Summary

It will be argued that the regulation of animal experimentation may benefit from a commitment in advance to a hierarchy of regulatory response. By this it is meant a commitment to try self-regulation first for most problems, but equally a commitment to escalate regulatory response when monitored self-regulation is found to fail. The stages of escalation suggested when self-regulation fails are "enforced self-regulation", followed by command and control regulation with non-discretionary punishment as the ultimate strategy.

I am not an expert on the practical realities of animal experimentation. I suppose I was invited to speak at this seminar because of some expertise I have on general strategies of regulating organizational conduct. As a citizen, I am also deeply concerned by what I see as widespread unnecessary and unconscionable experimentation on animals. When I was researching my book on the regulation of the pharmaceutical industry I visited the laboratories of 32 pharmaceutical companies spread across five countries (Braithwaite, 1984). At many of these companies I walked through the rows upon rows of dying animals in the toxicology laboratories. The monkeys who spend a confined existence hooked up to all manner of tubes and wires, the rabbits in stocks with chemicals being dropped into their rotted, emaciated eyes. The tragedy is that most of this testing is for the development of "me-too" drugs which involve no therapeutic advance over existing products: they are merely attempts by pharmaceutical companies to set their share of a market in which another company has a patent monopoly by developing a minor molecular modification on the patented drug. If we accept that in a variety of areas there is both animal experimentation which should not happen at all and necessary experimentation which should be conducted in a more humane fashion, then what regulatory strategy is best equipped to reduce the unwarranted suffering? Though there are clearly different views on how much of existing animal experimentation the world would be better off without, the regulatory strategies I will consider in turn are self-regulation, command and control regulation, enforced self-regulation and taxes on harm.

Self-regulation

By self-regulation I do not mean laissez faire - doing nothing - I mean a range of programs voluntarily entered into by the animal experimentation community to prevent abuses. Such self-regulation has a history in Australia going back to the first preparation of the "Code of Practice for the Care and Use of Animals in Research in Australia" by the National Health and Medical Research Council and the CSIRO in 1969 and the associated development of ethics committees.

There are a number of advantages to self-regulation. It involves minimum incursion on the freedom of people to act, and as Professor Holborn pointed out, with any kind of scholarship, freedom is an especially important value. An accumulation of restraints on scientific freedom puts creativity in jeopardy. Self-regulation is a very flexible strategy. In theory, if not always in practice, voluntary codes are easier to change and keep up to date.
than legislation. But perhaps most importantly, self-regulatory strategies allow for particularism – designing standards sufficiently flexibly and non-legislatively so that they can apply in different ways to different circumstances. If Dr Rowan was right yesterday when he said that the use of alternatives to animal experimentation is "a state of mind of the investigator", then self-regulation is the preferred strategy. The law is a blunt instrument for regulating states of mind.

For all these advantages, self-regulation suffers from the fundamental defect that in most areas of regulation it is just not credible. It lacks credibility because it has no teeth, no legal backing, so that when the crunch comes between complying with a voluntary code and spending a large amount of extra time and money, rational economic actors can exploit the privilege of self-regulation. As former Shell International Director, Geoffrey Chandler, once said: "Codes of conduct tend to be placebos which are likely to be less than a responsible company will do of its own volition and more than an irresponsible company will do without coercion."

Command and Control Regulation

The major alternative to self-regulation is command and control regulation. With animal experimentation this involves the government writing detailed rules to cover cage sizes and the like, employing an inspectorate to monitor compliance and initiate prosecutions against offenders. There is now a major literature attacking this strategy, much of it penned by conservative economists who live off corporate research funding, much of it overstated. But there can be no doubt that command and control regulation is prone to delay and unresponsiveness to changing technological and institutional realities, to red tape, unnecessary costs, and stultification of innovation. At the heart of these problems is the fact that statutes tend to encode standards to be applied in the same way to all animal experimenters – from the tiny high school laboratory to the transnational pharmaceutical company.

Sometimes this means that lowest common denominator standards are imposed on organizations which should be subject to much stricter standards because of the unusual suffering involved in their work or because of their capacity to pay for higher standards. In other circumstances it means irrational standards being imposed in circumstances where they have no practical relevance. Since between 10 and 20 per cent of experimentation runs a particular kind of risk, 100 per cent of the community of experimenters are saddled with a rule which would be better targeted only on the 1 per cent. One way of dealing with this dilemma is a compromise called endorsed self-regulation.

Enforced Self-Regulation

In his address yesterday, the Minister described the approach being considered by the government as enforced self-regulation. This is a term which I coined in an article I wrote for the Michigan Law Review in 1982 (Breathwaite, 1982). The Minister would seem to have taken some ideas from that article, though in other respects there would seem to be differences between the Minister's proposal and my model. The most notable difference would seem to be that while my model, as we shall soon see, is one of particularistic regulation, the Minister seems to favour primary emphasis on a universalistic code of practice with only limited scope for particularistic standards which vary from one research institution to another.

The Minister is proposing to require each organization to have an Animal Care and Ethics Committee. These will be mandated as a condition of licence. It is agreed with Professor Holborow that it is desirable that these lay persons represent the general public and that otherwise the research organizations will be open to the criticism of Minister with respect to the Animal Research Review Panel which will issue the licences, but not with the institution-level Committees.

The Animal Care and Ethics Committees will enforce compliance with a Code of Practice and will be expected to inspect its laboratories as well as approve desirable to require these Committees to report to the Animal Research Review of any complaint against a decision of a Committee.

I assume the Committees will have their performance randomly audited by inspectors sent out by the Animal Research Review Panel, and that when these audits fail to meet targets, there will be prosecutions, licence suspensions or licence revocations, so the self-regulation is enforced.

Of course, these audits need not be random. For example, one could require particularistic audits which might be of any complaint against a decision of a Committee.

Under my original enforced self-regulation model, the government would compel each organization to write its own code of practice tailored to the unique set of circumstances it faces and would either approve the code or send it back for revision if it was insufficiently stringent. At this stage in the process, community groups would be encouraged to comment on the proposed codes. Rather than having governmental inspectors enforce the codes, most enforcement duties and costs would be internalized by the organization, which would be required to have its own enforcement committee, inspectors, and to audit its efficiency and toughness. Such audits would pay particular attention to whether violators were being disciplined by the organization.

Government involvement would not stop at monitoring. Violation of the privately written and publicly ratified codes would be punishable by law. The regulative body would not ratify private rules unless they were consonant with particularistic rules and the irrationality of imposing standards on the majority which are only relevant to the activities of a minority. Particularistic rules can be more rational, more detailed (and therefore more useful in situations. Under enforced self-regulation, the particularism is achieved without the naivete of trusting the voluntarism of self-regulation. In a
sense, enforced self-regulation combines the flexibility of self-regulation
with the punitive dimensions of government command and control. However, there are
with the punitive elements of the enforced self-regulation model. The most
considerable weaknesses of the enforced self-regulation model. The most
important one concerns the administrative feasibility of the process of self-regulation
in animal experimentation. A more detailed account of both the weaknesses and
in animal experimentation. A more detailed account of both the weaknesses and
large number of codes written by an enormous variety of organizations involved
in animal experimentation. A more detailed account of both the weaknesses and
in the strengths of enforced self-regulation has been provided elsewhere

I do not necessarily advocate it as the best model for controlling animal
experimentation abuses. But it will throw out one of the other interesting feature
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Towards a Hierarchy of Regulatory Response

I don’t know enough about animal experimentation to hazard a view on what is
the optimum regulatory strategy in this area. In any case, there is always
doubt whether there is such a thing as an optimum approach. Up to this point
what I have described is a hierarchy of regulatory response – from the least
what I have described is a hierarchy of regulatory response – from the least

The hierarchy extends from more voluntaristic regulation, which is likely to
give experimenters a greater commitment to standards not imposed by coercion,
and to specifying at the one end, to more directive and punitive regulation at the other end, which
at the one end, to more directive and punitive regulation at the other end, which
provides stronger guarantees that the bad apples will not taint the entire group with their faults.
Obviously it is a voluntary regime that experimenters themselves believe in because
they have substantial control of it can be both more effective and cheaper, but only if self-regulatory disciplinary mechanisms
with teeth are actually working to bring irresponsible members of the

The important point I have been trying to make is that governments should not
have a view on what is the right regulatory approach for a problem like
eliminating abuses in animal experimentation. Nor am I suggesting that the
particular hierarchy of regulatory response I have advocated is the right one –
that is, escalation from self-regulation, to enforced self-regulation, to
command and control regulation with discretionary enforcement, to command and
total abolition which is

To illustrate an alternative, many economists are more attracted to taxes on
harm as an alternative to command and control as an ultimate sanction. This
could work, for example, by the regulatory body imposing a financial charge per
animal per day for all animals used in experiments. Depending on how
steep the fee was, this would increase incentives to use animals only when
this lesson with

the tripartite approach to occupational health and safety regulation we are
seeing in most jurisdictions, and the approach the Commonwealth has been
adopting to affirmative action.

Alternative Hierarchies

The important point I have been trying to make is that governments should not
have a view on what is the right regulatory approach for a problem like
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total abolition which is
There are many alternatives. You can follow the outside accountant model of corporate affairs or the independent actuary model of prudential regulation by requiring all organizations involved in animal experimentation to have their auditing firms licensed for the purpose by the government.

I trust in the discussion that people with more practical experience of animal experimentation and its regulation in Australia will come up with some critical comment on the strengths and weaknesses of the different alternatives discussed here today. Equally, I hope that discussion will be informed by my central point that there is no best regulatory approach, though there may be a best hierarchy of approaches to lay the basis for negotiated reduction in the frequency and the amount of suffering imposed on animals in animal experimentation.

References


THE LIMITATIONS OF LAW IN THE REGULATION OF ANIMAL WELFARE

Margaret A Stone

Summary

Social, political and moral factors all impose limitations on the legal system's capacity to regulate animal welfare. The legal system can implement regulations; it cannot decide the content of regulation. Therefore clear decisions between the competing moral claims of animals and of humans are required before the legal system is involved.

The consequences of any decisions to restrict or abolish animal experimentation must be faced so that a clear decision can be formulated. Where a clear moral decision cannot be achieved, as for instance with the issue of abortion, the usual result is much confusion over the appropriate rules that effective legal regulation is impossible.

Even where a clear decision on the moral issues is made the capacity of the legal system to give effect to that decision may be limited. The moral stance of the proposed reform may be too much at variance with prevailing social convictions. Enforcement may be seriously impeded not only through the non-cooperation of the public at large but also of those officials charged with enforcement.

Finally even where proposed changes embody a clear moral position which is more or less accepted by the majority of the community, political pressure imposed by a small but disproportionately influential lobby group may nevertheless prevent their successful implementation.

Over the last few days much has been said about our attitudes to animals and how they need to change. A number of speakers have either expressly or implicitly looked to the law to effect or at least consolidate such changes, whether to prohibit or severely restrict animal experimentation or to prevent such interference. My task today is to sound a note of caution even of pessimism. However much I would like to outline ways in which the problems so graphically illustrated could be solved by legislative or judicial intervention, I am in fact going to concentrate on the limits of effective legal action.

The limitations which confront the legal system are dealing with the interests of animals in the whole, and more specifically with the question of animal experimentation. The legal system can implement regulations can be divided (with some overlap) into three categories: SOCIAL, POLITICAL and MORAL LIMITS. Undoubtedly the last is the most important of these and considerably permeates the other two.

Moral Limits

Moral Limits to effective legal action stem from the failure of the community to make moral decisions that can be translated into legal safeguards, obligations and duties. The basic question here is, "Where on our moral scale do we place the interests of animals?" There can be many different opinions on this issue. Some have emerged in the course of this seminar. The first speaker, Professor Rollin seemed to come close to the view that the