

...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 Senatore 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 such outside member has said that it is not an easy role: if you are too complacent you will be regarded as a collaborator, if too stringent, as an obstructionist. One is led to wonder whether, if it is to remain on the 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 in the institutions working to a Code. A small inspectorate provides for some monitoring and for an independent investigation of complaints. This certainly provides for accountability. In view of the case made above for protecting animal interests, I do not believe that it unduly restricts freedom.

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REGULATORY STRATEGY AND ANIMAL EXPERIMENTATION

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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 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 get 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? No one at this seminar has argued that there is no 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 Holborow 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-legalistically 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 massive 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 root of all 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. Simply because 5 per cent of experimentation runs a particular kind of risk, 100 per cent of the community of experimenters gets saddled with a rule which would be better targeted only on the 5 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 (Braithwaite, 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. There must be at least one lay member on the proposed Committees. I must agree with Professor Holborow that it is desirable that these lay persons would be best selected from a panel of names submitted by animal welfare groups. Otherwise the research organizations will be open to the criticism of selecting tame laypersons. Such a selection mechanism was suggested by the 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 research proposals. For reasons which I will get to soon, it would be most desirable to require these Committees to report to the Animal Research Review Panel any failure of a researcher to rectify a breach of the code and details 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 reveal that the Committee has failed to make self-regulation work, 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 Committees to set targets for reducing the number of animals used in experiments, and audits could be concentrated on organizations which fail to meet their targets.

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 contingencies facing that organization. The Animal Research Review Panel 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 inspectors. The primary function of government inspectors would be to ensure the independence of the Animal Care and Ethics Committee and its 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 regulatory body would not ratify private rules unless they were consonant with legislatively enacted guidelines. The proposal therefore amounts to a mix of private and public enforcement of privately written, but publicly ratified rules.

One advantage of this compromise between self-regulation and command and control is that rules are tailor-made for the realities confronting particular organizations. They can therefore avoid the feebleness of lowest common denominator 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 securing convictions), and easier to change in light of new information or new 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 punitiveness of government command and control. However, there are considerable weaknesses of the enforced self-regulation model. The most important one concerns the administrative feasibility of the Panel ratifying large number of codes written by an enormous variety of organizations involved in animal experimentation. A more detailed account of both the weaknesses and the strengths of enforced self-regulation has been provided elsewhere (Michigan Law Review, v. 80, 1982).

I do not necessarily advocate it as the best model for controlling animal experimentation abuses. But I want to throw out one other interesting feature of the model as I proposed it in 1982. This turned on the requirement that each regulated organization have a compliance director responsible for co-ordinating inspections and audits to monitor compliance. My suggestion was that whenever the compliance director recommended that certain practices change to come into compliance with the organization's animal experimentation rules, any failure to comply with this recommendation would have to be reported by the compliance director to the government regulatory body. That is, it would be an offence by the compliance director not to report the refusal to come into compliance. This would give the compliance director (and his or her Animal Care and Ethics Committee) enormous clout within the organization; experimenters would know that the consequence of thumbing their nose at the compliance director would be that government inspectors would automatically be on their backs.

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 interventionist option of self-regulation, to enforced self-regulation, to command and control regulation. Within the latter category, regulatory response can be increased from command and control with discretionary punishment, to command and control where every detected violation must be cited and subjected to formal enforcement action. In general, my view is that regulatory bodies should begin at the bottom of this enforcement hierarchy and work their way up as less interventionist approaches prove ineffective. That is, the best regulatory strategy involves telling the industry that self-regulation will be tried first; if they do not make self-regulation work effectively, then regulatory intervention will be escalated to enforced self-regulation; if enforced self-regulation fails, then command and control regulation with discretionary enforcement; if that fails, then command and control regulation with non-discretionary sanctioning. Now it might be said that self-regulation has already been tried and failed with animal experimentation, and from what I have heard, that may be right. Certainly there seems to have been a collapse of public confidence in self-regulation. That is simply to say that we are already part way up the hierarchy of regulatory response I am advocating.

The hierarchy extends from more voluntaristic regulation, which is likely to give experimenters a greater commitment to standards not imposed by coercion, at the one end, to more directive and punitive regulation at other end, which provides firmer guarantees that the bad apples will not thumb their noses at the standards. Obviously 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

scientific community to heel. But I believe that because self-regulation is always such a potentially soft option for the regulated interests, unless a self-regulatory system is part of an explicit social contract with government that unless you make this work, there will be regulatory escalation to more interventionist approaches, self-regulation will be little more than a symbolic activity. Regulated interests can do a lot of things to give their self-regulatory systems credibility. They can invite their critics from animal welfare groups to audit their self-regulatory systems, or (as some indeed have done) to sit in on institutional review committees, to make minutes of such meetings and internal inspection reports freely available. They can introduce exchange audits where groups of animal welfare auditors from different organizations report publicly on the effectiveness of one another's compliance systems. They can publish statistics on how many experimenters have been disciplined and in what ways for breaching voluntary codes. But it would seem that the scientific community has not been prepared to do enough of these kinds of things to build confidence in their self-regulation, and so they should expect escalation of regulatory response.

Academics who talk about the existence of an optimum regulatory approach for a particular problem are therefore talking nonsense. What is the optimum depends on how constructively the regulated industry is responding at different points along the hierarchy of regulatory response. Optimum regulation emerges from processes of negotiation between affected interests. I believe Australian governments are now beginning to learn this lesson with the tripartite approaches 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 eliminating abuses in animal experimentation. Nor am I suggesting that the particular hierarchy of regulatory response I have suggested 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 control regulation with non-discretionary sanctioning. All I am saying is that regulatory bodies should have a commitment to escalation up some sort of hierarchy of regulatory intervention and that this commitment should be communicated in advance to the research community so that they are given a more explicit incentive to make less interventionist approaches work better.

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 was absolutely necessary. While command and control approaches might be better for ensuring that when animals are used, all reasonable measures to assure their comfort are taken, the tax on harm has advantages in minimizing the use of animals in the first place. Moreover, the funds collected by the charges could be used to support audits to ensure honest payment of the charges and supplementary command and control inspections on cage sizes and the like. Indeed, they could be used to fund research on alternatives to the use of animals in experiments. In general, I have been a critic of taxes on harm as a regulatory strategy, but in the animal experimentation area, it does have some special merit as the only approach short of total abolition which is directly targeted on reducing the actual level of animal use in experiments.

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 compliance with animal welfare standards audited by one of a number of auditing firms licenced 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 I have discussed briefly 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 experimentation.

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THE LIMITATIONS OF LAW IN THE REGULATION OF ANIMAL WELFARE

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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 standard can be formulated. Where a clear moral decision cannot be achieved, as for instance with the issue of abortion, the usual result is such 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 is dealing with the interests of animals in the whole, and more specifically with the question of animal experimentation 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 or scales 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