Protecting Animals versus the Pursuit of Knowledge: the Evolution of the British Animal Research Policy Process

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Abstract

Animal research in the United Kingdom is regulated by the Animals (Scientific Procedures) Act 1986, which requires a Government Minister to weigh the expected suffering of animals against the expected benefits of a proposed animal research project – the "cost-benefit assessment" - before licensing the project. Research into the implementation of this legislation has been severely constrained by statutory confidentiality. This paper overcomes this hindrance by describing a critical case study based on unprecedented primary data: pig-to-primate organ transplantation conducted between 1995 and 2000. It reveals that researchers and regulators significantly underestimated the adverse effects suffered by the animals involved, while overestimating the scientific and medical benefits likely to accrue. Applying dynamic policy network analysis to this case in the context of the evolution of animal research policy indicates that an elitist, policy community type network has persisted since shortly after the network's formation in 1876. Animal research interests have repeatedly withstood pressure for change from animal protection groups due to their greater resources, structural advantages, and a culture of secrecy that facilitates an implementation gap in animal research regulation.

Keywords

animal research, Animals (Scientific Procedures) Act 1986, implementation, policy community, policy networks

Introduction: Re-evaluating UK Animal Research Policy

In this paperI seek to describe and explain not only *what* has been happening to animals in British laboratories, but *why,* and how democratic, or politically legitimate, those outcomes are.

Despite the high level of public interest in this issue spanning a period of 135 years, except for the groundbreaking work of Garner (1998), there has been virtually no political science research in this area. To a large extent, this neglect has been due to an extreme level of official secrecy, which means that primary data relating to actual policy outcomes and the interactions between researchers and regulators has been basically non-existent. (Garner, 1998; French, 1975)

Thus, one of the major advances of this research is the utilisation of historically unprecedented confidential primary data relating to one of the most sensitive and controversial animal research programme in recent times: pig-to-primate organ transplantation ("xenotransplantation") conducted between 1995 and 2000. This information has been disclosed following the settlement of legal proceedings involving the writer and the research company, Imutran Ltd. and its parent corporation, Novartis Pharma (Townsend, 2003). The data forms the core of a critical case study that enables the previous research constraints to be significantly overcome, thus facilitating a novel re-examination of this policy area.

Understanding Policy Processes: Policy Networks, Historical Institutionalism and Critical Realism

I have utilised policy network analysis as my theoretical framework in my investigation of animal research policy. Policy network analysis is a prominent, orthodox tool in public policy research. It takes the relationships between group and state actors in a particular policy sector as its starting point in trying to explain policy processes (Marsh and Smith, 2000). The most influential policy network typology was developed by Marsh and Rhodes (1992).

The analytical utility of the Marsh/Rhodes schema arises from its postulation that variations in key dimensions of policy networks affect policy outcomes. Thus, at one end of the spectrum, policy networks with a broad membership, fluctuating access for different groups, distant state-group relationships and high levels of conflict – "issue networks" in the Marsh/Rhodes terminology - will tend to produce outcomes that fluctuate and do not consistently favour one set of interests. On the other hand, policy networks characterised by exclusive membership, close integration between state actors and group members, and consensus – known as "policy communities" – will tend to produce outcomes that consistently favour network members at the expense of excluded groups.

This policy network approach also takes into account how macro-level factors such as the broader power distribution in society or national political institutions set the context that constrains and facilitates certain forms of network and hence outcomes. As the policy networks approach has developed, its practitioners have explored how a network also dialectically interacts with agents and their perceptions of policy outcomes to influence change and continuity (Marsh and Smith, 2000). This dynamic policy networks approach is consistent with the "historical institutionalist" method, which emphasises the crucial insight that policy-making is "path-dependent": key choices made in the past shape the future evolution of a policy.

Underlying these advances in policy networks and historical institutionalism has been an attempt to grapple with a more fundamental method issue – how we understand the relationship between structure and agency, or between institutions and the individuals within them? To what extent do institutions constrain individual agency, or how can agents affect or act independently of their institutional context? I have taken a "critical realist" approach to these questions. This recognises, firstly, that nondirectly observable, informal institutions or structures may affect behaviour and power relationships. It also accepts that actors' interpretations of structures affect their behaviour and hence outcomes, and that those interpretations are influenced by social constructions of reality (Hay, 2002).

For critical realists, social reality is highly complex, irregular and dynamic. Thus there is an emphasis on understanding specific, unique events in great detail rather than collecting limited quantitative data from a wide range of cases. Therefore, in order to explain contemporary animal research policy, as implemented under the 1986 Act, it is necessary to reconstruct the historical evolution of this policy network. Thus my approach is one of "process tracing" that involves the building of an empirically-based narrative of the interactions that generate continuity and change in policy-making (Hay, 2002). This type of rigorous, "diachronic" (Hay, 2002) approach is essential to an optimal understanding of political processes.

The Evolution of UK Animal Research Policy: 1876-1986

From this historical narrative of animal research policy, five critical junctures emerge, set out at Table 1. These critical junctures arise from network interactions that cause instability, for example, where the very success of a policy community stimulates policy outcomes that cause public disquiet, thereby creating an opportunity for excluded animal protection groups to politicise an issue and pressurise the existing network structures. The junctures are windows of opportunity for change that may influence future policy trajectories.

Table 1: Critical Junctures in the Evolution of UK Animal Research Policy

Date	Event	Number of Experiments
1876	Assent of Cruelty to Animals Act	277 (in 1877)
1882	Experimental groups take over implementation of 1876 Act	800 (in 1885)
1906-1912	Royal Commission of Inquiry	95,731 (in 1910)
1965	Littlewood Enquiry	3,700,000 (in 1960)
1986	Assent of Animals (Scientific Procedures) Act 1986	3,480,300 (in 1988)[1]

A key research question relating to the first juncture is: whose interests were served by the 1876 Cruelty to Animals Act? It has been argued that the 1876 Act was a straightforward consequence of anti-vivisection agitation. But in fact the power advantages enjoyed by animal researchers included greater resources and lobbying skills, so they were able to change the fundamental nature of the 1876 Act during its passage. Hence, the new statute tended to enhance protection for researchers from possible prosecution under general anti-cruelty laws, rather than protecting animals.

As a new network, however, vivisectors had not yet institutionalised relationships with the Home Office (the UK Government department responsible for implementing the 1876 Act) to the absolute exclusion of antivivisectionists. In other words, the network displayed some issue network characteristics at this point. The Act also gave the Home Secretary a substantial degree of discretionary power over licensing decisions. This loose structure meant that 15% of licence applications were refused by the Home Secretary on the grounds of excessive suffering or lack of utility (French, 1975).

Once experimenters realised that the Act wasn't working as they desired and had anticipated, they applied their significant organisational and expertise resources in 1881-2 to effect network change. Thus, the Association for the Advancement of Medicine by Research (AAMR) – in reality, a pro-animal research coalition - confronted the government, asserted its unique expertise to judge the legitimacy of licence applications, and thus succeeded in capturing the policy process. That power relationship has proved extremely resilient.

Interestingly, while the AAMR propagandised for animal research on the basis of its general utility, it did not attempt to assess the utility of proposed animal experiments when approving applications. Cost-benefit considerations that reflected lay opinion regarding whether research should be permitted were removed from the policy process in favour of scientific self-regulation. Consequently, animal experimentation underwent rapid growth compared to the 1876-1882 period.

The events of 1882 established a network of the policy community type, which excluded animal welfare interests and saw close relationships between government actors and researchers and the entrenchment of an ideological structure that consistently reflected the beliefs and interests of the pro-vivisection lobby that prioritised the pursuit of knowledge and professional autonomy over animal welfare and public accountability. Therefore 1882 is the most plausible starting point for the institutionalisation of animal research policy.

Both the 1912 Royal Commission Report and the 1965 Littlewood Report followed a similar pattern. Although antivivisectionists had managed to politicise the issue to create a critical juncture, the research lobby prevailed. The constraining power of the animal research lobby's knowledge, expertise, organisational and social status resources was such that the pro-vivisection ideology, such as the notion of scientists and their interest groups should dominate the licensing system, had become hegemonic. The scientific lobby were thus able to protect network structures such as its *de facto* control over application approvals and the prevention of stricter controls on permissible pain that may have interfered with achieving the object of the experiment. However, the very success of the animal research policy community, in terms of continued increases in the scale of animal experimentation, was a significant factor in stimulating public opinion and animal protection groups as part of a process that eventually led to the Animals (Scientific Procedures) Act 1986.

This narrative of the evolution of animal research policy has enabled the elucidation of the belief systems and policy goals of the various interest groups. By comparing these with policy outcomes it is possible to determine "who gets what" and hence gain a better understanding of the power distribution in this policy area. My research appears to confirm the usefulness of Orlans' (1993) typology of animal-related belief systems in modern "Western societies".

Animal research groups tend to adopt an "animal use" ideology which is based on the following key principles:

- Animal welfare is secondary to research goals.
- Animal experimentation is considered "necessary" and hence permissible in the pursuit of knowledge without immediate or foreseeable human benefit.
- It is opposed to utilitarian scrutiny of experimentation proposals.

- It supports professional self-regulation and opposes lay interference in animal experimentation.

The "animal welfare" belief system, manifest in groups like the United Kingdom's RSPCA, comprises the following positions:

- Animal welfare should be given significant weight in policy making.
- Proposals for harmful uses of animals should be subject to independent utilitarian analysis.
- Animal experimentation is only considered "necessary", and hence permissible, to satisfy urgent and pressing human needs.
- Lay control is required to ensure consideration of the wider public - and animals' – interests.

The third major belief system engaged in this policy area is "animal rights", which reflects the beliefs of the major antivivisection lobby groups. The principles of these groups include the following precepts:

- All sentient animals have inherent value and share humans' interest in avoiding suffering.
- Fundamental rights to protection from torture, killing, and enslavement should extend beyond the human species to other sentient animals.
- The last principle implies the abolition of animal experimentation.

Such groups are also sceptical regarding the utility of animal experimentation. It is interesting to note, however, that in their policy interactions animal rights groups tend to adopt the animal welfare position, indicating the extent to which the policy debate is ideologically circumscribed and certain positions entirely excluded from meaningful consideration.

The Impact of the Animals (Scientific Procedures) Act 1986

Formal Changes: The Cost-Benefit Assessment and the Animal Procedures Committee

The 1986 legislation appears to be is highly significant because it seemed to introduce a novel legal framework that represented a fundamental change, from "animal use" to "animal welfare", in the way that animals' interests are considered. Previously, under the regime established by the Cruelty to Animals Act 1876, licenses for animal research had been granted without any regulatory scrutiny of the potential value of the proposals or the potential pain likely to be caused to animals (Garner, 1998). However, the putative regulatory system introduced by the Animals (Scientific Procedures) Act 1986 is based on a cost-benefit assessment that involves weighing adverse effects likely to be experienced by animals used in procedures against the likely benefit to accrue to "man, animals and the environment" (Animal Procedures Committee, 1998, 43; Hampson, 1989, 240-1). This cost-benefit assessment is supposed to be the core determinant of whether proposals to conduct animal research projects should be legally permitted and, if so, the level of officially-sanctioned animal suffering.

The creation of the Animal Procedures Committee (APC) to advise the Home Secretary was another key innovation of the 1986 Act because it appears to have opened up access to the policy process to previously excluded animal welfare interests. Furthermore, unlike its predecessor, it was empowered to investigate and advise on its own initiative and put an annual report before Parliament.

Concerns have been raised, however, not just by antivivisectionists, as to whether the implementation of the new statute has given animals' interests the level of consideration indicated by the formal legislative and administrative framework (FRAME Trustees, 1996). Assessments of the real impact of the 1986 Act have been severely constrained by official secrecy, until the publication of the confidential Imutran documents.

Case Study: Assessing Policy Outcomes and Network Interactions

The Imutran xenotransplantation case study, and in particular the primary data, provides new insights into the way that animal research projects are scrutinised and regulated. Furthermore, this research programme was subject to relatively close regulatory scrutiny. This is therefore potentially a particularly valuable "critical" case study because if it reveals a policy process that still reflects an animal use ideology and excludes animal welfare considerations, then its generalisability is enhanced.

The operation of the cost-benefit assessment of proposed animal research projects is a ready-made and highly appropriate tool to discern how much weight the government places on the interests of those affected by this policy area. The "cost" side of the cost-benefit assessment is supposed to be represented by a measurement of the research programme's severity. Individual protocols and the whole research project are categorised as being characterised by either "unclassified", "mild", "moderate" or "substantial" severity.

In this case study, 95% of the experiments were classified as being of moderate severity. The severity class of research affects the level of scrutiny given to a licence application. Substantial severity experiments on primates are examined by the Animal Procedures Committee, whereas moderate severity experiments are not. Research classed as moderate, as opposed to substantial, severity is also easier to licence because it makes it easier to pass the cost-benefit test. According to government policy statements, Imutran's moderate severity experiments should have merely caused "local problems" with the transplant site (Home Office, 2003). More generally, in moderate severity procedures, animals are supposed to be euthanased before they experience serious suffering and death due to the experimental procedures.

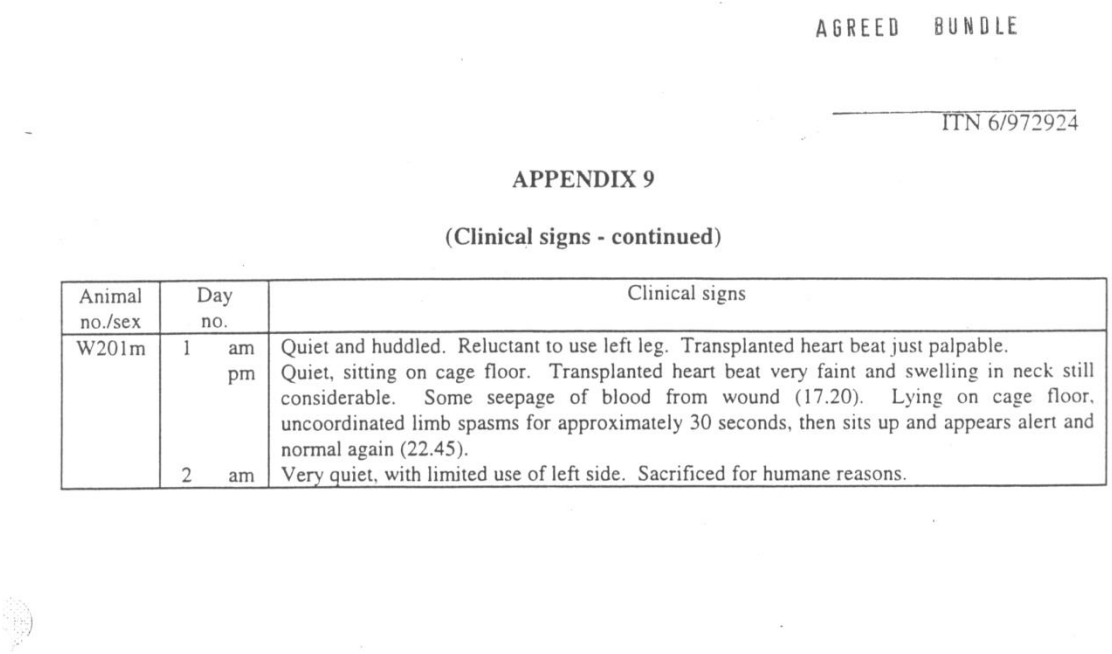
However, the following verbatim observations and comments from the researchers of primates used in moderate severity procedures, as revealed by the confidential study reports[2], demonstrate serious systemic welfare problems and lethal endpoints that breach the moderate severity limit:

- "Uncoordinated limb spasms" and "stroke"
- "in a collapsed state" and "found dead"
- "Gastro-intestinal toxicity, resulting in severe diarrhoea"
- "very distressed"
- "body and limb tremors"

- "grinding teeth, eyes rolling…"

Figure 1 is a scan of the clinical signs recorded for the last two days of Baboon W201m's life. He had a transgenic pig heart implanted into his neck in a protocol estimated to be of moderate severity.

Figure 1. Clinical Signs for Baboon W201m.



AGREED BUNDLE

ITN 6/972924

APPENDIX 9

(Clinical signs - continued)

Animal no./sex	Day no.		Clinical signs
W201m	1	am	Quiet and huddled. Reluctant to use left leg. Transplanted heart beat just palpable.
		pm	Quiet, sitting on cage floor. Transplanted heart beat very faint and swelling in neck still considerable. Some seepage of blood from wound (17.20). Lying on cage floor, uncoordinated limb spasms for approximately 30 seconds, then sits up and appears alert and normal again (22.45).
	2	am	Very quiet, with limited use of left side. Sacrificed for humane reasons.

The underestimation of severity is connected with the assessment of benefits insofar as Imutran appeared to believe that their transgenic pig organs would be able to keep primates alive for extended periods and in reasonable health, and thus would be likely to provide a source of viable transplant organs for patients on the waiting lists who might otherwise die.

During 1995 and 1996, Imutran had obtained approval for primate xenotransplantation procedures on the basis of claims in their licence applications that they were likely to:

1. establish an effective immunosuppressive regime that ensured long-term survival
2. demonstrate that a pig heart could support life in a nonhuman primate

However, an Imutran/Novartis confidential document entitled "Primate Development Plan" produced in April 2000 reveals that the lack of progress in overcoming immunological obstacles had led Novartis to set an eighteen-month time limit to decide whether xenotransplantation with their genetically-modified pigs was at all feasible.

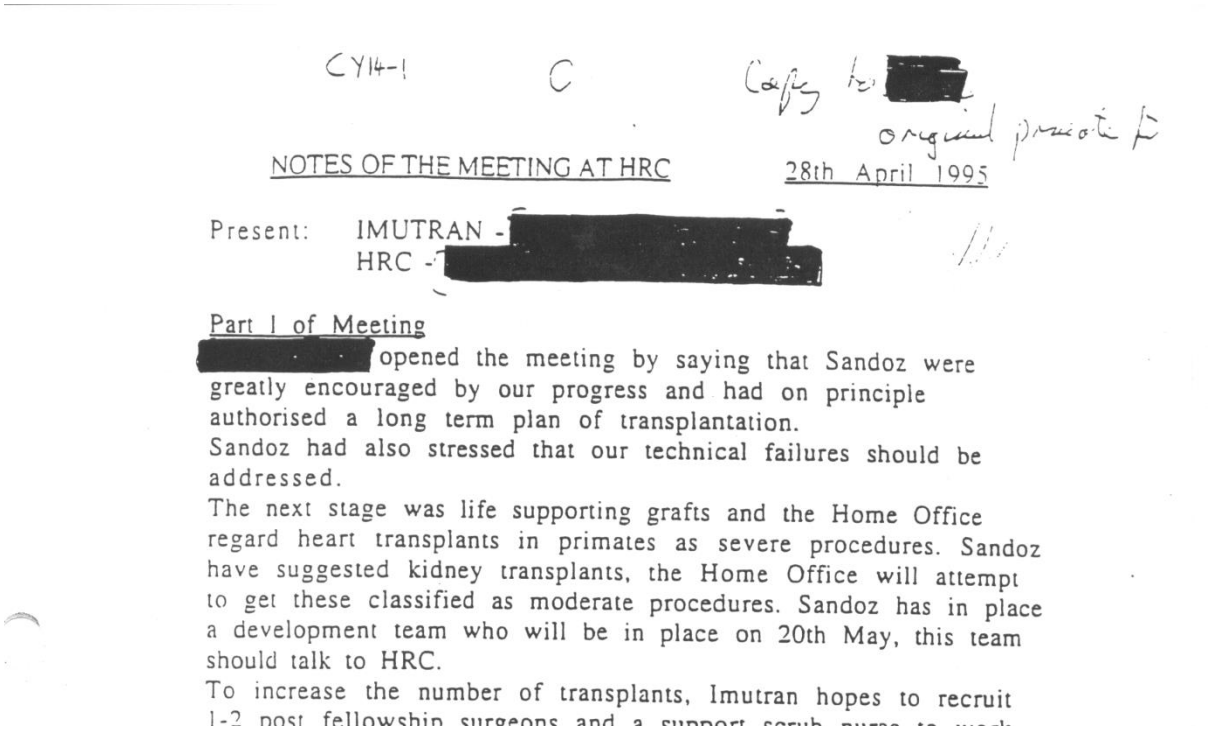
The government's UK Xenotransplantation Interim Regulatory Authority (UKXIRA), having considered the leaked confidential Imutran documents, averred in their annual report for 2000 that the likelihood of clinically viable pig organ transplants was "receding" (UKXIRA, 2001, 18). *New Scientist* magazine interpreted this as a polite way of saying that the technology was "dead in the water" (Anon.,

2002). Meanwhile, a transplant surgeon sitting on the committee told the open meeting to launch the 2000 annual report that Imutran's research had turned out to be a "blind alley" (Dark, 2001).

Despite five years of experimentation, immune responses were far from understood, never mind controlled. The fact that Imutran's research was permitted or allowed to continue, in spite of the lack of progress in achieving the objectives that had formed the basis of its authorisation, raises questions about the Home Office regulatory performance.

The Imutran research involved protocols the severity of which exceeded the "moderate" categorisation. The question is whether this was due to neglect, or to an intentional act on the part of the Home Office. The document in Figure 2, which shows minutes of a meeting between Imutran and the laboratory they contracted to perform the xenotransplantation studies, suggests that the Home Office went out of their way to breach the regulations to facilitate Imutran's experiments.[3]

Figure 2. Imutran/HRC Meeting Minute 28/04/95.[4]



CY14-1 C Copy to [redacted] original private file

NOTES OF THE MEETING AT HRC 28th April 1995

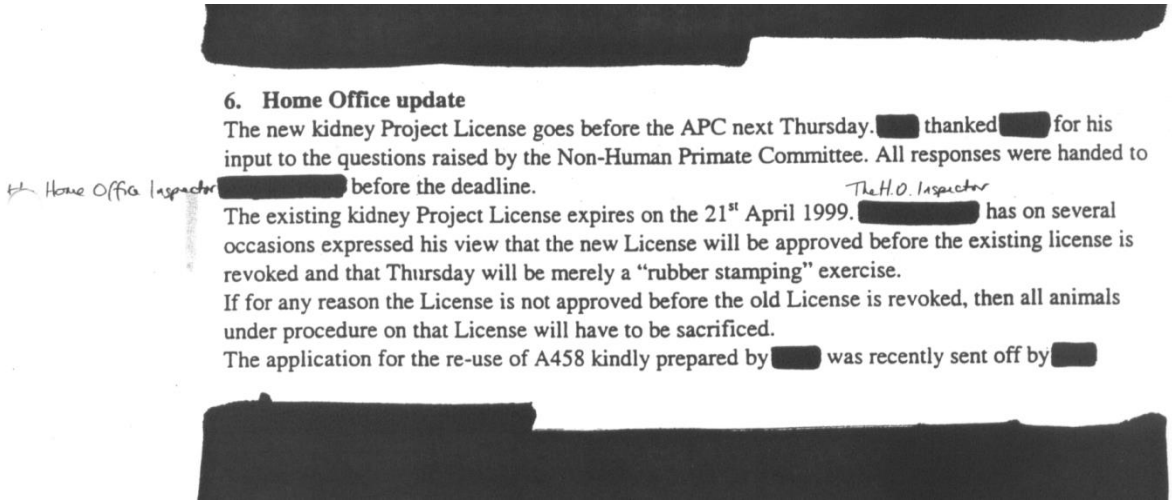
Present: IMUTRAN - [redacted]
HRC - [redacted]

Part 1 of Meeting

[redacted] opened the meeting by saying that Sandoz were greatly encouraged by our progress and had on principle authorised a long term plan of transplantation.
Sandoz had also stressed that our technical failures should be addressed.
The next stage was life supporting grafts and the Home Office regard heart transplants in primates as severe procedures. Sandoz have suggested kidney transplants, the Home Office will attempt to get these classified as moderate procedures. Sandoz has in place a development team who will be in place on 20th May, this team should talk to HRC.
To increase the number of transplants, Imutran hopes to recruit 1-2 post fellowship surgeons and a support scrub nurse to work

Minutes from a later Imutran meeting (Figure 3, below) reveal how Home Office inspectors assured Imutran that consideration of their research application to continue with pig kidney transplant experiments by the advisory Animal Procedures Committee would be a "'rubber stamping' exercise".

Figure 3. Imutran Meeting Minute March 1999.[4]



6. **Home Office update**

The new kidney Project License goes before the APC next Thursday. [redacted] thanked [redacted] for his input to the questions raised by the Non-Human Primate Committee. All responses were handed to the Home Office Inspector [redacted] before the deadline.

The existing kidney Project License expires on the 21st April 1999. The H.O. Inspector [redacted] has on several occasions expressed his view that the new License will be approved before the existing license is revoked and that Thursday will be merely a "rubber stamping" exercise.

If for any reason the License is not approved before the old License is revoked, then all animals under procedure on that License will have to be sacrificed.

The application for the re-use of A458 kindly prepared by [redacted] was recently sent off by [redacted]

[redacted]

Conclusion

This paper has reconstructed a historical narrative of the evolution of British animal research policy that indicates the existence of a policy community type network that was dominated by animal research interests and structured by an animal use ideology. The question remained as to whether the Animals (Scientific Procedures) Act 1986 resulted in significant change in the policy network whereby animal welfare interests were admitted into a new issue network alongside animal research actors, with policy outcomes correspondingly changing to reflect aspects of an animal welfare ideology.

However, the unique primary data presented in this critical case study of the implementation of the 1986 Act strongly suggests that researchers and Home Office inspectors cooperated to implement a skewed cost-benefit assessment which, throughout the lifetime of the project, underestimated animal suffering while exaggerating the potential benefits of the research. When scientific goals conflicted with the goals of reducing animal suffering, scientific goals prevailed. Consequently, the policy outcomes involved suffering that exceeded regulatory limits, with minimal benefits that failed to achieve the objectives that had formed the justification – both administratively and in public statements - for the Home Office's approval of the research. There is also evidence that on occasions these actors worked together to minimise the impact of APC scrutiny.

As this is a critical case study, the findings of which have the potential to be generalised across the policy area, it therefore appears that the evidence of maladministration and regulatory breaches relative to published policy laid before Parliament indicates a major implementation gap that in turn signifies the insulation of the network from Parliament, the public, and animal protection groups. This is a key sign of a policy community. Furthermore, the failure to implement the main formal regulatory innovations introduced by the 1986 Act suggests that the new law has not represented a significant policy change to one that reflects an animal welfare ideology. Thus, British animal research policy appears to remain dominated by animal research interests that interact with government actors in a policy community that excludes effective participation by animal welfare interests.

Notes

1. I have provided the figures for the number of tests to give an idea about how the practice expanded rapidly. In fact they peaked at about 5.5 million in the early 1970s and then reduced until 2001, before starting to increase again. The reason for the drop since 1970 is most likely due to economic factors and improvements in statistical and experimental techniques meaning that fewer animals were deemed required to produce 'valid' results.

2. The disclosed documents are accessible from www.xenodiaries.org. See also Lyons (2003).

3. Sandoz was the pharmaceutical company funding Imutran at the time. They later acquired Imutran and merged with Ciba to form Novartis Pharma.

4. The redacted words in Figures 2 and 3 refer tom individuals or the names of drugs. This redaction was part of the legal agreement that allowed publication of these confidential documents.

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