

The Legal Battle

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1. Introduction

Justified exposure of a horrific scandal

Five days after the original disclosure of the Diaries of Despair on 21 September 2000, Imutran Ltd obtained a temporary injunction from the High Court in London banning the publication of the report and the entire haul of leaked documents. The injunction did allow the documents to be disclosed to specified Government bodies. Imutran had claimed that the Defendants, Uncaged Campaigns Ltd and Dan Lyons (director of Uncaged Campaigns and author of the Diaries of Despair report) had:

- used and disclosed confidential information; and
- infringed the copyright in those documents which they claimed were copyright documents

Imutran’s action was *not* based on denials of the truth of our allegations and conclusions, but was founded exclusively on breach of confidentiality and copyright. Imutran and Novartis Pharma (who joined the action in April 2001) were seeking a permanent injunction preventing publication of the documents, together with costs and damages from the Defendants. We estimate their total costs to have been in the region of £500,000.

From the very beginning, we had defended our right to freedom of expression on the grounds that there was an **overwhelming public interest** in the publication of the Imutran documents because they revealed a number of extremely serious ethical and political concerns, particularly:

1. invasive and painful experiments on higher primates
2. the risk of dangerous viruses being spread to humans by Imutran/Novartis’ experiments

The importance of freedom of expression

“Modern democratic government means government of the people by the people for the people. But there can be no government by the people if they are ignorant of the issues to be resolved, the arguments for and against different solutions and the facts underlying those arguments.

The business of government is not an activity about which only those professionally engaged are entitled to receive information and express opinions.

It is, or should be, a participatory process. But there can be no assurance that government is carried out for the people unless the facts are known, the issues publicly ventilated. Sometimes, inevitably, those involved in the conduct of government, as in any other walk of life, are guilty of error, incompetence, misbehaviour, dereliction of duty, even dishonesty and malpractice...

Experience however shows, in this country and elsewhere, that publicity is a powerful disinfectant. Where abuses are exposed, they can be remedied...”

Lord Bingham in R v Shayler (21 March 2002; [2002] UKHL 11), discussing the importance of freedom of expression in a democracy.

3. the Home Office's collusive relationship with Imutran and its failure to monitor and apply regulations properly
4. inaccurate claims made by Imutran/Novartis concerning the success of their research and the welfare of the primates they have destroyed
5. the infliction of "severe" suffering on animals which is supposedly banned by British and EU legislation

Our legal argument relied on the common law Defence to a breach of confidence action (exposure of wrongdoing in the public interest) and on the similar statutory defence to actions for breach of copyright. We further contended that our right to freedom of expression, and the general public's right to receive information, under the European Convention on Human Rights had been violated, and that as the documents reveal public misconduct, a permanent injunction was not proportionate and that limited disclosure to Government bodies was not sufficient to remedy the violation.

The issue of the independence and integrity of the UK Government's Home Office (the department responsible for enforcing laws regulating animal experimentation) was a significant aspect of the Defence. Imutran and Novartis argued that disclosure of the leaked documents to the Home Office (and certain other Government departments) was sufficient to meet any public interest concerns arising from their documents. However, given that the documents provided strong evidence of deliberate malpractice and bias on the part of the Home Office, we believed that such disclosure was fundamentally inadequate in a democratic society.

We have won the right to publish the majority of the documents that we had listed as directly supporting the five key elements of the public interest defence. In addition, the Diaries of Despair report is now published in virtually complete form, and it contains additional significant information extracted from documents that remain injunctioned. The names of individuals and collaborating institutions have been removed from the documents, as well as the names of drugs and dosing regimes.

The outcome of the legal battle is an overwhelming endorsement for our campaign for an independent judicial inquiry into this horrific scandal.

Leading figures back publication

The importance of the documents for the purposes of informing the public in the subject of animal experiments is clearly set out by Professor Singer, DeCamp Professor in Bioethics at the Centre for Human Values, Princeton University, New Jersey, USA, who wrote to support the Defendants. Professor Singer states that

"... Prior to seeing this report ['Diaries of Despair'], I had quoted from press reports of these materials [i.e. the Daily Express articles of 21 and 22 September 2000] in a presentation to the Fifth World Congress of the International Association of Bioethics, held in London on September 23rd... They clearly considered information about the nature of primate research carried out by Imutran to be relevant to their understanding of the ethical issues raised by research on animals. Unfortunately, because I had not seen the original documents, I had to caution the audience that I was relying on a newspaper report that might not give a fair picture of the documents. **I regard it as essential for a fair assessment of the research that the documents be made available in full**, at least as far as the impact of the research on the animals is concerned... The use of animals in research is obviously, **an issue of great public concern...**" (emphasis added).

The Defendants also received support from:

- Professor Robin Downie. Professor of Moral Philosophy at Glasgow University and a former advisor to the Government on the ethics of xenotransplantation.
- Norman Baker MP, Liberal Democrat spokesperson on the Environment and Animal Welfare
- Dr Gill Langley, scientific advisor to animal groups and a member of the Animal Procedures Committee, which advises the Government
- The RSPCA, who intervened in the proceedings because of the serious suffering revealed by the documents.
- Two leading animal protection organisations, Animal Aid and the British Union for the Abolition of Vivisection, who both provided witness statements and other input and support.

2. The public interest

The fundamental principle to bear in mind is that each document, and the very fact of our legal victory, helps form a powerful case that an independent judicial inquiry is necessary in order to investigate and rectify the grave ethical, political and legal failures committed by the Government in its handling of the concerns raised by the Diaries of Despair exposé.

i) invasive and painful experiments on higher primates

Animal experimentation is a matter of profound public interest. Imutran's xenotransplantation research at HLS was particularly severe and controversial. The Government has claimed that informed public opinion is an influence on how animal research is regulated¹. Unfortunately, in practice, this is deceptive. Contrary to the rhetoric which applauds democratic participation in Government decision-making, the Government is behaving regressively and continues to block access to the information necessary for an enlightened public debate² and there is no evidence that the Government takes public opinion into consideration when regulating animal experimentation.

Enabling an informed public debate has been a major public interest consideration in favour of publishing the leaked Imutran documentation. Not surprisingly, public opinion regarding experiments on animals is strongly influenced by the severity of the suffering involved.³ This mirrors the cost/benefit assessment which is at the heart of UK legislation on animal experiments – an assessment which, in practice, is applied in a perverse manner by the Government.

The Animals (Scientific Procedures) Act 1986 makes it clear that the interests of animals should be taken into account when the Secretary of State assesses licenses. Without access to documents such as those leaked from Imutran, which undisputedly identify significant levels of suffering on the part of the animals involved, the general public cannot be in a position to hold the Secretary of State to account when deciding whether (s)he has given adequate weight to the consideration of animal welfare. By publishing Imutran's documents, Uncaged Campaigns are attempting to ensure that the interests of animals are recognised and weighed in the balance, as required by law, and that the general public is in a position to hold the Secretary of State to account in this respect.

Our legal victory means that the public can now view the evidence and judge for themselves, rather than relying on the selective presentation of information by those responsible for animal experimentation.

Much of this evidence is set out and explained in the Diaries of Despair report, particularly in chapters 4 & 6. The following documents also reveal the suffering and harm endured by the animals:

- the 'experimental design' and the 'clinical signs' from the study reports
- WCB29 (Document/Table: "Use of Baboons in Comparative IS Study." Estimated date: mid-May 1997. Includes information about "Outcome" of experiments such as 'Technical Failure', 'Rejection', 'Rejection Type', and 'Comments' such as 'Collapsed', 'Died on table'.)
- WCB30 (Letter from Imutran to a Home Office Inspector, 13 January 1998, including surgery reports for November and December 1997. Includes reports of outcome of experiments, such as "Renal Failure", "Euthanased, poor condition".)

¹ The Chief Inspector has stated that this process of weighing involves "... precedent, but also [must] accommodate developments in welfare, science, ethics, political thinking and **informed public opinion**" (emphasis added). Report of the Animal Procedures Committee for 1997, paragraph 3.8, p.52

² Government response to House of Lords Ad Hoc Select Committee on animal experiments.

³ "Let the People Speak", New Scientist, 22 May 1999.

- WCB31 (Letter from Imutran to a Home Office Inspector, 20 April 1998, including surgery report for March 1998. [Similar to WCB30])
- CY16 (“Kidney Summary since Sept. 1”. Describes fates of animals, e.g. “Grossly enlarged kidney...”)
- CY17 (MD Application, Pig to primate renal xenotransplantation. Describes intended experiments.)
- CY18 (Letter from Imutran to Home Office, 4 February 1998. Describes “unusually high level of technical failures”, “pancreatitis”, “renal vein thrombosis”.)
- CY19 (Letter from Imutran to Home Office, 11 February 1998. Attached: surgery reports for February 1998 and summary of results of study IAN009. [Similar to WCB30 & 31.]
- CY22 (“Clin/Path Meeting Minutes”. Date of meeting: 26th March 1999. Date of minutes: 12th April 1999. Describes outcome of experiments e.g. “Severe CMV infection”, “AVR with renal failure and primarily problems with the wound site which lead to euthanasia.”)
- CY23 (“Clin/Path Meeting Minutes”. Date of meeting: 23rd April 1999. Date of minutes: 26th April 1999. [Similar to CY22.]
- HLSAPP5B (Internal Imutran Memorandum, 9 August 1995. Refers to suffering of monkeys in study ITN3 – ‘general debility and non-specific diarrhoea’, ‘nausea secondary to the immunosuppressive agents’.)
- HLSAPP7B (“Database entries,” letter from Imutran, 14 May 1999. Includes pathology results e.g. “AVR/CXR with pneumonitis + pleural effusion”.)

ii) the risk of dangerous viruses being spread to humans by Imutran/Novartis’ experiments

Imutran’s internal documents and correspondence with infectious disease experts at the Ministry for Agriculture, Fisheries and Food (MAFF) reveal transplant procedures mistakenly carried out on primates carrying Herpes B virus, which is regarded as a potential danger by the UK Government. There is a clear public interest in establishing the facts about the possible threat to public health posed by this error, particularly in light of the fact that the experimental transplant procedures were conducted by transplant surgeons who would then perform transplants on immunosuppressed human patients – a worrying scenario highlighted in MAFF’s advice.

- WCB21 (Letter from Ministry of Agriculture, Fisheries and Food to Huntingdon Life Sciences, “IMPORT OF BABOONS...”, 8 February 1999.)
- WCB22 (Imutran Document, “Pre-surgery Anti-pig Antibody titres in baboons”, 06/03/98.)
- HLSAPP4A (“LATE ARRIVAL OF BLOOD SAMPLES,” fax to HLS from Imutran, 23 October 1996.)

iii) the Home Office’s collusive relationship with Imutran and its failure to monitor and apply regulations properly

In addition to the specific concerns raised within the originally leaked documents and dealt with here, there are other instances that demonstrate the Home Office’s bias and unwillingness to enforce the regulations supposed to govern animal experiments, leading to

horrific animal cruelty and a failure to punish breaches of the law. These are discussed in the "Home Office" section.

(a) Deliberate underestimation of animal suffering

Document CY14 (minutes of an Imutran/HLS meeting) describes how, back in 1995, Imutran report that "the Home Office will attempt to get [kidney transplants] classified as moderate procedures." An examination of the effects of these procedures on animals (see section 6.5 of Diaries of Despair and the clinical signs for all the kidney studies) will demonstrate that a 'moderate' categorisation for their severity (as opposed to a 'substantial' rating or a prediction of severe suffering which would automatically prohibit them) is impossible to justify (see box right). By underestimating suffering, the Home Office helps make it easier for the experiments to be permitted.

The Home Office also classified the following experiments as "moderately" severe:

- the transplantation of piglet hearts into the necks of baboons
- pig hearts into the abdomens of wild-caught baboons
- pig hearts into the abdomens of cynomolgus monkeys (ITN3)

Bending the rules past breaking point

The Home Office's 'Guidance on the Operation of the Animals (Scientific Procedures) Act 1986' described how the likely severity of procedures is assessed. 'Moderate' procedures include "surgical procedures provided that suffering can be controlled by reliable post-operative analgesia and care", while on the other hand procedures regarded as being of "substantial" severity include "Procedures... [that] result in a major departure from the animal's usual state of health or wellbeing... [including] some models of disease and major surgery where significant post-operative suffering may result. If it were expected that a single animal would suffer substantial effects, the procedure would warrant a severity limit of 'substantial'."

Pig-to-primate kidney xenotransplantation experiments (classified as 'moderate') involved the modelling of kidney rejection and thus failure, causing nausea, vomiting, lethargy and death as a result of blood poisoning. At the same time, various drug combinations were tested in the primates to investigate how they affected the rejection mechanisms. In actuality, these were just some of the effects:

Two days after transplant, **W560f** was killed. She had been lying on the cage floor and the grafted kidney had failed to produce urine after the operation had finished. **W548f** survived six days. For part of this time she had been reluctant to use her swollen legs, and had produced green vomit on day two. The morning of her sacrifice due to renal failure and a ureteric obstruction (blockage of the ureter, which carries urine from the kidney to the bladder), she was found "lying on the cage floor" and subsequently "very weak and unsteady when moving."

On **V337m's** seventh and final day, he was observed:

am:	Very quiet and subdued. Occasional trembling. Appears unsteady.
pm:	Huddled. Unwilling to move. Collapsed state. Sacrificed.

The suffering caused by these experiments was also far in excess of 'moderate'. The new documents leaked from the Home Office reveal that Imutran hugely underestimated the level of suffering in their applications for permission to conduct the research.

(b) 'Rubber stamping': the Inspectorate's private view of the regulatory framework

The minutes of an Imutran meeting in March 1999 (see document CY24-2) record that their Home Office Inspector "has on several occasions expressed his view that the new License will be approved before the existing license [sic] is revoked and that Thursday [i.e. a meeting of the Animal Procedures Committee to discuss the licence application] will be merely a 'rubber stamping' exercise." The APC relies on information given to them by applicants and the Inspectorate in their deliberations on whether to recommend to the Home Secretary that a project of animal research should be licensed and under what circumstances.

(c) Direct concealment of regulatory violations from Parliament and public

The closeness of the Home Office's relationship with Imutran and their associates even went so far as covering up for mistakes that lead to animal suffering and death during the xenotransplantation programme:

Three primates imported specifically for the Claimant's research died en route from the Philippines to Huntingdon Life Sciences (HLS), the company contracted by Imutran to carry out the work (see document CY5). The inadequate space and ventilation in the transport crates were considered to be contributory factors. Apart from the important ethical issue of the suffering of the animals in the course of this journey, which lasted 48 hours, the crates also breached fundamental requirements of international air transport regulations on size and ventilation – with tragic consequences. However, both the minutes for the APC's February 1999 meeting and Mr O'Brien's Parliamentary Answer of 28 June 2000 (Written Answers, Hansard 28 June 2000, Column 522W & 521W) fail to register this fact. Indeed, Mr O'Brien's statement in his answer of 28 June 2000 – "IATA minimum dimensions were not breached" - was untrue.

Other documents that expose weak regulation of primate importation are discussed in chapters 5 and 6 of the Diaries of Despair report. Published documents relating to this are:

- WCB1 (lack of independent advice regarding approval of supplier of wild-caught baboons)
- WCB3 (underestimation of journey time in applications to import wild-caught baboons)
- CY7 (report on discussion with Home Office Inspector)
- CY8 (letter and application to import monkeys)
- CY10 (letter and application to import monkeys)

(d) Covering-up for Huntingdon Life Sciences

The Home Office decided to re-issue Huntingdon Life Sciences (HLS) with a new Certificate of Designation (essentially a permit to conduct animal experiments) in 1997. In re-issuing the Certificate, the Home Office announced to Parliament and to the public that HLS had satisfied 16 conditions which were designed to prevent incidents of malpractice and regulatory breaches at the company, some of which were exposed by an undercover investigation broadcast on Channel Four in March 1997 ('It's a dog's life'). However, Imutran's documents show this not to have been the case (see section 7.5 of Diaries of Despair).

For example, just one month after the Home Office had given a new Certificate to HLS, a group of monkeys were illegally re-used in experiments at the establishment (see document hlsapp5a). This breach of the law should have been prevented by the implementation of the improvements that formed the 16 conditions laid down by the Home Office - but the department did not revoke HLS' Certificate in the light of these illegal procedures. Furthermore, Home Office ministers, officials and others have continued to claim, falsely, that HLS fully satisfied the 16 conditions. Errors and omissions in the conduct of the studies also took place during the period when HLS were said to be in the process of meeting the 16 conditions, and directly afterwards.

Perhaps the most startling errors at HLS are revealed by correspondence dated January 1999 (see section 7.8 of report and documents hlsapp7c & 7d). The letters themselves tell a powerful story as an Imutran scientist berates HLS for an accidental quadruple overdose of one monkey who died the following day, and the failure to take a vital blood sample at the necessary time.

In addition to the potentially devastating impact these failures may have had on animal welfare, they also represent evidence of manifold Good Laboratory Practice (GLP) shortfalls as well as undermining further the notion that HLS really did satisfy the 16 conditions set by the Home Secretary. Yet in a letter to Gerry Steinberg MP, Minister Mike O'Brien continued to maintain that "There have been no significant problems at Huntingdon Life Sciences since the events of 1997..."

(e) Breaches of absolute legal limits on suffering

See section 2(v) below

(f) The cost/benefit assessment

The cost/benefit assessment, which lies at the heart of the regulatory framework created by the 1986 Act (Section 5(4)), states that the Secretary of State must weigh the likely adverse effects on the animals to be used in a research programme against the benefits supposed to accrue as a result of the research before deciding whether to issue a licence for the animal experimentation.

These are the features of the crucial cost-benefit assessment described by the head of the Home Office Inspectorate charged with scrutinising applications to conduct vivisection:

- “Judgement on the likely severity of the adverse effects on animals”
- “Standards of care and accommodation”
- “Technical competence of the people and establishments to be involved in the project”
- “Relevance of the animal ‘model’ to human condition”
- “Likelihood of ‘success’”
- “How the data generated will be used”
- “Utility of the product or substance being tested”

Many factors relating to these considerations have already been discussed above. The Imutran documents reveal damning evidence that, far from conducting a rigorous assessment, the Home Office fails to take the suffering of animals into account while lacking the will to question either the ‘benefits’ predicted by researchers or their competence to conduct the experiments (see section 8.1 of Diaries of Despair).

Index of documents that demonstrate Home Office misconduct:

- All documents referred to in connection with (i) above (invasive and painful experiments on primates), because they demonstrate the “costs” inflicted on animals (due to be taken account of in the cost-benefit assessment).
- All the “New Documents” leaked from the Home Office in October 2002. See discussion of these documents for their relevance.
- I3 - Note of meeting between Imutran executives, 20 April 1995. (Reveals intention to manipulate the Home Office Inspector to ensure “upward support for the application”... while making him feel like “a jolly good bureaucrat”)
- WCB1 - Letter from Home Office to Imutran, 21 February 1997: “Animals (Scientific Procedures) Act 1986 – Overseas source of baboons.” (Approval of baboon cages on basis of information supplied by Imutran.)
- WCB3 - “Application from a Project Licence Holder or Deputy for Permission to Acquire Non-Human Primates from a Non-Designated Breeding Centre for use in Regulated Procedures.” Submitted 23.6.98. Approved 29.7.98. (Wild-caught baboon acquisition form – journey time underestimated.)
- WCB14 - Fax from wildlife broker to Imutran, 15.4.99. (Refers to South African baboon breeding project which was part of strategy to evade animal welfare regulations, known by the Home Office.)
- WCB18 - Letter from Imutran to Home Office Inspector, 10 February 1999. (Presumption of re-approval of monkey supplier following deaths in transit – reference to enclosed fax from South African institution regarding baboon breeding programme there which was part of Imutran strategy to evade animal welfare regulations.)

The RSPCA report comments:

“The ‘costs’ (harms) to animals both as sources of xenografts, and in particular in the associated research, are unquestionably extremely high... Having read and assimilated the information on survival contained in the study reports, the Society considers that in no way did the animals survive sufficiently well, with a sufficient quality of life post-transplant, for the transplant procedures to be considered successful. Hence we do not consider that a significant and justifiable benefit was being achieved.”

- WCB19 - Discussion document. "Cape Town possibilities for expanding Imutran Xenotx." (Reveals intention of Novartis to evade animal welfare regulations by relocating to South Africa.)
- WCB20 - Fax from South African Institution re: "BABOON BREEDING PROJECT", 31 May 1999.
- WCB26 - Fax from HLS to Imutran, shortly after Wednesday 23 June 1999, "Xenotransplantation Programme at Huntingdon Life Sciences." (Baboons held in captivity for several months in breach of a commitment to Home Office.)
- WCB24-1 "Home Office Six Monthly Report. July-December 1999. Imutran." (Confirms that baboons held in captivity at least six months, and lack of progress in the research.)
- CY5 - Letter (with attachments) from Imutran to Home Office Inspector, 11 August 1998, "RE Delivery of 33 Cynomolgus Macaques on 6 August 1998." (Deaths in transit, very long journey time compared to estimate, breaches of regulation denied by Home Office.)
- CY8 - Letter from Imutran to Home Office Inspector, 22.1.99. (Example of 30 hour journey time estimate.)
- CY10 - Letter from Imutran to Home Office Inspector, 10.5.99. (Example of 30 hour journey time estimate.)
- CY7 - Fax, Imutran to HLS, 19.11.98. ('Cosy' notice from H.O. inspector of likely re-approval of monkey supplier.)
- CY14 - "Notes of the Meeting at HRC, 28 April 1995." (Kidney xenografts – "the Home Office will attempt to get these classified as moderate procedures.")
- CY20 - "Progress Review Meeting Minutes". Meeting held 29 January 1999. Minutes generated 1st March 1999. (Reveals intention to kill 'unsuitable' monkeys – ethical and cost/benefit issues (wasted lives).)
- CY21-3 - "Responses to Comments Raised by the Primate Sub-Committee" (estimated date – *circa* March 1999) ("It should be noted that 120 animals is a maximum figure and, as clinical trials are initiated, the actual number of transplanted animals is likely to reduce." Demonstrates exaggeration of likelihood of successful research, raising concerns about cost/benefit assessment and showing Chief Inspector's review to be inaccurate.)
- CY24 - "Progress Review Meeting Minutes". 30th March 1999. (Reveals dismissive attitude of Home Office Inspector to Animal Procedures Committee – "rubber-stamping")
- Hlsapp1 - "Subcontractor Inspection Report" by Imutran, 8 February 1996. (Reveals GLP/competence failures at HLS).
- Hlsapp2 - "A report on the Good Laboratory Practice (GLP) status of historical studies conducted at Huntingdon Life Science on behalf of Imutran and recommendations for improvement" by Imutran, 28 February 1996. (Imutran criticism of HLS's ability to perform studies effectively.)
- Hlsapp4a - "LATE ARRIVAL OF BLOOD SAMPLES," fax to HLS from Imutran, 23 October 1996. (Demonstrates inadequate service from HLS – these samples required to calculate immunosuppressant doses, etc)
- Hlsapp4b - Fax to HLS from Imutran, 13/12/96. (Reveals sub-optimum performance of studies – reference to "recent graft failures" & the need to "reduce the drug related side-effects".)
- Hlsapp5a - "A report on the Accidental re-use of animals under Project Licence PPL 80/848," (including accompanying correspondence), 13 January 1998. (Illegal reuse due to communication breakdown – 6 weeks after re-issue of HLS' Certificate of

Designation after supposedly meeting 16 conditions designed to prevent such failures.)

- Hlsapp7c - "Further Drug Administration Error," letter from Imutran to HLS, 6 January 1999.
- Hlsapp7d - Fax from HLS to Imutran, 15 January 1999. (Acknowledging mistakes and failures at HLS during Imutran's studies.)
- Hlsapp8b - "Primate review report", internal Imutran email, 17/09/99. (Reveals "severe problems with data" – how the data is used is an element of the cost-benefit assessment, plus there are GLP considerations – this document also refers to "Regulatory impact " of the study data.)

(iv) inaccurate public statements by Imutran/Novartis

It is vitally important in a democratic society that truthful information is available to satisfy the justified high level of public interest and concern relating to animal experimentation and xenotransplantation research. Uncaged Campaigns and Mr Lyons argued in *Diaries of Despair* and in the legal proceedings that the Imutran documents revealed that public statements made by the company were on occasions significantly inaccurate, incomplete and misleading. Such economy with the truth would be likely to affect both the ethical and political debate regarding Imutran and Novartis' xenotransplantation research and could adversely affect animal welfare and the interests of patients. Furthermore, Imutran submitted false information to the Government in its applications for licenses to perform its experiments, a potentially criminal breach of the Animals (Scientific Procedures) Act 1986.

(a) Hyping xenotransplantation

Imutran and Novartis have been highly selective when disclosing the results of their xenotransplantation research programme. This would tend to encourage public and commercial support for the experiments – a level of support that may not have been forthcoming had the full facts been in the public domain. Only a small proportion of the primates sacrificed in the research are acknowledged in public – and these tend to represent the very longest surviving monkeys and baboons. The leaked documentation revealed significant differences between the version of events presented by Imutran in published scientific papers, and the real results of the research.

For example, one published paper - "Three-Month Survival of HDAFF Transgenic Pig Hearts Transplanted Into Primates", *Transplantation Proceedings*, 31, 958 (1999) – corresponds to two studies, ITN19 and ITN25 (see discussion in section 4.2 of the report). The confidential documents raised concerns about the accuracy of the reported drug regimes administered to the animals. The paper focussed on nine of the ten longest survivors from a group of 22 baboons – a major concern arising from this is that the public image of the results of the research does not reflect the full reality. On balance, the research caused far more suffering and death with lower average survival times than would be apparent from Imutran's statements – these considerations would have a direct impact on public opinion and the results of the cost-benefit assessment required in the licensing of the research.

Recorded incidences of hyperacute rejection (HAR) of transgenic pig organs that occurred during study ITN19, the abolition of which was said to have been the fundamental breakthrough achieved by Imutran, were not disclosed in this paper. If the transgenic organs did not reliably quell HAR then a fundamental question mark would have hung over the viability of Imutran's hDAF organs and undermined the potential benefits of the research claimed for by Imutran.

In this paper, Imutran also claimed that the immunosuppressive regime was "well tolerated by the recipients" – a perusal of the clinical signs for study ITN19 casts serious doubt on the accuracy of this statement.

Another paper - published in the Journal of Heart and Lung Transplantation in February 2000 – focussed on one single baboon who was the longest survivor with a life-supporting pig heart. The image of a totally healthy animal portrayed in this paper is exposed as an exaggeration by the confidential clinical signs and the unreported fact that the heart had swollen to three times its original weight by the time the baboon had collapsed and died.(see section 4.3 of the report).

Transplant patients and the public in general have consistently been led to believe that xenotransplantation offers a realistic prospect of providing a supply of organs for patients with organ failure. In 1995, Imutran predicted that the first human trials of their transgenic pig hearts would take place the following year.⁴ In 1998, imminent trials of pig kidneys were forecast.⁵ But despite an intensive research effort that has sacrificed hundreds of higher primates and thousands of pigs, the goal of achieving viable xenotransplantation remains as remote as ever. The development of the particular line of transgenic organs that Imutran had tested in cruel experiments for five years – known as hDAF – appeared to be in crisis, with Novartis setting an 18 month time limit (as of April 2000) for achieving a quantum leap in survival times.

For example, in a promotional booklet that was distributed at a meeting attended by MPs at Parliament in December 1999, Imutran and Novartis talk of

“*refining* the immunosuppressive protocols **that will be used** to prevent subsequent rejection following xenotransplantation” (emphasis added).⁶

However, a confidential report submitted by Imutran to the Home Office at the end of 1999 admits that

“at this time there is no therapy of which we are aware that will reverse this process [of rejection of xenotransplanted organs].”

This does not square with the notion of “*refinement* of immunosuppressive protocols”, we submit.

Behind the scenes, Imutran scientists consistently hinted at imminent clinical trials of their pig organs throughout their communications with the Home Office regulators in order to smooth the process of licence approval. The existence of such claims was explicitly denied in the Home Office’s response to Diaries of Despair.

Patients and their families have a genuine interest in knowing the true state of progress in relation to such technology. Furthermore, the potential to skew Government policy on transplantation is an obvious unwelcome repercussion of such hype, and the possibility of undermining the effectiveness of the human organ donor register – resulting in less organ transplants and therefore human suffering - has been noted by an expert advisory committee.⁷

(b) Secret suffering

Some of the statements highlighted in the previous section served a dual purpose of showing both the progress of the xenotransplantation research and also the animal welfare

⁴ “Pig heart transplant ‘breakthrough’ stirs debate over timing of trials”, Nature, Vol 377, 21 September 1995, pp.185-186. “Pig-to-human heart transplant slated to begin in 1996”, Nature Medicine, Vol 1, Number 10, October 1995, p.987.

⁵ New Scientist, “Waiting for a miracle – time is running out for organ transplants from animals”, 12.1.02, p.3.

⁶ “Xenotransplantation” by Novartis/Imutran, distributed e.g. at House of Commons December 1999.

⁷ “Animal tissue into humans”, A report by the Advisory Group on the Ethics of Xenotransplantation, Department of Health, 1996, para 4.110.

implications through rose-tinted spectacles. In fact, when responding to questions prior to publication of the exclusive newspaper story, Imutran told the Daily Express: "the animals do not suffer" and the newspaper reports this extraordinary comment three times in the initial exposé on 21 September 2000. It is also repeated in a Cambridge Evening News article.⁸ This is a blatant falsehood, and a very significant one at that.

The 1986 Act specifically regulates procedures likely to cause pain, suffering, distress and lasting harm. Clearly, the clinical signs show that the animals suffered. The RSPCA's report into the Diaries of Despair takes Imutran to task for its failure to acknowledge the suffering its research caused to animals:

"The Uncaged report also criticises Imutran for not acknowledging the extent of the suffering of animals in the research. This is also true of our experience of the statements made by the company outside of the scientific community and within the public domain. The RAD [The Society's Research Animals Department] has itself strongly criticised an Imutran leaflet for not acknowledging the animal suffering associated with the development of xenotransplantation."⁹

Indeed, references to experiments on primates are conspicuous in their absence from Imutran's PR material.¹⁰

Imutran's attempts to distort the evidence of the clinical signs continued in its submissions to the RSPCA and the Court. The RSPCA report is scathing about Imutran's attitude:

"In their response to the Uncaged report and in comments reported elsewhere, Imutran, however, seem either unwilling to acknowledge that the primates used suffered, or are ambivalent with regard to animal suffering."¹¹

The Society's report goes on to criticise Imutran's attempt to dismiss the relevance of clinical signs, where they claim that observations such as "quiet" and "huddled" are of no concern. These brazen denials were also made in an Imutran submission to the High Court. The RSPCA goes to some lengths to critique this interpretation, citing reports from animal behaviour experts who explain that "quiet" may instead "reflect listlessness due to illness, or apathy and withdrawal due to an under-stimulating environment." The Society goes on to make clear that the "huddled" monkeys were "at least as likely" to be in pain, and:

"In any case, it is not common place for healthy primates to rest in the presence of human technicians conducting thorough monitoring."

Contrary to their public statements however, Imutran's own confidential project licence applications, which they refused to disclose to the Court, make clear that such observations are indeed indicators of serious illness and suffering:

"Clinical signs associated with progressive and irreversible renal failure can typically be characterised by a number of common features... Physically the animal becomes progressively quieter (listless) and adopts a huddled/hunched posture, reflecting the rising blood creatinine level."¹² (See document ND24.23)

⁸ "Demo-hit biotech company to quit city", Cambridge Evening News, Wednesday 27 September 2000.

⁹ See page 12 of the RSPCA report, available via <http://www.rspca.org.uk/servlet/ContentServer?pagename=RSPCA/News/NewsArchive&articleid=1024472942660&newsmode=normal&marker=61>

¹⁰ See for example, leaflet ("Animal welfare – Xenotransplantation", Imutran, 1999 (distributed at House of Commons, December 1999)). Briefing ("Xenotransplantation" by Novartis/Imutran, distributed e.g. at House of Commons December 1999).

¹¹ See section 5.2.3 of the RSPCA report.

¹² Rising blood creatinine levels are an indicator of kidney failure. Creatinine is a waste product caused by muscle activity which is usually excreted in the urine.

These documents casts doubt on the accuracy of Imutran's public statements:

- 'Clinical Signs'.
- Study report IAN007, clinical signs, pp.63-65 for X201m (Discrepancy between public version and reality.)
- Study ITN19 – Clinical signs (These observations contradict Imutran's claim that the immunosuppressive regime used in this study (or in the animals focussed on in the paper) was "well tolerated".)
- WCB19 (South African baboon breeding programme representing a "unique opportunity" to evade regulations, contrary to Imutran claims of not wishing to avoid regulation.)
- WCB24-1 - ("At this time there is no therapy of which we are aware that will reverse this process." – Contrary to claims of "refinement" and "imminent clinical trials".)
- WCB26 (Together with WCB24-1, reveals wild-caught baboons in captivity raising serious ethical considerations and breaches of commitment to Home Office, contrary to assertions by Imutran that animal welfare is a top priority.)
- WCB29 (Reveals unreported incidents of hyperacute rejection)
- See also discussion of "New Documents" leaked from Home Office in October 2002.

(v) Illegal severe suffering?

In addition to the general public interest in the availability of information regarding the suffering of animals in research, our Defence also argued that Imutran's experiments contravened Schedule 2A to the Animals (Scientific Procedures) Act 1986 (which enacts Article 8 of the European Directive 86/609)¹³, as stated in sub-paragraphs 3.1 to 3.3 below.

- 3.1 All experiments shall be carried out under general or local anaesthesia;
- 3.2 If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure as far as possible that pain, suffering, distress or harm are limited and that *the animal should not be subject to severe pain, distress or suffering*;
- 3.3 An anaesthetised animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.

Even the Chief Inspector's review admits "However, I am of the opinion that in several instances there is, in retrospect, sufficient evidence (as recorded in the original study documents) for irreversible renal failure to have been diagnosed up to 24 hours before the endpoint was applied. I conclude that, in these cases, failure to implement the endpoint earlier did result in some unnecessary animal suffering."

Our contention is that the study design (as described in the surgical procedures and dosing regimens) would have inevitably caused 'severe' (according to any reasonable definition of the term) suffering, and thus they should not have been authorised by the Home Office in the first place. The following documents reveal particularly severe animal suffering caused by Imutran's research:

Clinical signs records for:

- W205m, W201m (ITN6)
- X214f, X229m, X200f, X225m, X207m, X211m, X240f (ITN19)

¹³ See section 2.2, p23 of report.

- X198f (ITN25)
- X215m, W213m, W211m, X221m, V687m (ITN9)
- X239m, X202f, X201m, X206f (IAN007)
- W264f (ITN3) (The clinical signs here are particularly vague, but other readings demonstrate 'severe' suffering. In document hlsapp5b (see below) the lethal effects of 'general debility and non-specific diarrhoea' are referred to, with 'nausea secondary to the immunosuppressive agents'.)
- W762f, W774f (ITN5)
- W17m (ITN8)
- 341m, 343f, 344m, 345f (ITN20)

Following studies are renal xenotransplantation experiments. See Chief Inspector's comment above.

- W435m, W556f, W560f, W548f, V337m, T381m, T397m, V7, T407m (ITN4)
- W39m, W144f, W47m, V510f, W43m, V484f (ITN12)
- V812f, W35m, W14f, W27m, X523m, X527m, X529m (ITN13)
- X525m, X531f, X532f, X537f, X528f, X524f [observed: "huddled on perch with head in its hands"], X536f [observed: "looking very weak with head in hands... vomiting profusely"] (ITN16)
- X541f, W704f, X526f, X533f (ITN18)
- X538f, X539f, X540f, X665m, X657m, X535f, X666f, X660f, X661m, X662f (ITN21)
- W337m, X664f, W50f, X520f, X530f, X652f, Y205m, Y203m, Y199m, Y207m, Y202f, Y213m, Y215m (ITN26)
- Y225m, Y148f, Y256f, Y251m (IAN009)
- A170f, A167f, A457m, A174f, A178f, A461m, A459m, A462f, A451m, A464m, A465m (IAN020)
- A171f, A472f, A467m, A338f, A475m, A474f (IAN022)

Other documents:

- WCB29 - (Mentions 'outcomes' such as 'Collapsed', 'Cerebral incident observed'.)
- WCB30 - (Includes surgery report stating 'Outcomes' such as 'Euthanased, poor condition, 'Renal failure/diarrhoea', 'Retroperitoneal bleeding', Pneumothorax', 'Wound infection'.)
- WCB31 - (Another surgery report, referring to 'outcomes', e.g.: "Found dead, stroke", "Euthanased, Myocardial infarction".)
- Hlsapp5b - (lethal effects of 'general debility and non-specific diarrhoea' are referred to, with 'nausea secondary to the immunosuppressive agents'.)
- CY18 (Describes (for study IAN009) "unusually high level of technical failures", "pancreatitis", "renal vein thrombosis".)
- CY19 – (Surgery reports for February 1998 and summary of results of IAN009, such as "Diarrhoea, a febrile", "Pancreatitis", "Ureteric obstruction".)
- CY22 – (Describes outcome of experiments e.g. "Severe CMV infection", "AVR (Acute Vascular Rejection) with renal failure and primarily problems with the wound site which lead to euthanasia".)

- CY23 - (Clin/Path meeting minutes describing animals with obstructions of the ureter, “cautery injuries in the ureter and bladder wall”, “peritonitis in the colon with a leak from the bladder and a collection of pus in the pelvis... many bleeding sites”, “clot in the ureter, which resulted in the animal being euthanased for renal failure”.)
- HLSAPP7A – (Clin/Path Meeting Minutes describing animals: e.g. A459 - “Euthanased due to worsening condition with bilateral effusion and respiratory failure... with possible bilateral pneumonitis/infection.”
- HLSAPP7B - (Pathology report – “Balantidium infection + sepsis”, “Severe CMV infection”)

3. Chronology

- May 2000 - Uncaged Campaigns (UCL) received several hundred unsolicited photocopied documents (including correspondence) and a CD-ROM containing 39 study reports that had been produced for Imutran ("the documents"). The documents concerned the xenotransplantation research programme carried out by Imutran.
- 21 September 2000 - On the basis of the documents and on the basis of information on the subject that was already in the public domain, UCL published on the internet a 150 page report entitled "Diaries of Despair" ("the Report"). The Report was written by Mr Lyons, was presented as a UCL publication and extensively quoted from the documents. Both the report and the documents (upon which it was based) were published on the Defendants website. The decision to add the documents to the website was made in order to substantiate the validity of the report's concerns.
- 21 and 22 September 2000 - the Daily Express published articles referring to the work of Imutran (and HLS), to "secret papers" which revealed the true extent of suffering of animals involved in the xenotransplantation experiments and to the exaggerated claims made in the past by Imutran concerning the success of the experiments.
- 22 September 2000 - UCL was contacted by Imutran's solicitors, Eversheds, and was informed that Imutran considered that the Defendants had, without prior authorisation, published confidential documentation which was Imutran's exclusive property which was covered by copyright.
- 22 September 2000 - On the same day UCL's then solicitors, Simons, Muirhead & Burton, offered to meet Imutran's representatives with a view to reaching a mutually satisfactory agreement. Whilst these discussions were ongoing, Eversheds persuaded UCL's Internet Service Provider to shut down www.uncaged.co.uk in the mistaken belief that this was the site on which Imutran's documentation had been published. In the light of Imutran's unilateral actions, UCL was happy to leave the full report and the Claimants' documents on www.xenodiaries.org pending a mutually satisfactory agreement between the parties which UCL continued to try to reach, or a court ruling
- 26 September 2000 - Mr Justice Hart granted an interim injunction against the Defendants (surprisingly, Imutran named Mr Lyons as a joint Defendant along with UCL), based on breach of confidence and breach of copyright. The injunctions prevented the Defendants from disseminating Imutran's documents to the general public.
- 10 October 2000 - This injunction was extended by Mr Justice Ferris and again on the 18th of October by the Vice Chancellor Sir Andrew Morritt pending a full hearing. Morritt VC heard the matter on the 14th and 18th of December 2000.
- 17 October 2000 - On legal advice, the Defendants offered to limit publication to the report and approximately 60 accompanying documents. Imutran responded with objections that the Defendants considered so extensive as to make further discussion futile. Accordingly, with the exception of individual names and addresses, the Defendants sought to publish all of the documents originally published and continued to contest the proceedings.
- 11 January 2001 - Morritt VC extended the injunction to trial or further Order and granted leave to appeal against his judgment. The injunction that was extended included a proviso which permitted distribution of the documents to a group of "authorised recipients"— Government bodies and departments - to whom Imutran sought to limit dissemination. These recipients are the Animal Procedures Committee (APC), the Good Laboratory Practice Monitoring Authority (GLPMA), the UK Xenotransplantation Interim Regulation Authority (UKXIRA) and personnel at the Home Office having responsibility for regulating animal experimentation. Morritt's judgment appears to have completely ignored Defence evidence and witness statements, and was flatly mistaken on matters of fact regarding evidence of Home

Office misconduct. Furthermore, his 'surprising' legal interpretations have since been contradicted.¹⁴ Sir Andrew Morritt has two hobbies listed in "Who's Who": fishing and shooting. This perverse judgment proves to be a hindrance, but is eventually overcome...

- 10 April 2001 – Novartis Pharma AG, Imutran parent company, join the action as a joint Claimant with Imutran. The Defendants become unrepresented as their solicitors come off the record.
- June 2001 – Dan Lyons applies to the Legal Service Commission (LSC) for legal aid, through solicitors Bindman & Partners. (Companies are ineligible.)
- August 2001 - a Case Management Conference (CMC) hearing at the High Court sets a pre-trial timetable, setting deadlines for responding to questions about the Defence case, exchanging lists of documents that each party would rely on in evidence at trial, and submitting copies of witness statements to be used at trial. Significantly, at the CMC, Dan Lyons (representing himself and Uncaged Campaigns) defeated an attempt by Imutran/Novartis and their solicitors to prevent the Defendants calling an Expert Witness to explain how the Home Office has connived with the company to break its own rules.
- September 2001 – Application to LSC refused. Review of refusal is requested.
- October 2001 – LSC review committee in Cambridge refuses to grant legal aid. Re-application sent to LSC head office.
- 20 December 2001 – LSC refuse to grant funding once again, citing Morritt's judgment as evidence that Defendants' prospects of success was 'poor'. LSC recommends obtaining counsel's (i.e. from a barrister or QC) Opinion on prospects of successfully defending the case.
- 21 December 2001 – Defendants serve a response to the "Request for Further Information about the Defence" which had been demanded by Imutran/Novartis. In this response we were required to explain in detail certain aspects of the Defence's legal arguments and list the documents which we believed demonstrated our case (these form the basis of the lists of documents provided above which we have now published.) Both parties have also had to compile a list of documents which are relevant to the case, whether they support or adversely affect their own position. We recognised that Imutran/Novartis' list was very thin, and saw the need to challenge them to disclose important, relevant documents that shed light on, for example, the suffering endured by the primates and the company's relationship with the Home Office. Imutran and Novartis claim that important documents – most of their press releases - were 'accidentally destroyed' because their PR firm sent them to the wrong department. We imagine this would be an unusual occurrence.
- February 2002 – Joint Opinion from two counsel advises that the prospects of success are better than evens, and also points out that the case raises significant human rights issues and serious matters of public interest. In Counsels' view, public funding (i.e. legal aid) should be granted. This Opinion is forwarded to the LSC for a review of their refusal to grant funding.
- 25 February 2002 – Funding refused again by LSC.
- March 2002 – Bindmans write to LSC informing them of an intended court action (judicial review) against them on the grounds that their refusal to grant legal aid is unlawful, in that it effectively denies Mr Lyons a fair trial, among other reasons.
- April 2002 – LSC agrees that the prospects of success are higher than they previously acknowledged and places the application before its public interest advisory panel (PIAP).

¹⁴ E.g. London Regional Transport and London Underground Ltd v The Mayor of London and Transport for London [2001] EWCA Civ 1491.

- 11 July 2002 – The PIAP reaches a unanimous decision that the case has a “significant wider public interest” and classed this as “high” – a rare categorisation. Bindman & Partners now go on the record for Mr Lyons following grant of public funding.
- August 2002 – Defendant’s solicitors write to request disclosure of a large volume of documents by Imutran/Novartis, and charge them with failing to fulfil their duty to disclose documents to the Court. Claimants refuse and hearing date is set for November.
- October 2002 – Defendants receive second leak of documents, this time from Home Office. These comprise many of the same documents whose disclosure was requested by the Defendants. The Defendants feel that these documents reveal evidence that strengthens their case considerably, and feel aggrieved that, in their view, these documents were unjustifiably withheld from them by Imutran/Novartis.
- November 2002 – Disclosure hearing postponed and trial date – 20 January 2003 – is ‘vacated’ (i.e. the trial is moved from that date).

April 2003 – A new Court Order is made after Imutran/Novartis surrender and agree to allow the Defendants to publish over a thousand pages of documents and the Diaries of Despair report.