

Diaries of Despair

Futile Atrocities

Parts in this section:

- Damning evidence
- The Diaries of Despair report
- Dead on arrival
- Savage science
- Science or alchemy?
- Government treachery
- Public interest wins out

Monkey W14f

Day 1: ... vomit, grinding teeth.

Day 7: ... dark loose faeces, semi-digested vomit, ... huddled, sitting on cage floor, dark loose faeces.

Day 8: Found dead.

The world of animal experimentation has traditionally been extremely secretive. That secrecy helps disguise both the destructive and violent nature of vivisection and also the falsity of claims for benefits from such brutality. It's deliberate manipulation of public opinion to protect a self-serving, deluded and barbaric practice.

The Diaries of Despair documents published here by Uncaged Campaigns represent a truly historic moment in one of the most controversial and significant public debates in modern times. By overcoming a legal attack designed to suppress the Diaries of Despair, Uncaged Campaigns have achieved an extraordinary victory for democracy and freedom of information. It is a blow for due process over brutal tyranny. This time, might is *not* right.

Damning evidence

The major haul of documents was leaked from Cambridge-based Imutran Ltd to Uncaged Campaigns in the spring of 2000. The cache of information included:

- 39 'study reports' contained on a CD-ROM, most of which described how, in experiments performed at Huntingdon Life Sciences (HLS), Imutran researchers transplanted organs from genetically-altered piglets into hundreds of higher primates: cynomolgus monkeys (a kind of macaque) and wild-caught baboons. The study reports included harrowing observations – 'clinical signs' - recorded twice daily as the previously healthy primates sickened and died after the experimental transplant operations. It was this disturbing evidence that inspired the title "Diaries of Despair".
- Internal reviews of the results of the experiments, giving further insight into the horrific impact on the animals.

- Confidential progress reports demonstrating the lack of success in the experiments, contrary to the PR image created by Imutran and their parent company Novartis.
- Communications with the regulatory body – the Home Office - revealing the indulgent and biased attitude of the Government towards Imutran and HLS.
- Faxes and letters with wildlife brokers concerning attempts to import primates from half way across the globe to meet a grisly fate at HLS.
- Investigations into failures during the research, including deaths of primates, breaches of laws and regulations, and failures to meet Good Laboratory Practice standards at HLS.
- Correspondence between Imutran and HLS regarding serious mistakes, broken pledges and inadequate service.
- In-house messages concerning severe problems encountered in the experimental programme, and disclosing potential public health hazards arising from experiments on infected primates.

In October 2002, Uncaged Campaigns received a second leak of documents exposing Imutran's vivisection activities, this time from the Home Office. These papers provide detailed and highly unusual information about how companies and institutions actually go about obtaining permission to experiment on animals. The evidence contained in this second leak intensifies the concerns raised in Diaries of Despair regarding the Government's rubber-stamp approach to approving vivisection licences. Furthermore, these documents reveal that 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.

The public never gets to see the manipulative and ruthless behaviour of big corporations and feeble Governments. The Diaries of Despair documents provides a truly unique opportunity to bring powerful wrongdoers to account.

The Diaries of Despair report

In the months following the Imutran leak, Uncaged Campaigns director Dan Lyons analysed the confidential documents and compared them closely with the rules and regulations enshrined in UK law, ministerial statements, as well as scientific reports and other statements issued by Imutran. It soon became clear that the secret evidence demonstrated that the rules that are supposed to govern animal experiments are, in fact, a sham. The Government directly colludes with the vivisection industry to help them evade the letter and spirit of the law. Ministers even conceal wrongdoing and animal suffering in statements to Parliament. Behind the smokescreen of confidentiality exists a culture of contempt for the rule of law and for the welfare of animals. This is a tragic scandal of historic proportions.

Originally published on 21 September 2000, the Diaries of Despair report organises and explains the significance of the Imutran documents. It reveals the awful cruelty inflicted on these higher primates – the cousins of human beings. The gaps and exaggerations in Imutran's carefully-filtered spin are exposed. Ultimately, the appalling failure of Government in its most fundamental duty – to enforce the law – is unmasked.

Dead on arrival

Thousands of pigs and several hundred higher primates were sacrificed in Imutran's ill-fated xenotransplantation research programme. The leaked documents focus on the ordeal endured by the primates – monkeys and baboons – who were the experimental recipients of Imutran's GM pig organs.

At least fifty baboons started life free, roaming the savannah of East Africa. But they were wrenched from their tightknit clan to suffer lonely and violent deaths thousands of miles away in a bleak, windowless laboratory at HLS in Cambridgeshire.

They were captured on behalf of wildlife dealer Mann & Miller Ltd, and held in a metal wire compound. Inspectors who visited the site have been 'disgusted' by the conditions there, as the primates scream and smash their heads on cage walls, driven mad by the isolation and confinement. This leaked fax (see report page 31) reveals that some baboons didn't even make it to Britain:

"He says that he lost 4 animals this week. He explained that the metal roof of the holding cage was struck by lightning in a thunder-storm and 4 animals died as a result of the strike..."

Another secret document (see report page 32) proves that the Home Office had been happy to approve these lethal cages solely on the basis of submissions from Imutran, a fact hitherto concealed from Parliament and the public.

Imutran's attitude to these unfortunate primates is chilling. In one fax (see report page 34) discussing the problems importing the baboons into Britain, an Imutran manager says:

"the broker feels sure the airline will do whatever we need to get these baboons shifted. Surely we can get the bloody things from Nairobi to Jo'burg. What say you?"

His boss replies:

"Do it."

In one shipment, the baboons spent 34 hours in cramped transport crates, a full 10 hours longer than the time approved by the Home Office. Yet the Home Office, typically, took no action. (see report pages 32-33).

Over four hundred cynomolgus monkeys were bred in captivity in Mauritius, Indonesia or the Philippines and exported to Britain to be killed by Imutran. In one shipment, three monkeys were found dead with blood oozing from their nostrils at Paris airport two days after leaving the Philippines (see document CY5). A secret review conducted by Imutran with the Home Office conceded that the deaths "were probably due to a number of factors": the crates had breached size and ventilation regulations. The compartments had been so small that the monkeys had not been able to stand, turn and lie down in a natural manner. The journey time has also been far longer than the estimate given by Imutran on their import application form.

The Government's response? Home Office Minister Mike O'Brien MP (now a junior foreign minister) misled Parliament in a Written Answer, stating that the crates had not broken rules on size dimensions and failing to admit the ventilation breaches (see report section 5.2).

shadowy

"... please note that throughout this investigation I have orchestrated it such that Imutran are entirely anonymous." Imutran scientist discussing the deaths in transit

Savage science

Between 1994 and 2000, Imutran's researchers transplanted GM pig hearts and kidneys into hundreds of monkeys and baboons.¹ In a bizarre effort to bypass several million years of evolutionary difference between pigs and primates, Imutran scientists, with backing from their masters at Novartis Pharma, invented experimental cocktails of powerful immunosuppressants to try to stop the natural rejection of the fundamentally 'foreign' organs. The spleens were removed from many monkeys to further weaken their immune systems. The consequences were truly horrific (see report chapters 4 and 6).

Having survived captivity and a long, dangerous journey, a quarter of the primates died from 'technical failures' – jargon for lethal shortcomings in the experimental surgery:

- Hearts from piglets would not fit into the necks of baboons (see document ND10.2), despite assurances to the contrary (see documents ND6.8 & 6.9).
- Victims were overdosed with anaesthetics (see document CY18.1).
- A pig kidney was accidentally frozen while waiting to be transplanted into the abdomen of monkey A166M – the transplant went ahead anyway and the primate died shortly afterwards (see document HLSAPP7B.2 and page 135 of the clinical signs for study IAN020).
- Another monkey died when a swab was left in his abdomen following surgery, leading to a lethal infection of the spleen (see documents CY22.2, HLSAPP7A.3, HLSAPP7B.2)
- A series of experimental surgeries performed by out-of-practice surgeons went fatally wrong (see document CY18.1). Lethal blood clotting and bleeding complications occurred on a regular basis throughout the whole period of research.
- A few pig organs were rejected almost instantaneously, undermining the only difference between Imutran's GM pigs and normal pigs (see document WCB29 and report page 57).
- Sometimes the hearts or kidneys would simply not function after transplantation (see document CY18.1).

Torment concealed by officials

In a report to the Home Office [document WCB18], an Imutran researcher tells an Inspector that an anaesthetic drug was prescribed at 'very high doses' to two monkeys, leading to their deaths.

The clinical signs [for study IAN009] reveal that one of those primates, Y148f, was found unresponsive and lying on the cage floor on the morning following transplant – she was then destroyed. Blood was noted around Y256m's penis and scrotum on his first day post-transplant. For the next three days he must have made a pitiful spectacle: slumped against the front of the cage, drifting in and out of consciousness, his turmoil punctuated by bouts of vomiting and salivation. He was finally killed on the fourth afternoon after transplant.

Government response? No punishment for these disastrous mistakes, then a desperate attempt to exonerate Imutran from blame while the true facts remained injuncted.

¹ Leaked documents from the Home Office reveal for the first time how Imutran also grafted monkey hearts into baboons, hoping to develop primate organs to market for transplantation into seriously ill infants. This scheme appears to have been knocked on the head when other scientists pointed out that transplanting primate organs into humans was a dangerous biohazard and unethical, both in terms of the proposed large-scale destruction of primates as well as the concept of using babies as the first human guinea pigs.

If the monkeys and baboons survived surgery, they then faced an inevitable, traumatic death from one or a combination of these factors: organ rejection and failure, infections resulting from severely impaired immune systems, and/or drug toxicity. For example, kidney failure results in an accumulation of waste products such as urea in the blood. This in turn leads to nausea, vomiting, lethargy, listlessness, swelling, huddling in pain, drowsiness, anorexia and eventually death.

The huge doses of immune-suppressing drugs – on occasions eight times higher than doses used in human beings – lead to deaths due to poisoning and/or infection. Some drugs caused internal haemorrhaging (see report pages 85-86 – describing studies ITN12, ITN13 and ITN21). Other torturous and potentially deadly illnesses included viral and protozoal infections, lymph cancer, intense nausea, severe stomach inflammation and diarrhoea, dehydration, fatal pneumonia, persistent wound infections and breakdowns, brain trauma, heart attack, pneumonia and anaemia.

Science or alchemy?

Way back in 1995, Imutran scientists told a news conference that they were ready to start transplanting pig hearts into humans within a year. This was based on the apparent success of their GM organs in avoiding the immediate, destructive *hyper-acute* rejection caused by such drastic cross-species transplants. Despite other scientists warning that there would be further, huge obstacles to pig organ transplants, Imutran scientists raised false hopes in transplant patients. In 1996, the Swiss multinational drug company *Sandoz* (now *Novartis Pharma* following a merger with *Ciba*) bought Imutran in the hope of cashing in on the biotech company's apparent success. The market for pig organ transplants was predicted to be worth \$6 billion annually. How much Imutran's founder scientists made from the sale of their company remains a mystery.

But, published scientific papers from Imutran have failed to reveal the full truth of their research (see page report page 53). Animals were claimed to be healthier than they really were (see report pages 56-58). Failures are very rarely reported publicly. Imutran promotional literature has played down the colossal barriers to transplanting pig organs into humans. Yet more predictions of imminent human trials have been made. Behind the scenes and with concern mounting regarding the dangers of virus transfer and lack of progress in extending survival times, in April 2000 Imutran were given just 18 months to engineer a quantum leap in survival periods to be able to commence tests on humans (see report page 17). However, Novartis abruptly closed Imutran down just six months later - five days after the news of *Diaries of Despair* broke.

Significantly, Imutran's experiments in the UK stopped in early 2000 and their research moved to countries in Europe and North America with virtually no controls on vivisection, not even on paper. Why did this happen? We know that Novartis actively considered proposals to move research on baboons to South Africa because of the absence of legal protection for animals (see document WCB19.2) Were their experiments on primates deemed too cruel and pointless even for their supporters in the British Government?

Expert advisors to the UK Government have since referred to Imutran's research programme as leading up a 'blind alley' and have expressed deep scepticism about

futile

"At this time there is no therapy of which we are aware that will reverse this process [of graft rejection]." *Imutran report to Home Office, early 2000.*

the prospects for viable pig organ transplants.² In five years of experiments, causing severe suffering to hundreds of primates and sacrificing thousands of pigs, Imutran and Novartis managed to squeeze average survival times up by a couple of weeks. Very little progress was made in overcoming the profound immunological obstacles to xenotransplantation. Is the notion of functioning pig organ transplants nothing more than scientific arrogance driven by personal ambition and commercial greed? Transforming organs from pigs into human organs appears to be nothing more than a modern form of alchemy.

A further, constant source of concern about xenotransplantation centres on the potential for new viruses or other diseases to be introduced into the human population via pig organs or cells. Types of retroviruses – cousins of the HIV virus - that cannot be removed from pigs have been shown to have the potential to infect and multiply in human cells. The spectre of creating another AIDS-style pandemic hangs over the whole technology of cross-species transplants³.

The contrast between the public relations image of Imutran's experiments and the harsh reality has a number of serious consequences. Firstly, it distorts democratic public debate about the ethical acceptability of xenotransplantation research. Then, the potential 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.⁴ It also signifies the ruthlessness of multinational companies in pursuing their business strategies regardless of considerations of compassion, fairness and democracy. Finally, it exposes the rotten core at the heart of the UK Government's regulation of animal experiments.

Government treachery

The Diaries of Despair reveals direct collusion between Imutran, Novartis and the Government, and systematic bias in policy on animal experiments. It provides irrefutable evidence of an unscrupulous regime and confirms a pattern that has emerged from several exposés of vivisection in Britain. Corporate lobbying has led to a contemptuous disregard for animal welfare and the rule of law on the part of the Government.

One of the key aspects of the UK regulatory system involves the banding of experiments according to their severity. One document exposes how the Government's Home Office deliberately and blatantly colluded with Imutran and its parent company (then known as 'Sandoz') to underestimate the suffering caused by many of Imutran's experiments (see document CY14.1). This would make it easier for the proposed experiment to receive a licence. Government inspectors

conniving

"... the Home Office will attempt to get the kidney transplants classified as moderate procedures."
Imutran report [CY14.1]

² 'Government death knell piece. UKXIRA Third Annual Report, September 1999 – November 2000. Department of Health, published February 2001, paras 6.8-6.15. See also transcript of UKXIRA Open Meeting, 7 February 2001. New Scientist, "Waiting for a miracle – time is running out for organ transplants from animals", 12.1.03, p.3.

³ UKXIRA Third Annual Report, September 1999 – November 2000. Department of Health, published February 2001, paras 6.23-6.26. See also transcript of UKXIRA Open Meeting, 7 February 2001.

⁴ "Animal tissue into humans", A report by the Advisory Group on the Ethics of Xenotransplantation, Department of Health, 1996, para 4.110.

show a lack of respect for the very regulatory system they are charged with enforcing, referring to an expert committee meeting to discuss an Imutran application as merely a ‘rubber-stamping’ exercise (see document CY24.2). Mistakes and breaches by Imutran and Huntingdon Life Sciences have been covered up by the Government – the documents reveal the deceit in stark terms (see report sections 7.5 and 7.8).

The central feature of the British law governing animal experiments is the cost-benefit assessment. By law, the Home Secretary must weigh up the costs of the experiments in terms of animal suffering, against the likelihood of potential benefits resulting from the experiments.⁵ In reality, the Government places no effective weight on the most fundamental interests of animals, while failing to question the unrealistic and heavily-spun claims of public health benefits put forward by researchers. The demands of the powerful and the influential hold more sway than the scientific reality, the wishes of Parliament, public opinion or the welfare of animals.

Uncaged Campaigns submitted the full dossier to the Government and asked for the establishment of an independent judicial inquiry into the scandal – this would be the only constitutionally appropriate method of investigation. Instead, the Home Office set up an internal review, carried out by the very body whose desperate failures were exposed by the Diaries of Despair – the Home Office Inspectorate. Furthermore, the internal review only dealt with a small proportion of the issues raised in Diaries of Despair. Even the toothless watchdog, the Animal Procedures Committee (APC), was stirred to criticism. The subsequent report of the Chief Inspector exploited the information vacuum created by the injunction, sweeping the scandal under the carpet with a mixture of inaccuracy and evasion.

The second leak of documents from the Home Office has allowed us to delve even deeper into the murky world of vivisection and the Government’s support for the practice. The correspondence between Imutran and the Home Office, together with applications for experimental licences reveal glaring falsehoods in the Government’s main political defence to this crisis, the Chief Inspector’s review. Imutran’s estimations of suffering and success are disclosed as economical with the truth. There are fascinating glimpses into a research programme out of control. While the Government was prepared to privately chastise Imutran (see documents ND13, ND15, ND17) when push comes to shove they lacked the political will and the integrity to uphold the rule of law in the face of undue pressure from business interests.

By trying to cover-up their failings, the Government has gambled that their shameful behaviour would remain hidden. They have lost.

cavalier

“Members strongly expressed the view that your response was still not satisfactory and that the failings listed above indicate a cavalier attitude to the controls of the Act. They are also extremely concerned that this attitude may extend to the care and welfare of animals.” *Letter from Animal Procedures Committee to Imutran scientist*

⁵ Animal (Scientific Procedures) Act 1986, section 5(4).

Public interest wins out

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. 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:

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

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. 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 and failures:

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

The issue of the independence and integrity of the UK Government's Home Office was particularly crucial to the Defence. Imutran and Novartis argued that disclosure of the leaked documents to the Home Office 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 inadequate in a democratic society.

We have now 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 enjoined.

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