

# **Diaries of Despair**

**the secret history of pig-to-primate  
organ transplant experiments**

**The need for an independent judicial inquiry**



Baboon X201m was captured from the wild in Kenya - and died 39 days after being transplanted with a transgenic pig heart by Imutran/Novartis at Huntingdon Life Sciences in spring 1998. He collapsed and died suddenly from a suspected heart attack, the pig organ having swollen to three times its original weight.

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## 1. Introduction

This briefing has been produced in order to explain why there is an urgent necessity for an independent judicial inquiry to investigate Imutran’s xenotransplantation research at Huntingdon Life Sciences and the Government’s failure to apply relevant laws and regulations, to the benefit of the companies and resulting in severe suffering for hundreds of higher primates.

The grounds for such an inquiry are to be found mainly in thousands of pages of documents relating to this research programme which were leaked from Imutran to Uncaged Campaigns in spring 2000. The call for an independent judicial inquiry stems mainly from the evidence of deliberate and systematic Home Office maladministration of animal research regulations, prioritising the demands of industry and resulting in extreme suffering endured by higher primates. The Home Office has consistently sacrificed animal welfare and the rule of law for the sake of commercial interests.

The Report, Diaries of Despair, was produced after analysis of the documents and already-published information, and was aided by professional scientific advice. Diaries of Despair meticulously related the evidence contained in the documents to the regulatory framework. A major exclusive article appeared in the Daily Express on the same day as the publication of Diaries of Despair (21<sup>st</sup> September 2000).

The Imutran primate research programme was probably the most severe research project that animals were subjected to during the 1990’s, taking into account the hugely traumatic nature of the procedures and the use of higher primates, including wild-caught animals, as well as thousands of pigs – acknowledged to be highly intelligent and sensitive animals. The experiments involved the transplantation of kidneys and hearts from genetically-engineered pigs into hundreds of macaque monkeys and wild-caught baboons. After the transplants, the primates were administered toxic cocktails of powerful drugs in an attempt to prevent rejection of the foreign organs. Every single one of the primates died in these experiments from causes such as organ failure, infections and drug poisoning/side effects.

The report was entitled ‘Diaries of Despair’ in reference to the suffering and death as described in the laboratory technicians’ own detailed records of the animals’ post-transplant lives. One monkey which had a pig heart attached to the blood vessels in its neck was seen holding the transplant which was “swollen red” and “seeping yellow fluid” for most of the last days of its life. Animals are described as quiet, huddled, shivering, unsteady and in spasm. Some had swellings, bruising or were observed with blood or pus seeping from wounds. Others vomited repeatedly, or suffered constant diarrhoea.

Not only have the animals suffered greatly – they have suffered in vain. In order to try to maintain investor and public support, over the past five years

## Expert Opinion

*"If we look at the situation with xeno'... There are what I would have to regard as the disappointing results of the pig-to-primate transplants that have been performed by a number of different groups around the world and my own opinion is that measures which only control hyperacute rejection would now seem to have been taking us up somewhat of a blind alley."*

Mr John Dark (Consultant Cardiothoracic Surgeon, Director (Cardio-Pulm. Transplants), Freeman Hospital, Newcastle), UKXIRA Member, reviewing Imutran's research at the Authority's meeting in February 2001 following the submission of the Diaries of Despair report to the Authority.

*"... drug regimens should be of a level that would be seen as acceptable and sensible if one was to extrapolate to the clinical situation. In animal model systems people can sometimes use very extreme protocols, and that in itself is a matter that needs ethical debate. But many of those protocols really bear no resemblance to reality in moving to man..."*

*...progress in this area I am certainly not seeing in less than a ten year scale, if at all."*

Professor Herb Sewell, Professor of Immunology, Nottingham University, UKXIRA Member, also reviewing Imutran's research at the February 2001 meeting

Imutran has claimed to have been on the verge of solving the mountainous biological obstacles to cross-species organ transplants. However, internal company reports admit that they have failed to make any significant progress in the last seven years.

It is the evidence about regulatory failures in particular which gives rise to the necessity for an independent judicial inquiry: those failures fall into three general categories:

1. The collusive relationship between the Home Office Animals (Scientific Procedures) Inspectorate (ASPI) and animal researchers in the licensing process and other aspects of the enforcement of animal research regulations.
2. Serious concerns about the manner in which the cost-benefit assessment and severity limits are executed by the Inspectorate, which fail to take due consideration either of the level of suffering of the animals subjected to xenotransplantation research or of factors which undermine the likelihood of any benefits accruing.
3. Other conduct by the Home Office in relation to this programme of research, such as the legitimacy of the decision to re-issue HLS with a Certificate of Designation in autumn 1997 and misleading Written Answers.

This briefing is necessarily deeply critical of the conduct of the Home Office. These criticisms, particularly those regarding the lack of good faith on the part of the Home Office, are not made lightly. However, the evidence clearly justifies - and demands - a critical attitude. We stand by our

criticisms. If the reader is in doubt about any aspect of the briefing, then we urge them to contact Uncaged Campaigns for clarification. They may also wish to submit questions to the Home Office - we wish them luck in trying to obtain an answer that is not economical with the truth.

The documents and the Diaries of Despair report based upon them are currently banned from publication due to an interim injunction on grounds of breach of confidentiality. Despite being unrepresented (at time of going to press), Uncaged Campaigns and Dan Lyons (Director and author of Diaries of Despair) are continuing to contest the case because of the overwhelming public interest (such as the need to expose Governmental failures) in the publication of the documents. However, the reports in the Daily Express concerning this issue that were published in late September 2000 are in the public domain, and they give a useful overview of some of the relevant issues. This briefing is quite severely constricted by the injunction.

The RSPCA downloaded the documents from a dedicated website before Imutran forced its closure. In October 2000, the RSPCA won permission to compile its own report, stating: "We welcome the opportunity to access information on this subject of wide public interest..." In August 2001, the RSPCA followed Uncaged Campaigns' lead and wrote to the Home Secretary to urge him to establish an independent judicial inquiry. In June 2002, the RSPCA finally published its own report which echoed the principle concerns highlighted in the Diaries of Despair report (available at [www.rspca.org.uk](http://www.rspca.org.uk)).

## 2. Suffering in Transportation

Almost 500 higher primates (captive-bred cynomolgus monkeys and wild-caught baboons) were transported from holding camps in Kenya, Philippines and Mauritius to the UK. Many aspects of these journeys, from the suitability of the foreign facilities through to the size of the transportation crates and the journey times demonstrate an unwillingness on the part of the Home Office to (i) enforce regulations and punish offenders, (ii) minimise animal suffering, (iii) be open and honest with Parliament and the public when lethal mistakes happen.

The Express reports :

“In one shipment three animals died – probably from suffocation – in a 35-hour trip from the Philippines.”

These deaths were referred to by Mike O’Brien MP, then Parliamentary Under-Secretary of State at the Home Office, in a Written Answer on 28 June 2000. One of his statements was this: “International Air Transport Association [IATA] minimum dimensions were not breached.” This was misleading. Mr O’Brien also mentioned that “all the dead animals had been in central compartments, which were less well ventilated.” Once again, this reference is economical with the truth. The IATA stipulates minimum ventilation requirements. Frustratingly, we cannot be more explicit yet because of the current injunction.

## 3. Regulation of experimental procedures on animals

At HLS, Imutran transplanted genetically-modified pig hearts and kidneys into the monkeys and baboons. The two central regulatory tools in place to control animal experimentation are:

- *A ban on “severe suffering”*. Current guidance claims that the Secretary of State will not licence procedures that cause “severe” suffering. The guidance in operation at the time includes a *de facto* ban on severe suffering in the conditions attached to personal licences (#14). Article 8 of the

European Directive 86/609 stipulates: “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 in any event the animal is not subject to severe pain, distress or suffering.**” (emphasis added)

- *The cost-benefit assessment*, aspects of which include (according to a Note by the Chief Inspector of the ASPI): “Judgement on the likely severity of the adverse effects on animals”; “Technical competence of the people and establishments to be involved in the project”; “Likelihood of ‘success’”; “How the data generated will be used”; “Utility of the product or substance being tested”.

The Diaries of Despair report exposes deliberate failures in the application of this regulatory system, and raises questions about the ability of the current legal framework to give due consideration, in practice, to the welfare implications of animal experiments.

## 4. Potentially illegal severe suffering

The impact of the experiments as related by the documents strongly suggests that the primates experienced severe suffering. One set of experiments involved the implantation of transgenic piglet hearts into the necks of wild-caught baboons. (Incredibly, the Home Office and Imutran decided that these experiments were only of “moderate” severity.) As the Express reports:

“A baboon which had a pig heart attached to the blood vessels in its neck was seen holding the transplant which was ‘swollen red’ and ‘seeping yellow fluid’ [both of these descriptions are verbatim quotes from the Imutran documents] for most of the last days of its life.”

The research involved the use of experimental, high-dose cocktails of immune-suppressing drugs in an ultimately futile effort to stop the foreign organ being rejected. When the porcine kidneys

# A “moderately severe” experiment?

The baboon pictured here is about to be subjected to a macabre procedure involving the transplantation of a pig heart into its neck. Imutran was licensed by the Home Office to perform this type of experiment. The subsequent suffering was recorded by lab technicians at Huntingdon Life Sciences. To take just one example:

“A baboon which had a pig heart attached to the blood vessels in its neck was seen holding the transplant which was ‘swollen red’ and ‘seeping yellow fluid’ for most of the last days of its life.”

Further disturbing evidence remains injunctioned. This kind of transplant, where the organ is transplanted into an unusual position, is known as a “heterotopic” transplant. Imutran’s primate research included a number of types of heterotopic transplant. In addition to the heart-into-neck grafts, the hundreds of pig kidney transplants were also “heterotopic”. The effects of these experiments are detailed in the main text below. In general, renal failure causes nausea, vomiting, lethargy, drowsiness and death. It is hard to imagine a more distressing and traumatic experience.

Under current legislation, programmes of animal experiments are given a severity rating: mild, moderate or substan-



tial. Most projects are rated as moderate or substantial. Home Office Guidance makes it clear that the severity band is the ‘cost’ to be taken into consideration when applying the cost/benefit assessment. Thus, the lower the apparent ‘cost’ to animals, the easier it is to obtain and justify a licence to experiment.

Imutran and the Home Office worked together (surprisingly, this is standard practice) in order to have these experiments classified as “moderate”. Given the severe suffering caused by the experiments, this is clearly a highly dubious rating.

started to fail, the primates’ blood became loaded with toxins which are normally excreted. With their immune systems ravaged by chemicals and the removal of their spleens, the primates became highly vulnerable to infections. The documents record how the drugs were implicated in cancer and internal bleeding in some of the primates. Technicians observed the animals “quiet”, “huddled”, “shivering”, “unsteady”, “in spasm”, “vomiting”, “severe diarrhoea”... . This evidence represents the tip of the iceberg.

An examination of the published papers describing the research reveals further evidence of horrific suffering:

- “... severe anaemia...”,
- “...cervical abscess eroding the internal jugular vein leading to haemorrhage and collapse of the animal...”,
- “...collapsed and died because of bronchopneumonia...”,
- “Five animals had to be killed because of gastrointestinal toxicity, resulting in severe diarrhoea.”

The issue here is not only whether the animals experienced severe pain and distress, but also that such severity was predictable given the nature of the procedures, and therefore the research should never even have qualified for a licence under British and European law.

## 5. The cost/benefit assessment

Apart from the severe suffering caused by the procedures, a great deal of evidence relating to other factors relevant to the cost-benefit assessment has come to light in the report, leaked documentation and other publications. This evidence further undermines the legitimacy of the research programme on cost/benefit grounds:

### 1. The high technical failure (TF) rates.

According to Imutran’s own statements, 25% of the primates died purely as a result of the trauma of surgery, before the experiment proper could commence. In one experiment, TF’s accounted for 62% of lives. In another study, 13 out of 22 pri-

mates were killed by surgery.

- 2. Failures in the performance of the experiments:** At Huntingdon Life Sciences, hundreds of stipulated readings were not recorded in error and medicines were left uncapped and unlabelled. A monkey died because the pig kidney it was about to be transplanted with was accidentally frozen. Another died after a swab had been left inside his wound during a transplant procedure. Imutran acknowledged that it had “severe problems” with the data.
- 3. The lack of success of the research.** Despite claiming in 1995 that human trials of pig hearts were only a year away, Imutran made very little progress in overcoming the profound immunological obstacles to xenotransplantation. The documents reveal (as reported in the Express) that the crisis came to a head at a recent meeting between Imutran and senior managers at Novartis. An eighteen month deadline was set for the research to show “substantial” increases in survival rates. The UK regulator, the UKXIRA, summed up the progress of xenotransplantation at its public meeting earlier this year. Transplant surgeon Mr John Dark described the Imutran research as “leading up a blind alley”. Professor of Immunology Herb Sewell said that he could not foresee clinical trials of pig organs “within ten years, if at all.” The UKXIRA Annual Report concluded in an understated fashion: “It seems, therefore, that the likelihood of whole-organ xenotransplantation (particularly for heart transplantation) being available within a clinically worthwhile time frame may be starting to recede.” The wording of this significant statement alludes to progress in the development of safer, more effective and more ethical treatments for organ failure that either expand the pool of human donors or treat organ failure with surgical techniques or artificial/bioengineered organs.
- 4. Public health dangers.** Even in the unlikely event that pig organs could evade

rejection and function adequately in the human body, the danger of transferring novel viruses, such as porcine endogenous retroviruses, into the human population remains a real concern. A number of studies have indicated this potential and, ironically, the attempts to alter the pig organs to avoid elements of the rejection may also enable viruses contained within the pig tissue to be similarly shielded. In addition, the experiments themselves may represent a public health hazard. Transplants appear to have been mistakenly performed by Papworth surgeons on primates who were positive for Herpes B, which is classified as a potentially dangerous pathogen. Imutran received warnings from MAFF and Porton Down regarding the possible risks to immune-compromised patients posed by transplant surgeons involved in invasive experiments on infected monkeys. This incident demands a full investigation.

Not only does it appear that the Inspectorate failed to conduct an adequate cost/benefit assessment at the outset of the project, but it also failed to take account of how this speculative research failed to fulfil the promise initially advertised by Imutran in 1995 (i.e. clinical trials of pig organs within one year): part of the Inspectorate’s role is to make an ongoing assessment of the costs and benefits of the programme in the light of changing scientific and ethical thinking.

## 6. Huntingdon Life Sciences (HLS)

The documents also reveal failures at HLS and inadequate Government regulation of the research centre, culminating in misleading statements made to Parliament made by Ministers. The ‘It’s a Dog’s Life’ scandal, which resulted in the suspension of HLS’ Certificate of Designation, occurred in the midst of the xenotransplantation research programme. On hundreds of occasions throughout this programme scientists failed to take readings and measurements from animals following operations.

The Home Office claimed in September 1997 that HLS had satisfied 16 conditions designed to prevent a recurrence of the brutality and failures revealed by *It's a Dog's Life*. This was simply untrue. To take just a few examples, the documents show that primates were illegally re-used at Huntingdon Life Sciences. In another serious incident, a female monkey had to be euthanased the day after she was given a dose of a drug four times higher than recommended. The records note that she was shaking and grinding her teeth. Imutran later wrote to HLS, saying the mistake was 'unacceptable'.

## **7. ASPI: policy, composition and workload**

The documents also raise serious concern about the appropriateness of the relationship between the Home Office Animals (Scientific Procedures) Inspectorate (ASPI) and those supposedly subject to regulatory control. One of the most startling aspects of the documents is the ASPI's cavalier attitude to the regulatory system as a whole and the Home Office's systematic inaction when licence conditions, statutory requirements and commitments are breached. Unfortunately, these aspects were not reported directly in the *Daily Express* and thus remain hidden from public scrutiny. However, our ongoing Defence in Imutran's claim for breach of confidentiality relies on the public interest in the exposure of these iniquities contained in the documents. We would not have continued to contest this case if we did not genuinely believe (a belief backed by legal opinion) that we were both morally and legally justified in publishing *Diaries of Despair* and the leaked documents.

The *Diaries of Despair* report and primary documentation were made publicly available because of the improper conduct of the Home Office that the documents show, and the track record of Home Office bias and concerns about the impartiality of the ASPI. Clearly, we could not rely on the Home Office to investigate properly concerns about its own conduct. Therefore, having taken legal advice and in view of the public interest in this matter and the evidence of deliberate Home Office misde-

meanours, we perceived the necessity to encourage informed public debate by publishing the documents, in the expectation that we could build a wide consensus for the need to investigate and reform Government policy. Naturally we also submitted the *Diaries of Despair* report and documents to both the Home Office and the Animal Procedures Committee (APC).

The concerns about the Home Office's conduct raised by the documents have been outlined above, within the constraints of the injunction. There have been other incidents, however, that have shocked the animal protection community. Recently, following evidence of breaches of animal welfare regulations at the Harlan-Hillcrest beagle breeding establishment, the ASPI conducted a report into the allegations. In April 2000, the APC discussed the incident and report at its meeting. The minutes record:

"...it was felt by a majority of members that the Inspectorate's report left a number of outstanding questions. Many members felt that that the report sought to exonerate Harlan-Hillcrest, with the risk of creating the impression that the conditions which prevailed there were deemed acceptable by the Inspectorate."

This is no surprise to seasoned animal welfare campaigners. It is significant, however, when a committee where the vast majority of members are not opposed to animal experimentation makes what amounts to a direct attack on the integrity of the ASPI.

Concerns regarding impartiality are intensified when one examines the composition of the ASPI. A Written Answer reveals that 17 out of the 21 members of the ASPI have been licensed under the 1986 Act – in other words they have been directly involved in animal experimentation. This does not engender faith in the impartiality of the ASPI.

There is an inherent problem relating to the conduct of the Inspectorate's work – apart, that is, from the affinities and mind-set that arise from the majority of members having previously worked as vivisectors. It is this: Any breaches or failings

identified through undercover work by campaign groups or by the media frequently amount to *de facto* criticisms of the Inspectorate itself for not preventing or otherwise acting to deal with the problems so identified. Such a situation creates a clear conflict of interest.

Even if the ASPI was impartial, it would be impossible for it to regulate animal experimentation effectively. The official workload assigned of the ASPI is unfeasibly huge. Each year **twenty-one Inspectors<sup>1</sup>** are charged with:

- overseeing over two and a half million “procedures” at approximately three hundred establishments
- assessing carefully nearly **one thousand new project licence applications**, each of which may run to **three drafts** as the Inspectorate works to facilitate the approval of a licence application
- monitoring a further three thousand ongoing projects.

Each of these ongoing projects lasts an average of approximately four years, and involves a mean of some 690 animals. The monitoring process must include the crucial cost-benefit assessment, features of which are:

- 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”;
- Soundness of experimental design;
- How the data generated will be used;
- Utility of the product or substance being tested;

Even with the best will in the world and a truly impartial approach, it would be impossible for 21 individuals to carry out these duties properly. Working from the figures above, it can be calculated that every year, each Inspector is charged with monitoring and/or assessing 180 project

licences. That pans out to about **one and a quarter days per year per project**, or about **50 seconds per animal**. No wonder the notion of “stringent legislation” is viewed as a cynical myth by informed observers. As part of its onerous duties, the Inspectorate is expected to make visits – some unannounced - to the Designated Research Establishments where project licences take place, as well as to Designated Breeding and Supplying Establishments. Facilities in which experiments take place are often large institutions with several departments conducting several projects. On average, each Designated Establishment hosts twelve project licences involving almost 9,000 animals. Any infringements discovered by the Inspectorate must be investigated.

No wonder the APC has stated:

“The successful operation of the 1986 Act depends upon self-regulation by the scientific community, assisted by the Home Office.”

This cannot be consistent with the harmonious line promulgated by the Government and the animal research industry that claims that animal experimentation is “strictly regulated”. Such a claim is a deliberate deceit specifically designed to mislead the public. Whatever one’s position on the justifiability of animal experiments, we should all agree that honesty is necessary for informed debate. The lack of honesty on the part of the Government is indicative of the weakness of its policy.

## 8. Home Office response to Diaries of Despair

On 29 September 2000, a week after we had sent the Diaries of Despair report to the Home Office, we received a response from Mike O’Brien MP, Home Office Minister. He stated in connection with Huntingdon Life Sciences:

“... a number of issues are raised in relation to the establishment’s compliance with the conditions of issue attached to the Certificate of Designation which merit further consideration and I will ensure that this happens.”

But with regard to the central recommendation for the setting up of an independent judicial inquiry, Mr O'Brien claimed:

"They [the allegations regarding the Home Office] all relate to administrative or regulatory issues and my immediate thoughts are that it would be entirely proper for the Home Office to investigate them subject to certain conditions."

Quite what Mr O'Brien precisely meant by this sentence remains a mystery 16 months later.

On 2 November 2000, a meeting took place between Mr O'Brien and Home Office officials, and Uncaged Campaigns together with representatives from the British Union for the Abolition of Vivisection and Animal Aid. However, Mr O'Brien had not read the Diaries of Despair report in preparation and was not keen (or in a position) to discuss the substantive issues, the meeting was therefore virtually pointless.

Following the meeting with Mr O'Brien, we received a letter from the Minister on 29 November 2000, timed to coincide with a Written Answer from the then Home Secretary Jack Straw. Once again, Mr O'Brien – having apparently discussed the matter with the Home Secretary, dismissed our recommendation for an independent judicial inquiry without explanation. Most extraordinarily, Straw and O'Brien retreated from the position stated in the Written Answer of 2<sup>nd</sup> November 2000. Instead of an investigation overseen by the Animal Procedures Committee, the Ministers revealed that they had:

"asked the Chief Inspector of the Animals (Scientific Procedures) Inspectorate to carry out a routine assessment of compliance with the relevant authorities but this will not amount to a special investigation."

Despite Mr O'Brien's earlier assurance that the concerns regarding HLS's regulatory compliance would be considered, the Chief Inspector's review focussed solely on Imutran's compliance. Most importantly, the review was conducted by - and failed to consider the conduct of – the Inspectorate itself.

The Home Office's dismissal of legitimate concern in this area extends even to its own advisory committee, the APC. The Chair of the APC has been forced to write three times to the Minister in order to try to extract a justification for the Home Office's refusal to initiate any form of special investigation. The Committee has expressed its "surprise" at the Home Office's inadequate response, particularly given the especially "serious" nature of the concerns that arise from the leaked documents (see the annex to the minutes of the APC's February 2001 meeting).

We are also concerned that the Home Office may have sought to obstruct the APC's deliberations on this matter. The Secretariat to the APC is supplied by and located in the Home Office. Until April 2001, the APC Secretariat had informed both ourselves and concerned members of the public that APC members had seen the full Diaries of Despair report. Following a direct question on this matter from myself, it transpired that this had not in fact happened and that the Committee had not been given access to the most important material – the primary documentation. Had this situation not been rectified, this would have severely hindered the APC's ability to scrutinise the matter properly. The Secretariat has since apologised to me for the "confusion". It may have been an innocent mistake, but when set in the context of the Home Office's general approach to such matters, one cannot help but be suspicious about this incident.

## 9. The Chief Inspector's Report

These are the general conclusions of our response to the Chief Inspector's report into Imutran's compliance with regulations:

- The Home Secretary's decision to request a report from the Chief Inspector (henceforth abbreviated to 'CI') with a narrow remit was unjustifiable. The CI's report intrinsically lacks independence and thoroughness. Our central criticism in the Diaries of Despair report (henceforth abbreviated to 'DoD') came about because of the strong evidence of inadequacies in the

Home Office's regulation of Imutran's research at Huntingdon Life Sciences. This has not been investigated.

- An investigation must be both independent and powerful enough to order witnesses to appear and obtain all necessary evidence. This is why we concluded that an independent judicial inquiry would be the most appropriate form of inquiry.
- The CI's report itself is unfair and stretches credulity in several respects. Through its language and its selective and distorted presentation of information, it seeks to exonerate Imutran, hide HLS from criticism (by surreptitiously including errors and regulatory breaches that were the responsibility of HLS in this report) and unfairly discredit myself and Uncaged Campaigns. The report also downplays the suffering experienced by the primates. On occasions, the CI blatantly misrepresents positions and statements in DoD.
- Ironically, the main conclusion that can be confidently drawn from the CI's report is that the Home Office continues to act in bad faith and show disregard both for animal welfare and the regulatory framework it is charged with executing.

A public copy of our response (i.e. with injunctioned information removed) can be located at [www.xenodiaries.org/responsetoaspi.htm](http://www.xenodiaries.org/responsetoaspi.htm) , or as a hard copy on request.

We have, however, forced the Chief Inspector to admit that certain breaches/discrepancies did take place:

- Imutran underestimated journey times (and therefore the likelihood of animal suffering) when applying for permission to import primates from Africa and the Far East. This is very significant: in one particularly lengthy shipment three monkeys died in transit.
- A pig kidney was damaged before transplantation into a primate due to human error. Despite this, the kidney was transplanted and, when it failed to function, the surgeons continued with the procedure –

the monkey died on the table. Imutran did not reveal the problems during the operation to the Home Office. The Chief Inspector reluctantly admits that the decision to proceed with the experiment despite the malfunctioning of the kidney was “an error of judgement.”

- Two drug-dosing errors occurred: in one case an animal was given a quadruple overdose of an immunosuppressant – she died the following day (the Chief Inspector tries to mitigate this incident by claiming that evidence “strongly suggests” that the death of the animal was not due to drug toxicity). In the other incident a blood sample was taken at the wrong time, thereby hindering attempts to calculate accurately the correct doses of immunosuppressants. These mistakes were the responsibility of HLS, yet this fact goes unreported in the Chief Inspector's review, which supposedly was restricted to Imutran's compliance with regulations.
- Procedures were undertaken without a relevant personal licence.
- Three monkeys were illegally re-used without permission.
- A required humane endpoint (when monkeys should have been euthanased as they were dying following pig kidney transplants) was not implemented in ‘several instances’, resulting in a further intensification of primate suffering for “up to 24 hours” according to the Chief Inspector.
- A swab was left inside a primate during a transplant procedure that was conducted without adequate staff. The Chief Inspector claims that neither the mistake nor the lack of proper staffing were subsequently reported to the Home Office in Imutran's submitted progress report. (The Express revealed that this had fatal consequences for the monkey: he died because the swab caused his spleen to go septic. Typically, the Chief Inspector's report attempts to conceal the disastrous welfare consequences of this mistake, despite the fact that some of the information was already in the public domain (therefore the omission

cannot be justified by reference to confidentiality and the current injunction.)

## 10. Home Office response to breaches and public concerns

In response to representations from concerned MPs and members of the public, the Home Office has issued a standard letter.

The first point made by the Home Office refers to general objections to the use of animals in research. However, in the context of Diaries of Despair, this is irrelevant because the central concern has been about the implementation of the regulatory framework, rather than the entire issue of animal experimentation per se - though we hope that by publishing Diaries of Despair we can contribute to an informed debate about animal experimentation in general. Thus the Home Office is deliberately misrepresenting the concerns central to the Diaries of Despair report.

The Home Office refers to “two newly identified infringements” that it deems are not worthy of prosecution. The Home Office omits to mention the nature of these infringements in its communication with members of the public and MPs. ‘One’ of those infringements is, in fact, the failure on “several” (the words of the Chief Inspector) occasions to put dying primates out of their misery at the time ordered by the Home Office – in other words additional, unlicensed suffering of a deeply traumatic nature caused by irreversible kidney failure. Furthermore, one would imagine that the infliction of unlicensed severe suffering would attract severe punishment in a “strict” regulatory system. Instead, the Home Office claims that the gravest breach of the law possible in this area does not merit prosecution: instead, they have been “dealt with by issuing letters of admonition to those responsible”. This astonishingly weak response cannot be consistent with Ministers’ claims that they “are working to ensure that the highest standards of animal welfare are being implemented.”

The Home Office’s deceitful and evasive response to the Diaries of Despair report merely serves to confirm the necessity of an independent judicial

inquiry to examine the Home Office’s regulation of Imutran’s xenotransplantation research and its implementation of the Animals (Scientific Procedures) Act 1986.

<sup>1</sup> The Home Office has recently appointed a small number of additional Inspectors in response to industry complaints regarding the time taken to “approve” licence applications (such comments from the pharmaceutical industry always use the term “approve” rather than “assess” which, we think, betrays the “rubber-stamp” practice of the regulatory system). These additional Inspectors will have the task of helping industry rather than reducing animal suffering. In any case, a handful of additional Inspectors comes nowhere near to fulfilling the basic requirements to enable proper scrutiny and enforcement of the 1986 Act.

## Further Reading and Information

“Cost/benefit Assessment - a note by the Chief Inspector”, Report of the Animal Procedures Committee 1997, pp. 50-59.

“Animal Tissue into Humans” (aka “The Kennedy Report”), Department of Health, 1996.

Minutes of Animal Procedures Committee meetings, available via the APC Secretariat, or at <http://www.apc.gov.uk/reference/minutes.htm>

UKXIRA Third Annual Report - September 1999 - November 2000, Department of Health.

Guidance on the Operation of the Animals (Scientific Procedures) Act 1986, Home Office.

## About the author

This briefing has been prepared by Dan Lyons, Director of Uncaged Campaigns and author of the Diaries of Despair report. Mr Lyons has an honours degree in Politics and Philosophy from the University of Sheffield, and is currently working towards a PhD on the subject of the ethical and political theory implications of xenotransplantation. His speciality is bioethics, and his work has been published in the Bulletin of Medical Ethics and Medical Law textbooks.

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