

# Uncaged Briefing on Home Office Response to Twelve Questions Raised in Uncaged Open Letter Concerning Imutran Xenotransplantation Research

This briefing is a meticulous and substantiated rebuttal of the latest Home Office statements in relation to evidence of its failure to properly assess and regulate the Imutran xenotransplantation research. This evidence was revealed by Uncaged’s public interest legal victory over Imutran/Novartis<sup>1</sup>. It clarifies several important instances of bias and maladministration on the part of the Home Office, and explains how the department is continuing to misrepresent the circumstances of this case. The systematic regulatory failure and the continuing lack of candour on the part of the Home Office demonstrate the urgent need for an independent inquiry into this affair.

## Lethal endpoints in experiments miscategorised as of ‘moderate’ severity (Questions 1, 2 and 3)

The central charge against the Home Office in this crucial aspect of its licensing – severity assessment - is that it assisted in the manipulation and evasion of regulatory requirements. This occurred through its failure to account for the known severity of the procedures, and its subsequent efforts to cover-up such maladministration and the clear breaches of the assigned severity limits.

The Home Office has finally acknowledged that several primates were allowed to deteriorate to such an extent that they were literally ‘found dead’ in their cages rather than being euthanased. This means that the animals were not put down before they suffered “a major departure from their usual state of health” as required by the “moderate” severity limit on the procedures. Yet the Home Office continues to obfuscate in order to protect both the researchers and the Inspectorate from the implications of these tragic regulatory failures.

### Dissembling denials of deaths

In its latest response, the Home Office asserts: “We have never denied that such deaths occurred.” This misses the point. The Home Office did not have to deny them because their review of Imutran’s research was published during the High Court injunction, which meant that, at the time, Uncaged could not publicly challenge its veracity.

The question put to the Home Office alluded to the fact that in its internal review of Imutran’s compliance with regulations, the Home Office omitted to mention these deaths even though they are clearly central to the remit of the review, and were referred to in the original Diaries of Despair report submitted to the Home Office in September 2000. It is not credible for the Home Office to justify its omission on the basis of its - to say the least - controversial unilateral decision to legitimise these deaths. If the Home Office was not trying to dissemble, it would have openly considered and explained its reasoning for such a counter-intuitive judgement.

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<sup>1</sup> Novartis are Imutran’s parent company. They joined the legal proceedings. The evidence is available via [www.xenodiaries.org/evidence.htm](http://www.xenodiaries.org/evidence.htm)

Severity categorisations are supposed to play a fundamental role in the implementation of the Animals (Scientific Procedures) Act 1986 (ASPA). The different classes are ‘unclassified’, ‘mild’, ‘moderate’, ‘substantial’ and ‘severe’ (this last being formally illegitimate).

The law requires that these classifications must be used by the Home Office to weigh the animals’ suffering against the predicted benefits of a research project: this weighing process is supposed to decide whether the research project should be licensed.<sup>2</sup> Severity categorisations also affect the level of scrutiny that a project licence application receives. “Substantial” severity experiments on primates are examined by the Animal Procedures Committee, whereas “moderate” procedures are not normally considered. Severity categorisations are determined cooperatively by the Home Office and research applicants and, according to public statements, are supposed to represent the absolute worst-case scenario that even one animal might suffer for a short time. Normally, there is no outside scrutiny of the validity of these decisions.

When the animal experiments are licensed, the severity categorisations are then used to indicate the uppermost limit of suffering permitted in the research. Any breaches of this limit are supposed to represent an infringement of the licence. It is usually impossible to determine independently whether severity limits have been complied with.

Before we consider the adequacy of the Home Office’s assessment and enforcement of severity limits, it is important to understand the nature of the Imutran xenotransplantation experiments. Each experiment anticipated an unprecedented combination of adverse effects on the primates’ welfare:

- toxicity tests of the experimental cocktails of immunosuppressive drugs, leading to symptoms such as haemorrhaging, severe nausea and gastro-intestinal toxicity, carcinogenic effects, systemic and wound infections
- major surgery – so invasive and dangerous that 25% of the animals perished within hours because of complications
- models of deadly disease – most of the primates were expected to suffer renal failure as a result of organ rejection
- additional lethal side-effects, e.g. stroke and brain haemorrhage.

At various points in this controversy, the Home Office has provided shifting, ambiguous and often inconsistent defences of its severity assessments and the distinction between ‘moderate’ and ‘substantial’ severity. In defending its ‘moderate’ severity assessments, the Home Office quotes

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<sup>2</sup> See Section 5(4) of the ASPA.

selectively from the definition of ‘moderate’ severity in the official Guidance on the operation of the ASPA: “most surgical procedures, provided that suffering can be controlled by reliable post-operative analgesia and care.”<sup>3</sup>

This is highly misleading in relation to the Imutran research for a number of reasons:

- the procedures were not merely ‘surgical’
- given that animals were found dead in their cages, their condition cannot be said to have been “controlled”
- equally, when an animal is observed “very distressed”, its suffering has clearly not been “controlled” in any meaningful sense
- immediately prior to the passage from the Guidance quoted by the Home Office, it gives “toxicity tests avoiding lethal endpoints”<sup>4</sup> as a further example of moderate severity procedures – but the Imutran procedures involved drug toxicity and did not avoid lethal endpoints
- the contrasting Guidance definition of ‘substantial’ procedures does in fact closely reflect the suffering caused by the supposedly ‘moderate’ Imutran procedures: “ ... *if they result in a major departure from the animal’s usual state of health or well-being. These are likely to include acute toxicity procedures where significant morbidity or death is an endpoint; ... 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.’*”<sup>5</sup>

Elsewhere, the department admits that it “accepted” Imutran’s desire for a ‘moderate’ classification, advanced on the basis of the claim that such procedures would only cause “*local problems*” with the transplant and “*should not seriously impair the welfare of the animals*”. This is contrasted with the higher classification of severity – ‘substantial’ – where “*some animals might die before appropriate clinical investigation and management, or euthanasia, could be applied.*”<sup>6</sup> But, clearly, if animals do in fact die before they can be euthanased then the procedures were of ‘substantial’, not ‘moderate’ severity. Furthermore, the project licence authorities that set out the legal conditions for Imutran’s experiments unequivocally state that for each ‘moderate’ protocol the endpoint for the experiment requires that the animals will be “humanely killed” once certain “complications” occur. At no point are

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<sup>3</sup> Home Office (August 2004). *Home Office Response to Twelve Questions raised by Dan Lyons, Uncaged Campaigns, about Imutran Xenotransplantation Research Licensed Under the Animals (Scientific Procedures) Act 1986*. Question 3.

<sup>4</sup> Paragraph 4.10

<sup>5</sup> Paragraph 4.11

<sup>6</sup> Home Office (June 2003). *Animals (Scientific Procedures): Imutran Xenotransplantation Research*. Paragraph 23.

lethal endpoints anticipated, and nowhere in the licences do Imutran or the Home Office state that the experiments will continue until the deaths of the animals. Indeed, to the best of our knowledge, at no point in the history of the Animals (Scientific Procedures) Act 1986 has the Home Office claimed that ‘moderate’ severity experiments might entail lethal endpoints.

For the Home Office to now suggest that lethal endpoints are consistent with moderate severity is to move the goalposts to such an extent that the regulatory system is gutted of any meaningful force. The fate of the primates found dead in their cages is irrefutable evidence of the Home Office’s misconduct.

**Question 4: How can the Home Office reconcile primates being “very distressed”, “in a collapsed state”, “in obvious discomfort” etc. with merely “local problems” with the transplant site or trivial welfare impairments?**

The Home Office response here provides a good example of the equivocation and dissembling that characterises its statements on this matter. In an effort to justify its underestimation of the severity of the Imutran procedures, the Home Office is misrepresenting the suffering experienced by the primates.

The Home Office response begins with a denial that they have described the suffering of the Imutran primates as involving “trivial welfare impairments”. But this is surely the impression that the Home Office is trying to foster when they suggest that the experiments “should not seriously impair the welfare of the animals”.

The Home Office then claims that our reference to “local problems” is part of a longer Home Office quote – “local problems of rejection” – related to just one specific baboon – W205m - who was transplanted with a pig heart into his neck, then suffered local inflammation and hence was observed in “obvious discomfort”. The Home Office response is untrue. In fact, our reference to “local problems” is drawn directly from the first bullet point of paragraph 23 of the Home Office memorandum to the Home Affairs Committee, which referred not to just one specific primate, but to at least 122 primates who underwent pig organ transplants where their own organs remained in place.

As we have explained at some length in our reply to the Home Office memorandum<sup>7</sup>, the suffering of many of these animals was clearly not limited to “local problems”, contrary to the Home Office’s claims. For example, these primates suffered many acute, systemic conditions such as death, collapse, “Abdomen swollen and appears fluid filled. Salivating. Very laboured breathing. Extreme difficulty

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<sup>7</sup> “In a collapsed state”: available at <http://www.xenodiaries.org/pr040210.htm>

trying to walk”<sup>8</sup>, “gastrointestinal toxicity, resulting in severe diarrhoea”,<sup>9</sup> “uncoordinated limb spasms” and “stroke”.<sup>10</sup>

The Home Office even misrepresents the suffering experienced by W205m. They claim that his recorded details “are entirely consistent with clinical signs resulting from local inflammation at the transplant site.” (We have appended the full clinical signs for this animal to the end of this briefing.) Firstly, the local inflammation clearly caused him enormous suffering, and the entire premise that “local problems” cannot cause serious welfare problems is sophistry. However, in any case he clearly suffered systemic welfare problems. The clinical signs record him being “quiet and huddled” for several days before his death. The RSPCA’s report into this research programme notes that in these circumstances this is potentially indicative of pain and that “it is not common place for healthy primates to rest in the presence of human technicians”<sup>11</sup>. Furthermore, he was also noted to be “unsteady” on several occasions. Eventually, the afternoon *after* it had been observed that he was “showing obvious discomfort” and “reluctant to move”, he was “sacrificed”.

The Home Office’s brief discussion of the primate noted to be “very distressed” does not appear to deny that he suffered a “serious welfare impairment”, yet the department has failed to acknowledge that this was a breach of the moderate severity limit and to punish those responsible for such unlicensed suffering.

The Home Office assertion that the observation “in a collapsed state” refers to one animal – V337m - is also seriously misleading. In fact, during ‘moderate’ procedures the condition of several primates was allowed to deteriorate to the point where they were found in a collapsed state (this is in addition to those found dead). Furthermore, the uncertainty said to surround the cause of V337m’s death is not consistent with the Home Office’s statement in their memorandum to the Home Affairs Committee.

## **Home Office refusal to substantiate its claims (Question 5)**

At various points since the Diaries of Despair report and documents were originally published in September 2000, the Home Office has adopted the tactic of attempting to refute the unambiguous implications of the leaked documentation by repeated references to additional, unpublished records (which are, in any case, irrelevant to the basic case). Now, when challenged to produce these records,

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<sup>8</sup> Monkey X214f

<sup>9</sup> Van den Bogaerde J and White DJG, “Xenogeneic transplantation”, *British Medical Bulletin*, 1997; 53 (no.4): 915.

<sup>10</sup> Baboon W201m

<sup>11</sup> RSPCA Report: Non-Human Primates in Xenotransplantation Research in the UK, June 2002: 33.

the Home Office claims that it is “not in a position to do so”. The Home Office is clearly trying to manipulate this debate through a combination of unsubstantiated claims and control of information.

The latest Home Office response achieves the extraordinary feat of claiming that they have no additional documentation while simultaneously making assertions that rely on such documents. The Home Office implies that such additional documentation is the property of Imutran/Novartis. However, the Home Office and the Animal Procedures Committee will have received several progress reports and other correspondence from Imutran, Home Office Inspectors will have compiled their own reports on the Imutran research, and Inspectors will have compiled papers for both the Animal Procedures Committee and for Ministers. For example, the Chief Inspector’s compliance review published in June 2001 claims to have taken over 250 hours of work, during which he claims to have:

- “Reviewed all of the original study documentation, including available video footage of study animals.”
- “Reviewed all of the recorded information maintained by the Home Office on the Imutran research programme.”
- “Interviewed Imutran management and staff, and other third parties, thought to have essential information relevant to the review.”
- “Sought supplementary information, clarification and comment from the Imutran management, and others, as required.”<sup>12</sup>

It is inconceivable that the Home Office has no documentation related to these activities, such as notes taken that formed the basis of the subsequent report. It appears that either the Home Office is misleading MPs and the public when it gives the impression that it has no relevant additional documentation, or it has divested itself of documents that were relevant to the court case, any future independent inquiry that has been called for in successive Early Day Motions since September 2000, and to the current inquiries of the Parliamentary Ombudsman.

## **Collusive relationships between Inspectors and researchers (Questions 6 and 8)**

The following confidential note of an Imutran meeting raises serious concerns that the Home Office’s role in the moderate categorisation for most of the experiments may have been more pro-active and collusive than they are willing to admit:

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<sup>12</sup> *Report by the Chief Inspector: Imutran Ltd.: Compliance With Authorities Issued Under the Animals (Scientific Procedures) Act 1986* (2001). Home Office: paragraph 4.1. Following these points, he utters the familiar line: “This review thus includes information not previously available to the Home Office, and not available to Uncaged.”

“Sandoz have suggested kidney transplants, the Home Office will attempt to get these classified as moderate procedures.”<sup>13</sup>

Despite being asked to explain in full the circumstances surrounding this apparent attempt to manipulate the regulatory system, the Home Office once again provides a vague and misleading account of its severity assessments that is flatly contradicted by the actual evidence. For example, the Home Office claims that severity limits are “thoroughly tested and challenged”, yet all the available evidence points the contrary. Indeed, the Home Office has admitted that it accepted Imutran’s severity limit proposals.<sup>14</sup>

The Home Office appears to be trying to mislead when it states in its response to question 6: “On the advice of the Inspectorate and the Animal Procedures Committee, Ministers required that some of the project licences should be given a substantial severity band.” In fact, in its memorandum to the Home Affairs Select Committee, the Home Office admits that the ‘substantial’ severity limits (which applied to only 16 out of over 500 procedures) were suggested by Imutran and accepted by the Home Office.<sup>15</sup> The substantial limit was allocated to procedures that were so intrinsically severe – involving the splitting of the breastbone and replacement of the baboons’ own hearts with that of a pig – that a moderate severity limit would have transparently implausible.

The Home Office goes on to state:

“The appropriateness of the severity limits and bands imposed was also discussed, and endorsed, when the Animal Procedures Committee considered the Imutran applications – see paragraph 32 of the APC Report for 1999.”

This is, once again, untrue. The quote for the 1999 discussion actually refers to the analysis of only a very small proportion of the Imutran research – the final few kidney xenograft procedures conducted under a new project licence PPL80/1336. This does not equate to a general endorsement of the Home Office’s acceptance of all of Imutran’s proposed severity limits, as the Home Office suggests. Furthermore, the quote itself from the APC report reveals substantive concern about the ‘moderate’ rating despite agreement (based on whatever information the APC was provided with by the Home Office) with the Home Office’s formal interpretation.

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<sup>13</sup> Document CY14 (28 April 1995). Sandoz were Imutran’s investors at the time, later merging with Ciba to form Novartis and then acquiring Imutran. Indexed Imutran documents are accessible from [www.xenodiaries.org/evidence.htm](http://www.xenodiaries.org/evidence.htm)

<sup>14</sup> Home Office (June 2003). *Animals (Scientific Procedures): Imutran Xenotransplantation Research*. Paragraph 25.

<sup>15</sup> It is slightly odd that the Home Office refers here to severity ‘bands’, when the discussion is focussing on ‘limits’ which play a different role in the regulatory system. Presumably they refer to ‘bands’ to try to avoid explicitly lying, though they are clearly attempting to create a false impression.

An extract from an Imutran meeting minute reveals:

“The new kidney Project License goes before the APC next Thursday... The Home Office Inspector has on several occasions expressed his view that Thursday will be merely a ‘rubber stamping’ exercise.”<sup>16</sup>

For the first time, the Home Office has stated that it has looked into this. Predictably, the Inspector is said to have refuted the remarks attributed to him, and the author of the minute is said to have conceded that the term ‘rubber-stamping’ was not used. In the absence of an independent inquiry, such assertions lack credibility. Indeed, the impression of a collusive relationship between Imutran and the inspectorate is corroborated by an earlier communication between Imutran and HLS. In relation to the forthcoming APC meeting, an Imutran official relates:

“For your information he [the Inspector] also told me that our application for a kidney transplant licence has been reviewed by the inspectorate and that we should expect to have some ‘I’s to dot and some T’s to cross’ before it goes to the APC.”<sup>17</sup>

The Home Office response offers an alternative interpretation that simply confirms the reality of the Home Office’s rubber-stamp view of licence applications:

“Rather, he [the Inspector] had expressed the hope – in order to avoid the need to kill animals already under study – that the replacement licence would become valid before the existing licence expired.”

This raises the question of why Imutran would begin experiments on animals when they knew that their project licence was about to expire – unless they had already been given indications that the APC would be manipulated in such a way to approve the application, as signalled in the leaked documents?

Furthermore, the replacement licence would potentially have led to five more years of such experiments, a much greater consequence than the immediate issue allegedly referred to by the Inspector of animals under study at the expiry of the existing licence, whose death could have been avoided by some other administrative measure.

## **Failure of Imutran to achieve research objectives (Question 7)**

The Department of Health’s xenotransplantation advisory committee, the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), having considered the Diaries of

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<sup>16</sup> Document CY24.2

Despair documents together with the lack of progress in Imutran's research, stated that the likelihood of clinically-viable pig organ transplants was 'receding'.<sup>18</sup> This was, as the New Scientist magazine put it, a polite way of saying that the technology was 'dead in the water.'<sup>19</sup> A transplant surgeon and member of the UKXIRA described Imutran's research as a 'blind alley'.<sup>20</sup>

Stated Home Office policy claims that animal research is permitted on the basis that it is "likely to achieve the stated objectives".<sup>21</sup> According to Home Office statements during the research programme, in reference to its statutory cost-benefit assessment of the Imutran research:

"the main and ultimate benefits of this research can only accrue if xenotransplantation can be used in clinical practice."<sup>22</sup>

Similarly, both the actual project licence forms (which are the *legal basis* of the licensing decision) and the Chief Inspector's review, list the pre-conditions for clinical trials of pig organs as the basis for the decision to permit the Imutran research:

1. Prevent hyperacute rejection and elucidate subsequent rejection mechanisms
2. Achieve long-term xenograft survival through an effective immunosuppressive protocol
3. Assess the ability of the organ to function sufficiently to maintain life of recipient

Imutran repeatedly indicated in communications with the Home Office that their research was likely to meet these pre-conditions in the near future. For example:

"These data reported here encourage us to believe that [blank] in combination with [blank] will form the basis of an immunosuppressive regime which would be approved by the Department of Health Xenotransplantation Interim Regulatory Authority for clinical use. Given the current success of these studies, we would ask for authority to continue to use [blank] and its analogues in baboons..."<sup>23</sup>

However, in response to increasing pressure over its conduct, the Home Office has recently provided a conflicting account of its scrutiny of Imutran's research. It now claims that the research was licensed merely on the basis of the 'benefit' of "answering scientific questions intended in the short-term to

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<sup>17</sup> Document CY7.2

<sup>18</sup> UKXIRA Third Annual Report, September 1999 - November 2000. Department of Health, published February 2001, paras 6.8-6.15.

<sup>19</sup> New Scientist, "Waiting for a miracle - time is running out for organ transplants from animals", 12.1.02, p.3.

<sup>20</sup> Transcript of UKXIRA Open Meeting, Wed 7 Feb 01.

<sup>21</sup> Hansard, Written Answers for 28 June 2000, Mike O'Brien, 125262 "Xenotransplantation".

<sup>22</sup> Letter from Steve Wilkes, Head of Animal Procedures Section, Home Office, to Dan Lyons, 3 March 1998.

<sup>23</sup> Document ND14.6

provide a better understanding of the immunology and performance of xenografts”. There are two issues with this position:

- While these controversial and severe experiments were taking place, the Home Office did not seek to justify them in terms of such an abstract outcome.
- Contrary to the Home Office’s answer to Question 7 of the recent Open Letter, this research objective corresponds only to the first of the three objectives listed above that had originally formed the basis of the permission for Imutran’s research and, in fact, Imutran did not even fully achieve this initial objective. The ‘legal’ objective - tangible medical benefits for humans - appears to have vanished in the latest Home Office version of events.

The reason why the Home Office has changed its story seems clear. Our public interest legal victory over Imutran/Novartis has naturally intensified scrutiny of the Home Office’s implementation of animal research regulations. Once again, the department is moving the goalposts in an attempt to justify its failure to properly assess and/or intervene in a failed programme of research, which had appalling consequences in terms of futile animal suffering.

## **Deaths in transit – covering up lethal regulatory breaches (Question 9)**

In August 1998, three monkeys were found dead, bleeding from the nostrils, en route from the Philippines to Imutran’s research programme in Cambridgeshire. The Home Office has repeatedly misled Parliament and the public by failing to own up to the fact that the transport crates breached International Air Transport Association (IATA) guidelines.

The Home Office states that “International Air Transport Association minimum dimensions were not breached”. However, advice attached to a letter from MAFF to the Home Office, dated 17 November 1998, clearly states otherwise:

“The over-riding rule is that dimensions must relate to the size of the animal. The reports from the consignor/shipper and consignee recognise that the dead animals were probably too large for their containers. It would not be possible for the regulations to be container size specific for every size/weight of each breed and species of animal. The principle is stated that ‘in general space to stand, turn, and lie down is required. It must be for the shipper to provide a container of appropriate size for the animal to be shipped.’”<sup>24</sup>

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<sup>24</sup> Document CY5.5

However, this is not the only breach wrongly denied by the Home Office. In Written Answers and in their latest statement, the Home Office has described the containers as “less well ventilated”. This story is, at best, economical with the truth. The MAFF advice to the Home Office is unequivocal:

“The letter from [blank] states that the dead animals were in compartments with ventilation on only two sides. The regulations specify ‘ventilated on at least three sides’. It would appear that the containers used do not fully comply with the IATA regulations.”<sup>25</sup>

Although the Home Office claims that “immediate action was taken” in relation to these deaths, such action did not in fact include any punishment against those responsible for the shipping of these unfortunate creatures. If vital regulations can be broken with impunity, then they are clearly worthless. When this situation is considered in conjunction with the Home Office’s consistent cover-up of these devastating breaches, one perceives an official attitude of disregard towards the regulatory system.

### **Misleading statements regarding research moratorium (Question 10)**

The Home Office has provided fundamentally inconsistent accounts of the circumstances surrounding a moratorium on Imutran’s research in mid-1999. The shifting lines taken by the Home Office seem to have been politically motivated:

Line 1: In the Chief Inspector’s compliance review, published in July 2001 while Imutran and Novartis were attempting to gain a permanent injunction preventing Mr Lyons and Uncaged disseminating the leaked documents, the Home Office claimed:

*“This moratorium was voluntarily proposed and implemented by Imutran management.”*

This gives the impression that Imutran were sensitive to their regulatory and animal welfare responsibilities: helpful to them in the context of the ongoing legal battle.

Line 2: However, the Home Office memorandum to the Home Affairs Committee, published in October 2003 after the settlement of the court case and in the midst of growing concern over its conduct, provides a contradictory version of events that is favourable towards the Home Office:

*“This was not resolved by negotiation with the project licence holder, and the Home Office implemented a moratorium on Imutran’s main programme of work.”*

Line 3: Now the Home Office has been challenged over these inconsistencies, it has failed to clarify the true situation. Instead, it has provided a third, different version of events:

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<sup>25</sup> *ibid.*

“The moratorium on Imutran’s operative surgery was agreed between Imutran and the Home Office...”<sup>26</sup>

“After discussion with Imutran this was put into effect by an administrative agreement...”<sup>27</sup>

Comparison of these three story-lines clearly demonstrates that the Home Office is prepared to issue misleading statements about its regulatory practices to the public and Parliament, to the benefit of itself and Imutran/Novartis. The first statement is particularly scandalous because it potentially prejudiced the legal proceedings between Imutran/Novartis and Lyons/Uncaged in favour of the former.

## **Home Office wrongdoing confirmed by Uncaged legal victory (Question 11)**

The Home Office has worked itself into an absurd position because it still refuses to acknowledge the fact that its conduct was at the very heart of the Imutran/Novartis vs Lyons/Uncaged case. It appears likely that the department is seeking to sow confusion regarding the implications of the outcome of the case because it is in fact *de facto* confirmation of Home Office misconduct. The true situation is illustrated by the following extracts from the pleadings, beginning with Imutran’s second witness statement that was submitted in pursuit of a total and permanent injunction:

*“The Home Office Inspectorate controls all animal experimentation in the UK...*

*In paragraph 15 Mr Lyons makes clear that the Defendants’ aim is to use our information and his analysis of its significance to put pressure on regulatory bodies ‘to adopt a more balanced approach to the issue of animal experimentation’...*

*It is my belief that any public interest considerations in favour of disclosure of Imutran’s copyright, private and confidential materials is adequately served by their disclosure to and use by the authorities I have mentioned [primarily the Home Office].*

*However, the Defendants wish to put pressure on regulatory bodies by making all our documents and information available to the public at large, and not only in this country but worldwide. Mr Lyons suggests (paragraph 19) that the regulators cannot be trusted to take a responsible approach, and makes a number of allegations of failings by the Home Office itself. I reject Mr Lyons’ criticisms of the ability of regulators to conduct a proper investigation...”*

Uncaged and Mr Lyons’ Defence, prepared by David Bean QC and Mark Afeeva of Matrix Chambers, stated:

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<sup>26</sup> Letter from Home Office to Dan Lyons, Uncaged, 26 October 2004.

<sup>27</sup> Answer 10, Home Office (August 2004).

*“The Claimant’s materials, in the view of the Defendants, showed that: ...*

- *The Home Office inspectors whose duty it is to monitor the activities carried out by or on behalf of the Claimant have a relationship with the Claimant that is too indulgent, in that the monitoring undertaken is ineffective and fails to ensure that the primates are protected as the law requires...*
- *Disclosure of the documents was in the public interest... The Defendants will in particular rely on the following facts and matters:*
- *The Claimants materials raised extremely serious questions concerning animal welfare, the regulation of the research by the Home Office... ”*

The Home Office’s statements in refusing to acknowledge this situation are simply an exercise in obfuscation. Contrary to their assertions, the Home Office has seen most of the evidence put forward in the case, which included some of its own documents. In correspondence to the Home Office and in public statements, we have made it clear that the evidence of Home Office wrongdoing is at the heart of our justification for attempting to publish the confidential information, and gives rise to the need for an independent inquiry. In addition, the Home Office has been in close contact with Imutran during the case.

Furthermore, the Home Office makes another misleading point when it says: *“Had Home Office regulation been an issue we would expect to have been advised accordingly and offered the opportunity to respond.”* In fact, we understand that it would have been extremely unlikely for a judge to call Home Office witnesses. The reality is that the Home Office were responding indirectly by publishing misleading and prejudicial statements that were relevant to the issues material to the case, such as the inaccurate Chief Inspector’s compliance review mentioned in the previous section. This Home Office document was actually presented by an Imutran lawyer at one hearing in an unsuccessful and incorrect attempt to persuade the judge that their clients had been cleared of wrongdoing.

## **Home Office shied away from legal proceedings (Question 12)**

In another misleading aspect of their version of events, the Home Office claims that they did not have the opportunity to initiate legal proceedings to prevent disclosure of a second leak of documents that emanated from themselves in October 2002. These Home Office documents comprised highly confidential project licences and communication between the Home Office and Imutran. By coincidence, Uncaged and Mr Lyons had applied to the High Court to force Imutran/Novartis to disclose these documents (among many others), as they were clearly relevant to the case and it was

believed that they would support the public interest argument in favour of disclosure. Sight of the documents following the leak confirmed that view. On the eve of the hearing of Uncaged's application, Imutran/Novartis capitulated and consented to extensive publication of the confidential documents from both leaks that they had previously sought to suppress.

Contrary to the Home Office's claims, the department did have the opportunity to try to prevent disclosure of these documents. A letter to Mr Lyons from the Chairman of the Animal Procedures Committee (to whom Uncaged had sent a set of the Home Office documents) reveals that the Chairman had passed the documents to the Home Office some time before 7 March 2003, approximately a month before the case was settled and the publication of the confidential Home Office documents. It was Uncaged's view at the time that the Home Office was unlikely to try to prevent publication of the documents because of the overwhelming public interest in their dissemination would lead to an embarrassing legal defeat. The Home Office's inaction and their subsequent attempts to misrepresent the situation tends to confirm that view.

The Home Office also seeks to give the false impression that they did not own the documents and therefore had no interest in them. To correct this inaccuracy, it is necessary to point out that in legal correspondence, Imutran/Novartis sought our agreement for the documents to be passed to the Home Office. Imutran/Novartis asserted that as the owner of the documents, the Home Office had the right to apply to the Court for an Order to prevent publication of these documents. This request was refused because it breached rules on the disclosure of evidence.

**Dan Lyons, Uncaged Campaigns**

**November 2004**