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## **A meeting with Dr John Landers, Chair of the Animals in Science Committee**

February 2014

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### **The Academy of Medical Sciences**

The Academy of Medical Sciences is the independent body in the UK representing the diversity of medical science. Our mission is to promote medical science and its translation into benefits for society. The Academy's elected Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service. We work with them to promote excellence, influence policy to improve health and wealth, nurture the next generation of medical researchers, link academia, industry and the NHS, seize international opportunities and encourage dialogue about the medical sciences.

### **The Society of Biology**

The Society of Biology is a single unified voice for biology, representing a diverse membership of individuals, learned societies and other organisations. Members include practising scientists, students at all levels, professionals in academia, industry and education, and non-professionals with an interest in biology. With such a broad membership, we are uniquely placed to represent the wider bioscience community and serve the public interest. We are committed to ensuring that we provide Government and other policy makers - including funders of biological education and research - with a distinct point of access to authoritative, independent, and evidence-based opinion, representative of the widest range of bioscience disciplines.

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## Summary

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The Academy of Medical Sciences and the Society of Biology welcomed the formation of the Animals in Science Committee (ASC), a non-departmental advisory body of the Home Office, in 2013, as part of the transposition of the European Union's Directive on 'Animals used for scientific purposes' into UK law. Both organisations recognise the importance of the ASC's role in advising the Home Office on the use of animals in scientific research, and are keen to support its work by facilitating engagement with the biomedical research community. In February 2014, the Academy and Society jointly held a meeting to allow Dr John Landers, Chair of the ASC, the opportunity to discuss the Committee's work with an audience of researchers from the organisations' Fellowships and the broader research community.

Dr Landers introduced the ASC by summarising its history, function and responsibilities. He highlighted the context in which the ASC functions: research using animals is broadly accepted by society subject to certain conditions and therefore appropriate regulation has to be implemented that is acceptable to society. The ASC's objectives include striking a balance between giving regard to the legitimate requirements of scientific inquiry to promote human and animal health and protecting animals against unavoidable suffering and unnecessary use in scientific procedures. In this task, the ASC engages with many stakeholders including Home Office staff, the scientific community, welfare groups and the public. Dr Landers emphasised the independence of the Committee, whose members have a variety of expertise and are members in their own right rather than as representatives of any organisations or groups. The ASC will complete its membership with the appointment of two additional members with expertise in veterinary science and biotechnology and/or pharmaceutical research soon, and will develop a communication network with Animal Welfare and Ethical Review Bodies (AWERBs) to help address its ongoing responsibilities.

The Q&A discussion addressed several topics including the role and scope of the ASC (diffusion of best practice, license applications and ethical decision-making), regulations covering the use of animals in science (reporting, defining 'legitimate' scientific requirements and what an 'attractive' regulatory environment looks like) and experiences of project licence holders (including contact with Home Office Inspectors and implementation of the 3Rs; the replacement, refinement and reduction of the use of animals in research).

All agreed that the meeting had been a constructive opportunity for dialogue between Dr Landers as Chair of the ASC and researchers involved in the use of animals in scientific research.

## Presentations

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### Introduction

The Academy's President, Professor Sir John Tooke PMedSci, highlighted the Academy of Medical Sciences' and Society of Biology's emphasis on the importance of using animals in research to benefit human and animal health. The President noted the commitment of both organisations to support animal research when no alternative means of producing comparable research are available, and their strong commitment to promote principles such as the 3Rs, openness on research practice, and appropriate regulation. The President also highlighted that the Academy and Society welcomed the formation of the Animals in Science Committee (ASC) in 2013.<sup>1</sup> Both organisations recognise the importance the Committee's work to address all aspects of the use of animals in research, including complex areas such as 'animals containing human material' (ACHM), which was the focus of a 2011 Academy of Medical Sciences' report.<sup>2</sup>

### Introduction to the Animals in Science Committee

#### *Dr John Landers (ASC Chair)*

Dr Landers talked about the formation, function and responsibilities of the ASC, as well the context in which the ASC functions. He noted that research using animals is a privilege for researchers granted because of the importance of their work, and this rests on a concordat between society and researchers, where the public broadly accepts animal research subject to certain conditions. This requires finding a societally approved balance between desirable and undesirable outcomes.

The functions of the ASC under Section 20 of the Animals (Scientific Procedures) Act 1986 (ASPA) are to:

- Advise the Secretary of State for the Home Department ('the Home Secretary' and Animal Welfare and Ethical Review Bodies (AWERBs);
- have regard to the legitimate requirements of science and industry, the protection of animals from avoidable suffering and unnecessary use in scientific procedures;
- Share best practice in relation to acquisition, breeding, accommodation and the use of protected animals; and share information with counterpart Committees in other nations.

Dr Landers emphasised that the ASC is independent and its constituent Chair and members do not represent any organisations with which they are affiliated. The ASC aimed to recruit ten members when it was formed in 2013: five with specialist competences, and five lay members. The following competences were sought for the Committee: commercial biotechnology and/or pharmaceutical research; statistics; animal welfare; veterinary science, and neuroscience. Appointments of experts in biotechnology/pharmaceutical research and veterinary science are currently being finalised. The ASC's membership is available online.<sup>3</sup> The Committee meets four times per year, and it is supported by a secretariat in the Home Office.

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<sup>1</sup> <https://www.gov.uk/government/organisations/animals-in-science-committee>

<sup>2</sup> Academy of Medical Sciences (2011). *Animals containing human material*. <http://www.acmedsci.ac.uk/policy/policy-projects/animals-containing-human-material/>

<sup>3</sup> <https://www.gov.uk/government/news/new-members-of-animals-in-science-committee-to-hold-first-meeting>

Dr Landers discussed the responsibilities of the Committee, which so far have focused mainly on strategy development, including the formation of sub-committees to address specific issues (which can co-opt additional members), and development of policy regarding the use of animals in science. The ASC is developing a working protocol, based on those of similar bodies such as the Home Office's Advisory Council on the Misuse of Drugs.<sup>4</sup> Briefly, these responsibilities are:

***Continuing responsibilities:***

- License applications: the ASC advises on applications referred by Home Office Inspectors (HOIs). The Committee is to review the procedure regarding referred applications.
- AWERB liaison: through the AWERB liaison sub-committee.
- Diffusion of best practice: through the 3Rs sub-committee (addressing the replacement, refinement and reduction of the use of animals in research).
- Outward engagement: engagement with stakeholder groups, public debate and sharing of information with equivalent EU committees through the ASC's Outward Engagement sub-committee.

***2013/14 responsibilities:***

- Guidance on ASPA: the ASC has advised on the development of a document describing Operational Guidance to ASPA, which was laid before Parliament in March 2014.
- Human admixed embryos: the ASC is also advising the Home Office on guidance for regulating potential experiments of this nature.
- Reporting on actual and cumulative severity: the ASC is awaiting a Ministerial letter to ask for advice on the pilot programme of work addressing this issue.
- The replacement of Section 24 of ASPA, which regulates the publication of animal research project licences, which are exempt from clauses in the Freedom of Information Act: the ASC is awaiting an opportunity to comment on feedback from a consultation on this issue and will assist in developing options for allowing greater openness and transparency by researchers.
- Investigation into non-compliance to animal research regulations at Imperial College London: the ASC is considering both the Home Office inspectorate's report and Imperial's independent Brown report.<sup>5</sup>

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<sup>4</sup> <https://www.gov.uk/government/organisations/advisory-council-on-the-misuse-of-drugs>

<sup>5</sup> Imperial College London (2013). *Independent Investigation into Animal Research at Imperial College London*. <http://brownreport.info/>

## Question and answer session

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There was a diverse and active discussion, chaired by Professor Dominic Wells FSB, Chair of the Society of Biology's Animal Science Group. The issues discussed can be grouped under three broad headings:

1. The role and scope of the ASC
2. Regulations covering the use of animals in science
3. Experiences of project licence holders

### **The role and scope of the ASC**

The issues raised here included licence applications, the responsibility of the ASC to diffuse best practice and ethical decision-making.

#### ***License application referrals***

In his presentation, Dr Landers noted that in instances where HOIs referred project licence applications to the ASC, he did not see the role of the Committee being to 'second-guess' the judgment of HOIs. Concern was noted from attendees that these applications are referred on because they are difficult to assess and therefore should be given appropriate consideration. Dr Landers emphasised that he recognises why the inspectorate feel a further opinion is needed and that he wants to continue to refine the criteria for referral and develop specific criteria for streamlining judgments on these more difficult applications (e.g. by potentially adding acceptance criteria that carry conditions for the researchers, such as additional reporting).

There was a query as to whether peer review evidence from research grant applications will be used by the ASC when making decisions on project licence applications referred by HOIs. Earlier discussions between the Home Office and research funders had reached agreement that these reviews, which often included important comments from the NC3Rs on animal welfare aspects of the proposed research, could be made available to the ASC. Dr Landers explained that the Committee has only received a small number of these applications so far (three to date) and therefore the sample is limited. However, these applications were all referred to assess the balance between costs and benefits; the scientific value of the proposed research was generally not in question, and there was no difficulty regarding the communication or complexity of the science involved in licence applications that could be aided by the use of grant applications. However, Dr Landers agreed that the ASC could make use of the reviews if needed.

#### ***Ethical decision-making***

There was a query regarding the ASC's role in ethical decision making. The process of ethical decision making has been reviewed many times previously, and there was concern that the Committee is being charged with entering this field. Dr Landers explained that the role of ASC is to identify and diffuse best practice of existing ethical decision making among AWERBs, rather than to review the process itself.

#### ***Diffusion of best practice***

When asked about how the ASC would achieve the diffusion of best practice on the use of animals in research in the research community, Dr Landers outlined that he believed the first step was to get a representative sample of the AWERBs and subsequently enhance lateral communication between the bodies. As a first step, the ASC has made progress in developing a database of AWERBs to aid communication, which didn't previously exist.

## **Regulations covering the use of animals in science**

The issues raised here included concerns about specific aspects of reporting requirements, the difficult regulatory environment confronting many scientists, including those recruited from outside the UK and discussion of what constitutes 'legitimate' scientific requirements for using animals in research.

### ***Reporting of severity and animal numbers***

Attendees raised concerns regarding the reporting requirements for the severity of procedures and queried whether the draft guidance on the operation of ASPA will be revised. Dr Landers noted that the ASC is able to comment on the ASPA guidance document as part of its work with the AWERBs.

Attendees also suggested that the regulatory environment may be negatively affecting the climate of public opinion on animal research in the UK relative to other countries. For example, neither the inclusion of genetically modified rodents used for breeding in total animal research numbers or the automatic categorisation of any animal death as a 'severe' procedure are universal practices in other EU countries. Dr Landers expressed his shared concern that this could impact UK competitiveness in areas of research reliant on the use of animals, and pointed to the need for more fine grain data on animal numbers used. However, he acknowledged the difficulties that face Government in presenting specific statistics in preference to total numbers. Regarding animal deaths and severity, Dr Landers has raised the concern of potentially unwarranted 'severe' labelling with the Animals in Science Regulation Unit (ASRU) of the Home Office. He also expressed his hope that more accurate and nationally and internationally consistent methods of presentation will be introduced in future.

### ***Defining 'legitimate' scientific requirements***

Section 20 of ASPA places a requirement on the ASC to have regard for the 'legitimate requirements' of science. There was discussion of how the ASC interprets the term 'legitimate', particularly in regard to commercially sponsored research. Dr Landers outlined that work judged to be of scientific merit by conventional peer review criteria and which is deemed to be lawful should not be unreasonably impeded. Furthermore, that commercial sponsorship of research does not automatically affect whether it is legitimate, a fact that needed to be more widely communicated.

### ***An 'attractive regulatory environment'***

There was discussion regarding Government references to creating an 'attractive regulatory environment' with respect to research using animals and what this means. Dr Landers outlined that regulatory environments are inherently onerous to some degree and that in his view, a regulatory environment can only be attractive so far as compliance with it incurs the lowest possible cost. The ASC is not resourced to review the regulatory burden on researchers but by engaging with AWERBs it can highlight issues, and interactions via organisations such as the Academy and the Society of Biology. Other Government Departments with vested interests in research such as the Department for Business, Innovation and Skills (BIS) will also help to relay concerns to the Home Office. Finally, Dr Landers added that the inspectorate is dedicated to addressing unnecessarily burdensome regulation which does not of itself actually improve animal welfare and that he hopes that the current regulatory regime is successful in demonstrating to the public that researchers conduct their work with proportionate and legitimate checks of costs and benefits involved.



## **Experiences of project licence holders**

Issues raised here included difficulties regarding inconsistency of HOIs and outcomes of implementing the 3Rs.

### ***Ensuring consistency between inspectorates***

There was much discussion of difficulties that some project licence applicants have experienced. Researchers have experienced delays in their research due to inefficiency in the project application system and there was discussion of the challenges raised when there are inconsistencies in the requirements of different inspectorates.

Dr Landers shared the concerns regarding application delays. The ASC is conscious of these problems and has engaged in discussion with stakeholder groups about delays. It was noted that the UK Biosciences Sector Coalition (of which the Academy and Society are both members) has also raised this issue with the Home Office. Dr Landers indicated that the move to an electronic system should improve the situation. However, he emphasised that some problems with inconsistency are unavoidable due to the difficulties of cost-benefit analysis and a lack of understanding in some areas necessary to make more consistent judgements. Individual, 'isolated' judgements of cost-benefit analyses are therefore inevitable sometimes. Dr Landers noted that if dramatic inconsistencies are occurring, these should be investigated by ASRU, which he thinks have a strong general commitment to counter them.

### ***3Rs***

Finally, there was a discussion on the 3Rs in practice— whether the number of animals used in science is actually decreasing, despite a commitment to the 3Rs. Dr Landers responded by emphasising that the concept of reduction is complex and total numbers should be perceived as weighted, since these also relate to the severity of the procedures undertaken. For example, 5 very severe procedures could be regarded as a worse scenario than one involving 100 mild procedures. Progress towards the 3Rs appears to be taking place in his experience and the ASC continues to work to reduce the number of animals used, though their ability to do this is related to their resources.

## **Concluding remarks**

In drawing the meeting to a close, Professor Wells thanked Dr Landers for providing this opportunity for discussion. Professor Wells also reiterated the support of the Society and Academy for the use of animals in research, as demonstrated through efforts to promote ongoing dialogue between relevant parties, work to improve transparency of the research community (for example, by assisting to develop the Concordat on openness on animal research<sup>6</sup>), and regular engagement with ASRU via the UKBSC, which is co-ordinated by the Society's secretariat.

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<sup>6</sup> <http://www.understandinganimalresearch.org.uk/policy/concordat-on-openness-on-animal-research>



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