

Institution: University of Cambridge
Unit of Assessment: UoA32B
Title of case study: Risk, Trust and Bioethics
1. Summary of the impact (indicative maximum 100 words) Tim Lewens' research into risk, trust and bioethics can be shown to have informed and influenced policy debate. This work has shaped reports of the Business Innovation and Skills working group on Science and Trust, and also reports from the Nuffield Council on Bioethics. Lewens' key contributions to the latter's Human Bodies Report have resulted in invitations to give evidence to the Welsh National Assembly, thus helping to shape the Assembly's drafting of its new bill on human transplantation. His work on the Council's report on Mitochondrial Disorders has been echoed in the Human Fertilisation and Embryology Authority's (HFEA's) recent advice to UK Ministers, which aims to inform forthcoming debate to alter existing legislation on experimental mitochondrial therapies. Lewens' research has also led to his being asked to take on consulting roles to industry, most recently with AstraZeneca.
2. Underpinning research (indicative maximum 500 words) Tim Lewens joined the department of History and Philosophy of Science (HPS) at the University of Cambridge in 2000, initially as a Junior Research Fellow. In 2002 he became a University Lecturer, was promoted to Senior Lecturer in 2006, to Reader in 2010 and now to a Professorship in the Department from this October. Since 2000 he has undertaken a series of innovative studies of the concepts of risk, trust and their related roles in discussions of bioethics and technology policy. Most of this work was conducted by Lewens working alone, but some elements of the work have involved substantial contributions from others. The most notable example of this collaborative work was the co-authored report on The Universal Ethical Code for Scientists and the 'Crisis of Trust in Science' (2010), which Tim Lewens wrote with Dr Stephen John, also of HPS. This piece of novel research, which argued against the very idea of a generic crisis of trust in science, and instead urged focus on more specific ways in which scientific evidence is used within policy formation, was commissioned as part of the government's Science in Society Programme review of 'Science and Trust' in 2009-10. In broad terms, Lewens' work on risk (e.g. Lewens 2007a, 2008) aimed to sketch a defensible version of the precautionary principle, and also to clarify the ethical status of various forms of risk cost-benefit analysis. His work in bioethics has assessed issues relating to modern biotechnology, risk and identity (e.g. Lewens 2002, 2004, 2009, 2012). He has criticised fashionable appeals to notions of human nature as they are often applied to debates over the introduction of new and potentially risky biotechnologies (Lewens 2012), arguing that biology grounds only very permissive conceptions of human nature, which cannot be used to justify conservative opposition to human enhancement. He has also been a consistent opponent of 'genetic exceptionalism', whereby genetic technologies are singled out for specific forms of regulatory oversight or ethical censure (e.g. Lewens 2002, 2004, 2009). In this work Lewens casts doubt on the basic ethical justification for wholesale bans on modifications to the 'germ-line', for example, in a manner which has consequences for the ethical permissibility of very new techniques for modification of mitochondrial genomes. In all cases, Lewens' work is grounded in appeals to work in modern biology, as well as to the broader historical contexts of these debates. He has consistently aimed to link this work to issues of political concern, as exemplified by his work on altruism and the political use of images of human nature in his (2007b) Darwin. This book distinguished various important notions of altruism, and clarified their relationship to moral images of human nature.
3. References to the research (indicative maximum of six references) <ul style="list-style-type: none"> • Lewens, T. 'Development Aid: On Ontogeny and Ethics' <i>Studies in History and Philosophy of Biological and Biomedical Sciences</i> 23 (2002), 195-217. DOI: 10.1016/S0039-3681(02)00017-1 • Lewens, T 'What is Genethics?' <i>Journal of Medical Ethics</i> 30 (2004), 326-328, DOI: 10.1136/jme.2002.002642. • Lewens, T 'Risk and Philosophy' in Lewens, T. (ed.) <i>Risk: Philosophical Perspectives</i>. London:

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Routledge (2007a) 1-20. Available on request.

- Lewens, T *Darwin*. London: Routledge (2007b). Available on request.
- Lewens, T 'Taking Sensible Precautions' *Lancet* 371 (2008): 1992-1993, DOI: 10.1016/S0140-6736(08)60857-0.
- Lewens, T 'Enhancement and Human Nature: The Case of Sandel' *Journal of Medical Ethics* 35 (2009): 354-356, DOI: 10.1136/jme.2008.028423.
- Lewens, T *The Universal Ethical Code for Scientists and the 'Crisis of Trust in Science'* (with Stephen John). Report to the Science and Trust Expert Group, Department of Business, Innovation and Skills (8th March 2010). Published online: <http://interactive.bis.gov.uk/scienceandsociety/site/trust/files/2010/03/Ethical-Codes-and-Trust-16-Feb-20101.pdf>
- Lewens, T 'Human Nature: The Very Idea' *Philosophy and Technology* 25 (2012): 459-474, DOI 10.1007/s13347-012-0063-x.

Except for the commissioned piece of research co-authored with John, these items have all undergone peer-review, and are published either by internationally respected presses, or by highly respected international journals.

4. Details of the impact (indicative maximum 750 words)

Lewens' research into risk, trust and bioethics has had broad impact across government, industry and the policy sector more generally.

Lewens' work on risk and precaution (Lewens 2008) was cited in the Nuffield Council on Bioethics' recent (2011) report on Human Bodies: Donation for Treatment and Research [1, p. 146]. As a Council member, and working party member, Lewens took a leading role in writing the report's ethical framework for donation, and that framework drew in important ways on his own background work on altruism (outlined in Lewens (2007b)). An official at the Nuffield Council clarified Lewens' involvement as follows: "The ethical framework in the Council's 2011 report Human Bodies: donation for medicine and research derived substantially from the original ethical analysis undertaken by Tim Lewens (a member both of the Working Party and of the Council itself): in particular his detailed analysis of the different claims associated with 'altruism', and his subsequent categorisation of particular forms of encouragement to donate bodily material as either 'altruist-focused' (interventions that act through encouraging altruistic motivations) or 'non-altruist-focused' (interventions that may act to encourage donation, regardless of whether or not the potential donor may experience altruistic motivations). This consideration of altruism was fundamental in shaping the Working Party's consideration of the role of incentives in the context of donation. In the additional contested area of consent for donation ('opt-in' vs. 'opt-out' arguments for organ donation in particular), Tim's analysis of the justifications offered for non-health opt-out schemes (such as those used for occupational pensions) was vital in leading the working party to conclude that the key ethical requirement in this area should be to ensure that the taking of bodily materials after death should be based on the clearest possible information as to the person's wishes." [2]

The report's recommendation for increasing payment to egg donors was taken up by the Human Fertilisation and Embryology Authority (HFEA). [3] Lewens' own involvement in working on the Human Bodies report, especially with respect to its discussion of 'opt-in' and 'opt-out' consent schemes for donation, resulted in an invitation to give oral evidence to the Welsh National Assembly in January 2013, in connection with its new Human Transplantation (Wales) Bill [4]. His comments during the evidence session on the need for clarity in communication associated with the proposed changes to an 'opt-out' system of consent, on the ethical defensibility of a system of 'presumed consent', and on the need to ensure suitable donation of materials for research purposes were all translated into recommendations in the National Assembly's Stage 1 Committee Report, published in March 2013 [5]. Lewens was named several times in this report as the source for these recommendations. He was subsequently invited (in April 2013) by the Human Tissue Authority (HTA)—the official regulatory body responsible for overseeing uses of human tissues—to

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offer advice and comment on its draft Code of Conduct applying to the new Welsh Legislation [6]. The Director of Strategy and Quality at the HTA has explained that “Dr Lewens was keen to work with us and his input on stressing the legislation was permissive rather than prescriptive, that Specialist Nurses for Organ Donation do have discretion and this should be highlighted and that there should be no inference that deemed consent was a lesser form of consent, all added significantly to the second draft of the document. Dr Lewens also suggested drafting amendments to change the tone of the document, which were a great help and we believe make the redraft more accessible. The draft document would not be either as well drafted or well thought through without the input of Dr Lewens, and we are grateful for his support.” [6]

Lewens’ work on trust, precaution, human nature and genetic enhancement (Lewens 2004, Lewens 2009, Lewens and John 2010, Lewens 2012) has been cited by two further Nuffield Council reports: one entitled Emerging Biotechnologies (2012), another entitled Novel Techniques for the Prevention of Mitochondrial DNA Disorders (2012) [7, pp. 54, 60, 61]. Again, Lewens was centrally involved in formulating the ethical arguments relating to identity and germ-line interventions which underpinned the Mitochondrial Disorders report [8]. The Director of the Nuffield Council, has stated that “The role that Tim Lewens played in the preparation and drafting of this important report was particularly notable. His work in developing the ethical considerations, and especially in addressing issues around identity in relation to genetic therapies, formed a very substantial part of the arguments that sit at the heart of the report. His further contribution in applying these ethical discussions to the novel case of potential treatments for mitochondrial disorders was also critical to the success of this report” [8]. Lewens presented results of that report at a launch event in the Palace of Westminster (June 2012), and at the Trilateral Meeting of the French, German and UK National Ethics Committees (November 2012). The report has been discussed in a recent (March 2013) Parliamentary Office of Science and Technology (POST) report on Preventing Mitochondrial Disease [9]. The Nuffield Council’s conclusions regarding the ethical permissibility of mitochondrial donation, the recommendation that gamete donors need not be mandatorily identifiable to children in this particular context, and the requirement of follow-up studies, were all echoed in the (March 2013) advice to Ministers from the HFEA [10]. Both the HFEA advice and the Nuffield Council Report aim to inform future parliamentary deliberations on whether to make these novel mitochondrial techniques legal.

Lewens and John’s 2010 commissioned report to the Department of Business, Innovation and Skills titled The Universal Ethical Code for Scientists and the ‘Crisis of Trust in Science’ provided a definition of trust and an analysis of the ‘crisis of trust’ in science, that was discussed and endorsed by the Science and Trust expert group in their final (March 2010) report to the then-Science Minister Lord Drayson [11]. The report’s action plan recommended numerous initiatives aimed at improving trust in science, and in 2012 an assessment of progress towards these goals was published [11-12].

More generally, Lewens’ work on science and trust, and his earlier articles on the ethics of bioethics, have led to invitations to consult to large pharmaceutical companies. In 2008, for example, Lewens was invited to overhaul AstraZeneca’s (AZ’s) global policy on bioethics and in 2010 he was asked to advise AZ on the ethical standing of research involving the use of foetal tissue. AZ’s Director of Science Policy explains that ‘Dr Lewens’ report...has resulted in a change of perception and understanding of the ethical and moral issues surrounding human foetal tissue usage maintained by the relevant team [at AZ].’ [13] AZ’s Director of Science Policy has relied on Lewens’ report when the issue has been raised at several policy meetings, the most recent of which took place in May 2013. [13]

5. Sources to corroborate the impact (indicative maximum of 10 references)

[1] Nuffield Council Report on Human Bodies. Published online:

<http://www.nuffieldbioethics.org/donation>

[2] An email from Person 1 (Assistant Director, Nuffield Council on Bioethics) (29th March 2012) confirms Dr Lewens’ contribution to the *Human Bodies* study.

[3] HFEA Chair’s Letter (28th January 2012) ‘Implementation of the Outcomes of the Donation Review’ <http://www.hfea.gov.uk/6966.html>

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- [4] Transcript of Lewens' evidence given to Welsh Assembly.
<http://www.senedd.assemblywales.org/documents/s14202/30%20January%202013.pdf>
- [5] Welsh Assembly Human Transplantation (Wales) Bill, Stage One Committee Report
[http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/cr-ld9275-e.pdf?langoption=3&ttl=CR-LD9275%20-%20Health%20and%20Social%20Care%20Committee%3A%20Stage%201%20Committee%20Report%2C%20Human%20Transplantation%20\(Wales\)%20Bill](http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/cr-ld9275-e.pdf?langoption=3&ttl=CR-LD9275%20-%20Health%20and%20Social%20Care%20Committee%3A%20Stage%201%20Committee%20Report%2C%20Human%20Transplantation%20(Wales)%20Bill)
- [6] An email from Person 2 (20th May 2013), Director of Strategy and Quality at the Human Tissue Authority (HTA) confirms Lewens' contribution to the HTA's draft Code of Practice relating to the new Welsh Legislation.
- [7] Nuffield Council Report on Mitochondrial Disorders. Published online:
<http://www.nuffieldbioethics.org/mitochondrial-dna-disorders>
- [8] A letter from Person 3 (Director, Nuffield Council on Bioethics) (October 2012) confirms Lewens' involvement in the *Mitochondrial Disorders* report.
- [9] POST Briefing Document on Mitochondrial Disorders. Published online:
<http://www.parliament.uk/briefing-papers/POST-PN-431>
- [10] HFEA Advice to Ministers on Mitochondrial Replacement. Published online:
<http://www.hfea.gov.uk/7790.html>
- [11] Science and Trust Expert Group: Report and Action Plan, available at
<http://interactive.bis.gov.uk/scienceandsociety/site/trust/files/2010/03/BIS-R9201-URN10-699-WEB.pdf>
- [12] Science and Trust action plan review, available at:
<http://scienceandsociety.bis.gov.uk/trust/2012/09/04/review-of-science-and-trust-action-plan-september-2012/>
- [13] An email from Person 4 (R & D Policy Strategy Leader, AstraZeneca), received 24th June 2013, explaining Dr Lewens' work on research using foetal tissue.