This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

Nuffield Consultation on Emerging Biotechnologies: List of questions

Please illustrate your responses, wherever possible, with specific examples. These may be drawn from your own experience or from other sources of which you are aware. Where you refer to other sources of information, it would be helpful to us if you would indicate the source. How are the terms 'emerging technology' and 'emerging biotechnology' used? Please give examples, if possible, of significant or inconsistent usage.

1 How would you define an 'emerging technology' and an 'emerging biotechnology'? How have these terms been used by others?

In my comments below when I am referring to an 'emerging biotechnology' in the context of health I mean one which has not been clinically used.

2 Do you think that there are there features that are essential or common to emerging biotechnologies? (If so, please indicate what you think these are.)

Whilst there may not be features which are essential to emerging biotechnologies there are some common features in that such biotechnologies challenge, enhance, manipulate, alter or affect existing conceptions of what it means to be human and what humans can do. They do this at times of uncertainty about their benefits and risks – the nature, extent and reach.

3 What currently emerging biotechnologies do you consider have the most important implications ethically, socially and legally?

My area of concern is xenotransplantation, primarily its regulation, and I am interested in this emerging biotechnology because of the inherent risks, risks which are not centred on the individual potential beneficiary but may place at risk the health of known and unknown others. I discuss the implications of clinically introducing this emerging biotechnology in S. Fovargue, *Xenotransplantation and Risk: Regulating a Developing Biotechnology* (Cambridge: Cambridge University Press, 2012), and my comments below are largely taken from relevant sections of this book.

4 Are there examples where social, cultural and geographical factors have influenced the development of emerging biotechnologies (either in the past or currently)?

In most societies there appears to be a "forward stampede" which advocates new biotechnologies, and this can distract attention from other, less technological, problems and solutions.[1] This "'technological imperative' to keep pushing back the barriers can place enormous strains on our legal and ethical institutions and frameworks of analysis. Yet the huge therapeutic potential requires us to embrace and confront these questions."[2] Because of this "technological imperative"[3] there is a tendency to assume that if something can be done it should be and, relatedly, there are the "seductive sirens of medical progress."[4] These might be appropriate in some situations but some emerging biotechnologies pose too great a risk to the intended beneficiary *and* others, such that fundamental questions need to be asked as to whether they should be clinically introduced. As Watson commented in 1971,"[t]he belief that surrogate mothers and clonal babies are inevitable because science always moves forward … represents a form of *laissez-faire* nonsense dismally reminiscent of the creed that American business if left to itself will solve everybody's problems. Just as the success of a corporate body in making money need not set the human condition ahead, neither does every scientific advance automatically make our lives 'meaningful'."[5] However, "a decision must be made within a given community as to whether to even allow the products of innovation to be applied."[6]

5 Are there examples where social, cultural and geographical factors have influenced public acceptance or rejection of emerging biotechnologies?

6 Are there examples where internationalisation or globalisation of research, markets and regulation have influenced the development of emerging biotechnologies?

Internationalisation and globalisation have undoubtedly influenced how emerging biotechnologies have developed because of the ease of transit of research, researchers, and knowledge globally, and the increased competition this has

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[1] F. Schumacher, *Small is Beautiful* (London: Vintage, 1973), p. 128.
[2] D. Price, *Legal and Ethical Aspects of Organ Transplantation* (Cambridge: Cambridge University Press, 2000), p. 2.
[3] I. Kennedy, *Treat Me Right – Essays in Medical Law and Ethics* (Oxford: Oxford University Press, 1988), p. 288.
[4] M.J. Hanson, 'The Seductive Sirens of Medical Progress – The Case of Xenotransplantation' (1995) *Hastings Center Report* 5, 5.
[5] J.D. Watson, 'Moving Toward the Clonal Man' (1971) 227 *The Atlantic Monthly* 50.
[6] E.R. Gold, W.A. Adams, 'Reconciling Private Benefit and Public Risk in Biotechnology: Xenotransplantation as a Case Study in Consent' (2002) 10 *Health Law Journal* 31, 33.

introduced for those involved. With regards to regulation, which can affect how a biotechnology is developed, there will be a fear of regulating 'too soon', introducing inappropriate requirements which may curtail promising advances, and allowing other countries to progress. At the same time, there are dangers with delaying regulation, waiting for the science to develop, and committees to report, as regulatory gaps may develop and a biotechnology may be in clinical use but essentially unregulated. International regulatory discussions may minimise these problems but each country may have a different cultural perspective on the implications of an emerging biotechnology, and whilst an apparent consensus on the importance of and need for international regulatory regimes for such a biotechnology may be reached, there is often a marked reluctance to act on this; with xenotransplantation a prime example. Furthermore, it is hard to see how such a regime could effectively work in practice because "there is not a natural culture of compliance in this field [of new technologies] (indeed, one might believe that there is considerable regulatory resistance both on the part of those with commercial interests in the development of the technology as well as on the part of those wishing to access the technology); and fast-moving technology represents one of the most complex challenges at the level of regulatory design."[7]

Decisions made in one country have affected behaviour, research and businesses in another, as the practice of 'health tourism' or 'cross-border care' have indicated. Indeed, 'havens' can develop where one country's regulatory regime is deemed too restrictive by researchers, patients etc and so trials, procedures etc are conducted in those 'haven' countries where the controls are perceived as being more relaxed. Evidence of 'bio-tourism' for IVF and stem cell research/treatments, for example, is increasing,[8] and it has been suggested that stem cell tourists travelling to China for 'treatment' led to regulations being introduced and Indian surrogacy laws are currently under debate because of the increasing 'trade' in this area.[9] A well-known example of health tourism in the English legal context is, of course, the Diane Blood case.[10] Additionally, the xenotransplant in India in 1996 of a pig's heart, lungs and kidneys into a human,[11] and pig islet cells into twelve teenagers in Mexico in 2002[12] have been suggested as examples of xeno-tourism,[13] and the risk of such tourism has been explicitly acknowledged in Australian and US reports on xenotransplantation.[14]

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[7] R. Brownsword, 'What the World Needs Now: Techno-Regulation, Human Rights and Human Dignity' in R. Brownsword (ed) *Global Governance and the Quest for Justice* (Oxford: Hart, 2004), p. 220, references removed.

[8] D. Campbell, 'Destination Spain: The Rise and Rise of Fertility Tourism', guardian.co.uk, 22 August 2010; BBC News, '"Stem Cell Tourism" in Germany', 23 June 2009: http://news.bbc.co.uk/1/hi/health/8115881.stm, accessed 25/3/11; House of Commons Science and Technology Committee, *Human Reproductive Technologies and the Law,* Fifth Report of Session 2004-5, HC 7-1, Volume I, paras. 380-382, 385-386.

[9] D. Cyranoski, 'Stem-Cell Therapy Faces More Scrutiny in China' (2009) 459 *Nature* 146; N. Hyder, 'India Debates New Surrogacy Laws', *BioNews* 594, 7 February 2011: http://www.bionews.org.uk, accessed25/3/11.

[10] *R* v. *Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687, CA.

[11] K.S. Jayaraman, 'Pig Heart Transplant Surgeon Held in Jail' (1997) 385 *Nature* 378.

[12] K. Birmingham, 'Skepticism Surrounds Diabetes Xenograft Experiment' (2002) 8 *Nature Medicine* 1047.

[13] A. Persson, 'Research Ethics and the Development of Medical Biotechnology' (2006) 13 *Xenotransplantation* 511; A. S. Daar, 'Xenotransplantation – Science, Risk and

Bio-tourism is, of course, not be limited to those seeking to access a biotechnological 'treatment' and may include companies and investigators and, with regards to xenotransplantation, it has been suggested that one reason Novartis closed its Imutran operation in the UK and moved it to mainland Europe, and then the US, was the UK's regulatory schemes for non-human animal experiments.[15] More recently, Lord Winston has stated that he had to move his research on producing transgenic pig sperm, to be used to breed genetically engineered pigs for use in xenotransplants, from the UK to the US because of the relevant regulatory schemes in the UK and Europe, including the time it took (two years) to receive a Home Office licence to conduct the research on "just six pigs."[16] Given the ability to move around the global with comparative ease and freedom, the challenge is to regulate "to allow for the development of a potentially beneficial new technology, while safeguarding public health",[17] and to do this within a global context. However, when countries stand at different places on the regulatory prohibitive-permissive spectrum, it can be harder to enforce the stance of those at the former end of the scale because it is known that there are countries situated towards the other end of the spectrum.

With regards to the internationalisation and globalisation of markets, the commercial companies which finance biotechnological research undoubtedly influence or have an impact on the development of emerging biotechnologies and their regulation. Indeed, there is a "conjunction of science, commercialization of university research, venture capital, risk, need, and glamour (we must not under-estimate the need in scientists to be the first; there might even be a Nobel prize here)."[18] This conjunction is particularly evident with xenotransplantation in the US, for example, where the Department for Health and Human Services has published a number of guidance documents specifically directed towards industry; indicating their prominent role in the field.[19] Such a conjunction is clearly

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International Regulatory Efforts' in T.A. Caulfield, B. William-Jones (eds) *The Commercialization of Genetic Research – Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), p. 135.

[14] Australia - National Health and Medical Research Council, *Discussion Paper – Xenotransplantation: A Review of the Parameters, Risks and Benefits* (2009), p. 18: http://www.nhmrc.gov.au/_files_nhmrc/file/about/committeess/expert/gtrap/nhmrc_xeno_discussion_paper_website.pdf, accessed 5/6/11; US - US Department for Health and Human Services, Secretary's Advisory Committee on Xeno, *Report on the State of the Science in Xenotransplantation* (2004), pp. iv-v, 25-27: http://www.nelsonerlick.com/PDF/NIH%20Report%20on%20State%20of%20Xenotransplantation%202005.pdf, accessed 14/6/11.

[15] 'Animal Lab Shuts Down After We Reveal Horrors', *Daily Express* 28 Sept 2000.

[16] R. Winston, 'Britain Squanders Pioneer Work on Organ Transplants', *The Sunday Times*, 7 September 2008.

[17] E.T. Bloom, 'Xenotransplantation: Regulatory Challenges' (2001) 12 *Current Opinion in Biotechnology* 312, 314.

[18] A. S. Daar, 'Xenotransplantation – Science, Risk and International Regulatory Efforts' in T.A. Caulfield, B. William-Jones (eds) *The Commercialization of Genetic Research – Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), p. 150.

[19] E.g. US Department for Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Guidance for Industry: Source Animal, Product, Preclinical and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans – Final Guidance* (2003): http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/ucm092707.pdf, accessed 16/3/11; US

necessary and often advantageous but "[t]he management and cultural practices of commerce differ from those of the traditional European professional medico-scientific approach."[20] There may, for example, be pressure on companies to announce scientific results and advances to shareholders and 'the market' sooner than is appropriate and without the necessary peer review of the work. Finance has an ever more important role in biotechnological developments and genetically engineered solid organ xenotransplants are likely to be a multi-million dollar market if clinical trials prolong life. Given this, calls for international collaboration may not be well received by those financing the research and accountable to shareholders and investors. Thus, whilst lip-service may be paid to the need for international and national co-operation, business confidentiality and financial implications may make this more difficult to achieve in practice.

Nevertheless, the role of the market, commerce, and investment cannot be ignored, nor can the impact of the internet in providing information on and 'marketing' new 'treatments'.[21] Politicians may also be wary of regulation which can be viewed as discouraging investment, so "[l]ocal regulation … can operate only in the shadow of whatever local political will prevails; and the prospect of regulatory arbitrage between jurisdictions competing to host technology-based business militates against the adoption and enforcement of regional or international minimum standards"[22] This pull of competing interests was noted in the UK Government's 1999 review on the regulation of biotechnologies,[23] and it has been suggested that the 1996 version of the Declaration of Helsinki was relied on in the UK's Clinical Trials Regulations, rather than the 2000 version which existed at the time the Regulations were passed, for political reasons.[24] Nevertheless, biotechnological development necessarily involves political, commercial, and global elements, and any proposed regulatory scheme must have the investigators on their side otherwise it will be meaningless. The issues

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Department for Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their intimate Contacts – Draft Guidance* (2002): http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm080375.pdf, accessed 23/3/11; US Department for Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Guidance for Industry - Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans* (1999): http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/ucm092866.pdf, accessed 23/3/1.

[20] M.H. Johnson, 'The Art of Regulation and the Regulation of ART: The Impact of Regulation on Research and Clinical Practice' (2002) 9 *Journal of Law and Medicine* 399, 401.

[21] E.g. S. Boseley, 'Government Warned On DIY Cancer Treatments' *The Guardian* 28 April 2008.

[22] R. Brownsword, 'What the World Needs Now: Techno-Regulation, Human Rights and Human Dignity' in R. Brownsword (ed) *Global Governance and the Quest for Justice* (Oxford: Hart, 2004), p. 203, 222.

[23] Cabinet Office, Office of Science and Technology, *The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review* (London: Cabinet Office, 1999), p. 2.

[24] H. Biggs, *Healthcare Research Ethics and Law: Regulation, Review and Responsibility* (London: Routledge-Cavendish, 2010), pp. 57-58.

noted here may be one of the reasons why no genetically engineered solid organ xenotransplants have yet been clinically performed.

7 How have political traditions (such as liberal democracy) and political conditions (e.g. war) influenced the emergence of biotechnologies?

8 Are there ethical or policy issues that are common to most or many emerging biotechnologies? Are there ethical or policy issues that are specific to emerging biotechnologies? Which of these, if any, are the most important?

Risk, responsibility, the global nature of health, public involvement in decision-making, public understanding of science, public acceptance and public agreement to clinical implementation, regulation, selection issues regarding first recipients. I do not believe it is possible or useful to prioritise these ethical or policy issues.

An emerging biotechnology such as xenotransplantation tests existing ethical frameworks because of the nature and extent of the risks it poses to the potential beneficiary and others. Some emerging biotechnologies challenge the trend in many Western countries to base health care systems on concepts of individual autonomy and individual rights and support not only the calls for a rethinking of autonomy but also the suggestion that individual autonomy cannot be the central ethical principle in health care.[25] More particularly, "[x]enotransplantation raises issues such as the protection of the interests of future generations, the prevention of harm, the acceptance of some harm for the achievement of a 'higher good', or the supremacy of the freedom to choose (autonomy)."[26] The risks of xenotransplantation highlight the fact that we are interconnected individuals who are related to, interdependent and reliant on others; thus, health care systems which are premised on legal and ethical notions of individual autonomy alone may not be appropriate for xenotransplantation with its potential to harm the intended beneficiary and others. Nevertheless, there is a tendency to assume that emerging biotechnologies can fit into existing ethical and legal regulatory structures without detailed consideration and discussion.

But the risks of xenotransplantation require a reconsideration of general and specific regulatory schemes and challenge accepted legal and ethical norms, especially those premised on individual consent. It highlights the difficulties with the legal and bioethical precedence which has been accorded to individual autonomy, particularly in the West, and in prioritising this principle over other concepts. It requires a review of the balance between the autonomy of the

[25] E.g. N. Manson, O. O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge: Cambridge University Press, 2007); M. Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) 65 *Cambridge Law Journal* 397; O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002).

[26] E.R. Gold, W.A. Adams, 'Reconciling Private Benefit and Public Risk in Biotechnology: Xenotransplantation as a Case Study in Consent' (2002) 10 *Health Law Journal* 31, 46.

individual and community interests in public health because "respecting the rights of the individuals who make up a society, important as this is, is not always sufficient to protect the society itself. Sometimes, in carefully justified instances, to do so we must give priority to the needs of the community over the claims of individuals."[27] Given the risks of xenotransplantation this is an emerging biotechnology where individual autonomy should not automatically rule, and a more communitarian and public health perspective may be appropriate where "the acceptability of an action is to be judged by the goodness or badness of its effect not on an individual *per se* but on persons as interdependent units of society."[28]

9 Do you think that some social and ethical themes are commonly overlooked in discussions about emerging biotechnologies? If so, what are they?

- Does society really need this emerging biotechnology and why?
- What would happen if the emerging biotechnology did not emerge?
- What are the (existing or emerging) alternatives?
- Intergenerational justice.
- Collective responsibility for global public health.
- Personal responsibility for health.
- Personally assuming risks which necessarily impact on others.
- Selection issues relating to the first clinical recipients.
- Post-clinical introduction risk identification, assessment, management and communication.

"The globalization of science, economics, and information all elevate transgenerational concerns *beyond* the domestic scale to an international one. Similarly, *bioethics* must move from the realm of individual concern to that of collective concern, and must ultimately be considered at a truly universal level."[29] Some of the problems of regulating risks on a global level include the fact that "[b]ioethics, in our pluralistic society, means respect for others and being able to compromise even on sensitive issues."[30] It is unclear whether this will be possible on a global scale where values, opinions, cultures, religions, faiths, and beliefs will undoubtedly compete and/or conflict. Nevertheless, "[t]he need to establish common values and benchmarks, as well as to promote ethical principles and standards to guide scientific progress and technological development … is becoming increasingly acute, especially in developing countries

[27] M.A. Sommerville, 'Searching for Ethics in a Secular Society' in *Ethics of Science and Technology, Explorations of the Frontiers of Science and Ethics* (Paris: UNESCO, 2006), p. 23.
[28] J.K. Mason, G.T. Laurie, *Mason and McCall Smith's Law and Medical Ethics*, (Oxford: Oxford University Press, 2011), p. 7.
[29] B.M. Knoppers, 'Reflections: The Challenge of Biotechnology and Public Policy' (2000) 45 *McGill Law Journal* 559, 563, reference removed. Emphasis supplied.
[30] N. Lenoir, 'Biotechnology, Bioethics and Law: Europe's 21st Century Challenge' (2006) 69 *Modern Law Review* 1, 1.

that do not equally enjoy the benefits of scientific and technological advances."[31] Xenotransplantation highlights the global nature of advances in health, risk, and some of the issues and problems with identifying and monitoring risks internationally. For example, if genetically engineered solid organ xenotransplants are prohibited in country V, will a patient be prevented from having the operation in country X or Y and, if so, how will this occur? If such xeno-tourism cannot be prevented, will it be possible to minimise the risks to the xeno-recipient and others? As the risks of xenotransplantation go beyond the recipient and are global in nature, in all the countries which have considered this biotechnology specific surveillance and monitoring schemes have been suggested and/or introduced.[32] Whether such schemes are or will be sufficient to control and monitor the known, unknown and unidentifiable risks posed by xenotransplantation is debatable. Of particular concern is xenotransplantation's global risk; risk which has been recognised by some of the relevant regulators.[33] Problems with monitoring xeno-recipients have been noted especially as "[f]requent and easy transit of individuals across national borders is a fact of modern life and ease of access to medical care anywhere around the globe has greatly increased the phenomenon of 'medical tourism'. Just as humans today travel more easily, microbes can spread, unhindered by borders."[34] Effective surveillance and monitoring regimes must exist if a genetically engineered solid organ is xenotransplanted into a human, but (how) can a sufficient and adequate *global* regime be devised, implemented and enforced? Practically, is it possible to regulate and contain global risks and, if not, should clinical xenotransplants proceed?

10 What evidence is there that ethical, social and policy issues have affected decisions in (i) setting research priorities, (ii) setting priorities for technological development, and (iii) deploying emerging biotechnologies, in either the public or private sector?

It is difficult to discover whether ethical, social and policy issues have a central role in (i)-(iii) because of the secrecy surrounding how such decisions are

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[31] H. ten Have, 'UNESCO and Ethics of Science and Technology' in in *Ethics of Science and Technology, Explorations of the Frontiers of Science and Ethics* (Paris: UNESCO, 2006), p. 6.

[32] E.g. Health Canada, *Proposed Canadian Standard for Xenotransplantation* (Ottawa: Health Canada, 1999); United Kingdom Xenotransplantation Interim Regulatory Authority, *Draft Report of the Infection Surveillance Steering Group of the UKXIRA*, (London: Department of Health, 1999); US - US Department of Health and Human Services, Food and Drug Administration, *PHS Guideline on Infectious Disease Issues in Xenotransplantation* (2001): http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Xenotransplantation/UCM092858.pdf, accessed 5/6/11.

[33] E.g. Australia – National Health and Medical Research Council, *Discussion Paper – Xenotransplantation: A Review of the Parameters, Risks and Benefits* (2009), p. 18: http://www.nhmrc.gov.au/_files_nhmrc/file/about/committeess/expert/gtrap/nhmrc_xeno_discussion_paper_website.pdf, accessed 5/6/11; UK – UKXIRA, *Draft Report of the Infection Surveillance Steering Group of the UKXIRA*, (London: DH, 1999).

[34] Organisation for Economic Co-operation and Development, *Xenotransplantation: International Policy Issues* (Paris: OECD, 1999), p. 43.

made. It appears that the driving force behind many developments is commercial; who will fund what depending on likely reward and the timescale for that reward accruing.

11 What ethical principles should be taken into account when considering emerging biotechnologies? Are any of these specific to emerging biotechnologies? Which are the most important?

Non-maleficence, justice, beneficence, equality, equity. These are not specific to emerging biotechnologies and the need for or use in prioritising them is debatable as their importance are likely to be context-specific.

12 Who should bear responsibility for decision making at each stage of the development of an emerging biotechnology? Is there a clear chain of accountability if a risk of adverse effects is realised?

The answer to the second question is largely no but will depend on the regulatory regime which has been implemented for a given emerging biotechnology. Taking xenotransplantation as an example, under the current UK regulatory structure clinical xenotransplants can be performed as 'experimental medicine', clinical research within the Clinical Trials Regulations, or as research involving NHS patients outside those Regulations.[35] Whilst research conducted under the Regulations should have a clear chain of accountability, this does not exist for the former and is debatable if it exists if clinical xenotransplants occur under the latter regulatory regime.

13 What roles have 'risk' and 'precaution' played in policy decisions concerning emerging biotechnologies?

It is unclear the extent to which ideas of risk or precaution have played in policy decisions to date, because how decisions are reached are unclear and not always transparent, but these must and should be amongst the key issues or concerns, particularly where the risks of an emerging biotechnology extend beyond the potential beneficiaries.

Risk, its nature, understanding of it, the possibility of explaining and then regulating it, is central to many emerging biotechnologies where much is unknown and uncertain about their benefits, risks and implications. However, one problem is that "[i]n the absence of hard data, attempts to assess risks and develop a rational policy are exercises in reasoned speculation."[36] Thus, "[h]ow can we appraise and predict such unknown health risks? What kind of balance

[35] Department of Health, *Xenotransplantation Guidance* (2006): http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_063074.pdf, accessed 3/6/11.

[36] L. Chapman, 'Speculation, Stringent Reasoning, and Science' (1999) 77 *Bulletin of the World Health Organization* 68, 69.

ideally should be struck between our obligations to accept some risk to ourselves in order to benefit designated individuals or groups of individuals whose lives might be sustained through our actions, and our obligation to protect and foster the health of the community – locally, nationally, and internationally? And if a biomedical procedure with the characteristics of xenotransplantation is clinically initiated, with what kinds of precautions, surveillance, social controls, and regulations should it be surrounded?"[37]

Where the risks are unidentifiable or latent until an emerging biotechnology is clinically in use, effective risk management will be difficult if not impossible to attain. Similarly, their benefits too will be uncertain; events of the future. There may be ways to regulate risk, such as a moratorium or via the precautionary principle, but will these strategies appropriately safeguard public health whilst also offering the possibility of benefit to individuals in need? Emerging biotechnologies raise questions about acceptance and understanding of uncertainty and risk, personally and to others; questions which it may not be possible to address prior to clinical introduction. Furthermore, we are not experienced in assessing risks and benefits which go beyond the individual, are largely unknown and unidentifiable, their extent unclear, possibly latent and not confinable – individually or country-wise; thus, "the key question today is how to develop an ethics discourse adequately evaluating the balance between a low (or unknown) risk of occurrence of an adverse event against the enormous negative consequences should that event come to pass."[38] And of note with emerging biotechnologies is how law regulates risk in two contexts: (i) as experimental procedures or medical research and the general regulatory framework which follows from the categorisation. The latter in the form of clinical trials are now statutorily regulated in England,[39] but regulation of the former is notably less clear. (ii) legal regulation via specific regulatory frameworks; such as those for IVF, gene therapy, and xenotransplantation.

Risk is a social construct,[40] is not static,[41] and describes an undesirable consequence that might occur but the occurrence of that consequence is not certain.[42] It involves the probability and magnitude of harm,[43] and there is an intrinsic and inherent element of uncertainty with risk because whilst knowing the probability of a possible outcome makes it a more concrete risk, it is still uncertain whether that risk will actually occur and, if it does, all of its consequences. Decision making in risk situations can be categorised as being (i) under known outcomes and probabilities, (ii) under uncertainty, where outcomes are known but not probabilities, or (iii) under ignorance, where neither outcomes

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[37] R.C. Fox, J.P. Swazey, *The Courage to Fail – A Social View of Organ Transplants and Dialysis* (New Brunswick: Transaction Publishers, 2002), pp. xviii-xix.

[38] A.S. Daar, 'Xenotransplantation – Science, Risk and International Regulatory Efforts' in T.A. Caulfield, B. William-Jones (eds) *The Commercialization of Genetic Research – Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), p. 129, 130.

[39] The Medicines for Human Use (Clinical Trials) Regulations 2004, S .I. 2004 No. 1031.

[40] See U. Beck, *Risk Society: Towards A New Modernity* (London: Sage Publications, 1992).

[41] M. McKee, R. Coker, 'Trust, Terrorism and Public Health' (2009) 31 *Journal of Public Health* 462, 464.

[42] S.O. Hansson, 'Philosophical Perspectives on Risk' (2004) 8 *Techné* 10.

[43] A. Edwards, G. Elwyn, 'Understanding Risk and Lessons for Clinical Risk Communication about Treatment Preferences' (2001) 10 (Suppl I) *Quality in Health Care* i9, i9.

nor probabilities are known.[44] Many emerging biotechnologies, including xenotransplantation, will fall within (iii) and may create an environment of "*manufactured risk*";[45] risk which is created by scientific and biotechnological advances and of which we have no prior experience to help calculate the probability of negative consequences occurring. Some emerging biotechnologies are examples of the changing nature of risk; change which has occurred because of the "greater connectedness of the world."[46] Risk assessment is essential to evaluate the dangers, communicate information, and develop appropriate means of controlling and managing them, and with the latter a precautionary approach may be of most use.

The precautionary principle essentially holds that "where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[47] It is "a risk management policy applied in circumstances with a high degree of scientific uncertainty, reflecting the need to take action for a potentially serious risk without awaiting the results of scientific research."[48] There is no agreed definition of the principle and its legal status is unclear,[49] but it is generally agreed that it is more appropriate to talk of a precautionary approach.[50] Such an approach is dynamic and commonly includes anticipating risk and harm, uncertainty, lack of evidence, acting in advance of established risks to minimise not necessarily eradicate risk, public participation in decision-making, and protecting existing and future generations.[51] It recognises that "the damaging effects of human activities may become irreversible *before* the scientific community can agree the precise nature and

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[44] A. Stirling, *On Science and Precaution in the Management of Technological Risk, Volume I A Synthesis of Case Studies* (Seville: European Commission Institute for Prospective Technological Studies, 1999) EUR 19056 EN, pp. 40-41.

[45] A. Giddens, 'Risk and Responsibility' (1999) 62 *Modern Law Review* 1, 4, emphasis in original.

[46] Strategy Unit, Cabinet Office, *Risk: Improving Government's Capability to Handle Risk and Uncertainty: Full Report – A Source Document* (London: Cabinet Office, 2002), para. 1.6.

[47] United Nations Rio Declaration on Environment and Development 1992, Principle 15.

[48] WHO, *Electromagnetic Fields and Public Health Cautionary Policies* (2000) http://www.who.int/docstore/peh-emf/publications/facts_press/EMF-Precaution.htm, accessed 5/6/11.

[49] For Europe see E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford: Hart, 2007), Ch. 6; more generally, United Nations Educational, Scientific and Cultural Organization (UNESCO), World Commission on the Ethics of Scientific Knowledge and Technology, *The Precautionary Principle* (2005), section 2.2: http://unesdoc.unesco.org/images/0013/001395/139578e.pdf, accessed 5/6/11.

[50] E.g. House of Commons Science and Technology Committee, *Scientific Advice, Risk and Evidence Based Policy Making Seventh Report of Session 2005*-6 vol I, (London: The Stationery Office, 2006) HC 900-I, para. 166; C.F. Cranor, 'Learning from the Law to Address Uncertainty in the Precautionary Principle' (2001) 7 *Science and Engineering Ethics* 313.

[51] M. Feintuck, 'Precautionary Maybe, But What's the Principle? The Precautionary Principle, The Regulation of Risk, and The Public Domain' (2005) 32 *Journal of Law and Society* 371; R.L. Keeney, D. von Winterfeldt, 'Appraising the Precautionary Principle – A Decision Analysis Perspective' (2001) 4 *Journal of Risk Research* 191.

scope of their impact."[52] It favours preventing false negatives, helping to avoid disease and possibly harmful exposures, and respecting autonomy by allowing people to choose the risks they want to bear.[53] Harms which may result from human actions should be avoided or diminished but these do not have to be certain outcomes; rather, "it is sufficient that they be *scientifically plausible*."[54] A precautionary approach recognises intrinsic and extrinsic links to the to-be-managed activity, and presumes a flexible legal approach which is open and adjustable.[55] It is not a formula and applying it requires "a judgement that takes into account the particular circumstances of the problem to be addressed."[56] Under this approach risky activities can be regulated, constrained or prohibited, even though the risks are scientifically uncertain, directed at community interests, and may harm individuals, the public and future generations.[57] It has an "intimate, though often implicit, connection with collective, democratic interests and the public domain, which it may serve to reassert in the face of increasingly dominant private interests."[58]

Adopting a precautionary approach does not automatically result in a moratorium, a choice between action and inaction, or allowing and blaming; rather it involves a process of "*learning through experimentations* and *acting while doubting*"[59] and focuses on appropriate responses to developments which may harm human health, for example.[60] It "[tempers] the permissive approach through the taking into account of risks which are uncertain. This permits a sound decision to be made based on adequate risk assessment."[61] Where there are recognised harms to human health but their extent is unknown, the person proposing the action has the burden of disproving risks;[62] they do not have to show there are no risks but must proactively seek to determine their nature and

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[52] J. Holder, S. Elworthy, 'The BSE Crisis: A Study of the Precautionary Principle and the Politics of Science in Law' in H. Reece (ed.) *Law and Science Current Legal Issues Volume 1* (Oxford: Oxford University Press, 1998), p. 129, 131, emphasis supplied.

[53] D. Jamieson, 'The Precautionary Principle and Electric and Magnetic Fields' (2001) 91 *American Journal of Public Health* 1355, 1357.

[54] K. Steele, 'The Precautionary Principle: A New Approach to Public Decision-Making' (2006) 5 *Law, Probability and Risk* 19, 19, emphasis supplied.

[55] L. Boisson de Chazournes, 'New Technologies, the Precautionary Principle, and Public Participation' in T. Murphy (ed.) *New Technology and Human Rights* (Oxford: Oxford University Press, 2009), p. 161, 165.

[56] Nuffield Council on Bioethics, *Public Health: Ethical Issues* (London: Nuffield Council on Bioethics, 2007), para. 3.19.

[57] E. Soule, 'Assessing the Precautionary Principle' (2000) 14 *Public Affairs Quarterly* 309; K. Steele, 'The Precautionary Principle: A New Approach to Public Decision-Making' (2006) 5 *Law, Probability and Risk* 19, 24.

[58] M. Feintuck, 'Precautionary Maybe, But What's the Principle? The Precautionary Principle, The Regulation of Risk, and The Public Domain' (2005) 32 *Journal of Law and Society* 371, 372.

[59] J. Dratwa, 'Taking Risks with the Precautionary Principle: Food (and the Environment) for Thought at the European Commission' (2002) 4 *Journal of Environmental Policy and Planning* 197, 207, emphasis in original.

[60] Nuffield Council on Bioethics, *Animal-to-Human Transplants - The Ethics of Xenotransplantation* (London: Nuffield Council on Bioethics, 1996), para. 6.22.

[61] Nuffield Council on Bioethics, *Public Health: Ethical Issues* (London: Nuffield Council on Bioethics, 2007), p. 180.

[62] Commission of the European Communities, *Communication from the Commission on the Precautionary Principle* COM(2000) 1 Final, para. 6.4.

magnitude.[63] The European Commission has stated that measures based on a precautionary approach should be proportional, non-discriminatory, consistent, based on an examination of the potential costs and benefits of acting or not, subject to review, and able to assign responsibility for producing scientific evidence.[64] A precautionary approach has, however, been criticised for being ill-defined, absolutist, 'anti-science', marginalising science, and deterring progress and development.[65] Nevertheless, if the risks are plausible and the precautionary measures adopted reasonable, these criticisms will not manifest and are unfounded.[66] A precautionary approach is identifiable in the European response to the BSE crisis where action was taken prior to a scientifically established link between BSE and vCJD,[67] and was stated to be the basis of the UK government's response to the public debate on GM crops.[68] The approach expands Mill's harm principle so that it encompasses public goods and possible harm to future generations.[69]

A more proactive response to emerging biotechnologies such as xenotransplantation is needed; an approach which involves asking whether it is needed in the first place, if it is then how much harm can be avoided while achieving its goals, and whether there are alternatives which avoid harm?[70] Regulatory measures which address and minimise the risks are required and if this is not possible then a moratorium should be considered. Where the effects of waiting for the risks to materialise may be catastrophic, a precautionary approach combined with the harm principle supports anticipatory state action to protect others.[71] Using the harm principle in circumstances of uncertainty is not unproblematic as it is easier to apply it where the harm is concrete and ascertainable, but interest in public health is a powerful reason for state interference in advance. The type of state intervention is, however, context specific and there will be cases where state intervention is not justified even though an individual's action has caused harm.[72]

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[63] R. Andorno, 'The Precautionary Principle: A New Legal Standard for a Technological Age' (2004) 1 *Journal of International Biotechnology Law* 11, 19.
[64] Commission of the European Communities, *Communication from the Commission on the Precautionary Principle* COM(2000) 1 Final pp. 3-4, para. 6.3.
[65] P. Sandin, M. Peterson, S.O. Hansson, C. Rudén, A. Juthe, 'Five Charges Against the Precautionary Principle' (2002) 5 *Journal of Risk Research* 287; T. O'Riordan, A. Jordan, 'The Precautionary Principle in Contemporary Environmental Politics' (1995) 4 *Environmental Values* 191.
[66] D.B. Resnik, 'Is the Precautionary Principle Unscientific?' (2003) 34 *Studies in History and Philosophy of Biological and Biomedical Sciences* 329.
[67] Department for Environment, Food and Rural Affairs, Scottish Executive Environment and Rural Affairs Department, Welsh Assembly Government, Department of the Environment in Northern Ireland, *The GM Dialogue: Government Response* (London: DEFRA, 2004), p. 3.
[68] *Ibid* and p. 5.
[69] K. Steele, 'The Precautionary Principle: A New Approach to Public Decision-Making' (2006) 5 *Law, Probability and Risk* 19, 24.
[70] D. Kriebel, J. Tickner, 'Reenergizing Public Health Through Precaution' (2001) 91 *American Journal of Public Health* 1351, 1352.
[71] S. Fovargue, S. Ost, 'When Should Precaution Prevail? Interests in (Public) Health and the Risk of Harm: The Xenotransplantation Example' (2010) 18 *Medical Law Review* 302.
[72] J.S. Mill, *On Liberty and Other Essays* (Oxford: Oxford University Press, 2008), p. 104.

14 To what extent is it possible or desirable to regulate emerging biotechnologies via a single framework as opposed to individually or in small clusters?

A single framework of common universal ethical and legal principles could be useful but given the diverse nature of emerging biotechnologies and their potential benefits, risks and impacts, individual or small cluster regulation is necessary. This should not, however, limit, prevent or hamper the development and expression of such common principles.

15 What role should public opinion play in the development of policy around emerging biotechnologies?

Public involvement in decision-making about emerging biotechnologies is essential as "[s]cience should not be expected to have sole responsibility for the future of [new developments in science]; there is a responsibility to society to involve all citizens in decisions to the extent that this is possible."[73] However, whilst the public should be involved in decisions about emerging biotechnologies, their opinion should not be determinative especially where 'public opinion' is loosely defined and determined, e.g. the so-called 'evidence' of public hostility and opposition towards using preimplantation genetic diagnosis for social sex selection. Public consultation, deliberation, and engagement in decision-making processes should be the norm, rather than seeking 'public opinion' once a decision has, effectively, been made and with that 'opinion' then used to support what has already been decided, or ignored and minimised as unrepresentative, uneducated or just plain wrong.

Public deliberation "actively engages the public … as partner and full participant in public health. It assumes and communicates that individual community members can be trusted to think and act collectively and voluntarily when threatened",[74] and can be viewed as "the social equivalent of informed consent."[75] Ideally it would occur at an early stage of a biotechnology's developmental process as research and development priorities are determined because "[i]f the public is not conscious or involved at early stages there is a risk of a strong reaction later if the outcomes of research or its applications are presented and found to be at odds with the values or expectations of stakeholder groups and publics."[76] Timing is important because "upstream" debate when new areas are emerging "enables society to discuss and clarify the public value of science",[77] and permits certain questions to be asked; "Why this technology?

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[73] R. Jackson, F. Barbagallo, H. Haste, 'Strengths of Public Dialogue on Science-Related Issues' (2005) 8 *Critical Review of International Social and Political Philosophy* 349, 350.
[74] J.F. Childress, R.G. Bernheim, 'Beyond the Liberal and Communitarian Impasse: A Framework and Vision for Public Health' (2003) 55 *Florida Law Review* 1191, 1215.
[75] Peter Healey as cited in House of Lords Select Committee on Science and Technology, *Science and Society*, Third Report (London: House of Lords, 2000), para. 5.2.
[76] R. Jackson, F. Barbagallo, H. Haste, 'Strengths of Public Dialogue on Science-Related Issues' (2005) 8 *Critical Review of International Social and Political Philosophy* 349, 353.
[77] J. Wilsdon, B. Wynne, J. Stilgoe, *The Public Value of Science: Or How to Ensure that Science Really Matters* (London: Demos, 2005), p. 29.

Why not another? Who needs it? Who is controlling it? Who benefits from it? Can they be trusted? What will it mean for me and my family? Will it improve the environment? What will it mean for people in the developing world?"[78] If engagement has not occurred at an early stage this does not prevent later consultation, but it may be of a different nature and type, **see q16 below**.

Public involvement in decision-making is imperative "[w]here there is much uncertainty about alternative courses of action, [because] it is risky for experts to decide without input from affected communities"'[79] Deliberative decision-making can improve the quality of decisions "by opening it up to scrutiny through a dialogue in which ideas are interplayed and flaws in reasoning exposed."[80] It is particularly important when a precautionary approach is adopted because without established facts it provides the basis for decisions in situations of ignorance, and as risk and uncertainty are socially constructed the public should debate them.[81] Different types of knowledge can be introduced, their reliability challenged, and when a precautionary approach engages the public potential problems may be anticipated before clinical application. Involving the public in framing and interpreting precaution should thus be "just one more process through which complex decisions can be made – a process which may help to bring us a few steps closer to see-through science."[82] However, a precautionary approach "requires … a degree of honesty around issues of uncertainty and hazard that has not always been forthcoming from business or from government", and this may not sit well "[i]n the age of 'political spin'."[83]

To be effective decision-making systems should be transparent and open, helping to develop a "credible decision-making process" which will inspire confidence and trust in decisions.[84] The risks of some emerging biotechnologies necessitate a societal decision as to whether the benefit an individual may obtain outweighs the burdens the public may have to bear; "[t]he associated social stakes are so extensive that it is difficult to see how technical experts acting as proxy on society's behalf can address them adequately."[85] At national levels the

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[78] J. Wilsdon, R. Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (London: Demos, 2004), p. 28.

[79] D. Kriebel, J. Tickner, 'Reenergizing Public Health Through Precaution' (2001) 91 *American Journal of Public Health* 1351, 1353.

[80] E. Fisher, R. Harding, 'The Precautionary Principle: Towards a Deliberative, Transdisciplinary Problem-Solving Process' in R. Harding, E. Fisher (eds.), *Perspectives on the Precautionary Principle* (New South Wales: The Federation Press, 1999), p. 293.

[81] *Ibid*, p. 292; L. Boisson de Chazournes, 'New Technologies, the Precautionary Principle, and Public Participation' in T. Murphy (ed.) *New Technology and Human Rights* (Oxford: Oxford University Press, 2009), pp. 178-181, 190.

[82] J. Wilsdon, R. Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (London: DEMOS, 2004), p. 54.

[83] D. Fischbacher-Smith, K. Calman, 'A Precautionary Tale – The Role of the Precautionary Principle in Policy-Making for Public Health' in P. Bennett, K. Calman, S. Curtis, D. Fischbacher-Smith (eds.) *Risk Communication and Public Health* 2nd ed. (Oxford University Press, 2010), p. 209.

[84] A Report by the Swedish Committee on Xenotransplantation, *From One Species to Another – Transplantation From Animals to Humans: Summary and Statutory Proposals* (Stockholm: Swedish Committee on Xenotransplantation, 1999) Swedish Government Official Report No. 1999: 120, p. 14.

[85] I. Welsh, R. Evans, 'Xenotransplantation, Risk, Regulation and Surveillance: Social and Technological Dimensions of Change' (1999) 18 *New Genetics and Society* 197, 212.

public need to be involved in meaningful dialogue on emerging biotechnologies because "[s]cience should not be expected to have sole responsibility for the future of [new developments in science]; there is a responsibility to society to involve all citizens in decisions to the extent that this is possible."[86] Such consultation should enable "creative and democratic thinking to work alongside traditional mechanisms of decision-making",[87] with the method(s) adopted matching the purpose; informing and empowering the public and, ultimately, aimed at making "better" decisions.[88] The public, in the UK particularly, has experience of not agreeing to but being subjected to risks it is vital that lessons are learnt from the BSE and new vCJD tragedies. These events diminished public trust in "apparently absolute, quantified risk assessments",[89] in the government as a credible source of expertise, and "specific institutional failures in providing protection from technological risks"[90] have increased this distrust. Xenotransplantation is an exemplar of the fact that risks from "contemporary techniques have implications across time and space"[91] and "when what we do transcends science and when it impinges on the public, we have no choice but to welcome the public – even encourage the public – to participate in the debate. Scientists have no monopoly on wisdom where this kind of trans-science is involved: they will have to accommodate to the will of the public and its representatives. The republic of trans-science, bordering as it does on both the political republic and the republic of science, can be neither as pure as the latter nor as undisciplined as the former. The most science can do is to inject some intellectual discipline into the republic of trans-science; politics in an open society will surely keep it democratic."[92]

Public consultation exercises are becoming more common in the UK and have been held on, for example, GM crops, gene therapy and xenotransplantation,[93] and lessons must be learnt from these experiences and those from elsewhere, with consideration given to the appropriate methodology in a specific context and country. For example, it has been suggested that public consultation in the US on the lines of that which occurred in Canada during the 2000s might not be possible because of US scientists' concerns with

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[86] R. Jackson, F. Barbagallo, H. Haste, 'Strengths of Public Dialogue on Science-Related Issues' (2005) 8 *Critical Review of International Social and Political Philosophy* 349, 350.
[87] A. Coote, J. Franklin, 'Negotiating Risks to Public Health – Models for Participation' in P. Bennett, K. Calman (eds.), *Risk Communication and Public Health* (Oxford: Oxford University Press, 2001), p. 193.
[88] *Ibid*, p. 192.
[89] I. Welsh, R. Evans, 'Xenotransplantation, Risk, Regulation and Surveillance: Social and Technological Dimensions of Change' (1999) 18 *New Genetics and Society* 197, 202.
[90] M. Tallacchini, 'Community and Public Participation in the Risk Assessment of Experimental Clinical Trials' (2007) 14 *Xenotransplantation* 356, 356.
[91] I. Welsh, R. Evans, 'Xenotransplantation, Risk, Regulation and Surveillance: Social and Technological Dimensions of Change' (1999) 18 *New Genetics and Society* 197, 202.
[92] A.M. Weinberg, 'Science and Trans-science' (1972) 10 *Minerva* 209, 222.
[93] E.g. Department of Trade and Industry, *GM Nation? The Findings of the Public Debate* (London: DTI, 2003); Wellcome Trust, *What Do People Think About Gene Therapy?* (London: Wellcome Trust, 2005); Nuffield Council on Bioethics, *Animal-to-Human Transplants - The Ethics of Xenotransplantation* (London: Nuffield Council on Bioethics, 1996), Annexes A and D; DH, *Animal Tissue into Humans* (London: DH, 1996), Annex B, Appendix C, respectively.

the Canadian methodology.[94] Experiences in the UK of engaging the public are developing, important and must continue because "overall experience suggests that policies and decisions made in collaboration with stakeholders tend to be more effective and durable."[95] If they are communicated with clearly, the public can be trusted to reach sensible conclusions, can identify "self-serving and partisan special pleading", may take its time to reach a conclusion but this is no bad thing.[96] The UK government has recognised the importance of public consultation, provided information on possible methods of participation, and noted the difference between consulting the public to obtain their opinion and consulting experts of a certain community to obtain technical advice or feedback.[97] There are, however, concerns about public participation, including that it is part of the largely discredited deficit model of science.[98]

One problem with seeking public opinion and engagement is that the lack of 'expert' knowledge about the risks of emerging biotechnologies may impact on public confidence in and an understanding of science, both of which are important because of the risks which may be engaged. Indeed, British experiences of the BSE crisis and the introduction of GM crops highlight the importance of such confidence, trust and understanding, but there is sometimes little space for wider public considerations and discussions. Nevertheless, the risks and benefits of emerging biotechnologies require public participation and involvement in decision-making processes as "[t]he public must be able to make informed choices with regard to practices which could endanger the future of our species and the principle of human dignity."[99] Yet the value of such consultations may be limited if 'expert' and public understanding of risk, along with the means of expressing it, is poor or restricted. Furthermore, public consultations can be criticised for limited publicity and appealing to respondents with vested interests, but difficulties or concerns about such consultations should not be used as excuses not to engage in them. Experiences of and lessons from public consultations in other areas and jurisdictions must be drawn on to improve what will always be an imperfect exercise. Public debate and consultation on emerging biotechnologies must be encouraged even though this will not be straightforward given that where ethically sensitive topics are concerned consensus is unlikely. Regardless, the public need to be involved in the decision-making process surrounding an emerging biotechnology such as

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[94] K.M. Allspaw, 'Engaging the Public in the Regulation of Xenotransplantation: Would the Canadian Model of Public Consultation Be Effective in the US?' (2004) 13 *Public Understanding of Science* 417.

[95] E. Green, S.D. Short, R. Duarte-Davidson, L.S. Levy, 'Public and Professional Perceptions of Environmental and Health Risks' in P. Bennett, K. Calman (eds.), *Risk Communication and Public Health* (Oxford: Oxford University Press, 2001), p. 60.

[96] M.H. Johnson, 'Regulating the Science and Therapeutic Application of Human Embryo Research: Managing the Tension Between Biomedical Creativity and Public Concern' in J.R. Spence, A. du Bois-Pedain (eds.), *Freedom and Responsibility in Reproductive Choice* (Oxford: Hart, 2006), p. 91, 106.

[97] House of Commons Science and Technology Committee, *Scientific Advice, Risk and Evidence Based Policy Making Seventh Report of Session 2005*-6 vol I, (London: The Stationery Office, 2006) HC 900-I, paras. 133-145.

[98] M. Michael, N. Brown, 'Scientific Citizenships: Self-Representations of Xenotransplantation's Public' (2005) 14 *Science as Culture* 39, 51.

[99] N. Lenoir, 'Biotechnology, Bioethics and Law: Europe's 21st Century Challenge' (2006) 69 *Modern Law Review* 1, 5.

xenotransplantation because they are, essentially, being expected to accept risks to themselves without specifically consenting to them. And if some form of participatory decision making is not possible, then it is important to consider whether an emerging biotechnology which inherently puts the health of more than just the potential beneficiary at risk, should be clinically introduced.

Nevertheless, the UK's *GM Nation?* public debate and public consultations on xenotransplantation in Australia and Canada show that it is possible to interest and engage the public in seemingly complex and complicated scientific issues which may have an impact on them, provided information is supplied in an accessible format.[100] Public deliberation should not seek to achieve consensus or manage discontent but to uncover, explore and, if possible, address concerns of the public.[101] The public should be involved in determining the frames of the debate and there must be "as much public access to [experts] knowledge and their deliberations, and wide public debate about what they say: their ideas, their evidence and their interpretations."[102] Information must be accessible, understandable, authoritative, and balanced so that all views are represented;[103] although it may be harder to develop a meaningful dialogue with the public when there is limited information available on an emerging biotechnology. Nevertheless, "the focus of these deliberative exercises should be an honest effort at relationship- and trust-building rather than persuasion, with mechanisms for actively incorporating the input of lay participants into decision-making."[104] Involvement in the decision-making process may translate

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[100] Department of Trade and Industry, *GM Nation? The Findings of the Public Debate* (London: DTI, 2003); Department for Environment, Food and Rural Affairs, 'GM Dialogue': http://webarchive.nationalarchives.gov.uk/20081023141438/http://www.defra.gov.uk/environment/gm/crops/debate/index.htm, accessed 16/3/11; Australia – National Health and Medical Research Council, Xenotransplantation Working Party, *Draft Guidelines and Discussion Paper on Xenotransplantation – Public Consultation 2002* (2002): http://www.nhmrc.gov.au/_files_nhmrc/file/about/committeess/expert/gtrap/xeno.pdf, accessed 16/3/11; National Health and Medical Research Council, Xenotransplantation Working Party, *Animal-to-Human Transplantation Research: How Should Australia Proceed? Response to the 2002 Public Consultation on Draft Guidelines and Discussion Paper on Xenotransplantation – Public Consultation 2003-04* (2003): http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e55.pdf, accessed 16/3/11; Canada - Canadian Public Health Association (CPHA), *Animal-to-Human Transplantation: Should Canada Proceed? A Public Consultation on Xenotransplantation* (Ontario: CPHA, 2001).

[101] F. Furger, F Fukuyama, 'A Proposal for Modernizing the Regulation of Human Biotechnologies' (2007) 37 *Hastings Center Report* 16, 19.

[102] A. Coote, J. Franklin, 'Negotiating Risks to Public Health – Models for Participation' in P. Bennett, K. Calman (eds.), *Risk Communication and Public Health* (Oxford: Oxford University Press, 2001), p. 188.

[103] F.H. Bach, A.J. Ivinson, C. Weeramantry, 'Ethical and Legal Issues in Technology: Xenotransplantation' (2001) 27 *American Journal of Law and Medicine* 283, 288.

[104] T. Bubela, M.C. Nisbet, R. Borchelt, F. Brunger, C. Critchley, E. Einsiedel, G. Geller, A. Gupta, J. Hampel, R. Hyde-Lay, E.W. Jandciu, A.A. Jones, P. Kolopack, S. Lane, T. Lougheed, B. Nerlich, U. Ogbogu, K. O'Riordan, C. Ouellette, M. Spear, S. Strauss, T. Thavaratnam, L. Willemse, T. Caulfield, 'Science Communication Reconsidered' (2009) 27 *Nature Biotechnology* 514, 517, references removed.

into greater confidence and trust in regulators and the government,[105] and deliberation should include a broad and diverse range of people representative of their local communities.

16 What public engagement activities are, or are not, particularly valuable with respect to emerging biotechnologies? How should we evaluate public engagement activities?

It cannot be categorically stated which engagement activities are 'particularly valuable' as this will be context-specific but reliance should not be placed on one such activity rather a selection should be used. Possibilities include opinion polls, surveys, deliberative polls, focus groups, consensus conferences, public meetings, citizens' panels, citizens' forums, *cafés scientifiques*, deliberative mapping, citizens' juries, referenda, citizen advisory committees. The type of public engagement will depend on when it is occurring; for example, small scale deliberation might be appropriate at earlier stages where there is uncertainty[106] and mass participation methods where more is known of the applications and consequences.[107] Public engagement does not have to be a 'one-off' event, and where is a significant lapse between the initial discussion and possible clinical application of an emerging biotechnology, for example, the public can be consulted again and involved in the decision-making process as to whether to proceed. Although there are limited empirical results on participation processes there are some broadly accepted 'rules of thumb'; the organization conducting it must be committed to it, a needs assessment is a critical part of planning for stakeholder participation, participants must be well informed about the issues on which they are to comment in order for them to be meaningful, and the success of the process will depend on how it has been designed, planned and implemented and other external factors.[108]

Wilsdon and Willis's suggestions for a 'Nano Nation?'[109] debate could be adapted for debates on emerging biotechnologies, with it made clear from the outset how the outcomes of debate will influence policy and decision-making.[110]

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[105] J.F. Childress, R.G. Bernheim, 'Beyond the Liberal and Communitarian Impasse: A Framework and Vision for Public Health' (2003) 55 *Florida Law Review* 1191, 1219; D. Coles, 'The Identification and Management of Risk: Opening Up the Process' in P. Bennett, K. Calman (eds.), *Risk Communication and Public Health* (Oxford: Oxford University Press, 2001), 203.

[106] E.g. E. Grießler, B. Littig, B. Hüsing, R. Zimmer, D. Santos, E. Munoz, G. Ponce, G., H. Gronke, P. Dordoni, *Final Report – Increasing Public Involvement in Debates on Ethical Questions of Xenotransplantation* (Vienna: Institute for Advanced Studies, 2004), p. 11; Science and Technology Policy Research Unit, Environment and Science Research Unit, Policy Studies Institute, 'Deliberative Mapping: Briefing 5 Using the Multi-Criteria Mapping Technique' (2004): http://www.deliberative-mapping.org/papers/f-briefing-5.pdf, accessed 5/6/11.

[107] R. Jackson, F. Barbagallo, H. Haste, 'Strengths of Public Dialogue on Science-Related Issues' (2005) 8 *Critical Review of International Social and Political Philosophy* 349, 356.

[108] V.M. Bier, 'On the State of the Art: Risk Communication to the Public' (2001) 71 *Reliability Engineering and System Safety* 139, 146-147.

[109] J. Wilsdon, R. Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (London: DEMOS, 2004), pp. 57-59.

[110] *Ibid*, p. 16.

This does not mean governments are bound by the results but that "a detailed rationale for ignoring informed public opinion"[111] should be provided and "policy proposals [should be] both reasonable and supported with reasons."[112] This is important because "sometimes an engaged public might reach collective decisions that go against the self-interests of scientists"[113] and the public might use the same material as regulators or experts but draw different conclusions. Secondly, the debate should be deliberative; allow the public to form their own views by discussing with others via a number of means and, as "the development of opportunities for public participation in public health is a complex and variable process",[114] a combination of opinion polls, surveys, deliberative polls, focus groups, consensus conferences, public meetings, citizens' panels, citizens' forums, *cafés scientifiques*, deliberative mapping, citizens' juries, referenda, citizen advisory committees should be employed.[115] This is necessary because "serious efforts at public engagement are likely to employ a mixed strategy – the various methods of addressing the public are not mutually exclusive",[116] and each method has its advantages and disadvantages and, for example, place different weight on the involvement of the public, how participants are asked for feedback, how much feedback influences final decisions, and the timing of consultation.[117] Such debates should influence biotechnology research, should not be a one-off event, and inform the UK's position at European and international levels.

17 Is there something unique about emerging biotechnologies, relative to other complex areas of government policy making, that requires special kinds of public engagement outside the normal democratic channels?

[111] F. Furger, F. Fukuyama, 'A Proposal for Modernizing the Regulation of Human Biotechnologies' (2007) 37 *Hastings Center Report* 16, 19.
[112] L.M. Fleck, 'Can We Trust "Democratic Deliberation"?' (2007) 37 *Hastings Center Report* 22, 23.
[113] T. Bubela, M.C. Nisbet, R. Borchelt, F. Brunger, C. Critchley, E. Einsiedel, G. Geller, A. Gupta, J. Hampel, R. Hyde-Lay, E.W. Jandciu, A.A. Jones, P. Kolopack, S. Lane, T. Lougheed, B. Nerlich, U. Ogbogu, K. O'Riordan, C. Ouellette, M. Spear, S. Strauss, T. Thavaratnam, L. Willemse, T. Caulfield, 'Science Communication Reconsidered' (2009) 27 *Nature Biotechnology* 514, 515.
[114] E. Green, S.D. Short, R. Duarte-Davidson, L.S. Levy, 'Public and Professional Perceptions of Environmental and Health Risks' in P. Bennett, K. Calman (eds.), *Risk Communication and Public Health* (Oxford: Oxford University Press, 2001), p. 51, 60.
[115] For explanations see http://www.peopleandparticipation.net, accessed 5/6/11; House of Lords Select Committee on Science and Technology, *Science and Society*, Third Report (London: House of Lords, 2000), Ch. 5.
[116] Wellcome Trust, *Information and Attitudes: Consulting the Public About Biomedical Science* (London: Wellcome Trust, 2005), p. 11.
[117] T. Bubela, M.C. Nisbet, R. Borchelt, F. Brunger, C. Critchley, E. Einsiedel, G. Geller, A. Gupta, J. Hampel, R. Hyde-Lay, E.W. Jandciu, A.A. Jones, P. Kolopack, S. Lane, T. Lougheed, B. Nerlich, U. Ogbogu, K. O'Riordan, C. Ouellette, M. Spear, S. Strauss, T. Thavaratnam, L. Willemse, T. Caulfield, 'Science Communication Reconsidered' (2009) 27 *Nature Biotechnology* 514, 515.

Where the risks inherently extend beyond the potential beneficiary public engagement must be compulsory and not optional, and referendums should not be ruled out.