Institution: University of York

Unit of Assessment: 23, Sociology

Title of case study: *Emerging biomedical technologies: shaping practices and influencing policy*

1. Summary of the impact

Professor Andrew Webster's sociological research on developments in biomedical science has been impactful in shaping regulatory practice and influencing policy in relation to biobanking, stem cell research and regenerative medicine. In particular, his research has been used to: change donation procedures to the UK Biobank; influence regulatory decisions made by the UK Stem Cell Bank Steering Committee (UKSCBSC); contribute to regulatory practices associated with clinical trial design and adoption, and inform the UK government's investment strategy in regenerative medicine.

2. Underpinning research

As Director of the Science and Technology Studies Unit (SATSU), Webster has undertaken a sustained programme of research on the impact of developments in biomedicine over two decades. The research has focused on the emergence of biomedical technologies related to biobanking, stem cells and regenerative medicine. Professor Webster has been at York since 1999.

2:1 Between 2006-8 Webster was contracted by the Wellcome Trust, acting on behalf of UK Biobank and its Ethics and Governance Council (EGC), to undertake primary research to examine public attitudes towards third party access to the bank. The findings showed that potential donors to biobanks have concerns over security of information. Another concern expressed by potential donors was the possibility that they might be contacted in the future by the biobank once they had deposited their samples. They thought that any re-contact would probably be an indication of ill health or increased risk of disease.

2:2 Between 2005-9 Webster directed the Economic and Social Research Council's (ESRC) Stem Cell Initiative, a £3.5m research programme that examined the social, regulatory and bioethical aspects of this emerging field. Working in collaboration with stem cell scientists (based at the University of Sheffield), Webster's own research project focussed on the scientific and regulatory problems associated with managing live tissue, and explored how this would impact on stabilising evidence which is an essential prerequisite for undertaking clinical trials. This work showed how standardisation of cell batches is especially pertinent to phase III trials, when variation in cell behaviour must be shown to be within tolerable limits across multiple clinical sites in order to gain regulatory approval. These findings had implications for clinical trial design and showed how trials might usefully be redesigned in order to incorporate non-trial evidence from hospital treatment. The research also raised important issues for patient safety and pointed to the need for new models of monitoring clinical trials.

2:3 In 2008-11, following up on the stem cell work, Webster was PI for a European Commission social science project on regenerative medicine (REMEDiE) that examined the socio-economic processes in the translation from lab to product, including intellectual property rights and business models. Three clinical and commercial models were identified that illuminated the strategic choices made by organisations in the wider context of regulatory environments: (1) a 'cells as drugs model', which adopts the pharmaceutical industry business model and involves the development of a standardized protocol that can be used as a therapy across a larger number of patients, and which is therefore potentially of greater commercial interest and, via economies of scale, available at a lower delivery cost to health services; (2) a 'service clinic model' in which cell therapies using autologous cell treatments are used on a patient-by-patient basis (this approach is akin to the way in which IVF clinics operate) and (3) a 'repository model' that depends on the use of cell storage (cryopreservation) for ready access for patients where a good match can be found (here the key to successful clinical outcomes and quality of life has been longer term follow up with patients by both clinicians and the suppliers). These models of translation from lab to product have informed the UK's investment strategy into regenerative medicine (see 4:4 below).

3. References to the research

Webster, A. (2002) 'Innovative health technologies and the social: redefining health, medicine and

the body' *Current Sociology*, 50: 443-458. DOI: 10.1177/0011392102050003009. This has had 118 citations in top-ranked journals such as *Social Science & Medicine* and the *Sociology of Health and Illness*. The paper provided a major statement on innovation in health technology based on the £3m ESRC/ Medical Research Council (MRC) Innovative Health Technologies UK peer-reviewed research programme that Webster led.

2) Webster, A. Martin, P., Lewis G., and Smart, A. (2004) 'Integrating pharmacogenetics into society: in search of a model', *Nature Reviews Genetics* 5: 663-669. DOI: 10.1038/nrg1430. This has had 84 citations in science journals including, *Nature Reviews Drug Discovery* and the *American Journal of Pharmacogenomics.* The research was supported by the Wellcome Trust.

3) Webster, A. (2007) 'Crossing Boundaries: Social Science in the Policy Room', *Science, Technology & Human Values*, 32: 458-478. DOI: 10.1177/0162243907301004. This has had 59 citations in top-ranked journals including *Social Studies of Science, The European Journal of Social Science, Sociological Research Online.* The paper prompted the editor to commission an exchange of papers by the leading scholars Brian Wynne (University of Lancaster) and Helga Nowotny (President and Chair of the European Research Council) with a response by Webster.

4) Webster, A. (2007) *Health, Technology and Society: A Sociological Critique*, Basingstoke: Palgrave Macmillan (shortlisted for *Sociology of Health and Illness* 2008 Book Prize). *Available on request*

5) Webster, A. and Eriksson, L. (2008) 'Governance-by-standards in the field of stem cells: managing uncertainty in the world of 'basic innovation'', *New Genetics and Society*, 27: 99-111. DOI: 10.1080/14636770802077009.

6) Webster, A. Haddad, C., and Waldby, C. (2011) 'Experimental heterogeneity and standardisation: Stem cell products and the clinical trial process', *Biosocieties,* 6: 401-419. DOI: 10.1057/biosoc.2011.17

Citations from Google Scholar, taken on 18/11/2013.

Grant funding on which the papers above are based includes:
1) Webster, A. (PI), 'Quality assured science: the role of standards in stabilising stem cell research', ESRC, £120,000 (2004-07) and the wider ESRC Stem Cells Initiative Directorship, £437,000 (2005-09).

2) Webster, A. (Coordinator) EC FP7, 'REMEDiE', £900,000 (2008-2011).

3) Webster A. (Chair and Grant Holder) 'Bio-objects: Governing Matters at the Intersection of the Society, Politics and Science', FP7 funded Collaboration in Science and Technology (COST) programme, 300,000 euros (2011-2014). This was only one of three social science Actions ultimately supported in 2011 from a competitive field of 400 outline bids submitted to the Commission.

4. Details of the impact

Webster's research in the field of biomedicine has been impactful both in terms of shaping practice and influencing policy in relation to biobanking, stem cell research and regenerative medicine by ensuring that a 'sociological voice' has been heard. Examples of his impact in these fields include the following:

4:1 *Changing donation procedures to the UK Biobank*. Following on from recommendations in the report by Webster, *Public attitudes to third party access and benefit sharing* (2008), the UK Ethics and Governance Council (EGC) and UK Biobank introduced significant changes to their practices. As a result of Webster's findings on public concerns (see 2:1 above) the UK Biobank has since produced regular biannual reports to the EGC describing their data management practices and their security systems. UK Biobank also acted on Webster's recommendation to give more information about its security measures. It did so by requiring since 2008 that the EGC employ information security systems in order to enhance its ability to advise on and monitor this area. In

addition, UK Biobank changed its recruitment information for potential donors to help reassure participants about the scale, form and robustness of the security of personal biodata. Furthermore, as a result of Webster's findings about anxieties among donors that they may be re-contacted by the bank some time after donation, the EGC recommended that UK Biobank investigate this in a systematic survey of participants once 500,000 participants had been recruited. Webster's research has therefore underpinned significant changes in practice that have been of value to both the bank and to donors and potential donors in terms of managing expectations and concerns.

4:2 *Influencing regulatory decisions made by the UK Stem Cell Bank Steering Committee (UKSCBSC)*. Since 2008 Webster has been on the government's UKSCBSC, responsible for agreeing the deposit of and access to banked cell lines by researchers. Underpinned by his research (see 2.3 above) Webster has made a significant contribution to Committee's decisions on, for example, regulation and intellectual property rights involving UK and international cases. For example, in February 2011, he was one of three members of the UKSCBSC responsible for meeting with representatives of the Bio-Industry Association's Cell Therapy and RegenMed Advisory Committee who were pressing for a change in the intellectual property rights of firms. Webster and colleagues advised against these demands for change because of concerns that this would restrict public access to stem cell lines for research purposes and reduce scope for innovation, a position adopted by the UKSCBSC.

4:3 *Contributing to regulatory practices associated with clinical trial design and adoption*. As a result of his directorship of the ESRC Stem Cell Initiative research programme, and his own related research into regulatory issues associated with clinical trials (see 2:2 above), Webster was invited in 2012 to join a Ministerial Industry Strategy Group (MISG) established by Sir Alasdair Breckenridge (Chair of the Government's Medicines and Healthcare products Regulatory Agency). Webster led the Socio-Economic and Policy Perspective strand at the MISG workshop which examined the regulatory framework of the stem cell therapy field. He also co-authored the MISG report, *Regenerative Medicine Regulatory Workshop* (2012). This report contributed to the UK Regenerative Medicine Community's evidence to the House of Lords, Science and Technology Committee's *Regenerative Medicine* inquiry (July 2013), which drew on Webster's work on the adoption of stem cell therapies through 'institutional readiness' and the need to rethink the epistemological assumptions of trialling (p. 1). This finding informed the Group's recommendation that the full potential of the NHS to support regenerative medicine needed to be released, for example, through the NHS National Institute for Health Research (NIHR) being more receptive to non-conventional forms of data and evidence. This is important in this context because processes of standardisation using conventional clinical trials do not apply for research dealing with live tissue. This was reflected in the House of Lords' report in the recommendation that the NIHR should create a regenerative medicine stream of its clinical research network to address 'the specific needs of regenerative medicine clinical trial design' (paragraph 89).

4:4 *Informing the UK government's investment strategy in regenerative medicine*. Data and findings from the REMEDiE project (see 2.3 above) mapped the current activity in the field across Europe to identify the scope for the commercial development of regenerative medicine. The sociological research has illuminated the strategic challenges and choices that commercial companies face in relation to regulation when making decisions about future investments. This work has been directly drawn upon by the House of Lords' *Regenerative Medicine* inquiry (July 2013) and the Department for Business, Innovation and Science's (BIS) report *Taking Stock of Regenerative Medicine in the United Kingdom* (July, 2011). In particular the project underpinned the report's development of an integrated 'national strategy focussing on improving the delivery, infrastructure, regulation and uptake of cell therapy and regenerative medicine' (p. 45). This is being advanced through the government's investment strategy by the Technology Strategy Board's (TSB) Cell Therapy Catapult (www.catapult.org.uk), established in 2012 to bring together businesses, scientists and engineers to transform ideas into products and services to generate economic growth.

The REMEDiE report (http://www.york.ac.uk/satsu/remedie/reports/) has also been utilised in the subsequent development of regenerative medicine strategy in the UK. Based on his research

expertise, Webster was invited to become a member of the Research Councils UK's (RCUK) Key Opinion Leaders group during 2011, with a Senior Scientific Officer at the MRC commenting that the REMEDiE report provided '*an excellent foundation for many of the issues we need to consider under the Forward Look exercise'.* This group met at a workshop to identify the future priorities for regenerative medicine research and development, taking into account current activities, opportunities, and scientific, clinical and commercial relevance.

This exercise led to the RCUK/TSB's *A Strategy for UK Regenerative Medicine 2012*. Webster drafted the specific social science components that problematize conventional trial design (see 2:2 above) and regulatory pathways that are now in the document (p. 17). Commenting on Webster's contribution to the strategic plan for regenerative medicine, a Senior Scientific Officer of the ESRC has said: *"This [social science input into the Strategy for UK Regenerative Medicine] was always going to be tough, because social science was seen as a 'small player' in a field of voluble and powerful big clinical and biological players. However, Andrew managed to get key aspects of social science included in the policy document. This was facilitated by his ability to provide inputs in a way that policy makers can actually use... I then asked him to take forward one of the outputs of the strategy, a workshop in an area of social science interest, thus his contribution spanned right though from drafting the strategy through to practical implementation of aspects of it."*

In 2013 Webster's work in this field was sufficiently well recognised for him to be invited to organise a House of Commons Workshop on regenerative medicine for the All-Party Parliamentary Group of MPs for Social Science and Policy in order to a) demonstrate how social science can engage with complex bioscience issues and b) to inform MPs of future challenges, especially in regard to clinical trials evidence, design and patients' long-term safety.

In summary, Webster's long standing engagement in a range of policy fora has ensured that those involved in the regulation of, and investment in, new biotechnologies take into account the wider socio-political processes which shape their emergence and are sensitive to the implications of their use in practice.

5. Sources to corroborate the impact

- Webster et al, (2008) *Public attitudes to third party access and benefit sharing: their application to UK Biobank* (online) http://www.egcukbiobank.org.uk/stellent/groups/egc/@msh_grants/documents/web_document/wtx052208.pdf (4:1)
- Minutes of the UKBiobank EGC: http://www.egcukbiobank.org.uk/stellent/groups/egc/@msh_grants/documents/web_document/wtx052638.pdf (page 3) (4:1)
- Council Secretary, UKBiobank EGC, Wellcome Trust, London (4:1)
- Director, UK Stem Cell Bank (4:2)
- *Regenerative Medicine Regulatory Workshop*, MHRA, London, 30th October 2012. Available here: http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con282165.pdf (4.3)
- *House of Lords Science and Technology Select Committee Regenerative Medicine Enquiry - Submission of written evidence from UK Regenerative Medicine Community*. Written evidence available to panel on request (4.3)
- *House of Lords Science and Technology Committee, Regenerative Medicine report*, HL Paper 23, (July 1 2013). This report also cited the REMEDiE project several times, see paragraphs 36-8. (4.3; 4.4)
- Department for Business, Innovation and Skills (July 2011) *Taking Stock of Regenerative Medicine in the United Kingdom,* p. 45; see also pp 23-26 and p. 40. http://www.bis.gov.uk/assets/biscore/innovation/docs/t/11-1056-taking-stock-of-regenerative-medicine. Further corroboration can be provided by the Private Secretary to the Secretary of State at the Department of Business, Innovation and Skills (4.4)
- Testimony from Senior Scientific Officer, Head office, Medical Research Council (4.4)
- Medical Research Council, (2012) *A Strategy for UK Regenerative Medicine*, London. See p. 17. http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC008534 (4.4)
- Testimony from Senior Scientific Officer, ESRC (4.4)