Institution: The University of Edinburgh

Unit of Assessment: 20 Law

Title of case study: Case Study 5: Overcoming regulatory impasse in stem cell research in Argentina

1. Summary of the impact

An AHRC and ESRC-funded Edinburgh research collaboration with the Argentinian Ministry of Science, Technology and Innovative Production (MOST), from 2007-2012, served as a key driver in the formation of regulatory structures, norms, knowledge and social understanding, helping to overcome state non-intervention in the regulation of regenerative medicine. As a direct result of engagement with the stakeholders in law/policy, medical and scientific communities, the research exposed a strong appetite for top-down legal intervention. This culminated in the first-ever model law presented by the MOST to the Argentine legislature (Congress) in 2013.

2. Underpinning research

The research relates to two overlapping projects undertaken between 2006 and 2012 by Harmon and Laurie of the University of Edinburgh (employed respectively from 2005 and 1995 onwards). The research programme addressed previously un-examined questions about the expectations and drivers of regulation (and the failure to regulate, in some cases) in Argentina. It adopted a socio-legal method to generate opinion evidence through a series of engagements with key stakeholders, domestic and international, and this served to inform and shape crucial next steps in Argentina towards more overt regulatory policies and action, including legislative intervention.

Dr Jose Barañao, Minister of Science, Technology and Innovative Production, has confirmed the collaboration to be: 'the first social science research conducted in the area of stem cells and regulatory medicine in Argentina'. (5.3) It demonstrated that regulation is not only welcomed in Argentina by research communities but that important lessons can be learned from experience of regulation in the UK and Europe.

Evidence was gathered through interactive workshops and follow-up face-to-face meetings. The first workshop (2007) examined normative possibilities and the UK experience in regenerative medicine, focusing on legal lessons learned. The second (2008) examined human tissue use and regulation, identifying gaps in the Argentine framework. The third (2009) looked at what to include in an Argentine law. The fourth (2010) examined biobanks and the regulation of human tissues and cells, and the fifth (2011) was a comparative exploration of the regulation of advanced medicinal products. Parallel semi-structured qualitative interviews were conducted with key stakeholders. Data and recommendations were disseminated in reports and policy briefs and considered by the Ministers of Science and Health and by representatives of INCUCAI (Argentine human transplantation authority) and ANMAT (Argentine medicines and medical devices regulator). All parties took part in the iterative process of research design and the production of key findings.

The research revealed a regulatory environment that was not operating optimally, and indeed was not operating as it was perceived to do by different groups of stakeholders:

- existing legal mechanisms did not adequately reflect common values deemed essential by key players in the research and regulatory environments;

- there was a strong conviction that regulation must be more proactive and grounded on more effective stakeholder interaction;

- the aspirations for regulation were diverse, but included a desire for top-down value-informed normative rules, reflective of transparency, honesty, democracy (from a procedural

perspective) and knowledge, solidarity, equality (from a substantive perspective).

Accordingly, the research outputs argued that:

1. regulation must better reflect the moral foundations of life science practices (3.1);

2. better evidence from society must undergird regulatory design to operationalise socio-moral values (3.2);

3. regulatory frameworks must place greater emphasis on identifying and realising positive social outcomes for emerging technologies (3.1 and 3.5);

4. while individual choice and protecting individual integrity are important, more emphasis should be given to community and the virtues that support solidaristic outcomes (3.3 and 3.4); and

5. an overt commitment to appropriate legal regulation is defensible and necessary in Argentina (3.2 and 3.5).

3. References to the research

Grants

'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina' (ESRC Grant RES-000-22-2678, £93,000) (PI: Harmon)

'Protection, Promotion and Regulation of Biotechnology in Developing Countries' (under auspices of AHRC research centre funding; £2,583,000 from 2002-2012) (PI: Laurie (2007-2012); Co-Is: Harmon and Arzuaga)

Publications

(3.1) S Harmon, 'Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina' (2008) 8 Developing World Bioethics 138-50 [doi: 10.1111/j.1471-8847.2007.00217.x]

(3.2) S Harmon, 'Regulation of Stem Cell and Regenerative Science: Stakeholder Opinions, Plurality and Actor Space in the Argentine Social/Science Setting' (2010) 2 Law, Innovation & Technology 95-114 [doi:10.5235/175799610791935407] listed in REF2

(3.3) S Harmon, 'Ambition and Ambivalence: Encouraging a Science Culture in Argentina through Engagement and Regulatory Reform' (2011) 5 Studies in Ethics, Law & Technology 1-26 [doi: 10.2202/1941-6008.1134] listed in REF2

(3.4) G Laurie, S Harmon and F Arzuaga, 'Foresighting Futures: Law, New Technologies, and the Challenges of Regulating for Uncertainty' (2012) 4 Law, Innovation & Technology 1-33 [doi: 10.5235/175799612800650626] listed in REF2

(3.5) S Harmon, 'Peering from the Shadows: Stem Cell Research and the Quest for Regulation in Argentina' (2012) 8 Stem Cell Reviews & Reports 640-46 [doi:10.1007/s12015-011-9331-x]

4. Details of the impact

The series of international workshops held by the Co-Investigators in collaboration with the Argentinian Ministry of Science, Technology and Innovative Production (MOST) served as both research method and impact-generator and resulted in more open debate than had previously been achieved in Argentina. These meetings were led by Arzuaga, who was appointed an

Edinburgh AHRC SCRIPT Centre Fellow (2006-) and subsequently appointed Chair of the Argentinian Advisory Commission on Regenerative Medicine and Cellular Therapies (2008). Research beneficiaries included the MOST, select Argentine policy and science elites (legislators, regulators, policymakers, key members of the life sciences, law and bioethics academic communities), and invited UK experts.

The impact of the research is that, through the systematic engagement of the research community and law and policy makers, the partnership between the University of Edinburgh, on one side, and Argentinian research regulators, on the other, overcame a long-standing impasse in Argentina with respect to state non-intervention in the regulation of regenerative medicine. There had previously been no thorough consideration of appropriate regulatory models for Argentina to promote research in this emerging field. More specifically, the iterative engagement and associated findings led to:

1. Influence on the annual agendas of the Advisory Commission on Regenerative Medicine & Cellular Therapies. The research directly influenced the unfolding policy programme by feeding empirical evidence, theoretical conceptions, and both normative and institutional recommendations into official processes and actions, especially that of the Commission, which has since become a key driving force in the life sciences in Argentina. According to its Chair, Dr Fabiana Arzuaga: 'This research served to inform and shape crucial steps in Argentina towards the construction of a legal framework and regulatory policies and action for stem cells research and therapies, which led to a proposal to modify the Civil Code of Argentina' (5.2).

2. Exposure of the reasons behind scientific and regulatory caution, as well as uncertainty of having a 'legal blank page'. Importantly, this included an appetite for top-down regulation in Argentina. The research provided regulators with evidence that stakeholders desired central normative guidance and oversight, a finding subsequently confirmed by a national survey (5.7). Recommendations about the need for a central regulatory authority form a central part of the new model law.

3. Mobilisation of a close network of Argentine and UK researchers and regulators which permitted swifter and more dramatic policy movement than had previously been experienced in Argentine science governance. The research did not just study key Argentine stakeholders, it brought diverse interested groups together, helping to forge relationships across user communities and fashion a more supportive environment in a morally contentious area. Dr Florencia Luna, bioethics member of the MOST, stated: '…the project has shown extraordinary results like creating engagement with law/policy, medical and scientific communities…and facilitated an unprecedented consideration of regulatory options' (5.4).

4. Facilitation and contribution to both the generation of law and the design and uptake of new models for performing regulation. Dr Gustavo Seveler of the MOST and leading medical researcher confirmed that: '…data and recommendations arising from the meetings were considered by MOST and INCUCAI [Argentinian Transplant Authority] as inputs of an iterative process of research design and production of key findings' (5.5).

The research created new lines of enquiry and helped to identify the instruments and institutions that would be suitable for Argentina. Its findings and conclusions fed directly into the document authored by the Commission, circulated throughout Argentina and resulting in a draft Life Sciences Law (setting standards for regenerative medicine research and patient care) that the MOST sent to the Argentinian Congress in 2013 (5.1 and 5.2).

The role of the research in overcoming impasse in health research regulation in Argentina is confirmed by Minister Jose Lino Barañao: '…this project contributed to ensuring that a values perspective was brought to bear on policy deliberations…and that conclusions of the research have been taken into account in the drafting process' (5.3). Dr Arzuaga of the Commission further commented: 'This experience combining research and policy decisions and actions is an extraordinary case that is now considered by the Commission as a model for many other areas of

science to transfer knowledge to real world' (5.2).

5. Sources to corroborate the impact

(5.1) A series of research-based policy briefs were considered by a range of policymakers, translated into Spanish by the Argentinian Ministry of Science, Technology and Innovative Production (MOST), and posted on the MOST's official website, an uncommon privilege. See http://www.mincyt.gob.ar/ministerio/comision-asesora-en-terapias-celulares-y-medicina-regenerativa-12 (http://tinyurl.com/nnuxevf). These provide evidence of endorsement by the MOST and form the basis for its future regulatory policy in the field of stem cell research.

(5.2) Testimonial from Chair of the Advisory Commission on Regenerative Medicine and Stem Cellular Therapies; also Research Fellow in Edinburgh SCRIPT Centre [to be supplied by HEI on request]. Can corroborate the direct influence of the research on the workings and recommendations of the Commission, including its input to the proposed model law.

(5.3) Testimonial from Argentinian Minister of Science, Technology & Innovative Production [to be supplied by HEI on request]. Can corroborate the unprecedented advances brought about by the research in overcoming regulatory impasse in a sensitive area of research and the effects this had on mobilising actors towards the introduction of regulatory reform.

(5.4) Testimonial from Chair of the Bioethics Programme at the FLACSO Institute and member of the Advisory Commission on Regenerative Medicine and Cellular Therapies [to be supplied by HEI on request]. Can corroborate the influence of the research on the workings of the Commission with respect to ethical insights and the importance of uncovering core values that inform regulatory law and practice.

(5.5) Testimonial from Research Director, Instituto FLENI, and member of the Advisory Commission on Regenerative Medicine and Cellular Therapies [to be supplied by HEI on request]. Can corroborate the influence of the research on the workings of the Commission with respect to the health researcher perspective as actors to be regulated.

(5.6) Testimonial from UNESCO Chair on Bioethics, member of the Advisory Commission on Cellular Therapies and Regenerative Medicine (MINCYT) [to be supplied by HEI on request]. Can corroborate the influence of the research on ethical deliberations of the Commission.

(5.7) Argentinian national survey on attitudes towards regenerative stem cell medicine: see http://www.celulasmadre.mincyt.gob.ar/Documentos/Valores_esperanzas_y_preocupaciones.pdf (http://tinyurl.com/or3fc7x). This provides confirmatory evidence that supports the research findings with respect to a desire for regulatory intervention in the sector within Argentina.