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Regenerative Medicine Governance: Report Of The Workshop On Governance Of Research Using Human Embryonic Tissue

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Workshop

Regenerative Medicine:
Research Using Human Tissue of Embryonic Origin
An International Interactive Workshop
Buenos Aires
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Workshop Sponsors

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1. Introduction

The appropriate creation and application of biotechnology throws up numerous challenges with which society must deal: scientific, environmental, social, ethical and legal. Human stem cell research (SCR), as an evolving exemplar of biotech innovation, is a nexus for many of these challenges and controversies. Although there is a growing body of social science work relating to the use of human stem cells (SCs), there is a dearth of work on the interaction of social values and law in the SCR context – with its tensions between promoting science, managing stakeholders and limiting risks – and of its pursuit in developing countries. The GET: Social Values Project – an ESRC-funded project entitled 'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina'[1] – is exploring how social and ethical values are, and can be, translated into legal rules. It is examining the conduct and motivating values of Argentine stakeholders as they work to formulate socially acceptable regulatory structures in this field. Objectives include mapping the most salient features of the social/moral/legal debates, developing dialogues with stakeholders to reveal the multiple goals envisioned for regulation as well as hurdles, and contributing to the debate surrounding, and formulation of, value-sensitive regulatory models. This workshop represents the third international interdisciplinary meeting of experts in which the Workshop Team participated and/or coordinated.

2. Workshop Summary

This workshop represented the third international interdisciplinary meeting of experts and Argentinean stakeholders in a process that is intended to culminate in the adoption of a stem cell or broader biosciences research governance scheme in Argentina. Unlike the first two conferences, also held at FLENI,[2] this was a smaller gathering made up of forty participants including the Minister of Science and Technology, regulators and policy advisors, scientists, clinicians, lawyers, and ethicists. The workshop proceeded with some formal presentations on a variety of scientific, ethical, and legal issues. The participants were then divided into groups to discuss various potential courses of action open to Argentina, including expressly (legislatively) permitting embryonic stem cell research, or prohibiting it. The groups deliberated for approximately 50 minutes and reported back to the plenary group. These reports were followed by an open plenary discussion and some closing comments from a representative of the host institution. As the report below demonstrates, the workshop was very well received and successful in generating discussion around a variety of issues and needs particular to the Argentine setting. Over the course of the workshop, several commonly shared concerns and operative values became apparent, and the event provides an evidence base from which further actions can be taken.

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[1]For more on the GET: Social Values Project, ESRC Award No. RES-22-000-2678, see http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/ and http://www.esrcsocietytoday.ac.uk/.

[2]Fundación para la Lucha contra las Enfermedades Neurológicas de la Infancia. See http://www.fleni.org.ar/.

3. Workshop Objectives

As an output of the GET: Social Values Project, this workshop was intended to test possible frameworks for advancing normative rules in the stem cell research setting through group deliberations of fact-specific problems and possible legal responses, thereby generating data on risks identified, moral positions held, and legal possibilities deemed suitable, by the participants. As a jointly sponsored and organised event, the workshop also had to meet the objectives of other institutions. Most notable among these was the Argentine Ministry of Science, Technology and Innovative Production, whose objectives were to elicit views from key stakeholders about the implications of permitting or not permitting embryonic stem cell research in Argentina. Given this background, the workshop was collaboratively designed to:

1. Bring a number of interested stakeholders from a variety of disciplines together in a reasonably intimate group setting;
2. Encourage them to think critically and collaboratively about issues arising from stem cell and cellular-based research; and
3. Develop some shared understanding of issues, values, and possible solutions for moving forward (from a governance perspective).

Aside from this deliberative function, it was envisioned that the workshop would result in (1) the evolutionary development of a procedure for encouraging constructive analytical debate that might be suitable to the Argentine environment, and (2) the development of some propositions related to stem cell and/or bioscience research that might be tested with various publics and other stakeholders, particularly those not represented at the workshop.

4. Workshop Presentations and Activities

4.1 Welcome

The workshop was held in Spanish and the proceedings were opened by Fabiana Arzuaga, Collaborating Investigator on the GET: Social Values Project, and Graeme Laurie, Principal Investigator on the ProReg Biotech Project.[3]

4.2 Formal Presentations

Dr Lino Barañao, Minister of Science and Technology,[4] welcomed the participants and then addressed the scientific aspects of cellular science. He indicated that this field implicates cloning, and that the pace of advancement is very fast, with things moving from concept to clinic quicker than normal, in large part as a result of commercial interests and public support for new therapies.[5] He reported that an

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[3]For more on this project, see http://www.law.ed.ac.uk/ahrc/research/viewprojects.aspx?id=13 and http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/relatedprojects.asp.

[4] See http://www.mincyt.gov.ar/.

[5] This was an interesting observation because, while techniques have found their way into the European clinical setting absent the long "pipeline process" characteristic of drug development and certification, this quick "concept-to-clinic" approach is not happening in Europe or the US.

Argentine lab has developed potentially implantable beating heart cells from embryonic stem cells, which are now being trialled in pigs. He also reviewed the status of induced pluripotent somatic cells, which may eventually negate the need for embryonic stem cells, but noted that one of the factors required in this process has been linked to tumour growth. Barañao concluded that, from a scientific perspective, key issues in the embryonic stem cell arena are (1) satisfying the quantities of quality cells needed to do research, (2) improving understandings of differentiation so that techniques can be improved, (3) eliminating tumour growth, (4) identifying and considering ethical issues on an ongoing basis, (5) determining whether derivative products are drugs, medical products or techniques, and (6) reducing the cost of therapies.

Dr Florencia Luna, former President of the International Association of Bioethics and current professor at FLACSO,[6] addressed the ethical element. She noted that the baseline question is whether the embryo is a collection of cells, a group of special cells, a potential person, or an actual person. One's vision of this will influence one's opinion of cell provenance, an issue which is also important given the role of commercial interests and potential for exploitation in cell sourcing (and she noted Argentina's culture and history of exploiting women). Luna highlighted the need to consider issues having reference to values like autonomy, beneficence, justice, solidarity, and welfare. In advancing the case of science in Argentina, she highlighted the need to disseminate good information without prejudice, and to practice (and demand) tolerance and respect for pluralism. Luna concluded by suggesting that there is a need for practical and coherent regulation in this field (and the regenerative medicine field more generally) which avoids the hypocrisy currently exhibited.

The legal issues implicated by cellular sciences of embryonic origin were addressed by four speakers as follows:

- Professor Graeme Laurie, Director of SCRIPT, the AHRC Centre for Research on Intellectual Property and Technology Law, University of Edinburgh, highlighted the governance regime in the UK, focusing on the HFEA and its recent amendment, and concluding with the regulatory roadmap that was recently jointly released. He demonstrated the level of complexity and agency interaction that has grown up in the UK – the first country in the world to attempt to regulate in this field – and noted that valuable lessons might be learned by other countries so that they might avoid unnecessary regulatory complexity while both promoting the science and adequately protecting research participants and patients.
- Dr Salvador Bergel, Professor at the University of Buenos Aires, stated that in Argentina there is no regulation governing assisted fertilisation or stem cell research, and that clinical research is deficiently governed by a Ministerial decision and not by a law. He suggested that, within the current legal structure of Argentina, it is possible to permit embryonic stem cell research, and the source would be the surplus embryos remaining from IVF centres, embryos which, in many cases, are discarded. Bergel supported his thesis with references to Articles in the Argentinean Civil Code and to the Latin American Convention of Human Rights (Convention of Costa Rica). He also referred to

[6] See http://www.flacso.org.ar/english/.

the scientific vision of Wolar about when human life starts and remarked that a social and legislative debate is necessary on these issues as soon as possible.

- Dr Gustavo Bossert, former Minister of the Supreme National Court of Justice, noted that, when controversial ethical issues are raised by a practice, Argentine law (primarily legislators, but also society) tends to look the other way, and he offered the example of IVF treatment, which remains unregulated. One particular hurdle in this field is the concept of "conception" in the Civil Code, which stipulates that conception is the moment at which the legal status of the human being begins. He remarked that the Civil Code does not explain exactly when this moment starts, but rather refers to the implantation of the egg inside the uterus of the mother (which actually occurs around the 14th day). He supported this statement with references to the treatment in the civil law of humans being born alive and not alive. Bossert also made observations about the civil law, inheritance law, constitutional law, and international treaties in force in Argentina relating to human rights, to demonstrate how they might influence the development of stem cell practices and regulation.
- Dr Claudio Bonadio, Justice, Federal Criminal Court of Argentina, complained that Argentina's current law is inflexible and anachronistic (as compared to the UK's more modern approach), and that the criminal law, where it is relevant, does not erect strong enough sanctions for improper conduct (and moreover is only triggered once damage has occurred). Bonadio emphasised the importance of information and consent to all elements of scientific and medical endeavours and called for a proactive and flexible law.

After these presentations, the session broke for a sustenance break and the participants were invited to review the posters that were located around the venue. These posters addressed the scientific and ethical issues of adult stem cell research, foetal stem cell research, and embryonic stem cell research, as well as values, the policymaking process, and the projects and workshop objectives. They were designed to help structure further thought and debate about the way forward for Argentina.

4.3 Interactive Group Session

When the workshop reconvened, the participants divided into two groups, each selecting a Chair/Rapporteur, and they separated to different rooms. They were asked to consider the pros and cons (or benefits and costs) of allowing research reliant on the use of embryonic material, and of disallowing such research. They were encouraged to identify the core issues that would need to be addressed and the values that were implicated, and to offer possible solutions. After some 50 minutes of discussion, during which the organisers circulated between the groups, the participants came together in plenary and reported their deliberations.

First, the Rapporteurs articulated which issues would be raised in the event that Argentina explicitly allowed research using embryonic material:

- There would need to be clarity around the issue of when, for legal purposes, the human person begins.

- There would need to be clarity as to the acceptable sources of stem cells so the provenance of material could be traced.
- There would need to be clarity around the issue of whether stem cell based therapies are considered to be drugs, products, or techniques.
- The current Penal Code is archaic and would have to be amended to complement the new law/regulation.
- A competent gatekeeper would have to be named and empowered to oversee this area and to ensure that it develops in a safe and useful manner.
- Certain powerful stakeholders are opposed to this research, including the Roman Catholic Church and certain elements within the Senate, and they would have to be engaged.
- Argentina is a federal state, so there would be inter-provincial issues to tackle, and the possibility of a patchwork of approaches within the nation.
- There is a (growing) gap in the technical knowledge of active stakeholders (protagonists) and the understanding of key decision-makers and the public, which could cause problems.

Second, the Rapporteurs identified issues consequent to disallowing research using embryonic material:

- Prohibition and/or the absence of regulation could result in increased medical tourism and embryo trafficking.
- The interests of vulnerable groups, like women, could be hindered by the absence of Argentine research (i.e. of research generating knowledge particularly relevant to Argentineans) or of appropriate legal protection within Argentina.
- Clandestine research could be conducted, which could result in bad science and the exploitation or abuse of individuals or groups, particularly traditionally vulnerable ones.
- There would be economic consequences as Argentine science fell behind and potential wealth-development opportunities were lost.
- Argentina could experience a "brain drain" (and therefore lose its competitive advantage) as researchers moved to jurisdictions with greater opportunities.

Finally, the Rapporteurs briefly outlined some possible "Argentine solutions" for addressing these issues:

1. There is a lack of clear public understanding of science, and of reliable and accessible information in the public domain. Greater efforts must be undertaken by the Ministry and other interested institutions to disseminate good information to the broader public.
2. There is a lack of evidence of social expectations of science and research available to policymakers. Greater efforts must be undertaken by the Ministry and other interested institutions to solicit good information from the broader public.

3. Human rights are important. The human right of freedom of research must be recognised and protected, particularly in the face of powerful institutions who would like to diminish it.
4. Certain positions adopted in the Civil Code have been overwhelmed by reality (e.g. fertility treatment occurs, PDG occurs, abortions are undertaken, excess embryos are being generated, and embryos are being used for research). The Civil and Penal Codes must not stagnate, but rather must change with changing realities. The Codes should be amended to reflect existing practices in reproductive medicine and research, and to protect research participants. Increasingly, doing nothing is not a viable option.
5. Argentina faces a very wide range of public health issues, including very basic ones relating to nutrition and other primary needs, and more complex ones caused by the both frenetic and sedentary nature of many modern lifestyles. While the more basic healthcare issues faced by Argentina should not stop it from pursuing research and the development of high technologies (some of which would seem like science fiction to many people), Argentina must be very careful about the potential benefits of such research. Argentina should develop its own specific cell lines and should make them available for research into public health matters particularly relevant to Argentina.

4.4 Concluding Remarks

The final open session in which participants could make comments or pose questions from the floor was followed by some closing remarks by Dr Sevlever who lamented that stem cell research is something of a glamorous science which raises great and improbable expectations. These are in no small part due to the media and to the claims of irresponsible physicians. The development time for novel treatments based on high technologies can take more than thirty years. As such, expectations need to be managed, a matter which is an ethical issue of some importance. On this and other ethical issues, researchers need regulatory guidance; guidance which recognises that this is a unique material – a healing cell. Moreover, even though Argentina faces a host of more basic health and welfare problems, this is important research that could (eventually) benefit an aging population, and so it must be structured and pursued responsibly. This means a multidisciplinary approach to governance, or to shaping the governance regime. Sevlever applauded the present workshop as a component of that process.

5. Analysis and Observations

5.1 Exploring Argentine Courses of Action

Interestingly, as should be obvious from the above, all participants adopted the position that the subject research should and would be permitted. Neither group spent any measurable time horizon-gazing about the implications (to science or society) of a future in which this research would be prohibited. Thus, they did not arrive at any solutions for alternative avenues for research in such a future. Indeed, no participant was prepared to engage with an oppositional position, even for purposes of better exploring the issues. We believe this consequence was the result of two factors:

1. While the institutional and professional backgrounds of the participants were quite varied, they could all be described as "progressive" (or "science protagonists" as opposed to "science antagonists" or "technophobes"), some even having vested interests in the adoption of pro-science policies.
2. Despite being given the space to step outside their experience, many participants declined to do so, demonstrating an overt or unconscious reluctance (or inability?) to set their interests aside and examine issues of a broader scope from different angles.

While a certain homogeneity of positions was expected given the participants who attended (i.e. all were from scientific or policy elites), we believe this homogeneity was amplified by a relative lack of opportunities in Argentina for interested stakeholders to come together with other disciplines and explore their ideas, concerns, and experiences. As such, this workshop appeared to be used by the participants, perhaps inadvertently, as an opportunity to confirm shared experiences, and to test shared objectives, rather than as an opportunity to explore a variety of alternatives. In support of this conclusion, we note that anecdotal evidence offered at and after the event to the effect that this was a "unique experience", particularly from a format perspective, not at all common in Argentina, and that, in some ways, this was a chance to consolidate the ideas of those "on the team" (the anticipation being that, at some point, this "team", though significantly enlarged, will have to face the opposing "team" if science and innovation is to truly and openly flourish in Argentina).

5.2 Identifying and Articulating Values Important for Argentina

Related to the above point, it was also observed that neither group seemed prepared to interrogate in any great depth the underlying assumptions or values exposed by their positions on the issues identified or the solutions offered (i.e. there was very little drilling down into their claims in an attempt to understand why they felt these implications were important, or likely, and what underlying value-positions drove their characterisations). We expect that this is partly due to the phenomenon noted above, and partly due to limitations imposed by the adopted methodology, some of which might be remedied in future offerings. For example, greater time and more explicit direction might be given to the participants' viewing of the posted material, smaller groups might be fashioned, and debate-structuring questions might be provided. (On the latter point, such questions had originally been prepared, but time pressures and the needs of certain partners required a re-focus away from those questions.)

Over the course of the workshop – both formal and interactive components – the operation of, or affinity for, certain value concepts became apparent. First, many of the contributions exposed a determination to ensure "equality". This was exposed in particular by numerous references to the need to protect vulnerable groups, especially women, and to ensure that the fruits of research would benefit the Argentine public, including less empowered and traditionally exploited segments. Second, many participants, at least implicitly, expressed a desire for "democracy", as evidenced by a number of facets of the discourse, namely:

- **Social Interaction:** There were recurrent references to the need for broader input from society. While many of these references exposed an assumption that public support might be won with the dissemination of more and better information (suggesting the operation of the deficit model of science understanding), these nonetheless underscored a genuine belief that the public has a stake and a valuable contribution to make in the governance of science. In this regard, several participants called for the discussion undertaken within the workshop to be transmitted to society, the hope being that it would be the first step in helping publics develop more nuanced and science-based understandings. Another suggested that an open, multi-disciplinary web-based forum might be created so that experts could explore issues together in the view of, and perhaps with the input of, members of the public. In short, there seemed to be a desire to co-produce with the public the Argentinean "position" on stem cell research so that when a law eventually reached the Congress, its deliberations and decisions could be "better".
- **Rational Law:** Many of the participants lamented the current state of the law – which was repeated described as "hypocritical" – and expressed the strong belief that the law must be honest and transparent, so that scientific practices could be equally transparent and open, and therefore better governed (and steps could be taken to ensure "good science" and patient protection). The current legal situation, although generally and by default allowing stem cell research to be undertaken, was considered to be bad for science, scientists, patients, and, ultimately, for Argentina. Too much must be undertaken in silence and this situation provides too much space for mavericks and unethical researchers.
- **Interaction with Legislators:** There was a general frustration expressed at the absence of any legislators at the workshop. Several had been invited, a few had accepted, none appeared.[7] There was some support for an approach to Congress for an "interview" or "evidence-offering" by the group.

Third, there was a clear, strong, and oft-stated allegiance to "autonomy". The participants felt that researchers must be given the space and support to undertake research they considered to be valuable, so long as such research is also ethical. They felt they should not be constrained in their liberty to pursue their own valid scientific ends by those who would impose their will upon them without having any basis in reason or rationality. However, there was also some recognition that this constraining approach may be driven by different value-perspectives that are worth exploring further in future. Several participants made reference to the human right of freedom of research, and the need for that right to be explicitly recognised in Argentina.

5.3 Mapping the Process

While serving as an opportunity for the GET: Social Values Project to observe and study stakeholder interactions, this workshop also formed part of a cautious, ongoing course of conduct undertaken or sanctioned by the Argentine Government, and more particularly by the Ministry of Science, Technology and Innovative Production, to

[7]The absence of legislators may have been influenced by the looming end of the legislative session and anticipated national elections.

gather evidence and to develop a human tissue governance regime. Previous and ongoing activities include:

- Resolution 214/2006 of the National Agency for the Promotion of Science and Technology, which created the Advisory Commission on Regenerative Medicine and Cellular Therapies This advises the Government on practical and ethical matters arising in this field and was subsequently transferred to the Ministry of Science, Technology and Innovative Production by Resolution 737/2008 of Ministry of Science, Technology and Innovative Production.
- Resolution 610/2007 of the Ministry of Health which created INCUCAI, which regulates the implantation of cells in human beings.
- November 2007 international conference, "Regulation of Clinical Research Involving Stem Cells: Learning from the Experiences of the UK".
- October 2008 international conference, "Second International Conference on the Regulation of Stem Cells and Human Tissue".
- Official Communication of the Science and Technology Commission of the Deputies Chamber, National Parliament: "Impact in Argentina of President Obama's Policy Lifting the Funding Ban on Embryonic Stem Cell Research".
- August 2009 international interactive workshop, "Regenerative Medicine: Research Using Human Tissue of Embryonic Origin".
- Formal Objection of the Advisory Commission on Regenerative Medicine and Cellular Therapies: "Legal Objections to Proposed Law 1584 –D-09, City of Buenos Aires".

One can see that explicit interactions with broader publics are absent from the above map, and this is a characteristic of the unfolding course of conduct that the workshop did not rectify (nor was it intended to). However, there was a clear desire on the part of most of the participants that broader publics and other stakeholders be more directly involved. Based on the discussions held, we suggest that support for the following propositions should be tested in different Argentine publics, most importantly representatives of the lay public (away from powerful institutions which might otherwise coerce them):

1. Argentina's national/federal government should move immediately to ban the use of human embryos or embryonic material in stem cell and other research. Agree? Disagree? Why?
2. Recognising the scientific, social and economic benefits stem cell research might bring, Argentina's national/federal government should permit but tightly regulate research using human embryonic material (including embryonic stem cells). Agree? Disagree? Why?
3. Argentina's national/federal government should refrain from acting at all and should instead permit the present state of affairs to continue. Agree? Disagree? Why?
4. Argentina's national/federal government should permit each individual province to determine the extent to which embryos or embryonic material can be used in scientific research. Agree? Disagree? Why?

After getting responses on these initial propositions, the following might then serve as a second-order list of questions to better elucidate respondent positions, interests and values:

- What, in your opinion, is the value of adult, foetal and embryonic stem cells?
- What moral concerns are raised by obtaining stem cells from embryos?
- How would you resolve them?
- What should the source of moral values be? (Where should they come from)?
- What moral values are implicated by embryonic stem cell research?
- What values are most important to you?
- Are you comfortable with science making fictions of our (old) beliefs?
- Do you think that current (social) conditions respect the individual?
- Should living people be given greater rights than embryos?
- Is an authoritative research governance body necessary?
- Should its focus be research governance or clinical governance?
- Should its remit be innovation promotion or healthcare enhancement?

Obviously, some groundwork would have to be laid before people might be expected to address these questions, but social scientific work conducted in other countries has demonstrated that, with relatively modest amounts of information, people can make reasoned judgments about complex issues.

6. Conclusions

On the whole, while certain procedural matters might have been undertaken differently, the workshop was a great success. Indeed, it was reiterated by a number of participants, both at the workshop and subsequently, that innovative meetings such as this were invaluable and might, in future, be expanded to include a wider cross section of stakeholders, including ones who might be expected to be ambivalent towards innovations in the sci-tech fields under discussion. From a substantive point of view, we can report the following:

- While the "safety" of the present "non-system" of governance was noted (i.e. powerful stakeholders believed to be antagonistic to stem cell and techno-science more broadly were not provoked), there was a general dissatisfaction with the present state of affairs. In particular, there were concerns that the applicable legal structure in Argentina is archaic and hypocritical, it does not encourage scientists to be open, communicative, and forthright with their work (which hinders the good pursuit of knowledge), and it does nothing to prevent bad research, thereby leaving Argentina's citizens vulnerable to abusive practices.
- There was a high level of homogeneity in the values expressed by participants, with equality, democracy, and autonomy featuring heavily. Additionally, as suggested by the above point, there was a broad consensus around the

importance of scientific integrity and honesty and how that fed into patient safety and wellbeing. (Again, we concede that this value-homogeneity is probably at least partially derivative of the relative homogeneity of the group.)

Obviously, the workshop was unable to deal with all the questions and issues raised by the participants, or even to explore them in the depth that might have been warranted or desired. In that regard, the Project Team hopes that this was just the start of an ongoing dialogue between these stakeholders which might expand further (see below). If participants have any comments on the issues raised or on the event itself, we invite you to send your thoughts via email to any of the Workshop Team.

7. Possible Next Steps

Based on the representations of the participants, we recommend that the following steps are supported:

1. The hosting by the Ministry of Science of further structured interactive workshops.
2. The formation of a network of individuals and institutions interested in this field, or, more particularly, interested in exploring the issues and possibilities of this field, and mutually producing a more articulated Argentine position which might serve as a stimulant for broader interaction. This Regenerative Medicine Network or Techno-Science Network could have a central website with both member (password protected) and public spaces, both of which would contain interactive elements.
3. The provision of funding (domestically and from abroad) to better educate interested publics of the capacities, limitations, and direction of research in this field, and of the issues raised by new technologies.
4. The provision of funding (domestically and from abroad) to more interactively engage with interested publics and stakeholders so that better evidence of Argentine desires, concerns, values, and risk-tolerances can be generated.

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