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**Peering from the Shadows:
Stem Cell Research and the Quest for Regulation in Argentina**

Shawn H.E. Harmon

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Abstract: Science has long been contentious and disruptive. Where it threatens entrenched powers, it has been muzzled, discredited, or simply outlawed. The pursuit of scientific research in social settings where bodies traditionally suspicious of science are politically powerful is doubly challenging when democratic traditions are weak or participative opportunities few, for then there is less opportunity to call upon the informed public to generate support which might circumnavigate the barriers created by these powers. In such situations, researchers can become isolated and marginalised, and potentially fruitful avenues of inquiry can be close off, and science can go ‘underground’ removing it from professional and public scrutiny alike. Drawing on evidence generated in the GET: Social Values Project, this paper considers the Argentine context and the general position of Argentine stem cell researchers as perceived by those researchers and non-researchers who are close to the field. In doing so, it argues that there is an important role for the law in supporting researchers and correcting the science environment, which, in Argentina, lacks transparency, dialogical spaces, appropriate policy influence, and more.

Keywords: Argentina; stem cell research; researchers; science culture; law; regulation

Disclosures: The author declares no conflict of interest.

PEERING FROM THE SHADOWS: STEM CELL RESEARCH AND THE QUEST FOR REGULATION IN ARGENTINA

INTRODUCTION

The pursuit of scientific knowledge is not amoral. It is not neutral. So science has long been contentious and disruptive. While the nature and range of socio-moral questions that are raised by scientific pursuits are diverse and context-specific, its destabilising effects increase when it fails to serve the political interests of entrenched powers.[1,2] In such cases, science has been muzzled, discredited, or simply outlawed. Consider the Catholic Church's reaction to Galileo,[3] or the varied responses by a range of organisations, including government, universities and industry, to environmental science.[4] One might also take notice of the suppression of, and assault on embryonic stem cell research, which has some reproductive medicine applications, by the religious and political right. While this antagonism is particularly visible in the US,[5] it is not exclusive to the US, and can be seen in various states around the world, including Italy and Germany.[6]

The pursuit of scientific research in social settings where bodies traditionally suspicious of science are politically powerful is doubly challenging when democratic traditions are weak or participative opportunities few. In such settings, there are fewer opportunities for protagonists to call upon the informed public to generate support which might circumvent the voids opened up, or barriers erected by, these powers. In such situations, researchers can become isolated and marginalised, and potentially fruitful avenues of inquiry can be closed off. This has implications for knowledge-creation, innovation, the timely translation of innovation into products useful to patients, commerce, and more.

Drawing on evidence generated in the 'Governing Emerging Technologies: Social Values and Stem Cell Research Regulation in Argentina' project (GET: Social Values Project),[7] this paper considers the general circumstances within which Argentine stem cell researchers find themselves, as perceived by those researchers and non-researchers who are close to the field. In doing so, it argues that there is an important role for the law in supporting researchers and 'correcting' the science environment in which researchers operate. In Argentina, despite several important salutary reforms (eg: the formation of the Ministry of Science, Technology and Productive Innovation and of a national Advisory Commission on Regenerative Medicine and Cellular Therapies, and their activities [8]), the science environment still lacks transparency, dialogical spaces, appropriate policy influence for society and key protagonists, and more.[9] This paper does not call for the hegemony of scientific knowledge, but rather for a democratisation of science, emphasising the role of regulation in this process.

METHODOLOGY

The GET: Social Values Project was designed to gather qualitative data around key issues of stem cell research governance in Argentina. The objective was to discover stakeholder values relevant to, and objectives for, this science and its governance, and the influence of these values, if any, in shaping science and regulatory directions. Following preliminary research, semi-structured interviews were conducted. Each

interview was, with permission, recorded. Transcription of the interviews was performed within the PI's host institution and subject to a Confidentiality Agreement.

Participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities. As the GET: Social Values Project was never intended to be a public engagement mechanism, the opinions of the broader (lay) public were not solicited. Rather, those originally viewed as most likely to influence the nature and content of bioscience regulation (generally) and stem cell research regulation (specifically) were targeted (ie: Argentine science and policy elites). It was felt that only by targeting those most engaged in pre-legislative processes could we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they eventually emerge), on the other. The original sample was supplemented by further participants through a snowball technique reliant on the social/professional contacts of the original sample members.

Open-ended questions and a relatively informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. Nonetheless, some formalism was observed insofar as the Principal Investigator and Co-Investigator wished to ensure a consideration in each case of certain broad topics, and topics were consistently broached in the same order, unless a particular exchange intervened to make an issue's immediate exploration more appropriate/convenient. The scope of evidence-gathering was limited by access to the participants; interviews were scheduled to fit as un-disruptively as possible into the participants' schedules and time availability varied. Ultimately, 22 semi-structured interviews lasting from 50 to 90 minutes were conducted.

The transcripts and interviewer notes were coded and analysed for emergent themes, and evidence relating to those themes were grouped together. The resultant dataset can be characterised as follows:

Theme 1 – Mapping the Landscape

- Stated understandings of the existing science setting in Argentina
- Stated understandings of the existing regulatory setting in Argentina

Theme 2 – Social Context

- Perceptions about social costs and benefits of stem cell research
- Knowledge of past or existing public debates and public understanding
- Opinions on hurdles to achieving acceptance of the science and legal regulation

Theme 3 – Regulatory Ambitions

- Opinions on the necessity of government regulation
- Opinions on the appropriate purposes and objectives (content) of regulation
- Opinions on the influence of the global nature of science and the value and limits of the UK model (which was being specifically considered as a potential model)

Theme 4 – Social/Moral Values Held

- Opinions about the appropriate source of moral values for Argentine society
- Values considered to be the most important for this field (and for inclusion within regulation)
- Opinions on how research regulation might address moral concerns and

promote responsible science

The data generated cannot be said to represent 'the Argentine view'. The participant pool was both too narrow and too small for such claims. Further, while the data categories were relatively well defined and developed by the conclusion of the project, and while some categories were experiencing substantial data repetition, no claim is made to data or theoretical saturation; new evidence was still emerging. Nonetheless, and vitally, the GET: Social Values Project captures important and heretofore largely untapped qualitative evidence of the views of key stakeholders from various facets of the stem cell and regenerative medicine field. The quotes used in this paper were chosen as representative of the evidence on the particular issue explored.

RESULTS

Tensions, Contradictions and Antagonists

All nations are as much a product of their past as they are of their present;[10] past incidents, accidents, and actors are as responsible for the present lived reality as the existing cadre of (well-intentioned?) social activists, political actors, and, for present purposes, scientific elites. In the case of Argentina, this past/present interaction has resulted in some strong tensions and contradictions. From a socio-political and economic perspective, its last 100 years have been characterised by generalised decline, intermittent military dictatorship and oppression, subversive and then explicit social activism, and emerging executive (or centralised and presidential) as opposed to participative (more openly democratic) governance.[11,12] From a scientific perspective, Argentina has had a century of historical bioscience excellence and generalised public respect for scientists, accompanied by strong science-sceptic public institutions and intermittent academic persecution and exodus.[13,14]

Unsurprisingly, the Catholic Church has played no small role in this social, political, and scientific evolution.[15-17] While there is a risk of broad-brushing away the diversity of opinions toward science within the Church, it can fairly be said that, on the whole, the Church has been suspicious of, and resistant to, many aspects and aspirations of science, particularly the biosciences. This is reflected by the public narrative adopted by the Church (and other conservative actors) in relation to the biosciences, including reproductive health and rights, and embryo and embryonic stem cell research.[18-20] It is also reflected by the dominant view of respondents in the GET: Social Values Project, many of whom viewed the Church, or at least its formal, public position, as antagonistic toward science generally and stem cell science more specifically.

For example, respondents felt that rigid Church positions and unreflexive religious dogma made it impossible to have reasoned and rational public discourses on any aspect of science that implicates the embryo. Respondent-4, R4, a stem cell researcher, said:

There are still people who are against abortion and they go to the hospital and try to convince very poor people that they shouldn't abort. It is the claim that God and angels will come and will lead them. I don't know. There is still a lot of work to do.

With respect to stem cell research dialogues, R16, a physician, stated:

[In] the scientific community ... we agree this kind of research is important, but there is a problem in Argentina with religion. ... People are confused, confused ideas from church [about] science. ... Of this research we did last year, 50% did not understand what the word cryo-preservation meant, and 40% did not understand what gene therapy meant – they collapse them into cloning and manipulation. ... This is the reason why I consider that, in Argentina, people's perception on science is important but uninformed I am afraid that with stem cells it will be the same.

It is conceded that public understanding of science is patchy around the world, and for a variety of reasons outside of religious dogma or institutions. For example, despite decades of public surveys in the US, a 2004 study found that scientific literacy hovers at 20%.[21] A UK study noted low levels of outright public understanding of science despite a decade of entrenched engagement exercises.[22] However, UK research has also found that these exercises have subtle but important positive outcomes for science citizenship and for the hosting institutions.[23] In any event, respondents in the GET: Social Values Project considered that the position and influence of the Church limited the possibility of adopting any rational regulation in this field. R11, a researcher, observed:

Here the influence of the Catholic Church is really, really important. So in terms of work with embryonic stem cells, I think it is almost impossible [to adopt a law], because the pressure of the Catholic Church is really, really high.

While the power of the Church is indelible, it is not ubiquitous. Certainly the Church is still politically embedded in Argentina [24] and it has been mostly successful with respect to delaying strongly-desired divorce reform (until the late 1980s), [25] shaping education (eg: blocking education reform bills as late as 1997), [26] and waylaying secular abortion policy both domestically and internationally. [24,27,28] However, its success against secular society and rights is not complete. For example, the Church has recently lost its political battle against same-sex marriage in Argentina.[25] And the separation between religious and personally held positions that these battles (and occasional losses) suggest was acknowledged by some respondents. For example, R19, a physician, health administrator, and policy advisor, noted:

I am sure that if we put the issue [of embryonic stem cell research] on the face, it's very probable the Catholic Church would take a position against that. And the Church influences, probably not the population, but the politicians.

By way of contextualising this personal break between support for the Church's official position, on the one hand, and individual values and actions, on the other, R19 told a story about a couple seeking IVF treatment for a 'saviour sibling' to an existing child with leukaemia, a practice which the Church decries and which the public generally defers to the Church:

Well the parents are primary school teachers, very well known people in

the neighbourhood. It's a poor neighbourhood. And everybody put money for the saviour sibling. And they collected, I think 50,000 pesos. And she explained to them what is happening and they not only approved that, but also put money to it. So, this is very interesting because people, in theory, they are saying, 'Oh I am against that', but when they are in the situation, they forget about theory

This evidence highlights one element of the 'hidden battle' relating to the biosciences that is underway in Argentina.[18]

Implications for Science Culture & Methods

In settings where well-entrenched and politically powerful social institutions (such as the Church) are so oppositional, and are perceived as being oppositional (even though they may be generally cherished), two interrelated phenomena become possible, even likely:

1. The prevailing science culture and the individual researchers' place in it become negative and embattled, sometimes untenable.
2. To a lesser extent, the methodological rigour, established and supported through open debate and rational critique within a field becomes weakened so that 'bad science' becomes possible.

These phenomena are more likely to ingrain where there is an absence of governmentally generated space to have open and informed discussions, and public bodies which might offer consistent and effective oversight of the science endeavour, both of which can be (and often are) the 'offspring' of law.

With respect to the first consequence – the science culture – researchers in Argentina are confronted with challenges and concerns that are not necessarily experienced to any comparable degree, or at all, by their colleagues in other jurisdictions, some with whom they may be collaborating. For example, Argentine researchers interested in embryonic stem cell research harbour serious concerns around such basic matters as their 'freedom to research'. They feel that this right may be jeopardised if they perform their work (of which they are rightfully proud) openly, or if they publicise their work, and it incites institutions which may be antagonistic and powerful. This perceived need to conduct science 'behind closed doors' can create something of a 'bunker mentality' accompanied by low-level 'fears' of exposure. R14, a lawyer, stated:

People – the Catholic Church – think ... the pre-embryo is a person. And here there are X number of very, very little persons which are frozen; that nature has been redone. ... This is because people don't have information. Scientists are not sure to announce to the people, the development, the results. If you don't get that kind of answers, like scientific investigations, it will be very difficult to form the conscience, form people's impressions of the necessity of research.

R15, an academic scholar and bioethicist, stated:

There [was] some buzz ... when the Obama position about accepting research with stem cells was brought up by the [Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies], but it's more like isolated voices. I think that behind the scenes, the root of the problem is the position of the Catholic Church. And that's why everybody tries to be cautious about what they say and how to deal with this issue. ... It is like everybody is afraid of the Church And so people that are doing assisted reproduction will save embryos and they will not destroy embryos and they will not accept that they do anything. ... And even the abortions that are accepted by law, they are not performed. ... I think there is really a silence about it. ... The researchers are not saying anything. We have really high quality centres for assisted reproduction, and people come to Argentina to do these treatments because they are cheap and very good. But at the same time, nobody will accept what they are doing. ... [N]obody is willing to go upfront and say, 'Well, we do this because it is important,' and it is difficult continuing to work with embryos.

This position was echoed by a member of the above-noted Commission, who stated that the Commission tried to encourage an open debate on stem cell research in 2007/08, but many of the key actors, including scientists and regulators, were reluctant to do so because of concerns about negative attention.

With respect to the second consequence – methodological rigour – the absence of informed discourse and of public bodies which might offer consistent and effective oversight creates space in which unethical research can, if not thrive, then at least find succour. R5, a stem cell researcher, observed:

I have seen publications on Argentinean groups that were doing clinical trials without the allowance of the ... government in international journals. So the scientific community should be much more strict on asking, for example, for the authorisation to do the clinical trial on which that paper was based. Because if that paper gets published then, for us in Argentina, it is more difficult to tell the patient, 'This clinic is doing something wrong'. Because the clinic then shows the scientific paper saying this clinical trial is validated. So we need to coordinate actions from that front a little bit better.

R6, a public health physician and policy advisor, stated:

You have problems in the academic institutions, [with] investigators, [and] with ethics committees. Ethics committees ... need training, starting with specific knowledge. They don't have it. And they don't have also, government support for this. That is a big problem because you can't approve or refuse something you don't know about. Then you have problems with investigators. I [know an] Argentinean investigator, he knows nothing about the international regulations.

R19 added:

You know that we have some places in Argentina – like St Nicholas in

the province of Buenos Aires – that are using cellular therapies for everything. And that is, they have protocols that ... don't have the approval of the Ministry of Health, and they don't have the approval of INCUCAI [the national tissue transplantation authority]. And they publish papers in the international level, because – I don't know why – because ... in the paper they have the IRBs in their institution. And so they have the informed consent of the patient because the patient is blind. And of course, the journals accept the papers. Probably in the international level there should be some regulation because this is stronger than recommendations. ...

As demonstrated, the irony of the negative or blocking attitude of institutions such as the Church is that, rather than stopping the science, it merely ensures that the science is conducted out of sight, where there is no protection for the morally significant embryo and where abuse can go unseen and unchecked.

From Shadows to Light

A common message from participants was that researchers are not comfortable exposing their research, or announcing their findings publicly. They are concerned about *anticipated* reactions from institutions like the Church, and *potential* reactions from a public (or publics) labouring under misunderstandings of science, which misunderstandings are, at least in part, encouraged by the Church (and others, including the conservative media). They consider that their work and their freedom to research is preserved, even if only precariously, by remaining in the 'shadows'; by simply getting on with their work as best they can and ensuring that they themselves comply with their own moral standards, which are often informed by international instruments and internationally agreed professional guidelines.

However, commendably, many of those who participated in the GET: Social Values Project indicated a desire to step out from the shadows within which they currently shelter; they wish to 'come out into the light', though not into the spotlight. R2, a researcher and regulator, stated:

Scientists who are doing .. things well are tired to listen to the advertising of other colleagues, who are not doing things so well. And they want to put the white over black in order to clarify the situation. And to give a framework for possible activity.

R16 reiterated this, stating that attendees at recent doctors' meetings claimed that they would like to work in stem cell science but they would like to have more contact with other supportive organisations, including international ones. A number of respondents articulated a desire to improve the situation within the field, first by forming more regularised means of coming together to discuss issues, set standards, and network within the field, and then by eventually interacting with the public more directly.

For the most part, the law was seen as a way of encouraging this movement into the light by providing some social/political 'cover'. The law or some other formal policy (stabilised or immortalised in a document) could serve as a state-sanctioned touchstone to which researchers might point, and on which they might rely, when their work (its scope, aims, or methods) is challenged, derided, or condemned by suspicious or antagonistic actors. While respondents acknowledged that regulation should

facilitate science, encourage useful outcomes, and demarcate forbidden pursuits and practices, they also suggested that it might provide them with ‘cover’. R5 captures this:

[T]he law is essential for scientists to do their research. But on the other hand I don’t think scientists should just stay in the dark and wait quietly for a law to be passed. So it is essential that we should be an active part of the discussion. It is essential for many because, one, of course, is legal. You want to do things properly. But on the other hand, it also validates your work to society and to everybody, because then they know we are doing things the right way.

Similarly, R14, a lawyer, suggested that regulation would be useful to reiterate the right to research in controversial fields such as assisted reproduction.

Of course, while most respondents felt that rational, evidence-based, and informed government boundary-setting was essential in the new sci-tech climate, they were not particularly encouraged by past efforts at science legislation in Argentina, which they described as often uninformed and ill-conceived. R20, an ethicist, acknowledged this reality and sympathised with the associated inclination to remain in the shadows so as to preserve the freedom that does exist:

To be honest, I am so sceptical of the possibility of regulating stem cell research that I totally understand why some people would much rather say, let’s not start anything, let’s keep things as they are and we will see what happens.

On the whole, however, despite the weaknesses associated with legal action, many saw the law as having a key role to play in any shift to be realised in Argentina.

DISCUSSION

In addition to the universally experienced burden of public expectation and pressure of funding shortages, Argentine researchers (in the stem cell setting) must contend with the multifaceted problem of suspicious public institutions interacting with pliable social/political actors, poor public education and science debate, vulnerable democratic practices, and fledgling and/or under-resourced science administrative bodies. The evidence generated by the GET: Social Values Project demonstrates that some of Argentina’s (very good) bioscience research is conducted from the ‘shadows’ created by the complex interaction of:

1. human rights and the ‘freedom to research’ (which bolsters them);
2. the desire to secure international partners (which further legitimises them);
3. a strongly sub-optimal socio-political climate, as it relates to stem cell and cellular research (which isolates and marginalises them);[9] and
4. the perceived suspicion and/or antagonism of powerful public actors which further negativises their work (and which restrains and scares them).

The resultant ‘shadow’ is the quiet anonymity that they cultivate and their reluctance

(or, alternatively, their lack of opportunities) to engage beyond their close professional community.

Of course, their silence surrenders the field to those suspicious/antagonistic institutions and the misunderstandings they permit, thereby impoverishing public discussions on science and perpetuating the sub-optimal environment that the researchers deplore. This retreat to the shadows also reduces the scrutiny to which science is exposed, both internally and externally, thereby permitting unethical research to persist (even if only in limited but persistent ways). And this is contrary to the very foundations of science, which include openness and repeatability. It undermines the entire exercise within the country, potentially robbing very sound science of credibility and legitimacy. This is an unethical and untenable situation.

The existing regulatory framework does not address this situation. Indeed, the regulatory framework was almost universally acknowledged as inadequate to meet the many demands placed on it by the modern biosciences. And certainly it was seen as unhelpful in counteracting the perceived power and influence of institutions like the Church, whose effect has been largely negative where (embryonic) stem cell research and regenerative medicine is concerned. This effect of the Church has been facilitated by the weak institutions within and around which the primary protagonists/antagonists interact.

But the law *can* help where it is well conceived and aware of the stakeholders' needs. While science regulation is frequently seen as bureaucratic – a box-ticking exercise which raises transaction costs and hinders actors in the effective and efficient shaping of science trajectories – it can have a much greater and more profound function, particularly in societies which are transforming (and therefore experiencing destabilisation). Many respondents in the GET: Social Values Project saw the value in some regulatory framework which contained a legitimating component. Such a legitimating component might be something as simple as a provision to the following effect:

This research – stem cell and cellular based research – is, in the usual course and where appropriately reviewed and confirmed, ethically defensible, publicly supportable, and internationally competent.

Ultimately, in addition to boundary-setting and capacity-building, the law can (and in Argentina should) reaffirm the right to research. It can and should have a liberating function, bringing people who consider themselves to be good citizens doing important work out of the shadows and into the light. In short, it can and should encourage, facilitate, and protect researchers, simultaneously nudging them to engage with the society they are hoping to help. In doing so, it can serve a trust-building function that will ultimately promote greater transparency, accountability and collegiality, an improved and more democratised working culture, and better science.

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