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Health Research, (Bio)Technology, Regulation & Values: Operationalising Socio-Moral Values in the Legal Setting

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DECLARATION

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I hereby confirm that all of the work in this thesis is my own except where explicitly stated otherwise.

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ABSTRACT

The rapidly evolving biosciences increasingly rely on the analysis, manipulation and reproduction of the human body. In the health setting, novel biotechnologies offer new methods/avenues for the investigation of wellbeing and the treatment of illness, but they do not just expand the clinician's toolbox, they increase the very scope of her work. By offering new (and formerly invisible) measures for health, they have created new categories of ill-health (ie: expanding the ways in which humans can be classified as abnormal, unhealthy, or diseased). In doing so, they contain huge marginalising potential. And they are evolving at a pace that the law cannot match.

Given this, important questions arise such as: What institutions are acting in this field and what is guiding them? How is health-related research being encouraged and regulated? How does the human subject figure in the bioeconomy? What values are we claiming and vindicating under existing regulatory regimes? What values ought we be emphasising bearing in mind social needs and individual rights? The body of work that forms this submission represents five years of socio-legal research and evolving thought on the topic of how values inform the law and are operationalised through the law and legal institutions. While the publications relied on are diverse, they all pursue small facets of this value inquiry.

The first theme addressed – international values and actors – is composed of three papers which explore broad internationally shared values claimed in legal instruments such as the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights, and institutions such as UNESCO and the EPO. A range of values emerge from these. Papers under the second theme – human participation in health research – explore how we access and use the human body in the modern biosociety/bioeconomy, and how we might better encourage subject participation in, and equitable benefit from, the biomedical research setting. Focusing on population biobanking, it assesses who has rights in the body and what those rights are, and how the existing environment interacts with our claimed values. Papers under the third theme – encouraging stem cell research in Argentina – explore governance instruments and their significance for realising claimed or desired values. These papers are informed by original empirical work conducted in Argentina over a 24-month period during which the Argentine government grappled with the realities of the new biosociety and the (perceived) need to facilitate

bioscience research and medical treatment using human tissue. While these papers represent only part of the scholarship deriving from this project, they deploy new evidence on the existing environment and the way forward in that jurisdiction.

As argued in the Critical Review, these publications form a broadly coherent and far-ranging body of interdisciplinary work which persistently questions the link between law and values and how we govern modern bioscience. While there are necessarily descriptive elements, the whole is critically analytical and normatively suggestive. In addition to summarising the aims, objectives, methodology, results and conclusions of these works, and indicating how they form a coherent body of work, the Critical Review goes further. Drawing on evolving thinking and recent scholarship, it argues for a regime less reliant on instruments and more reliant on expert institutions informed by, and charged with protecting, socio-moral values informed by the human rights paradigm.

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Health Research, (Bio)Technology, Regulation & Values: Operationalising Socio-Moral Values in the Legal Setting

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I. INTRODUCTION

This Critical Review is an umbrella paper for a PhD by Research Publication which comprises a body of work (Work) consisting of nine papers written between 2005 and 2010 and representing an evolving socio-legal critique. In each case, the papers were internally reviewed, revised, peer-reviewed, re-revised, and published in reputable academic journals of international standing. Combined, they constitute approximately 55,000 words (81,000 with footnotes). The research that these papers represent relies on both desktop-based critical analysis (case-studies) and fieldwork-based empirical research (qualitative interviews). This Critical Review summarises and integrates the Work, but also deepens the ideas, justifies the undertaking, and further develops the argument, and it proceeds as follows.

Part II addresses the issues of scope (thesis), methodology, and originality. First, it identifies limits in scope and articulates the general thesis. Second, it outlines the methodologies adopted. Third, it makes a claim of original contribution which is born out in the subsequent Parts. In Part III, the nature of the analytical touchstones relied on throughout the Work is explored (ie: what is meant by 'values'?). Parts IV and V go on to tell two stories which are related in that both rest on two primary premises:

♠ Research Fellow, Innogen, ESRC Centre for Social and Economic Research on Innovation in Genomics; Research Fellow in Medical Law & Technologies, SCRIPT, AHRC Centre for Research on Intellectual Property and Technology Law; Member of the Nova Scotia Bar; BA (summa cum laude), Saint Mary's University (1993); LLB (Dean's List), University of New Brunswick (1996); LLM (Distinction), University of Edinburgh (2004). The author would like to acknowledge and thank the kind support of the ESRC to parts of the research forming the underlying Work, as well as the support of SCRIPT and Innogen, and the consistent support, encouragement, and valuable feedback of Professor Graeme Laurie.

1. that values are vitally important to the law (and to regulatory institutions and guiding instruments in the absence of hard law); and

2. that there is an unmet need for evidence as to which values are considered to be important and necessary (because they implicate legitimacy, accountability, expectation, or trust, etc.) by relevant stakeholders in the biomedical research setting, and how they should be defined.

Part IV tells the first story, which is the easier, more obvious story to tell. It is the story of the publications which, together, aim to demonstrate that values are, in fact, deemed important by a range of stakeholders, but that we (as a society) have not yet agreed on how, or when, or which ones should be operationalised, with the result that many often remain rhetorical. This story relies on, and advances, three claims:

1. that important shared values are either explicit or implicit in key international instruments in the bioscience/biomedicine setting;

2. that in specific research settings shaped by existing law, values are sites of conflict, but are underutilised as a means of helping to understand and/or resolve conflict; and

3. that values are less well articulated and operationalised in jurisdictions and bioscience pursuits that are less (regulatorily) developed, but they are considered no less important (so, again, offer an opportunity to pull stakeholders together and advance the law).

In addition to summarising each publication, this Part articulates key positions and conclusions, and shows how the publications organise to form a coherent critical whole.

Part V shifts to the second story, which is not obvious within the Work because it is assumed or indirectly advanced. To some extent, it is the necessary preface to the first story. This story aims to justify the link between law and values while recognising the need for balance between legal certainty and flexibility. In doing so, it relies on, and advances, two claims:

1. that values are fundamentally implicated by, and integrated with, the bioscience/biomedicine context and therefore must strongly inform regulatory institutions and instruments; and

2. that values, like law, are socially constructed and fluid and so must be constantly (systematically) reconsidered and redefined for the regulatory undertaking.

This Part, offers original material in support of ideas that are assumed throughout the Work. In Part VI of the Critical Review, a schema for a new regulatory regime for the evolving biosciences is advanced; one less reliant on legal instruments and more on expert institutions informed by, and charged with protecting, socio-moral values.

II. SCOPE, METHODOLOGY, AND ORIGINALITY

Scope of the Work

While certain theoretical ideas *are* critical to the Work, and theory flows into and out of the research, the Work is neither theory-bound nor theory-driven; it does not expound a new or test an existing legal or philosophical theory, nor does it explore or systematically apply any one theory, and there was no intention toward a strong philosophical angle in any publication. Rather, the Work is concerned with the law in society. Law-in-society studies are all about the law's interactions with individual and institutional actors, with practices, and with parallel systems of rules and norms, including socio-moral values. This Work addresses how the law emerges from the social environment, how far the law is consistent with itself and its stated values, and how the law interacts with its social environment.

The general thesis is that 'values' are vitally important to the optimal working and legitimacy of institutions and instruments which are expected to operate in contested social settings. Any setting where science innovation, healthcare, commerce, and human bodies intersect will be a contested setting. If the value content of an institution or instrument in this 'bio-setting' is unclear, or, if values are clear but they remain un-vindicated, the institution/instrument will be a site of avoidable and de-legitimating contestation and uncertainty, the former which the law seeks to minimise and manage, and the latter which it seeks to avoid altogether.

So the Work is concerned with the 'values' which the law is being asked (sometimes

implicitly) to promote and reify in a given context because those values are, or are felt to be, particularly important to that context (here the bioscience context).[1] The desktop-based critique of institutions, instruments, and/or practices is grounded on formal claims to values and on ideas about which values ought to be advanced given the unfolding social circumstances (ie: it is both analytical and prescriptive). The fieldwork-based exploration of stakeholder views is aimed at discovering the content or nature of values held by specific individuals, and the values felt by them to be important for embodiment in governing instruments (ie: it is both descriptive, or interpretive, and prescriptive). So both approaches contain descriptive and normative elements.

Methodologies of the Work

Such a thesis demands not only analytical work concerning the presence and clarity of values in legal institutions and instruments, but also an assessment of law in society (ie: of how laws are perceived and what desires stakeholders have for laws, from both value and practical perspectives). The Work engages with both, assessing some leading institutions and instruments with respect to the former, and generating new empirical data with respect to the latter. In doing so, the Work adopts the socio-legal approach to examining the law in society. That approach has been described as follows:

> … [T]he aim [is] to understand [law] as a part of society, having a distinct social form and intersecting with other social forms. Its methods are eclectic rather than pure, with sociology and social theory its main sources of ideas and approaches, while anthropology and political science are constantly invoked.[2]

The methodologies of the socio-legal approach include:[3]

1. mapping the social world of law (ie: institutions and instruments) so that its prominent features can be described;

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[1] In doing so it takes notice of arguments claiming that the effectiveness of legal argumentation is tied to its conformity with the values held by those to whom the argument is addressed: J. Ghestin & G. Goubeaux, *Traité de droit civil: introduction générale*, 3rd ed. (France: Librairie Générale de Droit et de Jurisprudence, 1990) at 46.

[2] D. Galligan, *Law in Modern Society* (Oxford: OUP, 2007), at 28.

[3] *Ibid*, at 34-38, drawing on E. Durkheim, *Rules of Sociological Method* (NY: Free Press, 1938), J. Rawls, *A Theory of Justice* (Oxford: OUP, 1972), J. Finnis, *Natural Law and Natural Rights* (Oxford: OUP, 1980), R. Dworkin, *Law's Empire* (Cambridge: Harvard U Press, 1988), and J. Habermas, *Between Facts and Norms* (Cambridge: Polity Press, 1996).

2. examining individual and patterns of responses to this social world (ie: examining the meanings attributed to the features by actors);

3. examining social spheres and how they limit or influence actors' responses to law (ie: recognising that actors are socialised beings who operate within social institutions and according to social mores which influence them); and

4. positioning the law in a moral context so as to uncover its moral and pragmatic foundations (ie: understanding how broader principles and associations are expressed and so how it relates to them).

The Work adopts the first, second, and fourth methodologies, and it is the concerns of the fourth methodology which sit at the heart of the thesis, and on which the empirical research was focused.

The first and second methodologies are exemplified by the desktop research, which draws on legal, ethical, social science, and related literature. Using a case-study approach, the Work either uses values to critique subject-specific legal instruments and institutional decisions, or derives values from such instruments and decisions, simultaneously using those derived values to evaluate the instruments and the practices they permit (or encourage). In short, the values come from the instrument and are used to assess the consistency of the instruments with values deemed important or explicitly claimed. In this way, the socio-legal-moral world is uncovered and described, and conclusions can be drawn about the potential effectiveness and success of the subject instruments and institutions in relation to stated objectives.

The fourth methodology is also addressed by the desktop research but is supplemented by the empirical research, which aims to articulate some values considered relevant to the setting, and to test those articulations against respondents' experiences and conceptions, thereby expanding the catalogue of values considered important. In this way, a greater evidence-base is generated for saying something about law in society and for making policy recommendations in this arena. The empirical contribution derives from an ESRC-funded project designed to gather qualitative data around values and stem cell research

governance in Argentina.[4] While the data generated cannot be said to represent the Argentine view – the subject sample was too narrow and too small for such claims – it captures important qualitative evidence from key stakeholders.[5] Twenty-two semi-structured interviews lasting 50 to 90 minutes were conducted, and, with permission, recorded and transcribed. Open-ended questions and an informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. In some cases, more structured information was obtained through questionnaires. The evidence was coded and analysed for emergent themes, and sections relating to those themes were grouped together.

Original Contribution of the Work

As stated above, the Work is *not* about legal theory (which formulates abstract descriptions of the law as a means of aiding understanding of the law), nor is it concerned with the values of the legal system itself, an example of which might be 'certainty' or 'reproducibility' (ie: it does not engage with the substantial philosophy of law literature on legal values[6]). Rather, it accepts that, in the field of health-related biosciences and biotechnologies, the legal, the social, and the philosophical are intimately interwoven, and the disciplines of law, social science, psychology, anthropology, and analytical and applied ethics are persistently called upon to 'solve' matters of governance, strategy, and conceptions of, and matters of choice in, the life well lived.[7] The proximity of these disciplines, and the arguable convergence of the 'bioethical' and the 'legal', particularly the human rights component of the legal, makes a socio-legal value assessment timely and important.

Bearing the above in mind, the Work queries whether the law is linked, adequately or at all, to core socio-moral values in the health and biomedical setting. It argues that such a

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[4] For more on "Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina", Award No. RES-000-22-2678, see http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/.

[5] Participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities. I interviewed at least one, but often multiple, respondents from each of the following categories: cabinet level politician; national congressional member; national regulatory agency member; national advisory committee member; medical clinician, medical researcher, basic scientist, ethicist, academic lawyer. As the Project was never intended to be a public engagement mechanism, the opinions of the broader public were not solicited. Rather, those originally viewed as most likely to influence the form and content of bioscience and stem cell regulation in Argentina were targeted (ie: Argentine science policy elites), for, it was felt, only by targeting those most engaged in the pre-legislative process could we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they emerge), on the other.

[6] Such as P. Stein & J. Shand, *Legal Values in Western Society* (Edinburgh: UEP, 1974); G. Samuel, *The Foundations of Legal Reasoning* (Amsterdam: MAKLU, 1994); others.

[7] R. Ashcroft, "Could Human Rights Supersede Bioethics?" (2010) 10 Hum Rights L Rev 639-660.

linking is justified, and efforts should be made to ensure that values are sufficiently expressed and operationalised. The tackling of this question and the synthesis of the evidence from the above methodologies, spread over the nine publications and this Critical Review, makes up the 'original contribution', as does the pursuit of a process for exploring values in law and policy formation in Argentina (which process is of wider general significance). In short, the consistent consideration or application of the chosen touchstones – values – and their assessment and deployment using multiple research methodologies, including those resulting in new qualitative evidence from a jurisdiction for which there is very little evidence or scholarly attention, is unique, and the delivery of that evidence to key Argentine policymakers using multiple avenues is also unique.[8]

Of course, all of the above begs an important preliminary question: What is meant by the term 'values'?

III. VALUES: DEFINING THE ANALYTICAL TOUCHSTONES

Values can be understood as having three qualities – vagueness, overlap, and universality – which qualities are explored below in an effort to make clear the nature of the analytical touchstones that are relied on throughout the Work.

Vagueness

The first and foremost quality of values is that they are vague, defying simple or precise definition. The conception of values adopted throughout the Work is captured by the following mutually-enhancing propositions:

- Values are concepts and virtues worthy of esteem in and of themselves because they

[8] As evidenced by reports from Argentina that (1) the GET: Social Values Project was the first socio-legal research undertaken in this area in Argentina; (2) the findings and preliminary conclusions were released to a range of key actors and the general public; (3) the action plan and position of the Advisory Commission on Regenerative Medicine and Cellular Therapies has been informed by our normative conclusions; (4) the interviews and publication of results generated an important stimulus amongst key actors, and helped to better elucidate the importance of social values and social beliefs as part of the background of a law; and (5) there is interest that this project represents one step in the process of generating a normative framework in Argentina, and that further contributions are desired moving forward.

support human flourishing, both individual and collective; they are ideas or ideals about what is good and right, and they are inextricably linked to respect for persons, fulfilment of basic needs, and development of personality.[9]

- Values are an amalgam of high-level or abstract morally-founded ideas or ideals that can be disembodied from the specific, but from which action-guides beyond interests can be distilled, and through which human life and activities can be evaluated; they are the underlying attitudes or expectations which tend to justify the elevation of human life above other life, and promote the wellbeing of, and respect for, persons.

- Values contribute to personal identity in that they are deeply held and so constitutive of the self. When they are shared or commonly understood, they additionally contribute to social identity because they encourage the forming of bonds with others. As such, they partially form (or inform) the overall social environment (in this case the biomedical research and healthcare setting).

Overlap

The second quality is 'overlap', here signifying that values are neither wholly 'moral' nor wholly 'legal', they are rather 'socio-moral' in nature and relevant to the legal enterprise.[10]

According to Kant and many since, 'morality' is comprised of both *a priori* and *a posteriori* cognition.[11] The former is a collection of fundamental propositions of right conduct and are derived from and by reason (ie: they come from within and provide a conceptual framework that enables us to have, to categorise, and to evaluate experience).[12] The latter is the experiential knowledge that arises from living and doing; it is external rather than internal. The whole gives rise to practical philosophy. Associated with morality and the philosophical undertaking are 'morals', which are maxims conforming to the 'ultimate moral norm' (whatever that is and which will likely vary across theories). Morals expound human obligations in very general terms and indicate the quality of a person's character (eg: the

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9 J. Waldron, "Particular Values and Critical Morality" (1989) 77 California Law Rev 561-589; J. Raz, "The Role of Wellbeing" (2004) 18 Philosophical Perspectives 269-294.

10 A feature engaged with in Papers-7-9, and Part V below.

11 E. Kant, *Foundations of the Metaphysics of Morals* (1785); E. Kant, *The Metaphysics of Morals* (1797).

12 R. Sullivan, "Introduction" in M. Gregor (ed.), *The Metaphysics of Morals* (Cambridge: CUP, 1996).

maxim 'do not tell lies' typifies the virtue of 'honesty'); they are rules which enhance character and facilitate appropriate social intercourse. Morality and morals, if put into practice, should make things better for humans, counteracting some of the destructive elements that characterise the human condition (eg: environmental problems, knowledge/capability shortcomings, our own 'limited sympathies' toward others).[13] Of course, the affinity between values and morals should be obvious. Both reflect Raz's definition of a thing that offers (good) reasons for action,[14] and Giddens' definition of ideas held by individuals and groups about what is desirable, proper, and good (or bad).[15] They hearken back to MacCormick's "background moral view" insofar as, rather than being specific and contextual, they are broad and influence people's worldview.[16] And they unquestionably 'trickle down' from the range of moral theories which locate morality diversely in autonomous judgments,[17] a sense of community and community-encouraging practices,[18] a sense of virtue and particular virtues,[19] and so on. But they do not owe their allegiance to any one of these theories.[20]

Similarly, values can be differentiated from the familiar legal concepts of 'principles' and 'rights'. Principles can be understood as standards that are to be observed, not for purposes of securing desirable outcomes, but because it is a requirement of justice or some dimension of morality.[21] Principles are of the same genus as values but they are less elevated conceptually; they are more instrumental than values, which both underlie principles and sit above principles in abstraction.[22] Conversely, 'rights' are of a different magnitude altogether. They are more concrete and instrumental. They can be expressions of values, or vehicles for realising or operationalising values, and in that way the two interact closely, but

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13 G. Warnock, "The Object of Morality" (1993) 2 Cambridge Q Healthcare Ethics 255-258.

14 J. Raz, *The Morality of Freedom* (Oxford: Clarendon Press, 1986), at 397.

15 A. Giddens, *Sociology* (Cambridge: Polity Press, 2006), at Glossary.

16 N. MacCormick, "Jurisprudence and the Constitution" (1983) 36 Current Legal Problems 13-30.

17 E. Kant, *supra*, note 11, as explored in H. Paton, T*he Moral Law: Kant's Groundwork of the Metaphysics of Morals* (London: Hutchinson, 1981); A. Wood, *Kant's Ethical Thought* (Cambridge: CUP, 1999); others.

18 See M. Walzer, *Spheres of Justice* (Oxford: Blackwell, 1983); A. MacIntyre, *Whose Justice? Which Rationality?* (Notre Dame: UND Press, 1988); M. Sandel, *Liberalism and the Limits of Justice*, 2d ed. (Cambridge: CUP, 1998), who draws on Aristotle and Hegel in response to J. Rawls, *supra*, note 3.

19 See A. Anscombe, "Modern Moral Philosophy" (1958) 33 Philosophy 1-19; M. Slote, "Virtue Ethics and Democratic Values" (1993) 14 J Social Philosophy 5-37; R. Hursthouse, *On Virtue Ethics* (Oxford: OUP, 1999); S. Darwall (ed.), *Virtue Ethics* (Oxford: Blackwell, 2003), who draws on Plato, Aristotle, and ancient Chinese philosophy.

20 And the ability of these theories to adequately solve moral conflicts has been questioned on the grounds that they are too contestable: G. Warnock, *supra*, note 13, at 257.

21 R. Dworkin, *Taking Rights Seriously* (Cambridge: Harvard U Press, 1978), at chs. 2 and 4.

22 W. Twining & D. Miers, *How to do Things with Rules: A Primer of Interpretation*, 3d ed. (London: Weidenfeld & Nicolson, 1991), at 56, articulate a 'ladder of abstraction' as a continuum of categorisations from low to high levels of generality.

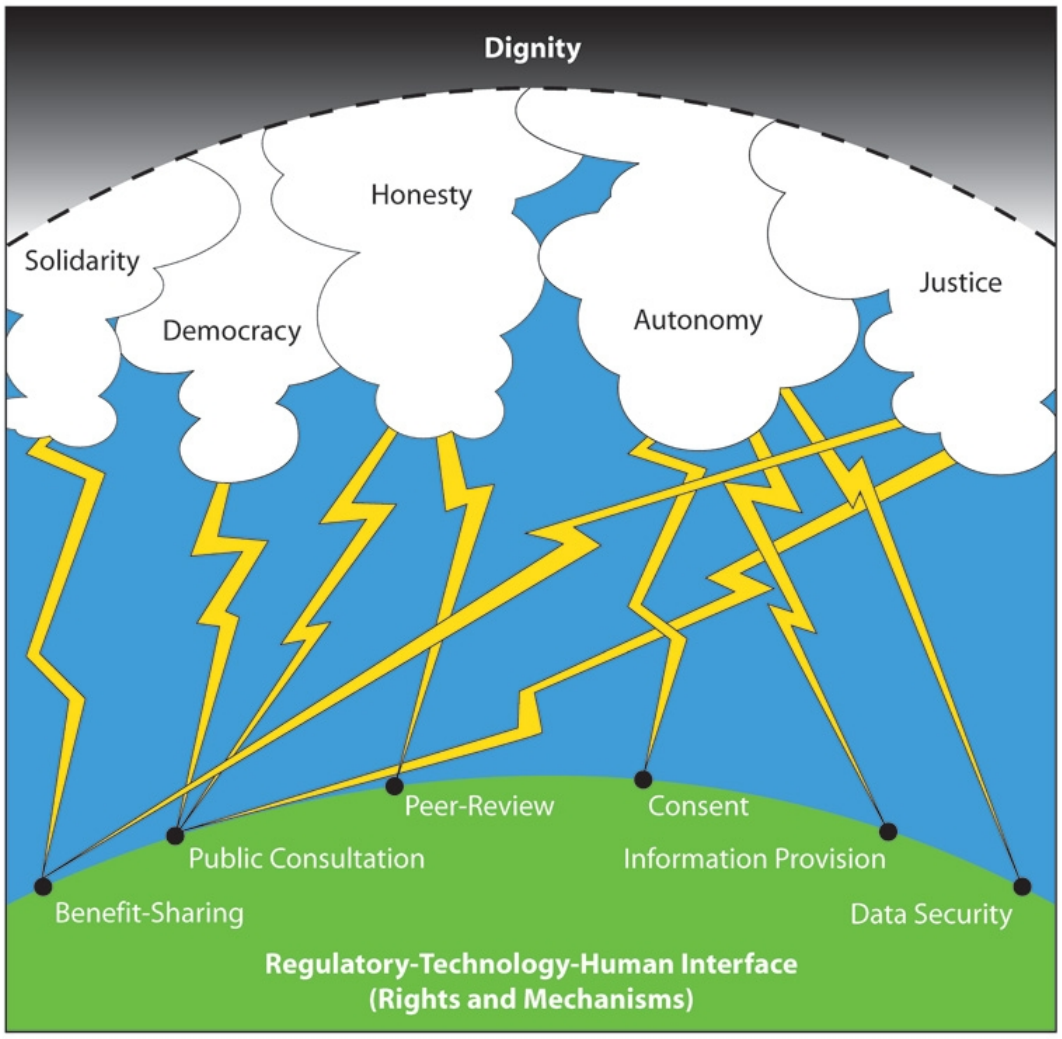
rights are not (usually) themselves values. For example, the legally protected ability of the patient to give or withhold consent in the medical context is a right, a legal mechanism aimed at realising the higher level principle of respect for physical integrity, which we erect as a principle of modern medical law based on our shared notion of the value of human dignity and respect for persons.[23] For an illustrative depiction of the differences between values and these legal concepts, see Figure 1. As can be seen, the differences are perhaps more in scope and abstraction than in character, and, as with morals, the concepts are not mutually exclusive.

FIGURE 1

From Values to Principles to Legal Mechanisms

[23] Workshops have been dedicated primarily to the concept of 'respect for persons': Workshop on Data Sharing in Genomics: Ethical Issues, 20 September 2010, moderated by P. Boddington. In recognition of its interaction with dignity, I define this concept as empowering persons, through basic needs fulfilment and the provision of opportunities, to pursue (if not maximise) their potential to contribute to society in some positive way (ie: a way that advances or enriches society and/or culture and/or the life-chances of others).

Values in the Bioscience Environment



Dignity, as an overarching value and objective, hangs above all else like the upper atmosphere, feeding into the high-level values - solidarity, democracy, honesty, autonomy, justice - which themselves are as clouds filling the sky. These values inform more instrumental (legal) principles and in that way shape legal mechanisms. So, for example, autonomy supports principles like physical integrity, empowerment, and privacy, and therefore support mechanisms like consent, data security procedures, and information provision practices, which operate 'on the ground' at the regulatory-technology-human interface.

Universality

The third quality of values is 'universality'. Although values can be complex, overlapping and opaque, and are therefore often unarticulated or hidden, they are widely held;[24] some level of commitment and adherence to them transcends time, geography, and culture.[25] MacCormick argues that some ideals exist, not just as expressions of animal wellbeing, or as means of satisfying passions, but in and for themselves as matters of standing interest and concern to (all) humans as thinking, communicating, social animals:

> The conclusion … is that there really are objective human goods, of a kind which it is rational for anyone to take as good reasons for decisions, acts, activities and grand projects within some plan of life. Whatever we do, and whenever we wonder what to do, reflection on the presence of such reasons may enable us to come to what seem to us sound decisions about the things we should do or be doing.[26]

By way of example he argues that, given our communal co-existence with others, we have reasons, universally applicable, for seeking and maintaining peace, or at least a diminution of communal strife.[27] MacCormick further notes that all monotheistic religions – which encompass a dramatic quilt-work of cultures – share a range of very basic socio-moral tenets, with many peoples believing that certain values (characteristics and forbearances) are 'written in the hearts' of human beings; he concludes that people are therefore norm-users before they are norm-builders,[28] which conclusion supports the universalist claim. Others have also argued that certain values transcend context insofar as they encompass essential human needs and interests possessed by all peoples equally (and therefore serve as value

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[24] A. Bruce & J. Tait, "Interests, Values and Biotechnological Risk" in K. Andersson (ed.), *Values in Decisions on Risk Proceedings Symposium Proceedings* (Stockholm: VALDOR, 2003) 109-118.

[25] This conception posed methodological challenges, particularly for the fieldwork. On the one hand, it might have fallen down, thereby isolating the empirical work from the rest of the Work from a conceptual point of view. Alternatively, its imposition may have stifled the imagination of participants and skewed the results. Ultimately, it was felt that some prescription was warranted if the value inquiries were to have any power (eg: comparability); participants needed to be given the option of adopting a shared conception. Thus, participants were made aware of this conception of values at the outset, but were free to amend it in keeping with their own ideas and experiences, so the danger of being too prescriptive was offset by giving participants a chance to amend the conception. In the result, participants did confirm and use this conception of values, many implicitly.

[26] N. MacCormick, *Practical Reason in Law and Morality* (Oxford: OUP, 2008), at 36.

[27] *Ibid*, at 53.

[28] *Ibid*, at ch 2. Similarly, Hume and Smith expound on the shared features of human nature, claiming that the natural inclination to sympathise/empathise with others and to feel shame is a means of explaining the nature of morality: D. Hume, *A Treatise of Human Nature* (L. Selby Bigge & P. Nidditch (eds.) (Oxford: Clarendon Press, 1978)), A. Smith, *The Theory of Moral Sentiments* (D. Raphael & A. MacFie (eds.) (Oxford: Clarendon Press, 1976)).

foundations for human rights).[29]

The international political/legal community has taken actions which suggest some broad agreement on certain basic values. For example, the Preambles of the United Nations Charter (1949), the Universal Declaration of Human Rights (1949), the International Covenant on Civil and Political Rights (1966) and the International Covenant on Economic, Social and Cultural Rights (1966) all recognise the inherent 'dignity' of human beings and their 'equality', citing them as the basis for the international human rights regime.[30] The practices of UN bodies, human rights agencies, some states, and civil society organisations are also said to support the universalist claim.[31] Enduring controversies in the human rights arena, which arena is intimately linked to morality and increasingly to bioethics,[32] have revolved around relativist claims that cultural and social/political conditions legitimately influence the interpretation and specification of rights and undermine the universalist claim. Drawing on the value of 'tolerance',[33] relativists reject the legitimacy of external critiques of cultural practices and rights derogations, often on the basis that such critiques represent (1) moral/legal imperialism, or (2) misunderstandings of local values and traditions.[34] However, the following destroys the imperialism claim:

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[29] In the human rights context, it has been argued that rights are founded on: the fulfilment of human potential (A. Gewirth, *Human Rights: Essays on Justification and Application* (Chicago: UCP, 1982)); ideas of social justice (C. Beitz, "Human Rights and Social Justice" in P. Brown & D. MacLean (eds.), *Human Rights and US Foreign Policy* (Massachusetts: Lexington Books, 1979) 45-63); the promotion of human needs (C. Bay, "Self-Respect as a Human Right: Thoughts on the Dialectic of Wants and Needs" (1982) 4 Hum Rights Q 53-75); and the realisation of equal respect and concern (J. Nickel, "Equal Respect and Human Rights" (1982) 4 Hum Rights Q 76-93).

[30] Which has become the dominant international value paradigm, a claim supported by the ratification levels of the International Bill of Rights (which includes the above-noted instruments and further instruments on racial discrimination, torture, and the rights of women and children) and by the penetration of its ideals into the collective psyche. For a discussion of the place of dignity within the Work, see Papers-1, -2, and -8. Paper-5 notes the rise of the human rights paradigm. In this regard, we even see modern ethical assessments cast in human rights language: R. Ashcroft, "The Troubled Relationship Between Bioethics and Human Rights" in M. Freeman (ed.), *Law and Bioethics* (Oxford: OUP, 2008) 31-51.

[31] See D. Donoho, "Relativism Versus Universalism in Human Rights: The Search for Meaningful Standards" (1990-91) 27 Stanford J Int Law 345-391, at 357, and the sources cited at FN 50.

[32] R. Ashcroft, *supra*, note 7.

[33] For a discussion on the relativist use of tolerance, see S. Lukes, *Moral Relativism* (London: Profile Books, 2008), at 35-40.

[34] Most relativist arguments are advanced by repressive political regimes, or traditionally empowered but increasingly challenged stakeholders intent on retaining power and therefore limiting rights. They selectively promote social/cultural practices/traditions which preserve their authority, and they deny the relevance of so-called 'universal' rights and values as anathema to that culture. But politics should not be confused with culture, and culture should be understood as a range of contingent and contested practices and symbols which change in content and meaning over time. See J. Cobbah, "African Values and the Human Rights Debate: An African Perspective" (1987) 9 Hum Rights Q 309-331; A. Renteln, *International Human Rights: Universalism Versus Relativism* (London: Sage, 1990); A-B. Preis, "Human Rights as Cultural Practice: An Anthropological Critique" (1996) 18 Hum Rights Q 286-315; E. Zechenter, "In the Name of Culture: Cultural Relativism and the Abuse of the Individual" (1997) 53 J Anthropological Res 319-347; E. Reichert, "Human Rights: An Examination of Universalism and Cultural Relativism" (2006) 22 J Comp Social Welfare 23-36; others.

> Human rights ideas … arose not from any deep Western cultural roots but from the social, economic, and political transformations of modernity. They thus have relevance wherever those transformations have occurred, irrespective of the pre-existing culture of the place. … [A]s 'modernisation' progressed, an ever widening range of dispossessed groups advanced claims for relief from injustices and disabilities. Such demands took many forms … . Claims of equal and inalienable natural/human rights, however, became increasingly central. … The spread of modern markets and states has globalised the same threats to human dignity initially experienced in Europe. Human rights represent the most effective response yet devised to a wide range of standard threats.[35]

And the following refutes the misunderstanding claim:

> No culture … is 'by nature', or in any given or fixed way either compatible or incompatible with human rights. … Whatever their past practice, nothing in indigenous African, Asian, or American cultures prevents them from endorsing human rights now. Cultures are immensely malleable, as are the political expressions of comprehensive doctrines.[36]

It might also be noted that individuals and governments across regional, national, and supranational borders are increasingly adopting international human rights as modern *expressions* of cultural, ethical, and political values.[37]

All of this means that high-level values (as opposed to sometimes deceptively similar lower level principles or rights) can be, and are, shared across geography, culture, legal jurisdiction, and, to a lesser extent, time. Even those who might be labelled relativists at a rights level concede that significant agreement over high-level concepts exists, thereby justifying claims to 'overlapping consensus universality' at the level of value concepts.[38] And the empirical evidence generated in this Work supports the claim that, at high levels, there is a degree of universality to core values.[39] Of course, being committed to a value

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[35] J. Donnelly, "The Relative Universality of Human Rights" (2007) 29 Hum Rights Q 281-306, at 287.

[36] *Ibid*, at 291. This is supported by S. Lawson, "Democracy and the Problem of Cultural Relativism: Normative Issues for International Politics" (1998) 12 Global Society 251-271; J. Tilley, "Cultural Relativism" (2000) 22 Hum Rights Q 501-549; B. Turner, "The Problem of Cultural Relativism for the Sociology of Human Rights: Weber, Schmitt and Strauss" (2002) 1 J Hum Rights 506-587; and E. Reichert, *Social Work and Human Rights: A Foundation for Policy and Practice* (NY: Columbia U Press, 2003), who cautions that the power to define culture and associated norms falls to those in authority.

[37] D. Bell & H. Chaibong (eds.), *Confucianism for the Modern World* (Cambridge: CUP, 2003); M. Sim, "A Confucian Approach to Human Rights" (2004) 21 History Phil Q 337-356.

[38] See J. Donnelly, *supra*, note 35, who advances a "functional, international legal, and overlapping consensus universality" thesis.

[39] See Papers-8 and -9 and Part V.2 below. For now, note that, in expressing their opinions about values, respondents often drew on international instruments and articulations, particularly scientists involved in

because it is in some way essential to human wellbeing does not mean that there is no scope for legitimate disagreement over its precise definition, its ranking as against other values, or its practical consequences. Even Macklin concurs that universality must not be confused with absolutes (ie: the existence of value universals is not incompatible with culturally-influenced interpretations or mechanisms of operation).[40] This fact demands that we, at a minimum, understand the role of values, their content, and the reasons for preferring some over others, particularly in settings that are morally pregnant.

Conclusions: Properly defined values are useful touchstones which are under-utilised.

As argued below, the current subject – the biomedical research setting – is value-laden and controversial, which means that using values as a lens through which to consider issues is quite appropriate (indeed essential). Values are important to the setting, important to individuals, and important to achieving the healthcare aim of securing, or at least facilitating, human wellbeing and flourishing (ie: a good life well lived). And values are useful touchstones, legitimately preferred over others because they are, at least notionally, more amenable to legislative reification than theory-bound morals,[41] and more stable and enduring and less negotiable and expendable than legal principles. Regulation that complies with legal principles is merely internally consistent, and therefore probably resistant to constitutional or statutory challenge and/or judicial review. Regulation that complies with widely shared and strongly felt socio-moral values is likely to be socially embraced and therefore practically robust. Unsurprisingly, many values exist and might rightly influence bioscience/biomedicine governance. Obvious examples include human dignity, social solidarity, individual autonomy, respect for life, social democracy, and so on. Given this, it is essential that both conceptual and empirical work address themselves to the task of identifying (and enlivening) socio-moral values in the legal context. The policy process is enriched if thoughtful stakeholders give due consideration to the values attendant in policy

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international collaborations and therefore using extra-jurisdictional guidelines. This is in keeping with research which has found that most Chinese stem cell scientists refuse to differentiate between 'their' science and 'Western' science; they see a 'universal' science which must meet common scientific and ethical standards: M. Sleeboom-Faulkner, "Boundary Making and 'Good' Stem Cell Research in Mainland China: Including Bioethics, Excluding Debate" (2010) 4 EASTS J 31-51.

[40] See R. Macklin, *Against Relativism* (Oxford: OUP, 1999), who carried out research in Africa, Asia, and Latin America.

[41] Indeed, Warnock, *supra*, note 13, might differentiate values from morals on the basis that morality and morals, as artefacts of permission, debate and reasoning, ought to work in a non-coercive way, whereas values are open to coercive reinforcement; at least my conception of them and my willingness to embed them in the legal setting makes *me* interpret them as so amenable.

outcomes. One of the contributions of this Work is to persistently pursue this task across a range of subject areas implicated by the health environment.

IV. FIRST STORY: VALUES ARE CLAIMED BUT OFTEN UNREQUITED

This Part describes the publications and demonstrates how they relate to one another. Each publication pursues one or more of the following practical questions:

1. What institutions are acting in the health and biomedical research fields and how?

2. What values are being claimed for these related fields and for the associated legal regimes?

3. How is biomedical research being regulated and how does the human subject figure in assignments of value?

4. What values ought we to emphasise, bearing in mind social needs and economic drivers?

Collectively, they pursue essential facets of an overarching value inquiry, persistently considering how socio-moral values inform the law and are vindicated through the law and legal institutions, and what that means for researchers, physicians, and patients working and living (and dying) at the social/research/healthcare/regulation interface.

Claim 1: Shared values are discernable at the macro level, and are found in both instruments and institutional make-up.

This first claim relies on three publications 'themed' around a critique of specific international actors and instruments. These text analysis-based case studies (often containing prescriptive elements) examine some of the key institutions, instruments and values operating at the international health and bioscience research setting. In the course of doing so, they (1) outline the international health setting, emphasising its shared and global characteristics, (2) expose some of the bioscience practices operative in support of the modern healthcare setting, particularly as it is evolving in the West, and (3) identify some of the key interests

and values exemplified in the most important and prominent international institutions, instruments, and juridical developments.

Paper-1[42] acknowledges the challenges and tensions created by new biomedical developments and the tools they support (the example given is genomics), and argues that the new health setting makes the explicit presence of moral values in governing instruments essential. It then examines the Universal Declaration on the Human Genome and Human Rights (1997) and the Universal Declaration on Bioethics and Human Rights (2005); both are important soft law instruments, both claim that certain 'principles' are important, both claim to give legal/ethical guidance, and both claim to set legal/ethical boundaries. Paper-1 demonstrates how their provisions can be clustered around five dignity-dependent values – (1) individual autonomy; (2) social solidarity; (3) equality of peoples; (4) sanctity of life; and (5) scientific democracy – each of which is defined to the extent possible having reference to the instruments' provisions. Defining the values and understanding how they relate and compete is important because, given the non-binding status of these instruments, these values must be vindicated through other legal instruments. They will be operationalised (if at all) by informing the development of human rights through the UN, UNHRC and UNESCO, the development of public healthcare policy through the WHO, and the development of commercial and trade policy through the WTO and WIPO, the latter arena which looms so large in the shaping of bioscience investigations, technologies, and applications. Revealing the value domain opens the possibility of seeing how that domain is approached, either complimentarily or contrarily, in other regimes essential to the realisation of the aims of these particular instruments (ie: is their approach complimentary or contrary; this is a question which is pursued in the further papers). Unfortunately, neither instrument offers a framework for making sense of their claims (ie: neither marshal them in a coherent way or offer guidance for ranking principles or rights as against one another where they conflict). This diminishes their utility as both moral compasses and legal norm-providers.

In Paper-2,[43] the solidarity value and its concomitant duties are considered in greater detail: the transition from theoretical value, to evaluative rules, to specific directives in the human subject research setting is examined. The many roots of solidarity are acknowledged in the course of arriving at a three-proposition 'definition'. It is then argued that the context in which the value operates (and from which it should be evaluated) is the international one;

[42] S. Harmon, "Ethical Rhetoric: Genomics and the Moral Content of UNESCO's 'Universal' Declarations" (2008) 34(11) J Medical Ethics e24.

[43] S. Harmon, "Solidarity: A (New) Ethic for Global Health Policy" (2006) 14(4) Health Care Analysis 215-236.

for a variety of reasons associated with the modern global era, we must take a very inclusive view of the moral community. This is politically difficult but just. Paper-2 goes on to argue that, if solidarity is to be realised, value-grounded duties must be identified and pursued. Examples include the duty: (1) to research (or generate new knowledge); (2) to capacity-build; (3) to share; (4) to account; and (5) to participate. It then assesses the presence and specificity of these duties in the Helsinki Declaration: Ethical Principles for Medial Research Involving Human Subjects (2000) and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) with a view to inferring the level of support for solidarity to be found therein. It concludes that while they contain solidarity notions, the strongest solidarity-based duties are absent. It ends with a call for global citizenship and an approach to community supported by the solidarity value. The take-away point is that some of the most important international instruments make very little space for the operation of certain values (eg: solidarity), even when they claim some affinity for them, thereby rendering those values rhetorical and under-operationalised.

As foreshadowed in Paper-1, the commercial sector is very important in the health and bioscience research setting – patents are *de facto* tools for promoting and regulating innovation, and patent proceedings, particularly morality-based proceedings, are a forum for stakeholder participation in debates about the boundaries of bioscience – so Paper-3[44] examines the European Patent Office (EPO) and the Biotechnology Patenting Directive 98/44/EC (BPD). Although EPO rulings are not binding on European Patent Convention signatory or EU member courts, they are persuasive to policy-makers and courts. Paper-3 outlines European patent law and the transition that stakeholder engagement has undergone in this setting. It then examines the primary values and moral approaches identifiable in the BPD as a substantive output of a participatory exercise before going on to consider its application in two important EPO decisions. Finally, it queries how the moral base for such decisions might be broadened to give practical effect to some of the rhetoric contained in recent international instruments. In doing so, it revisits the solidarity value, demonstrating how it might operate within the existing model, and thereby serve as an important reformative vehicle.[45] The significance of Paper-3[46] is to demonstrate that, if values

[44] S. Harmon, "From Engagement to Re-Engagement: The Expression of Moral Values in Patenting Proceedings, Present and Future" (2006) 31(5) European Law Rev 642-666.

[45] A value-based assessment of the patent system in China is also undertaken in S. Harmon, "Biotechnology Innovation and Patenting in the Developing World: China – A Giant Among Nations?" (2007) 12 J Intel Prop Rights 72-85.

[46] And of S. Harmon, "International Public Health Law: Not so much WHO as why, and not enough WHO and why not?" (2009) 12(3) Med Health Care & Phil 245-255.

important to the health and bioscience setting are to be realised, a common understanding of them must be articulated and applied across sectors (ie: there needs to be inclusive, joined-up thinking, definitions, and means of vindication).

The joint effect of these publications is to uncover some important values that are claimed internationally (eg: dignity, autonomy, solidarity, justice). By virtue of their appearance and reappearance in multiple core instruments, it might be argued that they are universally accepted and well-entrenched, at least in the abstract. However, some are represented and operationalised far more consistently than others, despite those others being either explicitly or strongly implicitly claimed. While a range of values are claimed and pursued (through mechanisms erected), some of the most important values from a health-for-all perspective (eg: solidarity) are not effectively realised; they find no practical voice in legal rules or mechanisms. As noted in Paper-3, even when there is scope to give a wider range of values 'work' to do, some institutions balk at doing so, and thereby fail to realise any sort of increased joined-upness. One might conclude from this that the international regulatory system applicable to health bioscience is failing; it is not vindicating certain of its claimed values, and therefore not shaping activities as it might otherwise do (and was perhaps intended to do). Importantly, wholesale restructuring is not necessary; as argued, much can be done to ameliorate the conditions of the disadvantaged through adjustments to existing instruments or institutional practices.

Claim 2: In specific bioscience settings, values are sites of conflict but are under-scrutinised as sources of conflict-resolution, so value pluralities fail to enrich regulatory transitions.

The publications under this claim shift from the macro institutions/instruments setting to the more intimate human tissue use setting, which raises some of the most difficult challenges in the new bioscience environment (and comprises one of the fundamental changes alluded to in Papers-1-3, being the introduction of previously unimagined avenues of physical investigation, interference and exploitation). These publications are not about grand institutions and instruments and the values they implicate, but rather about a paradigm in a particular setting: property as a regulatory paradigm and tissue as an artefact of commercial value (Paper-4), of scientific value (Paper-5), and of personal value (Paper-6), and what legal and scientific institutions might do in the face of growing pressures exerted by this context. The combined objectives are to examine how we access and use the human body in the modern bioeconomy, and how we might better encourage subject participation in, and

equitable benefit from, biomedical research.

Paper-4[47] addresses the needs of modern biomedical research and individual rights from the broad market perspective. It acknowledges the growing importance of the body to medical research, the commercial value attached to bodies and their parts, and the consequent attachment of property interests to a growing array of body parts, which phenomenon is accompanied by a continued resistance to propertising the whole body. Similarly, resistance to extending commercial interests and associated property rights to originators of human tissue has also endured. Noting the ubiquity of property claims and the likelihood of successful property claims leading to markets in which originators might participate, Paper-4 assumes the formation of a legal 'tissue trade', offering an ethical foundation for such a trade and identifying the special implications of property law to such markets. In doing so, it considers the position of the common law and the *Human Tissue Act 2004*. Like Paper-1, it recognises the role of dignity in this assessment but also the difficulties of relying on dignity given its multiple interpretations. Thus, it considers a tissue market against four commonly understood principles – autonomy, beneficence, non-maleficence, and justice.[48] It concludes that a property model could further originator autonomy, promote beneficence toward patients, limit originator risk exposure to acceptable risks (supporting non-maleficence), and could be structured to promote justice. In short, a properly regulated market could improve the plight of patients without negatively impacting on originators. After considering the versatility of property as a concept, it highlights some of the practical implications of a tissue market and the ways in which the law would have to respond. It shows that conflict is *not* inevitable and *can* be overcome; a broad view and a value analysis can help us understand what is at stake and how we might better accommodate values (and potentially a wider range of options/rights). It shows that property is not necessarily antithetical to the values discussed.

Paper-5[49] narrows the focus to the biobank setting, reiterating changing research practices which have given rise to the need to specify rights to tissue, to manage those rights (and tissues), and to do so through effective and trust-worthy governance measures. In

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[47] S. Harmon, "A Penny For Your Thoughts, A Pound For Your Flesh: Implications of Recognizing Property in Human Body Parts" (2006) 7(4) Medical Law International 329-354.

[48] Although the term 'principles' is used, the concepts were approached as high-level concepts akin to values. Ultimately, this was an early article and my thinking about the concepts was still developing.

[49] S. Harmon, "Semantic, Pedantic or Paradigm Shift? Recruitment, Retention and Property in Modern Population Biobanking" (2008) 16(1) European J Health Law 27-43. This article follows on from S. Harmon, "The Recommendation on Research on Biological Materials of Human Origin: Another Brick in the Wall" (2006) 13(3) European J Health Law 293-310.

particular, Paper-5 dwells on the development and utility of consent in medical practice and human subject research, and the ways in which the hard-fought-for understanding of consent is stretched by practises central to biobank success. As an alternative to the intellectual and practical struggle over making consent work in this setting, it offers a model which respects the originator, promotes originator trust, and assures the stability of the biobank's resources, while simultaneously preserving our association of medical/research consent with something relational, powerful and directed at a specific matter. This model, which focuses on ethical recruitment and resource retention, is founded in property and grounded on respect for people. It is a preliminary exploration of a regime offering clarity around terms, practices and standards (re: sourcing, counselling, storing, coding and using samples) such that individuals might be assured that what they've agreed to will not be breached or exceeded, and that international collaborations can be pursued safely thereby maximising the benefits this valuable resource offers. It seeks to operationalise values in ways beyond (and better than) the mechanism of consent, which has become a site of confusion and conflict.

In Paper-6[50] the inquiry is narrowed again to a single case in which property in human tissue was claimed by originators, and, for the first time, judicially granted: *Yearworth & Others v. North Bristol NHS Trust*.[51] In *Yearworth*, the Court of Appeal explicitly extended property rights to tissue originators, though on what basis and to what effect is not satisfactorily clear, and the case is heavily criticised for this reason. Paper-6 asks what property is being used for (ie: what work is it meant to do?) and what entitlements are extended and limits imposed on tissue originators. It goes on to suggest that, while the inclusion of originators in the rights community when it comes to human tissue is welcome, a metaphor other than property might have been adopted. In particular, if 'control' was the essence of what the Court wished to protect, then 'dignity' might have founded an equally effective regime and *may* have proved less controversial. Ultimately, the decision is criticised for failing to adequately explore options, which failure was perhaps caused by (1) its failure to engage with the moral debate surrounding the property paradigm in the human tissue setting, and (2) its failure to address more comprehensively the values which must be vindicated in the human life and identity settings (including human dignity, autonomy, and equality).[52]

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[50] S. Harmon, "Yearworth v North Bristol NHS Trust: A Property/Medical Case of Uncertain Significance?" (2010) 13(4) Medicine, Health Care & Philosophy 343-350.

[51] [2009] 2 All ER 986 (CA).

[52] This may seem like a break from Papers-4 and -5 which defend property as a paradigm, but the point is that, in each case, values might have opened up new and possibly more suitable/palatable options.

New biomedical capabilities are creating new challenges and tensions, not least in the research resource collection and retention context. The new cellular research paradigm is shaped by the need for human tissue and related private data, so sourcing that tissue/data and ensuring that it remains accessible in a format that is practically useful is very important, but not so important that the integrity of the tissue originator can be forgotten (or should be unduly eroded). While the emphasis of Claim 1 (Papers-1-3) is the presence of values and associated duties, the emphasis of Claim 2 (Papers-4-6) is on rights contests as tempered by the needs of society for new knowledge and improved healthcare solutions. In exploring this evolving setting, tensions between values are exposed, and it is demonstrated that, while values are both legally and rhetorically acknowledged as important, the full range of values is rarely considered, sometimes as a result of the limited bioethical approaches (or perspectives) through which dialogues are mediated. For example, innovation and healthcare delivery have been 'mediated' through a small collection of approaches (eg: utilitarian,[53] dignitarian,[54] rightist,[55] principlist[56]), each of which is captured in different compartments of the complex regulatory environment. However, these approaches are 'evaluatively narrow'[57]

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[53] The utilitarian approach balances utility and disutility in arriving at its action preferences. If, after balancing preference, convenience, economy, pain and distress, the greater good for the greatest number of people is served by undertaking the action, the action should be pursued: R. Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12 Med Law Rev 14-39.

[54] The dignitarian approach, advocated by a diverse range of religious, communitarian, Kantian, and other stakeholders, is opposed to practices, processes, or products adjudged to compromise human dignity; they are not so much concerned with beneficial outcomes or rights protection: R. Brownsword, "Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'" (2003) 17 Notre Dame J Law, Ethics & Pub Policy 15-51; R. Brownsword, "Stem Cells and Cloning: Where the Regulatory Consensus Fails" (2005) 39 New England L Rev 535-571; R. Brownsword, *Rights, Regulation and Technological Revolution* (Oxford: OUP, 2008); R. Brownsword, "Human Dignity, Ethical Pluralism and the Regulation of Modern Biotechnologies", in T. Murphy (ed.), *New Technologies and Human Rights* (Oxford: Oxford Scholarship Online, 2009) 19-85.

[55] The rightist approach centralises its assessment of actions on human rights, collapsing ethics into human rights, and the ethical exercise into a quasi-legal one. It espouses rights to basic healthcare, family and reproduction, physical and informational privacy, access to information, and equality, giving individual rights priority over science and society, and emphasising the autonomy-based rights of consent and privacy. The core of this approach is contained in a variety of international instruments, including the Nuremberg Code (1947), Declaration of Geneva (1948), Biomedicine Convention (1997), Helsinki Declaration (2000), and UNESCO's Universal Declaration on the Human Genome and Human Rights (1997), International Declaration on Human Genetic Data (2003), and Universal Declaration on Bioethics and Human Rights (2005). This approach counts only the rights of fully formed humans: *Vo v. France* (2005), 40 EHRR 12 (ECHR); *Evans v. UK*, [2006] ECHR 200 (ECHR), wherein a six-month foetus and a human embryo respectively was found to have no standing.

[56] The principlist approach relies on four principles – autonomy, beneficence, non-maleficence, justice – which it describes as 'common morality' insofar they are shared by moral theories and accepted across cultures. Principlists hold the view that all ethical dilemmas can be solved by reference to these principles, though, typically, foremost among them is autonomy: T. Beauchamp & J. Childress, *Principles of Biomedical Ethics*, 5th ed (Oxford: OUP, 2001).

[57] Over-reliant on certain concepts, including individual 'risk', which limits the capacity of the framework to address other concerns. See S. Clarke & E. Simpson, *Anti-Theory in Ethics and Moral Conservatism* (Albany: SUNY Press, 1989).

and 'directively shallow',[58] characteristics which result in part from the restrictive value-preferencing identified above and the obvious 'blind spots' that this causes.

For example, both the dignitarian and rightist approaches adopt as their foundation human dignity and the need to avoid individual instrumentalisation. Dignitarians tend to be dogmatic, 'red-light' stakeholders who, in arguably vague assessments, forbid anything adjudged to be contrary to human dignity (as they define it). Their approach has been criticised as too abstract (ie: there is no agreed formulation of human dignity), and too rigid (ie: they focus on biological life to the detriment of other widely valued phenomena).[59] Rightists, having declared dignity as paramount, frequently devolve into elaborations of the mechanics of how best to ensure taking consent and protecting information; they have exploded certain lower level mechanisms into imperatives for almost all biomedical situations. And while they claim allegiance to other values (eg: solidarity), it is difficult to find them at the operational level.[60] Both rightists and principlists have been accused of being too individualistic; an over-emphasis on personal rights blinds them to other concerns, including public health objectives, which include social wellbeing and the community good.[61] The principlist approach, which considers the propriety of conduct through four principles, contains very little which assists decision-makers in choosing between principles when they conflict.[62] Thus, decision-makers are largely free to decide on any course without the need to be particularly rigorous or critical in their review, and they can find a means to defend their decision by simple reference to it being supported by one or more of the principles.[63]

Ultimately, in specific settings, changes to the legal environment are not necessarily shaped by full and forthright engagements with all relevant values, nor in ways that will be welcomed by various commentators. A better engagement at the level of values (rather than rights or principles or bioethical approaches) may point to ways out of potential conflict which would not otherwise be discovered. So there is fundamental value conflict (or

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[58] Lacking true action-guiding power and leaving decision-makers unencumbered when confronted with ethical dilemmas. See B. Gert et al., *Bioethics: A Systematic Approach* (Oxford: OUP, 2006).

[59] *Ibid*, and S. Harmon, "Of Plants and People: Why Do We Care About Dignity?" (2009) 10 EMBO Reports 946-948.

[60] Papers-2 and -5.

[61] Paper-1 and D. Callahan, "Principlism and Communitarianism" (2003) 29 J Med Ethics 287-291. The insinuation of consent into the practice of secondary research using health data, for example, limits more detailed considerations of how such data might be used, and forecloses potential research possibilities.

[62] M. Selgelid, "Universal Norms and Conflicting Values" (2005) 5 Devel World Bioethics 267-273.

[63] Principlism has been criticised on a number of other grounds as well: D. Callahan, *supra*, note 61; K. Clouser & B. Gert, "A Critique of Principlism" (1990) 15 J Med Phil 219-236; R. Davis, "The Principlism Debate: A Critical Overview" (1995) 20 J Med Phil 85-105; others.

plurality), but the depth of that conflict/plurality is not acknowledged in the law, and no great leadership is offered by the law or its institutions (eg: courts) in resolving that conflict (nor is it offered by prominent bioethical analyses). The result is that the law moves, but two failings are exposed in that movement. First, a rational and informed discussion of the values considered important to this setting is eschewed, which means that decisions are not as rich, or as nuanced, or as rigorously justified, nor as well located within the burgeoning scholarship, as they should be. Second, the narrowness of decision-bases, and the brevity (from a value perspective) of decision-communications, foreclose the exploration of legal (and practice) trajectory alternatives or futures, which means that values that are claimed to be socially important are once again left without concrete mechanisms for vindication.

Claim 3: The chasm between value-needs and value-operationalisation becomes more accentuated as one shifts to the geographic and scientific specific.

The publications under this claim transition further down from the macro and are concerned with values as law and policy-forming/facilitating devices (ie: values in the pre-law setting) within a specific geography (Argentina) and bioscience (regenerative medicine research). Although the role of the nation-state has diminished over the years,[64] it still represents a central legal entity when it comes to both bioscience and biomedicine/health governance and boundary-setting for stakeholder behaviour. Thus, it is essential to consider what is happening within individual jurisdictions, particularly if one wishes to consider the law in society. These papers are informed by original empirical work conducted over a 24-month period during which the Argentine government grappled with the realities of the new bio-society and the (perceived) need to facilitate bioscience research using human tissue (ie: its regulatory efforts in relation to the new research paradigm).[65]

Paper-7[66] begins with an examination of the international debate on the propriety of embryonic stem cell research (and the use of the embryo). It argues that they have turned on assessments of three overlapping questions relating to the (pre)individual – (1) When does human life begin? (2) What is the moral status of the embryo? (3) What is the meaning of personhood? – and on a balancing of our conflicting obligations to the collective (ie: our

64 Noted in Paper-2.

65 They represent only part of the scholarship being derived from this project, so only a partial view of the value landscape found in Argentina. While the empirical component asks, 'What do people ensconced in a different context (culture) make of normative concepts (values)?', the publications under Claim 3 offer only a partial answer. More will be said about that landscape in Part V.2.

66 S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8(2) Devel World Bioethics 138-150.

obligation to take action intended to alleviate the social damage caused by serious injury and debilitating disease, on the one hand, and to avoid the potential social damage caused by the outputs of those actions, on the other). Assessments have resulted in some four divergent positions characterised as prohibitive, restrictive, permissive, and facilitative, each of which is elucidated. Paper-7 concludes that each position is grounded on fundamental moral values aimed at promoting a just and moral society, but, perhaps ironically, they are grounded in a relatively *small* pool of values, which have been interpreted in conflicting ways (a plurality reinforcing Rawls' claim that irresolvable comprehensive conceptions of the good lie within the limits of reason, thereby constraining our capacity for agreement[67]). It then examines the very limited Argentine regulatory effort: the 1997 Decree prohibiting cloning. After reviewing its provisions for protections relating to the individual and the collective, it argues that the regulation is morally incoherent, socially inadequate, and democratically deficient, and therefore generally unsatisfactory, a conclusion born out by the empirical work subsequently conducted. These shortcomings may be partially explained by the narrowness of the instrument's value-based (ie: it was informed almost exclusively by a dignity-as-constraint perspective); further evidence that value plurality combined with reflexivity will yield better regulation.

Paper-8[68] highlights recent activities in Argentina which suggest that science is highly valued both generally and from a developmental perspective. However, despite Argentina's past bioscience successes, its efforts have traditionally sat on the periphery, a status on which Argentine stakeholders generally wish to improve. It considers one element of the means by which bioscience (regenerative medicine research), can be facilitated and enhanced in Argentina, namely the bioscience environment and its constituent parts, and it draws on empirical evidence obtained in the GET: Social Values Project. After modelling a social/science environment within which bioscience might effectively flourish, Paper-8 argues that interested actors must be given action space (ie: physical, temporal and cognitive space) to reflect on, discuss, and influence the structures of the model, so that the best combination of structure strengths, shapes, and roles can be found (ie: communication and action space must exist across the architecture of the model). It then demonstrates how the Argentine environment is sub-optimal, with multiple interrelated blockages stemming from

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[67] J. Rawls, *Political Liberalism* (NY: Columbia U Press, 1993). And see A. van de Putte, "Rawls' Political Liberalism: Foundations and Principles" (1995) 2 Ethical Perspectives 107-129; O. O'Neill, "Political Liberalism and Public Reason: A Critical Notice of John Rawls' Political Liberalism" (1997) 106 Philosophy Rev 411-428.

[68] S. Harmon, "Regulation of Stem Cell and Regenerative Science: Stakeholder Opinions, Plurality and Actor Space in the Argentine Social/Science Setting" (2010) 2(1) Law, Innovation & Tech 95-114.

'actor', 'artefact', and 'node' shortcomings. Focusing on one element of the reformative undertaking – legal reform (or action) within the policy/regulatory artefact – it reports that the evidence supports a claim that government boundary-setting is mostly welcomed, but that disagreements persist as to how to boundary-set. Given this plurality, Paper-8 queries how policymakers might respond. Referencing the UK and Brazilian experiences, it concludes that reform will require courage and the participation of publics, particularly in a democracy where science is part of a nation-building project or national re-imagining. In short, (science) democracy and engagement across sectors is needed, which engagement must extend to values.

Paper-9[69] further explores the democracy value, taking up the issue of plurality and engagement in arguing that, if a sci-tech culture is to be fostered in Argentina (or elsewhere), systemic changes around participation by publics in science debates and boundary-setting must be encouraged. It outlines the development of Argentine science, and the empirical evidence from the GET: Social Values Project about perceptions of the current state. It then argues that advantages might only be realised through the development of a sci-tech culture, which, based on interview responses, does not exist in Argentina, which itself faces a number of unique challenges. Nonetheless, there is substantial support for efforts to develop such a culture through increased and improved public education, public participation, and the formation of more joined-up regulation. The paper concludes with a call for 'compressed social evolution' and some preliminary ideas on how policymakers might begin that evolution. It notes that actions in this regard would do much to foster two values considered important by Argentine stakeholders: 'honesty in science and science governance' and 'public trust in science'.

Papers 7-9 focus on the legal and social/science environment in Argentina and consider how better to achieve a policy objective (eg: enhanced and expanded bioscience research as an element of sustainable development and healthcare improvement) through the improved operationalisation of a particular value (eg: democracy). As with the publications under Claim 2, they demonstrate the difficulty posed by social and moral plurality and therefore the need to erect participative structures so that the nature and extent of that plurality can be explored. At this point, we do not know the extent to which the existing social or policy plurality involves fundamental or intransigent value divergences. What is clear, from a value perspective, is that, though values are less well articulated and realised

[69] 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.

(from a legal or regulatory standpoint) in emerging bioscience/biomedicine fields in less regulatorily developed jurisdictions, they are nonetheless still considered extremely important by stakeholders. The current Argentinean regime permits value avoidance behaviour, or actions which are not at all compliant with values held dear in the research and healthcare context, a reality which was widely lamented.[70]

Conclusions: We claim and name, but often in vain.

The nine publications of the Work demonstrate that:

1. values are specifically recognised or referenced in the law, certainly at the international level (eg: UNESCO's Declarations, Helsinki Declaration, others);

2. supranational law makes space for values to shape decisions (eg: the morality provision in the Biotechnology Patenting Directive), but rarely provides means for follow-through on this; and

3. domestic regulation (eg: the 1997 Decree in Argentina; the *Yearworth* decision in the UK) is grounded squarely on moral judgments, though their value content is not well articulated, and instruments/institutions appear to have trouble engaging with value plurality, especially at sites where such engagement might do the most good from an operationalisation perspective (eg: courts and patent offices)

Ultimately, values are not well defined and not effectively translated into legally enforceable rules, or rather the full range of values claimed are not effectively operationalised by being translated into action-guiding rules. Some values (eg: autonomy) are 'over-represented' insofar as extensive legal mechanisms are erected to ensure their operation, or at least the operation of certain aspects of one interpretation of the value. Others (eg: solidarity) are largely left to 'wither on the vine'; they are claimed and named, but are unrequited or un-vindicated by existing institutions and instruments. The Work highlights the need to engage with values in the early stages of policy formation so as to reduce the scope for avoidance

[70] In the regulatory setting, such behaviour has been described as 'gaming': J. Black, "Principles-Based Regulation: Does it Travel Well?" presented at Wellcome Workshop, "Regulating Health Technologies", 12-13 May 2011, London.

behaviour in legal institutions later on (and gaming behaviour by other actors within the field). Doing so can help policymakers anticipate conflict, and positive deliberations around values can go some way to avoiding more intransigent conflicts later on (or mechanism conflicts the solution of which fails to address deeper causes of tension). All told, the following conclusion is supported: 'Current practices render rhetorical certain values claimed to be important, which suggests that there exists in law an institutionalisation or entrenchment of hypocrisy, a state-of-affairs that legal systems (should) hope to avoid.' One still might query whether this state-of-affairs is truly unacceptable, and, if so, why. This implicates the second story.

V. SECOND STORY: LAW MUST BE EXPLICITLY LINKED TO VALUES AND MUST EFFECTIVELY OPERATIONALISE VALUES

Whereas the first story focuses on how the world is and the ways in which it is deficient (ie: how law-value links are rhetorically claimed but poorly realised), the second story focuses on why the world should be different. This story, which is largely assumed in the first, is about the relationship between law and values, and it explores and defends the position that the law and values are properly conceptually linked, and therefore must be more comprehensively and effectively linked in practice so that cherished values can be better operationalised.

Claim 1: The biomedical arena is fundamentally value-laden and its regulation must rely on values, with which the law has a natural affinity.

Exposing the Value/Law Affinity

A central claim, assumed in many of the Work's publications, is that the law should be linked, preferably explicitly, to socio-moral values in particular settings, of which the biomedical setting is one very important example. Such a claim recalls the objective of morality, which is to facilitate a determination of what is right and wrong in a given situation (ie: to decide and justify what we owe each other in particular circumstances), and it therefore recalls the purposive overlap between morality and law. Of course, the idea that the law, or legal rules, ought to be explicitly morally/ethically grounded is not without

controversy. Thus, the claim that values must inform the law, and be operationalised through the law, demands some justification.

That justification begins with a recognition of the rich vein of legal theory, which, despite its factionalism, generally supports the idea that moral judgments are *often* an important and legitimate element of the law. Early guidance on the interaction between morality and law can be gleaned from Mill, for whom any conduct that involved harm to another was properly amenable to public regulation despite having a clearly moral element.[71] Similarly, despite their disagreement on other matters, Devlin, Hart and Dworkin all agreed that conduct involving an identifiable harm to society is properly a subject for public regulation; in this way morality seeps into the law and moral positions can be subsumed by the law.[72] Given the definition of values adopted in this Work,[73] such positions necessarily encompass the idea that *values* are engaged and are taken up or advanced (or dismissed) by the law, and that this is as it should be.

Further, and again despite their differences, both Hart (a positivist) and Fuller (a naturalist) agreed that the beneficial moral consequences of accepting any particular concept of law *are* relevant in determining which concept we ought to pursue, and that 'evil' (or 'immoral') directives can be legitimately disobeyed even if clothed as 'law'.[74] In their widely considered exchange, one can see that value judgments can be made *about* the law, and, importantly for present purposes, those judgments are properly coloured by the extent to which the law (or a theory of law) has beneficial moral consequences. In short, the best theory of law is one that has beneficial moral consequences (and thus advances cherished values supportive of human flourishing).

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71 J. Mill, *On Liberty* (1859) ch. 1, available at http://www.utilitarianism.com/ol/one.html.

72 H.L.A. Hart, *Law, Liberty and Morality* (Stanford: SUP, 1963); P. Devlin, *The Enforcement of Morals* (NY: OUP, 1968); R. Dworkin, *Life's Dominion* (London: HarperCollins, 1993).

73 Recall that values are defined as: concepts and outcomes worthy of esteem in and of themselves which partially form (or inform) the overall social environment; deeply held, high level morally-founded ideas or ideals about what is good and right and supportive of human flourishing, both individual and social (ie: they are action guides beyond interests), which are widely held; underlying moral attitudes or expectations which tend to justify the elevation of human life above other life, to promote the wellbeing of, and respect for, persons, and to serve as lenses for the evaluation of human life and activities. They contribute to personal and social identity and are complex, overlapping, opaque, and often unarticulated.

74 In "Positivism and the Separation of Law and Morals" (1958) 71 Harv L Rev 593-629, Hart argued that the identification of a directive as a law says nothing about its moral authority, for law and morality are separate entities; a legal directive may be immoral, but this does not make it any less a law; it may, however, justify people being disobedient to that law on the grounds that it is immoral. In "Positivism and Fidelity to Law – A Reply to Professor Hart" (1958) 71 Harv L Rev 630-672, Fuller argued that morality is a condition for legality (ie: some form of morality must be present for a directive to be properly identified as a law), so any directive which fails to be moral is also not legal (ie: is not properly characterised as a law). Fuller's position finds some solace in St. T. Aquinas, *Summa Theologiae* (T. McDermott (ed.) (London: Eyre & Spottiswoode, 1989)), who said, "An unjust law therefore appears to be no longer legal but rather a corruption of law".

MacCormick argued that morality and law are intimate concepts but that law has the added feature of its institutional character (ie: its many and multi-layered decision-making agencies).[75] While the deepest level of the law's normative character comes from morality, its unique institutional features (ie: its legislative acts, its executive actions, its judicial decisions) give it its 'positive' character.[76] In short, its institutional components, while carrying normativity, are enormously important to its positivity, and therefore to its differentiation from morality.[77]

The upshot is that, while law and morality *are* separate entities, it would be a mistake to divorce law from morality. Their close relationship is reiterated by MacCormick, who, in expounding upon legal reasoning, states:

> It is not that moral reasoning is a poor relation of legal reasoning. It is rather, if anything, that legal reasoning is a special, highly institutionalised and formalised type of moral reasoning. Of course, the very features of institutionalisation and formality create important disanalogies between [them] … [but] the disanalogies are greatly exaggerated … .[78]

The fact remains that laws and legal decisions are frequently directed at matters of considerable moral concern, and, in some circumstances, may derive their force (or social legitimacy) from their compliance with, or reflection of, common morality (or justice).[79] Indeed, it has been argued that consistency with a moral value can be a *necessary* condition for elevating a practice or norm to that of 'legal norm'.[80]

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75 N. MacCormick, *Institutions of Law* (Oxford: OUP, 2007).

76 *Ibid*, at 245. The greater accessibility of legal reasoning over moral reasoning, the former which uses analogy, precedent and institutions, is also noted in A. Goldman, "Legal Reasoning as a Model for Moral Reasoning" (1989) 8 Law & Phil 131-149.

77 One might argue that, while still largely valid, MacCormick's distinction is collapsing in the modern biomedical setting insofar as morality, or at least (bio)ethics, has an increasingly institutional character in the form of science advisory commissions, research ethics committees, and project- or technology-specific governance and oversight bodies. In the case of the former, one might note the role adopted by UNESCO (see Paper-1) and in the case of the latter one might note the position and authority of bodies such as the UK Stem Cell Bank or the UK Biobank Ethics & Governance Council (see Paper-6 and S. Harmon, "Control of Reproductive Treatment and Research: From the Moral to the Political to the Legal – and Back Again?" in C. Lyall, J. Smith & T. Papaioannou (eds.), *The Limits of Governance: The Challenge of Policy-Making for the Life Sciences* (Aldershot: Ashgate, 2009) 79-104).

78 N. MacCormick, *Legal Reasoning and Legal Theory* (Oxford: OUP, 1978), at 272-273.

79 N. MacCormick, *supra*, note 75, at 263-264, argues that law is necessarily geared toward some conception of justice, which itself has a supremely moral foundation, and it is through its intimacy with and obvious advancement of this moral touchstone that it may legitimately exercise its coercive power, whether for distributive, retributive, or corrective purposes.

80 See the defence of this proposition and to inclusive legal positivism in M. Kramer, *Where Law and Morality Meet* (Oxford: OUP, 2004), ch. 1.

Propriety of Values in the Health Setting

Admittedly, there is no simple formula for determining which practices that seem morally right (or wrong) should be made the subject of specific legal regulation (ie: which immoral practices should be identified within the legal system as unlawful and carry the possibility of sanctions), but I am not concerned with ossifying discrete moral judgments into specific legal rules. I am rather concerned with identifying those settings where socio-moral values simply must be actively engaged within ongoing or living legal processes, and offering a framework for doing so. I suggest that, in those human undertakings which potentially profoundly affect human integrity, morality is directly implicated and therefore ought to be explicitly engaged. To rephrase, whenever an endeavour poses a particularly high risk of harm to the physical or psychological wellbeing of individuals within society, or to society more broadly, the law should reflect morality, *or rather a corpus of widely shared socio-moral values which are appropriately defined by society*.

The broad human health setting is such that the regulation of its institutional and performative elements (ie: the permissions extended and limitations imposed in relation to health) should, on the whole, reflect socio-moral values. More specifically, I contend that (1) the nature of human health, (2) certain components of the health environment, and (3) the practice of human genomics and regenerative medicine research as an element thereof, all conspire to make this setting an appropriate one for the convergence and explicit cooperation of law and socio-moral values. Each of these three aspects are considered below as justifications for the linkage of values and law.

First, 'human health'. Defined as a general state of wellbeing, as opposed to just an absence of disease, human health matters to both individuals and societies. It has been variously characterised (1) as a 'fundamental freedom', enabling us to define our identity and to do things we value,[81] (2) as having 'special meaning' insofar as we strive to achieve good health in the face of conditions that mitigate against it,[82] and (3) as being a right 'fundamental to the attainment of peace and security'.[83] Regardless of its characterisation, good health is essential for the performance, maximisation, and enjoyment of almost all human activities. Without reasonable levels of health, individuals would be unable to participate in valued social activities such as child-bearing and -rearing, knowledge-

81 A. Sen, *Development as Freedom* (Oxford: OUP, 1999).
82 N. Daniels, *Just Health: A Population View* (Cambridge: CUP, 2008).
83 WHO, Constitution, Preamble.

generation and innovation, labour and wealth-generation, political action, social protection, and cultural manifestation/advancement, with the result that social structures would atrophy and fail, and valuable social pursuits would remain unfulfilled.[84] In short, individual and social functioning and flourishing, which are both moral values and moral objectives, depend in large part on good health. As an underwriter of flourishing, health is thus a morally charged concept and a morally grounded enabler. It is a 'moral good':

> … Health [is] intrinsically and instrumentally valuable … . … If we value individual's capability to be healthy intrinsically and instrumentally, deprivations in health are inequalities … [which] conflict with the view that justice requires public policies to bring "people as close to good functioning as their natural circumstances permit" … .[85]

All told, there is ample justification for claiming the existence of a moral responsibility in relation to health, and therefore a value component to health regulation.

The second aspect of the field which favours explicit value recognition is the 'health environment', which is a special form of social good with a unique organisation and unique deliverables.[86] Within this environment, two phenomena are particularly important to justifying reliance on values.[87] The first is our growing social complexity. Beginning with the individual and moving upward and outward, society is becoming more mobile and diverse, more interconnected in some aspects but more disjointed in others. Social contexts are overlapping and conflicting, and both commercial and legal practices are converging (though not evenly). Widening economic disparities, rapid population growth, the emergence and spread of infectious diseases, escalating environmental degradation, and ubiquitous conflict-spawned dislocation are resulting in individual and social tragedies from which increasingly informed people/victims/sufferers want deliverance.[88] They are looking, in part, to the biosciences and the law for that deliverance, and to *(bio)technologies* for

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84 The link between poor health and social and political instability and failure is supported by evidence: B. Kennedy et al, "The Role of Social Capital in the Russian Mortality Crisis'" (1998) 26 World Development 2029-2043; L. Gostin et al, "Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health" (2008) 96 Georgetown LJ 331-392; others.

85 J. Ruger, "Ethics and Governance of Global Health Inequalities" (2006) 60 J Epidemiology Community Health 998-1003, at 999.

86 It has been argued that the special nature of this environment militates against its organisation and deliverables being governed by market forces: R. Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: CUP, 2004).

87 Discussed in Papers-2, -3, and -9.

88 UNDP, *Human Development Report 1999*, at http://hdr.undp.org/reports/global/1999/en/; WHO, *The World Health Report 2003* (Geneva: WHO Publications, 2003); WHO, *World Health Report 2005* (Geneva: WHO Publications, 2005); D. Gwatkin, "Health Inequalities and the Health of the Poor: What Do We Know? What Can We Do?" (2000) 78 WHO Bull 3-18.

solutions to perplexing healthcare needs and shortages (the latter which continue to limit existing healthcare responses).[89] The second phenomenon is sharpening social plurality. Social dynamism and contingency (of relationships and identities), combined with information availability and other factors, is conspiring to accentuate social plurality (ie: a plurality of ideas, interests, conceptions of appropriate boundaries, etc.). This, in turn, drives ever-growing demands for social participation; individuals and groups want a voice or role to play in the development of (bioscience) policies, as demonstrated by the increasing use of bodies only peripherally related to science regulation as a means of engaging in debates over appropriate boundaries (eg: patent offices). While one might question the extent to which people actually achieve measurable influence over decisions, there can be little doubt that publics do want influence, and their interests and positions vary dramatically.[90]

The third important aspect is the (emerging) practices of human genomics and regenerative medicine research, which are potentially 'intimately harmful',[91] 'personally transformative',[92] and 'socially transformative'.[93] With respect to the former two, these practices analyse, uncover, and reproduce the human body. They *potentially* offer new and powerful methods/avenues for the investigation and redefinition of human wellbeing, and the treatment of human illness and injury. They are *expected* to vastly expand the number and scope of options in the clinician's toolbox, and are largely perceived to be (and are promoted as) 'enablers', enhancing diagnostic and treatment possibilities.[94] But they also demystify,

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89 Discussed in Paper-2 and, to a lesser extent, Paper-8. For a discussion of shortfalls in the transplantation context and the possibilities for reform therein, and the values and mechanisms to achieve same, see S. Harmon, J. Bai & C. Wang, "Organ Transplantation in China and Beyond: Addressing the 'Access Gap'" (2010) 11(1) Med Law Int 191-216.

90 In response to this, successive UK governments have 'gone to the people' with questions relating to the biosciences. The HFEA has held various public consultations, a recent one being on hybrids and chimeras: HFEA, *Policy & Guidance* (2008), available at http://www.hfea.gov.uk/en/1517.html. Consultations have also been held by public bodies such as the RCUK. See also UK Biobank, *Biobank UK: A Question of Trust* (London: UK Biobank, 2002), available at http://www.ukbiobank.ac.uk/docs/consultation.pdf. Note the engagement work of non-regulatory bodies like InnoGen (http://www.genomicsnetwork.ac.uk/innogen/), the BBC/Demos 'Listening Tour' (see http://scienceblogs.com/framing-science/2007/01/uk_launches_new_horizon_public.php), and others.

91 An activity is 'intimately harmful' when it harms the deeply personal self, either the self-in-flesh (ie: personal physical health and therefore the ability to flourish and contribute) or the self-in-being (ie: emotional or psychological wellbeing which are just as important as capabilities). This idea does not capture activities which might harm instrumental artefacts such as property.

92 An activity is 'personally transformative' when it could shift our understanding of humans in relation to themselves or others, or of society in relation to humans (ie: when it challenges existing conceptions of self and personal identities, or how they are formed and confirmed by social institutions).

93 An activity is 'socially transformative' when it could shift our understanding of society in relation to humans (ie: when it challenges existing conceptions of community and how they are formed and confirmed by social institutions).

94 They are perceived to be the most important avenues of future advancements in healthcare. A common observation: "It is becoming clear that genomics, the study of genes and their function, will have a major impact on the way we identify, prevent, diagnose, treat and modulate diseases in the new millennium": H.

manipulate, and appropriate the human body. Many *do not* have a good evidence base or success rate,[95] and many just as often inform us to no curative effect at all.[96] Additionally, by offering new and formerly invisible measures for human health, they are creating new categories of ill-health; they are intimately linked to fundamental issues of definition and personal identity (eg: what it means to be 'normal'; whether individuals fit the changing paradigms of 'healthy' and 'diseased'; when does human life or 'personhood' commence; what applications undermine claims to human membership, etc., each of which have marginalising potential). In this way they encourage *and* waylay physical and psychological flourishing, both intimate interests of the human agent. With respect to 'social transformation', genomics and regenerative medicine are expected to have (and are having) a much more broad and profound impact:

> [I]t is no exaggeration surely to say that we stand at the threshold of a revolution - a revolution in biotechnology, but equally a revolution in the terms of social existence.[97]

In committing (or committing us to) this revolution, the biosciences are both cause and consequence of the 'biomedicalisation' of humanity.[98] As the medicine of the 21st century evolves beyond the structures and boundaries that have been erected to regulate 20th century medicine, this biomedicalisation will redefine fundamental personal/individual relationships and boundaries,[99] and biotechnologies will serve as sites of social 'convergence' and

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Thorsteindottir, "Do Patents Encourage or Inhibit Genomics as a Global Public Good?" in B. Knoppers (ed.), *Populations and Genetics: Legal and Socio-Ethical Perspectives* (Boston: Martinus Nijhoff, 2003) 487-504, at 487. It is suggested that, as our knowledge of genomics increases, medical treatment will move from diagnosis by symptoms to diagnosis by symptoms and mechanisms, and healthcare could be tailored to individual patient groups (whereby subgroups receive particular medicine based on their pharmacogenetics) rather than standardised approaches tried on everyone: A. McCarthy, "Pharmacogenetics: Implications for Drug Development, Patients and Society" in P. Glasner (ed.), *Reconfiguring Nature: Issues and Debates in the New Genetics* (Cardiff: Ashgate, 2004) 83-95.

95 Teratomas caused by injected stem cells have been reported. For more on risk and safety: M. Kiuru et al, "Genetic Control of Wayward Pluripotent Stem Cells and their Progeny After Transplantation" (2009) 4 Cell: Stem Cell 289-300; P. Halban et al, "Current Status of Islet Cell Replacement and Regeneration Therapy" (2009) 95 J Clinical Endocrinology & Metabolism 1034-1043; others.

96 For more on information and privacy, and rights to know and not to know in the new information-rich genetic setting, see G. Laurie, *Genetic Privacy* (Cambridge: CUP, 2002).

97 R. Brownsword et al, "Human Genetics and the Law: Regulating a Revolution" in R. Brownsword et al (eds.), *Law and Human Genetics: Regulating a Revolution* (Oxford: OUP, 1999) 1-5, at 1.

98 A. Clarke et al, "Biomedicalization: Technoscientific Transformations of Health, Illness and US Biomedicine" (2003) 68 Am Sociological Rev 161-194. There are discourses on the 'biomedicalisation' of conditions such as aging, alcoholism, and dementia, and of whole fields such as psychiatry.

99 There are at least four fundamental relationships implicated: (1) Physician/Patient Relationship: This is transforming from one of person-to-person to one of team-to-person and team-to-genetically related kin. Decisions within this, still necessarily personal and intimate, relationship are now group-affecting and more potentially future-influencing. (2) Researcher/Subject Relationship: This is transforming from one of person-to-

'disruption'. They are 'convergent' in that they advance and are distributed through global commercial practices which are internationally standardised, and, as they impact on the enjoyment of rights and health around the world, they shape expectations for rights toward a more uniform understanding. They are 'disruptive' in that they alter our understandings of health and encourage greater demands on, and claims to, healthcare. They also destabilise professional roles and personal human identities. On roles, they offer investigations and actions that will be mastered and deployed by actors not traditionally associated with healthcare, thereby generating new professions and (inter)disciplines, and altering the human and social condition within which healthcare operates. Professional conflicts will emerge as traditional and new groups compete for legitimacy and power. On identities, as pointed out by McLuhan, "we become what we behold".[100] Thus, as novel practices and technologies become more embedded in social practices, including healthcare delivery, they will influence individual and group identities in both subtle and dramatic ways, both challenging and facilitating the realisation of values through a variety of means.[101]

Ultimately, the health environment and its biosciences are shaping the nature of future human existence and interaction. This is a morally pregnant function which deserves, and is particularly amenable to, value considerations. Thus, values should serve as the *starting point* for deliberation and legal action. However, the question remains: What do values bring? First, as medicine and technology moves beyond the alleviation of individual illness toward individual enhancement and the promotion of more profound health-related 'goods', questions about what we mean by 'goods' become more pressing. Values are an important component of assessing that question, and related questions about how far it is appropriate to pursue those goods. Second, and similarly, the possibilities and options for

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person (still relevant in the clinical research and clinical trials setting) to a more complex relationship often involving funders with commercial interests, research teams operating at arms length to (some) of the parties, recruitment and resource-holding intermediaries, a representative of which interacts with the subject, research subjects who may be patients or healthy volunteers, and a range of potential regulatory monitors/overseers. (3) Inner/Outer Self Relationship: This third relationship is that *within* the self (ie: the intimate relationship between the ephemeral consciousness and the physical body in which it resides). (4) Self/Other Relationship: This fourth relationship is diffuse and multi-faceted; it is that *associated to* the self and on which the self may be dependent (ie: the relationship between the intimate physical/cognitive/emotional individual, or self, and similarly or not-so-similarly situated others, and the relationship between that self and the physical world). In other words, the transmogrifying relationship that we and others have to our own and others' bodies and health, and to the future health of humanity.

[100] M. McLuhan, *Understanding Media: The Extensions of Man* (NY: McGraw Hill, 1964), at 23. McLuhan, who coined the term 'global village', said: "[W]e become what we behold; we first make the tools, then the tools make us."

[101] This theory, advanced by McLuhan in the media context, is largely proven: M. Castells, *The Power of Identity: The Information Age – Economy, Society and Culture* (Malden: Blackwell, 1997); M. Stefik, *The Internet Edge: Social, Legal and Technological Challenges for a Networked World* (Mass: MIT Press, 1999); R. Litan, "Law and Policy in the Age of the Internet" (2001) 50 Duke LJ 1045-1085.

engineering the society that we want are growing, but we have little in the way of tools to inform decisions about how and whether to proceed down certain paths or generally. Again, values can serve as a useful nexus for undertaking those challenging and morally charged debates. Discussions grounded in values, or using values as their point of departure, may be more accessible than those grounded in impenetrable, hide-bound moral theories, or in complex, top-down regulatory regimes, thereby giving a wider range of actors a valid voice, and they may therefore also be more fruitful.

Regulatory Track Record v. Regulatory Needs

As demonstrated in Part IV, existing regulatory institutions and instruments are ill-equipped to tackle the above questions, or to even offer responses which adequately acknowledge their relevance, and this at a time when techno-social developments, together with the accelerating pace of scientific innovation,[102] are imposing much greater and novel demands on regulatory frameworks.[103] This novelty stems from the obviously moral and deeply social character of emerging capabilities. Such features impose a need for greater social evidence and greater moral awareness, and demand solutions that have some moral foundation or value-basis, and some fundamentally social interactions. In short, traditional mechanistic and shuttered legal processes, particularly those that originated in response to very different and more limited health and research enterprises, are not appropriate.

Attempts to cope with the new reality have resulted in a dramatic expansion of laws, regulations, and oversight agencies/bodies operating in the related fora of bioscience, biomedicine and biotechnology.[104] Unfortunately, this regulatory 'construction boom' has

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[102] The biosciences are evolving at a pace that is impossible for the law to match, and they are doing so in a collaborative and dynamic manner. The volume of actors, the amount of capital, and the range of interests in the collection of sectors that comprise the biosciences (and biotechnologies) fields are expanding rapidly: see http://www.bio.org/; T. Schrecker, "Benefit-Sharing in the New Genomic Marketplace: Expanding the Ethical Frame of Reference" in B. Knoppers (ed.), *supra*, note 94, 405-421; J. Mertz, "On the Intersection of Privacy, Consent, Commerce and Genetics Research" in B. Knoppers (ed.), *ibid*, 257-268; P. Glasner & H. Rothman, "Introduction: What's New About the 'New Genomics'?" in P. Glasner (ed.), *supra*, note 94, 1-12.

[103] Recognised by A. Cockfield, "Towards a Law and Technology Theory" (2004) 30 Manitoba LJ 383-415.

[104] In the stem cell research setting the *Human Tissue Act 2004*, *Human Tissue (Quality & Safety) Regulations 2007*, *Human Fertility & Embryology Act 2008*, Medicines & Healthcare Products Regulatory Agency guidelines, EU Clinical Trials Directive 2001, EU Tissues & Cells Directive 2004, and others are relevant, as well as guidance from the International Society of Stem Cell Research, the National Research Ethics Service, the Hinxton Group, the UK Stem Cell Bank Steering Committee, Eurostem, and others, and there are still questions about authority at both the derivation and regulation of products stages: L. Bell & S. Devaney, "Gaps and Overlaps: Improving the Current Regulation of Stem Cells in the UK" (2007) 33 J Med Ethics 621-622

largely been reactionary, and has failed to deliver more effective, efficient, or defensible governance. Negative consequences of the prevailing milieu are:

- increased legal complexity and institutional overlap and reproduction, and concomitant rising transaction costs due to the administrative demands of navigating the regulatory environment;[105]

- heightened uncertainty and therefore risk of harm to patients/subjects, the environment, and society, and thus to the health and the scientific undertaking due to persisting gaps;[106] and

- policy gridlock or deference to powerful interests which have perpetuated or made more profound existing health inequalities.[107]

Recent reports reiterate the problem:

> … [T]his domain [the use of health records for genomic research] is affected by 43 relevant pieces of legislation. There were 12 sets of relevant standards and 8 professional codes of conduct. What this has bred is a culture of caution, confusion, uncertainty and inconsistency.[108]

And:

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[105] Note the difficulty regulators have had in coordinating their overlapping remits. In the UK, the DOH, HFEA, HTA and MHRA have negotiated a regulatory route map for stem cells: http://www.keele.ac.uk/research/istm/HTA/Governance/Interim%20UKSC%20routemap.pdf. Additionally, the many and similarly overlapping local or institutional bodies add another layer of complexity, and these bodies are only questionably prepared for their task: M. Hotopf et al, "Are Ethics Committees Reliable?" (1995) 88 J Royal Society Med 31-33; E. Angell et al, "Consistency in Decision Making by Research Ethics Committees: A Controlled Comparison" (2006) 32 J Med Ethics 662-664; L. Williamson et al, "The Regulation of Xenotransplantation in the United Kingdom After UKXIRO: Legal and Ethical Issues" (2007) 34 J Law & Society 441-464; S. Harmon & NK. Kim, "A Tale of Two Standards: Drift and Inertia in Modern Korean Medical Law" (2008) 5 SCRIPTed 267-293.

[106] Note the work of the International Risk Governance Council: http://www.irgc.org/. And see L. Bell & S. Devaney, *supra*, note 104, who note the HTA/MHRA discontent over who has responsibility over SC-based products.

[107] Note the ever-growing disparity between the 'haves' and 'have-nots', and the persistent disequilibrium between health risk and need, on the one hand, and health research funding and health spending, on the other: D. Gwatkin, *supra*, note 88; WHO, *supra*, note 88, S. Benatar, "Distributive Justice and Clinical Trials in the Third World" (2001) 22 Theoretical Med 169-176; Global Forum for Health Research, *10/90 Report on Health Research 2003-2004* (Geneva: GFHR, 2004); D. Resnik, "The Distribution of Biomedical Research Resources and International Justice" (2004) 4 Devel World Bioethics 42-57.

[108] House of Lords Science and Technology Committee, *2nd Report of Session 2008–09: Genomic Medicine* (London: Stationary Office, 2009), at para. 6.15.

> [T]here is evidence that UK health research activities are being seriously undermined by an overly complex regulatory and governance environment. … New regulatory bodies and checks have been introduced with good intentions, but the sum effect is a fragmented process characterised by multiple layers of bureaucracy, uncertainty in the interpretation of individual legislation and guidance, a lack of trust within the system, and duplication and overlap in responsibilities.[109]

In short, there are more instruments and institutions, but no great value-added, and no additional legitimacy, in part because these *ad hoc* responses have failed to appropriately reflect on or incorporate important socio-moral values. Even where specifically 'bio' instruments and institutions have been created,[110] there is a failure to adequately foreground the role and consequence of values. An example of a bio-instrument/institution is the *Human Fertilisation and Embryology Act 2008* and HFEA.[111] They are expected to deal with issues such as surrogacy and homosexual families, reproductive tourism, instrumental reproduction (eg: foetus sex selection and saviour sibling births), reproductive cloning, and virginal, post-menopausal and posthumous pregnancies, and cybrid research, all of which are morally controversial.[112] However, as demonstrated elsewhere,[113] explicit references to values are rarely found in the instrument's text or the institution's deliberations.

We must approach the whole bioscience/biomedicine universe in a much more grounded and holistic way, and in a much more proactive and compassionate way. We must give considered thought to how existing social conditions and new developments and technological convergences (across fields and in unison with more stable factors) engage our deepest concerns and objectives; how they interact with our view of a 'just society', a 'good life', and 'human flourishing'. Only then should we take (careful but now more confident) steps to fashion regulatory responses, which responses should be 'joined-up' across topic areas and fields, and need not necessarily be limited by or to existing mechanisms. If these joined-up regulatory responses are to be rational, effective and morally justified (as they must

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109 Academy of Medical Sciences, *A New Pathway for the Regulation and Governance of Health Research* (London: AMS, 2011), at 2 and 3.

110 'Bio-instruments' are those laws, regulations, and guides which address human health and healthcare and the technologies and/or practices which shape them. 'Bio-institutions' are public bodies, often created through bio-instruments, that are charged with making and/or enforcing rules in the morally charged arena that is human healthcare.

111 At the international level, UNESCO could be considered a 'bio-institution' and its Universal Declarations are 'bio-instruments'.

112 Such was recognised in *R v. HFEA ex parte Blood*, [1997] 2 All ER 687 (CA).

113 S. Harmon & A. Bruce, "Discursive Typologies and Moral Values in Stem Cell Politics, Regulation and Commercialisation: Some Preliminary Observations" (2009) 6(2) J Int Biotech Law 61-66, and (2009) 6(3) J Int Biotech Law 89-98.

be), they must emerge from our stated (and debated) values, and engage our values in real and functional/practical ways, and they ought to be clear about how they are doing so on both accounts. Better equipped 'bio-institutions' will have to be acutely aware of the potentially transformative and therefore deeply moral facets of their task, and be prepared to assess their fields and defend their positions – their decisions with respect to boundaries – from a moral, or at least a 'value', perspective.[114] They must operationalise values, doing so explicitly and rationally.

Claim 2: Values, like law, must be socially constructed and demand a constantly revisited evidence-base.

The Nature of Law and Values

It is widely accepted that both artefacts and ideas or beliefs can be socially constructed (ie: that the understanding, if not the very existence, of 'X' is dependent on contingent aspects of our social selves).[115] It is similarly accepted that the law (or the legal system) is not 'natural', but is rather a human/social construct open to human-initiated changes in understandings, concepts, and institutions, both across geographies and over time.[116] Changes in the nature, scope and foundation of law are not only possible, but have accelerated in the last 100 years:

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[114] Defending a decision from a value perspective falls short of an explicit and consistent philosophical defence, which would be far too onerous and unjustifiable given that no agreement yet exists as to the philosophical foundation of the law; note the ongoing debates between positivists, realists, naturalists, and others, as to the proper theoretical foundation of legal systems, and of what counts as 'fact' or indeed as 'law': R. Dworkin (ed.), *The Philosophy of Law* (Oxford: OUP, 1977). Additionally, while such an approach certainly draws morality and law closer together, it falls well short of the 'sin' of collapsing them together, a sin which would be open to strong criticism, particularly from positivists insistent on the sharp separability of morality and law: see S. Shapiro, "On Hart's Way Out" (1998) 4 Legal Theory 469-507, who might even contest the extent to which I claim the two systems should interact.

[115] For arguments that gender roles are not inevitable but are socially produced, see S. de Beauvoir, *The Second Sex* (NY: Vintage Books, 1989). For arguments that race has no consistent biological basis but is socially determined, see A. Appiah & A. Gutmann, *Color Conscious: The Political Morality of Race* (NJ: Princeton U Press, 1996). For a critique of the expansion of the constructionist approach, see I. Hacking, *The Social Construction of What?* (Cambridge: Harvard U Press, 1999).

[116] A claim made on behalf of social constructionists by F. Schauer, "The Social Construction of the Concept of Law: A Reply to Julie Dickson" (2005) 25 Oxford J Legal Studies 493-501. For more on the contingency of the concept of law, see B. Bix, "Raz on Necessity" (2003) 22 Law & Philosophy 537-559.

> What we have seen over much of the 20th century is change not only in the substance and the institutions of the law, but also in how we imagine just what law is, what it does, and how it relates to other social institutions.[117]

Thus, the law to which we are subject emerges over time through a process of ongoing construction (legislative debate and enactment/entrenchment, judicial and administrative interpretation and reification, and political and legal reform).[118] Even the institutions through which the law is interpreted and enforced are social (ie: constructed and empowered through political processes and interpreted and given meaning and power by society more broadly).

While accepting the above, it is important to understand that the law is not a *common* social construct. Like other social constructs/artefacts/institutions, it is entwined and socially embedded, but unlike others it is distinctive for its relative autonomy, its coercive authority, its complex matrix of powerful actors to support that authority, its instrumental deployment to achieve social goals, and its relatively high level of acceptance by, and penetration into the lives of, most actors:

> … [L]aw is itself a distinct social formation with its own character and features; … in the course of its interaction with other parts of society, law neither collapses into them nor becomes part of them. It retains a social character and distinctiveness not only at the level of theory but in practical social situations, which is to say it is itself a set of social categories with meaning and significance for those involved in legal activities.[119]

Both of these claims – that of social construction and of having a special nature despite this sociality – are applicable to values, or make the value-component of law all the more important to appreciate and understand, and, ultimately, to operationalise.

Recall that values are components of the moral universe which are deeply held, durable, and enduring (ie: ideas and ideals akin to norms), and that have a widely shared meaning, certainly at the abstract level. Recall also that values are understood as 'socio-moral' in that they are found within lived experiences. Some values are so fundamental to human existence that all (right and rational) people understand them, acknowledge them as important, and embrace them in some way. Concepts such as 'human dignity', 'solidarity',

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[117] F. Schauer, *ibid*, at 499, who also notes the sometimes stark transformations of the law, some prompted by WWII and the consequent Nuremburg Trials, some by the Warren Court in the USA, some by the development of information and other socially disruptive technologies, and more.

[118] This social construction is characterised by three core features: performativeness, reflexiveness, and collectiveness: L. Halldenius, "Liberty, Law and Social Construction" (2007) 28 History Political Thought 696-708, who draws extensively on Hobbes' view of the commonwealth in *Leviathan*.

[119] D. Galligan, *supra*, note 2, at 6.

and 'respect for life' are examples of values which are intimately entangled with encouraging human wellbeing/flourishing – a matter which admits of many base commonalities across time, place and circumstance[120] – and which have persisted as core human values for millennia. Of course, their *specific* meaning or the *demands* which they impose on individuals and groups shift over time. Though changes will usually be slow and gradual, and often more evident in their affect on the scope and application of the values and on their relative strength as compared to one another, rather than to the core of their moral content, changes *do* occur.[121] Values are *not* static. They are elastic and evolving.[122] Fluid. Though perhaps languidly so.

Thus, the second claim is that, while values are widely shared, they can be, they should be, and they are 'socially constructed'.[123] It is understanding them in contemporary contexts and then marshalling them appropriately (proportionately) that is important for the legitimacy and robustness of the regulatory undertaking (ie: policymakers and regulators must consider how values might be 'defined' or 'filled up' and must consider how they interact and interoperate). The empirical element of the Work (ie: the evidence derived from the GET: Social Values Project) engages with this demand, taking on board the idea that living morally is a function of (1) insight into ultimate moral rules, (2) the will to do the right thing, and (3) the exercise of moral imagination, and that this imagination relies on metaphors, which metaphors are influenced by new, but increasingly entrenched and powerful, biotechnologies.[124]

In short, bioscience and biotechnologies, which are dynamic and controversial, are exerting pressure on the boundaries of what we consider to be moral, and therefore on the

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120 So reiterated by B. Williams, *Ethics and the Limits of Philosophy* (London: Fontana, 1985), in refuting relativists but staking out a relativist niche for temporal distance in the language of appraisal.

121 An example of the changing positions of values relative to each other is the growing importance of the value of 'productivity' in the modern knowledge and innovation economy/society: S. Slaughter & G Rhoades, "The Social Construction of Copyright Ethics and Values" (2010) 16 Sci Eng Ethics 263-293.

122 Though not nearly as plastic as anthropological 'facts' have been described: P. Feyerabend, *Against Method: Outline of an Anarchistic Theory of Knowledge* (London: NLB, 1975); B. Latour, *Science in Action: How to Follow Scientists and Engineers Through Society* (Cambridge: Harvard U Press, 1985); T. Kuhn, *The Structure of Scientific Revolutions*, 3d ed. (Chicago: UCP, 1996); other adherents and extrapolators.

123 A proposition assumed in Papers-1-6 and sitting at the heart of the GET: Social Values Project, which grounds Papers-7-9.

124 M. Johnson, *Moral Imagination: Implications of Cognitive Science for Ethics* (Chicago: UCP, 1993). For more on the role of technology: J. Keulartz et al, "Ethics in Technological Culture: A Programmatic Proposal for a Pragmatist Approach" (2004) 29 Sci Tech & Human Values 3-29; T. Swierstra et al, "Exploring Techno-Moral Change: The Case of the Obesity Pill" in P. Sollie & M. Düwell (eds.), *Evaluating New Technologies* (Netherlands: Springer, 2009) 119-138. A. Cockfield, *supra*, note 103, states that the world is mediated by complex technologies and that technologies can undermine values and interests.

scope and content of the values which underlie moral positions and social actions.[125] This fact is reflected in the reconsideration of truths and values (in the UK and beyond) that was prompted by the success of *in vitro* fertilisation in 1978.[126] A similar reflection on core values is being prompted by the ubiquity of increasingly invasive information and surveillance technologies.[127] And this fact is supported by the empirical evidence generated by the Work; to the question of whether science moves morality, respondents stated:

> R1: I think, yes, I think that science influences. Because what was moral for the Victorian age is not moral now. Well, science influences everything [and] technology is a sign of science. Whatever we use, each device we use, was born in [science].

> R5: Yes. Actually there has been questions that have [been] raised because of scientific [advances] that nobody had thought about before, because technically it was impossible to think about. Cloning for example. So I think one tension is created by the speed of scientific discoveries and the speed of ethical debates on the new questions that science is making.

> R20: I think that science has been pushing the limits. And has this resulted in people changing their views? Well, yeah, probably people have changed their views on some things – their moral views on some things – because of how some practices became commoner and therefore, were acceptable to the common people.

So values change over time and at the instigation of strong and/or persistent social pressures,[128] which pressures include (or are exerted by) bioscience and associated technologies, a characteristic acknowledged by the respondents who opined that core values for bioscience should come from: (1) interpretations of set fundamental texts such as spiritual writings (but not religious dogma) and the Hippocratic Oath; (2) rational moral theory (including Hegel and Kant); (3) contemporary academic scholarship concerning justice and

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[125] In this regard, it has been argued that 'memes' – cultural items transmitted by repetition and comparable to genes in the biological world – are socio-cultural constructs which are continuously renegotiated, reinterpreted, recommunicated and reconstructed over time, and are influenced by core values which are embedded but similarly translated by user communities: S. Magala, "Social Life of Values: Cross-Cultural Construction of Realities" (2006), Erasmus Research Institute of Management Report, at http://publishing.eur.nl/ir/repub/asset/7645/ERS%202006%20019%20ORG.pdf.

[126] For more on the value-based responses to the first success of IVF in the UK: S. Harmon, *supra*, note 77.

[127] EGC, *Ethical Aspects of ICT Implants in the Human Body*, Opinion No. 20, 16 March 2005, available at http://ec.europa.eu/european_group_ethics/docs/avis20_en.pdf.

[128] The genocides of WWII offered an abrupt shift in, or perhaps a more focused examination of, moral values, with the holocaust becoming a shared descriptor of 'evil' even in societies which did not experience it in any direct manner: J. Alexander, "On the Social Construction of Moral Universals" (2002) 5 Euro J Social Theory 5-85.

risk; (4) international human rights ideas; and (5) individuals and communities in dialogue. Values were seen as concepts which help us to think more deeply about wellbeing and the consequences of our actions and rules on same, and it was felt that this thinking should be done 'out loud' and 'together'.

Evidence on 'Socio-Moral' Values

Given the social nature of values and the view that understandings of them are influenced by new technologies, it is obvious that an evidence-base must be developed; evidence about what values are considered to be important, how they might be described or 'filled up', and how they might be deployed to achieve regulatory outcomes (ie: how they might be operationalised through regulatory or governance mechanisms). Respondents in the GET: Social Values Project engaged with the first two evidential needs, but were not yet comfortable exploring the third, in part because such an inquiry had not previously been explicitly broached. On the first two evidentiary needs, the values claimed as important by respondents and the manner in which they 'filled them up' can be distilled as follows:[129]

- Wellbeing: Everything depends on human health. It is important to protect life, health, and wellbeing, both physical and psychological. Thus, restrictions on the pursuit of improving human wellbeing should be minimal.[130]

- Solidarity: This value focuses on social contacts, interconnectedness, emotional ties to others, and the common good. It reminds us of our obligations to take care of people and help those in a weaker position to have some possibilities and to live with freedom. It makes 'public ethics' important, which means we should measure the value of actions by how well they avoid selfish ends and generate social benefit (ie: are directed at solving society's problems).[131]

- Justice: This embodies equality and equity. It demands the protection of the rights

[129] The first five values (wellbeing, solidarity, justice, democracy, knowledge) were considered to be vital for the functioning of society; they were directed at society and were important to, and imposed duties upon, everyone in society. The next two values (dignity and autonomy) were focused more on individuals and on preserving the integrity of individuals. The final five values (liberty, honesty, rigour, transparency, reciprocity) related to, or were considered to be particularly important for, science and its continued legitimacy and vitality.

[130] Here 'wellbeing' implies that good health is more important than mere biological life.

[131] One respondent referred to Judaism and its admonition to do what is necessary to save others.

and wellbeing of the weak/vulnerable and the just sharing of benefits throughout society (ie: research benefits must be made available and optimised).

- Democracy: This encompassing value has several facets revolving around engagement, participation, contribution, and societal control. It encourages participation in boundary-setting and trajectory-determining (ie: good science needs more than just scientists, who have vested interest, thinking about science). It also embodies open debate and idea-exchange;[132] recognising that no one has the absolute truth – neither science, nor religion, nor philosophy – and that governance efforts must recognise this while at the same time providing limits. Democracy also acknowledges (and values) plurality, which is a reality in Argentine society. Thus, there must be a minimum level of liberty to act independently so long as others are not injured. Finally, democracy encourages accessibility of the governance framework (ie: the regulatory environment should not be too complex or rigid).[133] Valuing democracy means developing a common value-based or ethical language derived from communication so that values, trajectories, and boundaries can be explored.

- Knowledge: Knowledge, intrinsically valuable, needs to be generated within moral bounds, but it is appropriate to push boundaries (and science has done so). As part of this, creativity is very important; innovations in ways of thinking and opening up new pathways for creative thought.

- Dignity: This is a broad and diffuse value which seeps into all others. Generally, it was felt that we must recover the notion of the importance of humanity and of respecting people and frailties and vulnerabilities and potentialities. It requires a balancing of research with other values, always being careful not to instrumentalise people.

- Autonomy: This is based on free will, self-rule, and the creation of space for people to make decisions about themselves and for themselves. People must be allowed to

[132] One respondent stated: "I love discussion and want to open up the ideas of the people."

[133] One respondent suggested the need for something like Asimov's 3 rules of robotics, which were short, pithy, readily comprehensible, and offered a clear ranking which facilitates decision-making.

act in accordance with their feelings and desires. Thus, donors, subjects and patients must receive adequate information so they can weigh options and make informed decisions (to consent to or refuse certain courses), and it imposes on others the responsibility to hold personal information in confidence and to protect the privacy of others. It also grounds the idea that people should retain control of their body and their body parts and products.

- Liberty: A society must recognise some minimum level of freedom to act (and conduct research) in accordance with one's own feelings and values so long as others are not injured; very important in a plural society.[134]

- Honesty: Researchers and physicians must be honest with patients, about patients, and with research data, and they must not promise to do one thing and then do another. Researchers must avoid hyperbole and inflated claims.

- Rigour: Researchers have to take opportunities and push boundaries, but in the understanding that they have responsibilities to society and to good science, and therefore they must rely on, and generate, good evidence (eg: scientific veracity), and they must abide by research and clinical standards. Donors, subjects and patients must not be put at undue risk, and they must not be sold treatments that are not proved (eg: do not abuse patients but rather protect patients and research subjects). This value is closely allied to non-maleficence (do no harm) and beneficence (actively do good), and it encourages us to avoid unnecessary risks, manage acceptable risks, and improve the quality of life of people.[135]

- Transparency: This value imposes on researchers the need to be open about what they are doing and what they hope to achieve. Publics have the right to know what is behind the research (ie: the scope and purpose of research, research risks, benefits and expectations, researcher conflicts, the source and provenance of research resources like tissue, etc.). Research must be transparent, its governance must be transparent,

[134] One respondent stated: "If God made us, He gave us intelligence to research medicine and to improve our situation, and therefore it is important for researchers to have freedom to develop science."

[135] One respondent also referred to the safety of animals and the need to avoid unnecessary use of, and harms to, research animals.

researchers should be called upon to defend and/or explain their work, and they should be expected to record and make public their work. All of this will promote public trust.

- Reciprocity: Researchers must appreciate how the public and individuals contribute to research (particularly in the cellular-based research model) and must ensure that something goes back to them (ie: they must take into account the very important issue of public and population health). This value requires a greater connection to be made between research and clinical use (ie: research actions must have some public or population utility).[136]

Ultimately, these are the values that respondents felt were important at this temporal and technological point in history. While they may exhibit some indeterminacy, they expose many shared ideas and ideals. And importantly, they are not limited in their relevance to Argentina; nothing about the values claimed is particularly Argentina-specific. This suggests that values (or participatory and interdisciplinary value explorations and debates) could be a means for, *inter alia*, encouraging the harmonisation of objectives for, and regulation of, biosciences and medical biotechnologies. Currently, the time and space is rarely made to undertake these (arguably esoteric and non-instrumental) debates, with the result that regulatory efforts become technology-specific (or technique-bound), and quickly devolve into discussions of minutiae and mechanisms.[137]

Conclusions: Law needs values and values are diverse and socially constructed but commonly understood.

Whereas the first story considered how well the law operates from the perspective of reflecting values that stakeholders feel are important, and offered evidence that, at the

136 One respondent argued that Argentina cannot compete economically with other countries so it needs to use funds wisely to develop experience and translate research into clinical uses. Another respondent stipulated that researchers in the reproductive field have a responsibility under this value to ensure the birth of a healthy baby that is not compromised. This may not be an uncontroversial claim.

137 Many policy meetings in the bioscience setting begin and end with examinations of how new techniques and technologies interact with existing instruments, and how existing mechanisms might work or fail to work optimally. One notable exception is the recent workshop, intended to be one of several, hosted by the Nuffield Council and aimed at exploring the solidarity value, its meaning and implications: Nuffield Council on Bioethics, "Solidarity Workshop", 13 May 2011, London. As presumed by this meeting, a broader, value-based opening dialogue might expose greater and more imaginative regulatory possibilities.

instrument and institutional levels, some values are strongly claimed but poorly operationalised, this second story is concerned with the connection – or with exposing the connection – between law and socio-moral values, and with emphasising that this law/value relationship is increasingly important as our technological capabilities position us to alter fundamentally not only human wellbeing but what it means to be human at all.[138] It is equally concerned with the claim that values are properly socially constructed, and it exposes how different actors (in this case, a sample of interested Argentine stakeholders) understand socio-moral values. It offers evidence that, at the personal level, the range of shared values considered to be important to the bioscience/biomedical setting is wider than that typically acknowledged in international instruments (which, in addition to dignity and, notionally, solidarity, reflects a principlist approach to ethical dilemmas). The value conceptions espoused were rich, diverse and cumulative (ie: repeated by subsequent participants), and although local conditions sometimes prompted the advancement of certain values, none of the values articulated were jurisdiction- or culture-tied. Such evidence is important as we strive to construct a reality in which individuals and institutions are better equipped to make good and socially acceptable judgments which improve human flourishing.

VI. OPERATIONALISING VALUES THROUGH INSTITUTIONS AND PROCESSES

Having exposed shortcomings (and hypocrisies) in the existing governance matrix, and argued for an approach which explicitly considers and better operationalises our shared values, the next step is to suggest a way forward which better reflects our claimed values and social, ethical, and legal objectives. This Part *begins* that task. The premise is simple:

> Every regulatory system results in some person or body taking a decision, which will, in many cases, be as blunt as, 'Yes, we will do/permit X', and 'No, we will not do/permit Y'. Whether the process is paternalistic, democratic, consensus-based, or otherwise, this feature endures; it is the natural consequence of boundary-setting and the natural object of the law. The objective must be for that decision to be imminently defensible; acceptable on some level even by

[138] It is not concerned with the more dogmatic elements of moral or legal theory, nor is it concerned with the law/morality debate (ie: it makes no claim that fully formed judgments about what is right should be enacted in law).

> rational actors who disagree with it.[139] A fixation on rights, rules, and principles often hampers us from contemplating the bigger picture and from fashioning decisions which have this feature. A broader, more careful, and early examination of values may offer ways out of this cul-de-sac by expanding the conceptual space within which regulatory bodies work, and thus expanding the governance tools which might be fashioned and the opportunities which might be supported by these bodies.[140] This front-end-loading of value discussions can turn the difficulty of plurality on its head, transforming plurality from regulatory problem to regulatory opportunity.

While much more evidence is needed than this Work contains, this Part offers a preliminary vision of the structure of such a reflexive system, considering instruments, institutions, and processes.

Operationalisation Issue 1: Value Instruments

As demonstrated, there are values with which the law does not consistently engage, or to which regulatory regimes appear to be mostly blind. Solidarity is one example.[141] Science democracy is another example, at least in the Argentine setting.[142] One might argue that the existing value-emphasis is the natural result of legitimate value-preferencing within democratic processes. One might further claim that, although value-narrowness may define the legal/regulatory setting, it is a narrowness which, through its preferencing of autonomy and the extension of individual choice, permits plurality. In short, plurality at the 'top' is not necessary so long as it permits plurality at the 'bottom' (ie: an emphasis on dignity, autonomy and tolerance within our core instruments allows a panoply of values to thrive and operate at the individual action level).

Without wishing to dismiss bottom-based individual choice, which is important in

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139 As a member of society confronted with a decision on a medical intervention or research trajectory with which I disagree, I want to be satisfied (through the process for, and documents that support, the decision) that the decision reflects a consideration of the full gambit of relevant social values, including the ones I hold. I want to understand how that decision is supported by, and supports, a range of cherished values. I want to understand how those values that are less realised figured into the deliberation. I want to be assuaged that they were not completely dismissed out-of-hand.

140 Early, explicit, more inclusive value-based approaches to possibilities and problems may result in a re-weighing of what we deem important; things we currently emphasise might seem less significant.

141 Papers-1 and -2.

142 Papers-8 and -9.

liberal democracies (and to liberty generally), I would suggest that legislative/regulatory value-narrowness is still undesirable. A failure to adequately reflect the mosaic of shared values that societies (stakeholders) consider to be important is a systemic failure which will result, as demonstrated, in a failure to proportionately operationalise them, or, if this is not possible, to empower (much less encourage) actors to operationalise them through actions and decisions on the ground. This value inequality leads to 'distortion': the over-emphasis of some issues or risks and under-emphasis of others, and the over-reliance on certain mechanisms and under-reliance on others. Examples of this, as demonstrated in the Work, are the over-emphasis on issues of choice in treatment at the local level at the expense of equity in treatment more broadly, the emphasis on individual discomfort or inconvenience over public health needs, and the elevation of so-called informed consent as the panacea to all health research actions and health interventions. This distortion forecloses regulatory imaginaries and social futures.

The existence of certain trajectories – bioscience complexity and convergence, growing social plurality and dislocation, and the emergence of the law as a primary source of social shaping and integration[143] – means that, if left unchecked, this distortion will become more damaging to the bioscience undertaking and to the network-produced social fabric. Indeed, the third trajectory alone makes it increasingly pressing to reflect, at the level of instruments, the value plurality discovered in the Work, and to allow that plurality to inform governance actions. If regulatory instruments are intended to facilitate socially useful and acceptable choices as between values, courses, and outcomes, and to facilitate stakeholders in doing same – and they most certainly are – then they must be expressed in a value-cognizant and pluralist manner.

How might this be done?

One *might* operationalise values by articulating a more inclusive 'menu' of values and legally enshrining all of the rights they underwrite. While this might solve the issue of gross legislative over-representation of some values at the expense of others (and only then if a means of choosing between conflicting rights is created which ensures that some rights do not consistently trump others), it would create other problems, most importantly the devolution of values into rules and mechanisms frozen in time and place. Rules, legal mainstays because of their clarity and amenability to consistency and therefore certainty,

[143] The claim of the shaping and cohering nature of law is made by J. Habermas, *Between Facts and Norms* (Boston: MIT Press, 1996) and accepted in Paper-1. The human rights paradigm (and laws) are emerging as the dominant discursive paradigm: R Ashcroft, *supra*, note 7; A. Plomer, *The Law and Ethics of Medical Research: International Bioethics and Human Rights* (London: Cavendish, 2005).

typically involve an advance determination of permissible conduct, leaving only factual issues to be determined by decision-makers. But in the quicksilver and often controversial bioscience setting, this is not the best way to proceed (as demonstrated by the difficulty caused by the legal entrenchment of a particular scientific method for cloning, which method was quickly outdated).[144]

A *better* value-approach would be to enact a broad bioscience research law that specifically identifies and defines an inclusive (pluralistic) list of high-level socio-moral and scientific values, and which stipulates that they must be considered when actors (regulators, RECs, PIs, doctors, etc.) take actions. Such an instrument – the *Health and Bioscience Research Act*? – would, of course, necessarily set some clear boundaries and erect certain rules/mechanisms to be complied with (when circumstances warrant). However, by focusing on values, the instrument's emphasis would be a concern for (1) personal virtues, (2) the quality of decisions being made, and (3) the achievement of legislative/regulatory goals. It would be purposive, aimed at setting behavioural standards (rather than box-ticking) and ensuring the provision of (good) reasons for rules enforced and outcomes pursued. Such an instrument would allow regulators to evaluate actions and to make assessments (and level sanctions) even where rule-based gaps exist, so no bioscience action could be claimed to be outwith the regulatory framework. By capturing all stages of the bioscience enterprise (eg: material sourcing and derivation, storage, usage and sharing, product-development, in-human testing, treatment/product roll-out), it would serve as a one-stop instrument, allowing a wide range of instruments to be 'removed from the books'.

Importantly, this approach is not without precedent.

The 'principles-based' approach to regulation – applied to varying degrees in the corporate, accounting, and securities governance arenas, and exemplified by the approach adopted by the UK Financial Services Authority – is an outcome-oriented regime which identifies key principles and relies on both principles and rules and ongoing regulator-stakeholder communication.[145] It has been argued that a system which relies less on rules and more on higher, abstract directives, outcomes, and dialogue can be 'better' in that it is

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144 For more on the difficulties of definitions in science: H. Greely, "Banning 'Human Cloning': A Study in the Difficulties of Defining Science" (1998) 8 S Cal Interdisc LJ 131-152. For more on the shortcomings of rules: J. Black et al, "Making a Success of Principles-Based Regulation" (May 2007) Law & Fin Markets Rev 191-206.

145 M. Hopper & J. Stainsby, "Principles-Based Regulation: Better Regulation?" (2006) 7 J Int Bus L Rev 387-391; A. Anand, "Rules v. Principles as Approaches to Financial Market Regulation" (2009) 49 Harv Int LJ Online 111-115; L. Cunningham, "A Prescription to Retire the Rhetoric of 'Principles-Based Systems' in Corporate Law, Securities Regulation and Accounting" (2007) 60 Van L Rev 1411-1493, who emphases that principles and rules lie on a continuum and may both appear in a regulatory system.

more likely to (1) achieve statutory outcomes, (2) reduce cost, (3) stimulate innovation (substantive and regulatory), and (4) prove durable.[146] A system in which standards and boundaries are set by participants is particularly amenable in the bioscience setting where key actors (researchers and doctors) are already bound by ethical rules and the primary undertaking (science) is already shaped by ethical concerns.

Such a value-based instrument would obviate the need for a plethora of rules anticipating every possible situation, technology, or technique. Any uncertainty created would be alleviated by greater communication between regulators and regulatees, and by the joint formation of interpretations of values, regulatory objectives, and mechanisms to operationalise them, with some tolerances for different practices to emerge in novel settings. Indeed its success would depend on such communication, a feature it shares in common with principles-based regulation,[147] and which is further addressed below.

Operationalisation Issue 2: Value-Grounded Institutions

The key to the success of a value-based approach is attention to how values are interpreted and implemented, or operationalised. In this regard, strong institutions are necessary. But what are the institutions and how might they be structured?

Obviously, there are the courts, which would remain unchanged structurally but would be encouraged to think more deeply about values and outcomes and social futures by virtue of the instrument envisioned above. Nothing more will be said about them.

Additionally, and critically, a single regulatory body concerned with governance of bioscience research – from material sourcing and derivation, to storage, to usage and sharing, to product-development, to in-human testing, to treatment/product roll-out – is also warranted. While agency rationalisation has previously been considered and rejected in the UK,[148] it is now more widely recognised that the time has come for reform.[149] Recent

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146 C. Ford, "New Governance, Compliance, and Principles-Based Securities Regulation" (2008) 45 Am Bus LJ 1-60; J. Black, "Forms and Paradoxes of Principles-Based Regulation" (2008) 3 Cap Markets LJ 425-457.

147 J. Black et al, *supra*, note 144, at 197 and 204.

148 In 2004, the government recommended the merger of the HFEA and the HTA into the Regulatory Authority for Fertility and Tissue: Department of Health, *Reconfiguring the Department of Health's Arm's Length Bodies* (London: Queen's Printer, 2004). In 2007, the government tabled a Bill that would have merged the same bodies into the Regulatory Authority for Tissue and Embryology: M. Pembrey, "Reproducing Regulation: Issues Arising from the Human Tissue and Embryos (Draft) Bill" (2007) 423 BioNews, available at http://www.bionews.org.uk/page_37950.asp.

recommendations include cutting the number of health agencies by 50% and transferring cellular-based research oversight to either the Care Quality Commission, the Health and Social Care Information Centre, or a new agency (potentially named the Health Research Agency).[150] A new amalgamating instrument like that envisioned above would warrant a new regulator (eg: the Health Research Agency, or Bioscience Research Authority, or Cellular and Regenerative Medicine Research Authority) which would have strong expertise in the full range of activities and issues that arise in the bioscience (cellular and regenerative medicine) research field.

Importantly, the regulator created by, and tasked with implementing, the open and value-based instrument would have to refrain from adopting an overly laissez-faire approach.[151] It would have to set goals, enforce rules where they exist, continually refine values in cooperation with stakeholders, and consistently liaise with regulatees, even if technical standards and specific boundary rules might be left to professional bodies to which key actors (and publics) are more intimately associated. In short, it should and would have to emerge as an authoritative institution for stakeholders.

As indicated, a fundamental responsibility of this institution would be to actively and overtly *reflect on* the existing value-plurality as an integral part of the regulatory decision-making enterprise, and to therefore offer (1) more clarity and greater nuance around key concepts such as 'goods', 'harms', and 'public good', and (2) better reasons for option-preferences (ie: acknowledging value plurality and unambiguously justifying the choices it makes re value operationalisation, and pushing other decision-makers to do the same, something that has not been done particularly well to date).[152] This fuller airing of values and fuller exposition of possibilities can be expected to result in disagreement on how to rank and operationalise values,[153] but a suitably supported institution would surely be capable of managing that task, and building cooperation around value-commonalities is a good start.

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149 L. Bell & S. Devaney, *supra*, note 104; Academy of Medical Sciences, *supra*, note 108; J. Travis, "Report: Complex and Burdensome Rules Thwart UK Medical Research", 10 January 2011, *ScienceInsider*, available at http://news.sciencemag.org/scienceinsider/2011/01/report-complex-and-burdensome.html.

150 J. Travis, *ibid*; D. Cressey, "UK Embryo Agency Faces the Axe" (2010) 466 Nature 674; P. Montgomerie, "Regulators – What Will Happen Next?" (2010), available at http://www.sscn.co.uk/PublicAccess/AboutUs/Sectors/RegulatoryLandscape/tabid/167/Default.aspx.

151 C. Ford, "Principles-Based Securities Regulation in the Wake of the Global Financial Crisis" (2010) 55 McGill LJ 1-50.

152 As shown in Paper-6 and in S. Harmon & A. Bruce, *supra*, note 113.

153 I am not offering a recipe for avoiding disputes or arriving at 'correct' answers. The broader view espoused, while opening the possibility for wider agreement on core issues (and potentially better and more productive and creative relationships), would likely result in greater disagreement at the operational level in part because of the greater variety of options supported. Disagreement will never be avoided, but arbitrariness might be reduced and stalemates broken.

Success would depend on the regulator:[154]

- having a clear vision of its multi-faceted role as partner, trend-setter, overseer, sanctioner, and protector of the public good/interest;

- being sufficiently staffed and trained so it has the capacity and institutional judgment/philosophy to meet the needs of the field;

- being sufficiently supported by information management systems/technologies and the expertise and experience to assess relevant key data;[155]

- having multiple sources of information (so it is not reliant on industry) and the ability to audit, inspect, investigate, and sanction where appropriate;

- forging close and productive relationships with stakeholders so that a functioning interpretive community emerges that is comfortable discussing and defining (changing) values and shaping actions and outcomes;

- cultivating confidence in its own judgment and a healthy distrust of other interested stakeholders so that transparency is encouraged and public trust maintained;[156] and

- relying on clear and transparent processes and an evidence-base for decisions.[157]

The importance of such a regulator is all the more pressing given the palpable down-grading of political professionalism (in some jurisdictions moreso than others, but generally), and the increasing loss of the institutional memory and skill which allows evidence-based policy to

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154 For a similar list of critical factors in the principles-based context, see C. Ford, *supra*, note 151, at 31-36.

155 In this regard note that the FSA is pursuing the same 'PhD rocket scientists' that industry is pursuing: J. Hughes, "FSA Admits Errors Over Northern Rock", 27 March 2008, *Financial Times*, p. 7.

156 A notion considered important in the biobank governance setting: K. Ruyter et al, "From Research Exemption to Research Norm: Recognising an Alternative to Consent for Large Scale Biobank Research" (2010) 10 Med Law Int 287-314.

157 J. Frenk, "Balancing Relevance and Excellence: Organisational Responses to Link Research with Decision-Making" (1992) 35 Soc Sci & Med 1397-1404; G. Lomax, "Rejuvenated Federalism: State-Based Stem Cell Research Policy" in B. Capps & A. Campbell (eds.), *Contested Cells* (London: Imperial College Press, 2010) 359-375; others.

emerge.[158]

The work of this institution might be enhanced by the formation of an authoritative central bioethics committee (the closest in the UK being the Nuffield Council).[159] This notional National Bioethics Commission (NBC) – an independent body headed by a Bioethics Commissioner, Secretariat, and Deputy Commissioners – could be constructed around a broadened remit which includes three substantive functions: (1) providing advice and publishing opinions; (2) delivering education and certifying RECs; and (3) undertaking engagement and generating evidence. Its three units might function as follows:

- Opinions/Advice: This unit would be responsible for formulating Opinions on topics chosen by the NBC and offering Advices on questions posed by the government or the regulator, thereby allowing both subject independence and policy responsiveness. This unit would interact and cooperate with other relevant advisory and/or foresighting bodies. Obviously, it would be composed of a variety of disciplines so as to maximise the potential to capture diverse perspectives and ensure the best chance of roundly testing hypotheses.

- Education/Certification: This unit would work with post-secondary institutions to improve bioethical education, particularly for healthcare professionals (doctors, nurses, research students, etc.). It would fashion (or sanction) continuing education programmes, and be responsible for training and certifying all members of local RECs, thereby improving the capabilities and consistency of these bodies, which have been criticised for shortages in skill, transparency and independence.[160]

- Engagement/Evidence: This unit would be responsible for consulting with publics through a range of ongoing participatory exercises (eg: surveys, online consultations, workshops, round tables, and so on). By engaging with publics and feeding its findings into the work of the other units and the regulator, it would advance science

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158 G. Lomax, *ibid*.

159 See http://www.nuffieldbioethics.org/.

160 T. Lemmons & B. Freedman, "Ethics Review for Sale? Conflicts of Interest and Commercial Research Review Boards" (2000) 78 Milbank Q 547-584; I. Pritchard, "Travellers and Trolls: Practitioner Research and Institutional Review Boards" (2002) 31 Educational Res 3-13; J. Gold & C. Dewa, "Institutional Review Boards and Multi-site Studies in Health Services Research: Is There a Better Way?" (2005) 40 Health Services Res 291-308; L. Green et al, "Impact of Institutional Review Board Practice Variation on Observational Health Services Research" (2006) 41 Health Services Res 214-230; others.

democracy, ensure that key institutions are aware of the plurality of opinions that exists on given topics and what that plurality consists of, and it could build momentum toward tolerance of different views and mutual respect amongst stakeholders (which can be lacking).

While these units are separate, members would work across boundaries and enrich each others' functions, thereby modelling the principles of independence, transparency, interdisciplinarity, and clarity.[161] Such an organisation – which institutionally recognises and reflects the importance, financially and socially, of bioscience – could facilitate the advancement of moral and bioethical reflection, not only nationally, but within Europe, and it is in keeping with the non-linear, multi-level, and multi-actor method of governance that is emerging in the global era.[162] Such an institution would work closely with (and for) the regulatory institution, even taking regulatory staff on secondment.

Ultimately, the institutional setting could be improved and rationalised. The regime as a whole needs to be navigable and joined-up, the (fewer) institutions need to be accessible and interactive, and their decisions need to be comprehensive, action-guiding, and defensible. While there will rarely be a chance of achieving consensus across publics (as to certain actions or trajectories), there is value in greater reflection on values, stakeholder behaviour, and social futures, but that reflection must be reasoned and comprehensible if it is to contribute to 'good governance'.

Operationalisation Issue 3: Value-Reifying Processes

Though values may be similarly defined across jurisdictions, the range of those relevant, their scope, their interaction, and the means of their realisation might vary. Indeed, as one drops from values to principles to rights and finally to mechanisms of operationalisation (ie: the actions demanded of actors by specific instruments or regulatory decisions), there is much to contest, making clarity around values extremely important to how well the law works and how legitimate it is viewed.[163] There is an uneasy co-existence between

[161] G. Hermerén, "Conditions for the Proper Working of National and International Ethics Committees" (2009) 12 Ethically Speaking 9-11.

[162] See C. Lyall et al (eds), *supra*, note 77; M. Zamboni, "Globalization and Law-Making: Time to Shift a Legal Theory's Paradigm" (2007) 1 Legisprudence 125-153G.

[163] J. Donnelly, *Universal Human Rights in Theory and Practice*, 2d ed. (Ithaca: Cornell U Press, 1989), at ch. 5, notes a recurrent error in the manifold claims made by relativists and universalists alike. That error is the collapsing of values such as justice and fairness with practices aimed to realise these values (ie: with rights,

'universality' and 'plurality' which must be balanced if both legal certainty and flexibility are to be achieved, the former being a cherished value of the legal system and the latter being a necessary characteristic of regulation in the highly dynamic field that is bioscience (where any instrument that is technique-specific can be outdated and irrelevant within months). This raises the issue of processes.

It has been said of principles-based regulation, and the same is true of value-based regulation, that how principles (read values) are discussed, defined, and ultimately implemented (or operationalised) is as important as the instrument that serves as the fount; the formation of a robust interpretive community with ongoing and regularised communication is critical.[164] Importantly, as argued throughout the Work, this interpretive community must be inclusive. The reflexivity called for must not be an elitist or expert-driven exercise, nor can it be a theory-bound or philosophically-driven exercise; it must be a collaborative social undertaking applying comprehensible frameworks. No single stakeholder group has all the answers, or even all of the necessary tools to arrive at good answers. The regulatory process, and the bioethics on which it frequently relies, must be opened up:

> [B]ioethical analysis must … be richly multidisciplinary and even transdisciplinary; the disciplines invoked must extend beyond the currently well-represented disciplines of philosophy, religious studies, and experimental and clinical medicine, to include (*inter alia*) the history and philosophy of biology and medicine, economics, political theory, and the social studies of science.[165]

To these learned disciplines, we must add interested and sufficiently informed elements of the public. In particular, the process of better understanding, fleshing out, and contextualising the values intended to drive the biosciences and human society more generally should be a social process; a public process which considers the relationship of the individual with the broader, dynamic, plural society.[166] Others have also advocated a participative approach to eliciting evidence about human values and wellbeing, arguing that

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which are a particular kind of social practice, and with human rights, which represent a distinctive way to realise social values).

164 C. Ford, *supra*, note 151.

165 J. Robert et al, "Systems Bioethics and Stem Cell Biology" (2006) 3 J Bioethical Inq 19-31, at 28.

166 For more on the social character of the individual and the importance of the social to the ethical, see S. Gill, "Socio-Ethics of Interaction with Intelligent Interactive Technologies" (2008) 22 AI & Society 283-300. This might be equated with the 'cultural understanding of life' demanded by O'Malley et al, "The Study of Socioethical Issues in Systems Biology" (2007) 7 Am J Bioethics 67-78.

'empirical philosophy' will enrich ethical thinking and understanding.[167]

Given the above, public evidence must be generated and then integrated into the regulatory process and the deeper analytical reasoning demanded, and its generation must be ongoing (ie: 'learning loops' must be formed). Existing biolaws stipulate that neither illegality (often a populist-driven boundary),[168] nor public polls of popular opinion,[169] are adequate evidence of immorality, and that is as it should be, but solicitation of public opinion is important for offering evidence of social tolerances and trends.[170] Evidence must be generated through a range of discursive methodologies, which discourses must go beyond risk.[171] They should permit people to contribute to the exploration of foundational imperatives, core values, and moral agency, and thereby help generate richer understandings of life, science, and science in society, and facilitate better assessments of same, and they should be participants in discourses about health and regulatory goals and boundaries and means of achieving same.[172]

Some of this evidence can and should be supplied by increased socio-legal and social science research, which would feed into the early stages of regulatory decision-making. Further evidence would be generated by the NBC and the communication with, and calls for evidence by, the regulator itself. Generally, joined-up spaces must be created for genuinely open interdisciplinary contemplation of values and futures and the interaction of values, desired outcomes, rights, and action-boundaries. Conflicts at this stage, if managed properly, may serve to elucidate greater scientific, social, and regulatory possibilities. Currently, conflicts often occur at the level of legal rules; we fixate on these conflicts and they feel irreconcilable. By moving up, we see more: we can see how the rules are justified and potentially reconciled, or, if irreconcilable, how they interact with our cherished (and more important) values and are therefore suitably rankable in a given circumstance. Early, ongoing, values-based discourses may help us move beyond 'dead-end' mechanisms debates, and may alleviate the 'foreclosure' that permeates bioscience/biotech governance.

One example of a 'dead-end' debate is the 'consent in population genetics and

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167 D. Clark, *Visions of Development: A Study of Human Values* (Cheltenham: Edward Elgar, 2002); D. Clark, "Development Ethics: A Research Agenda" (2002) 29 Int J Social Eco 830-848; A. Sen, "Capabilities, Lists and Public Reason: Continuing the Conversation" (2004) 10 Fem Economics 77-80.

168 EU Directive 98/44/EC on Biotech Patenting, Art. 6(1).

169 *PLANT GENETIC SYSTEMS / Glutamine Synthetase Inhibitors*, [1995] EPOR 357 (EPO App. Div.), interpreting the European Patent Convention (1973).

170 In Eurobarometer 693 respondents identified peace, human rights and respect for human life as the three most important values: M. Salvi, "Editorial" (2008) 11 Ethically Speaking 3-5.

171 Argued in Papers-8 and -9.

172 Indeed, there are growing expectations that individuals and publics will have access to mechanisms of policy engagement: G. Lomax, *supra*, note 157.

biobank' debate. Consent is an important right emergent from a long-standing value and shaped by a particular history. However, consent is simply not suited to the biobank research model. Nonetheless, we are persistently forced to struggle with consent (ie: to fashion limitations or exemptions within the consent paradigm) in order to pursue goals in this arena. We need other governance mechanisms to encourage and justify trust in science and in researchers. We can use values to explore what other possibilities are supported even though they may erode or counteract traditional exercises of autonomy. They can help us think of whole new constructs differently grounded, the objective being to fashion governance systems that are simple, flexible, and trustworthy (which necessitates comprehensibility, commensurability, and transparency).[173]

One example of 'foreclosure' is the bringing of claims relating to medical practices and biotechnology deployments to the courts. Courts are bound by the instruments put to them. If only a narrow range of values is operationalised in those instruments (and such is typically the case), certain outcomes are unreflexively favoured and others uncritically foreclosed. Thus, if no solidarity-based concepts or duties are enumerated (or if there is no broad articulation of a range of values and therefore possible outcomes that are considered morally acceptable), then decisional options are foreclosed and legal outcomes limited. Liberal constitutions focus on individualistic values and individual rights (even if more communitarian values are claimed), so we have created manifold individual autonomy-advancing mechanisms, which courts discuss and apply. There is little scope for something else (as demonstrated by the narrow range of choices the court in *Yearworth* felt compelled to engage with).[174] If institutions (like courts) are forced to think about, and to operationalise, other values, then new rights and duties may emerge as supportable, and novel possibilities for action may be opened up.

The discursive environment elaborated above, if structured properly, offers a regulatory vision which more overtly reifies values to achieve better health and sustainable healthcare development within jurisdictions, and for the international community as a whole. It emphasises the need to take care to understand what values we as a society claim to have and, accepting their validity (ie: their ability to contribute to the common good), take positive steps to put them – all of them – into action. If the instruments we are employing in the health arena are not addressing a problem commonly viewed as serious and pressing (such as the healthcare deficit or the better use of NHS-held health data), then we need to reorient

[173] Paper-5.
[174] Paper-6.

those instruments, emphasising different values. Socio-moral and futures evidence derived from publics is critical in doing so. Importantly, evidence-generation should (quickly) expand beyond national boundaries so that international and universal values can be articulated and regulatory harmonisation (in keeping with the international nature of the science) can be achieved.[175]

Conclusions: A new, simplified, joined-up community of instruments, institutions, and public engagement will enrich bioscience and regulatory pursuits.

While leadership, boundaries, and oversight are all important, particularly given the raw power of new biotechnologies and the invasive and ubiquitous nature of the global information network into which they are plugged, old modes of regulation are not particularly appropriate, nor necessarily are the processes through which they come about or perform their tasks. At the very least one must admit that they are not coagulating into a user-friendly and coherent system through which to govern diverse but converging practices and thereby compliment health and sustainable development. A new way forward – a new way of pondering, producing, and preserving action-guides – is needed; one which is discursive and deeply reflexive (ie: supportive of the democracy value), but also flexible and responsive, and ultimately authoritative (an important feature which, as noted above, differentiates the law from other social systems); one which more explicitly, more effectively, and more legitimately operationalises the fuller range of values deemed important to this setting; one which de-emphasises static rules and emphasises values and which is deployed by expert institutions. I have refrained from offering a draft instrument, specifying the participatory mechanisms warranted, or suggesting what conclusions value-cognizant debates of specific bioscience questions should arrive at (eg: how should biobank governance and access be structured?) because, as must now be clear, I believe these answers must come from a deliberative and discursive process that is ongoing. Further, this process must distinguish between, and give equal weight to, risk and precaution, on the one hand, and promotion and innovation, on the other, and it must take into consideration commercialisation and markets (for the whole bioscience research and health delivery matrix

[175] An example of value-cognizance interrelating with harmonisation might be as follows: In Canada, payment for embryos for research is prohibited. In the UK, egg-sharing schemes whereby treatment rates are reduced so as to generate embryos for research are permitted. Can a Canadian researcher ethically import and use a UK cell line? Arguably, she can because, while the regulatory specifics differ, both jurisdictions share common values, including, importantly for this scenario, an imperative to avoid instrumentalising and commercialising humans/patients, the parameters of said imperative which are locally defined. By considering values, we see that the regimes are harmonised, though not standardised.

is embedded in, and reliant on, trade and commerce). Suffice to say that, as demonstrated by the Work, values can make a difference to all of these endeavours; values can open dialogues and open options, helping to illuminate new opportunities shrouded in the unknown, and that is what the new biosciences need.

VII. CONCLUSIONS

This interdisciplinary Work explores how we govern modern medicine and biosciences, and it persistently questions the link between law and values in our efforts to do so. The whole is critically analytical, and, though evolving, normatively suggestive.[176] Based on the case studies and empirical research, the following claims can be made:

- The law is an important social shaping tool, and, in the modern reality of global communities and interest plurality, it is one of the most important means of realising some level of social cohesion.[177]

- The biosciences are increasingly central to individual and social being and wellbeing, and therefore demand informed value debates around the law and its formation (ie: improved opportunities for science democracy in the pre-law setting), and value cognizance within the law (ie: links between, or reflections of, the socio-moral in the legal).[178]

- The conceptual differences in high-level fundamental values across jurisdictions are insignificant, as demonstrated by international instruments and the evidence generated in Argentina.[179]

- Some values (eg: autonomy and justice) are widely legally operationalised and strongly institutionally supported across biomedical contexts (eg: medical treatment, human subject research, biobanking, etc.), whereas others (eg: solidarity (internationally) and democracy (in Argentina)) are under-represented in binding

[176] Though it should be recognised that the analysis is incomplete, which is a function of the publication route chosen, the sample size of the empirical work, and the current incomplete state of the data analysis.
[177] Paper-3.
[178] Critical Review and Papers-6, -8 and -9.
[179] Papers-1, -2, -7, -8, and -9. The evidence-base for this claim needs to expand.

legal instruments and institutional actions.[180]

- The lack of operationalisation of certain values, which is partially answered by who has the most influence in this field,[181] impacts on how human rights are experienced, how stakeholders engage with and use regulatory bodies, and how the bioscience undertaking itself is approached.[182]

The challenge faced by policymakers is to ensure that future regulation and regulatory bodies take better account of the *full* range of values that are being claimed as important to human flourishing and the bioscience undertaking. Doing so *could* improve opportunities for research, rationalise and optimise regulation, and facilitate health and access to healthcare around the world.

The fundamental question, often glossed over in policy and legal discussions, is what sort of (moral) community are we creating, and what do we want it to look like in 20, 30, or 50 years. We can only begin to contemplate these questions once we have a firm grasp on what our most cherished values are, and a determination to discuss them openly, productively, and persistently in the health and policy settings.[183] Conflict will not be avoided and (value and interest) plurality will make the process difficult, but if we better wed our instruments, institutions, and actions to our shared values, we might come to a point where, despite conflict and plurality, decision-makers can confidently say, 'This is the way forward,' and be satisfied that society will accept that way and trust them to navigate the dangers. Further, whereas consistency may not always be possible, values may allow us to talk more fruitfully, enriching political and regulatory processes, and to understand our inconsistencies better.

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180 Papers-1, -2, -5, -6, -8, and -9.

181 Paper-3.

182 Papers-2, -3, -6, -8 and -9.

183 Recall that values are not theory-bound and do not require methodological or philosophical sophistication; they are beyond theory and so are accessible and amenable to participatory encounters.

ETHICAL RHETORIC: GENOMICS AND THE MORAL CONTENT OF UNESCO'S 'UNIVERSAL' DECLARATIONS

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Abstract: Genomic research is an expanding and subversive field, leaking into various others, from environmental protection to food production to healthcare delivery, and in doing so, it is reshaping our relationship with them. The international community has issued various declaratory instruments aimed at the human genome and genomic research. These soft law instruments stress the special nature of genomics and our genetic heritage, and attempt to set limits on our activities with respect to same, as informed by the human rights paradigm. This paper examines the primary thrust and, more importantly, the joint value position of the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights, concluding that, though important legal instruments from the human rights paradigm, these instruments, or rather the values contained therein, must find a more influential hard law voice and a broader policy environment.

Keywords: genomics; medical research; governance; law; ethics; bioethics; UNESCO; values

INTRODUCTION

Genomics can be characterised as a "transformative"[1] technology or practice insofar as it enables new forms of conduct (ie: permits new actions, objects and relationships) and serves as a crossroads for human identity and health, international science and commercialisation, and regulatory complexity and choice. As such, it is an ethically charged field that is most appropriately governed by instruments that are morally conscious and morally defensible.[2] Weakened social homogeneity, increased plurality, and reduced consensus around traditional morality,[3, 4] has resulted in the law emerging as a primary source of social integration.[5] Though the law need not be synonymous with morality,[6-8] it would be misguided to claim that the law (or legal instruments) should be divorced from morality. Indeed, it has long been recognised that the best law has a clearly identifiable if not explicitly moral foundation.[9-11]

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Given the above, this paper considers the ethical within the legal. In particular, it considers two leading international legal instruments which explicitly address human genomic research – the Universal Declaration on the Human Genome and Human Rights (1997) [12] (UDHG), and the Universal Declaration on Bioethics and Human Rights (2005) [13] (UDB) – with a view to identifying and defining the core moral/social "values" claimed therein. Values are here defined as deeply held ideas or moral concepts about what is good and right and supportive of human flourishing, and which contribute both to personal and to social identity. [14-16] With respect to the former, they are constitutive of the self. With respect to the latter, they are tenets of justice which promote wellbeing (ie: which promote respect for persons, fulfilment of basic human needs, and development of human personality).[17-18] In both cases, although values can be complex, overlapping and opaque, and are therefore often unarticulated or hidden, they are widely held and might be described as "universal" in that recognition of, and some level of adherence to, them transcends culture, a claim supported by their explicit and/or implicit inclusion in both international and domestic instruments.

THE UNESCO DECLARATIONS AND HUMAN DIGNITY

Upon review, it seems fair to suggest that the philosophical-moral foundations of these instruments are neither explicit nor apparently wholly consistent. To the extent that a philosophical foundation is operative, one might label it a human rights foundation, though human rights, from a philosophical perspective, is something of a derivative theoretical approach (ie: flexible, policy-driven and pragmatic).[19] However, as with most instruments within the human rights paradigm, they are founded on, informed by, and protective of, human dignity, a central and self-standing value which sits at the centre of bioethics (eg: dignity is referred to 13 times in the UDHG – Preamble, Articles 1, 2, 6, 10, 11, 12, 15, 21, 24; it is referred to 9 times in the UDB – Preamble, Articles 2, 3, 10, 11, 12, 28).[i]

The dignity invoked, though not specifically defined in either instrument, appears to draw on Kant insofar as it is based on the "unique capacity of human beings to reflect upon their own existence … to perceive injustice … and to exhibit the moral sense that gives expression to ethical principles" (UDB, Preamble, Para. 1),[20] and insofar as it relies on the conviction that: (1) humans should be treated not as means but as ends in themselves; and (2) freedom of rational choice in matters of self-development should be maximised so long as it does not infringe on the equal freedom of others. Given the ubiquitous nature of, and the multiple ways in which, dignity is deployed in these instruments (ie: it is addressed to individuals, groups and the species as a whole, and it has both a constraining and an empowering effect on behaviour), it is perhaps more appropriate to locate and articulate other values that are implicated in the genomic setting and adopted by these instruments.

A preliminary analysis discloses the existence of five "families" of provisions. The five conceptual nodes or categories around which the various Articles orbit are reflective of five notional values, namely (1) autonomy, (2) solidarity, (3) equality, (4) sanctity of life, and (5) democracy. One might go so far as to suggest that these values are dignity dependent. This may be debatable and, ultimately, much might be said about their foundation. For present purposes, it seems reasonable to posit that

[i] Dignity also features prominently in the Universal Declaration of Human Rights (1948), the European Convention on Human Rights (1950) and judicial interpretations of same.

they are, in many ways, supportive of the above conception of dignity, and, perhaps in equal measure, also informed by that value. In any event, a closer examination of the instruments is necessary to illuminate the meaning and scope of these values, which are intended to shape the genomic science of the future.

THE UNESCO DECLARATIONS AND OTHER CORE VALUES

Individual Autonomy

Despite references to actions which affect groups, there is an obvious emphasis on the individual in both the UDHG and the UDB. Inevitably, both emphasise the right of freedom of research and its benefit to mankind (UDHG, Article 12(b) [12]; UDB, Preamble, Para. 12 and Article 2(d) [13]).[ii] The one clear limitation they place on this right, however, is that it should never override respect for individual human rights and freedoms and ethical principles (UDHG, Article 10 [12]; UDB, Article 2(d) and 3(2) [13]). They go on to make the following stipulations with respect to research, diagnosis, and treatment:

- Genomic or other medical conduct can only be undertaken after full disclosure of the potential risks and benefits of that conduct to the individual (UDHG, Article 5(a) [12]; UDB, Article 6(1) [13]).

- Conduct must be preceded by free, informed and express consent of the person concerned (or, where the person lacks capacity, the consent of his/her representative and only for his/her direct benefit) (UDHG, Articles 5(b) and (e) [12]; UDB, Articles 6 and 7 [13]).

- Personal information (including genetic information) concerning an identifiable individual must be held in confidence and not disclosed for purposes other than those for which it was collected and consented (UDHG, Article 7 [12]; UDB, Article 9 [13]).

- Consent and confidentiality can only be limited by law for compelling public purposes and within the bounds of international law and human rights (UDHG, Article 9 [12]).

- Every individual has the right to decide whether to be informed of results and consequences of genetic tests (UDHG, Article 5(c) [12]).

- Every individual has the right to reparation for damage sustained as a result of genomic interventions (UDHG, Article 8 [12])

- Though cultural diversity is important, it must not be invoked to infringe upon individual rights (UDB, Article 12 [13]).

[ii] A right enshrined in the International Covenant on Economic, Social and Cultural Rights (1966), and the UNESCO Recommendation on the Status of Scientific Researchers (1974), and supported in the European context by *Huvig* v. *France* (1990) 12 EHRR 528 (ECHR), and *Niemietz* v. *Germany* (1992) 16 EHRR 97 (ECHR).

Although much can be (and has been [21-24]) said about the instruments' lack of specific guidance as to how some of these individual rights are to be realised (particularly in the genomic context where traditional understandings of, and limits associated with, them are less applicable), it is clear that both are heavily influenced by a shared vision of autonomy, a value which, based on the above, encompasses the idea that individuals, by virtue of being human and therefore having dignity and deserving respect, are entitled to exercise their free will and to govern themselves. This self-rule encompasses physical and legal liberty, and the right to be free from coercive or controlling influences with respect to same.[15, 25-26] For example, individuals who are the subject of conduct are to be informed and empowered, their privacy is to be protected, and actions which are damaging to their autonomy (ie: their physical being or their personal or informational privacy) are actionable. In short, the individual is to be informed and empowered so that s/he can exercise self-rule.

Social Solidarity

Despite strong support for autonomy in both instruments, solidarity (which naturally acts as a counter to the more selfish elements of modern individualism) is also extensively referenced, though again not explicitly defined.

The starting point for an understanding of the value must begin with the UDHG, which, in its Preamble, refers to "a spirit of mutual assistance and concern" and "the intellectual and moral solidarity of mankind", before declaring in Article 1 that the human genome underlies the fundamental unity of all members of the human family, and is, "in a symbolic sense", the "heritage of humanity". This term harkens back to international instruments which characterise space,[27] culture,[28] the moon,[29] and the seabed,[30] as the "common heritage of mankind" warranting special protection and special rules of exploitation. The concept shares with solidarity notions of global community, shared social purpose, common/public resources and intergenerational justice. Though some argue that inclusion of the phrase, "in a symbolic sense", weakens the Article (and the value captured therein),[31] others argue that it merely stresses that the genome is not to be appropriated, and that its value lays not in the commercial realm but in its innate capacity to underline a shared moral obligation to safeguard human existence in the face of the unknowns represented by biotechnologies.[32-33]

Both instruments seek to impose solidarity – with its notions of fraternity, mutual sharing, and assistance of those in need – on individuals, states and other organisations within society.[iii] Both imply a broad and multi-duty definition of the value, which duties must be pursued cooperatively and internationally (eg: Article 18 of the UDHG [12] encourages the fostering of scientific cooperation, particularly as between developed and developing nations; Article 13 of the UDB [13] encourages international cooperation in support of solidarity among humans). Proceeding from the proposition that safeguarding and promoting the interests of present and future

[iii] Article 13, UDHG, notes the responsibilities of public and private policy-makers. Articles 1(2) and 2(b), UDB, note that, although addressed to states, the UDB is intended to guide individuals, groups, communities, institutions and corporations, public and private. Article 14(1), UDB, notes the shared responsibility of all sectors of society to promote health and social development. Article 23(2), UDB, encourages the participation of numerous stakeholders in bioethics development, and Article 24(3), UDB, notes that individuals, families, groups, communities and states must all promote solidarity. Both instruments caution that they should not be interpreted by individuals, states or groups in such a way as to condone breaches of human rights, dignity or stated principles: see Article 25, UDHG, and Article 28, UDB.

generations is important, they articulate a number of issues that should always be considered when acting in the genomic and biomedical fields; stakeholders must:

- recognise that sci-tech developments should promote welfare, and must not infringe human rights and dignity (UDHG, Article 10 [12]; UDB, Preamble, Para. 12 [13]);[iv]

- recognise that sci-tech developments impact on individuals, groups, humankind, and future generations (UDHG, Article 1 [12]; UDB, Articles 2(g) and 16 [13]); [34]

- give due regard to vulnerability (noting that vulnerable populations and developing countries have special needs) (UDHG, Article 17 [12]; UDB, Preamble, Paras. 17 and 21, and Article 8 [13]); and

- give due regard to the interconnectedness of humans and other life forms and the biosphere more generally (UDHG, Article 17 [12]; UDB, Preamble, Paras. 17, 19 and 21, and Articles 2(g) and (h), and 17 [13]).

Additionally, both instruments enumerate the actions required of stakeholders operating in this field. Articles 12(b) and 13 of the UDHG direct scientists to offer relief from suffering and improve the health of individuals and of humankind, and, in doing so, to meet the standards of meticulousness, caution, intellectual honesty and integrity. Between them, these instruments direct states to:

- foster ethical research (including research on the identification, prevention and treatment of genetically-based/influenced diseases, both rare and endemic) (UDHG, Articles 14 and 17 [12]);

- establish multidisciplinary ethics committees independent from political, economic, scientific and medical authorities (UDHG, Article 16 [12]; UDB, Articles 19 and 22(2) [13]);

- disseminate scientific knowledge so that advances can be enjoyed by everyone (UDHG, Article 18 [12]; UDB, Article 24(1) [13]); and

- encourage measures that will enable developing states to share in the benefits of sci-tech research and to build capacity to undertake their own research (UDHG, Article 19 [12]; UDB, Articles 15 and 24(2) [13]), the equitable sharing of benefits accruing from commercial exploitation of the genome having been characterised as the most important human rights issue in the biotechnology setting.[35]

The combined effect of these provisions is to: (1) note that human identity is a multi-factoral and nuanced social construction, and the position of humans in the world is one of shared resources and mutual dependence; and (2) encourage individuals, organisations and states to pursue socially responsible scientific activities which will

[iv] Also note Article 11, UDHG, which goes on to claim that human reproductive cloning is contrary to human dignity, though it does not explain how or why.

improve the condition of human health around the world, preserve the biosphere and biodiversity, and materially benefit future generations.[v]

The solidarity value that is emergent is one grounded in the recognition that individuals are socially embedded. Drawing on principles of compassion and an interest in the well-being of others, it emphasises the collective, the observance of duties and the creation and preservation, through personal and collective action, of a just and decent society. It makes explicit the fundamental unity of humankind, the value of the human community, the importance of active good will toward others, and the promotion of freedom and the capacity in everyone to self-sustain. Generally, it implies a universal duty to contribute to society and to the betterment of life, and to undertake a common effort to protect the heritage of life. Moreover, it is not a purely rhetorical tool denoting a perceived fraternity, but rather an action-oriented value espousing social responsibility and common undertakings.

Equality of People(s)

Both instruments suggest that equality, which relies on beliefs that everyone is of equal worth/value, and that all people should therefore be treated fairly and equitably, constitutes both a moral touchstone and a key objective.

The Preamble of the UDHG "rejects any doctrine of the inequality of men and races", and stipulates that the recognition of genetic diversity "must not give rise to any interpretation of a social or political nature which could call into question the inherent dignity and … equal … rights of all members of the human family". Article 1 then states that the genome underlies the fundamental unity of all members of the human family.[vi] Article 2(a) states that everyone has a right to respect for their dignity (and rights) regardless of their genetic characteristics (ie: even if new technology discloses genetic illness or predisposition to same), and Articles 2(b) and 3 states that genetic determinism, which is rejected as invalid, is to be avoided.[37]

In the genetic context, discrimination can be defined as differential treatment of an individual (or group of like individuals such as family or community) on the basis of real or perceived differences from the "normal" genome. It has also been defined as differential treatment against persons in good health who, because of their genetic make-up, are at increased risk of becoming ill in the future. [38] A common fear is that one's genetic information, which is a personal, immutable characteristic, will be used to define and classify them according to race or other markers such as existence of deficiencies or physical/mental potentialities, and genetic information will therefore become a tool by which to perpetuate existing or create new social, economic or power divisions.[22, 39] Article 6 of the UDHG extends the prohibited grounds for unequal treatment to genetic characteristics.[40]

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[v] From a jurisprudential point of view, note that the European Court of Human Rights has rejected protecting 'future generations' (embryos) at the expense of existing rights-holders (see *Vo* v. *France*, [2004] ECHR 326 (Grand Chamber)) and rejected protecting future generations and the environment from the dangers of nuclear power absent a specific and imminent danger (see *Athanassoglou et al.* v. *Switzerland*, [2000] ECHR 159 (Grand Chamber)). However, the Philippine Supreme Court has allowed a class action on behalf of named plaintiffs and future generations in the context of preservation of public forestland (see *Oposa et al.* v. *Secretary of the Department of Environment & Natural Resources* (1993), 224 SCRA 792 (en banc)).

[vi] The scientific support for human unity includes evidence that there is no biological basis for the concept of race (certainly as we understand and deploy the term), a fact which has been cited as a significant contribution to the elevation of anti-discrimination provisions as undisputed universal norms at international law.[36]

The UDB builds on the understanding of equality elucidated in the UDHG, noting in its Preamble that all humans, without distinction, should benefit from the imposition of common ethical standards in medicine and bio-research, and that an important component of equality is attention to the position of women. It reiterates the aim of promoting equity, or, more precisely, equitable access to, and rapid sharing (of the benefits) of, medical, scientific and technological knowledge (UDB, Article 2(f) [12]). Articles 10 and 11 then state that the fundamental equality of all humans in dignity and rights is to be respected so that they are treated justly and equitably, and that discrimination against or stigmatisation on any grounds is forbidden. More specifically, Article 14(2) goes on to state that the highest attainable standard of health (measured by access to water, nutrition, healthcare, decent living conditions and environment, reduction of poverty and illiteracy, and the elimination of marginalisation and exclusion) is a fundamental human right without distinction of race, religion, political belief, economic or social condition, or scientific capability.

Unfortunately, neither "everyone" (Article 2, UDHG [12]) nor "all human beings" (Article 10, UDB [13]) are defined. From a practical point of view, this might be characterised as a significant oversight given the nature of genomic technologies (and related practices like embryonic stem cell research) which give rise to disagreements as to who might be included in these terms.[vii][70] Conversely, it might be conceded that irreconcilable positions on the beginning of personhood, both internationally and within domestic legal jurisdictions, made this a necessary lacunae. In any event, both instruments adopt a robust interpretation of equality, addressing fairness conceptually (through their claims that all people are equal in dignity) and more concretely (through their claims that all people have the right to equal respect and just treatment; not equal treatment *per se*, which might not serve the ends of the value at all, but rather with "equitable" treatment and the swift sharing of benefits so that good health can be realised by all). In short, the conception of equality captured by these instruments appears to comprise two primary elements, namely that, (1) medically and genomically, everyone must be treated appropriately based on what is owed to them due to their personal circumstances, and (2) legally, everyone is equal before and under the law, deserves the equal protection of the law, and is entitled to equal benefit of the law, regardless of personal properties/qualities (including genetic make-up).

Sanctity of Life

Like dignity, sanctity appears to be fully embraced by these instruments; the value gives both instruments context and colours the whole of their content, as evidenced by the recollection in their Recitals of prior instruments specifically addressed to the preservation of life.[viii] However, unlike dignity, which is frequently and explicitly

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[vii] The difficulties presented by the term in juridical settings is exemplified by *Vo* v. *France*, [2004] ECHR 326 (Grand Chamber), wherein the court appeared not to include a 20+ week foetus in that term, and, more recently, by the Korean Supreme Court which ruled that a 42+ week foetus was not a human.[41]

[viii] Both instruments refer to UN Convention on the Elimination of All Forms of Racial Discrimination (1965), UN Convention on the Elimination of All Forms of Discrimination Against Women (1979), and UN Convention on the Rights of the Child (1989). The 1965 convention addresses sanctity in its Preamble and Article 5(b), which articulates a right to security of the person and protection against violence and bodily harm: see http://www.ohchr.org/english/law/cerd.htm. The 1979 conventions addresses sanctity in its Preamble and Articles 3, 5 and 6: see http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm. The 1989 convention addresses

referenced, sanctity is an almost unspoken value which must be found in the character of the instruments; in their penumbra.

The Preambles – with their references to wellbeing and the protection of the human rights and dignity of all people, particularly the vulnerable – speak to this value in a general way. Additionally, both instruments (1) caution against the commercialisation of the human body,[ix] (2) stipulate that biomedical activities must be preceded by a risk-benefit assessment, and (3) highlight the fact that bioscience must be directed toward peaceful and socially useful purposes (UDHG, Articles 5(a) and 15 [12]; UDB, Articles 20 and 21(5) [13]). The UDB adds further to the elucidation of this value, claiming in Article 2(c) the promotion of respect for life as a specific aim, noting in Article 8 that, in advancing science, human vulnerability should be taken into account (eg: the personal integrity of the vulnerable should be protected), and claiming in Article 14(2) that the highest attainable standard of health is a fundamental right and that science and technology should advance access to healthcare, improve living conditions, and reduce poverty. Both instruments also suggest, through their treatment of healthcare and the environment, that genomic advances (and biomedical advances more generally) should contribute to the flourishing of human life. They also both suggest, by their attempt to avoid individual and group marginalisation and the commercialisation of human bodies, that actors should seek to avert harm to human life, even if that hampers future advances. As such, one can discern that the instruments celebrate the phenomenon of life and attach to it special individual and social significance, thereby suggesting that it (human life) demands special legal protection, and this is particularly the case in situations involving vulnerable people or groups.

However, despite the rich history of life-protecting instruments on which they draw, and the few provisions which appear to advance sanctity in the genomic innovation context, there is some ambiguity around the scope of the value embodied. It is unclear whether the sanctity advanced is informed by the idea that human life is intrinsically sacred or, alternatively, that it is specially valuable (ie: it is not obvious whether it is life *qua* life that is valued, a position called vitalism, or whether it is rather the conscious life lived), a matter which has implications for the scope of the value. To generalise, the "sacred" foundation is a religiously-informed one which often elevates life and its preservation to that of an overriding imperative of all people. By contrast, the "specially valued" foundation of sanctity is secularly-informed, and often makes life's special significance contingent on the presence of certain qualities associated with the lived human experience (eg: self-awareness, self-

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sanctity in its Preamble and Articles 2, 3, 6, 9 and 11. Article 6 articulates a right to life and directs states to maximise the survivability and potential of the child, and Article 9 addresses neglect and abuse: see http://www.unhchr.ch/html/menu3/b/k2crc.htm. In addition, the UDHG refers to the UN Convention on the Prevention and Punishment of the Crime of Genocide (1948) (see http://www.unhchr.ch/html/menu3/b/p_genoci.htm), and the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (1971) (see http://www.opbw.org/convention/documents/btwctext.pdf).

[ix] Article 4 of the first instrument states that the human genome in its natural state (ie: in its natural environment, being the human body) shall not give rise to financial gains. Article 15(2) of the latter instrument states that benefits (broadly defined) should not constitute improper inducements to participate in research. Presumably, these (partial) bans on commercialisation are based on the idea that money could lead to devaluing the person and endangering life. Given the ability of third parties to gain financially from the human genome through the patenting of genes and gene sequences, the ethical consistency of prohibiting individual gene originators from also gaining can be questioned. Indeed, the IBC subsequently issued an Advice alleging moral grounds for excluding the human genome from patentability.[42]

reflection, etc.). Their emphasis on general wellbeing, on science not being advanced at the cost of human rights (which are more commonly enjoyed by the functioning person), on the uniqueness and diversity of individuals (which becomes apparent through interaction), on the importance of culture and cultural diversity (which is only relevant to the conscious), and on erecting protections for the vulnerable in particular, doesn't push one definitively toward one interpretation over the other.

(Scientific) Democracy

Perhaps unsurprisingly given the remit of UNESCO and the legislative history of these instruments, both the UDHG and the UDB promote democracy. In this regard, the Preamble of the UDHG explicitly recalls the need to conform to the democratic principles of justice, liberty and peace, before going on to articulate in a variety of Articles the need for cooperation, the free exchange and dissemination of (scientific) information so that all members of society can benefit, and the generation of capacity through international stakeholder consultations and the creation of independent ethics committees. For its part, the UDB highlights the need to respect pluralisms and cultural diversity, and to engage in (international) dialogue so as to foster, *inter alia*, openness, engagement and transparency of decision-making (UDB, Articles 12, 18, 19(d) and 21(4) [13]). Like the UDHG, it also encourages bioethics capacity-building, and the free flow of information (UDB, Articles 23 and 24 [13]). The above suggests that the democratic concepts these instruments seek to encourage are plurality of ideas, facilitation of participation (though not forced participation), transparency of decision-making, and dissemination of outcomes, each of which might be considered essential to the realisation of good science governance by standards of (liberal) modern thinking.[43-44]

Summation: A Plurality of Conflicting Values

The application of dignity in both the UDHG and the UDB to the individual, the family, the community, and the species, gives that value manifold meanings supportive of conflicting consequences, and thereby reduces its utility as an evaluative moral concept. This is not fatal because both instruments evince a strong reliance on a plurality of other shared fundamental values, namely individual autonomy, social solidarity, equality of people(s), sanctity of life and (scientific) democracy, each of which are given substantive content through both the non-operative and substantive provisions.

Although one might subscribe to each of these values simultaneously, they can clearly be contradictory and competitive (ie: circumstances may arise where they cannot all be realised or vindicated in equal measure).[x] This might not have been a problem had the instruments also contained some ranking mechanism or decision-making framework for managing such conflicts. Unfortunately, both are drafted in somewhat absolutist terms, and claims that nothing contained therein should be interpreted as supporting activities contrary to "core principles" (UDHG, Article 25) or "human dignity" (UDB, Article 28), and that limitations of principles should be by law and in the interest of public safety, the protection of public health or the

[x] For example, within the UDB, note the conviction that the interests of the individual should have priority (Article 3(2)), on the one hand, and the need to promote the interests of future generations and protect public health (a decidedly non-individualistic framework for decision-making)(Articles 2(g) and 27), on the other, and the difficulty of reconciling them.

protection of the rights/freedoms of others (UDB, Article 27), offer minimal practical guidance for making decisions as to the appropriate balancing of values.[19, 45]

Nonetheless, it is fairly clear that the combined effect of the moral values advanced, though admittedly reflecting variable degrees of comprehensiveness, is to link genomic knowledge and research to the advancement of human health and wellbeing, and, specifically, with human rights; in essence, to make the preservation of the genome (which contributes to unity and diversity), and the dissemination of advances related thereto (insofar as they improve the human condition), imperatives which all people(s) have a right to demand of all stakeholders active in the field.

CONCLUSIONS: TRANSFERABILITY OF THE "UNIVERSAL" VALUES

It has been suggested that laws emergent from the human rights paradigm, which has become one of the most rhetorically and practically important/influential global legal paradigms in the modern era, are particularly appropriate for managing the ethical/moral concerns raised by genomic research,[46] and both the UDHG and UDB are clearly born of this paradigm and draw on its growing heritage of rights and values. In particular, both instruments erect human dignity as the core ethical value and place it at the centre of all decisions relating to genomic innovation and applications. But these instruments are more than just ethical guides. Both the UDHG and UDB are legal instruments insofar as they are intergovernmental agreements accompanied by commitments to political action. As such, and because they are intended to have binding legal consequences – if and when they become customary law, and one might note the moral and legal persuasiveness of the Universal Declaration on Human Rights (1948) – they have intrinsic value and relevance.[47-48] Having said that, however, it must be conceded that they are (currently) non-binding, declaratory and, unlike most forms of "hard law", they are pregnant with idealistic and (legally) vague rhetoric which must, certainly in the short term, find voice in other instruments if their underlying values are to be realised (or compelled) in practice.

In fact, if the values which these instruments erect are to truly realise their potential on the ground, they must experience widespread uptake, and not just in the human rights context, although that context is vitally important. Rather, these values must become "subversive" and "leak" into the many and varied fields and genres of law that are both directly and indirectly relevant to the practice and governance of genomics. From an international perspective, that means not only informing the development of human rights through the UN, UNHRC and UNESCO, but also public healthcare policy through the WHO and commercial and trade policy through the WTO and WIPO, the latter arena of which looms so large in the shaping of genomic investigations, technologies and applications. It means not only informing the operation of hard law instruments such as the Convention on Human Rights and Biomedicine (1997),[49] but also the operation of instruments such as the Paris Convention (1883),[50] the TRIPS Agreement (1995),[51] and the Doha Declaration (2001).[52]

In short, if the UDHG and UDB and the moral values they claim as essential to genomics are going to be realised, the commercial arena must represent a site of moral/ethical cohesion and legal enhancement. To realise this, the primary international commercial actors must expand their view of what is "valuable", and they must permit these values to shape both their view of the world and their interpretation and application of their most important legal instruments. Without this

cohesion, these values (and therefore the UDHG and UDB) will fail to reach (and therefore influence) a key constituency in the genomic field and will remain rhetorical. As such, the true test for the UDHG and the UDB, which test still lies before them, is whether they and their "universal" values can influence in a real way the manner in which stakeholders, both public and private, conduct themselves in the fora that really shapes genomics. Admittedly, it will be an uphill battle, but the conceptual and legal mechanisms already exist. For example, see Articles 7 and 27 of the TRIPS Agreement, which inject a moral element into patenting practices, and note the rise in morality-based opposition activity in European patent practices.

Therefore, watch this policy-making space!

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SOLIDARITY: A (NEW) ETHIC FOR GLOBAL HEALTH POLICY

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Abstract: This article explores solidarity as an ethical concept underpinning rules in the global health context. First, it considers the theoretical conceptualisation of the value and some specific duties it supports (ie: its expression in the broadest sense and its derivative action-guiding duties). Second, it considers the manifestation of solidarity in two international regulatory instruments. It concludes that, although solidarity is represented in these instruments, it is often incidental. This fact, their emphasis on other values and their internal weaknesses diminishes the action-guiding impact of the solidarity rules. The global health and human subject research scene needs a completely new instrument specifically directed at means by which solidarity can be achieved, and a reformed infrastructure dedicated to realising that value.

Keywords: health; healthcare; human subject research; ethics; values; solidarity; Helsinki Declaration; CIOMS Guidelines

INTRODUCTION

Scientific research and biotechnological[1] advances are expanding the breadth and scope of human activity. Nowhere is their impact more apparent than in the realm of human health, where they have contributed not only to new treatments, but also to new (and expanding) pressures/demands on healthcare systems.[2] The interaction between science/biotechnology and healthcare led Director-General of UNESCO, Federico Mayor, to suggest that efforts are needed to ensure that advances are solidly grounded on the essential values of mankind.[3] For purposes of this paper, "values" might be defined as deeply held ideas, or beliefs and moral concepts which contribute to personal and social identity. Of values, it has been stated that they:

> … are often hidden. … [T]his may be because some values are so deeply held that they appear to require no articulation, the presumption is that they are commonly shared and acknowledged. Society … often lacks formal frameworks for discussing values. Political and regulatory frameworks have actively

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[1] Biotechnology is here used to denote the application of new and emerging technologies to the study of living organisms or that uses living organisms or derivatives thereof to produce or modify (health) products and services. See the definition in the Convention on Biological Diversity (1992), signed by 168 states, as well as those at www.mayominnesotapartnership.org/glossary.htm and www.uni-hohenheim.de/biotech/eng/def_biotech.htm.

[2] D. Morgan, "Science, Medicine and Ethical Change" in A. Bainham *et al.* (eds.), *Body Lore and Laws* (Oxford: Hart Publishing, 2002) 329-342, at 329. Biotechnological advances will increase the variety and predictability of diagnostic processes, widen the scope and effectiveness of treatment processes, and generally alter the social setting within which medicine is practiced: S. Harmon, "The Significance of UNESCO's Universal Declaration on the Human Genome and Human Rights" (2005) 2:1 SCRIPT-ed, at www.law.ed.ac.uk/ahrb/script-ed/vol2-1/harmon.pdf.

[3] F. Mayor, "Preface" in *Proceedings of the First Session of the IBC* (Paris: UNESCO, 1994).

> discouraged discussion of values, partly because they do not have the mechanisms by which to deal with them. Values and intrinsic ethical objections are often seen as 'irrational' and therefore discounted. …[4]

I have suggested elsewhere that legal regulation of biotechnological advances are appropriately evaluated with reference to the touchstone values of human dignity, sanctity of life, autonomy, justice, and, crucially, solidarity, which values should colour the nature, content and interpretation of regulation directed at healthcare generally and genetic research and treatment specifically.[5] While much has been written about some of these values, this is less true of solidarity.

As such, this paper examines solidarity, not as an overarching moral or political theory, but as a moral/ethical value which ought to influence solutions to social/legal problems and which is supportive of derivative legal rules which can be used to evaluate legal and quasi-legal instruments; a means by which we can expand the basket of tools we use when approaching governance activities.[6] Part I briefly explores solidarity as a fundamental value, grounding its content/definition in claimed social beliefs and healthcare trends. Part II articulates some practical and concrete duties the value supports, using healthcare and, in particular, international human subject research ("HSR") as the context. Part III assesses two international instruments – the Helsinki Declaration: Ethical Principles for Medial Research involving Human Subjects (2000) ("Helsinki Declaration") and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) ("CIOMS Guidelines") – to identify whether and how the value finds expression in the international human research and healthcare context.

By examining the transition from theoretical value (Part I) and evaluative rules (Part II) to international directives (Part III), this paper offers some insights as to whether solidarity finds a policy voice commensurate with its theoretical ideal. In the absence of an adequate voice, it suggests a way forward for the better realisation of this important value.

I. THEORETICAL SOLIDARITY: THE SUBSTANCE OF (INTERNATIONAL) SOLIDARITY IN SOCIAL/LEGAL REGULATION

As indicated above, this Part offers a definition of solidarity as a fundamental value and the context within which it should be applied, drawing on longstanding conceptions of moral human interaction and certain trends in the modern healthcare context.

(1) Defining the Value

At the outset, one must concede that the idea of solidarity has many roots, conceptions and potential manifestations. For example, it has long been a touchstone in religious norms of human interaction (which are often the first/formative norms that humans learn and the most important moral rules to which humans adhere). Religious traditions have expressed it as:[7]

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[4] A. Bruce & J. Tait, "Interests, Values and Biotechnological Risk" (2003) Innogen Working Paper 7, at www.innogen.ac.uk/publications/ (Oct. 28/05).

[5] S. Harmon, "Regulation of Human Genomics & Genetic Biotechnology: Risks, Values and Analytical Criteria" (2005) Innogen Working Paper 40, at www.innogen.ac.uk/publications/.

[6] Attempts to define these and other values and to measure the propriety of tomorrow's biotechnologies have been undertaken within the rubric of various moral approaches, including principlism, virtuism, feminism, etc. For the purposes of this paper, no particular "approach" or overarching "theory" of rights or morality is espoused.

[7] For more on ethical norms in a variety of religious traditions, see A McFaden, *A Call to Personhood: A Christian Theory of the Individual in Social Relationships* (Cambridge: CUP, 1990), P. Morgan & C. Lawton (eds.), *Ethical Issues in Six Religious Traditions* (Edinburgh: EUP, 1996), M. Davis, "Constitutionalism and Political Culture: The Debate Over Human Rights and Asian Values" (1997) 10 Harv. H.R.J. 109-148, D. Louw, "Ubuntu: An African Assessment of the Religious Other" (1997) at www.bu.edu/wcp/Papers/Afr/AfriLouw.htm (July 25/05), W. de Bary, *Asian Values and Human Rights: A Confucian Communitarian Perspective* (London: Harvard U. Press,

- brotherhood, community, unity and interconnectedness,[8]
- mutual respect/love and reciprocity,[9] and
- generous, loving and just action toward others.[10]

In political discourse, solidarity is often viewed as a matter of individuals performing reciprocal duties and respecting reciprocal rights. This conception recognizes that individuals are grounded in communities and publics founded on shared identity (a sense of belonging, responsibility and moral commitment) and shared utility (a feeling of mutual dependence and shared self-interest in pursuit of opportunities and joint goals).[11] The manifestation of political solidarity culminated in the Polish Solidarity Movement of the 1980s, which advocated democracy and social justice.

Despite its general familiarity to many people, therefore, its multidimensional history and varied use will make any attempt to arrive at a workable definition somewhat controversial. Rather than settle on a concise definition for the value, it may be more useful to articulate it as a series of interrelated and mutually enhancing propositions which draw on some of the existing expressions. I suggest that solidarity is captured by the following:[12]

- **Proposition 1:** Solidarity recognizes that individuals are naturally and irrevocably embedded in social contexts; they are in a state of interrelationship or interconnectedness

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1998), D Elazar, "Jewish Civilization and Polity in a Globalized World: A New Vision for Organized Jewry" (1999), at www.jcpa.org/dje/articles2/vision99.htm (Aug. 18/05), G. Goldsand *et al.*, "Bioethics for Clinicians: Jewish Bioethics" (2001) 164 C.M.A.J. 219, J. Azariah, "Asian Bioethics in Global Society" in S. Sang-yong, K. Young-Mo & D. Macer (eds.), Asian Bioethics in the 21st Century (NZ: Eubios, 2003) 219-223, H. Halevi, "The Thirteen Principles of Jewish Medical Ethics" at www.jewishpeople.net/jewmedet.htm (June 2/04), D. Macer, "Love and the History of Chinese Bioethics" at www.phil.pku.edu.cn/post/center/love%20and%20the%20history%20of%20chinese%20bioethics.html (June 8/04).

[8] In African traditionalism, note the maxim *simunye* (we are one; unity strength). In Buddhism, Hinduism and Christianity, note concepts of brotherhood and interconnectedness. In Judaism, note *clal yisrael* (unity despite differences) and *brit* (the covenant which binds Jews to one another and to God, and the fostering of *reut* or "neighbourliness"). In Islam, note *tawhid* (unity and oneness of humanity).

[9] In African traditionalism, note the widely held maxim, *umuntu ngumuntu ngabantu* (to be human is to affirm one's humanity by recognizing the humanity of others). In Buddhism, note the admonition against excess. In Confucianism, note the emphasis on love of life and mutual respect. In Hinduism and Christianity, note concepts of reciprocity. In Judaism, note *arevut* (mutual obligation). In Islam, note *hubb* (love), *rahma* (mercy/compassion).

[10] In some African traditions, note *shosholoza* (working as a team; group spirit in adversity) and the shared responsibility of dialogue and cooperative action. In some Asia traditions, note *kalayanamitra* (friends helping friends). In Buddhism, note concepts of enduring sacrifice in others' interests. In Confucianism, note concepts of duties and action toward others. In Hinduism, note *da da da* (give and be merciful) and concepts of obligation to others. In Judaism, note *kiruv* (reaching out, partnering with humanity) and *tzedaka* (duties to help the poor). In Christianity, note John 15:13 (self-sacrifice) and Mark 10:21, Luke 6:20 and John 3:17 (mutual assistance, often in relation to the poor). In Islam, note *zakat* (obligation to give to the poor), *sadaqah* (charity/altruism), and concepts of *'adl* (justice) and *wast* (equilibrium) which underpin principles condemning exploitation and the isolation of oneself from the rest of humanity.

[11] W. Arts & R. Verburg, "Modernisation, Solidarity and Care in Europe: The Sociologist's Tale" in R. ter Meulen *et al.* (eds.), *Solidarity in Health and Social Care in Europe* (UK: Springer, 2002), 15-40, at 19. See also R. Houtepen & R. ter Meulen, "New Types of Solidarity in the European Welfare State" (2000) 8 Health Care Analysis 329-340, at 335-336, and M. Hayry, "European Values in Bioethics: Why, What and How to be Used?" (2003) 24 Theo. Med. 1999-214, at 207.

[12] Similar propositions are variously articulated in the following: R. Houtepen & R. ter Moulen, *ibid*, at 335-336, M. Hayry, *ibid*, at 207, J. Gevers *et al.*, "Popular Support for Health Care in Europe: Review of the Evidence of Cross-National Surveys" in R. ter Meulen *et al.* (eds.), *ibid*, 41-76, at 43, R. Houtepen & R. ter Meulen, "The Expectation(s) of Solidarity: Matters of Justice, Responsibility and Identity in the Reconstruction of the Health Care System" (2000) 8 Health Care Analysis 355-376, at 359, R. ter Meulen *et al.*, "Final Report: Solidarity and Care in the European Union" (2000), at http://europa.eu.int/comm/research/biosociety/pdf/bmh4_ct8_3971_partb.pdf (Aug. 24/05), and S. Benatar, A. Daar & P. Singer, "Global Health Ethics: The Rationale for Mutual Caring" (2003) 79 Int. Aff. 107-138, at 120.

with individuals, groups and society.[13] It therefore emphasises community.

- **Proposition 2:** Solidarity is grounded in compassion, fraternity and a genuine interest in the well-being of others, the ultimate goal being to construct, through personal and collective actions, both a "just" and a "decent" or "fair" society. It therefore emphasises equality and the active promotion of welfare.

- **Proposition 3:** Solidarity demands common action to uphold the complex of social relationships and values that is needed to realise useful standards of decency and justice. It therefore emphasises the role of duties flowing from and toward individuals and communities, and may require collective interests to take priority over the interest of individuals or sub-collectives.

Having settled on these propositions, one must delineate the "social context" within which to apply them.[14]

(2) Defining the Context

Modern social contexts are more diverse, overlapping and conflicting than ever before (ie: family, neighbourhood, trade organisation, class, nation, continent, religion, gender).[15] One might argue that adoption of a broad social context risks ignoring cultural, linguistic, national and racial differences, resulting in connections/identities that are too loose/weak to found compelling duties. However, given existing economic demographics and converging legal practices, I believe that the only social context that will vindicate the value and redress the social inequalities that currently exemplify human existence is the global one.

The current global setting is characterised by widening economic disparities,[16] rapid population growth,[17] the emergence and spread of infectious diseases,[18] escalating environmental degradation (due to the expansion of human population and human activities),[19] and ubiquitous

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[13] J. Habermas, *Zur Bestimmung der Moral* (Frankfurt: Suhrkamp, 1986), uses the term "intersubjectivity".

[14] Only by situating the individual within society can we determine whether we have obligations toward one another as citizens of a community: see B. Knoppers. "Of Biotechnology and Man" (2004) 7 Comm. Gen. 176-181.

[15] R. Houtepen & R. ter Meulen, *supra*, note 11, at 336, M. Hayry, *supra*, note 11, at 207, R. Ashcroft *et al.*, "Solidarity, Society and the Welfare State in the United Kingdom" (2000) 8 Health Care Analysis 377-394, at 378.

[16] The income of the richest 20% of humanity is 80x that of the poorest 20%, and more than 2 billion people live on less than US$2 per day: S. Benatar, A. Daar & P. Singer, *supra*, note 12, at 112. See also UNDP, "Human Development Report 1999" (1999), at http://hdr.undp.org/reports/global/1999/en/ (Aug. 17/05), and R. Falk, *Predatory Globalization: A Critique* (Cambridge: Polity Press, 1999).

[17] Global population has risen from 4,452,645,562 (1980), to 5,282,765,827 (1990), to 6,081,527,896 (2000), to 6,460,560,374 (2005): see www.census.gov/ipc/www/worldpop.html (Aug. 16/05). It is expected to rise to 9.1 billion by 2050: see www.overpopulation.org/faq.html (Aug. 16/05).

[18] Communicable diseases, which do not respect borders, continue to be the leading loss of human life: L. Garrett, *The Coming Plague: Newly Emerging Diseases in a World Out of Balance* (NY: Farrar, Strauss & Giroux, 1994). Contemporary examples of the mobility of infectious diseases are the SARS outbreak of 2003 and the more recent Avian Influenza pandemic; in a short time, it spread through multiple countries, resulting in tens of thousands of bird deaths and 63 human deaths: www.who.int/csr/disease/avian_influenze/country/case_table_2005_11_07/index.html (Nov. 8/05). For more on this, see www.fao.org/ag/againfo/subjects/en/health/diseases-cards/special_avian.html, and http://europa/eu/int/comm/food/animal/diseases/controlmeasures/avian/index_en.htm.

[19] Whereas the global population increases by approximately 3,000 every 20 minutes (+/-), one or more species of animal or plant life becomes extinct (some 27,000 species per year): www.overpopulation.org/faq.html (Aug. 16/05). Freshwater consumption has increased 6x in the last 100 years; 5 million people die annually from diarrhoea due to polluted water; 20% of the world's freshwater fish have disappeared or are endangered; some 63% of all species have been lost in the last 100 years and extinctions are occurring at increased rates; some 80% of forests have been cut worldwide and 40% of the remainder are threatened: L. Polansky, "The Ramifications of Population" (2000) 32 ZPG Reporter 5-13. Extinction rates are estimated at between 1,000 and 10,000 times greater than they would be naturally: S. Stuart, "Species: Unprecedented Extinction Rate, and It's Increasing" (2000) IUCN

armed conflicts (with resultant social dislocation),[20] none of the consequences of which are limited to the groupings identified above. With respect to health, this is resulting in a human tragedy and an ever-growing disparity between the "haves" and the "have-nots".[21] For example:

- though basic health(care) is viewed as a fundamental human right,[22] the 90/10 disequilibrium on global medical expenditure continues, and thereby ensures that enjoyment of health is very much differentiated between regions;[23]

- the public-to-private and developing-to-developed country migration of healthcare workers persists, and thereby negatively impacts on equitable healthcare delivery;[24]

- a model of development and international aid that is shaped by donor-agendas and characterised by poor coordination, weak management and inappropriate means of measuring benefits persists, and thereby fails to redress the healthcare deficit;[25] and

- private entities often fail to act in conformity with appropriate healthcare development practices,[26] erecting high drug prices,[27] conducting under-scrutinised multi-jurisdictional

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Special Feature at www.iucn.org/info_and_news/press/species2000.html (Aug. 16/05). Some 40% of the world's forests are threatened by mining, and 25% of the world's mammals and 11% of the world's birds are at risk of extinction due to population growth and loss of habitat: Population Connection, at www.populationconnection.org/factoids/ (Aug. 16/05).

[20] Health and security are linked: WHO, *The World Health Report 2003* (Geneva: WHO Publications, 2003). Increasingly vicious, ethnic-based wars in poor nations cause massive human suffering, social disruption, population displacement and loss of natural resources: M. Clarke, "War in the New International Order" (2001) 77 Int. Aff. 663-671. Some 90% of modern war victims are civilians, mostly women and children: Population Connection, at www.populationconnection.org/factoids/ (Aug. 16/05).

[21] See D. Gwatkin, "Health Inequalities and the Health of the Poor: What Do We Know? What Can We Do?" (2000) 78 Bull. WHO 3-18, S. Benatar, "Distributive Justice and Clinical Trials in the Third World" (2001) 22 Theo. Med. 169-176, and WHO, *World Health Report 2005* (Geneva: WHO Publications, 2005), at 13, wherein life expectancy by region is reported as follows: Africa – 46 (M), 48 (F); Americas – 71 (M), 77 (F); South-East Asia – 61 (M), 64 (F); Europe – 68 (M), 77 (F); Eastern Mediterranean – 61 (M), 64 (F); Western Pacific – 70 (M), 74 (F). The countries with the lowest life expectancy rates and healthy life expectancy rates are African. Compared to life expectancy in the UK of 76 (M) and 81 (F), life expectancy rates in Lesotho are 35 (M) and 40 (F), Swaziland are 33 (M) and 36 (F), and Zimbabwe are 37 (M) and 36 (F).

[22] See Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966). ["ICESCR (1966)"] Also see the Jakarta Declaration on Health Promotion into the 21 Century (1997), the People's Health Charter (2000), and J. Mann *et al.* (eds.), *Health and Human Rights* (NY: Routledge, 1999).

[23] WHO, *Investing in Health Research and Development* (Geneva: WHO Publications, 1999), Global Forum for Health Research, *10/90 Report on Health Research 2003-2004* (Geneva: GFHR, 2004), and D. Resnik, "The Distribution of Biomedical Research Resources and International Justice" (2004) 4 D.W.B. 42-57. Of 1,223 new drugs developed between 1975 and 1997, only 11 were for the treatment of tropical diseases, which are some of the largest killers: Y. Suzuki, "Keynote Address: International Conference of Drug Regulatory Authorities" (2003) at www.whqlibdoc.who.int/hq/2003/a79903_(chp3).pdf (Aug. 17/05). In 1993, cancer research spending in the UK alone was US$200 million, whereas malaria research spending was US$84 million worldwide: Nuffield Council, *The Ethics of Research Related to Healthcare in Developing Countries* (London: NCB, 2002), at 23, at www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_309.html (Nov. 30/05). Over 40 million people, mostly in resource-poor developing countries, have HIV/AIDS, and even those few that benefit from drug trials receive very little follow up treatment post-trial: Joint UN Program on HIV/AIDS, *AIDS Epidemic Update 2003* (Geneva: UN, 2003), available at www.unaids.org, and S. Benatar, "Global Disparities in Health and Human Rights" (1998) 88 A.J.P.H. 395-400.

[24] C. Sitthi-amorn *et al.*, "The Asian Voice in Building Equity in Health for Development – from the Asian Forum for Health Research" (2002) 17 Health Pol. Plan 213-217.

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[26] S. Benatar, *supra*, note 21, M. Angell, "The Pharmaceutical Industry – To Whom Is It Accountable" (2000) 352 N.E.J.M. 1902-1904, and Nuffield Council, *The Ethics of Clinical Research in Developing Countries* (London: NCB, 2001).

[27] Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: CIPR, 2002), at 6 and 24. The commodification of the intellectual property regime has permitted

trials which involve procurement of genetic samples,[28] and plundering underdeveloped countries for biological sources, and thereby instrumentalises large groups of people.[29]

Additionally, and ironically, this global health setting is exhibiting a marked and sharpening emphasis on the self, and not only by westerners familiar with rights-based language and ready to claim rights to health,[30] to reproduction,[31] and to information as well as informational and physical privacy[32] (as well as rights of/to privacy,[33] equality,[34] expression,[35] mobility,[36] freedom from arbitrary state interference[37]). This trend has lead to an emphasis on the vindication of autonomy-based individual rights in ethical and legal analyses (eg: as evidenced by the avalanche writing on consent in medical treatment),[38] and a growing discomfort with the recognition, imposition and enforcement of duties (eg: as demonstrated by our treatment of the environment,[39] and of fellow human beings in impoverished regions of the world[40]). In short,

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the pharmaceutical industry pursue artificial improvements (rather than truly new products) while keeping prices elevated: C. Chee Khoon, "Commodification and Market-Driven Biomedical Research" (2003), at www.biopolitics-berlin2003.org (Sep. 2/05).

[28] O. Corrigan, "Informed Consent: The Contradictory Ethical Safeguards in Pharmacogenetics" in R. Tutton & O. Corrigan (eds.), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (London: Routledge, 2004) 78-96. See also K. Shapiro & S. Benatar, "HIV Prevention Research and Global Inequality: Steps Towards Improved Standards of Care" (2005) 31 J.M.E. 39-37, wherein the authors describe several case studies.

[29] G. Stenton, "Biopiracy Within the Pharmaceutical Industry: A Stark Illustration of How Abusive, Manipulative and Perverse the Patenting Process Can be Towards Countries of the South" (2004) 26:1 E.I.P.R. 17-26. For examples of biopiracy, see www.grain.org.

[30] See Preamble, WHO Constitution (1948). Every country in the world is a party to at least one treaty addressing health-related rights, including the right to health: see www.who.int/hhr/en/ (Aug. 26/05).

[31] For more on this claimed right see A. Caplan *et al.*, "The Human Genome Project: What is Immoral About Eugenics?" (1999) 319 B.M.J. 1284, and B. Steinbock, "Rethinking the Right to Reproduce" at www.hsph.harvard.edu/organizations/healthnet/hupapers/reproright.html (Aug. 26/05).

[32] For an example such claims in a legal instrument, see the Convention on Biomedicine (1997).

[33] Internationally, see Article 12 (privacy, family, home, correspondence) of the Universal Declaration of Human Rights (1948), ["UDHR (1948)"] and Article 17 (privacy, family, home, correspondence) of the International Covenant on Civil and Political Rights (1966). ["ICCPR (1966)"] Regionally, see Article 8 (privacy, family, home, correspondence) of the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950). ["ECHR (1950)"] In the UK, see Article 8 (privacy, family, home, correspondence), Part I of Schedule 1 of the *Human Rights Act 1998* (UK) 1998, c. 42. ["HRA 1998"]

[34] See Articles 2 (entitlement to rights without distinction) and 7 (no discrimination) of the UDHR (1948), Articles 2 (no distinctions on named grounds), 3 (equality of men and women), 26 (no discrimination) and 27 (minority rights) of the ICCPR (1966), Article 14 (no discrimination) of the ECHR (1950), and Article 14 (no discrimination), Part I of Schedule 1 of the HRA 1998.

[35] See Articles 18 (thought, conscience, religion) and 19 (opinion, expression) of the UDHR (1948), Articles 18 (thought, conscience, religion) and 19 (opinion) of ICCPR (1966), Articles 9 (thought, conscience, religion) and 10 (expression) of the ECHR (1950), and Articles 9 (thought, conscience, religion) and 10 (expression), Part I of Schedule 1 of the HRA 1998.

[36] See Articles 13 (movement) and 14 (asylum) of the UDHR (1948), Article 12 (movement) of the ICCPR (1966), Articles 2 (movement) and 3 (no expulsion) of Protocol 4 (1963) of the ECHR (1950).

[37] See Articles 3 (life, liberty, security of the person), 8 (arrest, detention, exile), 10 (fair public hearing) of the UDHR (1948), Articles 6 (right to life) and 9 (liberty, security, fair trial) of the ICCPR (1966), Articles 5 (liberty, security) and 6 (fair trial) of the ECHR (1950), and Articles 5 (liberty, security) and 6 (fair trial), Part I of Schedule 1 of the HRA 1998.

[38] This trend has been highlighted by R. Chadwick, "The Iceland Database: Do Modern Times Need Modern Sagas?" (1999) 319 B.M.J. 441-444, R. Chadwick & K. Berg, "Solidarity and Equality: New Ethical Frameworks for Genetic Databases" (2001) 2 Nature: Rev. Gen. 318-321, D. Callahan, "Principlism and Communitarianism" (2003) 29 J.M.E. 287-291, S. Benatar, "Blinkered Bioethics" (2004) 30 J.M.E. 291-292, and others, who suggest that non-autonomy interests, when considered at all, are used to lead straight back to autonomy and individualism. Indeed, it has been claimed that autonomy is the primary if not the only interest worthy of protection: see R. Gillon, "Ethics Needs Principles – Four Can Encompass the Rest – and Respect for Autonomy Should be 'First Among Equals'" (2003) 29 J.M.E. 307-312.

[39] In 1998, the USA, with approximately 4% of the world's population, generated some 22% of the world's green-house-effect causing CO2 emissions: Your Planet Earth (2000), at www.yourplanetearth.org (Aug. 17/05).

[40] From 1982-1990, southern countries received US$927 million in aid, grants, trade credits, direct private

we (particularly in the west) are trading social context for individual freedom such that we are empowered and enabled, but isolated and disconnected; a trajectory that leads to an over-emphasis on consumption and inwardness with a corresponding alienation of the "other".[41] Such an emphasis makes it unlikely for the "haves" to seriously and effectively work toward the validation, empowerment and enhancement of the "have nots", especially those who may live (and die) thousands of miles away.

The immorality of the existing global milieu (whether assessed from a utilitarian, human rights or other perspective), seems self evident. Patients, wherever located, are becoming more aware of the expanding scope of healthcare capabilities, and have a legitimate interest in access to reasonable healthcare so they can maintain reasonably active and fulfilling lives. However, despite the incontrovertible truth that pursuit of human goals is heavily contingent on the health of people, communities and the environment (ie: nothing can be achieved without some reasonable level of health and fitness), they are unable to do so. There are no conditions under which we as moral agents can legitimately accept an expanding and fatal healthcare deficit for the global majority and a widely counter-productive emphasis on the importance of the individual as a self-motivated consumer of health and other resources extracted from around the world and with consequences for all parts of the world. Their continued existence suggests both that:

(1) our dominant ethical approaches to (health) problem-solving have obvious blind spots; and

(2) health solidarity, as an ethical value, must become a more integral aspect of these approaches, driving them toward responses that adopt a broad, community perspective and have a global reach.[42]

A global reach is all the more important given the rise of predictive medicine (involving genetic research and clinical genetics), which is driven by private global operators, thereby suggesting a need for regulatory responses which are similarly global.

(3) Summary / Conclusion

Solidarity, with its emphasis on the social context within which we live and our shared duties toward one another, encourages us to become "global citizens"; to be cognizant of and contribute to the global community to which we all belong and upon which we all rely. As defined above, solidarity is a moral vehicle for injecting legitimate concepts and considerations of community and interconnectedness into ethical and legal analyses. If the potential benefits of solidarity are to be realised (eg: redressing some of the shortcomings of the existing healthcare deficit), solidarity must be ranked equally with other popularly claimed and largely complimentary moral

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investment and loans, but paid out US$1.3 trillion in interest and principal. From 1991-1998, grants to developing countries went down from US$35 billion to US$23 billion. See S. Benatar, A. Daar & P. Singer, *supra*, note 12, A. Pettifor, *Debt, the Most Potent Form of Slavery* (London: Christian Aid Society, 1996), and P. Bond, "Globalization, Pharmaceutical Pricing and South African Health Policy" (1999) 29:4 I.J.H.S. 765-792.

[41] R. Brownsword, "Biotechnology and Rights: Where Are We Coming From and Where Are We Going?" in M. Klang & A. Murray (eds.), *Human Rights in the Digital Age* (London: Glasshouse, 2005) 219-234, at 232, and W. McKibben, *Enough* (London: Bloomsbury, 2003), at 47. See also J. Habermas, T*he Future of Human Nature* (Cambridge: Polity Press, 2003), F. Fukuyama, *Our Posthuman Future* (London: Profile, 2002).

[42] UNESCO, "Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics" (2005), at 10, has suggested that solidarity is an ethical imperative of growing importance given ideals of collective social protection and fair opportunity and the existence of serious inequalities in access to healthcare worldwide. S. Benatar, A. Daar & P. Singer, *supra*, note 12, claim that solidarity is the most important global health ethic and must be applied on a global basis. See also F. Mayor, "Statement at 'Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy'" 24th CIOMS Conference, Japan, 1990.

values such as sanctity of life and human dignity.

II. PRACTICAL SOLIDARITY: THE TRANSLATION OF (INTERNATIONAL) SOLIDARITY INTO RULES FOR HUMAN SUBJECT RESEARCH

If the solidarity value is to be realised, one must look beyond defining it and the social context to which it applies, and explore the types of actions which promote and flow from its realisation:

> What counts primarily is not an awareness of social association, but the actual practice of keeping associations intact and reforming associations in such a way that social ties may be upheld in a redefined way. This perspective [is] on action instead of merely values … . What counts is … the maintenance of a certain quality of social relationships.[43]

In short, one must articulate the quality of membership in society that is demanded by solidarity (regardless of the particular ethical theory to which one subscribes). As such, this Part offers some specific duties derived from the solidarity value which are applicable to the international healthcare and HSR context. In many ways, this is an imaginative exercise, the purpose being to determine the action that solidarity reasonably imposes (or could or should impose) on us as members of the global community toward others within that community. The duties articulated below are aimed at the realisation of a "decent" global society in which everyone's health is supported such that they can effectively participate in life. They address obligations to contribute to the common effort to protect life and equity in society, and they are not exhaustive. More could be added if one were to incorporate all health determinants (ie: education, nutrition, water, sanitation, communication infrastructure), but they are beyond the scope of the analysis, which now narrows to the promotion of global health through the development of biotechnology and research and HSR.

(1) Duty to Research

Propositions 1 and 2 above clearly suggest a duty to pursue scientific-medical knowledge for the "betterment of humanity" (ie: research directed toward preventing serious harm or providing significant benefits to humankind).[44] Given existing social and research structures, this duty settles on individual researchers, private entities and states.

With respect to public bodies, the realisation of this duty necessitates the strategic use of public research funds and the clear expression of research priorities to and from funding bodies. For example, public funds could be used for "frontier research" (ie: early stage or basic research which is amenable to multiple applications and could lead to unforeseen breakthroughs), and "gap research" (ie: projects which attempt to address diseases/conditions which are not as commercially lucrative and are therefore less likely to be tackled by private entities).

With respect to academic bodies and private entities, it suggests a similar responsibility to prepare morally defensible expressions of biotechnological/medical research priorities. Where notions of solidarity are steering health research, one would expect the research to be directed at conditions/diseases that are both widespread and, additionally, more narrowly experienced (and therefore not necessarily profitable to cure). Indeed, this would seem imperative given current concerns that market priorities are driving research and resulting in the value of research being measured by commercialisable results.[45]

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[43] R. ter Meulen *et al.*, *supra*, note 11.

[44] Indeed, the UN General Assembly has called for states to take measures to ensure that the results of scientific/technological advances are used for, and only for, the benefit of humankind: General Assembly Resolution 48/140, UN GAOR, 48th Sess., Supp. No. 49, UN Doc. A/48/49 (vol. 1) (1994).

[45] T. Schrecker, "Benefit-Sharing in the New Genomic Marketplace: Expanding the Ethical Frame of

(2) Duty to Capacity-Build

Given the stark and inequitable realities of the health deficit, and its dire consequences on individuals and populations, and given the wide disparities between the developed and the developing world with respect to the existence and application of ethical laws, regulations and guidelines and the existence of quality ethical review,[46] a "duty to capacity-build" is of vital importance. Such a duty is supported by Proposition 3 above, which, in practice, requires more enabled states and research bodies to enter into collaborations with less enabled states/bodies. Such activities would enhance the capability of "have nots" to identify local health priorities, to ethically review research proposals, to create opportunities for domestic researchers, and to avoid unfair research practices.[47] Importantly, capacity building must not only form an ongoing part of (ethical) multi-jurisdictional research, it must precede research:

> Parties affected by proposed health research projects need to become increasingly involved in designing and carrying out the research. … There is … broader recognition of the need and value of consulting local communities and involving potential participants in research early on in the process of designing research protocols.[48]

Pre-commencement collaboration and capacity-building is particularly important where host countries have set national health priorities, are endeavouring to ensure that research responds to societal needs, and are trying to weigh the benefits/risks to both participants and communities.

(3) Duty to Share

The solidarity value, by virtue of each of the above Propositions, supports a duty to disseminate and share biomedical knowledge and advances.[49] This is vital if exploitation is to be curtailed and the existing health deficit rectified. This duty imposes a responsibility on individual researchers, private entities and states to erect mechanisms for knowledge- and benefit-sharing (which includes making medical products available according to principles of fairness and decency[50]). Only by doing so can individuals enjoy their right to share in or enjoy the outcomes of scientific advancement, a universal right already enunciated in existing international human rights instruments,[51] and by the HUGO Statement on Benefit Sharing (2000),[52] which

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Reference" in B. Knoppers (ed.), *Populations and Genetics: Legal and Socio-Ethical Perspectives* (Boston: Martinus Nijhoff, 2003) 405-421.

[46] R. Macklin, "After Helsinki: Unresolved Issues in International Research" (2001) 11 K.I.E.J. 17-36.

[47] The necessity for such collaborations is identified in the Bangkok Declaration (2000). See also S. Tollman, "What Are the Effects of the Fifth Revision of the Declaration of Helsinki? Fair Partnerships Support Ethical Research" (2001) 323 B.M.J. 1417-1423. See also S. Benatar & P. Singer, "Beyond Helsinki: A Vision for Global Ethics" (2001) 322 B.M.J. 747-748. The idea of capacity building in less enabled states is being pursued within Europe through the EU Framework Programs and the work of the EST, which encourages joint projects, multi-state funding and international peer review: Conference, "Towards a European Research Area" (Oct. 19-21, 2005).

[48] M. Lansang & F. Crawley, "The Ethics of International Biomedical Research" (2000) 321 B.M.J. 777-778. See also F. Lolas, "Ethics in International Health Research: The Role of Transnational Organizations" (2000) at http://bmj.bmjjournals.com/cgi/eletters/321/7264/777 (Nov. 1/05).

[49] This duty is now widely acknowledged: D. Pullman & A. Latus, "Reconciling Social Justice and Economic Opportunism: Regulating the Newfoundland Genome" in B. Knoppers (ed.), *supra*, note 45, 543-564, at 543.

[50] For more on the inequity of the current distribution of medical resources, see www.pharmaportal.com, www.globalforumhealth.org and J. Watal, "Access to Essential Medicines in Developing Countries: Does the WTO TRIPS Agreement Hinder It?" (2000) Centre for International Development Discussion Paper No. 8.

[51] See Article 27 of the UDHR (1948), Article 15 of the ICESCR (1966), and Articles 1, 2 and 7 of the Convention on Biological Diversity (1992), which espouse sharing technology so as to exploit and preserve biological/genetic resources, and Articles 12, 15, 16, 17 and 18 of the same Convention, which envision sharing knowledge, research and biotechnology with developing states.

recommends that profit-making companies dedicate a percentage of their profits to healthcare infrastructure and/or humanitarian efforts. On a practical level, in the HSR context, one might expect governing/guiding instruments to directly and concisely address matters of (1) the standard of care of treatment to individual research subjects, (2) benefits for host populations , and (3) ongoing treatment for research subjects.

(4) Duty to Account

The solidarity value's emphasis on community and the construction of a just and fair society implicates a duty to account. That is the duty - of individual researchers, private entities and states - to report fully, honestly and regularly, on the performance of those tasks they have been given, to their stakeholders and the wider public so that their conformity to stakeholder/public interests and concerns can be monitored/measured.[53] Because failures also contribute to scientific knowledge and from failures one can find avenues to success, this includes reporting adverse results of ethical research, although it may not necessitate reporting adverse results from exploratory pilot studies aimed at generating hypotheses rather than proving them.[54] On a practical level, it requires legal instruments to clearly delineate and apportion oversight responsibilities and disclosure/dissemination responsibilities as between researchers and sponsors (whether private or public) so that accountability can be realised (and may demand the erection of variable standards and modes of disclosure/dissemination so as to ensure effective accountability in jurisdictions with low-capacity or inexpert institutions).

(5) Duty to Participate

It has been suggested that:

> … the fundamental reason why contemporary medical ethics has so little to say about public health is that its focus on individual autonomy suggests that all compulsion for the sake of health is wrong. … Thinking at the level of populations or groups requires a vetting of current ethical and legal principles and the development of a concept of the public good or of "common" goods.[55]

In short, an over-emphasis on autonomy-based individual rights causes problems for effective healthcare research, not only domestically, but internationally.[56] For example, strict compliance with western articulations of individual rights in countries where such rights are not similarly valued or defined could lead to misunderstandings and the abandonment of research that could benefit the host country. Similarly, strict compliance with such rights could impose onerous and expensive administrative requirements that cannot be met by researchers or participants in countries with diminished/developing capacity for research, and thereby hinder research.

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[52] HUGO Ethics Committee, "Statement on Benefit Sharing" (2000) at www.hugo-international.org/statement_on_benefit_sharing.htm (July 13/05).

[53] C. MacDonald, "Patents and Benefit-Sharing as a Challenge for Corporate Ethics" in B. Knoppers (ed.), *supra*, note 45, 505-523, at 515. See also S. Zadek, "Balancing Performance, Ethics and Accountability" (1998) 17 J. Bus. Eth. 1421-1441, at 1428, who states that social and ethical accounting, auditing and reporting provides a practical mechanism for companies to integrate new patterns of civil accountability and governance with a business success model focused on deepening stakeholder relationships around both financial and non-financial interests, and that effective methods for doing so are evolving.

[54] For the difference between these studies and hypothesis testing, and for a comment on the concerns about reporting the former, see L. Hirsch & H. Guess, "Some Clauses Will Hinder Development of New Drugs and Vaccines" (2001) 323 B.M.J. 1417-1423.

[55] B. Knoppers, "Of Genomics and Public Health: Building Public 'Goods'?" (2005) 173(10) C.M.A.J. 1185—1186.

[56] L. Eaton, "Nuffield Council Calls for Ethics Framework for Developing World Research" (2005) 330 B.M.J. 618.

The solidarity propositions reasonably impose a duty on individuals to contribute to the search for knowledge that will be used for the good of themselves and others (eg: to participate in HSR). This duty has been defended as follows:

> [T]here is clearly sometimes an obligation to make sacrifices for the community, or [for] an entitlement of the community to go so far as to deny autonomy and even violate bodily integrity in the public interest … . [W]e accept substantial degrees of compulsion or coercion in the interest of those coerced and in the public interest. Numerous examples can be given: limiting access to dangerous or addictive drugs or substances; … vaccination as a requirement … ; screening or diagnostic tests for pregnant mothers or for newborns; genetic profiling for those suspected of crimes; quarantine for some serious communicable diseases; … ; detention under mental health acts … . All of these [and others of a non-health nature, including jury duty, taxation, voting] involve some denial of autonomy [and] some imposition of public standards ...[57]

In short, so long as our own health is not unreasonably threatened and safeguards are in place to ensure respect of certain of our rights (eg: provision of information, anonymity of data, etc.), there is a strong argument for individuals having a moral obligation to take part in research where that research will further knowledge and help people in need, presently and in the future, locally and around the world.[58] Parenthetically, it is important to note here that the solidarity value does not abhor individual rights or enlightened self-interest. Rather, it recognises that individual freedom is contingent upon cooperative action toward others so they too can enjoy freedom; acts of solidarity are a means by which we empower others to pursue and by which others empower us to pursue our interests (the emphasis being on common interests which further the common good) and by which we realise our rights.

The most obvious consequence of this moral imperative to take part in research is that participation might be compelled without informed consent.[59] The subject's human rights are not so much trumped by society's interests as balanced against comparable rights of other people within the shared social context:

> [T]he contrast is not between vulnerable individuals … and an abstract entity such as 'society' … but rather between two different groups of vulnerable individuals. The rights and interests of research subjects are surely not served by privileging them at the expense of the rights and interests of those who will benefit from research. Both these groups are potentially vulnerable, neither is obviously *prima facie* more vulnerable or deserving of special protection.[60]

In articulating and promoting this duty, instruments would have to enumerate the purposes for which and the circumstances under which people (individuals and communities) are appropriately compelled to participate in research. Given the existing rights-based paradigm, the prominence of individual rights in international and domestic instruments, and the indisputable

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57 J. Harris, "Scientific Research is a Moral Duty" (2005) 31 J.M.E. 242-248.

58 See R. Chadwick & K. Berg, *supra*, note 38, at 320, and D. Macer & B. Su, "Privacy Versus Public Interest in Developing Human Genetic Databases" (2004) 14 Eubios J.A.I.B. 82-85.

59 J. Cassel & A. Young, "Why We Should Not Seek Individual Informed Consent for Participation in Heath Service Research" (2002) 328 B.M.J. 313-317, argue that over-reliance on autonomy-based consent in NHS research hinders the public good. Both H. Boter, *et al.*, "Patients' Evaluation of Informed Consent to Postponed Information: Cohort Study" (2004) 329 B.M.J. 86, and A. Dawson, "Methodological Reasons for Not Gaining Prior Informed Consent Are Sometimes Justified" (2004) 329 B.M.J. 87, also describe research projects where obtaining prior informed consent was not appropriate. S. Bhagwanjee *et al.*, "Why We Did Not Seek Informed Consent Before Testing Patients for HIV" (1997) 314 B.M.J. 1082, offer four conditions for foregoing consent.

60 J. Harris, *supra*, note 57.

good that stems from healthy levels of individual freedom, these circumstances would, presumably, be circumscribed. But their recognition and delineation are important if solidarity is to be realised in a practical sense.

(6) Summary / Conclusion

If solidarity is to be transformed from a purely rhetorical device into a practical device, it must be translated into social and political actions capable of recognition and enforcement in legal instruments.[61] The duties discussed above, though perhaps controversial, emerge from the solidarity propositions offered in Part I, and are all clearly capable of legislative enactment, or inclusion in international legal and policy instruments. Further, and importantly, being characterised as duties rather than rights, they are readily assignable and amenable to measurement (for compliance).

III. EXISTING SOLIDARITY: THE ARTICULATION OF (INTERNATIONAL) SOLIDARITY IN HUMAN SUBJECT RESEARCH

One must acknowledge that the autonomy value (and the individualist perspective) is dominant in both the Helsinki Declaration[62] and the CIOMS Guidelines[63], their core objective being to protect research subjects from the dangers of participating in research.[64] This is understandable given their genesis out of wartime medical research atrocities, and their evolution during a time when there was a perceived need to bolster the position of the individual. Given their tenor, one might question the choice of examining them for evidence of solidarity. However, I defend the choice on the following grounds:

- Although not legally binding (and with no enforcement mechanisms or sanctions for non-compliance), they are widely relied on in the biomedical research field around the world, often cited as the cornerstones of HSR.[65] The Helsinki Declaration in particular has been described as the most influential international instrument on ethical oversight of HSR,[66] portions of it having been incorporated into international guidelines, domestic regulations

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61 It is at this stage that the differences between solidarity and altruism become apparent. Legislators are reluctant to legally impose altruism, rightfully likening that concept to a personal sense of unselfish concern for others which cannot be compelled. Its very definition implies the observance of conduct that is not demanded. I would suggest that solidarity is more active and, with its derivative duties, more appropriately compellable.

62 The Helsinki Declaration, adopted in 1964 and most recently revised in 2000 (with two subsequent "Clarifications"), was a response to the abuses perpetrated in Nazi Germany against involuntary human research subjects in the name of biomedical science. These abuses prompted the Nuremberg Trials and the subsequent Nuremberg Code, drafted by the US judges who tried the cases.

63 The CIOMS Guidelines, adopted in 1982 and most recently revised in 2002, is primarily concerned with the application of the Helsinki Declaration principles in the context of multinational research implicating developing countries. It was largely a response to the special concerns arising from the HIV/AIDS pandemic and research activities related thereto: see www.cioms.ch/guidelines_nov_2002_blurb.htm (Sep. 8/05).

64 See H. Bastian, "What Are the Effects of the Fifth Revision of the Declaration of Helsinki? Gains and Losses for Rights of Consumers and Research Participants" (2001), 323 B.M.J. 1417-1423.

65 Z. Bhutta, "Ethics in International Health Research: A Perspective from the Developing World" (2002) 80 WHO Bull. 114-120. Nonetheless, and despite their moral authority, universal compliance with them has been questioned: E. van Veen, "Comments on the Draft CIOMS International Guidelines for Ethical Review of Epidemiological Studies" (2005) Medlawconsult, at www.medlaw.nl/documenten/comments.pdf (Nov. 3/05), and see comments in R. Macklin, *supra*, note 46, at 22-23.

66 See W. Carpenter *et al.*, "The Declaration of Helsinki and Clinical Trials: A Focus on Placebo-Controlled Trials in Schizophrenia" (2003) 160 A.J. Psychiatry 356-362, B. Christie, "Doctors Revise Declaration of Helsinki" (2000) 321 B.M.J. 913, F. Crawley & F. Hoet, "Ethics and Law: The Declaration of Helsinki Under Discussion" (1999) 150 Bull. M.E. 9-12, E. Deutsch & J. Taupitz, "Freedom of Control and Biomedical Research" (1999) 150 Bull. M.E. 22-24, and Editorial, "The Helsinki Declaration – Nothing to Declare" (1999) 353 Lancet 1285.

and human rights related instruments,[67] and informing the research protocols of various private entities.[68]

- They are directed at the health deficit in that their emphasis is multinational research and, in the case of the CIOMS Guidelines, protection of research subjects/communities/populations from the developing world.

- They were authored by broadly representative non-governmental organizations and were both recently revised.[69]

Ultimately, in the absence of any similarly respected international instruments founded on solidarity, the value must (currently) be sussed out of and vindicated through instruments like these. As such, this Part explores whether and to what extent these instruments recognise/promote solidarity in the HSR context. It does this by examining the position of the above solidarity related duties within them (ie: their presence, their clarity, and the extent to which they conform to the "ideals" suggested above).

(1) Duty to Research

The "duty to research" is addressed obliquely in Article 6 of the Helsinki Declaration, which states that proven prophylactic, diagnostic and therapeutic methods must be challenged and improved through research. A number of other provisions address not so much the "duty to research", but the need for sound scientific methods: Article 2 makes it a duty of all physicians to promote and safeguard "the health of the people"; Article 12 recommends caution with respect to research which might affect the environment or the welfare of animals. CIOMS Guideline 1 states that research must have "the prospect of discovering new ways of benefiting people's health". One might argue that this restricts opportunities for frontier science, but it is not difficult to find some health-benefiting hook to most well-planned research, and, given that the subject matter is HSR and experimentation, certain welfare-related limitations are reasonable. One can see that the "duty to research" finds only limited overt recognition in these instruments, the duty presumably being assumed. With respect to its more specific articulation, neither instrument goes so far as to emphasise or differentiate the specific duties of the specific actors as outlined above.

(2) Duty to Capacity Build

The "duty to capacity build" is not specifically addressed in the Helsinki Declaration, but CIOMS Guideline 20 enumerates several measures directed at enhancing ethical review and administrative expertise in developing world locales, including:

- strengthening review capacity by establishing competent independent review bodies;
- strengthening research capacity by training research and healthcare staff;

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[67] Z. Bhutta, *supra*, note 65, and D. Human & S. Fluss, "The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives" (2001), at www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf (Sep. 2/05).

[68] For example, Merck: L. Hirsch & H. Guess, *supra*, note 54.

[69] Although it has been accused of representing the "doers" of research and not the "researched", and of adopting an under-inclusive revision procedure (H. Bastian, *supra*, note 64), the WMA is comprised of representatives from approximately 80 national medical associations from all continents: see www.wma.net/e/about/index.htm (Sep. 2/05). CIOMS, founded under the auspices of the WHO and UNESCO in 1949, is comprised of 18 international organizations, 17 national representatives, and 25 associate members: see www.cioms.ch/frame_current_membership.htm (Sep. 7/05).

- developing technologies appropriate to healthcare and biomedical research; and
- educating the community from which subjects are drawn.

However, the CIOMS Guidelines do not specifically outline the ethical procedural characteristics of developed-developing world partnerships (eg: timing of capacity building activities, allocation of research roles, infrastructure investments, authorship credits, measures of capacity building among local researchers, health services and communities), which would seem essential if emerging jurisdictions are to enjoy some consistency of experience on which they can build their own expertise.[70]

(3) Duty to Share

Standard of Care: Article 29 of the Helsinki Declaration states that the benefits, risks, burdens and effectiveness of new methods should be tested against those of the best available method, and that placebos should only be used where no proven method exists. CIOMS Guideline 11 states that control groups should receive established and effective interventions and should only receive placebos where no effective intervention exists. The solidarity enhancing quality of these provisions is obvious – their intention being to get some reasonable level of treatment to participants.

However, difficult issues remain unresolved, such as the meaning of "standard of care" in the HSR context. Does it refer to what would constitute a best or ideal practice given the state of international medical knowledge? Or does it refer to the existing standard practice in response to that condition in the sponsoring country (often western), or the host country (which may have no standard because no treatment exists there), or is it some international standard (which might involve local/host experts determining the best maintainable diagnostic and therapeutic practices to be met given their circumstances)? This uncertainty diminishes the proscriptive value of these instruments. Indeed, an absence of precision has triggered controversy, with commentators (1) pointing to various (beneficial) projects which would not have proceeded had these provisions been interpreted so as to force provision of expensive western care in developing communities with little infrastructure to support or maintain it, and (2) lamenting the possible stymieing effect on research if it is so interpreted in future.[71] A solution which serves to reify the solidarity value probably lies in the "international standard" approach, which is more contextual in that it:

> … rejects the "bad, if not perfidious" local *de facto* standard while still permitting research to go forward that may not meet the stringent requirements of the global *de jure* standard. [It] would not permit researchers knowingly to deny subjects care that has proven effective for their illness in their population, and thus ensures that subjects … are not exploited. At the same time, [it] requires attention to substantive differences. In social, cultural and economic contexts and their impact on the permissibility of international research.[72]

In any event, it is clear that the provisions have the solidarity-promoting intention of ensuring some positive benefit to participants, but has no way of promoting much less ensuring any sort of consistent standard.

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[70] S. Tollman, *supra*, note 47.

[71] R. Macklin, *supra*, note 46, Z. Bhutta, *supra*, note 65, Z. Bhutta, "Standards of Care in Research" (2004) 329 B.M.J. 1114-1115, T. Richards, "Developed Countries Should Not Impose Ethics on Other Countries" (2002) 325 B.M.J. 796, N. Halsey *et al.*, "Ethics and International Research" (1999) 315 B.M.J. 965-966, and more.

[72] R. Macklin, *supra*, note 46, at 30. For a further discussion on this and the differences between the Helsinki Declaration and the old CIOMS Guidelines, see C. Weijer & J. Anderson, "The Ethics Wars: Disputes Over International Research" (2001) Hastings Centre Report 31, No. 3.

Benefits to Host Populations: Article 19 of the Helsinki Declaration states that research is only justified where there is a reasonable likelihood that the populations in which the research is being carried out stand to benefit from the results of the research. Similarly, CIOMS Guideline 10 stipulates that every effort must be taken to ensure that research is responsive to the health needs and priorities of the community/population of the host country and that the knowledge/intervention/product developed will be made reasonably available for the benefit of that population. Disappointingly, the instruments are not clear as to what constitutes "reasonable likelihood" of benefit, or what constitutes benefits being "reasonably available" (ie: what factors are relevant and how many are needed to tip the balance). This vagueness obviously has implications for the action-directing capabilities of these instruments.

Further vagueness-related concerns arise when looking at the instruments through the solidarity lens. For example, Article 19 of the Helsinki Declaration could be interpreted to limit participation in research to those who will benefit directly from the research (ie: to those who suffer from the condition investigated). Such an interpretation is bolstered by the overarching tone of the instrument and by Articles 5, 19, 24, 28 and 29, all of which suggest that the research must be in the direct interest of the subject him/herself.[73] Surely it is inappropriate to challenge the ethicality of research not directly beneficial to the participant(s) in experimental settings where consent has been obtained; such a challenge is offensive to solidarity in that it fails to acknowledge the duties to research and to participate. Alternatively, Article 19 could be interpreted as requiring researchers to ensure that the populations in which the research is undertaken (not necessarily limited to the participants *per se*) incur some identifiable benefit as a result of the research. On this point, it has been suggested that Article 19:

> … supports the position that to avoid exploitation, the research question and results should have relevance to and potential benefit for the population from which participants are drawn. However, it seems overly narrow and unjustifiable to restrict the notion of benefit to populations participating in research to benefits derived from the results of the research. A broader notion of benefits to the populations would recognise that benefits from the conduct of research (such as capacity development) and not restrict them to those linked solely with results.[74]

For purposes of realising solidarity, it is appropriate that subject communities/populations share in the benefits of the research. Whether that requires broad/diluted benefits such as dissemination of information/knowledge to subjects and capacity building in local communities, or narrow/direct benefits such as access to research outcomes (eg: new treatments or products if any are developed) by participants and/or their community, is open to debate.[75] For present purposes, the key is that the "duty to share" is clearly implicated, if not clearly articulated.

Continuation of Treatment: The idea that subjects (and communities) should continue to receive treatments on which they may have become dependent clearly implicates the "duty to share" by recognising that in "have not" communities, participation in trials is sometimes the only way to access new treatments (or any formal healthcare at all),[76] making the subsequent abandonment of subjects where some reasonable treatment has been developed or otherwise exists, morally questionable.

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[73] This interpretation is arrived at and lamented by J. Harris, *supra*, note 57, and by H. Forster *et al.*, "The 2000 Revision of the Declaration of Helsinki: A Step Forward or More Confusion?" (2001) 358 Lancet 1449-1453, who also cites the removal of the distinction between therapeutic and non-therapeutic research in the new version as a weakness. However, see C. Weijer & J. Anderson, *ibid*, at 18-20, who state that the previous distinction between therapeutic and non-therapeutic research was a major flaw.

[74] H. Forster *et al.*, *ibid*.

[75] For example, see some of the comments in Z. Bhutta, *supra*, note 65.

[76] See H. Bastian, *supra*, note 64.

Article 30 of the Helsinki Declaration, and its Explanatory Note, stipulate that, at the conclusion of studies incorporating medical care, subjects should retain the best proven care identified by the study. Similarly, CIOMS Guideline 21, which bolsters Guideline 10, stipulates that healthcare services should be provided throughout the course of the research and, where interventions or products are developed, they should be made "reasonably available" to the community/population concerned post-study. These provisions have generated vociferous debate,[77] stakeholders arguing that the concomitant added research preparation and expense could dissuade certain research. Similarly, it has been argued that:

> This debate needs to be resolved in a manner that does not preclude further development of health systems through targeted research. It should permit pragmatic improvement rather than waiting for revolutionary changes in health systems that may never happen. The development of low cost alternative interventions is only possible through such a process.[78]

Obviously, caution must be exercised in responding to complaints about added expenses because of the parochial interests which may be driving them.

For purposes of the present exercise, one can say that both instruments are supportive of the solidarity-justified duty to continue treatment at least for research subjects beyond the conclusion of the protocol where the known circumstances of the subject warrant it (although they pursue this in slightly different ways). Unfortunately, the provisions have met strong industry resistance, and the frailties of these instruments (eg: their non-enforceability) is here starkly exposed.

(4) Duty to Account

The Helsinki Declaration includes a host of "duty to account" provisions, many of them added in the most recent revision (and mostly as a means of protecting the individual). Articles 13, 14, 16 and 22 state that, where human subjects are anticipated, research protocols should:

- be preceded by careful risk/benefit analysis (with respect to both subject and society);
- contain information about funding/sponsors, affiliations and potential conflicts;
- contain a statement of ethical considerations;
- contain a statement of compliance with ethical principles;
- be reviewed by ethical committees independent of the investigator and the sponsor;
- be monitored on an ongoing basis and particularly in the case of an adverse event.

Article 27 also implicates accountability in its stipulation that funding sources, institutional affiliations, possible conflicts of interest, and results must be accurately reported and publicly disseminated.

Similar directions are contained in CIOMS Guideline 2, the Commentary for which specifically envisions possible reference to international review committees. Guideline 3 is directed at protecting the vulnerable by requiring ethical review in both sponsor country and host country. It tries to ensure that the most stringent and effective standards are applied, that there will be some capacity building in the host country, and that the research is responsive to the

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[77] See R. Macklin, *supra*, note 46, L. Hirsch & H. Guess, *supra*, note 54, , D. Human & S. Fluss, *supra*, note 67, and more. Indeed, there were almost immediate calls to revise Article 30, but the pressure to do so has thus far been resisted: see H. Frankish, "WMA Postpones Decision to Amend Declaration of Helsinki" (2003) 362 Lancet 963, and WMA, "Working Group Report on the Revision of Paragraph 30 of the Declaration of Helsinki", WG/DoH/Jan2004.

[78] A. Bhutta, *supra*, note 71.

health needs of the host population.[79] Guideline 18 imposes the responsibility of establishing confidentiality safeguards and reporting the limits of same to subjects.

Clearly both instruments are mindful of the concept of stringent accountability, and to that extent promote solidarity. The Helsinki Declaration's provisions in particular represent an improvement over previous versions; however, it fails to specifically recognize and address the ethical oversight and accountability duties of the host country.[80] The CIOMS Guidelines' dual review procedure avoids this weakness, but fails to identify the appropriate course when opposite outcomes on ethicality are arrived at by host and sponsor country institutions. This lack of clarity has led to debates over the danger of imposing inappropriate western principles to culturally distinct communities in developing countries, on the one hand, and the immorality of conducting research in developing countries just because it is cheaper and laws are more lax, on the other hand.[81]

(5) Duty to Participate

Given its historical backdrop, it is unsurprising that the Helsinki Declaration does not endorse the "duty to participate". Rather, it seeks to promote participation through individual participant protections. For example, Article 5 stipulates that the well-being of the subject takes precedence over the interests of science and society, and Article 8 states that research must promote respect for all humans and protect their health and rights. Curiously, however, Article 8 characterises subjects who will not personally benefit from research as "vulnerable" and in need of "special protection", thereby capturing those who are otherwise of sound mind and body (and suggesting that everyone is vulnerable and in need of special protection). Article 24 bars participation of incompetents except in very limited cases where the health of the population they represent (those with a similar condition?) is benefited and no competent subjects are available. Article 17 restricts research to that where the risks are assessed and managed, which could arguably bar pilot studies and phase I studies (which naturally entail unpredictable risks).

Although the "duty to participate" is equally absent from the CIOMS Guidelines, they arguably adopt a more balanced approach to participation promotion. Guideline 8 states, *inter alia*, that where no benefit is expected to the subject, the risk must be reasonable in comparison to the benefit to society, thus explicitly endorsing the possibility of exposing (healthy) individuals to risk for society. Guideline 12 highlights the need to choose research subjects with a view to the equitable distribution of benefits and burdens.[82] Guideline 13 and its Commentary offers more explicit action-guidance by specifying groups that are considered vulnerable and deserving of special protection, being those who are incapable of protecting their interests because they have insufficient power, intelligence, education, resources, strength or other needed attributes (ie: children, the mentally handicapped, subordinate members of a hierarchy, the poor, the aged, etc.).[83]

The Helsinki Declaration's over-expansiveness, which stems from its lack of clarity, is contrary to the solidarity value and may actually hinder research,[84] because it erects hurdles to the recruitment of participants and creates an atmosphere of "selfism" not particularly conducive to research participation. The CIOMS Guidelines, though falling well short of endorsing

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79 See Commentary on Guideline 3, at www.cioms.ch/guidelines_nov_2002_blurb.htm (Sep. 8/05).

80 S. Tollman, *supra*, note 47.

81 See the discussion in Nuffield Council, *supra*, note 26. D. Christie, *supra*, note 66, argues that something is either moral or not and the same ethical rules should apply wherever research is conducted.

82 H. Bastian, *supra*, note 64, considers this a "limited approach" to the concept of access to research, which is absent in the Helsinki Declaration.

83 Guidelines 14 (children), 15 (mental/behavioural disorder), 16 (women) and 17 (pregnant women) offer guidance in specific circumstances. For more on vulnerability, see R. Macklin, "Bioethics, Vulnerability, and Protection" (2003) 17 Bioethics 472-486, D. Zion *et al.*, "The Declaration of Helsinki, CIOMS and the Ethics of Research on Vulnerable Populations" (2000) 6 Nature Med. 615-617.

84 H. Forster *et al.*, *supra*, note 73.

research participation as a duty which we all have toward humankind and the society in which we live, offers better guidance which is directed at making participation safer and, by implication, more desirable.

(6) Summary / Conclusion

Although they are obviously founded on other values, particularly autonomy, both the Helsinki Declaration and the CIOMS Guidelines contain solidarity notions (ie: highlight the need for reciprocity, equity and accountability), which, if pursued systematically within the arena addressed, might enhance global health and healthcare equity, the ultimate goal being the realisation of a more just, fair and decent global society. However, the strongest measures for situating the person within the social context are absent. Given our consistent and continued failure to protect and equitably utilize resources from the global commons, from plants to people, the absence of more instructive and complimentary expressions (ie: the same duties in the same language) of the duties is disappointing. Indeed, their separate revisions, which occurred very close to one another, represent a real collaborative opportunity lost. A more cooperative approach to reforming the global HSR arena might have entailed the following:

- revocation of the "complex and often conflicting"[85] matrix of declaratory instruments in the HSR field, and collaboration between the WHO, UNESCO, WMA, CIOMS, and ICH, in drafting a single, overtly prescriptive, ethical instrument for use by all stakeholders which (1) contained concise rules and complete supportive commentaries, (2) emphasised the duties outlined above and articulating how they could be achieved by the various stakeholders, (3) offered factors for measuring compliance and success, and (4) suggested consequences for non-compliance;

- establishment of a single international auditor of all developing country HSR conducted by external sponsors so that systematic monitoring of research expenditure could be undertaken on an ongoing basis (which would allow for long term tracking and broad performance/outcome evaluations); and

- formation, education and funding of accountable and independent ethics committees in every developing country through a single program sponsored by the international community, including the WHO, UNDP, SIDCER, World Bank, which committees would be specifically capable of addressing the special issues which arise in developed-developing country research partnerships (ie: relevance to host healthcare priorities, scientific validity, international ethical acceptability, etc.).

Such an approach to the process of governance (as compared to the substance of the guidance) promotes solidarity in a number of respects. It models international cooperation and democracy, it capacity-builds in those who participate, and it brings an important field more in line with justice by rationalising and streamlining what is currently complex and disjointed. In addition to supporting solidarity, such an endeavour would offer policy-makers the opportunity to more explicitly include solidarity duties in the substantive provisions of the new instrument.

CONCLUSION

Over time, the conceptual framework structuring the delivery of personal healthcare has evolved from one characterised by paternalism to one of partnership (between physician and patient). A

[85] Nuffield Council, The *Ethics of Research Related to Healthcare in Developing Countries* (London: NCB, 2005) at www.nuffieldbioethics.org/go/ourwork/developingcountries/publication_169.html (Nov 30/05).

similar evolution has not been experienced in public healthcare, and certainly not at the global level; great swathes of people are treated paternalistically and disadvantageously with respect to access to knowledge, resources, and services. The causes of this uneven evolution are numerous and include the structure of the global market and its transfer of healthcare influence to profit-driven entities with self-serving agendas and paternalistic attitudes toward development, and the emphasis on the individual patient (and what s/he can secure for self) in "have" regions around the global. The result is that real advances for patients are unevenly enjoyed around the globe. It is past time to shift from this paradigm (which is not working) to one of global citizenship.

This paper explored a conceptual/ethical vehicle for pursuing that shift – the solidarity value. Greater attention to it and some of its derivative duties (eg: to research, to capacity-build, to share, to account, and to participate) in legal instruments and ethical assessments of domestic and international healthcare activities could lead to the adoption of conduct that could realise the benefits promised by the value, namely a fairer, just and descent society where people are not "left behind" on the basis of geography; a society that acknowledges and embraces its obvious and intimate global linkages. This paper also assessed two international instruments, using the solidarity duties as the evaluative criteria. Although some notions of solidarity are clearly present, they fall short of the ideal and have no chance of realising the paradigm shift called for here and elsewhere.[86] Indeed, that stakeholders cannot even agree on whether these instruments are "prescriptive" (stating ideals that ought to be met so as to ensure the highest standards), or "descriptive" (merely reflective of existing best practices to which most researchers adhere), makes the chances of them being used in any uniform way remote; they will continue to be used as researchers see fit.

Many of the characteristics of our converging global community reflect the truth of the sentiment contained in Donne's famous words:

> No man is an island, entire of itself;
> Every man is a piece of the continent, a part of the main.
> If a clod be washed away by the sea, Europe be the less
> …
> Any man's death diminishes me because I am involved in mankind.
> And therefore, never send to know for whom the bell tolls;
> It tolls for thee.[87]

In short, humans, collectively considered a class deserving of special respect and generally sharing a desire to be healthy, are irrevocable intertwined. We are comparably susceptible to disease, which creates needs in sufferers, families, carers and the community that are common around the world (ie: resources, basic treatment, emotional support, etc.).[88] We all experience and perpetuate the global health deficit in some way, and events in faraway regions can impact directly on our health, well-being and general conduct.[89] We all benefit to wildly varying

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[86] Calls for a shift from "adversarial national security paradigms" towards a more inclusive, compromising, multilateral and engaging "cooperative global security paradigms" have already been made: see S. Benatar, A. Daal & P. Singer, *supra*, note 12, at 129-138, M. MccGwire, "Shifting the Paradigm" (2001) 77 Int. Aff. 1-28, M. McGwire, "The Paradigm That Lost Its Way" (2001) 77 Int. Aff. 777-803, and I. Wallerstein, *The End of the World as We Know It: Social Science for the Twenty-First Century* (Minnesota: UMP, 1999).

[87] J. Donne, Meditation XVII, "Devotions Upon Emergent Occasions" (1624), at http://en.wikipedia.org/wiki/john_donne (Aug. 24/05).

[88] Although basic needs are common, disease burdens are not equally shared and capacities are not evenly enjoyed, so specific needs may be heterogeneous. As such, different communities will have different levels and particulars of needs (and responsibilities). This does not negate the validity of the statement that our needs draw us together, particularly now that global mobility is facilitating disease mobility.

[89] One need only look at the impact of the SARS outbreak in China, which spread across the ocean to Canada. For more on that outbreak, see www.who.int/topics/sars/en/, D. Macer (ed.), *Bioethics for Informed Citizens Across Cultures* (NZ: Eubios Ethics Institute, 2004), at 24, and more.

degrees from living in a society which pursues research; the very knowledge that research is being undertaken on conditions that we have or may eventually suffer from is a thread that ties all people together.[90] In short, we are not islands onto ourselves, but pieces of the whole, and we must strive to better act as though others' deaths diminish us as a collective. Unfortunately, there is a disconnect between the ideals expressed in our most aspirational (and recent) declarations on human and social rights (and in poetic sentiments like Donne's) and the instruments which more directly govern our actions (like the Helsinki Declaration and the CIOMS Guidelines). To shift the paradigm, we must redress this disconnect, and establish institutions with the ability to enforce conduct which is globally utilitarian and therefore better capable of actively enhancing the health and human dignity of everyone. In the HSR context, we might start by drawing more heavily on the solidarity value.

[90] J. Harris, *supra*, note 57.

FROM ENGAGEMENT TO RE-ENGAGEMENT: THE EXPRESSION OF MORAL VALUES IN EUROPEAN PATENT PROCEEDINGS, PRESENT AND FUTURE

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Abstract: In the regulation of new technologies, publics are often left questioning the value of their contribution to the final regulatory content, or feeling excluded from the regulation-making loop altogether. Dissatisfaction with upstream participation naturally results in stakeholders looking further downstream for influence. In the biotechnology arena, patent proceedings represent a participatory tool for stakeholders who may have been left out of or failed to achieve their goals upstream. Although they may have a reduced capability for shifting paradigms or shaping policy formulation, downstream expressions of values can be lively, and the acceptance or rejection of stakeholder positions by downstream regulators can be of great significance. Here the use of the morality provision in EPO proceedings is contrasted as between earlier and more recent decisions. It suggests which values have been given expression in this forum, how they have changed over time and how a wider pool of values might be incorporated into the existing system.

Keywords: health research; stem cells; governance; engagement; participation; patents; bioethics; values; solidarity; WARF; Edinburgh

INTRODUCTION

Biotechnologies are more important than ever before. Fluctuations in research funding influence (positively and negatively) scientific workforces and innovation and productivity trajectories. Advances drive social change and economic growth; new products and processes increasingly play a central role in our daily lives, shaping communication, information processing, health.[1] With respect to health, biotech research is resulting in increasingly sophisticated analyses of living matter, and is expected to lead to targeted therapies for simple and complex diseases, common and rare. Promoting and regulating biotech research and innovation, and determining the social uses to which it is appropriately put, is an important and sensitive undertaking which must include the public. We are currently in transition both with respect to how publics are engaged in this policy-making process and how the engagement outcome (law) deals with biotech innovation.

This paper has the dual purpose of examining both the engagement and the

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1 J. Morales & A. Coop, "Shopping for Science: Paths to Science for Everyone" (2005) 13 Natural Selections 1-3, and HM Treasury, *Science and Innovation Investment Framework 2004-2014* (2004) at www.hm-treasury.gov.uk/media/95846/spend04_sciencedoc_1_090704.pdf (Dec. 14/05).

expression of values during engagement exercises in the context of the Biotechnology Patenting Directive 98/44/EC ("BPD"),[2] which, given the ubiquity of patenting in the biotech field,[3] and the disputed consequences of patenting for its future development,[4] will be of increasing importance. Part I outlines the engagement transition and examines the engagement processes and moral perspectives associated with the formulation of the BPD. Part II outlines European patent law and examines the primary values and moral approaches identifiable in the BPD as a substantive output of a participatory exercise. The premise of Part III is that statutorily permitted legal interventions represent a participatory tool through which stakeholders can re-engage with policy and other stakeholders, reiterating their policy positions and influencing not the formulation of policy but the execution of policy and the realisation of rights and benefits thereunder. The intervention examined is genetic patent proceedings at the European Patent Office ("EPO"), which necessitate decisions on/at the commercialisation stage of innovation. Part IV queries how the moral base for such decisions might be broadened to give practical effect to some of the idealistic rhetoric in recent international instruments.

As a preliminary matter, it is appropriate to state the reasons for assessing EPO decisions. First, although the EPO is not an EU institution and is not bound by the BPD, its functions mirror the BPD's purpose. Indeed, it has amended its *Examination Guidelines* and its *Implementing Regulations to the EPC*, both of which serve as interpretive aids for the European Patent Convention ("EPC"), to conform to the BPD. As such, it represents the first and foremost institution to adopt the BPD. Second, recognizing that patents are tools for promoting and regulating biotechnology innovation, EPO proceedings, particularly morality-based opposition proceedings, have become an important forum for stakeholder participation, as evidenced by the following:[5]

(1) The EPO has a clear morality mandate under the EPC and has become a crucible for morally-based challenges to scientific innovation and commercialisation.

(2) Opposition decisions constitute governmental action which sets boundaries, provides science with legitimacy, and shapes conduct (influencing research programs and economic fortunes).

(3) Whereas the morality provision was originally viewed as an unremarkable and infrequently used but necessary safeguard at the

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[2] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, available at (30.7.1998) O.J. L. 213, at 13-21, and at http://europa.eu.int/.

[3] In 1980, 16 gene patents had been awarded; by 1990 there were over 6,000, and by 2000, there were over 355,000: J. Sulston, "Heritage of Humanity" (2002), at http://mondediplo.com/2002/12/15genome.pdf (Mar. 9/06).

[4] Some argue that it is necessary for biotech innovation and the development of disease cures. Others argue that it stifles innovation through its creation of complexity and additional research expense: R. Gold *et al.*, "Needed: Models of Biotechnology Intellectual Property" (2002) 20 Issues in Biotech. 327-329.

[5] See E. Armitage & I. Davies, *Patents and Morality in Perspective* (London: IPI, 1994), , S. Halliday & D. Steinberg, "The Regulated Gene: New Legal Dilemmas" (2004) 12 M.L.R. 2-13, R. Witek, "Ethics and Patentability in Biotechnology" (2005) 11 Sci. Eng. Ethics 105-111, and O. Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Aldershot: Ashgate, 2005).

margins of the system, it was not written to reflect that desire and has evolved into an increasingly-utilised tool for managing/influencing innovation.

(4) Oppositions have similarly evolved: in 1985, the EPO stated that it would be wrong to regard oppositions as contentious proceedings between warring parties where the deciding body takes a neutral position;[6] by 1993, it described oppositions as "contentious proceedings between parties normally representing opposite interests, who should be given equally fair treatment".[7]

Ultimately, although EPO rulings are not binding on EPC signatories or EU members, they are persuasive to policy-makers, and courts tend to accept their authority, making them a worthy subject for an assessment of the trajectory of European policy.[8]

I. ENGAGEMENT: THE PUBLIC IN THE POLICY-MAKING PROCESS

(1) Overview of Public Engagement Practices

Public participation was traditionally viewed (by policy-makers and scientific authorities) as a means of educating the public – instilling greater understanding of science. It was hoped that this transfer of knowledge would alleviate some of the ambiguity around science and relieve the "crisis of trust" surrounding biotechnologies and their regulation.[9] This was the general approach adopted during the controversial attempt to introduce genetically modified foods in Europe. The perception that authorities used public engagement processes as an *ex post facto* attempt at public legitimation spurred demands for greater transparency in governmental processes which touch on human biotechnologies and their regulation.[10]

Repeated calls for a shift from "government" to "governance" and an increased role for public participation in policy-making transformed the one-way educational model into a two-way dialogue; a more active public engagement characterised by information exchange.[11] However, this new model was criticised as

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6 *MOBIL OIL / Opposition by Proprietor*, [1985] O.J. EPO 299 (EAD).

7 *ROHM & HAAS / Power to Examine*, [1993] O.J. EPO 408 (EAD).

8 G. Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (Aldershot: Ashgate, 2003).

9 M. Jones & B. Salter, "The Governance of Human Genetics: Policy Discourse and Constructions of Public Trust" (2003) 22 New Gen. & Soc. 21-41.

10 C. Stewart Jr. *et al.*, "Transgenic Plants and Biosafety: Science, Misconceptions and Public Perceptions" (2000) 29 Biotechniques 832-843, G. Gaskill *et al.*, *Report: Ambivalent GM Nation? Public Attitudes to Biotechnology in the UK, 1991-2002* (London: LSE, 2003), and J. Tait, "Risk and Uncertainty in Genetically Modified Crop Development: The Industry Perspective" (2003) at www.innogen.ac.uk/publications/publication-2.

11 "Government" is a pattern of rule characterised by top-down decision-making by elected officials and hierarchically structured bureaucratic policy-makers within the context of the state and having recourse to its authoritative institutions. "Governance" is a pattern of rule characterised by increased networks of influence between civil society and the state and an increased role for non-government actors in policy-making. See I. Bache, "Governing Through Governance: Education Policy Control Under New Labour" (2003) 51 Pol. Studies 300-314, M. Bevir *et al.*, "Comparative Governance: Prospects and Lessons" (2003) 81 Pub. Admin. 191-210, and C. Lyall, Governing Genomics: New Governance Tools for New Technologies?" (2006) at www.innogen.ac.uk/publications/publication-45. Studies show that public understanding of biotechnology is greater and more critical than originally anticipated: A. Kerr *et al.*, "The New

occurring too far "downstream" (ie: after the innovation process was set, leaving little potential to influence the shape of that process or consider much less answer broader social/political questions surrounding the subject biotechnology).[12] A common criticism:

> … Processes of engagement tend to be restricted to particular questions, posed at particular stages in the cycle of research, development and exploitation. Possible risks are endlessly debated, while deeper questions about the values, visions and vested interests that motivate scientific endeavour often remain unasked or unanswered.[13]

Thus, even within the context of the governance model, the manner and function of participation needed to evolve.

Stakeholders thus tried to move public engagement "upstream" – before key development decisions (such as R&D priority-setting) are made and stakeholder positions entrenched.[14] "Upstream" mechanisms such as deliberative polling and mapping, focus groups, citizens' juries, consensus conferences and stakeholder study circles, were seen as capable of doing much more than simply examining the impacts, risks and consequences of the subject biotechnology.[15] If appropriately integrated into political decision-making, they could better address broader social/political questions like:[16] (1) For what purposes are we developing this biotechnology? (ie: what needs/desires are driving its development?) (2) Who should own/control biotechnology and related knowledge? (3) Who has responsibility for it and what is that responsibility? (4) Who benefits from the biotechnology?

Presumably having learned from the GM foods debacle, authorities moved discourses concerning human biotechnologies further "upstream". And although these discourses were widely viewed as improved, they still suffered from a lack of demonstrable impact. Some of the new "upstream" participatory models provided:

> … legitimacy to political decisions without requiring decision-makers to enact its recommendations when they ran counter to government policy. … [O]ne report of a consultation listed the issue of reproductive cloning as one where both government policy and the consultation results agreed. It then described an issue where they disagreed … then moved seamlessly on to reject the possibility of

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Genetics and Health: Mobilizing Lay Expertise" (1998) 7 Public Understand. Sci. 41-60, and B. Bates, "Public Culture and Public Understanding of Genetics: A Focus Group Study" (2005) 14 Pub. Understand. Sci. 47-65.

12 M. Kearns *et al.*, "Nanotechnology, Governance and Public Deliberation: What Role for the Social Sciences?" (2005) at http://nanoandsociety.com/ourlibrary/documents/NanoGov.pdf (Dec. 13/05).

13 DEMOS, *See-Through Science: Why Public Engagement Needs to Move Upstream* (London: Demos, 2004), at 18.

14 The Royal Society, *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (2004) at www.nanotec.org.uk/finalReport.htm (Dec. 14/05).

15 DEMOS, *supra*, note 13, at 41-45. See also S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: PUP, 2005).

16 M. Kearns *et al.*, *supra*, note 12.

amending existing legislation to reflect this response … .[17]

In short, participants wanted to know that their participation affected policies and trajectories of innovation, but were frequently left questioning the real value of their input; they had no way to measure the influence or efficacy of their contribution to the final regulatory content.[18]

So where does the policy-making process used for the BPD fall on this public engagement spectrum?

(2) Engagement Activities Surrounding the BPD

Although patents originated in an era of mechanisation, they have been extended to new areas of innovation (ie: chemicals, pharmaceuticals, software).[19] In terms of jurisprudence, the door for patenting biotechnology was opened in 1980 by *Diamond* v. *Chakrabarty*,[20] an American case wherein the patentee produced a bacterium which fed on oil. The Court held that a live, man-made micro-organism is patentable, saying that, "anything under the sun made by man" could be patented. After *Chakrabarty*, the US biotech industry positively bloomed.

Motivated by the diminishing competitiveness of European biotech companies, and the threatened relocation of European companies to the USA due to the perceived disadvantages of Europe's patchwork biotech patenting rules, the European Commission ("EC") sought to clarify patenting principles re: biotechnology and harmonise them across member states.[21] The EC's draft directive (initially prepared with little public debate) proved to be the first step in a long and acrimonious 10-year political struggle characterised by intense stakeholder activity all along the "stream" of development, from first presentation to final promulgation (though it is questionable whether much of that activity was planned at the outset).

The initial and subsequent drafts were supported and promoted by industry stakeholders, who consulted with the EC from early stages and continued to campaign/lobby as the process progressed. Adopting a primarily economic utilitarian approach, they argued, *inter alia*, that patents:[22]

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[17] M. Jones & B. Salter, *supra*, note 9, at 33, and DEMOS, *supra*, note 13, at 18. Commentary, "Going Public" (2004) 431 Nature 883, reports that, in 2003, the UK government held a public debate on genetic modification and "is widely believed to have ignored the results".

[18] DEMOS, *supra*, note 13, at 16, 22 and 38, and National Consumer Council, *Winning the Risk Game* (London: NCC, 2003), at 21.

[19] C. Martinez & D. Guellec, "Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan and Europe" (2004), at www.oecd.org/dataoecd/39/21/34447828.pdf (Jan. 18/06). Article 27(1) TRIPS Agreement (1994) states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." The first patent on living matter was granted in Finland in 1843 and then by the US in 1873 (to Louis Pasteur for a yeast free from organic disease): EGE, "Opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions" (1993), at www.eu.int/comm/european_group_ethics/gaieb/en/opinion3.pdf (Feb. 22/06).

[20] (1980), 447 U.S. 303 (USSC).

[21] S. Thaker, "The Criticality of Non-Market Strategies: The European Biotechnology Patents Directive (2003), at www.kellogg.northwestern.edu/academic/biotech/articles/shail.pdf (Jan. 18/06).

[22] Proponents included European, US and Japanese companies and trade associations, certain scientific organisation and patients' organisations. For more on their position, see S. Emmott, "No Patents on Life: The Incredible Ten-Year Campaign Against the European patent Directive" in B. Tokar (ed.), *Redesigning Life? The Worldwide Challenge to Genetic Engineering* (London: Zed, 2001)

- incite firms/individuals to invest and create;
- protect the value of the knowledge that resides in advances/inventions;
- encourage economic growth and competitiveness and therefore jobs;
- are properly available for any invention with a commercial potential; and
- have a natural and direct relationship with (medical) cures.

The drafts were condemned by anti-legislation stakeholders who advanced a plurality of moral approaches.[23] They argued, *inter alia*, that the granting of private monopolies over living material:[24]

- is fundamentally immoral and contrary to human dignity;
- is undemocratic and blocks access to fundamental resources (including food and medicine) to which all humans have rights;
- stifles research by driving up research costs and complicating the research arena, creating inefficiency and disincentives; and
- dilutes the patentability criteria, leading to the patenting of mere discoveries and the expansion of biopiracy.

The political storm, powered by divergent interests and visions of acceptable scientific endeavour, involved the use of public meetings and conferences, open letters and resolutions, submissions to MEPs, and tireless pamphleteering, picketing, lobbying and negotiating, and was punctuated by allegations of sharp practice and dishonesty (usually directed at pro-BPD industry).[25]

A consequence of the moral plurality was that stakeholders negotiated concessions to morally informed positions in their attempts to secure the inclusion of certain provisions.[26] The horse-trading resulted in the original draft being amended to include (1) a statement that the human body is not patentable, (2) a requirement that function must be disclosed in the patent application, (3) a limited farmers' privilege to

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373-384, and European Federation of Biotechnology, "Patenting in Biotechnology" (1996), at www.efb-central.org/images/uploads/patenting_in_biotechnology_english.pdf (Mar. 8/06).

[23] This loose alliance included hundreds of agencies, including the Green Party, Greenpeace, Friends of the Earth, GRAIN, ETC Group, ActionAid, European Farmers' Coordination, European Christian Environmental Network, European Ecumenical Commission for Church and Society, Church of Scotland, Misereor (German Catholic Bishops), EKD (German Evangelical Church), and more.

[24] See J. Thompson, "Against Patenting Lifeforms" (1995), at www.hindunet.org/srh_home/1995_11/msg00067.html (Feb. 22/06), H. Gavaghan, "EU Ends 10-Year Battle Over Biopatents" (1998), at www.sciencemag.org/cgi/content/full/280/5367/1188 (Feb. 22/06), J. Rifkin, *The Biotech Century: Harnessing and Remaking the World* (NY: JP Tarcher, 1998), J. Ikerd, "The Case Against Patenting Life" (2004), at www.ssu.missouri.edu/faculty/jikerd/papers/SFT-Patenting%20Life.htm (Feb. 22/06). See also the Joint Appeal Against Human and Animal Patenting (1995), discussed in T. Peters, "Opinion: Patenting Life: Yes" (1996) at www.leaderu.com/ftissues/ft9605/opinio/peters.html (Feb. 22/06).

[25] S. Emmott, "The Directive is Dead" (1995), at www.grain.org/seedling/?id=64 (Mar. 8/06), and others. For an example of an open letter to the EP: GAIA Foundation, "Consequences of the EU Patent Directive" (1998), at www.psrast.org/gaiapat.htm (Mar. 8/06).

[26] K. Liddell, "Developing Patent Policy In Pluralist Societies" (2002), at www.shef.ac.uk/ipgenethics/conference/papers/liddell.pdf (Jan. 18/06), at 4, and R. Gold, "The European Biotech Directive: Past as Prologue" (2001) 7 E.L.J. 331-366.

reuse the product of the harvest, (4) a power of referral to an ethics group, and (5) a morality provision with express reference to inventions which cannot be patented.[27] Attempts to include other limitations were abandoned as expediency required. For example, provisions (1) prohibiting the development and patenting of genetic weapons, (2) directed at limiting the possibility of biopiracy, and (3) broadening the scope of the farmers' privilege, all failed.[28]

In 1998, after multiple drafts and votes, a conciliation procedure, and the use, for the first time, of the European Parliament's veto power, the BPD was adopted.[29] Reflecting its difficult birth, it constitutes a hodgepodge of moral approaches, including utilitarian, human rights and dignitarian.[30] The utilitarian approach weighs probable benefits and harms/dangers in determining whether a particular course should be pursued. The particular utilitarian approach advanced is informed by neo-liberal capitalist ideology; it assumes that securing financial reward/gain is a "good", and adopts the traditional wisdom that permissive patentability encourages the "good" of economic growth and scientific advancement for the (potential) benefit of humanity (ie: corporate self-interest results in socially beneficial outputs). The human rights approach generally emphasises human agency and individual autonomy (ie: physical, psychological, economic and legal liberty and freedom from coercion). The dignitarian approach has been described as follows:

> [T]he dignitarian view gives voice to the interests of conservatism, constancy and stability [and] the articulation of the concern that we should … have the opportunity to hang onto those parts of the human condition that are familiar and reassuringly 'human'. … [D]ignitarians can claim to represent a kind of ethical last stand. At the moment, safety concerns allow the ruling synthesis to echo dignitarian disgust at the idea of human reproductive cloning. However, once it becomes a significant option for some humans, there will … be just one voice of opposition – that of the dignitarians.[31]

Generally, it laments human interference with the genetic building blocks of life, which are viewed as common assets of humanity, and the privatisation and commercialisation of life-based processes/products.

(3) Summation: Moving Public Engagement "Upstream" and the BPD's "Upstream" Course

Although one can debate how far "upstream" the BPD-related participation took place

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[27] S. Emmott, *supra*, note 22, at 382.

[28] S. Emmott, "European Patents Step Closer" (1997), at www.grain.org/seedling/?id=1 (Mar. 6/06).

[29] For more on this process, see O. Mills, *supra*, note 3, at 124-126, S. Thaker, *supra*, note 21, S. Emmott, *supra*, note 22, R. Gold & A. Gallochat, *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation and Lessons for Canada* (Ottawa: CBAC, 2001), and EC, *Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (Brussels: EU, 2005).

[30] These approaches and their representation are discussed by K. Liddell, *supra*, note 26, R. Brownsword, "Bioethical Issues of IPRs" (2002), at http://ipgenethics.group.shef.ac.uk/roundtable/papers/bruce.pdf (Jan. 18/06), and R. Brownsword, "Regulating Human Genetics: New Dilemmas for a New Millennium" (2004) 12 M.L.R. 14-39.

[31] R. Brownsword, *ibid*, at 20-21.

(ie: the EC had already prepared a draft text and opponents fought a rear-guard action to amend and/or kill it), there can be little doubt that it constituted public mobilisation and engagement. Drafting and adopting the BPD involved multiple steps and a host of diverse and competing stakeholders from government officials to industry operators to religious bodies to environmental activists, who engaged in a wide range of activities. When the BPD was finally adopted, it settled the legality of biotech patenting, but failed to settle the controversy, even becoming a nexus of controversy itself.[32] The process or the outcome or both failed to satisfy certain stakeholders, who now strive to express their values and advance their agendas further "downstream".

II. ENGAGEMENT OUTCOMES: VALUES AND MORAL APPROACHES IN THE (NEW) PATENTING REGIME

(1) Overview of European Patent Law

In principle, patents encourage and promote innovation and economic growth. Claims to that effect are frequently made as justification for expanding the role of patents in the economy.[33] In much of Europe, patenting is governed by domestic laws which conform to the EPC.[34] Under the EPC, patents afford patentees a nationally-bounded, exclusive, 20-year monopoly to exploit an invention in exchange for public disclosure of that invention.[35] Patents may be granted by domestic patent offices, but are more commonly granted by the EPO, which administers the EPC.[36] The EPO's general function is to support innovation, competitiveness and economic growth, and to strengthen cooperation and create standard rules of treatment and procedure,[37]

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[32] Although legally bound to translate the BPD into domestic law, member states balked on moral grounds, and some 8 members had to be referred to the ECJ for failure to implement. One such case is *Commission* v. *Italy*, [2005] EUECJ C-456/03 (ECJ) The French National Bioethics Committee, the G8 Ministers of Research and a number of lobby groups expressed concern over the BPD: T. Schweiger, "Update on the EU Patenting Directive" (2000), at www.gene.ch/genet/2000/sep/msg00024.html (Mar. 8/06). Subsequent legal instruments have recommended revisiting the issue: see Council of Europe, "Report on Biotechnology and Intellectual Property", Doc. 8459, July 9, 1999, and European Parliament "Joint Resolution on Patents for Biotechnological Inventions", RC/586117EN.doc, October 24, 2005, which (1) alleges lack of clarity as to whether a DNA patent, which must articulate a function, covers only the application function or other functions as well, and (2) requests that the EPO introduce a body to consider the ethical aspects of ethically sensitive patents prior to issuance.

[33] See EPO, Mission Statement (2001), at www.european-patent-office.org/epo/pubs/brochure/general/e/mission_e.htm (Jan. 20/06). However, there is little empirical evidence to support this claim: R. Gold *et al.*, *supra*, note 4, O. Mills, *supra*, note 5, at 12, K. Liddell, *supra*, note 26, and CIPP, *Genetic Patents and Health Care in Canada: An International Comparison of Patent Regimes of Canada and its Major Trading Partners* (Montreal: McGill, 2005). States that did not adopt patent systems in the 19th century experienced impressive economic and technological advancements, leading to accusations at the time that the patent system was "parasitic" and a "playground for plundering": G. Dutfield, *supra*, note 8, at 50-53.

[34] The EPC has 31 signatories. In the UK, it is given effect by the *Patents Act 1977* (UK). Articles 1-11 of the Biotechnology Directive are incorporated into the *Patents Act 1977* (UK) *via* the *Patents (Amendment) Act 2000* (UK).

[35] Articles 63 and 64 EPC.

[36] S. Basu, "Human Genome and Patent" (2002) 16 I.R.L.C.T. 339-357, reports that most UK biotech patents are granted by the EPO.

[37] With respect to the latter functions, see Preamble, EPC. For more on the EPO's purpose, see www.european-patent-office.org/epo/pubs/brochure/general/e/epo_general.htm (Feb. 2/06).

which function evolved out of the original premises of the EPC.[38] An invention can be registered/patented in multiple countries *via* a single process overseen by the EPO, thereby forming a bundle of patents.

Under the EPC, post-grant challenges to the validity of a patent may be initiated in the Opposition Division ("OD") of the EPO. Such proceedings are not an extension of the examination procedure.[39] They are a review of the acceptability of inventions on one or more of three grounds specified in Article 102 EPC (patentability, clarity of disclosure, and over-inclusiveness).[40] Oppositions, which must be instituted within nine months of issuance of a patent,[41] represent an exception to the rule that competence over granted patents is transferred from the EPO to domestic institutions. Although they can be paper reviews, oral hearings are not uncommon.[42] Oppositions have liberal standing rules: any natural or legal person can participate on payment of the requisite fee;[43] they can be filed on behalf of other persons;[44] and they are transferable *via* succession law.[45] In addition to the initial opponent(s) and the patentee, oppositions can involve interested third parties, offering the panel a larger pool of information upon which to base its decision.[46] The OD must render a decision based on the grounds of the opposition and the evidence tendered.[47] It must affirm, amend or revoke the patent, and its decision is unique in that it applies to the whole bundle of patents.[48] Where the decision is appealable, it must be "reasoned" and "written".[49]

Article 53 EPC authorises the EPO to refuse patents (or revoke them where granted and opposed) where the publication or commercial exploitation of the invention would be contrary to *ordre public* or morality.[50] It is not to determine the

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38 O. Mills, *supra*, note 5, at 29-34, and G. Oudemans, *The Draft European Patent Convention* (London: Stevens & Sons, 1963), at 2-4.

39 *MOBIL OIL / Opposition by Proprietor*, [1985] O.J. EPO 299 (EAD).

40 EPC Articles 52-57 (patentability), 83 (clarity of disclosure), 61 and 123 (over-inclusiveness), Clauses D-III-5 and D-V, EPO *Guidelines*, and "Note on Opposition Procedure in the EPO", [1989] O.J. EPO 417. Although considered a "streamlined" procedure, oppositions take years from filing to completion: S. Thorley *et al.*, *Terrell on the Law of Patents* (London: Sweet & Maxwell, 2000).

41 Article 99(1) EPC.

42 For more on the OD and opposition procedures, see EPC Articles 19, 99-104 and 113-126, Rules 55-63, *Implementing Regulations*, Parts D and E, *Guidelines*, and G. Paterson, *The European Patent System: The Law and Practice of the European Patent Convention* (London: Sweet & Maxwell, 1997), Ch. 4.B.

43 Articles 58 and 99(1) EPC, and Clause D-I-4, *Guidelines*.

44 *GENENTECH / Opposition on Behalf of Third Person*, [1999] O.J. EPO 245 (OD).

45 Clause D-I-6, *Guidelines*, and *MAN / Transfer of Opposition*, [1989] O.J. EPO 480 (EAD).

46 Article 115 EPC. In *PPG INDUSTRIES / Heat Processable Metallic Appearing Coatings*, [2004] E.P.O.R. 331 (EAD), in addition to the patentee and opponent, the AD heard from another 5 industry organisations with no direct interest in the subject patent.

47 Article 113 EPC. For more on admissibility and evidence, see Article 117 EPC, Rules 71-76, *Implementing Regulations*, Clause E-IV-1, *Guidelines*.

48 Article 102 EPC. Traditional infringement/enforcement proceedings are initiated in the domestic court of each country in which the patent is registered and infringed: Article 64(3) EPC.

49 Rule 68, *Implementing Regulations*.

50 Article 53(a) EPC states that "patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to *ordre public* or morality". Article 6(1) BPD states that "inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality". Theoretically, the EPC offers a broader exception to patentability. My view is that the difference is immaterial. It is unlikely that the publication of an invention will be contrary to *ordre public* or morality where the commercial exploitation is considered compliant with *ordre public* and morality; in short, the decision will always turn on commercialisation. Indeed, the EPO has reported that amending the EPC to remove "publication" and bring it in line with

morality *per se* of biotechnologies, but rather the morality of their commercial exploitation and the extent to which a patent should be granted as part of that exploitation.[51] Arguably, this is a patent law assessment well within the EPO's expertise (whose skill is in understanding how patent application claims translate into potential products/processes). Although the EPC offers no guidance as to the appropriate interpretive approach to applying Article 53,[52] the EPO has formulated its own guidance as follows:

> The purpose … is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour. Obvious examples … are letter-bombs and anti-personnel mines. In general, this provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public … would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[53]

This clearly sets the bar for EPO intervention on morality grounds extremely high. One might question whether the EPC wording warrants such a restrictive approach, but it follows from the patent community's (and EPO's) partiality toward patentability,[54] and the parallel marginalisation of morality in patenting by legal bodies.[55] Unfortunately, the guidance offers no insight into how the EPO will arrive at a conclusion as to what "society" views as "abhorrent".

So how does the BPD fit into this regime, what values have found expression in the BPD, and, importantly, what has it added?

(2) The Expression of Moral Values in the BPD

Using the moral approaches advanced by the stakeholders and identified in Part I, some of the BPD's key provisions can be explored.

(a) Utilitarian Approach

This approach weighs risks/harms against benefits such as individual financial reward, economic development, and scientific advancement which may promote

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the BPD would have no real impact on its current practice: Cabinet Chaillot, "Revision of the European Patent Convention" (2003), at www.chaillot.com/en/pages/p9.html (Feb. 22/06). Neither does the EGE articulate a difference in its consideration of these instruments: EGE, *supra*, note 14, and EGE, "Ethical Aspect of Patenting Inventions Involving Human Stem Cells" (2002), at www.eu.int/comm/european_group_ethics/docs/avis16-en.pdf (Feb. 22/06).

[51] This diminishes the persuasiveness of allegations that the EPO lacks the expertise in moral theory, ethics and public policy necessary to apply the morality provision, as suggested by the Nuffield Council, *The Ethics of Patenting DNA: A Discussion Paper* (London: NCB, 2002), at para. 6.18.

[52] This shortcoming and the various theoretical approaches that could be taken are discussed in D. Beyleveld & R. Brownsword, *Mice, Morality and Patents* (London: CLIIP, 1993), at 56-73.

[53] Clause C-IV-3.1, *Guidelines*.

[54] A. Warren-Jones, "Patenting DNA: A Lot of Controversy Over a Little Intangibility" (2004) 12 M.L.R. 97-124. For an example of the exercise of the EPO's presumption of patentability, see *HARVARD / Oncomouse*, [2005] E.P.O.R. 271 (AD).

[55] For the legal marginalisation of morality in patenting, see *Pays–Bas* v. *European Parliament and Council*, Case C-377/98, European Court of Justice, October 9, 2001, *sub nom*, *Kingdom of the Netherlands et al.* v. *Council of the European Union & the European Parliament (Approximation of Laws)*, [2001] EUECJ C-377/98 (October 9, 2001).

better healthcare and greater health.[56] This pro-patenting approach is apparent in Recitals 10 and 11, which precede the formal, operative provisions of the BPD:

> 10. Whereas regard should be had to the potential of the development of biotechnology for the environment and in particular the utility of this technology for the development of methods of cultivation which are less polluting and more economical in their use of ground … ;
>
> 11. Whereas the development of biotechnology is important to developing countries, both in the field of health and combating major epidemics and endemic diseases and in that of combating hunger in the world [and] the patent system should likewise be used to encourage research in these fields … .

Examples of its reification can be found in Articles 3 and 5. Article 3(2) clearly/explicitly extends patentability to biotechnologies:

> 3(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Article 3(1), together with Recitals 22, 24 and 34, quite practically, preserves the existing legal test for patentability (as established in Articles 52-53 EPC) and applies it in the biotech context:

- ***Novelty:*** The invention must be new and not form part of the existing "state of the art",[57] nor can it be something that exists in nature and is merely "discovered".[58] In the genetic context, a gene/sequence must be purified, isolated from the body and characterised, after which natural counterpart cannot destroy its novelty.[59]

- ***Inventiveness:*** The invention must not be obvious to someone skilled in the field. If someone so skilled would consider it obvious to go from what is known to what has been claimed/invented, then inventiveness is lacking. Genomics researchers must consider the invention not routine or ordinarily achievable. A gene/sequence which shares the same function and is closely related structurally to an existing sequence/invention will fail for lack of inventiveness.[60]

- ***Industrial Applicability:*** The invention must be capable of production and/or

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[56] See Recitals 1, 2, 3, 7, 8, 17, and 46, which generally state that biotechnology and the patenting of same plays an increasingly important role in economic wellbeing and the development of the internal market.

[57] The term "state of the art" comprises all matter (product, process, information about either) that has at any time before the date of the application been made available to the public by written or oral or other means: see ss. 2(2), 2(3) and 2(4) of the *Patents Act 1977* (UK) and Article 54 EPC.

[58] *Re American Cyanamid Co. (Dann's Patent)* (1971), 18 R.P.C. 84 (HL).

[59] *BIOGEN / Alpha-Interferon*, [1990] 8 O.J. EPO 335 (A.D.).

[60] A. Warren-Jones, *supra*, note 54, at 107.

practical use in some industry.[61] An isolated gene/sequence must have some practical probability (as opposed to a theoretical possibility) of application/function in some industry.[62] This utility must be disclosed in the patent application.[63]

Article 5(2), which is supported by Recitals 20-22, states:

> 5(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

This provision basically deems that the isolation and purification of natural substances are capable of being inventions. Pragmatically, they loosen the "inventiveness" criteria and blur the line between discoveries and inventions (and thereby reject the US requirements for patentability originally enunciated in *Chakrabarty*).[64]

The primary value which underlies the utilitarian approach is corporate/researcher autonomy (self-governance and freedom of will). However, this approach is not uni-dimensional. It limits patentability where harms/dangers are seen as too great, thereby endorsing a certain level of precautionism and a vision of justice. Such concessions to justice and/or decency are found in some of the Article 6(2) exceptions to patentability, notably human cloning, germline gene therapy, and industrial and commercial uses of the embryo.

(b) Human Rights Approach

This approach is sprinkled throughout the BPD. Recital 26, with no enforceable counterpart in the operative part of the BPD, states:

> 26. Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in

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61 For more, see C. Martinez & D. Guellec, *supra*, note 19, at 19.

62 Recitals 23, 24, and *Chiron* v. *Murex*, [1996] 18 R.P.C. 535 (CA). The proximity between inventiveness and utility was noted in *AGREVO / Triazole Herbecides*, [1996] E.P.O.R. 171 (AD).

63 The importance of functional claims not being too broad was expressed in *MYCOGEN / Transgenic Animal*, [1998] E.P.O.R. 114 (AD), and *ICOS / Transmembrane Receptor*, [2002] 6 O.J. EPO 293-308 (OD), which held that DNA sequence applications must disclose a credible function, which is not achieved where it claims sundry possible uses and the method for ascertaining the protein function.. Nonetheless, numerous (speculative) patents have been granted for genetic sequences whose full or even partial use is not known: Ontario, *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare* (Toronto: Ontario Government, 2002), at 35.

64 *Chakrabarty* grounded patentability on the fact that the bacterium had (1) "markedly different characteristics from any found in nature", and (2) the obvious potential for significant utility. This is stricter than the BPD's requirement that an element isolated from the body may constitute a patentable invention, even if its structure is identical to that of a natural element. Thus, although the EC cited *Chakrabarty* as its authority [EC, *Final Report: Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (Brussels, EC, 2002), at 17], it broke from the Court's stipulation that biological material, though isolated and purified, remains an unpatentable product of nature: see L. Palombi, "Patentable Subject Matter, TRIPS and the European Biotechnology Directive: Australia and Patenting Human Genes (2003) 9 UNSW L.J. 26-35.

accordance with the law.[65]

Recital 43 notes that fundamental rights as contained in the European Convention on Human Rights (1950) and member state constitutional traditions must be protected. More concretely, Article 11 stipulates that farmers can use the product of a harvest based on patented material for further propagation, and Article 12 stipulates that breeders can apply for compulsory, non-exclusive use of a patented invention. These provisions, which permit the limited redistribution of the benefits of genomic advances, expose values of justice and autonomy (which rest on the broad notion of valuing the worth of human beings).

(c) Dignitarian Approach

This approach is exposed by a number of Articles which endeavour to limit the patentability of genetic material. Article 5(1) states that "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions". As evidenced by Recital 16, this is directed at establishing limits to biotech patentability based on personal integrity and human dignity. Article 6(1), supported by Recital 37 and substantively equivalent to Article 53(a) EPC, states:

> 6(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

Article 6(2) offers some guidance by stating that the following are unpatentable: (a) processes for cloning human beings;[66] (b) processes for modifying the germline genetic identity of human beings;[67] (c) uses of human embryos for industrial or commercial purposes;[68] and (d) processes for modifying the genetic identify of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The dignitarian approach clearly emphasises the sanctity of life value (ie: human life and health above all other life and weighed equally as against other human life). It emphasises an interpretation of human dignity which holds that the human race's sense of its own importance should be maintained by affording it greater protection than other entities.[69] It seeks to preserve humanity's place in and relationship to nature, and to avoid the instrumentalisation of human life (ie: treating

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[65] For a discussion on the (potential) role of consent in patent law, see G. Laurie, "Patents, Patients and Consent: Exploring the Interface Between Regulation and Innovation Regimes" in J. Homsen (ed.), *Regulating Biotechnology* (London: Edward Elgar, 2006).

[66] Although "human cloning" is not defined in the operative part, Recital 41 limits the ban to reproductive cloning.

[67] Recital 40 also addresses germline genetics and the consensus within the EC that it offends human dignity.

[68] Recital 42, which states that it does not affect inventions for therapeutic or diagnostic purposes which are applied to human embryos and are useful to it, is relevant.

[69] M. Cutter, "Genetic Databases and What the Rat Won't Do: What is Dignity at Law?" in G. Arnason *et al.* (eds.), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases* (Reykjavik: UIP, 2004) 217-222, at 219.

humans solely as a means to an end). It also supports autonomy, but not to the extent that individuals are entitled to choose courses that compromise human dignity.

(3) Summation: Patenting Processes and the Hodgepodge Status of the New Regime's Morality

As evidenced by the fact that some of the BPD's provisions could be re-allocated differently amongst them, these moral approaches are not watertight categories. They overlap; it is their emphasis of particular values which varies, with the result that they promote different (and conflicting) rights/obligations. One might argue that a plurality of moral approaches within a single instrument is neither fatal nor even particularly harmful. However, in the case of the BPD, it has been problematic. The dearth of guidance regarding how these approaches (and values) are defined and properly balanced, particularly where they are implicated by new technologies outside those listed in Article 6(2), makes it difficult for decision-makers to know how to apply the BPD. It offers them broad discretion and a legal basis for contradictory outcomes, which hinders the BPD's capability to harmonise laws/practices across jurisdictions. Indeed, the BPD's validity was immediately challenged in part on the lack of legal certainty caused by this plurality.[70] This ambiguous outset suggests that the EPO is unlikely to adopt a robust and critical approach to the morality provision. At the least, however, one would expect it to (1) acknowledge and articulate competing interests and their underlying moral theories, (2) arrive at a means of measuring society's abhorrence to the commercialisation of opposed products/processes, and (3) use its "moral compass" to formulate a comprehensible and cross-jurisdictional commercialisation morality.[71] Let us see.

III. RE-ENGAGEMENT: GIVING VALUES PRACTICAL EFFECT THROUGH EPO DECISIONS

(1) The Early EPO Jurisprudence

The attitude and reasoning of the EPO in the "early" genetic cases which consider morality can be described as "circumspect". Generally, the EPO:

- adopted a restrictive view of the morality provision's functions and its role with respect to them, stating that the exceptions to patentability (eg: Article 53 EPC; Article 6 BPD) should be interpreted strictly/narrowly even where living matter is concerned;

- failed to articulate any broad, widely-held moral values (such as those which informed the BPD) other than to express the view that patenting is socially useful and to be encouraged;

- failed to engage in any real moral discussion beyond endorsing the need for a

[70] *Netherlands*, *supra*, note 55. For more on this case, see A. Scott, "The Dutch Challenge to the Bio-Patenting Directive" (1999) 21 E.I.P.R. 212-215, and S. Moore, "Challenge to the Biotechnology Directive" (2002) 24 E.I.P.R. 149-154.

[71] A. Warren-Jones, *supra*, note 54, at 114, suggests that the EPO does not need expertise in moral philosophy, simply a "moral compass" which accords with society.

"common European morality";[72]

- failed to invoke any of the touchstone values explicitly, though it implicitly elevated the sanctity of human life above other considerations,[73] and was compelled by compliance with the autonomy value;[74]

- held that Article 53(a) EPC (Article 6(1) BPD) requires a "standard of outrageousness test", but gave no guidance as to how an opponent might show the overwhelming consensus on the issue amongst the contracting states that it demanded, even rejecting polls/surveys;[75]

The reasoning in these cases is summed up in the following comments:

> … [I]t cannot be the role of the EPO to act as moral censor and invoke [Article 6] to refuse on ethical grounds … a patent … directed to an invention indisputably associated with medical benefits … . The technology underlying the present invention is undoubtedly controversial and the subject of intensive discussion … . However, there is at present no consensus in Europe … about … this technology, and public opinion is still being formed … . It would be presumptuous for the EPO to interfere in this debate. The [morality] provisions … are intended to exclude from patentability not subject-matter that is controversial, but rather that kind of extreme subject-matter … which would be regarded … as abhorrent.[76]

In each case, the EPO granted the patent, albeit sometimes on more limited claims. One could conclude from them that oppositions are not a fruitful means of re-engagement. Opponents have not been successful in (1) encouraging a consistent interpretation/application of the morality provision, (2) identifying what values the EPO relies on, or (3) revoking genetically-related patents. Additionally, lack of clarity as to the basis of decisions makes it difficult for stakeholders to confidently predict outcomes and to strategise appropriately to bring about desired outcomes.

So how do more recent cases involving new biotechnologies compare with the approach adopted in the early precedents?

(2) The Recent EPO Jurisprudence

In *EDINBURGH / Animal Transgenic Stem Cells*,[77] the patentee sought protection for a process for genetically modifying animal stem cells such that they had a survival advantage over differentiated cells (thereby overcoming the need to culture massive

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72 *PLANT GENETIC SYSTEMS / Glutamine Synthetase Inhibitors*, [1995] E.P.O.R. 357 (AD).

73 *HARVARD / Oncomouse*, [1989] O.J. EPO 451 (E.D.), appealed [1990] O.J. EPO 476 (AD), reconsidered [1992] O.J. EPO 589 (ED).

74 *HOWARD FLOREY INSTITUTE / Relaxin Hormone*, [1995] E.P.O.R. 541 (OD).

75 *LELAND STANFORD / Modified Animal*, [2002] E.P.O.R. 2 (OD).

76 *LELAND STANFORD*, para. 51. This patent was opposed by Bio-Pharmaceuticals, C. Then *et al.*, and *Bundeszentrale der Tierversuchgegner Osterreichs.*

77 Patent Application No. 94 913 174.2, July 21, 2002, Opposition Division.

cell populations comprised largely of unwanted cells).[78] The fourteen opponents[79] and five third-parties all objected to the patent, in part, on the morality provision, arguing that the term "animal stem cells" could include human embryonic stem cells ("ESC"), thus falling afoul the patentability exclusion relating to industrial and commercial use of embryos.

After an oral hearing, the OD defined morality as relating to the belief, founded on the deeply held norms of a particular society, that some behaviour is right and acceptable and some behaviour is wrong and unacceptable. It identified the subject society as European society/civilisation. Thus, inventions the exploitation of which is not in conformity with conventionally accepted norms of European culture are excluded from patentability. With respect to identifying "conventionally accepted norms", it stated:

> Neither the evaluation of the national legislation nor the assessment of the conventionally accepted standards of conduct of European culture has revealed a uniform approach with regard to human ESC, and … even a uniform estimation of the situation for all contracting states … would not automatically [suffice] under Article 53(a) EPC [to render an invention unpatentable]. …[80]

It determined that the case turned on whether Rule 23d(c) (Article 6(2)(c) BPD) should be interpreted narrowly to ban patents on human embryos as such or broadly to ban patents on human embryos and the cells retrieved therefrom by destruction of the embryos (ie: ESC). In answering this question, the OD noted:

- Patent law must be applied so as to respect the fundamental principles of dignity and integrity.[81]

- The illustrative list of unpatentable inventions is not exhaustive and can expand to processes for producing chimeras from "totipotent cells"[82] of humans and animals.[83]

- Although inventions using human embryos for industrial/commercial purposes are unpatentable, inventions for a diagnostic or therapeutic purpose which are applied and are useful to embryos are acceptable.[84]

It concluded:

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78 Human stem cells can be cultured from adults or embryos. Embryonic stem cells are cells cultured from early embryos, and have the potential to develop into a wide variety of specialised or differentiated cells.

79 Germany, Italy, Netherlands, and 11 other parties ranging from individuals (Dr. Tippe, Dr. Kaiser) to organisations (Greepeace, *Aktion Leben Osterreich*, *Alliance pour les Droits de la Vie*, etc.).

80 *EDINBURGH*, para. 2.5.3.

81 Recital 16 BPD.

82 "Totipotent" cells have the capacity to form an entire organism. They have "total potential". In humans, the fertilised egg forms a single totipotent cell. Only after approximately 4 days and several division cycles do they begin to specialise into "pluripotent" cells (which give rise to most tissue necessary for foetal development) and pluripotent cells into "multipotent" cells (which give rise to cells with specific functions).

83 Recital 38 BPD.

84 Recital 42 BPD.

> If the legislator had intended … to exclude from patentability only the human embryos as such, he would not have introduced both … Article 5(1) and Article 6(2)(c) … .
>
> The fact that [Article 6(2)(c)] refers to "uses" for "industrial or commercial purposes" is not of relevance in the given context. If patent applications are being filed there is always an industrial or commercial purpose implied because the only function of a … patent is to stop others from commercially/industrially exploiting the invention. Moreover, the reference to "use" … cannot have a bearing in considerations of an ethical nature. If the patenting of a product is ethically unacceptable, it is hardly conceivable that the patenting of "uses" of this product can be judged differently. Thus, it is considered that the exclusion of human embryos from patentability … also pertains to the "uses" of human embryos for whatever purpose.
>
> In consequence, [Article 6(2)(c)] in order to have a purpose exceeding the one of [Article 5(1)] has to be interpreted broadly to encompass not only the industrial or commercial use of human embryos but also the human ESC retrieved therefrom by destruction of human embryos.[85]

Breaking from precedent, the OD held that a broad interpretation of the exclusion is appropriate (ie: morality bars patents on human embryos and the ESC retrieved therefrom). It concluded that the claim was described such that it was caught by Article 6(2)(c). However, it upheld the auxiliary request which related to animal and human stem cells but excluded ESC. It concluded that stem cells isolated from adults or aborted foetuses are akin to any other cell isolated from an organism, which is patentable by operation of Article 5(2) BPD and Recitals 20 and 21.

The OD's decision – in particular its outright consideration of the patent's morality and its assessment and rejection of the EGE's ethical opinion – suggests that the OD has come a long way since the early cases in which it appeared happy to avoid engaging the morality question at all. That is not to say that its moral analysis represents the ideal. The OD conflated its legislative review and its assessment of conventionally accepted standards of (moral) conduct. It held that the lack of uniformity of ESC research regulation in Europe (ie: the patchwork of legality, illegality and legislative silence) confounds any attempt to identify conventionally accepted standards of conduct. So it neglected to try, arriving at its moral conclusion on the wording of the BPD. As such, the values it relied on are easy to identify – non-instrumentalisation and personal integrity. It exhibited a cautious (almost dignitarian) approach in that, despite dealing with pluripotent cell lines which could not develop into embryos, it invalidated the original patent on the basis of the Article 6 ground that the use of embryos for industrial/commercial purposes is immoral.

In *WARF / Primate Embryonic Stem Cells*,[86] the patentee sought protection for ESC cultures derived from rhesus monkeys and marmosets. Reference to "primate" was interpreted to include "human", although the generation of human ESC cultures

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85 *EDINBURGH*, para. 2.5.3.

86 Patent Application No. 96 903 521.1 – 2401, July 13, 2004, Examination Division. This case was appealed to the Technical Board of Appeal, which, by decision T 1274/04 – 3.3.08, dated November 18, 2005,.has referred the appeal to the Enlarged Board of Appeal.

was not exemplified in the application. As in *EDINBURGH*, the invention's patentability under Article 53(a) EPC and Rule 23d(c) (Article 6(2)(c) BPD) was questioned, although this time by the ED.

After an oral hearing, the ED noted that, although the application related to cell cultures, the method for their creation was included in the claim and the final product inherited technical features from its starting material – a preimplantation embryo. Thus, it must take into consideration the starting material and the process as well as the end product claimed:

> Since no alternative starting material is given but preimplantation embryos, the disclosed cultures … are inseparable from the methods that generate them and from the use of an embryo as starting material.[87]

In addition, it held that the description of the invention implicated human embryos by its claim that the process could equally be used to create human ESC cultures. The use of (human) embryos as starting material for the generation of products with industrial application is, it held, equal to industrial use of the embryo.

Having established the indispensability of embryos to the invention and the industrial use to which they are put, the ED considered the BPD's Recital 42 exception to the exclusion from patentability (ie: the industrial use exclusion "does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it"). It held that this invention did not fall within the exception because the generated ESC cultures served no diagnostic/therapeutic purpose useful to the originating embryo:

> … According to the application … [these cell lines] are highly desirable for the study of human pregnancy with a view to understanding the mechanisms involved and for … treating … human infertility. However, none of these goals relate to therapeutic or diagnostic purposes useful to the embryo that gave rise to said cells, although it is not disputed that achieving said goals would probably benefit the development of *in vitro* fertilisation methods and/or infertility treatments. ...[88]

It dismissed the patentee's caution that such an approach would exclude from patentability all products traceable to ESC and thereby gravely endanger biotech innovation, stating that this position failed to appreciate that such products may be developed through methods that do not include direct use of human embryos. In denying allegations that it adopted an erroneously broad interpretation to the exclusion, it stated:

> … The relevance of [Article 6(2)(c)] in assessing the patentability of the claimed subject-matter is found … not from a broad interpretation of said [Article] but rather from the significance of the teachings of the entire application (use of a human embryo and culture method) which are indispensable for the generation of the claimed subject-matter

[87] *WARF*, para. 10.
[88] *WARF*, para. 11.

(human ESC cultures).[89]

The ED concluded by saying that the clear wording of the BPD and its direct applicability to this invention made resort to moral philosophy unnecessary.

Although the EPO denied adopting a broad interpretation of the morality provision, it certainly gave it more work to do by holding that the application was not limited to the claimed subject matter, but to the invention in its entirety, including all aspects that make it available to the public:

> … [T]he ED in *WARF* rejected [a strict] approach, preferring an holistic consideration of the totality of the inventive process and not just of the claimed invention. The message from the ruling is that the moral concern goes far beyond patenting itself and extends to general instrumentalisation. It implies that mere involvement – use – of embryos in the research and development of an invention is sufficient to bar the patentability of that invention.[90]

Unfortunately, the decision does not offer any reliable insight into the direction of the EPO's moral leaning or the underlying values being brought to bear. It specifically declined to enter into any moral discussion or to offer any guidance as to what evidence (of morality) might prove persuasive in future cases.[91] It limited itself to reading the claims and offering an almost literal interpretation of the legal provisions without elucidating any overt morality. However, by adopting a more holistic approach which more readily implicates the exclusions to patentability, one can argue that it has given greater life to the sanctity and dignity values emphasised by the dignitarian approach, which decries human embryonic research, and has eroded the economic utilitarian dominance, which claims that commercialisation decisions are properly that of the researcher. In short, it has shifted its perspective slightly and this may bring hope to stakeholders who oppose genetic patents.

(3) Summation: EPO Conduct and Stakeholder Engagement in Transition

Regardless of how oppositions were originally viewed, they are now "legal battles" fought by socially conscious NGOs in the trenches of commercialisation.[92] Indeed, their liberal standing rules and the number and scope of participants in the cases reviewed suggests that oppositions could and should be a useful forum for lively re-engagement (ie: for the exploration of fundamental moral and commercial questions in the context of specific inventions). The early cases were not. The latter cases moreso; they represent a shift in the EPO's view of its role, but not a drastic shift. *EDINBURGH* and *WARF* were not decided by balancing competing visions of science and morality, but by an interpretive approach which gave greater effect to the

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89 *WARF*, para. 12.

90 G. Laurie, "Example of the Moment: Embryonic Stem Cell Patents – The European Experience", presented at Conference on Bioethical Issues of Intellectual Property in Biotechnology, September 6-7, 2004, Tokyo, at 8.

91 *WARF*, para. 12. However, at the oral hearing, it stated that the applicable moral standards are those evidenced by national laws and common religious beliefs in EPC states existent at the date of filing: *WARF*, Minutes, paras. 4.1 and 4.2.

92 T. Schweiger, "Patenting Life" (1999), at http://archive.greenpeace.org/geneng/reports/pat/pat002.htm (Mar. 8/06).

wording of the BPD (albeit for the first time). The EPO did not (1) acknowledge and articulate competing interests and their underlying moral theories, (2) arrive at a means of measuring society's abhorrence to the commercialisation of opposed products/processes, or (3) use its "moral compass" to formulate a comprehensible and cross-jurisdictional commercialisation morality. In the result, even the latter cases have been described as "crude" and "absolutist" and open to ethical criticism.[93] Stakeholders are still left with real questions about what moral approaches and values motivate the EPO. Indeed, recognising the lack of clarity on this issue and the controversy surrounding its own decisions, the EPO has announced a moratorium on applications involving human ESC technology.[94] As such, questions remain as to where the new cases leave the patent system.

IV. FUTURE ENGAGEMENT: EXPANDING THE VALUE POOL

(1) Adopting the Orphan Value

Modern healthcare is transitioning towards "genomic medicine" and is increasingly reliant on biotechnological advances.[95] Solidarity is a core value of modern healthcare (and the welfare state) and has been described as essential for redressing the growing global healthcare deficit.[96] Given that intellectual property rights play an ever-expanding role in both healthcare and genomic research, the solidarity value is surely relevant to the patenting regime and ought to play a role in the EPO's morality-based deliberations.

Solidarity may have been advanced by some of the stakeholders during the "upstream" negotiations, but it found little expression in the final version of the BPD. This value is grounded in compassion, fraternity and an interest in the well-being of others. It recognises that individuals are naturally and irrevocably embedded in social contexts and therefore emphasises the creation and preservation, through personal and collective action, of a just and decent global society.[97] This socially-connected and common-action-promoting notion of solidarity is recognised in religious and philosophical thought and in a host of international instruments.

With respect to its interplay with intellectual property and commercialisation, the value is embodied at international law in the characterisation of Antarctica,[98] space,[99] culture,[100] the moon,[101] and the seabed,[102] as the "common heritage of

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93 G. Laurie, *supra*, note 90, at 9.

94 S. Schubert, "Europe Halts Decisions on Stem-Cell Patents" (2005) 435 Nature 720-721.

95 WHO, *Genetics, Genomics and the Patenting of DNA: Review of Potential Implications for Health in Developing Countries* (Geneva: WHO, 2005).

96 M. Frankman, "Fractals and the Common Heritage of Humanity" (1993), at http://icesuite.com/mf/mf/fractals.html (Mar. 9/06), and S. Harmon, "Solidarity: A (New) Ethic For Global Health Policy" (2006) forthcoming in Health Care Analysis.

97 For more on this value, see S. Harmon, *ibid*, R. Houtepen & R. ter Meulen, "The Expectation(s) of Solidarity: Matters of Justice, Responsibility and Identity in the Reconstruction of the Health Care System" (2000) 8 Health Care Analysis 355-376, R. ter Meulen *et al.*, "Solidarity and Care in the EU" (2000), at http://europa.eu.int/comm/research/biosociety/pdf/bmh4_ct8_3971_partb.pdf (Aug. 24/05), S. Benatar, A. Daar & P. Singer, "Global Health Ethics: The Rationale for Mutual Caring" (2003) 79 Int. Aff. 107-138, and M. Hayry, "European Values in Bioethics: Why, What and How to be Used?" (2003) 24 Theo. Med. 1999-214.

98 Antarctic Treaty (1959).

99 UN Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon & Other Celestial Bodies (1966).

100 UN Convention for the Protection of the World Cultural and Natural Heritage (1972).

mankind" warranting special protection and special rules of exploitation. It is implicated in the genomics field through the characterisation of the genome and genomic information as the "heritage of humanity".[103] Characterising the genome as the "heritage of humanity" underlines human unity and implies the following elements: (1) non-private/national appropriation; (2) common or international management; (3) use only for peaceful and socially useful purposes; (4) equitable sharing of benefits (just distribution); and (5) protection/preservation for future generations.[104] The interrelationship between the "heritage of humanity" concept and solidarity is obvious: they share notions of global community, shared social purpose, common resources and intergenerational justice.

The realisation of these aspirational elements is thrown into doubt by corporate practices and research-stifling patent thickets of the economic model that governs society and corporate scientific activity, limits commercial/political imagination, and shapes the nature and direction of genomic research.[105] Some suggest that this individualistic, market/profit-driven model is fundamentally incompatible with the genome as the "heritage of humanity".[106] The same might be argued in relation to the solidarity value, particularly in its purest and most robustly defined form. However, I am not concerned with the deeper philosophical debate about the compatibility of solidarity fundamentalism with the economic model.[107] Given the entrenchment of the economic model and this paper's modest aim of looking at engagement and morality within that model (ie: the patent regime), I wish to limit the analysis of the solidarity value to its potential application within the model by the EPO.

So what might be the practical effect for commercialisation if the EPO were to adopt solidarity as one of its moral touchstones?

(2) Solidarity on the Ground

One could argue that solidarity has already been translated into action through

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101 UN Agreement Governing Activities of States on the Moon & Other Celestial Bodies (1979).

102 UN Law of the Sea Convention (1982).

103 UNESCO Universal Declaration of the Human Genome and Human Rights (1997), AMA Position Statement: Human Genetic Issues (2002), HUGO Statement in Benefit-Sharing (2000). See I. Ramonet, "Friendly Mutants" (2000), at http://mondediplo.com/2000/08/01leader.pdf (Mar. 9/06).

104 C. Byk, "A Map to a New Treasure Island: The Human Genome and the Concept of Common Heritage", R. Ida, "Human Genome as Common Heritage of Mankind – With A Proposal", and D. Shapiro, "UNESCO's International Bioethics Committee and the Declaration on the Human Genome", all from the Bioethics in Asia Conference, November 1997, Japan, at www2.unescobkk.org/eubios/asiae/biae26.htm (Mar. 9/06), and B. Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey" (1999) 22 Nature Genetics 23-25.

105 With respect to sharp practices and greed, note the conduct of Myriad Genetics Inc. and Human Genome Sciences Inc. With respect to research-stifling tangles of IP rights, note that gene patents number well over 355,000 and surveys indicate that researchers are deterred from working on particular gene targets due to fear of infringement actions and/or expensive licenses: J. Sulston, *supra*, note 3, and P. Gepts "Who Owns Biodiversity and How Should the Owners be Compensated?" (2004) 134 Plant Physiology 1295-1307. For more on the economic model and the operation of the biotech market, which has been described as "morally perverse", see L. Cahill, "Genetics, Commodification and Social Justice in the Globalization Era" (2001) 11 Ken. Inst. Ethics J. 221-238.

106 L. Demaine & A. Fellmeth, "Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent" (2002) 55 Stan. L.R. 303-462.

107 That is not to say that such ideological/philosophical debates are not important. If we only strive to be practical within the confines of the existing economic model, we will never explore alternate world views or change the dominant frame of reference.

prohibitions on (1) human cloning, (2) germline gene therapy, and (3) owning genes in their natural state, and (4) through the recommendation to benefit-share, and is therefore already realised in the patenting regime and enforceable in EPO jurisprudence. I would argue that these actions, which are equally informed by the dignitarian and the human rights approaches, do not adequately reflect the deeper meaning or significance of solidarity. Something more is needed. Having said that, the following suggestions are not reflective of solidarity in its purest form. They are rather a means of advancing notions of solidarity within a system with which the value interacts uncomfortably.

Recognising that solidarity does not despise self-interest where it enhances the greater good, and accepting (with a grain of salt) the common wisdom that patents promote innovation and healthcare advances, the simplest and most direct action the EPO might take in support of solidarity would be to reinvigorate the patenting criteria of novelty, inventiveness and industrial applicability (ie: take seriously its gatekeeper function). The distinction between a discovery and an invention has been so blurred and the patentability criteria so diluted as to be almost meaningless in the gene patenting context.[108] It is widely argued, even by scientists, that the routine purification and replication of gene sequences outside the body does not properly constitute an invention:

> The essence of a gene is the information it provides – the sequence. Copying it into another format makes no difference. It is like taking a hardback book written by someone else, publishing it in paperback and then claiming authorship because the binding is different.[109]

Conceding that the BPD adopts the position that isolation/purification can result in an invention (despite its own Recital 34[110]), the EPO could nonetheless stiffen the burden of proof imposed on applicants. Indeed, it could adopt a "substantial transformation test" whereby a product must be substantially transformed such that it has a new and distinct character or use before it can obtain patent protection.[111] Only a substantive transformation justifies granting an individual monopoly, which necessarily infringes solidarity broadly described. Although other values might be supported by the adoption of such a test (or the more rigorous application of the patentability criteria), solidarity is enhanced because, presumably, fewer patents would be awarded. This would serve to keep more information in the pre-competitive public domain and would expand the freely available prior art, both consequences which are supportive of the collective notions embodied by solidarity. Given that patents are not the primary motivation for innovation,[112] and that patents would still be available for end-products, research should not be hindered and the EPO would still be performing its innovation/economy promoting function.

In the absence of this front-door approach, the EPO is given a back-door approach – the morality provision. The effective and legitimate use of this option for

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[108] L. Demaine & A. Fellmeth, "Natural Substances and Patentable Inventions" (2003) 300 Science 1375-1376.

[109] J. Sulston, *supra*, note 3.

[110] Recital 34 states that the BPD "operates without prejudice to concepts of invention and discovery as developed by national, European and international law".

[111] P. Gepts, *supra*, note 105, at 1301.

[112] Patents are rated below trade secrets and rapid innovation as a stimulus for research: W. Lesser & M. Mutschler, "Lessons from Patenting of Plants" in M. Rotschild & S. Newman (eds.), *Intellectual Property Rights in Animal Breeding and Genetics* (UK: CABI, 2002) 103-118.

giving legal effect to the full range of moral values (including solidarity) would require the EPO to sharpen its moral analysis, adopting a more contextual approach. As previously stated, the crux of the EPO's function is to determine the moral acceptability of the state sanctioning a single entity to commercially exploit an invention. Thus, as foreshadowed above, in undertaking this process, the EPO should explicitly:

(1) acknowledge and articulate competing interests and their underlying moral theories/values;

(2) arrive at a means of measuring society's abhorrence to the commercialisation of the invention (which may entail considering the source materials and underlying processes of an invention and determining the nature and scope of the application/claims and the morality surrounding the science as a means of grounding or contextualising the assessment); and

(3) articulate a comprehensible and cross-jurisdictional commercialisation morality which adopts solidarity as one of its guiding values (ie: heeds the manifold claims in international instruments and by NGOs and scholars that genes are the "heritage of humanity").

In doing so, the EPO would have to recall (1) the special position of the genome to modern healthcare and in the human psyche, (2) the legal/moral obligation to use genetic information for the benefit of humanity, and (3) the moral responsibility to preserve it (and its utilisation) for future generations, and embed them into its Article 53 morality assessments. So oriented, it could justify the preservation of much genetic knowledge as a global common resource which transcends national (and corporate) boundaries and which imposes on stakeholders duties akin to the five elements described above.[113]

(3) Summation: New Values for the New Regime and More With Which to Engage

Much can be done to ameliorate the more harmful effects of the economic model and to enhance the patenting process as a useful site of re-engagement for stakeholders without concluding that IPRs are absolutely wrong and must be prohibited in the biotech field or that patent proceedings will hijack more explicit policy-making fora. Just one possibility is to expand the moral values in play in patent proceedings (ie: "cosmopolitanise" the moral options where patents converge with genomics so they are less homogenous/limited). Reliance on the solidarity value (implicated in this field by the rhetorical description of genes as the "heritage of humanity") would serve to enlarge the EPO's ethical resource base and, where it is called upon to render morality-based decisions, make those decisions more reflective of the moral positions being advanced in law and society.

CONCLUSION

[113] R. Chadwick & S. Wilson, "Genomic Databases as Global Public Goods" (2004) 10 Res Publica 123-134, and D. Resnik, "The Human Genome: Common Resource But Not Common Heritage" (2004), at www.library.wur.nl/frontis/ethics/13_resnik.pdf (Mar. 9/06).

Parts I and II demonstrated that meaningful public engagement opens up questions, provokes debate, exposes differences, interrogates assumptions, and can lead to more versatile policy decisions.[114] That is not to say that the foundational tenets upon which a law is built will necessarily weaken when challenged "upstream"; despite the vociferous challenges to the morality of patenting living matter, neither the economic model nor the patent regime's inexorable march to expand its reach could be shaken. Part III demonstrated that, where stakeholders are ineffective at achieving their ends "upstream", they will turn to "downstream" mechanisms to advance their agenda. Early patent proceedings, which proved as ineffective at stemming the bio-patenting tide as "upstream" mechanisms, show hints of the moral approaches implicated by the BPD, but very little overt recognition. However, the EPO has recently exhibited a greater willingness to undertake analyses of the morality of inventions (as measured against the legal texts rather any particular moral theory). If the shift continues, it will undoubtedly offer hope to stakeholders that oppositions could become more valuable as an avenue for multiple stakeholder re-engagement. As it stands, they are still left without any real sense of which values will be upheld and which defeated in any given case. This vagueness poses a problem for legal legitimacy and continuity. In the expectation that the shortcomings identified in Part III can be addressed, Part IV offered the solidarity value as a legitimate moral touchstone in patent proceedings. It recommended its adoption as a means of expanding the EPO's moral menu and suggested some possibilities for its reification within the confines of the dominant economic model.

The above makes clear that steps should also be taken by legislators to reform the patenting regime so that it better reflects and more equitably performs its role in human health, global biodiversity and scientific advancement. Thought should be given to how it could enhance our idealistic rhetoric. An important aspect of this reform could be the restructuring of patent proceedings in recognition of their importance as "downstream" mechanisms of engagement. Some options include:

- The examination, opposition and appeal processes could be more transparent and judicial. The EPO could institute comprehensive reporting of decisions, which should all be written, and the roles of examiner, opposition arbitrator and appeal division member could be clearly separated.[115]

- The role of morality in the patenting process could be strengthened by making an ethical evaluation a mandatory part of the patent application process. An EPO which embraces its statutorily mandated morality function, in addition to soliciting opinions from the EGE, might train its examiners/arbitrators in moral thought.[116] Practice in this area exposes the fallacy of the ECJ's claim that the patent regime operates separate from other regulatory systems (separate from what happens before and after the patent grant), so adequately arming EPO members working at the front lines seems reasonable.[117]

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114 DEMOS, *supra*, note 13, at 40.

115 The EPC allows members to sit at different levels, though not on the same case.

116 Mandatory ethical evaluation has been recommended by EGE, *supra*, note 50, and T. Sampson, "Achieving Ethically Accepted Biotechnology Patents: A Lesson from the Clinical Trials Directive" (2003) 25 E.I.P.R. 419-425.

117 Extending the research regulatory regime and requiring researchers to obtain consent from research participants before seeking a patent is explored in G. Laurie, *supra*, note 65.

- The BPD (and EPO rules) could be amended to exclude specific examples from the morality-based exclusions to patentability. Although inventions relying on reproductive cloning or germline therapy may be reasonable examples of what society currently considers immoral, specific examples date in this quicksilver field. A morality-based exemption which better defines the terms "*ordre public*", "morality" and "commercial exploitation" and which identifies the values sought to be protected (eg: dignity, sanctity, autonomy, justice and solidarity) may be more beneficial. The substance of the morality being applied could be also made more transparent by enumerating admissible sources for measuring public attitudes toward biotechnologies (ie: international instruments, domestic laws, polls, surveys, referenda, etc.). Presumably, such a morality framework would require the EPO to consistently articulate those values and consider them in the context of specific inventions, and to be more exacting in its analyses of what commercial exploitation is or might be for an invention and what society considers immoral.

With respect to giving solidarity some impact on the ground, legislators could amend regulatory instruments to recognise two categories of research: (1) that directed at and resulting in findings concerning genetic structure and function; and (2) that resulting in products and processes with demonstrated practical applications. The former could be open, free and unpatentable (thereby eliminating barriers to knowledge circulation and research tools), whereas the latter could be patented.[118] Other options include shorter monopolies on biotechnology patents (in recognition of their special nature and their importance as research tools in pursuits aimed at improving human health), the restriction of biotech patents to those inventions which have a direct consumer market, or the strict banning of "reach-through" claims (ie: patent claims that could extend to future inventions or which reach beyond the patented invention or platform to seize a share of revenues from another's future end-product sales).[119]

Regardless of the specific options chosen to reify our moral values and give stakeholders a more effective voice in the patenting process, it is clear that no field of law (particularly where it governs genomics and human and environmental health) can ignore its responsibility to facilitate, not only human understanding, but justice, equality and community. It has been stated that:

> … [E]ach generation receives a natural and cultural legacy in trust from previous generations and holds it in trust for future generations. This relationship imposes upon each generation certain planetary obligations to conserve the natural and cultural resource base … and also gives each generation certain planetary rights as beneficiaries of

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[118] R. Ida, *supra*, note 104, suggests that such patents could be registered with an international agency that maintains a central bank of all human genomic research and negotiates and administers all licenses. Similar calls for a global organisation to act as a genome information- and fund-trust have been made: B. Looney, "Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement" (1994) 26 Law Pol. Int. Bus. 231-272, and US National Research Council, *Evaluating Human Genetic Diversity* (Washington: NAP, 1997).

[119] For more on such claims and strategies, see R. Eisenberg, "Reaching Through the Gene" (2003), at http://law.wustl.edu/Academics/Faculty/Bios/Kieff/HGPIP/Final/GEN_50_CH10.pdf (June 19/06).

the trust to benefit from the legacy of their ancestors.[120]

We must take a hard look at how the patent regime (and the economic model) fails to recognise this and falls short of the conduct necessary to both preserve and best exploit our common genetic resource.

[120] E. Weiss, *In Fairness to Future Generations: International Law, Common Patrimony and Intergenerational Equity* (NY: Transnational Publishers, 1989), at 2.

A PENNY FOR YOUR THOUGHTS, A POUND FOR YOUR FLESH: IMPLICATIONS OF RECOGNIZING PROPERTY RIGHTS IN OUR OWN EXCISED BODY PARTS

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Abstract: The implications of recognizing property in our own excised body parts are vast and far reaching, involving ethical, legal and practical issues that cut across many aspects of modern social intercourse and legal regulation. Arguments both for and against such recognition are well rehearsed; enough has been written to fill a small library, or at least a large bookshelf. A significant portion of the work considers the role and impact of such recognition on human dignity. Indeed, given the special status accorded the human body, it is impossible to avoid human dignity and its interaction with the various choices presented by the adoption of a property model. However, reference to this general ethical value is of little assistance. Here, the ethical foundation of a property model is considered within the context of medical ethical four principles, namely autonomy, beneficence, non-maleficence and justice. If such a model promotes these principles, it can be ethically defended. The primary implication of recognizing property in our own excised body parts – the emergence of transactions relating to such parts as between originators and third parties – is assessed against these principles and found to be ethically defensible. In the course of that assessment, many of the derivative implications of adopting such a system (procurement, risk, allocation) are discussed. The necessary alterations to or limitations of the more purely property law principles are also briefly considered, namely issues of title, transfer, valuation and quality. The paper concludes that a property model is ethically supported and legally manageable, and, despite the near impossibility of seeing it come to fruition, it may be the only way to truly engage potential "donors" and recognize in them the same value and rights currently enjoyed by other actors in the body part industry.

Keywords: genetics; human tissue; transplantation; property; property in the body; values; ethics; law

INTRODUCTION

"… The pound of flesh … is dearly bought, is mine, and I will have it."[1]

Social organization introduced human subjugation and the enduring struggle to control our bodies.[2] Modern medical science has introduced previously unimagined avenues of physical investigation, interference and exploitation, expanding that struggle to some fantastic/macabre issues which have significant social implications.[3] It has irrevocably altered the limits of medicine, necessitating a "reconstitution of the body"[4] and forcing us to reconsider our relationship and that of others to our bodies and parts thereof and the value of same to ourselves and society, both in life and death.[5] Rights of control over our bodies are now claimed by "originators"[6] in relation to: [7]

(1) living bodies (ie: interaction between doctors and patients in the medical context);

(2) living excised body parts ("EBPs")(ie: organs, organ fragments and systems from our living body and our recently deceased corpse);

(3) living excised body tissues ("EBTs")(ie: tissue/genetic samples, sperm/egg specimens, etc.); and

(4) corpses (ie: disposition of our remains).

The law must respond to and offer guidance in these circumstances, but it lags behind medical science in its regulation of practices and arbitration of claims.[8] Piecemeal attempts at regulation have resulted in a morass of conventions, laws, codes, rules, circulars and practice notes from a host of international, national, municipal, professional and advisory bodies, all of which are

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1 W. Shakespeare, *The Merchant of Venice*, Act 4, Scene 1.

2 An early example is slavery. A more recent example is women. See E. Richardson & B. Turner, "Bodies as Property: From Slavery to DNA Maps" 29-42, and A. Bottomly, "The Many Appearances of the Body in Feminist Scholarship" 127-148, both in A. Bainham *et al.* (eds.), *Body Lore and Laws* (Oxford: OUP, 2002). Bottomly notes that women have long been trying to establish ownership over their bodies and control over their bodily functions.

3 Examples of advanced interference include our new capacity to (1) relocate parts of a body to other parts (skin grafting), (2) harvest, store and transplant them in other people (blood, bone marrow, reproductive material and organs), and (3) identify and alter base genetic material (gene mapping and sequencing). These advances are accompanied by social, moral and ethical changes, a dynamism which is essential to a pluralist society: K. Mason & G. Laurie, "Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey" (2001) 64 Mod. Law Rev. 710-729, at 710, and M. Freeman, "Does Surrogacy Have a Future After Brazier?" (1999) 7 M.L.R. 1-26.

4 D. Morgan, "Science, Medicine and Ethical Change" in A. Bainham *et al.* (eds.), *supra*, note 2, 329-342, at 329, and W. Strong & S. Lynch, "Ethical Issues in Living Related Donor Liver Transplantation" in A. Caplan & D. Coelho (eds.), *The Ethics of Organ Transplants* (NY: Prometheus Books, 1998) 41-47, at 41.

5 An example of such a re-evaluation is the Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield Council, 1995). ("Nuffield Report")

6 "Originator" refers to the donor or original possessor (as a living whole) of the excised body part or tissue.

7 See E. Richardson & B. Turner, *supra*, note 2.

8 P. Matthews, "The Man Of Property" (1995) 3 M.L.R. 251-274, at 251, notes that as old things disappear (ie: importance of religion) and new things appear (ie: transplantation), existing rules become inadequate.

"obituaries for activities that began long ago".[9]

Although increased originator control over and rights in EBPs need not be premised on property,[10] the concept is not new, having been formulated by Locke, and is a likely solution.[11] As such, this paper considers the implications of recognizing originator property claims over their own EBPs. However, because the implications are so numerous and wide ranging, the assessment is limited to those issues surrounding a single implication, namely the emergence of a market in EBPs wherein originators are active participants capable of entering into primary transactions with respect to their EBPs. Although a property model need not inevitably lead to commerce, the likelihood of it doing so is overwhelming.[12] This is supported by the thriving illegal market that already exists,[13] the great financial rewards that can be derived from the use of EBPs/EBTs,[14] and the alleged absence of any principled reason barring a court from viewing EBPs as property and finding equitable solutions for dividing the "spoils".[15] Thus, an "organ trade" is the most obvious implication and will be assessed by:

(1) offering an ethical foundation for an EBP market (which will address practical implications such as procurement, participant risk and allocation); and

(2) identifying the special implications of and for such markets to property law (which will comprise issues of title, transfer, value and quality).

It is expected that this substantive assessment will demonstrate that a *sui generis* property system, relying on unique limitations, is ethically defensible and practically manageable. Before embarking on this assessment, however, a brief review of the existing legal regime is warranted.

ANALYSIS

> *"In an era when parts can be routinely detached from one body and plugged into another; … when a foetus can be nurtured in an artificial womb, or jobbed out to a surrogate mother; … when we … rebuild faces, breasts or thighs to conform to the moment's ideal of beauty – the concepts and definitions, values and beliefs, rights and laws, must be radically overhauled."*[16]

I. THE EXISTING LEGAL POSITION – NO PROPERTY / NO BENEFIT.

A detailed analysis of the existing legal regime governing bodily control is not within the purview of this paper. Suffice to say, the claimed guiding principle is that there is no property in the body.

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9 J. Black, "Regulation as Facilitation: Negotiating the Genetic Revolution" in R. Brownsword *et al.* (eds.), *Law and Human Genetics: Regulating A Revolution* (Oxford: OUP, 1999) 29-68, at 29.

10 D. Beyleveld & R. Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: OUP, 2001), c. 8.

11 J. Harris, "Who Owns My Body?" (1996) 16 Oxford J.L.S. 55-84, at 68.

12 P. Matthews, *supra*, note 8, at 272-273.

13 Berkeley, http://sunsite3.berkeley.edu/biotech/organswatch (Oct. 11/05).

14 A. Grubb, "The Nuffield Council Report on Human Tissue" (1995) 3 M.L.R. 235-236, at 235.

15 Commentary, "Theft of Body Parts: Property & Dead Bodies" (1998) 6 M.L.R. 247-253, at 251.

16 W. Ewing, *The Body: Photographs of the Human Form* (San Francisco: Chronicle Books, 1994), at 9-10.

This principle finds its origins with Coke,[17] whose *dicta* found voice in cases such as *R.* v. *Sharpe*,[18] *R.* v. *Price*,[19] and *Williams* v. *Williams*.[20] Both the historical foundation of the principle and its propriety in the modern context have been questioned,[21] and, in any event, it is not consistently applied:

- **Corpses:** In *Doodeward* v. *Spence*,[22] the Court recognized third party "ownership" in preserved bodies where some minimal skill had been applied such that they acquired different attributes. The *Human Tissue Act 2004* ("HTA 2004"),[23] assented to on November 15, 2004, and scheduled to come fully into force in April 2006, preserves this exception to the "no property" rule.[24] In addition, it permits possession ("storage" and "use") of the body of a deceased person by persons licensed by the new Human Tissue Authority,[25] and relies on language of "donation" (which assumes some element of ownership).[26]

- **Products:** In *R.* v. *Herbert*[27] (cut hair), *R.* v. *Welsh*[28] (urine sample) and *R.* v. *Rothery*[29] (blood sample), actions in theft were sustained against those who stole products of the body from those in lawful possession of same.

- **EBTs:** In *Moore* v. *Regents of the University of California*,[30] the Court held that a third party could have a proprietary interest in EBTs, basing this conclusion in part on (1) its view that a cell-line is distinct from the original cells, and (2) its concern that research not be hindered by restricting access to "raw material". The HTA 2004 permits licensed persons to remove, store and use "relevant material" (material, other than gametes, which consists of or includes human cells, but does not include embryos outside the human body or hair and nails from the body of a living person[31]) for a number of purposes, which

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17 According to P. Skegg, "Human Corpses, Medical Specimens and the Law of Property" (1975) 4 Anglo-Am. Law Rev. 412, Coke stated, "The burial of the cadaver (that is *caro data vermibus*) is *nullius in bonis*."

18 (1857), 169 E.R. 959.

19 (1884), 12 Q.B.D. 247.

20 [1881-85] All E.R. 840.

21 K. Mason & G. Laurie, *supra*, note 3, indicate that the early cases misinterpreted or misapplied the principle, the applicability of which they question. See also Commentary, *supra*, note 15.

22 (1908), 6 C.L.R. 406 (Aust. H.C.), approved in *R.* v. *Kelly*, *infra*, note 34.

23 (UK), 2004, c. 30. Prompted by the Bristol Royal Infirmary and Alder Hey scandals, the HTA 2004 repeals and replaces, *inter alia*, the *Human Tissue Act 1961*, the *Anatomy Act 1984* and the *Human Organ Transplants Act 1989*. It identifies the purposes for which corpses can be stored and used and for which human organs and tissue can be removed (from corpses and living persons), stored and used, and it erects the Human Tissue Authority, which has guidance, licensing and oversight responsibilities. For more on the HTA 2004 and the new regime, see www.opsi.gov.uk/acts/en2004/2004en30.htm and www.dh.gov.uk/assetroot/04/10/36/86/04103686.pdf.

24 HTA 2004, ss. 32(9) and (10), which are already in force, except from the prohibition in commercial dealing in human tissue material which is the subject of property because of an application of human skill.

25 HTA 2004, ss. 1(1), (2), (3) and Schedule 1.

26 HTA 2004, s. 8.

27 (1961) 25 J. of Crim. Law 163. A lock of Byron's hair was sold at Sotheby's Auction House in 1970 for £320: P. Skegg, *supra*, note 17.

28 [1974] R.T.R. 478 (C.A.).

29 [1976] R.T.R. 550 (C.A.).

30 (1990), 793 P. 2d 479 (Cal. S.C.), reversing (1988), 249 Cal. R. 494 (C.A.).

31 HTA 2004, s. 53.

include, *inter alia*, obtaining scientific or medical information about a living or deceased person, research, and transplantation.[32] One can infer that storage and usage rights visit upon licensed persons certain proprietary rights, and that interference with those rights will result in legal consequences.

- **EBPs:** In *Dobson* v. *North Tyneside Health Authority*[33] and *R.* v. *Kelly*[34] the Courts recognized property rights in EBPs where they had been subjected to dissection, preservation or otherwise acquired different attributes by the application of skill. Those who apply such skill (ie: doctors, researchers, etc.) obtain title and can transfer same to successors in title. In addition, the Secretary of State has statutory power to charge for body parts not readily available to any person,[35] certain (US) organizations acquire EBPs and supply them to researchers on a commercial basis,[36] and both transplant services and pituitary glands from cadaver brains are sold commercially.[37]

In short, property concepts and property rights pervade the law governing the human body, but property rights are generally denied to originators. This led Broussard J., dissenting in *Moore* v. *Regents of the University of California*, to observe that, "the majority's analysis cannot rest on the broad proposition that a removed part is not property, but … on the proposition that a *patient* retains no ownership interest in [an excised] body part … ."

The legal position of originators in relation to primary EBP transactions will also be governed by the HTA 2004. The HTA 2004 refers to "controlled material", which is defined as any material which consists of or includes human cells, is (or is intended to be) removed from the human body, is intended for transplantation and is not gametes, embryos or material which is the subject of property because of the application of human skill.[38] Sections 32 and 33 of the HTA 2004 make it an offence to:

- give or receive a reward for the offer to supply or supply of a controlled material;
- receive a reward to seek a supply for a controlled material;
- initiate or negotiate transactions for reward concerning a controlled material;
- manage or control an organization pursuing such transactions for reward;
- publish or distribute an advertisement inviting such transactions for reward;
- remove transplantable material from the body of a living person, subject to exceptions;[39]
- use transplantable material from the body of a living person, subject to same exceptions.

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[32] See Schedule 1 of the Act.

[33] [1996] 4 All E.R. 474 (C.A.).

[34] [1998] 3 All E.R. 741 (C.A.).

[35] See s. 25 of the *National Health Service Act 1977* (U.K.), 1977, c. 49, and P. Matthews, "Whose Body? People As Property" (1982) 36 Current Legal Problems 193-239, at 225.

[36] G. Dworkin & I. Kennedy, "Human Tissue: Rights in the Body and Its Parts" (1993) 1 M.L.R. 291-319, at 305, cite the International Institute for the Advancement of Medicine and Human Biologics Inc.

[37] L. Lehtonen, "The Bioethics Convention of the Council of Europe and Organ Sharing for Transplant Recipients in Scandinavia" (2002) 21 Med. Law 745-751.

[38] HTA 2004, ss. 32(8) and (9), and s. 33(7). These more inclusive definitions replace the definition of "human organ" in s. 7(2) of the *Human Organ Transplants Act*, which meant any part of the body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated.

[39] The exception is articulated in HTA 2004, s. 33(3), which states that the Secretary of State may lift the operation of the offence where the Authority is satisfied that no reward has been given, such other conditions as are specified are satisfied, and such other requirements as are specified are complied with.

"Reward" is defined as "any financial or other material advantage",[40] but does not include money or money's worth to the holder of a license as consideration for transporting, removing, preparing, preserving or storing controlled material, nor expenses incurred by third parties for these same activities, nor does it include the reimbursement of expenses or lost earnings incurred by the originator, so far as reasonably and directly attributable to the supply of the material.[41]

This "no property" position is fortified by the Nuffield Report,[42] the Biomedicine Convention[43] and its Additional Protocol,[44] Medical Research Council Guidelines,[45] and General Medical Council Guidelines,[46] and is defended by arguments like the following:

> … It [a transaction for reward] reflects a commodification of bodies, a dilution of altruism, and it fails to meet both logical and economic objections. For example, voluntary consent to sale would be self-refuting as the organs would come from those who (a) were economically coerced, (b) had a hopelessly misguided perception regarding the transaction, or (c) were reasonably wealthy but obsessively concerned with accumulating money at any price. None of these categories should be considered as an acceptable basis for the distribution of transplant organs.[47]

One implication of recognizing originator property in EBPs would be the necessary reform of the HTA 2004 and the rationalization of the many international and domestic instruments and guidelines which impact on body control. A uniform theoretical foundation to all rights in the body and EBPs (by originators and third parties) would have to be formulated.

II. ETHICAL FOUNDATION FOR RECOGNIZING PROPERTY IN OUR EBPs.

Any activity closely linked with bodily integrity, medicine and healthcare must be ethically supported, particularly where science, research and business converge.[48] Thus, the greatest implication of (and hurdle to) recognizing originator property rights and primary transactions in

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40 HTA 2004, s. 32(11).

41 HTA 2004, ss. 32(6) and (7).

42 *Supra*, note 5. For a critique of this, see P. Matthews, *supra*, note 8, who concludes that it relies on property and a complex of other areas of law with bald conclusionary leaps, all intended to ensure that the one person who has no property in her EBPs is the originator (ie: it erects presumptions of abandonment and makes broad interpretations against the donor as to the meaning and content of consent).

43 Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine, E.T.S. 1997, No. 164. Article 21 states that "the human body and its parts shall not, as such, give rise to financial gain".

44 Additional Protocol of the Convention on Human Rights and Biomedicine Concerning Transplantation of Organs and Tissues of Human Origin, E.T.S. 2002, No. 168. Article 21 reiterates the prohibition on financial gain with some qualifications, and Article 22 prohibits organ trafficking.

45 MRC, *Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2001), Part 2.

46 GMC, *Guidance for Doctors on Transplantation of Organs from Live Donors* (1992).

47 D. Lamb, *Organ Transplants and Ethics* (Aldershot: Avebury, 1996), at 138.

48 L. Bently & B. Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" (1995) 3 M.L.R. 275-291, agree, noting the ambivalence toward or suspicion of science and big business, and suggesting that even the law is finding it more and more difficult to place trust in the scientific community.

EBPs is that of ethical grounding; the need to debunk current ethics-based reactions antagonistic to a property model on the one hand and to support the property model with a sound ethical foundation on the other.

Ethical debates about EBPs often turn on considerations of "human dignity", which is premised on the idea that every human being, regardless of status or capacity, has inherent value and the right to be treated as having worth.[49] It is enshrined in most religions,[50] cultures[51] and legal traditions,[52] and has resulted in special status being accorded to the body.

Antagonists to the property model argue that human dignity and the concomitant status of the body precludes identifying EBPs as property subject to primary transactions, because such identification "instrumentalizes" the body, treating it as a means (or object) rather than an end.[53] Thus, they use dignity to justify constraints on activity. However, over reliance on human dignity to impose constraints is problematic because this same principle can simultaneously support opposing claims and views.[54] For example, human dignity can be viewed as an empowering principle. As such, it grounds autonomy.[55] One could argue that failure to respect one's freely entered contracts (which result in no harm to others), even where they concern transactions considered undignified, treats one as an object and offends autonomy and thus dignity.[56]

The tension between these two positions is exemplified by *R.* v. *Brown*,[57] wherein consenting adults participating in physically abusive sado-masochism were charged under the *Offences Against the Person Act 1861*. The majority, relying on dignity, held that the prohibition against such activity is for the protection of society (which views the infliction of pain as evil) and society's basic values.[58] Lord Mustill, dissenting, also recognized the role of dignity, holding:

> … [T]he state should interfere with the rights of an individual … no more than is necessary to ensure a proper balance between the special interests of the individual and the general interests of … the populace at large.[59]

The accuseds appealed to Strasbourg, but the majority held that Article 8 (private life) of the European Convention on Human Rights[60] ("ECHR") could not be stretched to protect one's

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[49] D. Beyleveld & R. Brownsword, *supra*, note 10, at 15-17, and P. Walsh, "Principles and Pragmatism" (1995) 3 M.L.R. 237-250.

[50] Self-mutilation is widely forbidden on the ground that it is an affront to damage the body, which ultimately belongs to God or over which God exercises final authority: D. Lamb, *supra*, note 47, at 105.

[51] Most people's sense of personal identity, regardless of origin, is strongly bound to their bodies: see N. Zohar, "Toward Justice in the Organ Trade" (1993) 27 Is. L.R. 541-565, at 551.

[52] See, for example, the Preamble to the Biomedicine Convention and other international instruments.

[53] The idea that humans must be treated as ends in themselves, not as means to an end or someone else's end originates with Kant: see D. Beyleveld & R. Brownsword, *supra*, note 10, at 87-110.

[54] See M. Bedjaoui, *Proceedings of the Third Session of the International Bioethics Committee of UNESCO*, September 1995, vol. 1, at 144, D. Beyleveld & R. Brownsword, "Human Dignity, Rights and Genetics" 69-88, at 88, and A. Pottage, "The Inscription of Life in Law: Genes, Patents and Bio-politics" 148-173, at 155, both in R. Brownsword *et al.* (eds.), *supra*, note 9, who note the weaknesses of deploying human dignity as a constraint on practices that are intuitively disliked.

[55] See D. Beyleveld & R. Brownsword, *supra*, note 10, at 22-25, H. Hart, *Law, Liberty and Morality* (Oxford: OUP, 1963), and A. Gewirth, *Reason and Morality* (Chicago: UCP, 1978).

[56] D. Beyleveld & R. Brownsword, *supra*, note 54, at 79.

[57] [1993] 2 All E.R. 75 (H.L.).

[58] *Ibid*, at 84.

[59] *Ibid*, at 116.

[60] European Convention for the Protection of Human Rights and Fundamental Freedoms, E.T.S. 1950, no. 5.

immorality.[61]

Given the dualistic nature of "human dignity", it is more useful to measure the extension of property rights against four commonly used principles of bioethics – (1) autonomy, (2) beneficence, (3) non-maleficence and (4) justice – which are themselves grounded in or sensitive to "human dignity."

(1) Autonomy

The many definitions of autonomy rest on the worth of individuals.[62] Its central concept is that one's body is a central part of oneself and control over same is integral to individual integrity, even though that control may result decisions/actions which lead to death.[63] Comprising physical, emotional, economic and legal liberty and the right to be free from coercion re: same,[64] autonomy is generally considered the most fundamental of the ethical principles where it is exercised with due regard to the rights of others and society.[65] It is argued that respect for autonomy enhances dignity:

> … [S]urrendering one's body parts and transferring one's rule-preclusionary control from oneself to another … cannot, *as such*, violate dignity as the ground of generic rights, since not to grant this power to agents is to violate their generic rights. Furthermore, we fail to see how such actions could *per se* violate dignity as a virtue – after all, if this were possible then it must be contrary to dignity as a virtue (or the ground of generic rights) to donate a kidney to save the life of another.[66]

In the medical context, autonomy, which finds legal expression in the requirement for consent, enables a person to decide what treatment or bodily interference she will accept.[67] Limits on consent are acceptable, but must be minimal and ethically grounded. In the context of excision of body parts for transplantation purposes, an originator's decision can be characterized as ethically autonomous where the following are present:[68]

(1) knowledge and understanding of (a) the nature of the procedure, (b) the physical risks of same, (c) likely short- and long-term health consequences, and (d) quality

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61 *Brown et al.* v. *U.K.* (1997), 24 E.H.R.R. 39 (E.C.H.R.). Another example of the clash between interpretations of human dignity is the dwarf-throwing case discussed in D. Beyleveld & R. Brownsword, *supra*, note 10.

62 See T. Beauchamp & R. Faden, *The History and Theory of Informed Consent* (Oxford: OUP, 1986), at 7, G. Dworkin, *The Theory and Practice of Autonomy* (Cambridge: CUP, 1988), at 6, and O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: CUP, 2002), at 23.

63 See *Re C (Adult: Refusal of Treatment)*, [1994] 1 W.L.R. 290 (H.L.), and an abundance of academic work, including K. Mason & G. Laurie, *Mason & McCall Smith's Law and Medical Ethics*, 7th ed. (Oxford: OUP, 2006).

64 S. Aksoy & A. Elmali, "The Core Concepts of the 'Four Principles' of Bioethics as Found in Islamic Tradition" (2002) 21 Med. Law 211-224.

65 See J. Harris, *supra*, note 11, at 62, R. Scott, *Rights, Duties and the Body* (Oxford: OUP, 2002), at 11 & 14, and the limitations placed on unfettered individual rights in Article 8 of the ECHR (and other ECHR rights).

66 D. Beyleveld & R. Brownsword, *supra*, note 10, at 192, who conclude that being both means and end does not affront dignity.

67 See K. Mason & G. Laurie, *supra*, note 63.

68 See R. Strong & S. Lynch, *supra*, note 4, at 43.

of life prospects;[69]

(2) voluntariness and an absence of coercion;[70] and

(3) legal capacity and mental competence.[71]

In the context of EBP transactions, the ethical formulation of autonomy can be said to have been fulfilled where originators meet or comply with these conditions.

The primary charge against the existence of autonomy is coercion (a failure at factor (2)). Antagonists argue that (1) it is primarily the poor who will sell EBPs, and their economic position negates free will (ie: they are coerced by the offer of money and are exploited on the basis of their financial position), and (2) recognizing property in EBPs might lead to crime (forced removals) and is the first step in a slippery slope to slavery.

On the first point, there is no evidence that people in financial difficulty cannot make reasoned, autonomous decisions regarding money (or their body); they frequently make difficult decisions within their limited options:

> … [A]ll human actions take place under certain constraints and pressures, frequently with direct ramifications for the actors' well-being, and even survival. In the face of scarcity and … dangers, people regularly struggle against natural and social realities; insofar as there is human freedom, this is its basic condition. Thus, even presuming that the would-be vendor is aiming to avoid starvation, it is far from clear why this motivation renders the deed less voluntary than other common acts.
>
> * * *
>
> … [W]hat forces [the vendor's] hand is not the offer to buy his kidney (or labor), but rather his grim background conditions, the realities of scarcity. And as long as these conditions exist, it is hard to see how the buyer's offer can be condemned on the grounds of "coercion".[72]

The global capitalized social structure chosen by (imposed on) us, which provides the comforts of life and the luxury of choice unevenly, should not be used to deny people the few choices they might have because of the very economic situation forced upon them.[73] Given their position, it is not ethically appropriate to further limit their choice:

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[69] See Articles 20 and 25 of World Medical Association, *Statement on Human Organ & Tissue Donation & Transplantation* (52nd WMA General Assembly, October 2000) at www.wma.net/e/policy/uma.htm (Feb. 18/04). See also ss. 3(2)(a) and (b) of the old HOTA Regulations.

[70] Consent is addressed in Article 5 of the Biomedicine Convention and Articles 11, 12, 13 of the Additional Protocol. See also Article 23 of the WMA Statement, *ibid*, and ss. 3(2)(c) and (d) of the HOTA Regulations.

[71] A concept with which physicians and lawyers are well acquainted, and which is well established in property and sale of goods law: see H. Beale (gen. ed.), *Chitty on Contracts*, 28th ed. (London: Sweet & Maxwell, 1999), at ch. 8 and ch. 43. It is addressed by Articles 6 and 7 of the Biomedicine Convention and Article 14 of the Additional Protocol.

[72] N. Zohar, *supra*, note 51, at 552 & 554.

[73] An argument made by Marx in relation to labour and by J. Radcliffe-Richards *et al.*, "The Case For Allowing Kidney Sales"(1998) 352 Lancet 1950-1952, in the context of EBP sales.

> Consider unskilled laborers in desperate poverty, willing to be hired for twelve-hour workdays at below the minimum wage. If we forbid this, … we leave these people unemployed and even worse off. … If there are people in desperate need, their co-members [in society] with means are morally bound to help them … . … [B]anning organ sales [however] is not likely to be joined to an effort to alleviate the desperate conditions of prospective vendors. …[74]

In any event, EBP sales may not be limited to the poor. Wealthy, informed, rational originators may also consent to primary transactions.[75]

Further, the current practice of seeking EBPs from living related donors does not protect originators from coercion. Donors are subject to a more insidious coercion in the form of psychological pressure, self-imposed or exerted by other family members.[76] Indeed, antagonists' autonomy/consent arguments against primary transactions are equally applicable to present practices.[77]

On the second point, primary transactions in EBPs are qualitatively different from slavery,[78] which is clearly outlawed.[79] They involve the *voluntary* use of the originator's EBPs *for the profit of the originator*. With respect to criminal procurement, existing criminal and civil laws prohibit and provide remedies for the type of activities that would be necessary to pursue such a course. Further, it takes a high degree of expertise to usefully extract an organ for transplantation. This, combined with short warm anoxic times, hospitalization needs and storage requirements are not conducive to a burgeoning illegal procurement system (based on kidnapping), which has never been substantiated.[80] It is further argued:

> [I]t is unreasonable to justify the banning of an activity which may bring relief … and save … life, on the basis of a concern that criminal activity may develop around it. A properly ordered society deals with these risks and does not desist from pursuing vital activities because of them.[81]

We do not ban land ownership because it could lead to trespass or sexual intercourse because it could lead to rape, so a ban on freely entered into primary transactions because it could lead to

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74 N. Zohar, *supra*, note 51, at 562. A. Barnett *et al.*, "Improving Organ Donation: Compensation versus Markets" in A. Caplan & D. Coelho (eds.), *supra*, note 4, 208-218, at 213, also point out that economic conditions, not the market, is the source of exploitation.

75 See S. Wilkinson & E. Garrard, "Bodily Integrity and the Sale of Human Organs" (1996) 22 J.M.E. 334-339.

76 See D. Lamb, *supra*, note 47, at 107, J. Radcliff-Richards *et al.*, *supra*, note 73, L. Ross *et al.*, "Ethics of Paired-Kidney-Exchange Program (1997) 336 N.E.J.M. 1752-1755 (citing several studies), A. Campbell *et al.*, *Medical Ethics*, 2nd ed. (Oxford: OUP, 1998), at 57, and J. Kahn, "Would You Give a Stranger Your Kidney? The Ethics of 'Unknown' Kidney Donors" (1988) at www.cnn.com/HEALTH/bioethics/9807/stranger.kidney (Feb. 18/04).

77 As argued by S. Wilkenson & E. Garrard, *supra*, note 75.

78 G. Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: CUP, 2002), at 317.

79 See P. Matthews, *supra*, note 8, and Article 4 of the Universal Declaration of Human Rights (1948), and Article 3 of the European Convention on Human Rights (1950).

80 B. Cohen *et al.*, "Commerce in Transplantation: How Does it Affect European Legislation?" (2000) 14 Clin. Trans. 28-31.

81 J. Weisman, "Organs As Assets" (1993) 27 Is. L.R. 610-623, at 617.

crime is an unwarranted restriction on autonomy. Regardless, it is within the capacity of the legal system to erect safeguards to limit crime and ensure genuine consent.[82]

The above demonstrates that there is ethical support for a property model permitting primary transaction in EBPs in that it would permit informed originator's to exercise autonomous judgment (thereby promoting human dignity) to perform an act that does not injure others.

(2) Beneficence

In the medical context, beneficence often relates to treating and healing patients. However, it can encompass acts of kindness, mercy, charity, altruism, love and humanity more generally; the promotion of the welfare of others.[83] Beneficence therefore requires us to consider the plight of the patient, the one person we know to be in need of compassion and acts of welfare promotion.

World-wide EBP demand/need exceeds supply and the gap is growing.[84] For example, it has been reported that there are 40,000 patients waiting for a kidney in Western Europe alone.[85] In addition, the growing waiting lists mean that more patients die waiting. For example, in the UK, in 1998, 4,640 patients were on waiting lists.[86] In Europe, by 2010, the wait could be 10 years and already 15% to 30% of patients die waiting.[87] Further, transplants are almost always preferred to other forms of treatment (ie: kidney transplants provide a better quality of life than dialysis and cost less than alternative chronic therapy).[88]

Despite this situation, antagonists lament that an EBP market would reduce altruism and solidarity and destroy the spiritual structure upon which organ transplantation is based.[89] However, one can question both the "spiritual structure" of current practices,[90] and the analogy to the blood market.[91] Further:

- The existence of a market does not preclude purely altruistic gifting, which could still be encouraged.[92]

- The existence of payment does not negate concern for others or the feelings of solidarity and responsibility originators may feel knowing they helped another.[93]

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82 S. Wheatley, "Human Rights and Human Dignity in the Resolution of Certain Ethical Questions in Biomedicine" (2001) 3 E.H.R.L.R. 312-325.

83 S. Aksoy & A. Elmali, *supra*, note 64.

84 M. Revel, "Research on Animal Cloning Techniques and their Implications in Medical Ethics: An Update" (2000) 19 Med. Law 527-543.

85 R. Vermot-Mangold (Rapporteur), "Trafficking in Organs in Europe" (2003) Doc. 9822. In the USA, organ demand is critical and even a 20% increase in donations would only dent the need: J. Kahn, *supra*, note 76.

86 J. Montgomery, *Health Care Law*, 2nd ed. (Oxford: OUP, 2003), at 443. In the USA, 70,000 patients sit on waiting lists and more than 12 die every day because vital organs are unavailable: R. Shapiro, "Legal Issues in Payment of Living Donors for Solid Organs" (2003) Human Rights 19-20.

87 R. Vermot-Mangold (Rapporteur), *supra*, note 85, and A. Rogers, "European Health Ministers Split Over Organ Trafficking" (2003) at www.thelancet.com/search/search/isa (Feb. 10/04).

88 D. Lamb, *supra*, note 47, at 11-12, says a successful transplant with 1-year post-operative therapy costs less than a single year of dialysis. In 1983, transplantation cost US$5,000-US$8,000; dialysis cost US$35,000 annually.

89 Citing R. Titmuss, *The Gift Relationship: From Human Blood to Social Policy* (NY: Pantheon Press, 1971).

90 See N. Goolam, "Human Organ Transplantation: Multicultural Ethical Perspectives" (2002) 21 Med. Law 541-548, at 544.

91 See N. Zohar, *supra*, note 51, at 563.

92 K. Mason & G. Laurie, *supra*, note 3, at 728.

93 D. Beyleveld & R. Brownsword, *supra*, note 10, at 42.

- The EBP sale may well be made by the originator for an altruistic purpose (ie: the money received may be used for the medical treatment or the education of another).[94]

- We do not extend this reasoning to doctors, who are paid for their services, and few would suggest that their actions never comply with the principle of beneficence.

Some argue:

> … [T]here is something suspect about telling people that their contributions will be devalued if paid for. … [M]any people who are paid for their work at the same time feel that they are making a valuable contribution. When great sums are paid for works of art, this is hardly a sign or a cause of diminishing their intrinsic value or our respect for those who produce them. Opposition to "commodification" thus sometimes sounds … like clamoring to continue getting something for free, and trying to press its providers into moral service.[95]

The law's recognition of the sanctity of life,[96] and the cross-cultural agreement that one must make every effort to save life,[97] combined with the above supports a utilitarian approach toward achieving beneficence, which approach is achieved by a property model which allows originator transactions.

(3) Non-Maleficence

Non-maleficence is often defined as doing nothing which causes injury. A more contextual approach directs people to be compassionate and generous.[98] Consideration of this principle in the context of EBPs requires a focus on the risk to the originator.

Antagonists argue that this principle bars physicians from excising parts/organs intended for sale because there is no therapeutic benefit to originators; it is mutilation, which is socially unacceptable. However, the following invalidate this argument:

- As a matter of law and policy transplants are accepted, as are the concomitant risks they represent to originators.[99]

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[94] A. Campbell *et al.*, *supra*, note 76, at 57. In any event, the death of altruism means little when patients are dying on waiting lists because of an already existing dearth of altruism.

[95] N. Zohar, *supra*, note 51, at 564-565. See also M. Radin, "Justice and the Market Domain" in J. Chapman & J. Pennock (eds.), *Markets and Justice* (NY: NY U. Press, 1989) 165-197, at 175, and R. Arneson, "Commodification and Commercial Surrogacy" (1992) 21 Phil. & Pub. Aff. 132-164.

[96] As enunciated in *Airedale NHS Trust* v. *Bland*, [1993] 1 All E.R. 821 (H.L.), *Re B (Minor)(Wardship: Medical Treatment)*, [1990] 3 All E.R. 927 (C.A.), *An Hospital NHS Trust* v. *S. et al.*, [2003] E.W.H.C. 365 (Fam. Div.), and *Pretty* v. *UK*, [2002] 2 F.L.R. 45 (E.C.H.R.).

[97] In the Torah, preservation of life supercedes all duties and prohibitions other than adolatry, incest and shedding blood. In the Talmod, the possibility of saving life outweighs other considerations and permits risk to the lifesaver. In the New Testament, we are told to emulate Jesus who gave his very life for the sake of others. See N. Goolam, *supra*, note 90, and M. Halperin, "Organ Transplants from Living Donors" (1993) 27 Is. L.R. 566-587.

[98] S. Aksoy & A. Elmali, *supra*, note 64, at 219.

[99] See, K. Mason & G. Laurie, *supra*, note 63, at 483-484, J. Montgomery, *supra*, note 86, at 446, and *Re Attorney General's Reference (No. 6 of 1980)*, [1981] 1 All E.R. 1057 (H.L.).

- The existence of donation, transplant technology, demand exceeding supply and the existence of a worldwide market economy (which naturally responds to supply deficits with monetary inducements), has made EBP sales impossible to prevent.[100] Originators willing to sell their EBPs despite the illegality of doing so are driven into the unregulated black market, with the consequence that they are not protected and face greater risk.[101]

- Technical skills in transplant surgery are growing exponentially (outpacing society's ability to supply[102]) and most subject organs can be removed with minimal short-term[103] or long-term[104] health concerns if done properly.

- There may be good (non-therapeutic) reasons why originators are willing to accept some risk, and the law accepts this as relevant. For example, in *Re Y (Mental Incapacity: Bone Marrow Transplant)*,[105] the Court recognized emotional/psychological and social benefits to an incompetent donor, concluding that they outweighed the physical risk and the excision was therefore in her best interests.

- Society does not protect other potentially economically vulnerable people from pursuing dangerous occupations or activities (ie: soldiers, police officers, firefighters, miners, boxers, F1 drivers).[106] Surrogacy, which offers the closest analogy, is legally sanctioned.[107] Under surrogacy arrangements, a couple use the womb of another woman to produce a child. The surrogate undertakes a potentially risky, time-consuming and uncomfortable service which, although capable of being characterized as instrumentalization or commodification of the body/womb, is a valid participation in the statutorily tolerated market in reproductive labour and which is viewed as a socially useful undertaking.[108] A parallel service argument can be made for EBP primary transactions.

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[100] As argued by both J. Weisman, *supra*, note 81, at 613, and J. Dukeminier, "Supplying Organs for Transplantation" (1970) 68 Mich. L.R. 811, at 812. For statistics on the black market, see Berkeley, http://sunsite3.berkeley.edu/biotech/organswatch, which names Argentina, Brazil, China, Columbia, France, Germany, India, Italy, Mexico, Russia, S. Africa, Turkey, the UK and the USA as active in the market.

[101] See N. Velasco, "Organ Donation and Kidney Sales" (1998) www.thelancet.com/search/search/isa (Feb. 10/04), D. Josefson, "Selling a Kidney Fails to Rescue Indians from Poverty" (2002) 325 B.M.J. 795, M. Friedlaender, "The Right to Sell or Buy a Kidney: Are We Failing Our Patients?" (2002) 359 Lancet 971-973, and J. Siegel-Itzkovich, "Israel Considers Paying People for Donating a Kidney" (2003) 326 B.M.J. 126.

[102] D. Lamb, *supra*, note 47, at 1.

[103] T. Peters *et al.*, "Living Unrelated Kidney Donors: A Single Centre Experience" (1999) 13 Clin. Trans. 108-112, and T. Peters *et al.*, "One Hundred Consecutive Living Kidney Donors: Modern Issues & Outcomes" (2002) 16 Clin. Trans. 62-68, note a 2-8 day recovery period with a brief post-operative course of pain medication.

[104] See M. Halperin, *supra*, note 97, who cites F. Vincenti *et al.*, "Long Term Renal Function in Kidney Donors: Sustained Compensatory Hyperfiltration with No Adverse Effects" (1983) 36 Transplantation 626, D. Weiland *et al.*, "Information of 628 Living-related Kidney Donors at a Single Institution with Long Term Follow-up in 472 Cases" (1984) 16 T.P. 5, and J. Tapson, "The Risk of Donor Nephrectomy" (1985) 8 I.J.A.O. 13-16.

[105] [1997] 35 B.M.L.R. 111 (Fam. Div.).

[106] See M. Freeman, *supra*, note 3, at 5, who questions why we shouldn't make money from our bodies given that we permit it in the form of athletes and models.

[107] Surrogacy arrangements are recognized by s. 30 of the *Human Sterilization & Embryology Act 1990*. For a discussion on same see Commentary, "Surrogate Arrangements & Parental Orders" (1995) 3 M.L.R. 204-208, and Commentary, "Surrogate Contracts: Parentage" (1995) 3 M.L.R. 219-221.

[108] See D. Satz, "Markets in Reproductive Labour" (1992) 21 Phil. & Pub. Affairs 107-131, and L. Purdy,

Thus, although some originator risk exists, it is minimal, within our capacity to regulate, and within a competent originator to accept in the course of helping another human being; for we are reminded that a "total" human – one who is social, rational and moral – is sensitive to imperatives to help others and accepts some risk in doing so.[109] All of this relieves physicians from interpreting non-maleficence as barring removal of certain body parts bound for market.[110]

(4) Justice

Justice, often linked with healthcare budgetary assessments, is accepted as meaning the fair, equitable and appropriate treatment of someone in light of what is owed to that person; it is used to balance competing claims and achieve a fair distribution of scarce resources.[111] In the EBP market context, the distribution of scarce EBPs would be thus measured.

Antagonists argue that it would be undesirable to permit a market because associated pressures would force resources to be distributed according to the relative economic power of the recipient. This need not be the case.

With respect to procurement, independent licensed third parties (ie: certified brokers, insurance organizations or trusts) who have contracted to do so, could solicit and purchase EBPs from originators within defined geographic and/or temporal boundaries. They could ensure compliance with existing guidelines relating to information and consent (ie: explain nature and risks of procedure, ensure understanding of same, confirm consent, absence of duress, right to withdraw consent),[112] oversee appropriate recuperative treatment, and distribute the EBPs to transplant teams *per* established criteria.[113]

With respect to allocation, transplant teams could allocate EBPs to patients on national or regional waiting lists according to existing medical criteria, which includes considerations of length of time on waiting list, severity of need, probability of benefit/success (measured by disease/condition type, probable complications and ability to overcome same and histo-compatibility), and excludes discrimination on social status, lifestyle or behaviour.[114]

Thus, proper regulation of the process minimizes the procurement and allocation dangers of a property/market model and could fulfil the justice principle better than the current regime, which offers little incentive to donors and procurement officers, and little hope for patients.[115]

(5) Conclusion

Reproducing Persons (USA: Cornell U. Press, 1996).

[109] D. Lamb, *supra*, note 47, at 105.

[110] Which would be somewhat hypocritical given the number of cases in which patients are permitted to die (ie: *Airedale NHS Trust* v. *Bland*, *supra*, note 89, *Re C (Minor)(Wardship: Medical Treatment)*, [1990] Fam. 26 (Fam. Div.), and *Re B (Minor)(Wardship: Medical Treatment)*, [1981] 1 W.L.R. 1421 (C.A.)).

[111] S. Aksoy & A. Elmali, *supra*, note 64, and T. Beauchamp & J. Childress, *Principles of Biomedical Ethics*, 4th ed. (NY: OUP, 1994).

[112] See Articles 5-9 of the Biomedicine Convention and s. 3(2) of the old HOTA Regulations.

[113] Market proponents have offered several suggestions for procurement and distribution and the separation of same. See J. Radcliffe-Richards *et al.*, *supra*, note 73, A. Barnett *et al.*, *supra*, note 74, and J. Weisman, *supra*, note 81, at 618.

[114] See WMA, *supra*, note 69, Articles 30 and 32, and the Canadian Medical Association, *Organ & Tissue Donation & Transplantation Policy (1987)* at www.cma.ca (Feb. 20/04).

[115] A. Barnett *et al.*, *supra*, note 74, at 209-210. They also argue that the market would eventually correct the current imbalance such that supply and demand would be even and prices stable.

Considering primary EBP transactions within the context of the four bioethical principles highlights many of the implications of recognizing property in our own EBPs. It challenges many of the arguments against recognizing property and provides an ethically sound case for extending such rights. In particular, a property model would further originator autonomy, promote beneficence toward patients, expose originators to acceptable risks and thereby comply with non-maleficence, and could be structured to ensure justice. A property model could improve the plight of patients without negatively impacting on originators. A complete absence of exploitation may be unachievable,[116] but the existing system has not avoided exploitation. Ultimately, if adopting a property model could increase the supply of necessary EBPs for life-saving transplantation, denying it may be immoral.[117]

III. SPECIAL PROPERTY LAW CONCERNS RELATED TO RECOGNIZING PROPERTY IN OUR OWN EBPs.

A property model is more palatable if the nature of property law is understood. "Property" is a relationship to an item, not the item itself.[118] "Property rights" are specific rights, including the right to exclude others, which attach to definable, identifiable, transferable items, and they can be full or limited.[119] "Property law" is a complex social institution which organizes items and services for which there is greater potential demand than supply.[120] It has certain attributes which make it amenable to absorbing claims relating to EBPs:

- **Versatility:** It has proved versatile, metamorphosing over the centuries as a result of changing concepts of social and economic value, to address realty, chattels, intellectual products, personality and image, and other areas of human endeavour over which we wish to exercise personal control. Although various disciplines share common principles and overlap, they offer different causes of action and remedies, and could be further expanded.[121]

- **Limitability:** It recognizes moral limitations in the use of objects over which we have rights.[122] Related to this moral awareness are legal limitations which it imposes on the use and enjoyment of property. As such, limits could be imposed on the rights over and use of EBPs so that divestiture against one's interests could not be achieved (ie: divestiture of vital organs).[123]

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116 A. Campbell *et al.*, *supra*, note 76, at 57, feels it's impossible to stamp out in a capitalist society.

117 J. Weisman, *supra*, note 81, at 618.

118 P. Matthews, *supra*, note 35, and K. Gray, *Elements of Land Law* (London: Butterworths, 1987), at 8.

119 P. Matthews, *ibid*, at 193-195, J. Weisman, *supra*, note 81, at 610, R. Smith, *Property Law*, 3rd ed. (London: Longman, 2000), at 3, as well as *Blade* v. *Higgs* (1865), 11 E.R. 1474 (H.L.) and *National Bank Ltd.* v. *Ainsworth*, [1965] A.C. 1175 (H.L.).

120 J. Harris, *supra*, note 11, at 56-57.

121 P. Matthews, *supra*, note 35, at 252-255, and K. Gray, *supra*, note 118, at 11, where it is noted that the changing objects of property has resulted in the abandonment of property in wives and slaves.

122 J. Harris, *supra*, note 11, at 60-61, K. Gray, "Property in Thin Air" (1991) C.L.J. 252, and S. Worthington, *Personal Property Law* (Oxford: Hart Publishing, 2000).

123 See K. Mason & G. Laurie, *supra*, note 3, Commentary, *supra*, note 15, at 251, and P. Matthews, *supra*, note 35, at 252-256.

- **Sensitivity:** It is sensitive to and interacts easily with other areas of law, cooperating with public and private domestic and international law.[124] Unfettered enjoyment of property is restricted by traffic, planning, conservation, environmental and other public laws, and an EBP property model could be similarly sensitive.

By extending "property rights" to EBPs, we recognize that originators have rights as against others, and that, within limits defined by law, they can alter or transfer their rights by agreement.[125]

That is not to say that existing principles/mechanisms are sufficient, nor that those which might apply can do so unaltered.[126] Given the special status of EBPs, certain events/processes require attention, namely rights creation, transfer of rights, valuation of EBPs, and quality of the EBPs.

(1) Implications for Transferring Property Rights

An EBP property model would rest on the principle that one "owns" one's body and can exclude all others from it. It would have to address the special requirements that EBPs demand.

First, it may stipulate that lawful transfer of title in EBPs requires a written contract between (1) originator, (2) procurement agent and (3) head of the surgical team (on behalf of the receiving health authority).

Second, it may require that all contracts contain certain standard statutory rights and obligations regarding information, consent, convalescence treatment, etc. For example, the procurement agent and surgeon could certify that existing information and consent protocols had been met and provide a health status certificate post-operatively.

Third, all contracts could be subject to scrutiny by and registration with the Human Tissue Authority (or some designated living transplant authority) and payment might be made to a special trustee prior to excision (thereby avoiding payment/title disputes and ensuring that the money can be easily recovered by the authority if the originator exercise's his right to withdraw consent prior to the operation[127]).

Fourth, contrary to existing property practices, the EBP model could stipulate that ownership, possession and title are inseparable.[128] In short, while subject parts/organs remain a part of the body (ie: are only notional EBPs), no third party can have any interest in them enforceable against the originator. Thus, although an originator could contract to have certain statutorily identified parts excised and could sell same to statutorily defined parties by way of statutorily structured written contracts,[129] the contract would remain executory and unenforceable against the originator until performance is complete (ie: the contract would not vest actionable title with the purchaser). Ownership, possession and title might pass to the health authority along

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[124] S. Worthington, *supra*, note 122, at 3.

[125] In support of this, see *Attorney General* v. *Nazira Levi*, Custodian File 1402/70 (unpublished), cited in J. Weisman, *supra*, note 81, at 621, wherein the Court stated that only once removed did a kidney become the object of a property right such that its transfer could be viewed as a gift under the law.

[126] J. Harris, *supra*, note 11, at 65, and S. Worthington, *supra*, note 122, at 3.

[127] A right widely accepted: L. Ross *et al.*, *supra*, note 76.

[128] For a discussion of these concepts, see S. Worthington, *supra*, note 122, ch. 2.

[129] Such statutory limitation/definition of that which can be consented to is common. For example, see the *Offenses Against the Person Act 1861*, the *Abortion Act 1967*, the *Tattooing of Minors Act 1969*, and the *Prohibition of Female Circumcision Act 1985*, and others. In addition, see *R.* v. *Donovan*, [1934] All E.R. 207 (C.A.).

with the EBP itself and then on to the recipient (researcher or patient), but special consideration of the exact *scintilla temporis* (moment of passing of title from originator to purchaser) would be necessary.

Fifth. the law would have to address those situations in which property typically transfers or is valued without the "owner's" consent. For example:

- **Bankruptcy:** Following an assignment in bankruptcy, there is typically an accounting and estate auction, the funds from which are used to satisfy creditors. With respect to valuing estates, the statute could deny recognition of property in the bankrupt's body or in EBPs held or contracted for by a health authority; there could be no forced removals or sales.[130]

- **Financial Aid:** The market value of EBPs could be statutorily exempt from the calculation of assets of those applying for social assistance or other financial aid.[131]

- **Wills & Estates:** Similarly, EBPs could be waived from assessment of a deceased's estate. However, the statute might recognize (1) testamentary instruments which donate EBPs to a health authority, and (2) executor/administrator sales of EBPs of a corpse where such sales are not contrary to express testamentary directions, in which case the purchase funds could form part of the residue of the estate.

In short, EBPs should not be involuntarily valued, auctioned or removed by third parties and specific performance of contracts would have to be banned.[132] Such restrictions have practical and moral grounds (ie: they would infringe the very autonomy and dignity intended to be recognized).

Finally, the law could recognize that an originator has no right to the return of EBPs once they are removed, nor any right of recovery against innocent third party recipients. Indeed, it is not uncommon for one who has property rights in something to nonetheless not have an automatic right of recovery enforceable as against others.[133] Given the contract/transfer mechanisms envisioned, illegal removals would be rare, but compensatory recovery in such circumstances could be limited to those who committed the assault or failed to comply with contract terms.[134]

(2) Implications for Valuing the Asset

Another special problem is that of valuing EBPs. Antagonists of the property model argue that it would be wrong to value EBPs as if they were physical commodities, the body having value/significance beyond the physical. They should not be subject to the vagaries of a market economy. However, we frequently value (through the market) items with significance beyond the material/physical:[135]

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130 See N. Zohar, *supra*, note 51, at 543, who bases this restriction on moral grounds.

131 *Ibid*, at 543.

132 J. Weisman, *supra*, note 81, at 622.

133 R. Smith, *supra*, note 119, at 13.

134 G. Dworkin & I. Kennedy, *supra*, note 36, at 310, suggest that fears about stolen EBPs are overestimated.

135 See both J. Herring, "Giving, Selling and Sharing Bodies" 43-61, and G. Radick, "Discovering and Patenting Human Genes" 63-78, at 65, both in A. Bainham *et al.* (eds.), *supra*, note 2.

(1) wedding rings (highly emotive and sentimental) are bought and sold;

(2) damage to reputation (a highly personal and intangible commodity) is subject to economic analysis;

(3) physical injuries (commonly viewed as impossible to adequately compensate) are given monetary value and subjected to market pressures; and

(4) EBTs held by third parties (ie: naturally occurring chemical compositions isolated in their pure state) are subject to fluctuating market valuations.

Further, the market is pervasive in our global community. Our health, development and aspirations are bound up in relationships to others and influenced by the market; everything we are and hope to achieve is interconnected and valued in some way.[136] Even healthcare, including scarce life saving resources, is distributed according to market principles and pressures.[137]

As such, although EBPs have personal/moral significance/value, they are amenable to market valuation and subjecting them to same (and permitting originators to control and benefit from them) does not diminish their special status, but gives recognition to that special status and its enduring nature.[138] The challenge for a property model is to be sensitive to that special status (that non-economic value). This might be done by limiting the number of parties able to operate in the market, or by identifying non-monetary forms of compensation (ie: tax deductions, increased medical insurance coverage, queue-jumping for like EBPs, funeral expense coverage, or a combination thereof in addition to expense coverage, either tied to or in lieu of monetary payment).[139]

(3) Implications for Quality / Merchantability

Antagonists of the property/market model argue that it would lead to the sale of defective organs by those in financial stress and therefore in poor health.[140]

Quality could be assured by providing a thorough statutory screening process whereby originators are interviewed and examined so as to obtain information applicable to compatibility, general health and the existence of various diseases and conditions. Where originators successfully complete these tests, patient claims relating to rejection or failure could be barred.[141] In any event, originators – whose files would be maintained by the Human Tissue Authority – could remain anonymous.[142]

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136 J. Herring, *ibid*, at 44.

137 See N. Zohar, *supra*, note 51, at 545-551.

138 G. Laurie, *supra*, note 78, at 317.

139 Suggestions for methods of payment can be found in A. Jonsen, "Ethical Issues in Organ Transplantation" in R. Veatch (ed.), *Medical Ethics*, 2nd ed. (London: Jones & Bartlett, 1997) 239-274, at 253, and J. Kahn, "Organ Donation – We'll Make It Worth Your While" (1999) at www.cnn.com/HEALTH/bioethics/9905/organ.donate/template.html (Feb. 18/04).

140 See M. Brams, "Transplantable Human Organs: Should Their Sale by Authorized by Statute?" (1977/78) 3 Am. J. of Law & Med. 183, D. Meyers, *The Human Body and the Law*, 2nd ed. (Edinburgh: UEP, 1990), and others, who point to the lower quality blood obtained by sale as compared to donation.

141 In short, the *Sale of Goods Act 1979* (UK), 1979, c. 54, and the *Supply of Goods and Services Act 1982* (UK) 1982, c. 29, would be suspended as they relate to claims against EBP originators by health authorities or patients.

142 A status affirmed in the blood donor context in *AB* v. *Scottish National Blood Transfusion Service*, [1990]

Originators aside, there is precedent for the applicability of the general law of medical negligence and consumer protection against the health authority and transplant team. In *A* v. *National Blood Authority*,[143] the Court held that the plaintiff blood recipient who contracted hepatitis C from contaminated blood products was entitled to rely on the *Consumer Protection Act 1987* as against the Authority. Similarly, in *Veedfald* v. *Arhus Amstkommune*,[144] the E.C.J. held that product liability did not attach to a donated kidney, but rather to the processes and applications to which the kidney and the patient were subjected.

Thus, appropriate screening measures and existing precedent in the blood and transplant fields offer solutions to the problem of ensuring EBP quality and avenues of compensation for lack of same.

(4) Conclusion

The above are just some of the legal and practical implications of recognizing property rights and primary transaction in our own EBPs. Although the property regime is broad and flexible, any shift to a property model relating to originators would best be governed by a statute which recognizes and accounts for the *sui generis* nature of EBPs. Some tentative solutions to the highlighted problems/issues are offered, but there are other concerns that might arise for originators, physicians, recipients and lawyers working "at the coal face". What the above demonstrates, however, is that these problems can be addressed in a reasonable and rational manner which recognizes the dignity of the originator and does not overly stretch the limits of the property system.

CONCLUSION

"Whoever saves a life, it would be as if he saved the life of all people."[145]

This article has considered one particular implication of recognizing property in our own EBPs, namely the ability of originators of EBPs to enter into primary transactions to sell their EBPs to third parties during their life. An assessment of its ethical foundation and its interaction with certain property-specific concepts demonstrates that a *sui generis* property system applicable to EBPs is neither unethical nor beyond the contemplation of existing legal principles. A property model properly conceived could result in:

(1) originators finally achieving autonomous status and equal standing in the burgeoning (and lucrative) global medico-scientific market; and

(2) patients finally receiving the best treatment within reasonable timeframes.

It could broaden both the scope of bodily control and individual economic rights and activities without seriously endangering the special position of the body and its parts in the human psyche

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S.C.L.R. 263.

143 [2001] 3 All E.R. 289 (Q.B.).

144 (2001), 66 B.M.L.R. 1 (E.C.J.).

145 Quran, 76:9.

and social interaction.

Attempts to limit originator rights based on instinctive feelings of revulsion, "sniff-test" moral reactions or references to vague ethical concepts are not appropriate.[146] In *Dudgeon* v. *UK*,[147] the Court specified that it is improper for the state to prohibit actions simply on the basis that those actions shock, offend or disturb the general public. In any event, general opposition to expanding the rubric of property is "irrational" in that it is "decades too late".[148] Property and property rights already attach to our bodies: we talk of "owning" our body (consent and refusal of treatment supports this position), we can "gift" our EBPs (the procedure for which mimics gifting in any property text), and third parties can own our corpses, EBPs and EBTs. Today's youth accept that originators should be able to benefit financially from their EBTs and there are many examples of peoples and communities moving toward property models of self-ownership so as to protect their interests.[149] These shifts are evidence of the social, moral and ethical change that is necessary for the continued health of a modern, pluralist society, and they should not be ignored.

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146 See J. Harris, "Clones, Genes and Human Rights" in J. Burley (ed.), *The Genetic Revolution and Human Rights* (Oxford: OUP, 1999) 61-94, for a critique of "olfactory reasoning".

147 (1981), 4 E.H.R.R. 149 (E.C.H.R.).

148 G. Dworkin & I. Kennedy, *supra*, note 36, at 316, discussing arguments against genetic "intermeddling".

149 G. Laurie, *supra*, note 78, at 315 and 319-324.

SEMANTIC, PEDANTIC OR PARADIGM SHIFT? RECRUITMENT, RETENTION AND PROPERTY IN MODERN POPULATION BIOBANKING

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Abstract: Evolving uses of human biological material, including their collection and retention in biobanks and their distribution to diverse projects, are sites of great tension from the human rights perspective. In the medical-legal setting, these rights are often protected and realised through consent practices. In the biobank setting, there endures a widely shared concern over consent, and the many divergent ways it is fashioned and deployed. This article reconsiders consent in the biobank setting, first, addressing the theoretical foundation of consent and its deployment in the broader medical context, second, examining the nature of biobanks and the uncomfortable position of consent therein, and finally, offering a means of approaching recruitment and retention in the biobank setting which is sensitive to originator interests, including human dignity, doing so within the rubric of a property model.

Keywords: Population Biobank – Human Tissue – Consent – Withdrawal – Property – Interests

INTRODUCTION

Evolving medical and research practices, including the collection and retention of human biological material in biobanks for distribution to researchers of diverse background and interest, are considered to be of significant scientific, healthcare and commercial value,[1] but they are also sites of great tension from the human rights perspective, implicating rights to bodily integrity, self-governance, personal security, public interest and common good. In the medical setting, many of these rights are protected and realised at least in part through consent practices (as well as privacy and information security practices). Indeed stakeholders have worked terribly hard – in a setting characterised by a long history of medical paternalism and recent revelations of research abuses – to empower patients and human research subjects, and to transform their interaction with the medical-research community into a relationship of mutual trust and dialogue which operates on a morally-grounded conception of consent (ie: consent which unfolds as a process). These were achievements fought for

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[1] J. Kaiser, "Population Databases Boom: From Iceland to the US" (2002) 298 Science 1158-1161.

under the banner of human dignity, and they remain incomplete and ongoing.

But biobanking is a medical endeavour of a different character and magnitude. It sits uncomfortably at the "common good" and "individual interest" intersection, as evidenced by the pools of ink spilled, and numerous concerns aired, over its practice, and the construction and deployment of consent in the biobank setting, which is diverse and inconsistent.[2] Indeed, consent practices represented a central issue in the recent Tiss:EU conference,[3] the inaugural output of a European FP7 project intended to assess the impact of European Union regulatory activities on member states with respect to the procurement, storage and transfer of human tissue and cells in Europe.[4] My own concern derives from the (sometimes) unreflective use of consent in combination with its uneasy interaction with the needs and aims of the biobank setting.

Given the above, this short article reconsiders this setting, and suggests a way forward that eschews the consent paradigm, places greater emphasis on the common good elements of biobanking, and might permit us to avoid the knots in which we tie ourselves trying to make consent work in this unique and critical field of health research. First, it briefly considers the theoretical foundation of consent and its deployment in the clinical and clinical trials contexts, where its continued strength and robustness is essential (because it actually has a chance of addressing the risks to which individuals are exposed). Second, it briefly considers the *sui generis* nature of biobanks and why consent is such a vexing issue therein. Finally, it offers an alternate means of approaching recruitment and retention of participants in the biobank setting, suggesting a governance framework which is both more intellectually honest (than many current practices) and still protective of human dignity, which is such an important value in this field.[5]

I. THE MEDICAL CONTEXT: THE WHY, WHO, WHEN AND HOW OF CONSENT

There exists – particularly in the West – a strong moral conviction, grounded on notions of human dignity and respect for individual autonomy, that everyone has the right to self-determination with respect to their body. And this conviction has been translated into a legal recognition that every person has the right to have his or her bodily integrity protected against invasion by others, and the legal rule that consent must precede any such touching. Non-consensual touching, no matter how innocuous, constitutes an actionable assault, even if committed by well-intentioned medical personnel in the healthcare setting.[6] Indeed, this protection of personal integrity, both physical and psychological, has been elevated to an international human right.[7]

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[2] See G. Helgesson *et al.*, "Ethical Framework for Previously Collected Biobank Samples" (2007) 25 Nature Biotechnology 973-976, and others, including note 3, *infra*.

[3] "First International Conference of Tiss:EU Project: Ethical & Legal Aspects of Research with Human Tissue in Europe", 26-28 June 2008, Göttingen.

[4] For more on the Tiss:EU Project, see http://www.tisseu.uni-hannover.de/index.php.

[5] I concede that some of the argument may be seen to rest on semantics (ie: the characterisation and naming of what is transpiring at the recruitment/retention phase), but it is ultimately important for our broad understanding of the term "consent" and its retention of power, and for the theoretical basis on which we construct our involvement in biobanks more generally.

[6] K. Mason & G. Laurie, *Mason & McCall Smith's Law and Medical Ethics*, 7th ed (Oxford: OUP, 2006) at 349.

[7] See *YF v. Turkey* (2004) 39 EHRR 34 (ECHR).

Of course, the exercise of individual autonomy through the giving or refusal of consent must, in the general course, be coincident with legal competence, and the disclosure of information to the subject. With respect to the former – competence – it is accepted that consent is only possible within the context of relationships between people "in the maturity of their faculties".[8] With respect to the latter – information – it is accepted that, from a moral point of view, a person should only be exposed to risks that s/he has or can agree to;[9] although the amount and quality of the information appropriately disclosed is much debated,[10] it is generally accepted that it must be sufficient (for the reasonable person in the particular circumstances prevailing).

In the clinical setting, then, and barring the emergency situation, the patient must give his/her explicit or implicit consent prior to any medical intervention. That consent must be underwritten by legal competence to make a decision, and by sufficient disclosure of information relevant to the course recommended (which would include information about risks, benefits and potential alternatives). Although the research setting is of a different character, consent is still (viewed as) the "lynchpin" to ethical acceptability,[11] and consent must similarly be accompanied by competence and information disclosure. More specifically, the research subject must consent, typically in writing, prior to formally entering the research protocol. As part of that consent process, s/he must usually be advised of the nature and objectives of the particular project to which s/he is attached, and s/he must be advised of the reasonably anticipated risks, consequences and (hoped for) benefits, and the alternatives to participation.[12] Of course, all of this is done to ensure that subjects, who are often drawn from vulnerable groups, are not harmed, exposed to unnecessary risks, or unduly instrumentalised.

II. THE BIOBANK CONTEXT: AN UNEASY ACQUAINTANCE WITH CONSENT

What may not be obvious from the above articulation of consent is that there are a host of research models, each varying in the level to which the researcher interacts with or acts upon the subject. For example, research relying on material contained in biobanks is of a different hue than clinical trials relying on the active involvement of

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8 J. Mill, "On Liberty" in M. Warnock (ed.), *Utilitarianism, On Liberty and Other Essays* (London: Fontana, 1962), at 135. Competence exists when the individual has the ability to: (1) understand and recall information relevant to the medical course under consideration; (2) process or deliberate on that information; (3) decide to accept or reject a particular course, having weighed the nature, risks and consequences of a course as well as the alternatives; and (4) communicate that decision. Special rules and procedures exist with respect to minors and the mentally incapacitated.

9 K. Mason & G. Laurie, *supra*, note 6, at 395-399.

10 One might note here O. O'Neill, "Some Limits of Informed Consent" (2003) 29 JME 4-7, who is sceptical about how much we demand of consent, questions the extent to which it truly empowers people, and suggests that its value is really limited to ensuring that people are not deceived.

11 K. Mason & G. Laurie, *supra*, note 6, at 655.

12 For more on the demands of consent in the research setting, see the Medical Research Council's *Good Research Practice* (2000) and *Human Tissue and Biological Samples for Use in Research – Operational and Ethical Guidelines* (2001/2005), the European Union's Directive 2001/20/EC and Directive 2005/28/EC, both of which lay down good practice for clinical trials on medicinal products for human use, the European Council's Convention on Biomedicine (1997), the World Medical Association's Helsinki Declaration (2000), the Council for International Organizations of Medical Sciences' Guidelines on Human Subject Research in Developing Countries (2002), and the Council of Europe's Additional Protocol on Human Subject Research (2005).

individual participants (and there are a variety of different types of biobanks), and research on data alone is of a further differing character. For present purposes, let us focus on research on tissues or generated data (genetic, phenotypic, lifestyle, environmental, and demographic) held in new biobanks, of which there was a boom in formation with the turn of the millennium.[13] In contradistinction to old and sometimes surreptitiously accumulated collections of biological samples – which raise their own special concerns – modern biobanks are unique in that they are:[14]

- collective – they rely on mass participation;
- inclusive – they often recruit healthy people and are often deemed most effective when they also include children recruits;
- prospective – they endure for a long time into the future and ideally beyond the life of original participants; and
- purposively indeterminate – it is impossible to inform participants of specific future research ends and therefore of potential risks and benefits.

As a repository of samples and data intended for future, ongoing and repeated use, we do not (and cannot at the time of tissue collection) know:

- the identity or location of all the potential users;
- the ends to which all the research will be put;
- the eventual (but hopefully therapeutic) outputs;
- the governance structures of the place(s) where materials will be used;
- the lifespan or security of the biobank.

In short, biobanks are an exercise in the unknown; they are future-oriented and optimistic; although we believe they will contribute to high-powered future research, new understandings, and the discovery and generation of new therapeutic products and processes, we really do not know what their ultimate value or their social risks/consequences might be.

This veiled future, together with past scandals and missteps,[15] has been the source of much consternation, and has spawned a groundswell of governance activity, some of it binding regulation, much of it not.[16] Unfortunately, much of this

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[13] B. Elger & A. Caplan, "Consent and Anonymization in Research Involving Biobanks" (2006) 7 EMBO Reports 661-666.

[14] For more on their nature, see G. Williams, "Bioethics and Large-Scale Biobanking: Individualistic Ethics and Collective Projects" (2005) 1 GSP 50-66.

[15] With respect to practices concerning previously existing biobanks, one might note the Alder Hey and Bristol scandals in the UK. With respect to missteps regarding prospective biobanks, one might note the Icelandic Health Sector Database.

[16] Note that Australia, Canada, Estonia, France, Germany, Iceland, Japan, Sweden, Switzerland, the UK and the USA have all issued their own guidelines, and see the WMA's Declaration on Ethical Considerations Regarding Health Databases (2002), UNESCO's International Declaration on Human

regulation is inconsistent, even on the all-important issue of consent,[17] where, in addition to minor variations in terms and practices that are discernable from country to country, there exists a more fundamental divergence in approach as between North America and Europe.[18] In the former, many biobanks have tried to employ a limited or specific consent, which has led to a reliance on a multi-layered approach and a long, detailed form by which the individual agrees to specified uses.[19] Contrarily, in much of Europe and elsewhere, the very concept of consent has been stretched to include a "blanket consent", "broad consent", "comprehensive consent", or "general consent", where originators are asked to consent to their material (physical and informational) being used in unspecified future research. In such a situation, the "informedness" which underlies proper, ethical consent cannot be fulfilled, making any claim to having obtained consent as we wish and need it to mean in the clinical and research setting a fallacy. As a concession to the impossibility of respecting people through robust consent,[20] participants are not infrequently given a right to withdraw from the biobank at any future time without the need to give reasons and without fear of adverse consequences.

Given the demands of consent in the clinical and clinical trials setting, the nature of biobanks, and the uncertainties and inefficiencies created by diverging approaches, why are we still talking about "consent" in the biobank setting? The very use of the term raises as many questions as it assuages concerns. For example, consent-related issues that remain the subject of debate (and which were raised to varying degrees at the recent Tiss:EU conference) include:

- whether the consent obtained (particularly under past practices) relates to use of the tissue, or use of the data, or both;

- whether ethical consent properly demands the re-contacting of tissue originators for each new use not specifically consented to in the original exercise;[21] and

- whether consent, particularly re-contacting, introduces notions of ownership of

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Genetic Data (2003), the COE's draft Recommendation on Research on Biological Materials of Human Origin (2006), and the OECD's draft Guidelines for Human Biobanks and Genetic Research Databases (2008).

[17] B. Knoppers, "Biobanking: International Norms" (2005) 33 J Law Med Ethics 7-14.

[18] B. Elger & A. Caplan, *supra*, note 13. However, note might be taken of the efforts of P3G to produce a generic consent form so as reduce inconsistency and inefficiency: B. Knoppers, "Biobanking, Population Genetic Research and Informed Consent", presented at "One Origin, One Race, One Earth: Genetics, Human Rights and the Next Phase of Human Evolution", U. of Calgary, 16 November 2007, Calgary, Canada.

[19] The USA has wedded this to an expansion of the definition of "non-identifiable"; information so characterised is seen as carrying no risk to the originator and so relieves the researcher of the burden of re-contacting.

[20] A "robust consent", in my view, is an ongoing, information-reliant exchange between parties, and this cannot effectively and efficiently be realised in the biobank setting. Having said that, I concede that some might defend this broad consent as perfectly justifiable (or robust) on the basis that research activities with which the biobank is associated will be made public and people who bother to keep themselves informed often have the right to withdraw their consent, thereby preserving consent as a process.

[21] An approach which recognises consent as a process rather than an event, but which has been challenged as prohibitively expensive, inefficient and potentially impossible: P. Furness & M. Nicholson, "Obtaining Explicit Consent for the Use of Archival Tissue Samples: Practical Issues" (2004) 30 JME 561-564.

excised body parts and generated data and injects notions of property over the body.[22]

Despite these resolution-resistant issues, we seem to have an irresistible inclination to force many (or most) medical ethical issues into the consent paradigm, an inclination which has already been challenged by commentators noting that consent is not the only answer to all ethical concerns,[23] but is rather simply a means to an end, that end being to respect persons and their interests.[24]

Certainly we can perform a comprehensible and robust consent process with respect to the physical act of excising the tissue itself, and this seems rather unproblematic. However, for most other treatments of the tissue and its generated data, and its use by (unknown) future researchers, we should be very reluctant to call what we are doing "consenting the subject" as that important term and essential practice is manifested in other medical settings. We must recognise that the consent paradigm is ill-fitting to the biobank setting with the result that, with respect to the overall undertaking, we can only ever achieve a shadow of consent, particularly in new, broad-purpose, future-oriented biobanks such as UK Biobank and Generation Scotland.

III. BIOBANK GOVERNANCE: A FRAMEWORK FOR MOVING FORWARD (AND MOVING ON)

Rather than continue the intellectual and practical struggle (and wheel-spinning) over how to make consent work in the biobank setting, we might just look for an alternative model; one that (1) respects the originator, (2) promotes his/her trust in the endeavour, and (3) assures the stability of the biobank's resources, while simultaneously preserving our association of consent in the medical context with something relational, powerful and directed at a specific matter. I suggest that this might be done by extending the property model which already suffuses the human tissue realm.

Although the current general position is that there can be no property in the human body,[25] this is not a consistently applied proposition. For example, with very little additional contribution,[26] third parties can obtain property in corpses, biological products of the body, and excised body parts and tissues.[27] In short, property rights are already enforced at various stages of our treatment with the body, and property concepts pervade the law governing the human body – even to the point of

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22 A notion which has been strenuously resisted by many stakeholders who are concerned with commodification of the (whole) human body and with tissue originators deriving any financial benefit therefrom.

23 O. Corrigan, "Empty Ethics: The Problem with Informed Consent" (2003) 25 Sociology of Health & Illness 768-792.

24 K. Mason & G. Laurie, *supra*, note 6, at 682.

25 A proposition which finds its origins with Coke (see P. Skegg, "Human Corpses, Medical Specimens and the Law of Property" (1975) 4 Anglo-Am Law Rev 412) and which has been reiterated in judicial precedents and policy statements, including the Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal Issues* (London: Nuffield Council, 1995), and the UK *Human Tissue Act 2004*.

26 And under exceptions that have been characterised as misguided and insufficient: see R. Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control* (Oxford: Hart Publishing, 2007), at 143.

27 See the discussion in S. Harmon, "A Penny For Your Thoughts, A Pound For Your Flesh: Implications of Recognizing Property in Human Body Parts" (2006) 7 Med Law Int 329-354.

characterising the transfer of tissue from originators to third parties as "donation", which assumes some proprietary interest – but property rights are generally denied to originators.[28] However, to recognise originator property interests would require only a minor adjustment in our theoretical thinking, and such becomes more palatable if the nature of property is understood.

Properly understood, the recognition of property in something is the recognition of a relationship of interest to that subject in a person.[29] Property rights are a variable and shifting bundle of rights and duties which attach to definable, identifiable, transferable subject matters or items,[30] and the long-established right to control our (whole) bodies and to enjoy bodily integrity and be free from invasion is consonant with this construction.[31] Moreover, property is not a natural right, it is merely a socially-constructed right which is legally defined and has evolved over time; it is a social institution which organises items (and services) for which there is greater demand than supply.[32] Moreover, it has certain attributes which make it amenable to absorbing originator claims in this setting, including the following:

- Versatility: The property model has metamorphosised over the centuries as a result of changing concepts of social and economic value, addressing realty, chattels, intellectual products, personality and image, and other areas of human endeavour over which we wish to exercise personal control.[33]

- Limitability: It recognizes moral limitations in the use of objects over which we have rights and vindicates them through legal limits.[34]

- Sensitivity: It is sensitive to, and interacts with, other areas of law, cooperating with public and private domestic and international law (eg: unfettered enjoyment of property is restricted by traffic, planning, conservation, environmental, and other public laws).[35]

By extending the property model to originators, we recognise that they have interests and deserve rights of control as against others, and that, within legally defined limits, they can alter or transfer their rights by agreement. The following sections consider recruitment and retention in the biobank setting within the rubric of a property model, the idea being to fashion a system that respects the originator, promotes his/her trust

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28 An outcome recognised by Broussard J, dissenting, in *Moore v. Regents of the University of California* (1990), 793 P 2d 479 (Cal SC), reversing (1988), 249 Cal R 494 (CA).

29 P. Matthews, "Whose Body? People As Property" (1982) 36 Current Legal Problems 193-239, and K. Gray, *Elements of Land Law* (London: Butterworths, 1987), at 8.

30 P. Matthews, *ibid*, at 193-195, J. Weisman, "Organs As Assets" (1993) 27 Israel LR 610-623, at 610, R. Smith, *Property Law*, 3rd ed. (London: Longman, 2000), at 3, and others. And see recent judicial statements to this effect in *Phillips v. Washington Legal Foundation* (1998), 524 US 156 (SC) and *Yanner v. Eaton*, [1999] HCA 53 (HCA).

31 In the UK, this was enunciated in W. Blackstone, *Commentaries on the Laws of England*, 1783, 9th ed., vol I, at 129, and recently reiterated in the medical context in *Re F (Mental patient: Sterilisation)*, [1990] 2 AC 1 (HL) and *Chester v. Afshar*, [2005] 1 AC 134 (HL).

32 J. Harris, "Who Owns My Body?" (1996) 16 Oxford J Law Soc 55-84, at 56-57.

33 P. Matthews, *supra*, note 29, at 252-255, and K. Gray, *Elements of Land Law* (London: Butterworths, 1987), at 11, where it is noted that the changing objects of property has resulted in the abandonment of property in wives and slaves.

34 J. Harris, *supra*, note 32, at 60-61, and S. Worthington, *Personal Property Law* (Oxford: Hart Publishing, 2000).

35 S. Worthington, *ibid*, at 3.

in the endeavour, and assures the stability of the biobank's resources while preserving our understanding (and ideal) of consent as outlined above.[36]

(1) Recruitment: Obtaining Originator Material

Currently, and without enumerating all of the many ways in which (potential) originators may be identified and contacted, recruitment is achieved through the solicitation of consent to participate. In the European context, the consent sought is broad and general and suffers from the frailties noted above. However, it is perhaps more desirable to separate the excision and the use of the tissue into separate processes.

With respect to the first process – excision – we can sensibly imagine (and perform) a robust consent process as it is idealised and understood in the clinical setting. The originator and exciser, who may have an ongoing clinical relationship, meet in a place where an exchange of information about the procedure, its risks, and its consequences can be fully realised. The originator can probe, ask questions, or articulate fears, and the exciser can respond, assuage, and proceed (or not), and s/he can follow up in the usual post-procedure manner to ensure full recovery from the intervention. Ultimately, the originator consents to an excision of tissue for the purpose of offering that tissue to a biobank. As suggested above, this preserves our (hard fought for) understanding of consent and seems largely unproblematic.

It is with the second process – subsequent (often unspecified) use of the tissue and generated data – that consent encounters its insurmountable hurdles. Here we might be better served recognising that people have property in their bodies, including their excised tissue and generated data.[37] So doing respects people by taking notice that they have interests in relation to both their whole, undivided selves and their divided or separated selves (a condition which is increasingly important in the modern biotechnological context).[38] The objective, then, is to fashion an event under this model which, in the context of recruiting participants, recognises and addresses these interests, which interests I contend are as follows:[39]

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[36] I recognise that the extension of the property model to originators would necessitate rationalisation of both the property and human tissue use regimes. Exploring the contours of that rationalisation is beyond the scope of this modest work. I also recognise that the tide is running against the recognition of property at present, though the effect of such a recognition might be that practices around human tissue use might become more principled: see R. Hardcastle, *supra*, note 26, at 172.

[37] I recognise that a widely shared concern with the adoption of a property model is that a market may emerge around the sourcing of body materials from originators. Addressing this concern is beyond the scope of this short article, but I note several points: (1) property is not inseparable from markets; (2) individuals can have property rights in something without the concomitant right to divest themselves of that item for money; (3) resistance to a property model has done nothing to avoid the formation of (black) markets in body material.

[38] One can assume that a person who loses a finger in an accident would claim a right to possess and control (a property interest in) that excised part despite its separation, and there would be few so bold as to deny that interest, but there is little in the way of legal protection of that interest.

[39] Hardcastle, *supra*, note 26, at 1 and 173, articulates four of these interest. With respect to the first two interests, however, he suggests that they are interests of control – control of the disposal and profits. However, I believe we need to recognise that we do not live as islands onto ourselves (to borrow a phrase from J. Donne, Meditation XVII, "Devotions Upon Emergent Occasions" (1624), at http://en.wikipedia.org/wiki/john_donne [accessed 24 Aug 2005]). As such, we should recognise that full and individual "control" may rarely ever be possible (or appropriate); there are many things, both important and intimate, that we do not "control". Though "control" may be the deep-seated desire, I think the defensible interest is rather one of "influence".

(1) an interest in influencing the use and disposal of excised tissue;

(2) an interest in influencing the profits that may be derived from the tissue;

(3) an interest in being free from emotional distress;

(4) an interest in preserving his/her autonomy; and

(5) an interest in contributing to knowledge for the improvement of human well-being and health.[40]

An event which recognises and addresses these interests, without necessarily vindicating all of them, together with the framework which supports that event, is the means through which we extend respect to originators of material in the biobank setting.

Let us turn first to the framework, which ought to be strong, transparent, consistent for biobanks within a jurisdiction, and, ideally, replicated in large part across jurisdictions. The UK Biobank's governance regime represents a valuable existing model,[41] but it is, of course, neither statutorily set nor binding on other biobanks with which UK Biobank might interact. The Council of Europe's Recommendation on Research on Biological Materials of Human Origin (2006),[42] represents a commendable first effort at offering a harmonised model, but, as I note elsewhere,[43] it falls well short of an ideal (and, in any event, relies squarely on the consent paradigm). Given the needs identified, a statutory framework would be best. Preliminarily, one expects that the necessary governing framework would have to:

- identify and define governing values (eg: solidarity, human dignity, autonomy, equality, trust, etc.);

- articulate biobank objectives/duties, including the use of its resources to contribute to basic knowledge, public health, saving lives, and improving life-quality;

- enunciate ethical guidelines re: best research practice (to be applied to all research projects submitting a request to the biobank for material), together with a concise statement of the types of research for which the biobank's resources will never be used;

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[40] This interest is grounded on solidarity, a moral value we all share to varying degrees and one that underscores our shared objectives (and indeed duties) toward contributing to the welfare of our shared communities and our fellow man. This value has been explored in greater detail by S. Harmon, "Solidarity: A (New) Ethic for Global Health Policy" (2006) 14 Health Care Analysis 215-236.

[41] See UK Biobank, Ethics and Governance Framework, v. 3, 2007, at http://www.ukbiobank.ac.uk/docs/EGF20082.pdf [accessed 17 July 2008].

[42] Rec(2006)4, March 15, 2006, 958th Meeting of the Ministers' Deputies.

[43] S. Harmon, "The Recommendation on Research on Biological Materials of Human Origin: Another Brick in the Wall" (2006) 13(3) European J Health Law 293-310. For a further examination of the final version of the Recommendation, see H. Nys, "Research on Human Biological Materials and the Council of Europe: Some Unanswered Questions, Overlaps and Empty Boxes" (2008) 15 European J Health Law 1-6.

- erect security protocols and practices for protecting the privacy of originators, relying on terms that are harmonised across jurisdictions;

- enumerate the duties of the custodian of the biobank, including explicit duties to proactively and demonstrably steer the usage of the biobank toward broadly beneficial projects that will enhance (public) healthcare and thereby maximise their contribution to worthy, publicly-endorsed ends;[44]

- outline the decision-making processes to which the custodian must adhere, as well as the custodian's monitoring duties, together with instructions as to when the custodian should exercise the right to withdraw the biobank's resources from a project;

- require that all research entities submitting a request to the biobank for material (1) meet the biobank's guidelines for best practice, (2) receive permission from an external, independent ethical review board, and (3) verify that they understand their duties with respect to dissemination of knowledge and benefits derived from their use of the resource;[45]

- require an ethical governance committee comprised of ethical, policy, legal, lay and scientific members to whom the custodian reports regularly, and which conducts regular audits on implementation of procedures;

- make the biobank sensitive to public opinion by erecting a public engagement process with components that are both (1) general and ongoing, and (2) limited, focused and initiated from time to time, thereby promoting public input, particularly with respect to technological changes or new understandings that might shift research agendas;

- address the economics of running a biobank, including funding sources and allowable fees for making the resource available to private researchers;

- enumerate prohibited actions in relation to the custodian and the users (researchers);

- enumerate sanctions for breaches of its provisions, enforceable against the custodian and against users (researchers) by the statutory oversight body;

- address the very real possibility of collapse and cessation of activities, articulating baseline principled rules with respect to winding down and the transfer or destruction of the material which made the resource so valuable in the first place.

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[44] A duty suggested by G. Williams & D. Schroeder, "Human Genetic Banking: Altruism, Benefit and Consent" (2004) 23 New. Gen & Soc. 89-103, at 97.

[45] It is important to erect duties for private, profit-seeking research entities because biobank usage is now, and is expected in future, to be driven largely by economic interests, and because publics have concerns around the role and conduct of profit-seeking entities in human subject research and public healthcare agenda-setting: G. Williams, *supra*, note 14, S. Wilkinson, "Biomedical Research and the Commercial Exploitation of Human Tissue" (2005) 1 GSP 27-40, and others.

This framework should recognise the originator's proprietary interests in his/her excised tissue and generated data, and should elucidate of the full scope of concomitant rights an originator can exercise with respect to excised tissue and its generated data. The originator is respected at the outset insofar as his/her interests are given voice. Where an interest is not vindicated, respect is still extended insofar as principled reasons for the failure would be articulated. In this way, the originator is made to understand what portion of the bundle of rights that is his/her property interests is transferred to the custodian, and what additional rights and duties the custodian has in that item to which property attaches (ie: in the tissue and data).[46]

With respect to the mechanics of the event, the competent originator (or his/her guardian/proxy) would be provided with all of the information associated with the framework and its operation, and the exercise of rights necessitated by it (and by whom). The originator would then "agree" to "transfer control" over the material to the custodian of the biobank. By this transactional event, the originator's relationship with (and claim to) the material is ultimately severed and, to use a property term, s/he abandons his/her claim to the material, agreeing that it is the custodian who thereafter constitutes the only individual who can give "consent" to the use of the material for specific projects. However, the originator does so on the understanding that clear parameters for the use of the material by the biobank and others exist, and certain ethical thresholds will be enforced in the later use of that material.

Returning to the originator's interests, by choosing to participate in an endeavour with the above framework, which addresses future use broadly, penalties for failures, and disposition when (if) winding up the biobank, the originator has made a decision which might be characterised as "influencing" the use and disposal of excised tissue. Similarly, although s/he does not have a direct and immediate influence over the profits generated by the biobank or the client researchers, the careful selection by the custodian (as directed by the framework) of the most publicly appropriate projects (which might contain benefit sharing elements) goes some way in addressing this interest. No one can be guaranteed freedom from emotional distress (and some become more easily distressed than others), but the framework outlined, which includes specific "no-go" areas, monitoring, and provisions for prosecution of breaches should give the originator some solace that all of the research supported will be such that s/he need not become distressed. The originator's autonomy is fully respected through the dualistic recruitment process, and is thereafter not implicated by the use of the material (so long as informational security is enforced, and same is clearly addressed by the framework). Finally, the originator is obviously assured that s/he is contributing to knowledge for the improvement of human well-being.

Importantly, the biobank is not getting the consent of the originator to use the material in future research. Rather, it is obtaining all of the property interests in the material from the originator so that the biobank (or its custodian) can exercise consent with respect to all individual research projects as they are proposed. This process takes place within a strong framework by which the originator is assured that s/he can trust in the undertaking (and in science, its tools and its protagonists more generally).[47]

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[46] I recognise that one cannot convey more interests or rights in an item than s/he, by law, holds, but of course the custodian, upon coming into possession of items of a certain character (ie: excised tissue and associated transfer agreement), may have a wider range of interests and exercisable rights than that held by the conveying originator.

[47] It is well known that trust is an essential component of the success of biobanks and of medical research more generally: see M. Hannson, "Building on Relationships of Trust in Biobank Research"

(2) Retention: Assuring Biobank Continuity

Obviously, if biobanks are to deliver their anticipated benefits, they need long life spans and an ever-growing (or at least large and relatively static) bio-resource inventory. As such, tissue/participant retention is essential. This is addressed in the proposed approach by the complete transfer of property interests from originator to custodian, which transfer is and should be explained to the originator as an exhaustion of the originator's rights; a severing of control over the originator's interests in relation to this particular material with the practical implication that individuals cannot withdraw their tissue/data from the biobank. It should, of course, be noted that the originator retains some influence through the participation in the general and specific public engagement exercises envisioned by the framework. Additionally, s/he might exercise influence by discontinuing the ongoing communication of health and other information, if that is part of the setup.

Currently, originator "consent" for the biobank to use his/her material can be withdrawn at any time and for any (and no stated) reason. Presumably, this right is included as a means of (1) preserving consent as a process, and (2) promoting public trust in the biobank. With respect to former, it must be conceded that this "process" falls well short of the ideal articulated above whereby consent involves an informational exchange undertaken within a relationship that facilitates that give-and-take – there is no true relationship here and information is often only obtained by the originator if s/he is prepared to educate herself.[48] With respect to public trust, it must be conceded that withdrawal misses the point utterly – if the originator is prepared to withdraw his/her consent, then, presumably, trust has already been lost and having (or exercising) a right to withdraw will do nothing to promote or rebuild that trust.

The right to withdraw (consent) is a curious entitlement in other respects as well. First, it is not clear what ongoing entitlement would underlie the exercise of the right:

- Property Right? Under current conceptions, the originator has no property in the material, so no foundation can be laid with respect to his/her ownership of the material, nor can any residual property rights in them be claimed.

- Integrity Right? Of course, once the tissue is excised, the originator is at no further risk of physical harm from any research to which it might be subjected, so the protection of one's own physical integrity cannot form its basis either.[49]

- Privacy Right? The right to withdraw is not conditional on there actually arising a privacy concern, but if the originator feared injury from a breach of privacy point of view, there is no associated right to claim damages for a breach of the scope of consent given leading to privacy infringement.

Second, it is equally unclear what interests are being protected through the right.

(2005) 31 JME 415-418, and G. Haddow, G. Laurie, S. Cunningham-Burley and K. Hunter, "Tackling Community Concerns About Commercialisation of Genetic Research: A Modest Interdisciplinary Proposal" (2007) 64 Social Science & Med 272-282.

[48] Although this may be as straight forward as consulting the biobank's website.

[49] It is difficult to imagine how the recognition of personality rights in continental systems would be infringed by the use of excised tissue and anonymised data in closed laboratory settings.

Having reference to those already identified, we can say the following:

- It cannot be the interest of influencing use and disposal of excised tissue, for all one is doing by withdrawing is terminating use, not directing its use to ends considered to be more acceptable, and it fails to address the particular manner of disposal altogether.

- It cannot be the interest of influencing the profits that may be derived from the tissue, for individual withdrawals of tissue from the bank are unlikely to have any effect whatsoever on research agendas or formulations of benefit sharing.

- It cannot be the interest of freedom from emotional distress, for if one is withdrawing, then, again the distressful event has presumably already occurred to prompt the reaction (eg: the research project with which one has a problem has already been given access to the biobank or will proceed regardless of the presence of one's material).[50]

- It might be the interest of autonomy, for one is exercising a choice, but withdrawing one's consent/material does not expand one's capability to influence research direction or facilitate one to participate in research deemed worthy (ie: it does not expand choice).

- It cannot be the interest of solidarity, for pulling out of (ethically approved) research does nothing to contribute to knowledge for the improvement of human well-being and health; indeed it weakens the resource base and makes practical outputs that much further away.

On the whole, then, the right of withdrawal, although preserving some minimal control over the material in the originator, is not a particularly effective right, and certainly not one that will seem satisfactory to the originator who still wishes to contribute to knowledge generation. Its primary effect is only to diminish the value of the biobank (and therefore the potential benefit to society). As such, as noted above, the transfer of control of the material to the custodian should be considered a final disposition by the originator. One need not recoil from this element of the model. First, it is familiar and accepted insofar as it is in keeping with how property interests can be (and are typically) divested. More importantly, it is only done in a setting with clear parameters for use, transparent processes for decision-making, and enforceable sanctions for failure to meet either. Most importantly, it preserves the biobank as a resource for good science and, ultimately, human healthcare improvement.[51]

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[50] I concede that something short of an actual distress-provoking event may occur. For example, one's confidence in the system of protection may diminish, or one's view of privacy may simply change, but one imagines that, in the normal course, this will be a rarity.

[51] I have tried to address the "what's in it for me" question, and it is the tragedy of our times or our nature that I am forced to do so. I concede that I may not have addressed it satisfactorily for those who feel I have taken something away (from the individual), but I suggest that, in exchange for that withdrawal, I have offered a strengthening of the overall system together with an assurance of (potentially) greater stability of the resource. Moreover, this is no less final than sample recruitment in the human stem cell setting where private or public/private entities secure material from which to derive stem cell lines.

CONCLUSION

One may charge that this criticism of the use of consent is a purely semantic (even pedantic) complaint, and consider it perfectly acceptable that "consent" can mean different things and demand different processes in different contexts within the medical setting. It may be that the complaint at the core of this article is indeed semantic, but language and terminology are important elements of creating and reaffirming social realities. The approach advanced here – its process and terminology – has the benefit of preserving the quality and strength of consent as it is used in the medical context, rather than stretching our understanding of it out of all proportion for the purpose of pursuing biobanks. Given the terrible atrocities that have been perpetrated against individuals in the name of medical research, the relatively recent and fragile break we've made with the heavily paternalistic practices of the past, and the fundamental link that consent (when approached robustly) has to realising certain moral values and human rights, this approach is both justified and reasonable.

One may question whether the practicalities of the approach outlined above are dramatically different from that which is already practiced in many cases. It may be that many elements of the model proposed are already contained in existing structures,[52] but some of the most important elements – enforceable sanctions, user duties, and cessation of activities – are almost universally absent. This represents a more holistic regime which might be more likely to result in transplantation to other jurisdictions, thereby leading to greater harmonisation and more confident and effective use of research resources. Moreover, through the inclusion of oversight by a statutory authority with investigative and sanctioning powers, it goes further in protecting the interests of the public.

Finally, one may wonder at the exclusion in the model offered of an ability to withdraw, a circumscription of rights which (arguably) hints at a reversion to paternalism. It may be that complete divestment of control (other than participation in engagement exercises), with a concomitant inability to pull material out of the biobank, smacks of retrenchment and conflicts with the underlying concern for consent articulated. However, the biobank context is very different from the clinical and human subject research contexts, where a divestment of rights/interests could have very different consequences and, in any event, are permitted under certain conditions (eg: think of the proxy decision-maker situation). Further, as noted above, a right to withdraw is very different from, and in no way influences, research direction control. Withdrawal only diminishes the value of the resource contrary to its very *raison d'etre* (which is to provide a broad-based resource with numbers capable of generating useful data in the genomic and systems biology era).

Let us be honest in the concession that, right or wrong, the body is currently seen (and largely treated) as an open source of biological material which can be mined for commercial gain by the elite alone – we are "biocows" to be "milked" (to borrow an image which arose at the Tiss:EU conference). Moreover, in the biobank context, we are (necessarily) treating people as means,[53] and we are trying to "clean" that instrumentalisation through some notional "consent" process, which is nothing like

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[52] I take notice of the practices of UK Biobank, which has gone to great lengths to promote trust and transparency. For more on UK Biobank, see http://www.ukbiobank.ac.uk/.

[53] This is particularly so in instances where originators are not provided with information derived from their tissue that may be relevant to them, as is the norm.

the consent that we usually demand in the medical context (and it does not deserve the title). As such, no one can agree on how to do it; the North American approach injects complexity and what might be unkindly characterised as a ruse;[54] the European approaches rely on differing ethical foundations and practicalities,[55] and they represent a shift from classical human subject research ethics without signalling that shift by offering a change of terminology.

If we wish to respect people, we should identify (and identify with) their interests and concerns, we should address their interests and concerns in the structures we rely on to steer our scientific endeavours (which are ever more powerful and influential on society), and we should be clear and transparent in the manufacture of the models we use to govern health science and the position of the individual in that endeavour. Focusing our efforts on imagining a principled and honest model that protects our achievements in related (medical) settings could facilitate the operation of biobanks. I have tried to do that here, drawing on a regime (ie: property) that individuals and communities can identify with, and one that is already insinuated in every aspect of the health research exercise.

This represents a preliminary exploration of a regime offering clarity around terms, practices and standards (re: sourcing, counselling, storing, coding and using samples) such that individuals might be assured that what they've agreed to will not be breached or exceeded, and that international collaborations can be pursued thereby maximising the benefits this valuable resource offers. I of course welcome further consideration or critical assessments of that preliminary exploration.

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54 See the terminological expansion articulated above and explained in footnote 19, *supra*.

55 B. Elger & A. Caplan, *supra*, note 13, and B. Knoppers, *supra*, note 17.

YEARWORTH v. NORTH BRISTOL NHS TRUST: A PROPERTY/MEDICAL CASE OF UNCERTAIN SIGNIFICANCE?

Shawn H.E. Harmon

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Abstract: It has long been the position in law that, subject to some minor but important exceptions, property cannot be held in the human body, whether living or dead. In the recent case of *Yearworth and Others v North Bristol NHS Trust*, however, the Court of Appeal for England and Wales revisited the property debate and threw into doubt a number of doctrines with respect to property and the body. This brief article analyses *Yearworth*, (1) reviewing the facts and the Court's decision with respect to the originators' proprietary and contractual interests in their body and bodily products, (2) considering the significance of relying on property and its use a legal metaphor, (3) questioning the scope of the property right created, and (4) querying whether an alternate conceptual approach to extending rights and a remedy was warranted. It concludes that, while *Yearworth* engages with, and impacts on, important theoretical and practical issues – from legal, healthcare and research perspectives – it does not offer a great deal of guidance and, for that reason, its precedential significance is in doubt.

Keywords: medicine and healthcare – law – property – body tissues and products – negligence

INTRODUCTION

It has long been the position (in law) that property cannot be held in the undivided human body, whether living or dead.[1] In the UK, this orthodox view was expounded in the seventeenth century,[2] and reiterated thereafter in *R v Lynn* (1788), *R v Sharpe* (1857), *Foster v Dodd* (1867), *R v Price* (1884), and *Williams v Williams* (1881-85). More recently, in *R. v Bentham* (2005), the House of Lords held that a person does not 'possess' his body or any part of it.[3] This prohibition has also largely obtained with

[1] With respect to living bodies, see Matthews (1982), who noted that interference with a living body is an invasion of a personal (not a proprietary) right. With respect to dead bodies, see *Haynes Case* (1614), 77 ER 1389, and Sir Edward Coke, *Institutes of the Laws of England* (1641), 3-203, who stated, "The burial of the cadaver (that is *caro data vermibus*) is *nullius in bonis*."

[2] Though see Mason and Laurie (2001), who suggest that it derives from a misinterpretation of precedent.

[3] One should note that this was a criminal case concerned with whether the defendant had 'possession' of a weapon, in this case his hand inside his jacket pocket and held to look as if it was a firearm. The (only) relevant statement comes from Lord Bingham, who, at para. 8, stated: "… One cannot possess something which is not separate and distinct from oneself. An unsevered hand or finger is part of oneself. Therefore, one cannot possess it. Resort to metaphor is impermissible because metaphor is a literary device which draftsmen of criminal statutes do not employ. What is possessed must under the definition be a thing. A person's hand or fingers are not a thing. If they were regarded as property for purposes of s. 143 of the 2000 Act, the Court could, theoretically, make an order depriving the offender of his rights to them, and they could be taken into the possession of the police."

respect to excised body parts (Skegg, 1975), though in *Doodeward v Spence* (1908), the High Court of Australia recognised third party ownership in a preserved foetus, holding that the lawful exercise of skill which gave the foetus attributes different from a mere corpse founded a right to proprietary possession. This 'attribution of skill' exception found its way to the UK in *R v Kelly* (1998), wherein the Court of Appeal recognised property rights in excised body parts where they had been subjected to dissection or preservation, or had otherwise acquired different attributes by the application of skill.[4] In the recent case of *Yearworth and Others v North Bristol NHS Trust* (2009), the Court of Appeal for England and Wales revisited the property issue. This article analyses *Yearworth*, (1) reviewing the facts and the Court's decision with respect to the originators' proprietary interests in their body and bodily products, (2) considering the significance of relying on property and its use a legal metaphor, (3) questioning the scope of the property right created, and (4) querying whether an alternate conceptual approach to extending rights and a remedy was warranted. It concludes by considering the precedential value of *Yearworth*.

BACKGROUND AND DECISION

In *Yearworth*, six claimants were diagnosed with cancer and consented to chemotherapy at the Southmead Hospital. As the treatment had the possibility of rendering them infertile, the hospital, which operated a fertility clinic licensed under the *Human Fertilisation and Embryology Act 1990* (HFEA 1990), offered to freeze and store samples of each claimant's semen for his subsequent use. Each claimant agreed and produced a sample. The agreement resulted in the generation of a Sperm Storage Request, a Consent to Storage and Use, and a Sperm Storage for Those Undergoing Chemotherapy for each claimant, which contained a variety of representations, including some relating to storage and future use. Following completion of the documents, and prior to the use of the sperm, the storage system failed, causing the samples to be irreversibly damaged.

Each claimant alleged that he suffered an adverse or traumatic reaction to the news, including mental distress or mild/moderate depression. The defendant Trust admitted that it had a duty to take reasonable care of the sperm and that it had failed to do so by neglecting to top up the liquid nitrogen tanks when it knew or ought to have known that they required attention. However, it denied liability, arguing that, even if its breach caused injury or distress, the claimants were barred from recovery because the loss of sperm was neither a 'personal injury' nor 'damage to property'.

In the appeal proceedings, the claimants advanced three arguments, namely that, due to the Trust's negligence, they suffered (1) tortious personal injuries, (2) tortious damage to property, and (3) losses resulting from breach of bailment conditions.[5] The decision of the Court was given by Lord Judge CJ (Sir Anthony Clarke MR and Wilson LJ concurring).

On the personal injury claim, the claimants argued that (1) the sperm had been inside their bodies, (2) damage to it while inside them would constitute a personal injury, (3) its ejaculation makes no difference given that it was *not* intended to be abandoned and it *was* intended to retain its original biological function and purpose (ie: to fertilise a human egg). In support of their position, they cited a German case which held that bodily parts, including eggs extracted for re-implantation, retained a

[4] This approach was more recently applied in *AB v Leeds Teaching Hospital NHS Trust* [2004] EWHC 644 (QB).

[5] This last claim was argued for the first time in, and at the invitation of, the Court of Appeal.

functional unity with the body such that injury to them could constitute physical injury, and, although stored sperm would not be re-implanted, it would be illogical for the law to treat damage to it differently.

Lord Judge CJ noted the practical legal constraints which compelled the German court to adopt this view (para. 22) and dismissed the personal injury claim perfunctorily (para. 23), stating:

> 23 [I]t would be a fiction to hold that damage to a substance generated by a person's body, inflicted after its removal for storage purposes, constituted a bodily or "personal injury" to him. … We must deal in realities. To do otherwise would generate paradoxes, and yield ramifications, productive of substantial uncertainty, expensive debate and nice distinctions in an area of law which should be simple, and the principles clear. Even if we were to admit [the claimants' argument], the law would swim into deep waters in relation to the continued biological activity, and the function, of several other bodily substances or parts.

Ultimately, Lord Judge CJ was not convinced that damage to an excised part or product – which could no longer be felt – could be characterised as a 'personal injury to the body', and he seemed concerned with the complexity and uncertainty to which a personal injury basis would give rise.

On the issue of a property right in the sperm, Lord Judge CJ opined that a claim for negligent loss of property must be founded on legal ownership or possessory title retained by the claimant. Importantly, and drawing on Rose LJ's opinion in *Kelly*, Lord Judge CJ explicitly stated that advances in medical science are demanding a re-analysis of the common law's approach to ownership of parts and products of living bodies, and he rejected the suggestion that the *Human Tissue Act 2004* (HTA 2004) could be used to confine the common law's treatment of body parts or products as property if the common law rested on a broader basis (para. 38).[6] He later stated:

> 45(d) … [W]e are not content to see the common law in this area founded upon the principle in *Doodeward*, which was devised as an exception to a principle, itself of exceptional character, relating to the ownership of a human corpse. Such ancestry does not commend it as a solid foundation. Moreover, a distinction between the capacity to own body parts or products which have, and which have not, been subject to the exercise of work or skill is not entirely logical. …

While Lord Judge CJ took notice of the HTA 2004, which, in s. 32(9), entrenches the *Doodeward* 'application of skill' exception to holding property, he pointed out that it was only peripherally relevant because gametes, which, according to s. 53(1), are governed by the *Human Fertilisation and Embryology Act 1990* (HFEA 1990), were in issue.[7] As such, he considered the respective positions of the parties under the HFEA 1990:

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[6] In *L v Human Fertilisation and Embryology Authority and Secretary of State for Health* [2008] EWHC 2149 (Fam), the Court also stipulated that the common law 'does not stand still'.

[7] At the time of the case, the 2008 amendments to the HFEA 1990 were not yet in force, but none of the amendments would have had any bearing on the case.

- The claimants' alone, through their bodies, generated the sperm, and the sole object of the sperm (and its storage) was for the claimants' subsequent use to reproduce (para. 45(f)).

- The HFEA 1990 was designed to give legal effect to principles of good practice in modern reproductive medicine, and should not deprive individuals of the ability to recover damages for breach of a statutory duty (para. 41).

- One of the pillars of the HFEA 1990 is the stringent requirements around informed consent, which make clear that only the claimants have *rights* in relation to the sperm, and the Trust has *duties* and *limitations* (para. 44).

- The interjection of the need for third party support (eg: expert storage and medical assistance to make subsequent use of the sperm) does not diminish a right held by an individual (para. 45(f)).

Noting that the Trust's actions precluded the claimants from exercising their right, Lord Judge CJ held that the claimants had ownership rights in their sperm and could sue for interference with those rights.

Having found that the control the claimants could exercise over their stored sperm was sufficient to found a property interest, Lord Judge CJ went on to consider bailment, which arises from taking temporary possession of another's goods, and involves an assumption of responsibility for their safe-keeping and return. Under the circumstances, in paras. 48 and 49, Lord Judge CJ held as follows:

- The Trust voluntarily chose to take possession of the sperm, and, though it received public funds to support such activities, its bailment was gratuitous insofar as the claimants were concerned.

- The Trust acquired exclusive possession of the sperm, and, having accepted that possession, undertook certain duties in relation thereto, including careful storage.

- The Trust held itself out as having special skills, and, by its own admission, failed to employ them appropriately when it allowed the nitrogen levels in the storage tank to drop and the storage temperatures to rise.

Lord Judge CJ concluded that a gratuitous bailment existed, and that, in addition to being liable under tort for damage to property, the Trust was liable under bailment.

On the issue of damages for psychological injury, Lord Judge CJ directed that each claimant would have to demonstrate that his distress or psychiatric injury was a reasonably foreseeable consequence of the breach of duty, whether the duty was considered under tort or bailment (para. 54). He concluded that, while the bailments in question were not commercial, they were certainly directed at offering the claimants peace of mind with respect to the potential to have children in the future where their reproductive capacity was under threat. As such, the claimants could

recover damages if they could prove (1) the foreseeability of mental distress, and (2) mental distress in fact.[8]

These, then, are the facts and *ratio* of the case. But what of the value of this decision and what does it really mean for practitioners in the medical law context? It is to this question that we turn in the following sections, first addressing the use of property as a remedy-grounding concept, before looking at the possibility of alternative foundations for protecting the rights and interests of tissue originators.

PROPERTY AS METAPHOR?

Ironically, one is left wondering what the language of property in *Yearworth* means for those operating in the biomedical setting and the law relating to human bodies, tissues and products. There is very little work in the decision linking the claims to the concept of property, and, as shall be addressed below, little more directed at elucidating the scope of the rights erected. On the first issue, one wonders whether the language of property in *Yearworth* is simply being used as a metaphor?[9] It would seem so from Lord Judge CJ's comment at paragraph 28:

> The concept of ownership is no more than a convenient global description of different collections of rights held by persons over physical and other things.

However, he never grounds his use of property by clearly articulating the collection of rights envisioned or the basis of the extension of rights to the claimants (other than that they alone produced the sperm). As such, it is never made exactly clear what property is a metaphor for. Is it simply a means of extending some level of *control* to actors, including originators of tissue, in the new bio-economy? Given that most people are familiar with the idea of property, broadly conceptualised, and with the language of property, is it a means of offering *predictability* in a novel and highly fluid setting? Or is it simply a pragmatic means of securing *justice*, of providing a remedy, that has been denied to so many tissue originators in the past?

Lord Judge CJ considers both common law precedents and statutory provisions, rejecting and relying on both in turns. In the end, the rights granted under the HFEA 1990, particularly those around consent, seemed persuasive. So perhaps the decision and the use of property is really a metaphor for 'control', but again, one cannot be sure. The single short reference to Honoré cites one of the eleven incidents of ownership (eg: the right to use) but fails to explore these incidents in any systematic way. Even accepting the reference to Honoré, Lord Judge CJ failed to ground his finding of property in any particular moral theory or value, nor did he engage meaningfully with the very rich and important bioethical and legal scholarship on the subject of property in the human body. Additionally, he made no broad statement of principle other than that the common law must keep pace with medical science. His most telling statement is the following:

> 28 We have no doubt that, in deciding whether sperm is capable of being owned for the purpose which we have identified [future

[8] It should be noted that it is not clear from the case whether the claimant must demonstrate the manifestation of a psychiatric injury, as is the case in tort.

[9] Recall that, quite simply, metaphors allow us to understand and experience one kind of thing in terms of another (Lakoff and Johnson, 1980).

> functional or reproductive use], part of our inquiry must be into the existence or otherwise of a nexus between the incident of ownership most strongly demonstrated by the facts of the case (surely here, the right, albeit limited, of the men to use the sperm) and the nature of the damage consequent upon the breach of the duty of care (here, their inability to use it notwithstanding that this was the specific purpose for which it was generated).

As such, after reviewing the development of the common law in relation to living bodies, corpses, parts of corpses, and parts and products of living bodies, he concluded that the claimants alone generated the sperm for the sole purpose of using it for their own benefit, and by virtue of the HFEA 1990, the claimants alone could order the destruction of the sperm (para. 45).

At this point, it is worth stating that an inquiry into the metaphor used or intended is not a matter of mere academic concern. On the issue of metaphors, it has been claimed that:

> … [M]etaphor is but an aesthetically pleasing way of communicating meaning that could have been expressed literally. Metaphor set forth by the comparison view is not that metaphor is strictly equivalent to a literal expression, but that there is an analogical relation between the two parts of the metaphor, i.e. metaphor is an implicit simile (Caenave, 1979, p. 20).

However, there is a strong argument that metaphors are much more powerful; they are not mere comparative tools. This approach views the metaphor as having cognitive value by inextricably intertwining with the legal subject:

> … The system of commonplaces or implications attending the subsiding subject fosters insight into the principal subject by demanding simultaneous awareness of both subjects that is not reducible to any mere comparison between the two (Murray, 1975, p. 288).

In short, the metaphor carries the observer beyond the original subject, contributing to the subject in a substantive way.

Given the decision in *Yearworth*, the human person – the originator of tissue and bodily products – is pulled into the property matrix. Obviously, there is a certain utility associated with the use of property because of the social familiarity we have with it. However, there is also a lot of (negative) baggage associated with the property paradigm which then gets associated with (or heaped onto) the person. In particular, its intimacy with materiality, markets, and financial-over-social merit makes its extension to the body controversial; the nature of its development creates a tendency to instrumentalise, and that is something we generally deplore when it comes to the person and the human body.[10] Given the controversial nature of the property metaphor, it was incumbent on the Court to offer some clarity around what

[10] In this regard, see Campbell (2009), who, in ch. 2, argues that the property paradigm is dehumanising.

questions the use of this metaphor answers and evades (ie: what is the scope of the right being created).

SCOPE OF THE PROPERTY RIGHT?

Of the many practical questions that remain unanswered by *Yearworth*, perhaps the most crucial one, again ironically and as noted above, relates to the nature and scope of the property right purported to be created. Because it is not clear what work the property paradigm is being asked to fulfil, it is not clear what bundle of property rights might have been extended to originators by this decision, nor is the range of the circumstances covered by the decision apparent. What if no documents amounting to gratuitous bailment had been involved? What of the situation where the institution is not licensed under the HFEA? What other rights does the claimant have with respect to the tissue other than return for his own agreed functional use? How far does the case and its finding of property go?

Given the above, including the unresolved foundations and purpose of the property finding, we are left to wonder whether the finding of property sounding in a cause of action is restricted to gametes and reproductive tissue, or, less restrictively, to body products for which there exist written agreements and duties the breach of which correlates to the originator's intended use, or, more expansively, is applicable to tissue originators and actors in the biomedical law setting more generally. Alternatively, might *Yearworth* have wider implications than to the medical law setting, and be transformative of tort and contract law more generally as it relates to claims made by individuals in relation to their bodies and their parts and products?

While it might be unfair to pose these questions at this early stage, one might expect to discern some indication of the case's intended scope from the language of the decision itself. Unfortunately, as lamented above, no great statements of principle were made or defended, and no great clarity emerges as to the intended scope of the rights discussed. At one point, Lord Judge CJ is careful to state that:

> 45(b) The present claims relate to products of a living human body intended for use by the persons whose bodies have generated them. In these appeals we are not invited to consider whether there is any significant difference between such claims and those in which products are intended for use by other persons … .

And:

> 45(f)(v) In reaching our conclusion that the men had ownership of the sperm for the purposes of their present claims, we are fortified by the precise correlation between the primary, if circumscribed, rights of the men in relation to the sperm, namely in relation to its future use, and the consequence of the Trust's breach of duty, namely preclusion of its future use.

In short, the Court was careful not to engage with any theoretical or practical questions (relating to property and the human body) beyond the narrowly articulated facts of the case. While this is not uncommon in the slow evolution of the common law, many will not appreciate the lack of direction for future cases.

ALTERNATE METAPHORS?

While the sheer weight and prevalence of property, combined here with the range of commercial interests operative in the biomedical setting, makes it difficult to avoid the property paradigm, the widespread concern over instrumentalisation and the potential negative consequences of propertisation should perhaps prompt us to inquire whether an alternative metaphor might have been deployed. It has been argued that (1) the foundation of the (legal) metaphor is the imagination, and (2) the use of metaphor in law as a naming vehicle requires that it be grounded in the relevant human condition (Murray, 1984). On the issue of imagination, note the following:

> All human rights, laws, and ideals of society were philosophical and before that they were not even languaged and therefore not in existence. But somewhere, sometime, someone thought the idea and named the law. When the legal concept grew beyond its ideal stage and became public as part of the social psyche, it became a reality. It became the law. So, too, there are many new ways of living and socialising which have not yet become the law, and this is because they have not been imagined and languaged into existence. The imagination then is the creative source … of metaphorisations (Murray, 1984, p. 723).

With respect to the 'human condition' in which the metaphor is properly grounded, one might consider the following: the need to promote, and the desire to experience/realise, justice, efficiency, democracy and human value in the face of quickly evolving biomedical knowledge and practices which increasingly threaten traditional views of social and economic propriety and human identity. Lord Judge CJ himself noted the ever-expanding frontiers of medical science and the need for the common law, including tort and contract law, to keep pace (paras. 3 and 45(a)).

Bearing these points in mind – the need for imagination and grounding in the social reality – one alternate approach may have been to give greater credence to the personal injury basis argued by the claimants. Obviously, such an approach is not without its difficulties, as pointed out by Lord Judge CJ, but a morally grounded principle and an intelligently structured and limited rule might have been fashioned using 'personal injury' as a metaphor.

By way of (very preliminary) consideration of such an approach, we might, at the outset, recognise the following matters:

- gametes (like sperm) have a very personal and unique biological origin and function;
- the gametes retained an ongoing function intended to be used if these claimants were rendered infertile;
- the claimants saw the sperm as an extension of their living being, and their natural inclination may have been to make claims such as, "I made or produced that sperm and it is a part of me"; and
- the claimants simply wanted control of that special product and an avenue for recovering damages where their interests had been negligently interfered with.

Bearing this in mind, the Court might have concluded that the sperm, being a unique product which originally formed a unity with the body and subsequently retained its function and purpose, remains personal and can be injured in certain limited circumstances such that damages are warranted. While there might be no general damages for pain and suffering at its loss (ie: destruction of the sperm would not cause pain or injury to the person), there might well be pecuniary losses and losses resulting from emotional trauma, again if such was foreseeable and the circumstances warrant. Ultimately, the need for limits and caveats should not necessarily be a bar to this approach. We have, for example, erected all manner of limiting rules around rights attending to the foetus (ie: foetuses have an expanding repertoire of rights as it comes closer to term, but can only vindicate them if it is born and living and duly represented).

Of course, the personal injury metaphor is not the only alternative metaphor. Scotland offers another non-property approach, one based on personality protection:

> [R]ights of personality protect the non-patrimonial [non-economic] or dignitary aspects of the human person – who a person is rather than what a person has. The concept of rights of personality … was …unarticulated, in common law systems until very recently. (Whitty and Zimmermann, 2009, p. 3)

Traditionally, the '*actio injuriarium*'[11] was available for, *inter alia*, insults or affronts to honour and threats of harm, and was supported by broad understandings of dignity (or the desire for the law to promote respect for others' dignity). And it is such a dignity-based action which might be used to protect interests such as those advanced by the claimants in *Yearworth* (ie: interests in having the life they set for themselves protected to some extent, and of having a means of recovery when that life and their dignity is infringed by the negligence of others).

This action was successfully deployed in *Stevens v Yorkhill NHS Trust and Another* (2007), wherein the parent 'pursuer'[12] argued that, despite authorising a post-mortem on her daughter, it was never explained to her that such post-mortem entailed removing and retaining organs. Her discovery of this led to shock and psychiatric injury (ie: severe depression), and, ultimately, to loss of employment. She argued, *inter alia*, that there exists under Scots common law an action in its own right for wrongful interference with a body (in this case a corpse). On this point, the Court considered *Pollock v Workmen* (1900), *Conway v Dalziel* (1901), and *Hughes v Robertson* (1913), and noted that they were not superseded by the *Human Tissue Act 1961* or the *Human Anatomy Act 1984*. It stated:

> 43 It would appear … that in addition to supporting the proposition that an unauthorised post-mortem can constitute an independent legal wrong, the case of *Hughes v Robertson* also lends some support to the line taken in *Conway v Dalziel* that the removal

[11] The term 'actio injuriarium', also appearing as 'actio iniuriarum', refers to a right of action for wrongful conduct resulting in an affront to honour and feelings (or personality), and which entitles the victim to claim damages. It is an old claim received into Scots law from Roman law many centuries ago. For more on this action, see MacQueen (2005) and Reid (2007).

[12] The term 'pursuer', in Scots law, refers to the party who initiates a lawsuit with the intent of obtaining a legal remedy, and it is the equivalent of 'plaintiff' or 'claimant' in other jurisdictions.

> and retention of organs can itself constitute a separate and independent legal wrong.

And:

> 57 [T]he unauthorised post-mortems … disclosed such an insensitivity to the feelings of their relatives … that such conduct constituted an affront to their dignity as relatives of the deceased so as to justify being classed as a civil wrong … .

The Court concluded by considering damages by way of '*solatium*'[13]:

> 62 In my opinion Scots law recognises as a legal wrong for which damages by way of *solatium* can be claimed the unauthorised removal and retention of organs from a dead body. The Scottish cases suggest that the true juridical basis for this type of claim lies in the *actio injuriarium*.

Ultimately, the Scottish Court acknowledged the existence of an independent action based on wrongful interference with (or treatment of) a body (and its parts), which action is based on an affront to human dignity (Whitty and Zimmermann, 2009). The pursuer need not engage with the property paradigm.

The question remains: What might or should dignity mean in this situation?

One must concede at the outset that the utility of dignity as a legal value has been questioned (Feldman, 1999), and it has been described as overly vague (Macklin, 2003, Harmon, 2006). Nonetheless, the value remains popular and widely claimed, readily understood (at least in general terms), and clearly of relevance to the treatment of human beings and their parts and products (eg: we all wish to generally protect and enhance human dignity, for ourselves and others, and to avoid instrumentalisations of the person and his/her parts which could be damaging). Moreover, its use is in conformity with the burgeoning body of international biolaw with respect to the position of the person and the body in the modern biomedical setting.[14]

While a more precise definition might be (and would need to be) fashioned, for present purposes, broadly construed, dignity might capture the idea that persons and their desires have value. It supports mid-level legal principles like autonomy (self-rule), privacy (shelter from oversight or interference), and personal identity (or the construction of a public persona), which are all reasonably well understood. Interestingly, one can already (arguably) detect a movement toward dignity-based actions in the negligence jurisprudence. For example, in *McFarlane v. Tayside Health Board* (2000), a wrongful pregnancy case, the court awarded a sum for the wrongful affront to the parent's autonomy. In *Rees v. Darlington Memorial Hospital NHS Trust* (2004), dignity was recognised as an important human right. In *Murray v.*

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[13] The term 'solatium' refers to claimable damages in a personal injury claim that are 'non-patrimonial', that is damages for emotional distress and/or pain and suffering experienced by the victim (as opposed to patrimonial damages, which include more readily quantifiable economic losses): see Scottish Law Commission (2008).

[14] In this regard, note the Universal Declaration of Human Rights (1948), the Biomedicine Convention (1997), the Universal Declaration on the Human Genome and Human Rights (1997), the Universal Declaration on Bioethics and Human Rights (2005), and others.

Express Newspapers plc (2008), the court referred to dignity in recognising parental rights to control the size of their family

Ultimately, then, if (originator) control is the interest to be protected, and if a remedy for its interference is the objective to be realised, then a non-property approach (or metaphor) reliant on negligence but grounded in dignity could be imagined. In the present circumstances, a dignity-based *actio injuriarium* might provide a remedy where, through another's negligence, one's life options are damaged (or limited) through harm to a functional body product that once formed a unity with the claimant. A Court need not turn to the property metaphor (ie: we need not rush into the arms of the property metaphor/maelstrom). With some imagination, alternate metaphors or approaches to control and justice can be articulated, and they might be more readily acceptable than property.

CONCLUSION

What makes the *Yearworth* case significant? Quite simply, it constitutes the first instance that an appellate court has seriously considered the question of originator property in human material, and it has done so directly where previous courts have shied away from the issue. It has apparently cleared away a controversial piece of legal artifice, and extended the right of body-product ownership to originators of those products within a certain context/relationship, thereby opening up new remedial possibilities.

What detracts from *Yearworth's* significance? First and foremost, the decision is limited to very narrow circumstances (ie: the remedy is limited to persons who stored gametes for their own use and these gametes were damaged). However, more importantly, it is wanting on a number of fronts. *Yearworth* was ripe for an articulation of relationship, and a statement of law, as elegant as that offered by the revolutionary decision in *Donoghue v Stevenson* (1932),[15] but it did not offer them. Indeed, its lack of value-engagement, opaqueness around the work 'property' is supposed to perform, and its general absence of statements of general application relating to rights and duties, all combine to undermine its general significance.

Ultimately, one would have hoped for much more from the Court, particularly in light of:

- the (precarious) position of the person in modern medical practices (including biomedical research);
- the deep and widespread debate about the propriety of empowering the individual through the property paradigm;
- the values which must be vindicated in the human life and identity settings (including human dignity, autonomy, and equality); and

[15] *Donoghue v Stevenson* (1932) was transformative of the common law. It was immediately recognised as a legal turning point with respect to its holding that individuals have duties toward persons whom they will never meet but might foresee as being injured by their actions (Pollock, 1933). Fifty years post-decision, it was viewed as the "single most important decision in the history of the law of torts" (Linden, 1983), and the "most important decision in all the common law" (Smith and Burns, 1983). Sixty years post-decision, it was still described as "revolutionary", having reshaped the law of product liability and torts (Ferrari, 1994).

- the possibility of securing rights of control and remedies through other means (as has been done in Scotland).

In the result, we are left with more questions than answers. While it engages with, and impacts on, important theoretical and practical issues – from legal, healthcare and research perspectives – the guidance it offers is minimalist and patchy, and, for that reason, its precedential significance is in doubt.

In the end, we are left to wonder at the potential significance of *Yearworth*. It may well be both a 'first step' and a 'next step' in the advance of the property paradigm: a 'first step' in that it finally extends rights to originators of (at least) products, and a 'next step' in that it is one more in a long line of cases which chips away at the 'no-property in the human body' rule. The scope of the holding will have to be tested in future cases where non-reproductive tissue is in question and different relationships obtain. If it *has* opened the door for tissue originators in a broader way, *Yearworth* may found a new line of cases which will, hopefully, engage more fully with the conceptual and ethical elements of the relationships and transactions at issue. If this is the case, one might characterise it as transformative of the common law in a slow burning sort of way.[16] Time will tell.

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[16] For an imaginative and activist judge, the *Yearworth* decision would perhaps suffice as a launch pad for articulating the general justice requirements with respect to living bodies and originators of parts, tissue and products, but it is a hope reliant on future cases and judges.

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EMERGING TECHNOLOGIES AND DEVELOPING COUNTRIES: STEM CELL RESEARCH (AND CLONING) REGULATION AND ARGENTINA

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Abstract: Innovation is the mantra of the modern, knowledge-based political-economy, and biotech innovation is one of the central pillars of the new 'innovation society'. Healthcare innovation – a key component of the biotech stream of innovation – is both an integral part of the innovation society and is reshaping that society. An important facet of healthcare innovation is stem cell research (SCR). This paper explores the moral controversy surrounding human embryonic SCR (hESCR) and assesses its legal position in Argentina. An analysis of hESCR is important/timely because it is a much-hyped pursuit to which much hope is attached, and, simultaneously, a much-maligned pursuit to which much antipathy is directed. It is also the site of mammoth bioethical clashes around unique issues relating to (1) the wellbeing of the embryo, the harvesting of which currently requires its destruction, and (2) the wellbeing of the collective, which is notionally threatened by certain processes associated with hESCR, most notably cloning, or 'somatic cell nuclear transfer'. An analysis of hESCR (and SCR more generally) in Argentina is important/timely because Argentina is a southern, economically fragile, developing country that is actively pursuing regenerative medicine and SC solutions to health problems. Indeed, Argentina is one of a handful of developing countries taking steps to build a competitive domestic market.

Keywords: stem cells; stem cell research; embryos; governance; law; bioethics; values; moral positions; Argentine

INTRODUCTION

Innovation is the mantra and arguably the engine of the modern, knowledge-based political-economy, and biotech innovation is one of the central pillars of the new 'innovation society'. Healthcare innovation – a key component of the biotech stream of innovation – is both an integral part of the innovation society and is reshaping that society, introducing new lexicons, redefining our understanding of desirable and undesirable bodily states, re-forging our relationships with our bodies, other people and

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the environment, and so on.[1] An important facet of healthcare innovation is stem cell research (SCR); research exploring the functions of or relying on stem cells (SCs). SCs are cells that divide asymmetrically; their division gives rise to an identical daughter cell (ie: thereby self-renewing) and to a differentiated cell (ie: one with a different and specialised function). Although different SCs exhibit different levels of plasticity depending on when they are harvested,[2] SCs no longer require proof of principle,[3] and are generally accepted as a source of great potential for human welfare.

This paper explores the moral controversy surrounding human embryonic SCR (hESCR) and assesses its legal position in Argentina. An analysis of hESCR is important/timely because it is a much-hyped pursuit to which much hope is attached, and, simultaneously, a much-maligned pursuit to which much antipathy is directed. Frequently considered to be superior to adult SCR,[4] hESCR is the site of mammoth bioethical clashes around unique issues relating to (1) the wellbeing of the embryo, the harvesting of which currently requires its destruction,[5] and (2) the wellbeing of the collective, which is notionally threatened by certain processes associated with hESCR, most notably cloning, or 'somatic cell nuclear transfer' (SCNT[6]). An analysis of hESCR

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[1] For insight into how SCR interacts with and influences culture, see C. Hauskeller. Science in Touch: Functions of Biomedical Terminology. *Bio & Phil* 2005; 20: 815-835. She concludes that biomedical science (its aims and developments) is so closely related to the cultural milieu and to social aims and development that the realms are inseparable.

[2] Totipotent SCs, harvested from the 8 cells of the zygote at approximately 36-hours post-fertilisation, can give rise to an entirely new organism, including the cells needed for human development. Pluripotent SCs, harvested when the inner cell mass of the blastocyst (ie: the mass which could otherwise form the embryo and evolve into the foetus) reaches approximately 25 cells, can differentiate into any and all of the 200+ cell types which comprise the human body, but cannot give rise to the extra-embryonic cells necessary to support the development of a foetus *in utero*. Multipotent SCs, harvested from the primordial germline cells of early aborted foetuses or from mature tissue (eg: from any post-foetal stage of life of the organism, including the late foetus, umbilical cord blood, children and adults), can give rise to the cell types regenerative of the tissue in which they normally reside.

[3] A. Chapman et al. Report: Stem Cell Research and Applications: Monitoring Frontiers of Biomedical Research. 1999. Available at http://www.aaas.org/spp/sfrl/projects/stem/report.pdf [Accessed 2 Oct 2006].

[4] See K. Devolder. Human Embryonic Stem Cell Research: Why the Discarded-Created-Distinction Cannot be Based on the Potentiality Argument. *Bioethics* 2005; 19: 169-186, p. 169. For more on why researchers prefer ESCs, see R. Lovell-Badge. The Future of Stem Cell Research. *Nature*. 2001; 414: 88-91, and A. Newhart. The Intersection of Law and Medicine: The Case for Providing Federal Funding for Embryonic Stem Cell Research. *Vill Law Rev*. 2004; 49: 329-361. For a contrary view, see B. Capps. Bioethics and Misrepresentation in the Stem Cell Debate. 2005. Available at http://www.ccels.cardiff.ac.uk/literature/publications/2005/capspaper.pdf [Accessed 15 Mar 2006], L. Epatko. Adult Stem Cells: Conflicting Research. 2004. Available at http://www.pbs.org/newshour/science/stem-cells/conflicting-research.html [Accessed 3 Oct 2006], and M. Shamblott et al. Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells. *NAS Proceedings*. 1998; 95: 13,726-13,731.

[5] B. Salter & C. Salter. Bioethics and the Global Moral Economy: The Cultural Politics of Human Embryonic Stem Cell Science. 2006. Available at http://www.ioh.uea.ac.uk/biopolitics/publications/working_papers/wp3.pdf [Accessed 5 Oct 2006]. They state that hESCR generates cultural conflict not because its subject is SCs but because its subject is hESCs.

[6] SCNT is a process whereby the nucleus of an adult cell is inserted into an enucleated egg, which is then induced to divide, thereby producing a blastocyst that is a genetic match to the adult cell/nucleus donor. For SCR purposes, the resulting cloned blastocyst is not permitted to develop into a full embryo; rather the pluripotent ESCs of the blastocyst are harvested and can then be used to treat the donor/patient without fear of immunological responses. This process is called therapeutic cloning, and is contrasted with reproductive cloning only in so far as its purpose rather than its technique is different. If the purpose of SCNT is human reproduction, the blastocyst would be implanted in a woman's uterus and permitted to grow into a baby. See Select Committee. 2002. *Stem Cell Research Report*. London: House of Lords. Available at http://www.parliament.the-stationary-office.co.uk/pa/ld200102/ldselect/ldstem/83/8301.htm

(and SCR more generally) in Argentina is important/timely because Argentina is a southern, economically fragile, developing country that is actively pursuing regenerative medicine and SC solutions to health problems. Indeed, Argentina is one of a handful of developing countries taking steps to build a competitive domestic market.[7]

Given the above, Part I examines the bioethical concerns raised by hESCR and attempts to articulate the moral values exposed by these concerns. Values are the underlying moral attitudes or foundation stones which tend to (1) justify the elevation of human life above other life, (2) elucidate the equality of all human life within the species, and (3) promote the wellbeing of and respect for persons. Here, values are understood as the deeply held and sometimes unarticulated ideals and principles which we as a society and as individuals hold, and which move societies/communities to respond, either positively or negatively, to possibilities.[8] Part II shifts its consideration to the translation of these moral values (and ethical positions) into compelling action-guiding rules.[9] It assesses how these underlying values have manifested (if at all) in regulatory instruments relevant to hESCR in Argentina. The paper concludes with an assessment of the adequacy of Argentina's regulation and some suggestions for moving forward.

ETHICAL DEBATES AND MORAL VALUES UNDERPINNING hESCR

Positions on the use of the embryo turn on an assessment of three overlapping questions relating to the (pre)individual (eg: When does human life begin? What is the moral status of the embryo? What is the meaning of personhood?), and a balancing of our conflicting obligations relating to the collective (ie: our obligation to take action intended to alleviate the social damage caused by serious injury and debilitating disease, on the one hand, and, on the other, to avoid the potential social damage caused by the outputs of those actions). Assessments have resulted in the development of at least four divergent (ethical) positions.

Prohibitive Position

This position holds that human life and personhood occur simultaneously at the moment of conception, and the embryo's unique potential to develop into a complex organism substantially different from any other known entity endows it with a right to special protection.[10] Thus, it is immoral to take any action which prevents the embryo from

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[Accessed 26 Sep 2006].

[7] H. Greenwood et al. Regenerative Medicine: New Opportunities for Developing Countries. *Int J Biotech*. 2006; 8: 60-76; K. Thorn. World Bank Working Paper: Science, Technology and Innovation in Argentina: A Profile of Issues and Practices. 2005. Available at http://siteresources.worldbank.org/intargentina/resources/sciencetechnologyandinnovationinargentina.pdf [Accessed 3 Oct 2006].

[8] For more on values, see S. Harmon. Regulation of Human Genetics and Genetic Biotechnology: Risks, Values and Analytical Criteria. *InnoGen WP-40*. 2005. Available Available at http://www.innogen.ac.uk/assets_innogen/dynamic/1132844739842/Innogen-Working-Paper-40.pdf; A. Bruce & J. Tait. Interests, Values and Biotechnological Risk. *InnoGen WP-7*. 2003. Available at http://www.innogen.ac.uk/assets_innogen/dynamic/1118847372616/Innogen-Working-Paper-7.pdf.

[9] For more on the translation of values into binding rules, see S. Harmon. Ibid.; K. Henley. Abstract Principles, Mid-Level Principles and the Rule of Law. *Law & Phil*. 1993; 12: 121-132; M. Bayles. Moral Theory and Application. *Soc Theo & Pract*. 1984; 10: 110-114.

[10] See J. Deckers. Why Current UK Legislation on Embryo Research is Immoral: How the Argument from Lack of Qualities and the Argument from Potentiality Have Been Applied and Why They Should be Rejected. *Bioethics*. 2005; 19: 251-271; Pontifical Academy for Life. Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells. 2000. Available at

fulfilling its potential. Emphasising the risks over the (potential) benefits of hESCR, it expresses concern over instrumentalisation and questions the morality of a society (and the position of individuals within it) which routinely destroys early human life for inquisitive purposes. A component of this argument is the claim that hESCR is too closely tied to SCNT; advances in therapeutic SCNT (intended to increase the number of SCs available and to eventually overcome immunological responses in patients), eliminate important obstacles to the acceptability of reproductive SCNT (eg: lack of safety[11]) with the result that hESCR constitutes a slippery slope to the eventual (inevitable) application of SCNT as a means of reproduction, which raises a host of social woes.[12] As such, proponents would prohibit procuring or using hESCs, or indeed conducting embryonic research, for any purpose other than assisting reproduction.

This position relies on two overarching core values. The first, 'human dignity', generally encapsulates the idea that individuals must be afforded honour and respect, and that the human species has a unique value which must be maintained through enhanced protection.[13] A violation of dignity occurs whenever an act directed toward another is viewed, on an *objective* basis, as humiliating, insulting, shameful, contemptuous or damaging to the whole of humanity. In this respect, dignity is deployed as a *constraining mechanism*, with its limits determined by some authority and imposed on everyone. The second value, 'sanctity of life', generally connotes an aversion to harm and an elevation

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http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html [Accessed 18 Oct 2006]; R. Doerflinger. Destructive Stem-Cell Research on Human Embryos. *Origins*. 1999; 28: 769-773.

[11] Currently, SCNT is inefficient and, for reproductive purposes, both ineffective and unsafe: see the survey of scientific opinions in G. Annas & S. Elias. Politics, Morals and Embryos. *Nature*. 2004; 431: 19-20, at fn 13 and 90. As such, there is an international consensus to the effect that it is unethical: see Article 11 of UNESCO's Universal Declaration on the Human Genome and Human Rights (1997), Article 1 of the Council of Europe's Additional Protocol on Cloning Protocol (1998), and others. See also R. Chester. Cloning Embryos from Adult Human Beings: The Relative Merits of Reproductive, Research and Therapeutic Uses. *New Eng LR*. 2005; 39: 583-607. It has been postulated, however, that once our understanding increases such that reproductive SCNT is safe, the prevailing consensus may disintegrate: R. Brownsword. Stem Cells and Cloning: Where the Regulatory Consensus Fails. *New Eng LR*. 2005; 39: 535-571.

[12] It is claimed that reproductive cloning would: cause emotional and psychological suffering in clones due to a lack of sense of independent self; infringe the clone's autonomy through parental selection practices which impose characteristics that circumscribe their ability to experience an 'open future'; compromise the clone's dignity due to the 'unnatural' intervention in the reproductive process that spawned him/her; create confusion and ambiguity around familial relationships; alter the culture of reproduction such that children would be seen as commodities with characteristics to be bartered and selected; encourage a culture of market and consumption around children (made worse by inevitable disreputable cloners and consumers); and encourage eugenic selection processes and discriminatory attitudes based on new categories. In short, children would be either 'damaged goods' or 'finished goods', but they would be 'goods' in the instrumental meaning of the word. Families would be confusing morasses with greater potential for exploitation, and society would become more discriminatorily balkanised with negative knock-on effects for justice. See B. Taylor. Whose Baby Is It? The Impact of Reproductive Technologies on Kinship. *Hum Fert*. 2000; 8: 189-195; R. Santorum. The New Culture of Life: Promoting Responsible and Appropriate Medical Research. *Notre Dame JLEPP*. 2003; 17: 151-156; C. Sunstein. Is There a Constitutional Right to Clone? *Hastings LJ*. 2002; 53: 987-1005; L. Andrews. Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning. *Harv J Law & Tech*. 1998; 11: 643-681; L. Wu. Family Planning Through Human Cloning: Is There a Fundamental Right? *Col LR*. 1998; 98: 1461-1515; D. Davis. Genetic Dilemmas and the Child's Right to an Open Future. *Rutgers LJ*. 1997; 28: 551-592.

[13] M. Cutter. 2004. Genetic Databases and What the Rat Won't Do: What is Dignity at Law? In *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases*. G. Arnason et al., eds. Reykjavik: UIP: 217-222, p. 219.

of human life above all other forms of life.[14] In a similarly dogmatic vein, sanctity is interpreted such that human life is deemed intrinsically valuable/sacred and deserving of priority over all other considerations, including comfort, health, actualisation, and the advancement of knowledge.

Restrictive Position

Proponents of this position adopt comparable stances on the commencement of human life and personhood and similar interpretations of dignity and sanctity, which values figure prominently in their ethical judgment. However, they marshal these in support of a less strict (and less consistent) approach to using hESCs. They would prohibit procuring hESCs, but would allow research to continue on those cell lines already in existence, viewing the unethical damage to have already been done.[15]

Permissive Position

Proponents of this position believe that, though genetically human, the embryo has none of the necessary characteristics of personhood (eg: uniqueness, sentience, and the cognitive capabilities of consciousness, reasoning and self-awareness).[16] Drawing support from religion, biology, and law,[17] they argue that, although embryos are deserving of some 'moral awe',[18] they are not sacrosanct. As such, using embryos left over from IVF treatment for virtuous ends is more consonant with attributing moral status to them than is destroying them.[19] By utilising existing embryos before they are in a position to 'experience' loss, this position affords them moral status (greater than if those embryos were simply discarded). They stipulate, however, that embryos must never be *created* for the sole purpose of destruction/research; to do so would be to legally create an underclass of beings with a purely instrumental role in society.[20]

Like those above, permissive proponents rely on dignity and sanctity. However, dignity is viewed as an *empowering* value. Espousing a *subjective* interpretation, proponents perceive a violation of dignity whenever an act is perpetrated against another which *that other* considers humiliating, insulting, contemptuous or damaging (ie: its

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[14] P. Suber. Against the Sanctity of Life. 1996. Available at http://www.earlham.edu/~peters/writing/sanctity.htm [Accessed 5 Aug 2005].

[15] The US federal funding policy of supporting research on SC lines created before 2001, but not permitting the creation of new lines represents such a bifurcated approach, which, coincidentally, leaves private sector conduct unregulated, and has been described as ethically inconsistent: see BBC, Bush 'Out of Touch' on Stem Cells. 2006. Available at http://news.bbc.co.uk/2/hi/science/nature/5197926.stm [Accessed 18 Oct 2006]. For US opinion polls on SCR, see http://www.pollingreport.com/science.htm.

[16] For an interesting discussion on the status of the embryo, see H. McLachlan. Persons and Their Bodies: How We Should Think About Human Embryos. *Health Care Analysis*. 2002; 10: 155-164.

[17] See H. Greely. Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions. *PLOS Medicine*. 2006; 3: e143; C. Dabu. Stem-Cell Science Stirs Debate in Muslim World Too. 2005. Available at http://www.csmonitor.com/2005/0622/p15s02-wogi.html [Accessed 29 Sep 2006]; L. Cahill. The Embryo and the Fetus: New Moral Contexts. *Theo Studies*. 1993; 54: 124-142.

[18] A term used by A. McCall-Smith & M. Revel (Rapporteurs). 2001. *Report to the IBC: The Use of Embryonic Stem Cells in Therapeutic Research*. Paris: UNESCO. Available at http://portal.unesco.org/shs/en/file_download.php/64b74abda57372bdc22570b42c1718f1stemcells_en.pdf [Accessed 5 Oct 2006].

[19] R. Isasi & B. Knoppers. Beyond the Permissibility of Embryonic and Stem Cell Research: Substantive Requirements and Procedural Safeguards. *Hum Reproduction*. 2006; 21: 2474-2481, p. 2477.

[20] W. Cheshire Jr. Small Things Considered: The Ethical Significance of Human Embryonic Stem Cell Research. *New Eng LR*. 2005; 39: 573-582.

breach depends on the individual's sensibilities).[21] Sanctity refers not to the un-utilisable sacredness of life, but to the uniqueness of the *lived* human experience (beyond mere biological existence), thereby taking into account other life interests (eg: health, comfort, social interaction).[22] These interpretations implicate another core value: 'autonomy', which encompasses physical and psychological liberty and the right to be free from coercion within the reasonable limitations imposed by cherished relationships (eg: familial or community).[23] Thus, proponents afford respect to individuals by recognising their autonomous right to make moral judgments (about their embryo and research) and their moral agency around donation.

Facilitative Position

This position views the embryo as nothing more than a collection of cells like that of other bodily tissue. Demanding consistency, proponents argue that, if it is morally acceptable to create embryos to help the infertile (or to conduct pre-implantation genetic diagnoses), it can be no less moral to create them to help the ill or injured (or for research that will benefit the ill/injured). Moreover, the most ethically and practically defensible position for a diverse, pluralistic society, they claim, is one which affords individuals, and therefore society, options. Society must not be held hostage to the restrictive beliefs of a minority.[24] Rather, our obligation to do everything possible to alleviate the suffering of existing and future human beings must be approached robustly; intergenerational justice demands that we enhance the life chances of emerging and future generations.[25] Positive action must be undertaken even where such action incurs costs and/or creates risks. If hESCR has the potential to achieve this social end, then, despite its costs, there is a moral duty to pursue it and the limitations imposed on its pursuit must be minimal and narrow.[26] Given the above, proponents of this position view (1) the use of embryos surplus from IVF, and (2) the *creation* of embryos for research purposes either through IVF-facilitated gestation or through SCNT as acceptable. That is not to say that every use is acceptable; frivolous uses (eg: for the creation of cosmetics or for use in animal feed) diminish the moral respect shown to the embryo and are unacceptable. But generally, conducting controversial research in the absence of knowledge about its ultimate social impact is acceptable and must be permitted because such research *may*

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[21] For more on this, see D. Statman. Human Dignity and Technology. 2004. In Arnason et al., *op. cit.* note 13, p. 223-228; A. Capron. Indignities, Respect for Persons, and the Vagueness of Human Dignity. 2003. Available at http://bmjjournals.com/cgi/eletters/327/7429/1419#44060 [Accessed 2 Aug 2005]; D. Beyleveld & R. Brownsword. 2001. *Human Dignity in Bioethics and Biolaw*. Oxford: OUP.

[22] K. Boyd. Medical Ethics: Principles, Persons, and Perspectives: From Controversy to Conversation. *J Med Ethics*. 2005; 31: 481-486.

[23] Harmon, *op. cit.* note 8; R. Scott. 2002. *Rights, Duties and the Body*. Oxford: Hart Publishing; S. Aksoy & A. Elmali. The Core Concepts of the 'Four Principles' of Bioethics as Found in Islamic Tradition. *Med Law*. 2002; 21: 211-224; T. Beauchamp & J. Childress. 1994. *Principles of Biomedical Ethics*, 4th ed. Oxford: OUP. R. Gillon. Ethics Needs Principles - Four Can Encompass the Rest - and Respect for Autonomy Should be 'First Among Equals'. *J Med Ethics*. 2003; 29: 307-312, argues that autonomy must be respected if morality is to exist.

[24] K. Devolder. What's in a Name? Embryos, Entities and ANTities in the Stem Cell Debate. *J Med Ethics*. 2006; 32: 43-48; J. Childress. An Ethical Defence of Federal Funding for Human Embryonic Stem Cell Research. *Yale JHPLE*. 2001; 2: 157-165.

[25] It is a curious juxtaposition that sees proponents of this position invoking the wellbeing of future individuals to justify use of embryos to which they attach no significant moral value.

[26] O. Corrigan et al. Ethical, Legal and Social Issues in Stem Cell Research and Therapy. 2005. Available at http://www.eeescn.org.uk/pdfs/elsi_paper.pdf [Accessed 3 Oct 2006], p. 6.

prove beneficial to society.[27]

Proponents attach great importance to autonomy, giving full credit to the individual's right to make choices and take actions based on personal beliefs; indeed, they insist that the state must *enable* individuals to do so.[28] As such, donors must be empowered to gestate and offer embryos for research and the betterment of humanity. Similarly, researchers must be given latitude in exercising their moral right to pursue scientific knowledge.[29] The value of 'solidarity' is also implicated. Solidarity recognises that individuals are naturally and irrevocably embedded in social contexts and thus have a duty – grounded in compassion, fraternity, interest in human welfare, and a desire to construct a just and decent society where everyone's life chances are supported – to undertake personal and collective actions to promote the welfare of individuals and society; enhancing the health and quality of life of living and future humans is imperative.[30] Although autonomy and solidarity often in conflict, this position ties them together through its claim that the moral life requires *positive action* in response to identified, response-demanding human needs, and that individuals must therefore be empowered to undertake that positive action. The fact that new ideas and technologies create controversy and resistance (because they challenge existing thinking, boundaries and visions of the world) is of little consequence.

Summation: legitimate plurality and enduring controversy

Although the motivating interests of the proponents of the competing positions have not been investigated, it is clear that each position is grounded in fundamental moral values aimed at promoting a just and moral society. Moreover, and perhaps ironically given the irreconcilability of these positions, they are grounded in a relatively *small* pool of moral values, which values have been interpreted in conflicting though not necessarily unreasonable ways. The resultant moral plurality bears out a claim articulated by Rawls that irresolvable comprehensive conceptions of the good lie within the limits of reason, thereby constraining our capacity for agreement.[31] The moral foundation of the present plurality – a plurality symptomatic of a globally communicative modern society that has

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[27] J. Shaw. Stem Cell Science: When Medicine Meets Moral Philosophy. 2004. Available at http://www.harvardmagazine.com/on-line/070483.html [Accessed 29 Sep 2006], quotes Prof. R. Losick making a similar argument in the context of the academic world (ie: universities have a responsibility to support controversial basic research on the understanding that it may or may not be beneficial to the world).

[28] Beauchamp & Childress, *op. cit.* note 23, p. 125.

[29] A right that is well established at international law: see provisions in the Universal Declaration of Human Rights (1948), the International Covenant of Social and Cultural Rights (1966), the Universal Declaration of the Human Genome and Human Rights (1997), and the Preliminary Draft Declaration on Universal Norms on Bioethics (2005).

[30] S. Harmon. Solidarity: A (New) Ethic for Global Health Policy. *Health Care Analysis*. 2006; 14: 215-236. See also S. Benatar, A. Daar & P. Singer. Global Health Ethics: The Rationale for Mutual Caring. *Int Aff*. 2003; 79: 107-138; R. Houtepen & R. ter Meulen. The Expectation(s) of Solidarity: Matters of Justice, Responsibility and Identity in the Reconstruction of the Health Care System. *Health Care Analysis*. 2000; 8: 355-376; R. ter Meulen et al. Final Report: Solidarity and Care in the European Union. 2000. Available at http://europa.eu.int/comm/research/biosociety/pdf/bmh4_ct8_3971_partb.pdf [Accessed 24 Aug 2005].

[31] See J. Rawls. 1993. *Political Liberalism*. NY: Columbia U. Press; and the comments on same in A. van de Putte. Rawls' Political Liberalism: Foundations and Principles. *Ethical Perspectives*. 1995; 2: 107-129; J. Rawls. The Idea of Public Reason Revisited. *U Chi Law Rev*. 1997; 64: 765-807; O. O'Neill. Political Liberalism and Public Reason: A Critical Notice of John Rawls' Political Liberalism. *Phil Rev*. 1997; 106: 411-428.

become subjective and individualistic[32] – has disinclined proponents of one position from conceding to the others' positions. In short, a consensus on the acceptability and scope of hESCR has been and will remain elusive, even within relatively small juridical boundaries.[33]

So what is to be done? In a democratic setting, with institutions geared toward enabling personal freedom and plurality, we might rely on the personal morality of actors within the field. Indeed, such an approach would likely suit certain actors. However, in a deeply divisive field like hESCR – which, in addition to morality, implicates commerce and development, technology and innovation, public and private actors, and individual and public health, present and future – stakeholders might rightly claim that public, not private, morality is important, and they may reasonably demand that actors be bound by something more than personal judgments based on individually-held values – something more coercive. The most appropriate and effective form of coercive boundary-setting is legislated regulation:

> [Given that] … pluralism makes it impossible to presuppose a system of norms of correct behaviour which can be comprehended by everyone and accepted by all members of society … positive law … must serve the social order … and be strong enough to end the struggle of convictions and competing interests.[34]

However, it has been suggested that excessive legal coercion with inadequate common deliberation and discussion causes democratic societies to perish.[35] The answer to such concerns is deliberative democracy, which, through multiple engagement mechanisms, requires stakeholders to justify their demands for collective action by giving (and debating) reasons that can be accepted by those ultimately bound by decisions. Indeed, it is said that deliberative democracy (1) promotes openness and fairness, and minimise strategic manipulation, (2) promotes respectful decision-making in morally conflictual settings, (3) reduces the chance and consequences of acting with incomplete understanding, (4) promotes legitimacy in the face of decisions surrounding scarce resources, and (5) encourages solidaristic perspectives on public issues.[36] Though deliberative exercises may never achieve consensus around the scope of hESCR (because

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[32] H. Sandkühler. Pluralism and the Universality of Rights. 1998. Available at http://www.bu.edu/wcp/papers/law/lawsand.htm [Accessed 9 Mar 2007].

[33] McCall-Smith & Revel, *op. cit.* note 18, state that status or personhood arguments have been prolonged and marked by utter failure to reach agreement. Lack of consensus is exemplified at the international level by the prolonged attempt to realise an international declaration on cloning technology and the politics surrounding its eventual failure in February 2005: see UN, Press Release: Legal Committee Recommends UN Declaration on Human Cloning to General Assembly: UN Doc. GA/L/3271, February 18, 2006. Available at http://www.un.org/news/press/docs/2005/ga13271.doc.htm [Accessed 10 Oct 2006]. See also L. Walters. Human Embryonic Stem Cell Research: An Intercultural Perspective. *Ken Inst Ethics J*. 2004; 14: 3-38.

[34] Sandkühler, *op. cit.* note 32.

[35] J. Bohman. Public Reason and Cultural Pluralism: Political Liberalism and the Problem of Moral Conflict. *Pol Theory*. 1995; 23: 253-279.

[36] P. Hamlett. Technology Theory and Deliberative Democracy. *Sci Tech & Human Values*. 2003; 28: 112-140; A. Gutmann & D. Thompson. Deliberating About Bioethics. *Hastings Centre Report 27*. 1997; 3: 38-41. For more on deliberative democracy, see A. Gutmann & D. Thompson. 1997. *Democracy and Disagreement*. Boston, MA: HUP; E. Charney. Political liberalism, Deliberative Democracy and the Public Sphere. *Am Pol Sci Rev*. 1998; 92: 97-110; J. Dryzek & C. List. Social Choice Theory and Deliberative Democracy: A Reconciliation. *Brit J Pol Science*. 2003; 33: 1-28; J. Dryzek Deliberative Democracy in Divided Societies: Alternatives to Agonism and Analgesia. *Pol Theory*. 2005; 33: 218-242.

of the well-articulated, entrenched plurality outlined above), and therefore derivative statutory regulation may not represent public articulation of *universally* accepted behavioural norms, where outputs clearly draw on widely held values openly debated, deliberative democracy-spawned regulation is valid and plays an important role in the construction of a just and moral society.[37] Indeed, only through the use of deliberative democracy (public engagement) can we be reasonably confident that (1) all interested stakeholders have participated, (2) all actors have adequate notice of socially acceptable conduct, and (3) all actors are subject to the same mechanisms for enforcing that conduct, all of which are morally defensible elements of a pluralistic democracy. There is obviously a risk that such an exercise will result in a regime that restricts conduct and therefore thwarts research, but that is a matter for (further) social/political negotiation.

REGULATION AND CONTROL OF hESCR IN ARGENTINA

Argentina has *not* enacted any law which explicitly governs hESCR, or the related fields of IVF or embryonic research, nor even articulated much in the way of public policy on same.[38] Indeed, the only statutory instrument potentially relevant to hESCR is the Prohibition on Human Cloning Research (1997 Decree),[39] which, it must be conceded, is silent on matters relevant to SCR except insofar as cloning is closely associated with hESCR. Thus, although the 1997 Decree is directed at cloning, and therefore only tangentially impacts on hESCR, and although it was not arrived at deliberatively after public debate, it will nonetheless be the subject of the remainder of the analysis, which will assess its content in relation to the (pre)individual and the collective, both of which are, as demonstrated above, the subject of moral concern.

Legal protections for the (pre)individual

The only substantive provision of the 1997 Decree is Article 1, which states that 'all cloning experiments relating to human beings are prohibited'.[40] Assessed in its own right (as an explicit prohibition of a specified, though not well-defined scientific activity), its intent is self-evident and one can reasonably assume that its motivating ethical position is the restrictive position with its concomitant underlying values. Reference to its Recitals only adds minimally to our understanding of Argentina's position. For example:

- Recital 1 states, *inter alia*, that it is the inviolable duty of the state to defend the dignity of the human being.[41] Although it fails to define its interpretation of human dignity, the 1997 Decree deploys it in the constraining sense. One can therefore assume that the legislators felt cloning would diminish human dignity in

[37] And the law must be seen as ethically sound if it is to operate effectively (ie: be observed by its target population): Capps, *op. cit.* note 4.

[38] Isasi & Knoppers, *op. cit.* note 19, p. 2475. F. Arzuaga, e-correspondence dated October 30, 2006, indicates that there have been no official government position papers or reports on SCR to date, though the Science & Technology Promotion Agency created an Advisory Commission on Stem Cells in October 2006, which Commission has not yet produced its opinion.

[39] Presidential Decree No. 200/1997.

[40] Article 1 states, "El Presidene de la Nacion Argentina en Ecuerdo General de Ministros Decreta: Prohíbense los experimentos de clonación relacionados con seres humanos". The remaining 3 provisions of the 1997 Decree merely direct further action and stipulate that the 1997 Decree is to be inscribed as the law of the land.

[41] Recital 1 states, "Que es function indelegable del Estado la defensa de la dignidad de la persona humana, la preservación de su salud y la calidad de vida de los habitants".

some way, though it is wildly speculative to offer any insight as to how they may have thought it did so.

- Recital 3 states that scientific advances in the public domain have resulted in human cloning research being possible, thereby creating ethical and moral problems that run contrary to the values and customs of the people.[42] This is further reference to a moral foundation, but there is no reference to the specifics of the ethical/moral problems envisioned, nor, more importantly, aside from the previous bland reference to dignity, is there any articulation of what the "values and customs" of the people might be and how they impact on the individual.

- Recital 6 states that the government has taken account of the opinions of different religious groups and scientific institutions, and the positions of different countries that have adopted a view on the subject.[43] However, it gives no hint as to which groups/institutions/states it considered or found compelling, and so, again, one is left in the dark as to the precise moral foundation of the prohibition.

Given the above, although there are gigantic gaps in the teachings discernable from the 1997 Decree's very curt and minimalist text, it can be inferred that constraining and restrictive interpretations of dignity and sanctity are operative. Somehow cloning diminishes the dignity of the individual and it must therefore be prohibited. From this we can infer that, to the extent that the prohibition is motivated by a desire to protect the individual at all, it effectively translates these motivating values into legal rules (ie: constraint is the order of the day).

But what might this position on cloning say about Argentina's position on hESCR, and, more particularly, the position of the embryo (pre-individual) and donor (individual), and are the values identified consistently realised? One can infer from the text and tenor of the instrument that Argentina's approach to hESCR may be similarly restrictive. If research involving therapeutic cloning infringes or is an affront to the dignity and sanctity of the individual, then, to be consistent, Argentina should adopt a prohibitive or restrictive position on hESCR, or at least offer some protection for the dignity and sanctity of the embryo and the individual in the hESCR.

However, there is no legal protection (of the dignity and sanctity) of the embryo or (of the dignity and autonomy) of the individual participant/donor in either the 1997 Decree or in any other enforceable regulatory instrument.[44] The practical consequences of this carving out of cloning for particular attention, combined with silence on other issues, would seem to be that both the use of surplus IVF embryos and the gestation of embryos for obtaining hESCs for research is permitted. Similarly, given the legislative silence on the issue of international collaborations and the importation of SC lines, it would seem that both (1) the importation and use of SC lines derived from surplus

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[42] Recital 3 states, "Que los avances cientificos que son de conocimiento público posibilitan la realización de experimentos de clonación humana que plantean problemas éticos y morales que se contraponen a las pautas y valores culturales propios de neustro pueblo".

[43] Recital 6 states, "Que, igualmente, ha tomado conocimiento de las opinions formuladas por representantes de distintos credos religiosos e institutciones cientificos y de las deciciones adoptadas por gobiernos de diversos países fijando posiciones concretas al respecto".

[44] L. Baranao, President, National Agency for the Promotion of Science & Technology, representations made at informal meeting in Edinburgh on October 26, 2006. The Argentine Ministry of Health has commenced work on human subject research guidelines, but no results have yet been published: F. Arzuaga, *supra*, note 40.

embryos, and (2) the importation and use of SC lines derived from therapeutic cloning, is also permitted.

In light of this apparent permissiveness, which seems out of step with the 1997 Decree, one would hope for some guidance – either in the 1997 Decree or some related instrument (given Recital 4, which specifies the need to regulate practices associated with cloning and human experimentation[45]) – regarding Argentina's position on:

- the status of the embryo and a definition of same;[46]
- when (or whether) the embryo can be used to derive SCs for research purposes;
- the status of and protections for individuals participating in SCR and/or the related fields of IVF or human subject research more generally.

However, none is offered and, presumably, limits on personal actions are left to non-governmental instruments or personal morality/conscience.

Legal protections for the collective

As suggested above, cloning is a particularly important site for considerations of collective wellbeing, and issues relating to collective wellbeing require balancing actions and restrictions with a view to promoting a moral and just society. In the present context, and to grossly oversimplify the problem, a balance must be struck between permissive, human rights-based, and solidarity- and autonomy-inspired scientific freedom, on the one hand, and restrictive, risk-based, and dignity- and sanctity-inspired limitations, on the other hand. Does the instrument offer guidance on and (moral) justification for the balance it has struck via its operative provisions?

The 1997 Decree does, by virtue of its explicit prohibition of cloning in Article 1, offer some (minimal) guidance on the balance deemed appropriate for Argentina with respect to the scope of health research. Unfortunately, little can be said about the underlying values by which the state is being compelled to engage in this limits-setting exercise, although the same assumptions as made above likely apply. Recital 3 hints at a moral awareness and Recital 1 references human dignity (now collectively understood as serving to promote the dignity of society as a whole). It could be argued that this limitation sits uneasily with the recognition, also in Recital 1, of the state's duty to preserve the health and quality of life of its citizens, a claim that seems to implicate the solidarity value.

Ultimately, by virtue of the 1997 Decree, Argentina has implied that morally grounded health research is considered important, but that health research which implicates human cloning cannot, for some reason which is not made clear, be considered moral, and therefore cannot be pursued.

Summation: a moral/legal disconnect

Through the 1997 Decree, Argentina has attempted to regulate not hESCR but rather one

[45] Recital 4 states, "Que, por ello, resulta de urgente necesidad reglamentar, controlar y fiscalizar todas las actividades relacionadas con los experimentos de clonación, en particular con seres humanos".

[46] The importance of such a definition and its absence in Argentina is noted in R. Isasi et al. Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia and Africa. *J Law Med. & Ethics*. 2004; 32: 626-638.

scientific process (cloning) associated with hESCR (and particularly important to issues relating to collective wellbeing). As such, it is conceded that evaluations of the 1997 Decree as a regulatory instrument for hESCR may be unfair, but those above (and the conclusions below) are warranted insofar as they comment on (1) the general worth of the instrument, and (2) its potential impact on hESCR, in whose orbit it obviously spins.

With respect to the worth of the 1997 Decree in its own right as a regulator of research relying on cloning techniques, this minimalist instrument exhibits some terrific shortcomings, most particularly related to its potential efficacy. It contains no provision for monitoring activities or enforcing compliance with its prohibition (or for furthering moral values embodied in its prohibition, which are, in any event, left undefined). Further, the 1997 Decree directs the Ministry of Health and Social Action to write a bill related to this matter (cloning and associated practices?) within 60 days.[47] However, there has been no follow-up regulation addressing these matters or otherwise offering guidance relating to hESCR.

With respect to the second point – the 1997 Decree's impact on hESCR – when measured against its own disclosed awareness of regulatory need in this area, its utility is little better. For example, Recital 2 stipulates the need to 'ensure and guarantee' the correct utilisation of techniques and procedures applicable to human beings.[48] Similarly, Recital 4 notes 'the urgent need to regulate and control all activities *associated with* cloning, especially experiments involving human beings'.[49] However, its application is limited to cloning and it ignores hESCR, inarguably a procedure/technique both 'associated with' cloning and 'applicable to' human beings. And again, as noted above, no further regulation addressing these matters has been adopted.

On balance, Argentina's attempt at regulation could be characterised as morally incoherent, socially inadequate, and, in light of the importance of deliberative democracy noted above, democratically deficient:

- Morally Incoherent: Argentina's approach exposes an apparent disconnect between the broad, fundamental values (apparently) held by Argentine society and the official legal position which obtains (with respect to hESCR). With respect to its value-position, Argentina has: (1) ratified the American Convention on Human Rights (1969),[50] which states that every person has the right to have his life protected by law from the moment of conception;[51] and (2) constitutionally entrenched catholic dogma,[52] which views the creation of embryos for research purposes as the creation of 'sacrificial victims predestined to be immolated on the alter of scientific progress'.[53] Thus, although Argentina's

[47] Article 2 states, "Encomiéndase al Ministerio de Salud y Accion Social que, en un plazo no mayor de Sesanta (60) días, elabore el proyecto de ley respective".

[48] Recital 2, which states, "Que, asimismo, el Estado debe asegurar y garanatizar el correcto empleo de los procedimientos y técnicas de uso y aplicación en los seres humanos".

[49] Recital 4.

[50] American Convention on Human Rights, 1969, OAS Treaty Series, No. 36.

[51] Ibid: Article 4.

[52] See s. 2, Argentinean Constitution 1853. Available at http://www.oefre.unibe.ch/law/icl/ar00000_.html, which obliges the federal government to 'support the Roman Catholic Apostolic religion'.

[53] Pontifical Academy for Life. The Dignity of Human Procreation and Reproductive Technologies: Anthropological and Ethical Aspects. 2004. Available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pont-acd_life_doc_20040316_x-gen-assembly-final_en.html [Accessed 31 Oct 2006]. Indeed, it has been noted that Latin American legislators receive mandates from the Vatican and frequently act under Vatican morality rather than exercise their own free choice: F. Zegers-Hochschild. Attitudes Towards Reproduction

legal and constitutional character and conservative social history *suggest* that it should hold the 'restrictive position' outlined in Part I, the regulatory status of hESCR does not reflect these positions. The regulatory position is that only the performance of SCNT for deriving (1) hESCs for research, or (2) embryos for reproduction, is forbidden. One might claim that autonomy (manifesting respect for others by allowing them to make decisions for themselves) is exposed by this state of affairs. Researchers (and companies) are permitted to pursue their work largely unfettered by regulatory limitations or oversight, and one can only hope that they will work toward ends that are socially useful. However, one can contest this proposition, arguing that the researcher liberty which apparently prevails does not 'promote' autonomy; it does not create space/opportunity to do a particular thing or range of things. It is therefore stretching the inference to claim that inactivity can masquerade as respect for autonomy.

- Socially Inadequate: A number of circumstances which obtain in Argentina make the unregulated and unsupervised advancement of SCR potentially dangerous. First, although some treatments have been administered for years (eg: bone marrow transplants for leukaemia patients[54]) and research is advancing apace (eg: SCs are being used to examine protein, gene and cancer functions and to promote healing in neural fibres[55]), fundamental hurdles remain to our understanding of how SCs work inside and outside the body (eg: SC lines are difficult to maintain, have yet to efficiently produced large quantities of cells, and experience random differentiation and genetic instability, and the movement and behaviour of SCs introduced into a natural environment cannot yet be predicted[56]). Second, the usual shackles of developing country innovation (eg: underdeveloped technical, financial and legal capacity) are only partially present in Argentina, which has already taken many positive steps to build its SCR capacity and is now advanced in its health research and SCR activities. With respect to the former, although its overall R&D spending is relatively low by international standards (ie: in 2004, R&D spending represented 0.44% of GDP, and of that, 14% related to health research), Argentina is one of the top 25 most productive research countries and is listed as a world player in SCR spending.[57] With respect to treatments, adult SC-based cerebral infarction treatments and diabetic insulin production

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in Latin America: Teachings from the Use of Modern Reproductive Technologies. *Hum Reproduction Update*. 1999; 5: 21-25. This deference to the church goes so far as to criminalising abortion in all circumstances and refraining from legislating on IVF: see E. Rivera-Lopez. Ethics and Genetics in Latin America. *Developing World Bioethics*. 2002; 2: 11-20.

[54] Chapman et al., *op. cit.* note 3.

[55] Devolder, *op. cit.* note 4; Corrigan et al., *op. cit.* note 26; E. Singer. Stem Cell Mix Helps Paralyzed Rats Walk. 2006. Available at http://www.technologyreview.com/printer_friendly_article.aspx?id=17029 [Accessed 29 Sep 2006]; S. Kadereit & P. Hines. An Overview of Stem Cell Research. *New Eng LR*. 2005; 39: 607-622, p. 613.

[56] Kadereit & Hines, ibid; Select Committee, *op. cit.* note 6, at para. 2.13; Shaw, *op. cit.* note 21, p. 37; E. Singer. Turning Stem Cells into Tissues. 2006. Available at http://www.technologyreview.com/printer_friendly_article.aspx?id=16374 [Accessed 29 Sep 2006]; S. Ertelt. MIT Prof: Embryonic Stem Cell Research Nowhere Close to Helping Patients. 2006. Available at http://www.lifenews.com/printpage.php [Accessed 12 Oct 2006].

[57] See Biocrawler, Stem Cell. 2006. Available at http://www.biocrawler.com/encyclopedia/stem_cell [Accessed 12 Oct 2006]; C. Morel et al. Health Innovation Networks to Help Developing Countries Address Neglected Diseases. *Science*. 2005; 309: 401-403. This is in contrast to the dismal state of science funding in 2002, the height of Argentina's economic crisis: C. Marzuola. Argentina's Crisis Heralds Time of Torment for Scientists. *Nature*. 2002; 415: 104.

treatments have been administered to patients,[58] and multi-centre international SC collaborations are being pursued with respect to congestive heart failure.[59] Third, biotechnology (and SCR) represents an opportunity for developing countries like Argentina to build capacity alongside developed countries, thereby blurring the developed/developing divide (ie: it represents a 'leapfrog' technology similar to mobile phones).[60] For this to occur and for maximum benefit to be realised, an innovation-friendly environment must be fostered. Such an environment does not entail abdication of moral limits or public oversight, but is characterised by regulatory clarity and flexibility.[61]

- Democratically Deficient: Argentina is often described as 'hyper-presidential' because of the Constitutional emphasis on the President's superiority and his practical capability, through decrees and vetoes, to exercise legislative authority in a unilateral and discretionary way.[62] The 1997 Decree is an example of a Presidential exercise of authority; indeed, it is an example of a 'need-and-urgency' decree, a form of legislative action introduced in the 1980s and subsequently validated by the Supreme Court,[63] whereby the President identifies an area of emergency or urgency and issues binding legislation thereon with little or no democratic participation or oversight. Although the Legislature has the power to approve or amend decrees, many are met with silence (ie: tacit approval) and, where they are amended, can be returned to their original form via the President's veto power.[64] Given this environment, and the legislative inactivity which followed the 1997 Decree, it can fairly be characterised as a top-down and not deliberatively conceived instrument.

In short, and on the whole, Argentina's regulatory situation is fairly characterised as

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[58] See Greenwood et al., *op. cit* note 7, p. 68; H. Pilcher. Bone Marrow Stem Cells Help Mend Broken Hearts. 2004. Available at http://www.bioedonline.org/news/news.cfm?art=936 [Accessed 30 Oct 2006]; Medical News Today. Stem Cells Implanted in Brain of Patient Who Suffered a Cerebral Infarction. 2005. Available at http://www.medicalnewstoday.com/medicalnews.php?newsid=25613 [Accessed 3 Oct 2006].

[59] Greenwood et al., *ibid*, p. 68. Argentina is constitutionally obliged to foster international relationships and pursue international trade opportunities: s. 27, Argentinean Constitution 1853.

[60] E. DeSilva. Biotechnology: Developing Countries and Globalization. *World J of Micro & Biotech*. 1998; 14: 463-486, claims that the globalisation of biotechnology acknowledges the participation of developing countries in emerging markets of novel bioproducts.

[61] This endeavour comprises one of the "grand challenges" identified by F. Collins et al. A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era. *Nature*. 2003; 422: 835-847.

[62] M. Llanos. Understanding Presidential Power in Argentina: A Study of the Policy of Privatisation in the 1990s. *J Latin Am Studies*. 2001; 33: 67-99. Indeed, between 1983 and 1995, approximately half of all Argentine legislation originated in the executive: B. Lamounier. Strengthening the Role of Legislatures in Hemispheric Relations. 2002. Available at http://www.thedialogue.org/publications/2002/fall/legislatures.pdf [Accessed 23 May 2007].

[63] *Peralta* v. *Estado Nacional*, (1991) 141 El Derecho 519-548 (SCA). This was the most controversial in a series of Supreme Court cases which extended the President's tenuous and previously rarely used power of rule by decree. For a discussion of this and other cases and the 'creep' of the President's legislative power, see C. Larkins. The Judiciary and Delegative Democracy in Argentina. *Comparative Politics*. 1998; 30: 423-442; K. Eaton. The Logic of Congressional Delegation: Explaining Argentine Economic Reform. *Latin Am Res Rev*. 2001; 36: 97-117; R. Chavez. The Evolution of Judicial Autonomy in Argentina: Establishing the Rule of Law in an Ultrapresidential System. *J Latin Am Studies* 2004; 36: 451-478; H. Fix-Zamudio. Emergency Power and Defence of the Constitution. *Mex Law Rev*. 2007; 7: 801-860.

[64] G. Negretto. Government Capacities and Policy Making by Decree in Latin America: The Cases of Brazil and Argentina. *Compative Pol Studies*. 2004; 37: 531-562.

unsatisfactory. To its credit, Argentina has recognised this, and has undertaken preliminary steps toward a new state of governance.[65] One can only hope that it takes this opportunity to develop a morally grounded and more comprehensive regime for SCR which offers those working in this controversial field sound and explicit guidance and a means to test boundaries. Despite the level of SCR activity already underway in Argentina, one might equally hope that stakeholders will seriously consider the social implications of such cost-intensive research (resulting in cost-intensive treatments) given Argentina's economic inequity and healthcare fragility.[66] Of course, given the government's multiple roles, including strengthening and modernising the economy and closing the developing/developed divide so that the welfare of all Argentineans is improved, this latter concern may not loom large in the stakeholders' minds.

CONCLUSION

Stakeholders are confronted by a society that is increasingly complex and confusing (characterised, as it is, by rising populations, greater interconnectedness, and an increasing number and scope of human activities). Examples of this abound, but a particularly relevant one given the present context is the biomedicalisation of society. Under this process, aspects of life previously outside the jurisdiction of medicine are increasingly viewed as medical problems. This social transformation is facilitated by new biotechnologies, which are transforming diagnostic and treatment options.[67] A consequence of this social complexity and the (new) moral pluralism that it engenders is that the law must regulate relations and activities that were previously unregulated or regulated solely by adherence to (agreed) moral practices; the law is called upon to perform more contested and burdensome functions in the governance of society.

One activity that the law is being called upon to respond to is that of biotech innovation and, more particularly, SCR, which is shaped by two core phenomena that make voluntary reliance on personal morality inadequate, namely disease and commercialisation:

- Disease: Chronic, degenerative and acute diseases visit massive economic and

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[65] Arzuaga, *op. cit.* note 38; Baranao, *op. cit.* note 44. In April 2004, the Committee of Ethics in Science & Technology urged the government to lift its blanket ban on cloning so as to allow therapeutic cloning, and to rescind its support for the UN Resolution which would ban all forms of cloning: R. Sametband. Argentina Urged to Support 'Therapeutic' Cloning. 2004. Available at http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=1380&language=1 [Accessed 31 Oct 2006].

[66] For more on the former, see C. Valdovinos. Growth, Inequality and Social Equity in Argentina. *En Breve*. 2005; 82: 1-4; L. Gasparini et al. Argentina: Monitoring Socio-Economic Conditions in Argentina, Chile, Paraguay and Uruguay. 2005. Available at http://www.wds.worldbank.org/external/default/wdscontentserver/wdsp/ib/2005/07/15/000011823_20050715164315/rendered/pdf/329490v10argen1rsion0lcshd01public1.pf [Accessed 15 Feb 2007]. For more on the state of healthcare, see J. Uribe & N. Schwab. The Argentine Health Sector in the Context of the Crisis. 2002. Available at http://wbln0018.worldbank.org/lac/lacinfoclient.nsf/d29684951174975c85256735007fef12/3d29a0ed02294a8b85256db10058dbdd/$file/argentinapabp6.pdf [Accessed 15 Feb 2007].

[67] For an exposition of this concept, see A. Clarke et al. Biomedicalization: Technoscientific Transformations of Health, Illness and US Biomedicine. *Am Soc Rev*. 2003; 68: 161-194, who argue that biomedicalisation contributes to and is manifested by (1) the politico-economic constitution of corporatised research, (2) the social emphasis on health risk and the means to monitor same, (3) the increasingly technoscientific nature medical practices, (4) the transformation of biomedical knowledge/information production, management, distribution and utilisation, and (5) the transformation of the human bodies and identities according to biotech undertstandings.

psychological costs on societies, both developed and developing; in many cases, mortality rates are climbing and quality of life (and care) are dropping. Moreover, these diseases increasingly transcend national boundaries (eg: HIV, SARS, Avian Flu). In such a setting, stakeholders (governments, commercial enterprises, healthcarers, patients groups) are turning to innovative avenues of health research like SCR to provide new, novel and cost-effective means of treating disease. As activities increase, actor pools expand, and capabilities improve, clear and comprehensive regulation becomes more important.

- Commercialisation: The direction of biotech and genomic innovation/evolution is driven in large part by corporate agendas, themselves influenced by what is perceived to be most lucrative in global markets.[68] Contributing to this phenomenon is the fact that academic institution and private company relationships are both increasing and being strengthened.[69] In consequence, healthcare research (and SCR) regulation is becoming an important mechanism of corporate conduct / business practice regulation, as well as an important element of delivering useful healthcare.

Given the above, and the fact that SCR is an increasingly prevalent and deeply divisive aspect of a quickly evolving social setting, and moreover it is one which incites (often polemical) intercourses amongst publics, decisive legal action preceded by adequate engagement exercises is essential. Whole new subject-specific regimes are not always necessary, but a regime which considers all of the most important elements of the issue and offers a (reasonably) holistic and consistent response is warranted. In the present case, that means regulation which:

- identifies the forms of health research society considers both acceptable and urgent;

- structures the pursuit and influences the direction of that research to facilitate socially acceptable outputs (eg: addresses issues such as sourcing, storing and utilising SCs, and cloning human embryos for research purposes); and

- articulates the limits of health research and research outputs so that they are timely and socially useful (eg: directly and through research commercialisation policies and product and process licensing practices).

Such a regime has the potential to foster innovation while at the same time assuaging our worst fears of misconduct and misapplication.

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[68] K. Rajan. Subjects of Speculation: Emergent Life Sciences and Market Logics in the United States and India. *Am Anthropologist*. 2005; 107: 19-30.

[69] H. Moses et al. Collaborating with Industry – Choices for the Academic Medical Centre. *New Eng J Med*. 2002; 347: 1371-1375.

REGULATION OF STEM CELL AND REGENERATIVE SCIENCE: STAKEHOLDER OPINIONS, PLURALITY AND ACTOR SPACE IN THE ARGENTINE SOCIAL/SCIENCE SETTING

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Abstract: This paper articulates in broad terms a model bioscience environment and its primary constituent parts, which include bioscience policy and regulation, technology deployment and stakeholder engagement, and science innovation systems. Then, having reference to empirical data generated by the GET: Social Values Project, it offers an explanation of how the Argentine environment departs from that ideal model. Finally, focusing on one constituent part of the environment – the policy and regulatory space – it reports on Argentine stakeholder opinions and desires and what these mean for the potential to adopt facilitative regulation in Argentina. It concludes that the Argentine scientific environment is sub-optimal and poorly equipped to deal effectively and positively with the plurality of ideas that people have for both the trajectory of science and its regulation. It ends with a call for further research which broadens the evidence base and thereby facilitates the improvement of the social/science environment and its constituent parts.

Keywords: biotechnology – stem cells – research – regulation – legislation – ethics – plurality – innovation – actor networks

INTRODUCTION

There has been a lot of noise from Argentina, both before and since the 2007 formation of the Ministry of Science, Technology and Innovative Production (MOST), about the importance of science both generally and developmentally, and there has been some interest from Argentine policymakers and regulators in stem cells as a means of building competitiveness in the biosciences,[1] where Argentina has enjoyed historical success.[2] Recent activities have included the following:

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1 See P. Smaglik, "Argentina's Pivotal Moment" (2008) 451 Nature 494-496.

2 Argentina has had a number of Nobel Laureates in the biosciences, including Bernardo Houssay, Luis Leloir, and César Milstein, and some elements of Argentine research have been described as close to the 'frontier' of international knowledge: see P. Kreimer and M. Lugones, "Rowing Against the Tide: Emergence and Consolidation of Molecular Biology in Argentina, 1960-90" (2002) 7 Science, Technology and Society 285-311.

- promotion of international networks and increasing public funds available to sci-tech and bioscience development;[3]

- formation of the Advisory Commission on Regenerative Medicine and Cellular Therapies by the MOST in 2008;

- issuance of governmental press releases calling attention to the benefits of biosciences like stem cell research;[4] and

- signing of international agreements with specified groups to promote scientific innovation and international cooperation.[5]

Despite these efforts, it remains to be seen whether Argentina can effectively build on its achievements and existing strengths and realise international bioscience competitiveness in anything other than a peripheral manner.[6]

This paper considers one element of the means by which bioscience, and more particularly stem cell and regenerative medicine research, can be facilitated and enhanced in Argentina, namely the bioscience environment and its constituent parts. In doing so, it draws on evidence generated by a project entitled 'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina' (GET: Social Values).[7] After outlining the methodology adopted for the empirical research, the paper articulates in broad terms a model for a positive bioscience environment and its primary constituent parts which can be distilled from this and other evidence. Then, having reference to the empirical evidence, it offers an explanation of how the Argentine environment departs from that model. Finally, focusing on one constituent part of the environment – the policy and regulatory space – it reports on Argentine stakeholder opinions and desires and what they mean for the potential to adopt facilitative regulation in Argentina.

METHODOLOGY

The GET: Social Values Project was designed with the intention of gathering qualitative data around key issues of bioscience, and in particular stem cell research governance, in Argentina, the objective being to discover stakeholder values relevant

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[3] J. Niosi and S. Reid, "Biotechnology and Nanotechnology: Science-Based Enabling Technologies as Windows of Opportunity for LCDs" (2007) 35 World Development 426-438, and E. Trigo and E. Cap, "Ten Years of Genetically Modified Crops in Argentine Agriculture" (2006), available at http://www.inta.gov.ar/ies/docs/otrosdoc/resyabst/ten_years.htm [accessed 4 August 2009].

[4] See Argentine Science and Technology Commission, National Congress, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009], and Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies, Ministry of Science, Technology and Productive Innovation, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009].

[5] N. Bar, "El Rating de la Ciencia", *La Nación*, 13 May 2009, available at http://rcdtx.lanacion.com.ar/nota.asp?nota_id=1127536 [accessed 3 August 2009].

[6] For more on the traditionally peripheral nature of Argentina's scientific endeavours, see P. Kreimer and M. Lugones, supra, note 2.

[7] Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina (ESRC Responsive Grant Award No. RES-000-22-2678). For more on the Project, see the official Project website at http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/index.asp, or go to ESRC Society Today at http://www.esrcsocietytoday.ac.uk/.

to, and objectives for, this science and its governance. While the data generated by the 22 semi-structured interviews cannot be said to represent the Argentine view – the subject sample was too narrow and too small for such claims – it captures important qualitative evidence of the views of key stakeholders in the field. Moreover, it has been welcomed by relevant stakeholders as an early and important first step in examining the social context of bioscience (and stem cell) innovation in Argentina. It has enjoyed the support of the Argentine policymaking community, which has facilitated access to some of those actors most interested in, and relevant to, stem cell research governance.

Prior to commencement, the GET: Social Values Project was subject to initial institutional ethics review and then funding body ethics evaluation. Research participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities.[8] As the project was never intended to be a public engagement mechanism, the opinions of the broader general public were not solicited. Rather, those originally viewed as most likely to influence the nature and content of bioscience and stem cell regulation in Argentina were targeted (ie: Argentine science policy elites), for, it was felt, only by targeting those most engaged in the pre-legislative process could we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they emerge), on the other.

Following preliminary desktop research on the regulatory setting,[9] semi-structured interviews lasting 50 to 90 minutes were conducted. Each interview was, with permission, recorded. Open-ended questions and an informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. In some cases, more structured information was obtained through questionnaires. Transcription of the interviews was performed within Innogen (one the Principal Investigator's host institutes) and that work was subject to a signed Confidentiality Agreement. Anonymised transcripts were shared between the Principal Investigator (in Edinburgh) and the Collaborating Investigator (in Buenos Aires) and have been retained for archiving. Every line of transcription and interviewer notes was coded and analysed for emergent themes, and sections relating to those themes were grouped together. The whole assessment was refined through an iterative process, thus enabling different perspectives and interpretations to be incorporated. The quotes used in the present paper were chosen as reflective of widely canvassed themes, and are deployed to make particular points or support particular claims or recommendations.

ANALYSIS

I. DOING 'GOOD' SCIENCE: THE SOCIAL/SCIENCE ENVIRONMENT AND ACTOR SPACE

[8] The investigators interviewed at least one respondent, but often multiple respondents, from each of the following categories: cabinet level politician; national congressional member; national regulatory agency member; national advisory committee member; medical clinician, medical researcher, basic scientist, ethicist, academic lawyer.

[9] See S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8(2) Developing World Bioethics 138-150.

It is clear from actor-network scholarship,[10] and (related) innovation systems scholarship,[11] that the advancement of science is not realised by any linear or straightforward process; it involves a plethora of interdependent public and private actors and evolving social networks interacting with each other and with existing technologies, and it equally relies on other factors such as laws, rules, norms and routines, all feeding essential information into the innovation cycle which, when operating properly, generates new knowledge and better products and practices. Bearing this in mind, I suggest that the 'best science'[12] is most likely to emerge from a dynamic, inclusive and positive/facilitative value-conscious social/science environment. Such an environment is characterised by the ability of diverse stakeholders to (safely) advance their ideas of the good life and the just society, and their (reasoned) notions of morally defensible science. A healthy social/science environment is richly populated by 'actors', 'artefacts' and 'nodes', and it is absolutely reliant on the open exchange of ideas and therefore the co-production (and reproduction) of actors, nodes and artefacts, and, ultimately, of scientific knowledge and useful products and processes.

In this model, 'actors' are individuals, institutions, organisations and social networks; a diverse collection of interested people and entities with overlapping and shifting allegiances *to* actor groups and alliances *with* actor groups. Actors generate and release, and, in turn, receive information and ideas, thereby helping to shape one another and giving content to both the subject matter (here bioscience) and the environment.

'Artefacts' are vital structures/scaffolds which link the specific environment to other external or related environments, and which, more importantly, serve an ongoing shaping/influencing and/or monitoring function within the subject environment. They are designed by humans and, in turn, influence the action and imagination of humans through their interaction with each other and with the actors (ie: they inscribe their characteristics on the human psyche but are similarly influenced and continually reconstituted by human actors). Artefacts can include (1) national (or regional) science policies, including funding policies, and science regulation and related legislation, (2) formal and informal national, regional or sectoral innovation systems (which implicates the former but also includes industry actors, objects, and shapers, and active international collaborations), and (3) existing technologies and technical practices. Ultimately, artefacts contribute to the generation of science innovation and to the translation of that innovation into socially useful products and practices, each exerting their own influence and limitations. When the social/science environment is healthy, its constituent elements reproduce, mutually

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[10] See P. Gao, "Using Actor-Network Theory to Analyse Strategy Formulation" (2005) 15 Information Systems J 255-275, S. Fox, "Communities of Practice, Foucault and Actor-Network Theory" (2000) 37 J Management Studies 853-867, A. Prout, "Actor-Network Theory, Technology and Medical Sociology: An Illustrative Analysis of the Metered Dose Inhaler" (1996) 18 Sociology of Health & Illness 198-219, and more.

[11] See C. Edquist (ed.), *Systems of Innovation: Technologies, Institutions and Organisations* (London: Routledge, 1997), J. Niosi, "National Systems of Innovations are 'X-Efficient' (and 'X-Effective'): Why Some are Slow Learners" (2002) 31 Research Policy 291-302, F. Malerba, "Sectoral Systems of Innovation and Production" (2002) 31 Research Policy 247-264, J. Fagerberg et al. (eds.), *The Oxford Handbook of Innovation* (Oxford: OUP, 2006), C. Lyall, "Changing Boundaries: The Role of Policy Networks in the Multi-Level Governance of Science and Innovation in Scotland" (2007) 34 Science & Public Policy 3-14, and more.

[12] Here 'best science' means that science which achieves a balance between efficient development and production, socially utility, and public acceptability, all of which will be negotiated depending on the particular innovation .

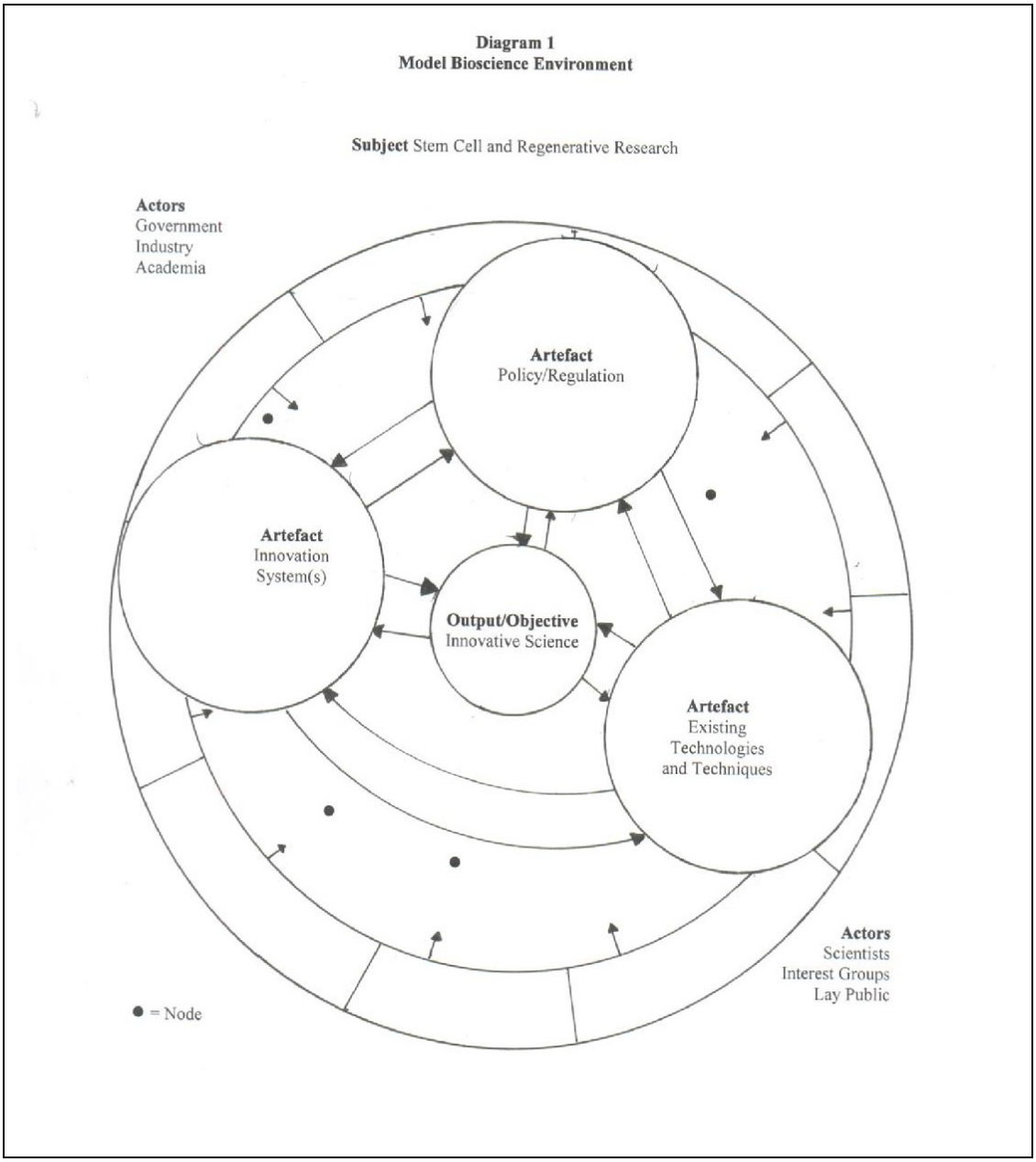
modify, and reconstitute themselves through a multi-directional interactive process that is facilitated by the nodes (but is by no means reliant on the nodes).

'Nodes' are notional intersections at which actors and artefacts come together to discuss, assess and perhaps adjust or correct the environment; these intersections may be geographic or temporal, institutional and ongoing, or intermittent or ad hoc. They serve as opportunities for actors to (re)shape the environment or constituent elements thereof in a proactive and productive way.

The similarities of the above model to a living cell are apparent, and appropriately so, for, like a cell, a healthy social/science environment is a living, thriving thing which must be nourished. Generally, one can imagine the following: the specific subject – in this case stem cell and regenerative science – is like a cell membrane, forming a thin, porous conceptual layer which encircles the social/science environment; actors, like the larger organism, might be seen to encase the membrane/subject, injecting and receiving information and thereby helping to shape both the subject and the environment; artefacts are like endoplasmic reticulum, contributing directly and indirectly to the primary output of the environment – bioscience; nodes are like mitochondria, generating the energy necessary to sustain or enhance the greater environment. Represented diagrammatically, a healthy environment might look as depicted in Diagram 1.[13]

[13] Though an argument can be made that the boundaries between the Artefacts themselves and between the Artefacts and the Output should be closer and more blurred. As previous scholarship has suggested, the separation between science and politics, for example, as distinct spheres of activity is not defensible. Science shapes politics – offering issues, influencing debates, impacting on careers – and science is shaped by political agendas and values. In short, knowledge in different walks of life develop together and influence each other. As such, one could argue that the environment is not quite as 'clean' as suggested, but the Diagram is appropriate insofar as it highlights the mutual interactions and major architectural elements.

Diagram 1
Model Bioscience Environment



Importantly, each artefact within the environment should be optimised if innovation opportunities are to be maximised (though weaknesses in one may be compensated for by aspects of the others). In order to optimise each artefact, interested actors must be given action space, that is the physical, temporal and cognitive space to reflect on, discuss, and influence the structures, so that the best combination of structure strengths, shapes and roles can be found. In short, communication and action space must exist not only at the nodes but within the artefacts themselves. The fact is that the nodes, while dynamic and energy-giving, might not be integrated into the governance structure. But the artefacts require some permanent space which offers opportunities for ongoing engagement so that confrontation can be transformed into collaboration and the environment itself can be influenced toward positive ends. Ultimately, each structure must afford interested actors space to critically assess the role and functioning of the structure itself, and to reform the structure and therefore the whole environment more generally, the primary aim being to improve science and, through science, society.

The question of whether the social/science environment is operating optimally – and therefore generating good science and scientific innovation (and perhaps also governance innovation) – is complex, requiring evidence from a range of actors and having reference to the policy objectives for the science in question. For present purposes, the question is: Based on the evidence available, to what extent does the Argentine environment reflect this notional model?

II. THE ARGENTINE CONTEXT: EVIDENCE AND THE SOCIAL/SCIENCE ENVIRONMENT

At the outset, it might be conceded that there will be very few jurisdictions which meet the ideal social/science environment, either from an architectural perspective or from an outcome perspective (ie: consistently generating the best science in the most efficient manner). Having said that, the evidence generated in the GET: Social Values Project, combined with scholarship on the Argentine science setting,[14] suggests that the Argentine social/science environment (in the bioscience context) is not particularly 'healthy'. Although select bioscience activity is internationally recognised and competitive,[15] and although Argentina's reproductive medicine services are second to none, we might suspect that the environment within which they work is sub-optimal with multiple interrelated and cascading blockages stemming from actor, artefact and node shortcomings.[16] The following section confirms this by considering some of the evidence in relation to each major element of the model environment

With respect to the relevant actors, there is evidence that:

- the range of empowered actors in the bioscience environment is narrow (ie: there is little diversity in active stakeholders);
- the representational possibilities of divergent actor viewpoints is uneven (ie: the formal dialogue is dominated by a few powerful institutions, most notably the Church);[17]
- the space within which actors can (publicly) operate is confined (ie: there are few opportunities for interested actors to network and to present a (unified) counter-point to some of the formal narratives); and

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[14] See P. Kreimer and M. Lugones, supra, note 2, P. Kreimer, "Science and Politics in Latin America: The Old and the New Context in Argentina" (1996) 1 Science, Technology and Society 267-289, P. Kreimer and M. Lugones, "Pioneers and Victims: The Birth and Death of Argentina's First Molecular Biology Laboratory" (2003) 41 Minerva 47-69, F. Luna and A. Salles, "On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina" forthcoming in Developing World Bioethics, and more.

[15] In particular, one might take note of the activity being undertaken at the FLENI, Leloir Institute, Hospital Garahan and others.

[16] Note that the consequences of a persistently sub-optimal social/science environment can be inefficient use of, or diminishing availability of, science funds, decreasing quality of science and/or low levels of innovation, or weak public support of science and/or scientist migration to other jurisdictions, depending on what element of the environment is exerting negative impact.

[17] For more on the role of the Church, see F. Zegers-Hochschild, "Attitudes Towards Reproduction in Latin America: Teachings from the Use of Modern Reproductive Technologies" (1999) 5 Human Reproduction Update 21-25.

- there is general public support for science and scientists but also high science illiteracy and a willingness by portions of the public to self-censor actual values and ideas in the face of strong oppositional voices.

Specific responses in the GET: Social Values Project which reflect these findings are as follows:

> R5: [E]ach country should try to contribute to the debate … . I don't know the view of my country. I have no idea. I could guess, but I don't know. One group is very loud; that doesn't mean that they are many because they shout so loud. I would really like to know what my country's people would like to say about this subject [stem cell research].

> R11: … [P]eople here that make the law don't take care of scientists' opinions. They consult other people who are [involved] with political groups, not good groups [interested in] law, ethics [or] research. Here the influence of the Catholic Church is really, really important.

> R16: There is a wide gap between these: science, society and social conception of science. Of the research we did last year, 50% didn't understand 'cryopreservation' and 40% didn't understand 'gene therapy'; they collapse it into cloning and manipulation. … This is the reason why I consider that, in Argentina, people's perception of science is important but uninformed. … I am afraid that with stem cells it will be the same.

Another respondent (R15) stated that there had been a 'buzz' since US President Obama's statement on stem cell research funding, but that voices remain isolated because the rigid position of the Catholic Church forces people to be quite cautious about how they approach science discussions.

Ultimately, the relationship (and particular power dynamic) between certain central actors (eg: the church, media and political elites) serves as a bottleneck, blocking other actors from a more active role within the social/science environment. Thus, many actors who are otherwise interested in this setting are (or certainly feel) disempowered and unable to access in meaningful ways the spaces within which discussions might be undertaken and important decisions might be made.

In relation to the artefacts, two in particular were identified as deficient by respondents: the science policy/regulatory artefact and the existing technologies/techniques artefact. With respect to the former, most of those interviewed reported an inability to shape science legislation or to steer legislation and/or regulation in a rational and positive direction. For example:

> R11: Yes, [we need a law] but [a] rational [law]. I am afraid because in the past when the government [adopts] legislation about science—well not really good. …

> R15: It is very difficult to pass a logical law in [reproductive medicine] … which is a related field. … It is not only the Church, but also a lot of newspapers that are very controlling in the way they [present] abortion

and [similar] topics.

> R16: There is no regulation. We have discussed [fertility treatment regulation] since 1989 … but it hasn't been made into law because [of] the 'beginning of life' debate. It has made it impossible to regulate [this] work, for moral and religious reasons – I think it is more religious than moral.
>
> R20: 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' … .

Another respondent (R5) shared the above frustration at the inability to shape good science regulation, but stated that scientists must form their own views about boundaries, and should (somehow) take part in any discussions which lead to a law.

With respect to the latter artefact – existing technologies and techniques – respondents articulated a lack of space to openly and intelligently explore the possibilities (for Argentina) of existing technologies and techniques. Technologies and practices are either consciously shuttered or hidden or, more often, simply not communicated to, or discussed within, the public (ie: science is performed behind closed doors and good science communication is not the norm). One respondent (R14) stated that scientists are not comfortable with announcing their research or their findings publicly because of feared reactions based on misunderstandings of science, and the respondent analogised this silence – this aversion to confrontation – to that experienced around the issue of divorce, an issue which bubbled below the surface for many decades until it exploded in the 1960s. One member of the Advisory Commission on Regenerative Medicine and Cellular Therapies stated that they tried to encourage an open debate on stem cell research in 2007/08, but many of the key actors were reluctant to do so because of concerns about negative attention.[18] Such an atmosphere, which might be characterised as defensive and oppressive, is detrimental to science and scientists themselves, and makes it impossible to deploy existing technologies to their maximum benefit.[19]

With respect to nodes, there have been and remain very few dynamic intersections of communication and creation. The Argentine MOST (and its predecessor, the Science and Technology Agency) sponsored two international policy conferences, one in 2007,[20] and one in 2008.[21] Both of these were ad hoc, as was a subsequent interactive workshop co-hosted by the Argentine Advisory Commission

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[18] This member was not a respondent in the GET: Social Values Project but a member with whom the author had direct and ongoing communication.

[19] An example of uneven (and therefore unjust) deployment of existing technologies and techniques in Argentina is the deployment and availability of safe abortion practices. Cutting edge technologies and techniques are available, and are sourced by some, but are unavailable to the majority of people, primarily the poor, because abortion is still illegal in Argentina.

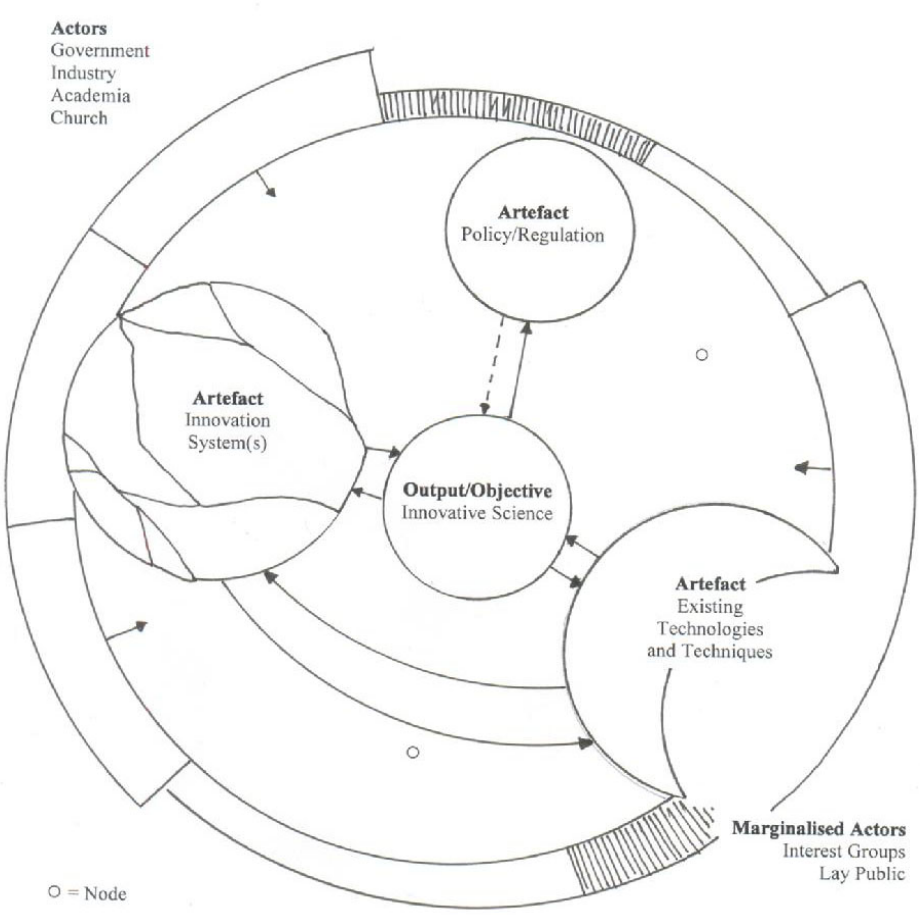
[20] Argentine Science and Technology Agency, "Regulation of Clinical Research Involving Stem Cells", 29-30 November 2007, Buenos Aires. For a report on this, see S. Harmon, G. Laurie and F. Arzuaga, "Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina – Learning from the Experiences of the UK" (2008), available at http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/Report%20Nov%2007%20Stem%20Cell%20Workshop.pdf.

[21] Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies, "Second International Conference on the Regulation of Stem Cells and Human Tissue", 14 October 2008, Buenos Aires.

on Regenerative Medicine and Cellular Therapies and the GET: Social Values Project., which workshop was attended by some 40 invited participants.[22] In the latter case, participants lamented the absence of a more regularised means of coming together to discuss issues and to network in this field. One respondent (R16) reiterated this, stating that attendees at recent doctors' meetings indicated that they would like to work in this area (ie: in stem cell science) and they would like to have more contact with other organisations, including international institutions. The respondent also expressed a desire to discuss, work and learn in a more networked manner.

Based on all of the above, the Argentine stem cell and regenerative science environment might be diagrammatically represented as in Diagram 2.

Diagram 2
Argentine Bioscience Environment



[22] Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies and GET: Social Values Project, "The Regenerative and Cellular Sciences: Values, Objectives and Issues for Implementation – An Interactive Workshop", 18 August 2009, Buenos Aires. For a report on this, see S. Harmon, "Regenerative Medicine Governance: Report of the Workshop on Governance Research Using Human Embryonic Tissue" (2009) 6:3 SCRIPTed 729-740.

Note that certain actors, most notably the lay public and patient groups, are thin/weak or missing (or blacked out from a communications point of view). Aside from the policy element, the policy/regulatory artefact is undernourished. There is almost no relevant existing legislation/regulation,[23] and the discursive space is largely closed down by powerful actors antagonistic to bioscience. The existing technologies artefact is partially concealed through science community silence and a relatively low level of science literacy, which means that technologies which are already being used (albeit unevenly) are not having the shaping effect on the environment that they might otherwise have. Although this was not addressed directly in the responses, the innovation systems artefact is not ideal (and is therefore represented as fragmented).[24] Finally, available nodes of communication and dynamism are few and are not yet well entrenched. Such then is the general social/science environment in Argentina; a sub-optimal environment the shortcomings of which include an inability to measure or cope with plurality as it relates to science trajectories or means of governing same, facts which are mostly apparent to many of the respondents in the GET: Social Values Project.[25]

Is there capacity and a will to improve the social/science environment in Argentina? Based on observed expertise and interview responses, the answer is clearly 'yes', and there are already some positive signs. For example, the National Institute for Organ Donation and Transplantation (INCUCAI) is becoming a useful conduit of scientific information and technical guidance for (an admittedly narrow range of) interested actors, a fact suggested by several respondents. More importantly, the MOST is evolving as an important site of information, action and motivation, as is the Advisory Commission on Regenerative Medicine and Cellular Therapies, which serves an important reflective or evaluative function. The work of these bodies since 2007 has made at least one element of the first artefact – science and funding policy and science legislation/regulation – quite robust and internationally engaged, and this largely as a result of the efforts of the new Minister of Science, Líno Barañao,[26] but even this space has been opportunistic and largely limited to science and policy elites.

However, as is perhaps clear, the scope of the task facing the MOST and other interested stakeholders is substantial. The remainder of the paper focuses on one element of the undertaking: legal reform (or action) within the policy/regulatory

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[23] Both the Prohibition on Human Cloning Research, Presidential Decree No. 200/1997 and the *Transplantation Act 2007* are only peripherally relevant to this setting.

[24] For a critique of the innovation system artefact, see D. Chudnovsky, "Science and Technology Policy and the National Innovation System in Argentina" (1999) 67 CEPAL Review 157-176, C. Correa, "Argentina's National Innovation System" (1998) 15 International J Technology Management 721-760, K. Thorn, "Science, Technology and Innovation in Argentina" (2005), available at http://siteresources.worldbank.org/INTARGENTINA/Resources/ScienceTechnologyandInnovationinArgentina.pdf [accessed 22 February 2010], C. Morel et al., "Health innovation Networks to Help Developing Countries Address Neglected Diseases" (2005) 309 Science 401-403, and more.

[25] Put very succinctly, the interaction in Argentina of science, politics and society, the latter which is heavily and, from a rationalist's point of view, negatively influenced by the church, is not an ideal recipe for supporting (cutting edge) science and channelling it towards socially approved and useful purposes. The theoretical characterisations here are helpful for discussing their interaction and mutual reliance and for singling out aspects of an otherwise sometimes murky Argentine setting so that they can be considered in more manageable portions and thereby more carefully scrutinised.

[26] Several respondents singled out Minister Barañao as being a central figure, noting his particular experience and qualities as being important to this moment for science in Argentina.

artefact.

III. THE REGULATORY ARTEFACT: COPING WITH PLURALITY

Action and actor space at one artefact can be very important not only for the development of that artefact (and its outputs) but also for the overall social/science environment. More specifically, it has been suggested that action within and by the policy and regulatory artefact is vitally important to the science environment and to the beneficent potential of science:

> In democratic societies, technological development and application operates, so to speak, with a social licence – a licence which itself is subject to the overriding restraints of respect for human rights and human dignity. Accordingly, it falls to politicians and regulators, and ultimately to the law, to set the limits of technological innovation, to coordinate the assessment and management of risk, to design procedures for public participation, and to set the terms of compensatory responsibility. … [I]t also falls to the regulators and to the law to establish a governance environment that is supportive of desirable technological innovation and that ensures that benefits are fairly shared.[27]

In short, the convergence of diverse and novel technologies and their rapid penetration into the lived human experience, demands governmental action.

The empirical evidence generated by the GET: Social Values Project suggests that Argentine stakeholders – at least those interviewed – desire to have some boundaries articulated for bioscience, particularly that in the medical setting. Known boundaries, it was felt, would have at least two salutary effects. First, they would limit scientists by making clear what ends and/or methods are deemed to be (in)appropriate after existing methods and trajectories had been considered rationally (ie: it would reduce the possibilities of mavericks damaging the science/research reputation and agenda).[28] Second, they would empower scientists in a positive way by assuring them that all of their activities within that articulated sphere are defensible and need not be sheltered from public scrutiny (ie: it would encourage the unveiling of science without putting scientists on the defensive).

However, although almost all respondents felt that *government* boundary-setting (in particular) would be valuable, there was no consensus on how that boundary-setting might be achieved, and they did not all agree that formal regulation was essential. In this regard, opinions fell broadly into four camps:

- Camp 1 – No Legislation: It is too early for legislation in the stem cell setting (R7). Alternatively, legislation ought to be avoided because the tendency in Argentina is to ban and pass bad laws (R16). It might be better for this area to first be quietly overseen by a regulatory committee under the Ministry of Science or Health so some oversight and advice can be offered as the field develops, and any furore is avoided (R21).

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[27] R. Brownsword and H. Somsen, "Before We Fast Forward – A Forum for Debate" (2009) 1 Law, Innovation & Technology 1-73, at 2.

[28] Returning to the social/science environment and the cell metaphor, unchecked science can easily go out of control and/or lose social utility, and might be seen as cancer.

- Camp 2 – Narrow Legislation: A stem cell-specific law is important because of the socially important issues thrown up by this research (R5, R10, R11, R14, R17, R19).

- Camp 3 – General Research Legislation: Stem cell practices and issues are shared with other research and medical practices and techniques so a general medical research law is more useful, under which technique-specific regulations might be drafted by the executive on an as-needed basis (R1, R4, R6, R8, R18).

- Camp 4 – General Medical Legislation: It is much more important to regulate the clinical setting than basic research; the safety of the patient is the most important element currently missing from the Argentine biomedical regulatory setting so it would be better to have a medical law (R3, R12, R15).

In short, and potentially compounding the confusion and dissatisfaction caused by the existing legislative and regulatory silence from the policy/legislation artefact, there was a plurality of opinions as to how this artefact (or bodies within it) should respond and shape itself with respect to science boundary-setting, and there was a scepticism as to whether the artefact could shake itself into action and set a course that engaged with this plurality (and other pluralities that might arise).

Given this plurality (on both the role of law and the shape/nature of publicly set boundary-setting for science) – a plurality which we might assume will be reproduced across society[29] – it remains to be determined how Argentine policymakers might respond. How might these very diverse (indeed contradictory) opinions be taken into account and (at least some of them) be put into action?[30] That is a big question for another time, and one dependent on a broader base of evidence than presently exists, but the outlook is not wildly encouraging. Some preliminary observations supported by the evidence are as follows:

- The present manifestation of the broad Argentine social/scientific environment, with its uneven access to voice and its few nodes for open public debate, seems ill-suited to exploring a plurality of science and boundary opinions in a constructive manner, and less suited to encouraging a negotiated narrowing of options such that action which is generally supported can be taken.

- Similarly, the potential of the policy/regulatory artefact to address a plurality of opinion in relation to either science boundaries or, more importantly,

[29] Though we should be cautious about extrapolating too much from respondent areas of agreement (eg: that science is beneficial and should be facilitated) and disagreement (eg: on legal responses), it is reasonable to assume that inclusion of a wider range of stakeholders (eg: interested segments of the public) will result in even greater plurality, not only on the legal element of the policy/regulatory artefact, but, perhaps more importantly, on the bioscience endeavour more generally, where we might expect some very deep divisions on issues of whether to pursue stem cell research, how to apply stem cell research outputs, and therefore how to regulate activity in this field.

[30] Given the plurality of opinion which we can assume exists in Argentina with respect to stem cell and regenerative science more generally, and given the problems that the current socio-legal context is creating, I would suggest that this particular plurality is indeed one that should be serious considered, actively engaged with, and eventually acted upon, one way or another.

methods for articulating and narrowing the plurality and then enforcing the boundaries ultimately agreed (ie: for shaping the artefact itself) seems seriously constrained due to a shortage of meaningful (and entrenched) policy discussion nodes and existing legislative fallowness.

- The possibility of the best placed and best suited actors in the subject environment (eg: the MOST and Ministry of Health) adopting a pragmatic but explicit (as opposed to pragmatic but veiled or partially hidden) course which legally entrenches bioscience innovation facilitation seems remote.[31]

Argentina might do well to look at what other jurisdictions have done when confronted with new technologies and social uncertainty. Some 30 years ago, the UK formed the Committee of Inquiry into Human Fertilisation and Embryology, which reflected upon and undertook extensive public consultation about reproductive clinical medicine and related research, knowing full well that a central question was the value to be given to human life and how the law should respond.[32] On the issue of plurality, (then) Dame Mary Warnock reported that the Committee encountered very diverse and strongly held opinions and understood that it would be impossible to satisfy all interested parties.[33] As such, a majority of the Committee settled on a compromise between sacralisation and instrumentalisation of the embryo, concluding that the human embryo had a "special status" entitling it to "some protection in law", and it advanced the view that, while the law must not outrage the feelings of too many people, it could not possibly reflect the feelings of them all.[34]

Of course, while it can be useful to explore successful policy practices, transplanting them from one jurisdiction to another is not necessarily the answer, especially where the cultural affinity of the receiving jurisdiction for the practice might be assumed be weak. Even if the Argentine appetite is weak for a lightning-rod body seeking public evidence and offering guidance, philosophical and legal, one gets the sense that Argentina's new MOST *is* open to ideas for improving both the actor space within the policy/regulation artefact as well as the general environment. Having said that, it seems unlikely that Argentine policymakers will, at this stage, take such a bold step as to, on the one hand, publicly acknowledge the (presumed) plurality of opinion on stem cell and regenerative science and the multiple courses open to it from a governance point of view (ie: the plurality of pluralities), and, on the other hand, explicitly define a course for acceptable uses of human tissue (including embryos) in stem cell and regenerative science. The existing social/science

[31] A key assumption being made here – and in developed country legal circles more generally – is that the policy/regulatory artefact should encourage and facilitate science innovation: see R. Brownsword and H. Somsen, supra, note 27, and S. Harmon, "Ambition and Ambivalence: Encouraging a 'Techno-Science Culture' in Argentina Through Engagement and Regulatory Reform" submitted.

[32] Established in July 1982, the Warnock Committee had the remit of: considering recent and potential developments in medicine and science related to human fertilisation and embryology; considering what policies and safeguards should be applied, including considering the social, ethical and legal implications of these developments; and making recommendations with a view toward legislation. The Committee contained seven doctors/researchers, three lawyers, two social workers, a theologian, a health administrator and an entrepreneur. It heard some 21 oral representations, considered evidence from hundreds of interested individuals and organisations, and received 695 letters and submissions from the public.

[33] M Warnock, *A Question of Life: The Warnock Report on Human Fertilisation and Embryology* (Oxford: Basil Blackwell, 1985) at 1.

[34] Ibid, at xvi and 63.

environment, which is heavily influenced by the dominant features of the broader socio-cultural-political environment, makes this a politically costly undertaking, and one potentially damaging to the interests of science protagonists.

That being said, there are recent Latin American examples of such bold moves being taken. Here the experience of Brazil, a similarly Catholic country, might be instructive. In March 2005, after years of campaigning by researchers and patient groups, the Brazilian Congress passed (by a vote of 352-60) the *Biosafety Law*.[35] Article 5 of that law allows the use of human embryos produced by IVF, if:

1. the embryos have been frozen for more than three years;
2. the embryos would be unlikely to survive if transferred to a woman;[36]
3. the progenitors give consent; and
4. they will not be used for therapeutic cloning.

In May 2005, the then Attorney General filed a Direct Unconstitutionality Claim,[37] alleging that the constitution stipulates that life occurs at the moment of conception and Article 5 therefore contradicts the constitutional principle of the inviolability of life. In April 2007, after some delay, the Brazilian Supreme Court held public hearings (for the first time in its history) during which it heard testimony from a range of experts. On 29 May 2008, the 11-member Court ruled, by a vote of 6-5, that Article 5 was constitutional. Throughout this period (pre-2005 to 2008), stem cell research suffered some uncertainty in Brazil (and stem cell projects had great difficulty finding funding),[38] but by October 2008 the first Brazilian stem cell line had been announced.[39] Also during this period, as a direct result of the legislative action, Brazil experienced intense information exchange and debate:

> The hearings at the Supreme Court demonstrated a democratic aspect of Brazilian society. Rarely has Brazilian society discussed any aspect of science or public health with such an intensity. Rarely have so many well-informed people expressed an opinion about a subject with legal, religious and scientific implications. Never before have Brazilian media realised such a wide coverage of science communication in a short period of time.[40]

Confirming scholarship in this arena,[41] this Brazilian adventure demonstrates the central role of the mass media in the policymaking arena – as attention-influencer, issue-definer, symbol-creator, and opinion-shaper. Indeed, it has been reported that the media's explanations were essential to the approval of the law.[42] Moreover, and

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35 Law No. 11,105, 24 March 2005.

36 This non-viability condition was defined in Decree No. 5,591, 22 November 2005, as those embryos with proven genetic alterations that prevent development due to lack of cleavage.

37 Ação Directa de Inconstitucionalidade 3,510. The subsequent Attorney General filed a supporting brief with the Supreme Court.

38 M. Leite, "Stem Cell Research in Brazil: A Difficult Launch" (2006) 124 Cell 1107-1109.

39 D. Diniz & D. Avelino, "International Perspective on Embryonic Stem Cell Research" (2009) 43 Rev Saúde Pública 541-547.

40 C. Jurberg et al., "Embryonic Stem Cell: A Climax in the Reign of the Brazilian Media" (2009) 18 Public Understanding of Science 719-729, at 727.

41 See M. Nesbit & B. Lewenstein, "Biotechnology and the American Media: The Policy Process and the Elite Press, 1970-1999" (2002) 23 Science Communication 359-391.

42 C. Jurberg et al., supra, note 40.

very importantly, while it presented evidence on both sides of the debates, it did not bow to religious pressures but rather, at least in its selection of letters to be published and settings from which to broadcast, it evinced a bias reflective of public opinion as polled shortly before the Supreme Court's decision.[43]

The Brazilian experience demonstrates that, even in Latin American jurisdictions where the conservative Catholic Church has significance political and social influence, there is scope to fundamentally alter a key artefact (the policy/regulation artefact and its outputs) and thereby reform the whole social/science environment, and to do so by making morally-pregnant bioscience debates public and taking proactive steps to facilitate biosciences through law. It also suggests that doing so will inevitably be difficult and socially disruptive, but not necessarily damaging to science institutions and pursuits. Of course, much will undoubtedly depend on (1) the relative strengths of leading protagonists (eg: political and policy leaders) and resisting institutions (eg: the Church), (2) the willingness of supporting institutions (eg: eminent science bodies and academic institutions) to strongly engage, and (3) the responsibility and fairness of the media, which is generally recognised as a critical actor (ie: it must be prepared to reflect widely held social values for which there is some empirical base). One of the benefits of country-based studies like the GET: Social Values Project is to begin to provide that evidence base.[44]

In the absence of systemic or overt reform in Argentina, at least in the short term, one wonders whether the regulation of stem cell and regenerative science might best be achieved 'through the back door', as outlined by R21 in Camp 1 above. The approach suggested is not exactly 'status quo' because it envisions the formation of a specialised committee that advises scientists and reviews protocols put to it; it would be more proscriptive than the existing Advisory Commission on Regenerative Medicine and Cellular Therapies, which advises primarily upward, not outward. Such a body would probably be welcomed by the science community and pro-science publics insofar as it is flexible and helps to gradually develop regulatory capacity while building science momentum.

On the negative side, such an approach would inevitably be characterised by a distinct lack of clarity around boundaries and limits on acceptable behaviour, and by weak oversight and enforcement (ie: it would permit malfeasance and leave both it and misfeasance largely unpunished). Additionally, scientists who feel more secure undertaking their work quietly and anonymously would not be encouraged to open themselves and their work to public scrutiny any more than at present. Finally, it

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[43] A January 2008 survey of Public Opinion Research Institute of Brazil (IBOPE) demonstrated that 75% of a 1,863 person sample (all between the ages of 16 and 70, and 1,230 of whom claimed Catholic membership) were in favour of embryonic stem cell research. A television poll reported that 66.7% of respondents were in favour of the use of embryonic stem cells, and letters to *O Globo*, a widely circulated newspaper, indicated a 64.7% favourable rate for stem cell research: C. Jurberg et al., ibid.

[44] The value of country-based studies has been noted by such luminaries as Sheila Jasanoff: see S. Jasanoff, "Controlling Biotechnology: Science, Democracy and 'Civic Epistemology' – Review Symposium" (2008) 17 Metascience 177-198. While acknowledging the importance of international institutions and "global socio-technical imaginaries spawned around biotechnology", she rightly asserts that politics, including science and technology politics, are local. If one wishes to influence sci-tech trajectories or boundaries, one engages national institutions. Thus, while international values and principles and international discourses are critical, possibilities for action are often (sometimes exclusively) national. This makes country studies (and comparative country studies) valuable, often beyond the subject country, and this is certainly the case for Latin American countries. While they are by no means homogenous, they share a lot of socio-economic and cultural features, making one relevant to another.

would fail to address the hypocrisy lamented so strongly:

> R13 (Translator): He is saying that we of course have the capacity [to have a debate on stem cell research]. We are sincere but there is hypocrisy. We have a tremendous struggle to manage every day … so starting to make the circle of information increase [is important].

Similarly, R15 expressed a need for more honesty in science settings; currently people say one thing but do another, or do something and say nothing at all, a hypocrisy which is perpetrated within the legislative, the scientific, and the public settings.[45]

The bottom line remains that most respondents are desirous of, and prepared for, something to happen in the Argentine policy/regulation artefact, and they generally hope that it is rational and sensitive to social and science needs, even if they diverge somewhat on what they feel is the best way forward from a policy or legislative point of view.

CONCLUSION

I have argued that the best science is developed at the nexus of three interacting and co-producing artefacts within a more diffuse but positive social/science environment which includes publicly acknowledged science/knowledge needs and desires. Where these artefacts are open, dynamic and relatively harmonious, the best science is most likely produced. Drawing on a variety of sources, including empirical evidence, I have also argued that the Argentine model is not at all optimal: its actors are too unevenly empowered; its artefacts are either underdeveloped (the policy/regulatory artefact), or veiled (existing technologies), or fragmented (the innovation systems artefact); and its nodes are ad hoc and weakly action-guiding. Finally, focussing on the science policy/regulation artefact and the actor space in relation thereto, I have argued that there is a plurality of opinions amongst elite stakeholders with respect to how best to proceed in relation to stem cell and regenerative science.

Through this undertaking, the reader will have (hopefully) gained a better understanding of the complexities of the social/science environment and of the encouragement of innovation therein, and, more centrally, of Argentina's position in comparison to the model environment, as well as of some of the key issues facing Argentina, one of the most important of which is plurality. Of course, exposing this plurality is important but insufficient. given the incapacity of the Argentine social/science environment and bioscience policy/legislation artefact to measure this plurality or to cope with it in a constructive manner, in part because of an absence of actor space therein.[46]

Having been put on notice that plurality (or a particular plurality) exists, it behooves actors (including Argentine policymakers and researchers interested in Argentina) to expand the evidence base, measure plurality more accurately, and respond to it practically and rationally. A next important step may be to solicit thoughtful value evidence from other important stakeholders such as Church and media representatives and publics, and then to ease cautiously into a more active public engagement programme sponsored by the MOST, the Ministry of Health, and

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[45] See also the discussion in F. Luna & A. Salles, supra, note 14.

[46] Related to this, neither the credibility of science nor the aspirations of publics for science can be accurately gauged in Argentina

interested academic institutions.[47] The bottom line is that Argentina would do well to fashion a bioscience regulatory framework worthy of the scientists currently plying their trade in Argentina – they and the legacy they are fulfilling deserve no less.

It has been argued that political cultures (and we might say social/science environments) manifest in the routinized ways that knowledge is produced, disseminated, evaluated and deployed in society.[48] By creating the MOST, Argentina has begun to shift the boundaries of science and politics and thereby alter its political culture (and social/science environment). However, a positive and enduring reshaping, as demonstrated by Brazil (which is still consolidating after a major shift), requires courage and the participation of publics, particularly in a democracy where science is part of a nation-building project or national re-imagining.[49] As hinted at by recent evidence,[50] one *might* discover greater consensus than formal dialogues to date have suggested, and therefore greater scope to facilitate the scientific and regulatory work being pursued in Argentina.

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47 The ultimate goal being to reform the science policy/legislation artefact and/or its primary relevant instruments, or both, thereby improving the relevant institutions, the broader artefact and, ultimately, scientific outputs and uptake.

48 S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (NJ: Princeton U Press, 2005).

49 This is certainly the case in Argentina, as it was in the UK and the US: see S. Jasanoff, ibid.

50 See L. Vaccarezza, C. Polino and M. Fazio, "Measuring Public Perception of Science in Ibero-America: The RICYT/OEI's Study and Argentina's National Survey" in B. Bonnmatí (ed.), *Scientific Knowledge and Cultural Diversity: PCST-8 Proceedings*, (Barcelona: Rubes Editorial, 2004) 436-443, and G. Stekolschik et al., "Does the Public Communication of Science Influence Scientific Vocation? Results of a National Survey", Public Understanding of Science, published online 13 July 2009 and available at http://pus.sagepub.com/cgi/rapidpdf/0963662509335458v1 [accessed 15 February 2010].

AMBITION AND AMBIVALENCE: ENCOURAGING A 'SCI-TECH CULTURE' IN ARGENTINA THROUGH ENGAGEMENT AND REGULATORY REFORM

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Abstract: Science matters. Science matters to the development of knowledge, to the sustainability of development, and to the shaping of social mores. Countries transitioning from developing to developed must be prepared to make science work for them, and to forge a vision to become competitors in some aspects of science innovation. Drawing on data generated by the 'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina' Project (ESRC Award No. RES-000-22-2678), this paper (1) outlines the empirical project and methodology on which the analysis and conclusions rely, (2) places the current Argentine bioscience setting in context by briefly reviewing the development of bioscience in Argentina, (3) explores understandings of the social dimensions of bioscience innovation in Argentina, and the possibilities of enhancing public support for stem cell and regenerative medicine research in Argentina, and (4) offers some preliminary thoughts on a model of socio-legal activity directed at encouraging social engagement with, and uptake of, high technologies such as these in Argentina, noting the particular hurdles that must be faced. It concludes by emphasising that stakeholder desires (as evidenced by respondent statements) must be wedded to positive stakeholder action despite the multiple challenges (and pitfalls) identified.

Keywords: innovation and development – developing countries – science and technology – participation and engagement – social values – regulation – Latin America – Argentina

INTRODUCTION

It is a fact of the modern, global, information/knowledge-based socio-economic milieu that 'science and innovation matter'. Capacity, activity and innovation in high technologies are widely seen to be (and therefore are) important elements of sustainable development, critical to social and economic life in the new world order, which is characterised by unstable global economics, collaborative international science, near instant communication, and, arguably, socio-cultural convergence.

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Indeed, both governments and non-governmental organisations are seeking to use the sci-tech field as an engine for growth and competitiveness. The biosciences sector more specifically, together with nanotechnology, has proven very appealing to industry, academia, policy-makers, and segments of the polity, who see them as important vehicles for the delivery and advancement of modern healthcare (Scientific American). Within the biosciences, regenerative medicine and its related biotechnologies have emerged as particularly powerful mobilisers. They are noteworthy because their significance goes well beyond the economic; from a social perspective they are 'change-instigators'. For example, they:

- redefine how we characterise health and ill-health, normalcy and abnormality;
- influence how we investigate health and disease;
- transform our ideas of what might be possible from a health perspective; and
- shape how we structure healthcare delivery.

However, becoming a leader (or even a competitor) in the emerging (bio)techno-based era places a variety of demands on policymakers. They must:

- commit significant financial and human resources to a variety of (bio)technologies;

- target specific (bio)technologies in which to build national strengths;

- understand how knowledge is generated and facilitate its creation/dissemination; and

- encourage the (relatively) rapid uptake and (relatively) smooth integration of technologies into society.

Each of these demands are challenging, especially for countries transitioning from economic and/or social instability to some more robust and resilient level of development. Nonetheless, as experience from China and the UK attest, each must be positively and actively engaged with if capacities are to be strengthened and competitiveness encouraged.

It is towards the last of these demands – facilitating the social uptake and integration of technologies – that this paper is directed. While this demand has many facets, this paper will focus only on the social dimension, addressing the interaction of science and scientists with the community and the role of science communication. In considering this broad issue, it will draw on evidence obtained from Argentina on a narrower issue – stem cell and reproductive medicine research and its governance. First, it briefly outlines the empirical project and methodology on which the analysis and conclusions rely. Second, it places the current Argentine bioscience setting in context by briefly reviewing the development of bioscience in Argentina. Third, drawing on the project data, it explores understandings of the social dimensions of bioscience innovation in Argentina, and the possibilities of enhancing public support for stem cell and regenerative medicine research in Argentina. Fourth, it offers some preliminary thoughts on a model of socio-legal activity directed at encouraging social engagement with, and uptake of, high technologies such as these, noting the particular hurdles that must be faced in Argentina. The paper concludes by emphasising that stakeholder desires (as evidenced by respondent statements) must be wedded to

positive stakeholder action despite the multiple challenges (and pitfalls) identified.

THE 'GET: SOCIAL VALUES' PROJECT: A METHOD OF EVIDENCE-GATHERING IN THE ARGENTINE BIOSCIENCE CONTEXT

The data which forms the basis of the following analysis was generated by a project entitled 'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina' (ESRC Responsive Grant Award No. RES-000-22-2678).[1] Following participation in two preliminary policy conferences, we conducted 22 semi-structured interviews with diverse stakeholders in the Argentine stem cell field, and co-hosted an interactive workshop together with the Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies, which workshop was attended by some 40 invited participants.[2]

Given the relative dearth of work on the interaction of social values and law in the stem cell research context – with its tensions between promoting science, managing stakeholders, and limiting risks – and of its pursuit in developing countries, the GET: Social Values Project was designed and funded with the intention of gathering qualitative data around key issues of bioscience and in particular stem cell research governance in Argentina. While the data generated cannot be said to represent the Argentine view – the subject sample was too narrow and too small for such claims – it represents important qualitative evidence of the opinions and views of key stakeholders in the field. Moreover, it has been welcomed by relevant stakeholders as an early and important, if small, project examining the social context of bioscience (and stem cell) innovation in Argentina, and it has enjoyed the support of the Argentine policymaking community, which has facilitated access to some of those most interested in, and relevant to, stem cell research governance.

Prior to commencement, the GET: Social Values Project was subject to initial institutional ethics review and then funding body ethics evaluation. Research participants were chosen from the medical and scientific, academic and policy, and

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[1] For more on the GET: Social Values Project, see http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/, or go to ESRC Society Today at http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/ViewAwardPage.aspx?data=%2fFrXHTl993o2s3j2qzndQ%2btMvLMb0c%2ba0yxfTTX2AHVlOW%2bL7eMI%2f6qVw9YoT8G3jr7S83IFcVwVQf7LeaV9OUrixXUodr65P0aHNkG8IOUtyKQw%2f33F7mTLpnKmhpUrwJMULgcuCcAEYBqEOe5Ee7oV%2fluZamljCzOhpptxWZGaWc5VwiKA1Tnox0xhzAl0hIB4X%2fcoTpHqbTmfGH7%2fp4%2f%2fyqUPSi96jyp%2bSGYDGLgb7R26FoE9r0YlHAVoUmQx&xu=0&isAwardHolder=&isProfiled=&AwardHolderID=&Sector=.

[2] The two policy conferences were the "Regulation of Clinical Research Involving Stem Cells", hosted by the (then) Argentine Science and Technology Agency in Buenos Aires on 29-30 November 2007, and the "Second International Conference on the Regulation of Stem Cells and Human Tissue", hosted by the Advisory Commission on Regenerative Medicine and Cellular Therapies in Buenos Aires on 14 October 2008. For a report on the former, see S. Harmon, G. Laurie and F. Arzuaga, "Report: Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina Learning from the Experiences of the United Kingdom" (2007), available at http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/Report%20Nov%2007%20Stem%20Cell%20Workshop.pdf. The workshop, "The Regenerative and Cellular Sciences: Values, Objectives and Issues for Implementation – An Interactive Workshop", was co-hosted by the GET: Social Values Project and the Advisory Commission on Regenerative Medicine and Cellular Therapies in Buenos Aires on 18 August 2009. For a report on this workshop, see S. Harmon, "Regenerative Medicine Governance: Report of the Workshop on Governance of Research Using Human Embryonic Tissue" (2009) 6:3 SCRIPTed 729-740.

legislative and regulatory communities.[3] As the project was never intended to be a public engagement mechanism, the opinions of the broader general public were not solicited. Rather, those originally viewed as most likely to influence the nature and content of bioscience and stem cell regulation in Argentina were targeted (ie: Argentine science policy elites), for, it was felt, only by targeting those most engaged in the pre-legislative process might we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they emerge), on the other.

Following preliminary desktop research, semi-structured interviews lasting 50 to 90 minutes were conducted. Each interview was, with permission, recorded. Open-ended questions and an informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. In some cases, more structured information was obtained through questionnaires. Transcription of the interviews was performed within Innogen (one the Principal Investigator's host institutes) and that work was subject to a signed Confidentiality Agreement. Anonymised transcripts were shared between the Principal Investigator and the Collaborating Investigator and have been retained for archiving. Every line of transcript and interviewer notes was coded and analysed for emergent themes, and sections relating to those themes were grouped together, and the whole assessment refined through an iterative process, thus enabling different perspectives and interpretations to be incorporated.

The quotes utilised in the present paper were chosen as representative of widely canvassed themes, and are deployed to make particular points or support particular claims or recommendations.

BIOSCIENCE DEVELOPMENT IN ARGENTINA: FROM 'SCIENCE PERIPHERY' TO 'HIGH-SCIENCE HUB'?

Despite being a developing or transitioning country, Argentina has a long history of scientific competence and success, right up to the present.[4] In the late 19th century, Domingo Sarmiento, President of Argentina, and Juan María Gutiérrez, Rector of the University of Buenos Aires (UBA), adopted a policy of drawing immigrant scientists to Argentina. By the early-mid 20th century, native researchers such as Bernardo Houssay, who won a Nobel Prize in 1947 for his work on the function of the hypophysis, and Luis Leloir, who won a Nobel Prize in 1970 for his work on metabolic pathways, were conducting early biomedical science (eg: molecular biology and chemistry) and collaborating with the international scientific community; they were forging an Argentine context that has been described as "scientific excellence in the periphery".[5] Since those halcyon days (for Argentine science and Argentina

[3] The investigators interviewed at least one respondent, but often multiple respondents, from each of the following categories: cabinet level politician; national congressional member; national regulatory agency member; national advisory committee member; medical clinician, medical researcher, basic scientist, ethicist, academic lawyer.

[4] See S. Maheshwari, "Cloned Cows Can Produce Insulin in Their Milk, Claim Their Creators" (2007) *Free Press Release*, available at http://www.free-press-release.com/news/200705/1178276885.html [accessed 4 August 2009], and M. Triunfol, "Latin American Science Moves into the Spotlight" (2007) 131 *Cell* 1213-1216.

[5] See P. Kreimer, "Migration of Scientists and the Building of a Laboratory in Argentina" (1997) 2 *Science, Technology & Society* 229-259. See also H. Vessuri, "Bitter Harvest: The Growth of a Scientific Community in Argentina" in J. Gaillard, V. Krishna and R. Waast, eds., *Scientific Communities in the Developing World* (London: Sage 1997) 307-335.

generally), a number of distinct scientific periods and characterisations are discernable (though not uncontroversial or uncontested):[6]

- 1945-55 – Peronist-Prompted Exodus: Under the centralist Peronist regime, science was perceived as elitist, and many scientists, who were primarily employed in public universities such as UBA, were dismissed, with many choosing exile, some in independent domestic institutes, most in foreign labs. Between 1950 and 1956, hundreds of scientists and professionals left Argentina.

- 1956-66 – Houssay-Led Golden Decade: Following the fall of Perón, science was restored as a respected and publicly supported endeavour. The National Council for Scientific and Technological Development (CONICET) was formed in 1958 under Houssay and instituted a degree programme for research, a grant scheme for young researchers, and subsidies for investigators. Ongoing international collaborations were encouraged and the research sector positively bloomed as space was created for the generation of new knowledge. Scientists returned to Argentina in numbers, including César Milstein, who subsequently won a Nobel Prize in 1983 for his work on monoclonal antibodies. Importantly, this was a period of scientific independence from political power and social oversight, though a schism developed between those scientists who advocated pure science and those who advocated science for social needs (or local usefulness).

- 1966-83 – Dictatorial Persecution and Exodus: While the dictatorship viewed certain sciences as essential to its cause (including physics and nuclear and aerospace sciences and related technologies), the previously rapid growth of Argentine science was halted by the military's seizure of power in 1966, which resulted in the dissolution of much academic science. Following the '*noche de los bastones largos*' (night of the long canes) there were mass resignations from science faculties (including some 8,600 from UBA), and a progressive exodus of scientists and professionals from Argentina to whatever jurisdictions offered professional opportunities. After a very brief democratic reprieve in the early 1970s, the resumption of military rule was accompanied by persecution, assassination and torture. A further exodus followed, this time to preserve life rather than professional opportunities, and a near complete disintegration of the technology policy framework was experienced.

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[6] See P. Kreimer, *ibid*, P. Kreimer, "Science and Politics in Latin America: The Old and the New Context in Argentina" (1996) 1 *Science, Technology & Society* 267-289, A. Paladini and A. Barrios Medina, *Escritos y discursos del Dr. Bernardo Houssay* (Buenos Aires: EUDEBA, 1990), M. Bastos, "What Hope can Democracy Bring to S&T Policy Making in Latin America? INTECH Discussion Paper" (1995), available at http://www.intech.unu.edu/publications/discussion-papers/9505.pdf [accessed 1 December 2009], P. Kreimer and M. Lugones, "Rowing Against the Tide: Emergence and Consolidation of Molecular Biology in Argentina, 1960-90" (2002) 7 *Science, Technology & Society* 285-311, P. Kreimer and M. Lugones, "Pioneers and Victims: The Birth and Death of Argentina's First Molecular Biology Laboratory" (2003) 41 *Minerva* 47-69, A. Feld and P. Kreimer, "Internationalism and Cooperation in Science and Technology Policies in Argentina: Origins and Current Challenges", presented at PRIME-Latin America Conference, Mexico City, 24-26 September 2008, A. Parson, "PABSELA: A Research Highway Between Two Hemispheres" (2008) 2 *Cell: Stem Cell* 414-415, and others.

- 1983-2000s – Restoration and Crisis: When democracy was restored, the new government promoted science as a valued undertaking, and many scientists returned to Argentina, but resources were woefully inadequate, and the scientific community became more competitive and less collegial. By the mid-1990s, the number of Argentine researchers working abroad exceeded the number of career CONICET researchers, and the international character of science left little room for Argentina, whose scientific community was often oriented toward topics of a non-essential and non-urgent nature. It was perhaps a perception of irrelevance that contributed to the opinion, expressed in 1994 by the then Minister of the Economy, that Argentina's scientists should devote their time to washing dishes. The financial crisis in the early years of the new millennia caused further disruption to Argentine science and innovation, both of which suffered through a period of depressed funding. Indeed, funding was only raised to (the still low amount of) 0.65% GDP in 2003. Even leading institutions such as the Leloir Institute often relied on outdated equipment.

Though the cumulative effect of this history was the attenuation of Argentine sci-tech capacity, there nonetheless endured a rich vein of biomedical research interest and excellence in Argentina, and the field was facilitated by the creation in 1982 of the National Programme for Biotechnology and Genetic Engineering (which became the National Prioritised Programme for Biotechnology in 1991), and by the formation of a number of centres, fora and commissions between 1985 and 1999.[7] In short, in keeping with the widely held view that technological innovation is an integral part of human existence (even survival), it again become the policy of Argentina to build competitiveness in high sciences, particularly the biosciences where Argentina has enjoyed success. In furtherance of that policy, Argentina has:

- promoted international networks and made public funds available so that it might better compete;[8]

- formed the first Ministry of Science, Technology and Productive Innovation (in 2007), which has undertaken a variety of initiatives to stimulate science and research excellence, including the formation of the Advisory Commission on Regenerative Medicine and Cellular Therapies;

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[7] For example, note the formation of the Argentine-Brazilian Centre for Biotechnology (1985), the Argentine Forum for Biotechnology (1986), the National Commission for Agricultural Biotechnology (1990), the National Commission for Biotechnology and Health (1993), and the Commission for Bioethics and Biotechnology in the Chamber of Deputies (1999).

[8] See E. Trigo and E. Cap, "Ten Years of Genetically Modified Crops in Argentine Agriculture" (2006), available at http://www.inta.gov.ar/ies/docs/otrosdoc/resyabst/ten_years.htm [accessed 4 August 2009], W. Surman, "GM Crops in Argentina" (2007) *New Agriculturalist*, available at http://www.new-ag.info/07/02/develop/dev2.php [accessed 4 August 2009], and J. Niosi and S. Reid, "Biotechnology and Nanotechnology: Science-Based Enabling Technologies as Windows of Opportunity for LCDs" (2007) 35 *World Development* 426-438. It should be noted that, in Argentina, the government remains the primary funding source for science, with the majority of research being performed in governmental institutions and universities: Ministerio de Ciencia y Tecnología de la República Argentina, *Indicadores Ciencia Y Tecnologia: Argentina 2006*, available at http://www.mincyt.gov.ar/indicadores_2006/publicacion/indicadores_2006.pdf [accessed 13 January 2010].

- issued governmental press releases calling attention to the benefits of biosciences like stem cell research;[9] and

- signed international agreements with specified groups to promote scientific innovation and international cooperation.[10]

While Argentina's efforts to build high technology strength as a means of development has been noted,[11] and while some elements of Argentine research have been described as "close to the 'frontier' of international knowledge",[12] Argentina remains some (substantial) distance from being a "high-science hub",[13] a fact which was well recognised by all respondents in the GET: Social Values Project. Nonetheless, and despite a general pessimism toward the government's capacity or will to realise Argentina's science potential through sufficient funding or rational policy,[14] there was expressed a cautious optimism about bioscience research in Argentina, with respondents claiming that it is expanding, and that, aside from some presumed and some specifically known exceptions, the quality of existing research is very good. Respondent 5 (R5) stated:

> … As a consequence of the interest of the Minister of Science, I think this [stem cell research] is one of the things that is growing fast in the country. … But now we have, besides these ten [stem cell] projects, this cluster for stem cell research that involves nine different institutions in the country with fourteen different projects.

R7 concurred that stem cell science is becoming important, saying, "It's a very interesting line of research, quickly growing here, quickly growing." R17 stated:

> We are behind the development in the rest of the world. And I want to see a change about this because I think we can work in both … the basic way and in the clinical trials.

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[9] See Argentine Science and Technology Commission, National Congress, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009], and Argentine Regenerative Medicine and Cellular Therapies Commission, Ministry of Science, Technology and Productive Innovation, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009].

[10] N. Bar, "El Rating de la Ciencia. *La Nación*", 13 May 2009, available at http://rcdtx.lanacion.com.ar/nota.asp?nota_id=1127536 [accessed 3 August 2009].

[11] See K. Thorn, "World Bank Working Paper: Science, Technology and Innovation in Argentina: A Profile of Issues and Practices" (2005), available at http://siteresources.worldbank.org/intargentina/resources/sciencetechnologyandinnovationinargentina.pdf [Accessed 3 Oct 2006], H. Greenwood et al., "Regenerative Medicine: New Opportunities for Developing Countries" (2006) 8 *International J Biotechnology* 60-77, and S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8 *Developing World Bioethics* 138-150.

[12] See P. Kreimer and M. Lugones, *supra*, note 6, at 306.

[13] See A. Parson, *supra*, note 6.

[14] In this regard, note that a tension continues to exist between policies and funding for knowledge production and knowledge application. Chagas disease is an example of an Argentine (and Latin American) problem that has garnered both social and scientific attention but not funding sufficient to see the development of useful products to market: see A. Feld and P. Kreimer, *supra*, note 6.

Similarly, R18 thought that science funds should be used to gain experience so that Argentine research could be done "expertly". R21 was hopeful that concrete developments could be made in Argentina in the upcoming years such that new models and new techniques for applying stem cells could be achieved which might facilitate clinical practice.

Ultimately, then, while Argentina may fall short of 'high-science hub' status, there is ambition and an increasing mobilisation of science resources, particularly since the appointment of Lino Barañao as Minister of Science, who respondents acknowledged as a rare breed in the upper echelons of government insofar as he has scientific knowledge, realistic objectives, and widespread respect. However, the cautious optimism (and hopefulness) that was generally shared by all respondents was almost always tied to a perceived need to do a number of things better. One such thing is to understand the association between science promotion and scientific robustness on the one hand and scientific democracy on the other, and to integrate that democratic dimension into science endeavours and policies.

THE DEMOCRATIC DIMENSION OF BIOSCIENCE INNOVATION: DESIRES AND HUDLES IN THE ARGENTINE SETTING

Public engagement with respect to science and emerging technologies has become a hallmark of many modern knowledge-based political economies, particularly those in Europe and North America. It is likely that this is so because of the many benefits that are claimed to derive from appropriate public communication of science and technology. For example, studies show that it:

- promotes curiosity and inspires imagination;[15]
- arms people with the knowledge to develop within, and face challenges posed by, modern society;[16]
- places science in its proper socio-political context;[17]
- promotes science as an activity;[18] and
- encourages the vocational uptake of science,[19] including in Argentina.[20]

However, if communication or engagement is to be effective, it must be something more than piece-meal responses or reactions to assaults against science; it must be ongoing and creative, and it must become embedded. Indeed, one might argue that any attempt to develop through science and/or technology, or, more ambitiously, to

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15 M. Alcíbar, "Discursive Re-Contextualisation of the Media Popularisation of Science and Technology" (2004) 31 *Anàlisi* 43-70.

16 M. Calvo Hernando, *Periodismo Cientifico* (Madrid: Paraninfo, 1992).

17 Y. Jeanneret, *Writing Science* (Paris: Presses Universitaires de France, 1994).

18 P. Fayard, *La Communication Scientifique Publique* (Lyon: Chronique Sociale, 1988).

19 D. Nelkin, *Selling Science: How the Press Covers Science and Technology* (New York: W.H. Freeman, 1987).

20 G. Stekolschik et al., "Does the Public Communication of Science Influence Scientific Vocation? Results of a National Survey" (2009) *Public Understanding of Science*, available at http://pus.sagepub.com/cgi/rapidpdf/0963662509335458v1 [accessed 5 January 2010].

build advantages (regional if not international) in targeted high-technologies such as biomedicine, must be accompanied by efforts to develop a 'sci-tech culture',[21] if not broadly, then at least sectorally.

A 'sci-tech culture' is a socio-scientific-political condition of familiarity and comfort with science. It is an environment wherein stakeholders recognise that the development of science and technology is (1) uncertain and risk-bound (requiring boundaries to be tested and pushed, sometimes with unknown consequences), and (2) controversial and value-laden (not neutral, but grounded in the protagonists' values and desires), and that, despite these characteristics, technological innovation is still facilitated and is the accepted norm. This culture fosters a reasonable tolerance for envelope-pushing and risk-taking by encouraging rational and interactive social consideration of science. It does not demand a blind acceptance of all science and its outputs, but rather a mature understanding of science, its potentialities, and its social impacts, with a recognition that *good* science and socially *useful* technologies flourish when they are encouraged and celebrated rather than endangered or embattled; it requires recognition by people that one need not choose between science and other closely held or traditional values; they are not mutually exclusive but can be used in cooperation to achieve valued ends.

Of course, one cannot expect the adoption of a sci-tech culture to be monolithic – not all people will embrace technology, and, of those who do, reasonable disagreement over all manner of issues might be expected. In short, plurality can be anticipated. Some disagreement might be forestalled by ensuring that research (and certainly research supported by public funds) is clearly directed toward addressing pressing public issues. But reducing *hostility* towards technology, and narrowing disagreement over its pursuit and deployment is, in many respects, a matter of debate and engagement which must be facilitated by public institutions and mediated through publicly accepted mechanisms. As should be obvious, it is the responsibility of democratic governments and invested stakeholders to co-opt and mobilise interested segments of the polity and to work cooperatively to forge this culture and to build support by *empowering* the public to express their *true* desires and values.

It may come as little surprise that a sci-tech culture does not exist in Argentina.[22] Dating as far back as Argentina's Golden Decade, science communication has not been something that has been vigorously promoted. Indeed, many of the formal or institutional voices in Argentina, where they have addressed science at all, have been characterised as anti-science, and are at least very selective in the types and scope of science that they accept. For example, despite value heterogeneity across society, and despite a widespread break from church dogma in personal practices,[23] much of the public narrative on reproductive health, abortion and

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[21] A sci-tech culture can be differentiated from a technoscience culture in that the former is a socio-political culture facilitative of science and technology uptake while the latter, though perhaps incorporating some of the same, is characterised by technology convergence and is lamented as being characterised by the elevation of technology over pure science for its own sake: see P. Forman, "The Primacy and Science in Modernity, of Technology in Postmodernity, and of Ideology in the History of Technology" (2007) 23 *History and Technology* 1-152, B. Bensaude-Vincent, "Technoscience and Convergence: A Transmutation of Values?" (2008), available at http://hal.archives-ouvertes.fr/docs/00/35/08/04/PDF/06BBV.pdf [accessed 5 July 2010], and others.

[22] In fact, the existence anywhere of a true or fully realised sci-tech culture is in some doubt. South Korea, the USA, the UK, and latterly, China, probably represent the closest examples.

[23] M. Gogna et al., "Abortion in a Restrictive Legal Context: Obstetrician-Gynaecologists in Buenos Aires, Argentina" (2002) 10 *Reproductive Health Matters* 128-137, and F. Luna and A. Salles, "On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina" (2010) *Developing*

stem cell research has been driven by the conservative position of the Catholic Church,[24] and reiterated by a conservative press and judiciary.[25] Nonetheless, given the increasingly transformative nature of biosciences like stem cell research, and given the amount of public funds spent on regenerative medicine, even in Argentina, it is reasonable to expect that programmes/policies should be girded by public consideration (and support).[26]

With respect to the respondents in the GET: Social Values Project, while some reported being involved in closed-doors debates – usually with colleagues or within professional organisations, including ethics committees, and sometimes with individual government representatives – none had taken part in any broad social debates about stem cell research, nor were they aware of any such debates, although two noted that stem cell and reproductive research had, recently, been the subject of some popular magazine articles. Despite this relative silence, most recognised the value of engaging with the public over bioscience and other sci-tech issues. However, respondents felt that certain barriers made good science communication (and the concomitant development of a sci-tech culture) particularly challenging and potentially conflictual in Argentina, and they identified several key challenges:

1. the perceived anti-science position of the Catholic Church, which neither fosters nor embraces rational debate;

2. the largely conservative media, which is more interested in spectacular headlines and selling copy than in educating or expressing nuance;

3. the legislative branch of government, which is reliant on the former two institutions and which is highly scientifically illiterate; and

4. the social context of Argentina, which is not one of easy open debate and which is faced with a variety of social problems more pressing than bioscience development or social engagement around science.

Nonetheless, there was expressed hope that Argentina *could* develop a greater and

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World Bioethics, early online at http://www3.interscience.wiley.com/cgi-bin/fulltext/123243513/PDFSTART [accessed 11 June 2010].

[24] See Congregation for the Doctrine of the Faith, *Instruction Donum Vitae on Respect for Human Life in its origin and on the Dignity of Procreation* (1987), available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html [accessed 3 August 2009], Pontifical Academy for Life, *Declaration on the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells* (2000), available at http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html [accessed 21 April 2009], and Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Bioethical Questions* (2008), available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html [accessed 3 August 2009].

[25] See F. Luna and A. Salles, *supra*, note 23, and S. Chaher et al., "El Aborto en la Prensa Gráfica Argentina: Monitoreo de 10 Casos" (2008), available at http://www.artemisanoticias.com.ar/images/FotosNotas/informe%20monitoreo%20final6-08%5B1%5D.pdf [accessed 3 August 2009].

[26] P. Tigeras Sánchez and J. Pérez del Val, "Science and Society: A Dialogue for the Future", in B. Bonmatí, ed., *Scientific Knowledge and Cultural Diversity: PCST-8 Proceedings* (Barcelona: Rubes Editorial, 2004) 407-409.

broader sci-tech culture through enhanced science democracy. The gradual formation of channels of communication between state and society has been noted,[27] and the desire to interact with society amongst bioscience stakeholders is demonstrated by responses like the following:

> R11: I want social debate about stem cells, but I think this is not currently an agenda of the government to have this kind of debate. … We in society need to think and to express the opinion regarding stem cell therapies.

Similarly, both R4 and R20 were unequivocal that not enough is said about science, and in this case stem cell research, in Argentina.

Given the apparent openness to increased engagement, at least amongst project respondents, the question remains, what is to be done to encourage this engagement, or the formation of a sci-tech culture, in Argentina?

RE-IMAGINING ARGENTINA: A MODEL FOR FORGING A SCI-TECH CULTURE?

While one respondent lamented that there exists no mechanisms for beginning the necessary dialogue, and while few other respondents had concrete ideas about suitable mechanisms, the evidence generated in the GET: Social Values Project supports a number of courses of action. Taken as a whole, support for three courses can be gleaned – (1) increasing public education, (2) institutionalising public participation, and (3) adopting rational, joined-up regulation – each of which will be addressed briefly.[28]

Public Education

Certain orthodoxies have evolved in the science governance setting. One of the strongest is the idea that resistance to new or proposed scientific directions is merely a function of people's ignorance of science, and that support for, and trust in, science will grow if the public is informed about science processes and potentialities (ie: if they can be 'filled up' with neutral and accurate scientific information).[29] This orthodoxy, commonly called the 'deficit model', assumes that social resistance to sci-tech innovations might be alleviated by public education campaigns aimed at increasing science literacy (or, more accurately, at selling science as a good and worthy public undertaking).[30]

The validity of this assumption, and of the model itself, has been challenged on the basis that it fails to recognise that science itself is not neutral, but rather is influenced by values, agendas, and social forces, and that resistance to science can originate from factors other than ignorance (eg: adherence to cultural associations,

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27 M. Bastos, *supra*, note 6.

28 It should be reiterated that the evidence generated in the GET: Social Values Project related primarily to ambitions and objectives for stem cell and/or regenerative medicine research, although some respondents did express a broader view. Thus, while these courses are supported by the respondents with respect to strategies for encouraging social uptake of stem cell science, they are equally, I submit, strategies for generating a sci-tech culture more broadly, and the deployment of these ideas (and of this evidence) for same is therefore legitimate.

29 W. Bodmer, *The Public Understanding of Science* (London: The Royal Society, 1985).

30 C. Toumey, "Science and Democracy" (2006) 1 *Nature: Nanotechnology* 6-7.

reliance on norms contrary to scientific endeavours, extreme risk aversion, and social (mis)trust of potentially risky technologies and the institutional/governance framework which will deploy them).[31] Having said that, the deficit model is not without some foundation. Low levels of understanding do not stop people from forming risk perceptions,[32] and it is implausible that well-informed and poorly-informed people make their minds up in the same way.[33] In short, accurate information and understanding are valuable to better evaluation and decision-making.

The evidence obtained in the GET: Social Values Project supports the conclusion that Argentine stakeholders believe that a lack of good public understanding is currently a key barrier to efficiently advancing science in Argentina. For example, R4, R6 and R9 indicated that people, including politicians, cannot discuss emerging biosciences rationally because they do not have the appropriate knowledge-base. R19 pointed out that Argentina is like two countries: the "people in the margins" have no information whereas the "upper class" has information, but not good information because it comes from the media. R20, who stated that people "just do not know what is going on," suggested the following:

> Informing people [is important], but … I mean really informing people. I'm not talking about propaganda or … brainwashing, I'm talking about them saying – 'This is what [stem cell research] is, these are the costs and these are the costs, there are many things we don't know' – because I think that kind of view is good from the scientific community.

Most respondents opined that, where people have views at all, their views are often very simplistic and they expect breakthroughs sooner than realistically possible, which could hurt the pursuit of science in the long term.[34] For example, R1, a regulator, stated:

> [There is] much more fantasy about [stem cell science]. I think the media contributes a lot to this fantasy; that everything is going to be cured … .

R8 stated:

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[31] J. Ziman, "Public Understanding of Science" (1991) 16 *Science, Technology & Human Values* 91-99, B. Wynne, "Knowledges in Context" (1991) 16 *Science, Technology & Human Values* 111-121, B. Wynne, "Public Understanding of Science Research: New Horizons or Hall of Mirrors?" (1992) 1 *Public Understanding of Science* 37-43, A. Gross, "The Roles of Rhetoric in the Public Understanding of Science" (1994) 3 *Public Understanding of Science* 3-23, M. Siegrist et al., "Salient Value Similarity, Social Trust, and Risk/Benefit Perception" (2000) 20 *Risk Analysis* 353-362, and S. Priest, "Misplaced Faith: Communication Variables as Predictors of Encouragement for Biotechnology Development" (2001) 23 *Science Communication* 97-110.

[32] A. Hamstra, "Biotechnology in Foodstuffs: Towards a Model of Consumer Acceptance", in *SWOKA Research Report No. 7* (The Hague: Instituut voor Consumerntenorderzoek, 1991), L. Frewer, R. Shepherd and P. Sparks, "Biotechnology and Food Production-Knowledge and Perceived Risk" (1994) 96 *British Food Journal* 26-33, and A. Mucci and G. Hough, "Perceptions of Genetically Modified Foods by Consumers in Argentina" (2003) 15 *Food Quality & Preference* 43-51.

[33] P. Sturgis and N. Allum, "Science in Society: Re-Evaluating the Deficit Model of Public Attitudes" (2004) 13 *Public Understanding of Science* 55-74.

[34] One might note that, while these complaints have also been made in the UK, the social embedding of sci-tech innovation here means that such shortcomings are not *necessarily* a threat to scientific pursuit or uptake.

> [People] have this simple view of [stem cell research]. … They think we are very close. They think that this stem cell research will prevent future diseases [and] cure all the genetic diseases. I mean, there is a lot of bad information and fantasy. … And people get very disappointed when someone says, 'Look, we are far away from having this as a normal therapy.'

R11 indicated that the misunderstanding is not limited to the lay public:

> Oh, a lot of fantasies. Even talking with doctors, they have a lot of fantasies. … [They] think that there could be some kind of magic treatment in stem cells. I think we need a lot of … education … .

Moreover, the danger to the progress of science was recognised if people have an inadequate knowledge-base or false information. For example, R5 stated:

> I am totally convinced that … if the public is not ready ... fears will emerge … and [people] will confuse [processes] so people need to be informed first for any country to make a profitable debate.

It is essential, then, that a portion of society becomes reasonably conversant about the nature and potential (presumed) applications of science and emerging related technologies, as well as their broader implications. This can be achieved, in part, through public education campaigns about the international/broad state of knowledge, domestic strengths and activity, innovation trends, existing and anticipated (realistic) public benefits, and longer-term desires for technology. However, an important caution must be issued: increasing science literacy in Argentina (or anywhere) must not become merely an exercise in 'selling science'. If public education is to contribute to the formation of an enduring affinity for science and innovation, it must:

- relate the formal contents of scientific knowledge (ie: the state of the art, trends, and short, medium, and long-term objectives);
- explain the methods and processes of scientific inquiry (ie: its approaches to formulating and then answering questions, and its means of funding and reporting same); and
- expose the culture of science and its particular values (ie: its means of patronage and exclusion, organisation, and control, and how they are embedded in scientific pursuit).

It is unlikely that there will exist a unanimously agreed goal (or set of goals) for science, or an agreed conception or objective (or set of objectives) for participation in science governance. This is a natural tension associated with plural societies. Nonetheless, key policy actors must speak with as unified a voice and as focussed, cohesive and honest a message as possible. Though complete 'public understanding' is unachievable, it is also unnecessary; only a critical mass of the target society need comprehend the subject technologies for (quality) public debate to thrive.

This raises important questions about when education should begin and at

whom it should be directed. Building momentum for fundamental social change requires capturing imaginations at an early stage, and at least one respondent lamented the state of Argentinean middle and high school education with respect to science. A failure to inspire at this age can foreclose opportunities later in life, and will certainly put the longevity of any cultural shift in jeopardy. Obviously then, a multi-pronged approach is necessary, with some elements directed at school students, others at university students, others at adults, and yet others at specifically targeted groups.[35]

Public Participation

In response to the deficit model, scholars and stakeholders have argued for a more respectful, and potentially more successful, means of both generating support for scientific endeavours and involving publics in science policymaking. This 'contextual model' recognises that non-experts can acquire, comprehend, and deploy technical knowledge, and it involves individuals (specifically lay individuals) in a variety of upstream engagement activities, the objective being to better inform policy decisions and to promote policies that will enjoy greater and quicker uptake and thereby generate more immediate and durable social benefits.[36]

Respondents in the GET: Social Values Project identified a clear shortcoming in existing debates, noting that, when they exist at all, they are often limited to economic aspects of science and need to be expanded to include questions of research, planning and desired therapies. The value of real debate was noted by multiple respondents. R5 stated:

> [E]ach country should try to contribute to the debate … . I don't know the view of my country. I could guess, but I don't know. … I would like to know what my country's people would like to say about [stem cell research and bioscience more generally].

> [It] is very important to open the debate and to have opposite visions of the subject sitting at the same table and think that maybe both have rights; that not one has the truth and one has not – maybe both have the truth. You need to really conclude what is the best for the country and for the people of the country. That is … why I think it is so crucial that we debate these things openly.

While anticipating the emotional nature of any potential debate, R3 nonetheless stated:

> I think it is beneficial. But we have to be very responsible in this because Argentina has a trend to have discussions like a civil war … and some days it's not easy for the Argentinean society. … But … it is

[35] P. Jensen et al., "Scientists who Engage with Society Perform Better Academically" (2008) 35 *Science & Public Policy* 527-541. With respect to targeted groups, it may take a special effort to avoid recreating and entrenching for the foreseeable future traditional gender roles which not only close scientific research doors to women, but which, in the reproductive and regenerative medicine contexts, could have serious implications for women's (reproductive) rights and health, a fact stressed by at least one respondent in the GET: Social Values Project.

[36] C. Toumey, *supra*, note 30.

> unavoidable. You have [to] discuss things. You have to make a debate [with different] points of view.

It was additionally acknowledged that participation would help everyone, including scientists, who do not know enough about law or ethics.

While many of the respondents remained unclear as to the exact nature or structure of the improved engagement they sought, some clearly leaned toward a contextual participatory model. Of course, a participatory model may contain a deficit (ie: information provision) element, but it is deeper, soliciting much more from the target audience.[37] Thus, while testing and enhancing levels of science literacy, it should additionally solicit cultural predispositions, important value-perspectives, and shared visions of potential futures, and may even contribute to changes in how science is undertaken. Of course, the functional limits of these exercise must be acknowledged (eg: they involve relatively small numbers of people).

Sceptics and science antagonists are, of course, inevitable in such an open approach, and their mobilisation in Argentina can be predicted. The key for science protagonists (such as the Ministry of Science) is to neutralise the most damaging consequences of discord, and to harness the most positive and creative consequences of disagreement. Thus, it is absolutely essential to fashion engagement exercises which draw on, and vindicate, democratic principles such as respectful dialogue, reason, and consent. Antagonists with inflexible agendas who wish only to hijack the participatory process – which process must be ongoing – might simply be excluded, for they cannot add any value to the exercise.[38]

Ultimately, some form of controlled engagement which feeds into optimistic but cautious, evidence-based, and forward-thinking policies must be utilised if the generation of a sci-tech culture is to be encouraged.[39] Well-conceived participation will:

- mobilise the imagination and thereafter the energy of publics, which will, in turn, contribute to the improvement of subject technologies, or the development of new ones altogether;

- give rise to thoughtful and reasoned support within the interested sectors whose enthusiasm and action can infect other, ambivalent, or even mildly oppositional, segments of society, thereby creating a social momentum; and

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[37] C. Pitkin and A. Leitch, "Science Communication as Community Engagement: A Case Study in Regional Australia", in B. Bonmatí, ed., *supra*, note 26, 395-399.

[38] Such antagonists frequently ignore the fact that the knowledge-attitude nexus which policy-makers are trying to understand, is often contingent, and must therefore be explored through a variety of fora and then re-tested. For more on this contingency, see M. Bauer et al., "European Public Perceptions of Science" (1994) 6 *International J Public Opinion Research* 163-186, and E. Einsiedel, "Understanding 'Publics' in the Public Understanding of Science", in M. Dierkes and C. von Grote, eds., *Between Understanding and Trust: The Public, Science and Technology* (Amsterdam: Harwood, 2000) 205-216.

[39] While the idea of 'controlled engagement' may have Orwellian undertones, it is only intended to signal that the integrity and therefore the legitimacy of the process must be protected from those who would use it for ends other than to feed good qualitative evidence to the policymaking process (ie: those who would resist serious debate or the engagement with reason or rational argumentation). On this point, one notes the shortcomings of the modern media: see D. Dickson, "The Case for a 'Deficit Model' of Science Communication", 27 June 2005, *Science & Development Network*, available at http://www.scidev.net/en/editorials/the-case-for-a-deficit-model-of-science-communic.html [accessed 3 August 2009].

- create new roles for actors, including scientists and lay publics, and thereby redefine relationships, as has occurred in other jurisdictions.[40]

Examples of mechanisms which might serve as vehicles for doing this include focus groups, interactive workshops, citizen juries, surveys, large-scale polls, and so on, but could also involve more creative methods, such as game playing, issue-exploration through art or theatre or public festivals.[41]

Through such engagement and the positive mobilisation that it can promote, a sci-tech culture might be encouraged. In its absence, social understanding and uptake of innovations may remain tentative, sporadic and controversial, making it difficult to develop technologies and processes tailored to Argentina's environmental, cultural, and socio-economic setting.[42] A failure to tailor innovation to Argentina's needs will mean that Argentina will not benefit sufficiently from the technological revolution to which it is already contributing.

Joined-Up Regulation

While the above inclusive and interactive governance processes are important, there remains a central role for governments or arms-length governmental bodies, which should be clear about their policy goals.[43] Given the uncertainty around predicting future technologies and their interactions with complex systems, it is important for governments to imagine good/ideal outcomes for society, for public health, for sci-tech innovation, and for the industries implicated, and to fashion a regulatory framework that makes it possible. At the same time, they must recognise that regulation will constitute only one *component* of a broader innovation and health delivery landscape with both formal and informal elements.[44] As such, they must

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[40] J. Pont, "Public Participation in Climate Change Knowledge Production: An Assessment of Communication Models", in B. Bonmatí, ed., *supra*, note 26, 387-389, and T. Tramullas et al., "Science and Society: Twelve Cliché Questions and Forty-Eight Controversial Answers" in B. Bonmatí, ed., *ibid*, 385-387.

[41] One might query whether the creation of curiosity and trust, a common consequence of public engagement, can be the explicit goal of public engagement, and, if it is made to be so, whether this undermines the goal of public engagement. While public engagement has been directed at encouraging better science or science policies, I believe it has always had an element of promoting science curiosity or of 'science-ism', and encouraging trust through the involvement in trajectory-choice. That these effects are explicitly recognised and desired does not detract from the value or legitimacy of the engagement project so long as that project is pursued in good faith and with transparency.

[42] However, I note that GM crops, a lightning-rod for controversy in the UK, was widely adopted by Argentine farmers with very little debate, and was (for the most part) silently accepted by a public with other, more pressing concerns: see A. Mucci, G. Hough and C. Ziliani, "Factors that Influence Purchase Intent and Perceptions of Genetically Modified Foods Among Argentine Consumers" (2004) 15 *Food Quality & Preference* 559-567, and Scientific American, Worldview Project, available at http://www.saworldview.com/. Indeed, almost all respondents in the GET: Social Values Project confirmed that the adoption of GM crops did not give rise to significant debate in Argentina, partially because its most direct and immediate impact is on farmers, as opposed to broader groups (like patients).

[43] See C. Lyall, J. Smith & T. Papaioannou (eds.), *The Limits of Governance: The Challenge of Policy-Making for the Life Sciences* (Aldershot: Ashgate, 2009).

[44] Maximising bioscience benefits may also necessitate considering ways in which Argentina might improve regional infrastructure and therefore conditions for bioscience innovation so that it retains a regional competitive advantage. For more on the regional element of innovation, see T. Papaionnou, "Regional Innovation and Pubic Policy" (2007) *Briefing No. 13*, available at

identify the links between socio-economic, innovation, and health objectives, and understand them as integrated entities.[45] They must strive for a degree of 'joined-upness' so that actions at one innovation focal point (eg: stem cells) do not cause unanticipated problems at another (eg: human trials or commercialisation), each of which will have unique, context-dependent issues, players and risks.[46]

While most respondents in the GET: Social Values Project felt that historical efforts at legislating science in Argentina were not particularly well conceived, or were now simply too outdated to be maximally effective, they almost unanimously felt that rational, evidence-based, and informed government boundary-setting was essential in the new sci-tech climate. R2, a regulator, suggested that the governance regime must facilitate science while demarcating forbidden pursuits and practices, thereby giving actors clear guidance. R10, a legal-ethical academic, stated:

> I think that, today, you need to regulate because the power and possibilities in the scientific field are so much, and the possible effects are so terrible … . With a lot of care … and consulting specialists [scientific and bioethical], something must be done.

R12, a federal judge, noted the quality of Argentina's science and opined that good regulation which encourages useful outcomes would be helpful.

While all respondents in the GET: Social Values Project felt that government boundary-setting is essential, they did not all agree that formal regulation was essential. Indeed, in this regard, opinions fell into four primary camps:

- No Legislation: It is too early for legislation in the stem cell setting; it might be better for this area to be overseen by a regulatory committee first so some oversight and advice can be offered as the field develops, and any furore is avoided (R7, R21,). Alternatively, legislation ought to be avoided because the tendency is to ban and pass bad laws (R16).

- Narrow Legislation: A stem cell-specific law is important because of the socially important issues thrown up by this research (R5, R10, R11, R14, R17, R19).

- General Research Legislation: Relevant issues and procedures are shared with other practices and techniques so a general medical research law is more useful, under which technique-specific regulations might be drafted by the

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http://www.genomicsnetwork.ac.uk/media/regional%20innovation%20and%20public%20policy.pdf [accessed 21 April 2009].

[45] The benefits of early inclusion of these broader considerations is supported by empirical research conducted by Innogen in the area of bioscience innovation: see T. Papaionnou, "Building Innovative Capabilities Through Pubic-Private Collaboration in Genomics and Biotechnology" (2007) *Briefing No. 12*, available at http://www.genomicsnetwork.ac.uk/media/building%20innovative%20capabilities.pdf [accessed 21 April 2009].

[46] S. Harmon and G. Laurie, "The Regulation of Human Tissue Use and Regenerative Medicine in Argentina: Making Experience Work" (2008) *Policy Brief No. 4:2008*, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre [accessed 21 April 2009]. Multiple respondents in the GET: Social Values Project expressed a preference for a general law on basic and non-clinical research to which dependent and more specific regulations could be added where necessary which address specific technologies.

executive on an as-needed basis (R1, R4, R6, R8, R18).

- General Medical Legislation: It is much more important to regulate the clinical setting than basic research; the safety of the patient is the most important element currently missing from the Argentine biomedical regulatory setting (R3, R12, R15).

Despite this divergence of views, most respondents recognised the need for a rational joined-up bioscience regime with some boundary-setting and oversight functions performed collaboratively by the Ministries of Science and of Health, having first identified and framed core themes and public objectives for bioscience. Such collaboration is essential insofar as it would better encourage the formulation of jointly relied-on processes which capture the diversity and richness of opinion and thereby offer a broader, more creative base from which to adapt regulation, which will concomitantly address a wider range of concerns. A proper foundation will also go some way to avoiding 'factionism'; if the regulatory system is too complex (and too onerous), many potential players will be squeezed out, and if the whole does not interact rationally and simply (funding, research governance, corporate governance, intellectual property, etc.), expenses will be wasted and opportunities lost, as developing countries are discovering all the time.

Summation: The Need for Compressed Social Evolution

Shifting social perspectives is never easy – social mores transform slowly, unevenly, even osmotically – and the formation of a sci-tech culture in Argentina poses no mean task, though one should take notice of the general esteem in which scientists are held by most Argentineans.[47] Importantly, there are precedents of such cultures having been fostered elsewhere. Although obviously an uneasy comparator, China is compelling insofar as it managed its transformation while shifting from developing to developed, doing so from an arguably less enviable socio-economic position than Argentina enjoys, and with a much larger polity to reverse and mobilise.[48] Like China, Argentina might encourage the formation of a sci-tech culture through 'compressed social evolution'; that is the consciously accelerated transformation of the socio-cultural environment toward a desired perspective. It is 'compressed' insofar as it is not purely evolutionary or a matter of happenstance, but is rather more consciously (and conscientiously) directed, with policy leaders identifying, targeting and achieving ambitious but realistic socio-scientific/technological objectives while simultaneously (and aggressively) building public support for same.[49]

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47 Stekolschik et al., *supra*, note 20.

48 China is socially, politically, legally, culturally, historically and geographically different from Argentina, and its lower tolerance of sharp divergence from state objectives negates a need for it to navigate the 'minefield' that Argentine policymakers and science protagonists might expect: See F. Luna and A. Salles, *supra*, note 23.

49 Through persistent public education, targeted public funding of science, and domestication of international standards (and interpreting them on a utilitarian basis), China has transformed itself from insular, rural, agrarian society to international leader in a variety of technology sectors, including agro-genomics. Since the end of the Cultural Revolution in 1978, and particularly through the 1990s, China adopted a science-solutions approach to development and social change, deploying science and encouraging scientific uptake and innovation whenever possible, and rewarding same through funding and recognition. China continues to make strides by identifying Chinese needs and strengths for saturation funding, and it is retaining governmental authority in the face of international dilution of

While one might acknowledge that technologies (or their deployment) are not always positive, there is ample evidence to the effect that selective pursuit of high technologies can be beneficial to developing countries in Argentina's position.[50] In undertaking the shift envisioned in this paper, however, it is conceded that Argentina must find some balance between caution and pace in innovation while simultaneously building social momentum around sci-tech and exercising ongoing reflexivity or self-assessment and re-evaluation in relation to sci-tech advances.[51] In pursuing this course (or rather *if* pursuing this course), Argentina will alternatively suffer and benefit from a number of factors particular to its temporal and cultural context.

On the negative side, all things have accelerated since China embarked on its course. Thus, whereas Argentina may wish to be cautious and measured, it might rather have to be more decisive, undertaking a concerted not-so-long march which facilitates the (rapid) formation of said culture. Similarly, efforts might be expected to trigger the mobilisation of certain conservative institutions while shining a harsh light on scientists who may just wish to simply 'get on with it' in anonymity. Finally, Argentina might be hindered by the fact that, like many other developing countries, it faces a host of more pressing social problems that clamour for public funds, a fact acknowledged by a number of respondents.

On the positive side Argentina ought to be facilitated by the fact that members of the Argentine public ascribe to scientists a high level of credibility and prestige.[52] Moreover, a national survey in 2003 found that most Argentineans have favourable attitudes toward science and technology, and that most Argentineans believe that (1) science and technology improve culture and quality of life, and (2) the government should increase public funding of science and technology.[53] Having said that, it also found that a majority of the population is poorly informed about science and technology issues, and, overall, the general positive attitude is accompanied by a precautionary attitude toward the consequences of science utilisation.

Ultimately, scientists and policymakers must interact more openly, positively and profitably with the Argentine polity over stem cell research and other biosciences, and it is naïve to think that Argentina can or should avoid the suggested

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sovereign capacities: see S. Harmon, "Biotechnology Innovation and Patenting in the Developing World: China – A Giant Among Nations?" (2007) 12 *J Intellectual Property Rights* 72-85, S. Harmon, "International Public Health Law: Not so much WHO as why, and not enough WHO and why not?" (2009) 12 *Medicine, Health Care & Philosophy* 245-255. Importantly, as alluded to above, the Chinese have a dearth of robustly democratic institutions, a condition with which Argentineans are not similarly faced. This fact makes it easier for Chinese authorities to compress social evolution. In the Argentinean case, as indicated in the main text above, compression would entail a concentration of promotional and participatory efforts, without the same narrowing and silencing mechanisms that might be expected in the Chinese context.

[50] For more on technology leap-frogging, see B. Petrazzini and A. Guerrero, "Promoting Internet Development: The Case of Argentina" (2000) 24 *Telecommunications Policy* 89-112, R. Davison et al., "Technology Leapfrogging in Developing Countries: An Inevitable Luxury?" (2000) 1 *E Journal Info Systems Developing Countries* 1-10, J. Cascio, "Alternative Energy in Pakistan" (2003), available at http://www.worldchanging.com/archives/000234.html [accessed 28 September 2009], J. Cascio, "Leapfrog 101" (2004), available at http://www.worldchanging.com/archives/001743.html [accessed 28 September 2009], and T. Altenburg, H. Schmitz and A. Stamm, "Breakthrough? China's and India's Transition from Production to Innovation" (2004) 36 *World Development* 325-344.

[51] A. Moutinho, "Public Policies for Scientific Culture: When Maturity Brings About Evaluation" in B. Bonmatí, ed., *supra*, note 26, 405-407.

[52] Stekolschik et al., *supra*, note 20.

[53] L. Vaccarezza, C. Polino and M. Fazio, "Measuring Public Perception of Science in Ibero-America: The RICYT/OEI's Study and Argentina's National Survey", in B. Bonmatí, ed., *supra*, note 26, 436-443.

transformation, despite the pitfalls it engenders. Advancing a sci-tech culture is probably imperative if Argentina wishes to maximise potential, generate new possibilities, and emerge as an international competitor (or regional leader) in the new scientific era. The overall evidence obtained in the GET: Social Values Project suggests that, while Argentina does not yet manifest a sci-tech culture characterised by robust science democracy and engagement as a means of encouraging curiosity and public support of science endeavours, there is support for its creation, at least amongst the stakeholders interviewed, all of whom had a positive outlook on the possibilities that high technologies offer Argentina, and they felt that much depends on individual personalities, particularly the widely respected Minister of Science, Lino Barañao.

CONCLUSION

The empirical evidence generated by the GET: Social Values Project tells a particularly Argentine story. It is a story of:

- Sadness: that healthcare and science education are enjoyed so unevenly in Argentina where such good science is being pursued;
- Acceptance: of past failures and injustices in the science (and social) setting;
- Ambition: to perform more world class bioscience;
- Optimism: in the domestic human resource capacity to achieve bioscience innovations;
- Concern: that Argentine biosciences will never mature to a truly internationally competitive scope and level unless the public is supportive;
- Ambivalence: over whether good public engagement can be achieved in the prevailing social setting; and
- Distress: that the social and political setting may continue to hamper Argentine science and knowledge generation for some time to come.

This paper engaged with the latter elements, arguing that the formation of a sci-tech culture, and the concomitant acceptance of new technologies, will be enhanced where people are satisfied that (1) the technologies could be beneficial to society and/or themselves, (2) they have had some role in the consideration of those technologies, and (3) there are reliable mechanisms to encourage their proper development and just deployment. The 3-pronged model articulated above, and generally supported by respondents in the stem cell and regenerative medicine research context, could help lead Argentina to such a state, but it obviously requires exposure of actions and desires. And in the Argentine context, there is a danger to such exposure, and in making hidden battles public (and explicit): scientific privileges which are currently enjoyed could be challenged or even retracted. But some aspects of value battles can be turned to more productive dialogues if the polity is respectfully engaged, and, as

already claimed,[54] some values that are currently politically enforced do not actually represent the true values of the polity. Having been so engaged, those who remain opposed to specific technologies might nonetheless be satisfied that (1) their own concerns were heard and understood, and (2) they will be able to (personally) avoid specified and deplored technologies once they are mainstreamed. This is how society accommodates plurality and evolves to better reflect the true values and practices of its people.

In any event, the evidence generated thus far, admittedly a drop in the proverbial bucket, and relating only to stem cell and regenerative medicine research, suggests that (at least some) Argentine stakeholders are interested in shaping policies which are democratically founded, which encourage honesty in all parties, and which contribute to international socio-ethical debates. What does all of this mean for the immediate future of policy-making in Argentina? I would suggest that Argentine policymakers might:

- acknowledge that well-conceived participation encourages trust, honesty, and dialogue (ie: stakeholders being prepared to expose their interests and objectives, conscientiously exchange ideas, and refine their positions), and therefore should (1) recruit allies in civil society and, at both closed and public meetings, (a) consider technological trends, objectives and value, and (b) develop understandings of assumptions, agendas, desires, and underlying moral values driving various stakeholders;

- consider how biosciences are changing and could change Argentine society and healthcare, now and in the future, for elites and the general population, and therefore should (2) undertake and/or fund a variety of horizon-gazing exercises, some expert driven, some more broadly inclusive; and

- recognise that innovation is interdisciplinary and that regulation can affect a variety of practices, some of them not directly governed by that instrument, and therefore should (3) fashion a governance regime which recognises inter-operability without recreating complexity (ie: avoid technologically-contingent regulation and encourage regulation that is navigable by non-experts shepherding research from bench to bedside).[55]

It is reasonable to believe that these steps could vindicate two of the values consistently claimed as important by all respondents in the GET: Social Values Project, namely ‘honesty in science and science governance’ and ‘public trust in science’.

[54] F. Luna and A. Salles, *supra*, note 23.

[55] In this respect, note C. Lyall, J. Smith and T. Papaioannou, *supra*, note 43.