Governing Risk, Engaging Publics, and Engendering Trust

Governing Risk, Engaging Publics and Engendering Trust: New Horizons for Law and Social Science?

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Abstract: Modern biosciences require governance frameworks that are capable of simultaneously managing risk, coping with uncertainty, combatting ambivalence, and building trust, all the while encouraging the delivery of those instrumental outputs that we value/demand. This multi-dimensional task makes the design and delivery of good governance frameworks extremely difficult. Efforts to date have, by and large, failed, particularly where the law has been relied on. Preoccupation with risk has tended to shape regulatory systems, but the conception of risk relied on is deficient, and its use is often oriented to support precautionary approaches in the absence of 'evidence'. Our collaborative efforts lead us to suggest that more robust mechanisms need to be deployed which reveal and promote interactions with a fuller gamut of risks, and that these must be seen as relative to the twin objective of both protecting and promoting the range of interests involved in any given technology endeavour. We do not argue that the law should be ignored, but that a reflexive mode of governance which is 'performed' in a manner reflective of the dynamic nature of science and which uses the law more effectively as a value- and institution-framing mechanism is demanded.

1. Introduction

Many consider that we now live in a 'risk society' (ie: a society in which the risk of harm or injury is ubiquitous, placing citizens in a perpetual state of radical 'uncertainty' and requiring risk-mitigation responses from law and other social institutions). Moreover, many view these risks as being both qualitatively and quantitatively different from those faced in previous eras (Beck, 1992). Some might argue that the risk paradigm is a consequence of the triumph of individualism and our associated desire to control all instances of chance that might ill-affect our lives. Others might argue that it is an outcropping of our growing desire to shape and manage our natural world and thereby gain some control over our destinies. Regardless of the exact fount of our risk preoccupation, there can be little doubt that some risk emerges from our own undertakings. For example, risk is implicated (and elevated) by the practices we adopt and the technologies we develop in an effort to remake nature and ourselves within it (eg: nuclear power, regenerative medicine, etc). As demonstrated below, the seeming ubiquity of risk has led to governance strategies, processes, and instruments that focus on and are shaped by risk, but often these simply beget alternate risks. In short, as has been demonstrated by social scientists, the innovations we institute to cope with risk are generating further risks with the result that risks are 'manufactured' by the modernisation process itself (Giddens, 1990; Beck, 1992). This

makes risk a multi-faceted 'problem' requiring investigation and responses from many perspectives, and therefore from many disciplines (and 'interdisciplines').

While this paper is a response to the idea of risk as a social driver, it does not pretend to deal with its many facets. After commenting briefly on risk, its public existence, and the governance processes and mechanisms it has (at least in part) spawned, the paper focuses more specifically on one such mechanism – the law. Drawing on our legal and sociological research, and on our joint or interdisciplinary experience, we consider the following question:

> How adequately does the law respond to increasingly complex systems of knowledge and action that are increasingly driven by risk concerns and engaged publics?

In doing so, we ground our reflections on biomedical science, described by some as a 'post-normal science' (Funtowics and Ravetz, 1993). More specifically, we focus on biobanking. We justify this choice as an example of a recent technological and social advance that has generated much uncertainty, largely because the potential and associated risks are unknown. This uncertainty has posed considerable challenges for law and governance mechanisms – making the field a fitting focus for our principal research question. After addressing this initial question, we ask the following:

> How does or should the law fit into a broader governance framework that takes adequate account of uncertainties, including but not exclusively those pertaining to risk, and that includes robust and effective public engagement at its core?

In considering this question, we argue that governance frameworks, including the law, must include appropriate public engagement provision. Not only can this help to deliver legitimacy in those frameworks but it can serve as a means to engender trust in them. A further tenet of our contribution is that a risk-based approach need not be one that leads to undue regulatory burden or excessive legalistic control. Indeed rather the contrary – an appropriate approach to risk can help engender effective and proportionate governance mechanisms which, we believe, are the optimal approach to biobanks (and other new and emerging technologies). It is a cross-cutting theme of our paper that we need not have recourse to law to achieve these ends. Indeed, in many respects law is ill-suited to deliver the kinds of mechanisms we propose.

2. Articulating, Reducing, and Managing Risk

On the whole, we expect our governance frameworks to defend against risk and to promote a range of valued outcomes, including better health, safety, productivity and prosperity. While many biosciences can improve healthcare systems, increase the enjoyment of health, and/or rehabilitate the environment, thereby reducing all manner of potential risks, they can also contribute to risks, both tangible and intangible. They do so by posing dangers to environmental and communal stability, personal integrity, and fundamental rights, to name a few examples. Moreover, the quest for longevity, a unifying objective for much healthcare and bioscience innovation, is not an unqualified good. It carries its own risks of health and psychological

harms associated with significant old age. In short, biosciences promise dualistic or sometimes utterly unknown (or unknowable) consequences.

Given this reality, concerns quite naturally arise about how to manage not only the risks of the biosciences but the biosciences themselves. A common policy or governance tool designed to help in this regard is the 'risk assessment', which, in the usual course, is divided into four primary steps (Cheng et al 2006; Marchant et al 2008):

1. hazard identification;
2. exposure response observation and analysis;
3. risk characterisation; and
4. risk management response (via acceptable risk approach, cost-benefit analysis approach, or feasibility approach).

We also see this type of approach being extended to intangible harms, such as threats to personal privacy. Health-related research must now be conducted in an environment of strict control of personal data and where privacy impact assessments are expected to be a central feature of any governance framework (Laurie & Sethi, 2011; Information Commissioner's Office, 2012). Unfortunately, the preliminary nature of our understandings of the risks associated with many biosciences and biotechnologies introduces difficulties into all of these steps with the result that risk articulations are tentative and sound assessments are not yet within our grasp (Weisner et al., 2006; Handy and Shaw, 2007; Oberdörster et al., 2007; Bowman and Hodge, 2008). Law and legal institutions are face with profound dilemmas in such circumstances. Should law intervene to prohibit new and emerging technologies when the uncertainties are too great (and so when the real risks are largely unknown)? Conversely, can law legitimately be deployed to promote particular advances when there is little evidence that possible risks are real or have any significant likelihood of becoming so?

None of this is new. Collingridge (1982) identified the essence of the problem as follows: To intervene too early will mean that there is insufficient, conflicting or confusing data about the nature and impact of the new technology to act effectively; to wait too long will mean that the technology has become entrenched in a particular social context, and influence and change become correspondingly more difficult to effect. What this suggests is that hard law (statutory intervention or other instruments) might frequently find itself in a form of stasis faced with significant risks and uncertainties, and the limits of its role will accordingly be considerable.

Given the manifold uncertainties, and the potential mistrust to which they can give rise, we often turn to soft law governance tools such as the 'precautionary principle', which asserts that, where there are threats of serious damage beyond a *de minimus* range from a given activity, lack of full scientific knowledge about, or proof of, those threats, must not be used as a reason to avoid or postpone cost-effective measures to minimise or avoid them (Clarke 2005). While the precautionary principle has been criticised on a number of grounds (see Clarke 2005; Marchant et al 2008; Faunce 2008), it has also been lauded for expanding the traditional cost-benefit analysis that is adopted with respect to risk, and for encouraging an expansion of the considerations or criteria for assessing the biosciences and their derivative technologies (Jordan and O'Riordan 1999).

In any event, the biosciences, the risks they engender, and the diverse applications of the

precautionary principle have all contributed to an ambivalence around biosciences (or bioscientific objectives). Lay ambivalence can take many forms, including an apparent unwillingness to engage with science and technology, non-compliance with treatment, and outward expressions of distrust in bioscience discussions (Kerr and Cunningham-Burley, 2000) This ambivalence is fed in no small part by the mass media and its techniques for reporting on the biosciences. Generally, the media exercises a strong influence over risk perceptions but:

> There is an ominous and widening gap between scientists' assessment of various risks and the popular perception of those risks, a gap that threatens to lead ... to unfounded and crippling anxieties (Paulos, 1988).

In the public health and vaccination context, it has been argued that, while the media should exert a positive influence, it more often neglects issues important to public health and gives undue prominence to (often inaccurate) 'scare' stories, examples of which include those around MMR and autism, which stories affect public behaviour in ways that increase health risks (Tallis, 2004; Sykes, 2011; Salisbury, 2012). The crucial importance to public health of delivering accurate data to and through the media was recently noted in *Walker-Smith v GMC* [2012] EWHC 503 (Admin).

A consequence of all the above, together with risk, uncertainty, ambivalence, and fear (note the claims of 'golem science' (Collins and Pinch, 2001)), is that greater demands are being placed on frameworks aimed at securing, simultaneously, scientific progress, human wellbeing, economic prosperity, and trust and support for the scientific endeavour. People want heightened or 'better' governance. Unsurprisingly, this has led to calls for the 'democratisation of science'. The common wisdom is that governance would be improved if publics contribute to deliberations on important ethical, legal, and social issues raised by innovation and emerging technologies. The aim is not to deliberate on the science but rather to tap into the experience and knowledge of the public and incorporate their values into the organisation and trajectory of science and its regulation. So approached, public engagement can improve decision-making, improve decisions, and more effectively inform normative boundaries. In short, effective deliberations can ask and explore probing and pertinent questions, and can constitute or inform governance regimes where law has reached its limits.

Of course, difficulties remain. First, there is an extraordinarily diverse range of groups and individuals in society, which makes the term 'public' much criticised; the term 'publics' is preferred. This can make choosing participants a contested matter. Second, innovative participative processes such as citizen juries are recommended to take place 'up-stream' so that publics can influence decision-making before decisions are finalised (Wilsdon & Willis, 2004) . However, at this formative stage of the science, the relevant ethical and social issues can be quite vague or uncertain, which means that useful engagement is not easily accomplished (Haddow et al., 2008). Third, questions persist as to whether public engagement is actually a true form of public 'participation' because engagement does not necessarily mean empowerment. Approached as an instrumental political endeavour aimed at enhancing legitimacy and science-society relationships and embedding existing power structures, public engagement can be characterised as 'collaborator' with only cosmetic impact (Fiorino, 1990).

Given these difficulties, careful consideration is required around key questions such as:

(1) When and how should space for critical dialogue and enquiry via public engagement activities be opened up? (2) How should engagement link to decision-making, at what stage, and over what issues? (3) Whose participation should be included and what outputs should be acted upon? Despite these difficulties and the potential of a policy 'backlash' against public engagement, there is increasing recourse to this process as a means of informing (and sometimes driving) governance mechanisms (Haddow et al., 2007). Curiously, however, such exercises can push policymakers back *toward* the law as a means delivering 'governance'. Law has been a prime objective for many policymakers (and has thus been both beneficiary and scapegoat). However, how adequately does the law respond to increasingly complex systems of knowledge and action that are increasingly driven by risk concerns and engaged publics? It is to this question that we now turn, having reference to the practice of biobanking.

3. The Limits of Law Exposed by Biobanking

For many, not least lawyers, recourse to hard law (legislation and subsidiary regulatory instruments) is a first natural reaction to new social phenomena such as changing biomedical practices and technologies. And of course the law has played its part in getting the biosciences to their present stage; it has promoted and sheltered the biosciences and encouraged (ensured?) them to develop in responsible ways. The law can and has been called upon to protect and promote core values and interests through the acknowledgment of (agreed) boundaries and the erection of specific rules, and it has served that purpose to varying degrees of success. That being said, the law is also often prescriptive, inflexible, and static (frozen in time and technological capability). Despite its ossifying potential, governments have embraced a form of public engagement aimed at informing the manufacturing of law and policy. Public consultation is now a *de rigeur* of legislative processes, although surprisingly little evidence is available on whether and how responses are taken into account. The sceptic might see this as little more than a veneer of legitimacy added to the development of regulatory processes, and it is unclear and unproven that such exercises *de facto* result in more trust in the governance mechanisms which eventually emerge. The problem is compounded by two additional factors. First, a one-off consultation at the beginning of a legislative process cannot hope to anticipate, let alone respond effectively to, future developments. Public engagement should not just be a snap-shot of current opinion but rather an enduring dialogue between publics and policymakers. Secondly, the lack of transparency and opportunity for future input to processes is very likely to undermine rather than engender trust in them.

These factors are presented in a particularly acute form precisely because the evolving biosciences are dynamic and quickly moving. They demand responsiveness and adaptability by their very nature. Consider the case of biobanks, which can be differentiated from more traditional medical research practices in that they are (Harmon, 2008):

- 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 repositories of samples and data intended for future, ongoing and repeated use, one 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; or the lifespan or security of the biobank. Laurie (2011) confirms that biobanks are particularly challenging (for law) because of their (1) structural diversity (heterogeneity), (2) purposive uncertainty, and (3) intended longevity (temporality). In short, biobanks are complex research undertakings embedded in complex research networks (Kaye et al., 2012). They are, by their very nature, exercises in the unknown.

Given these characteristics, existing legal mechanisms have been widely viewed as inadequate (see, for example, Cutter et al, 2004; Gibbons, 2007). Unfortunately, attempts at bespoke legal frameworks have not been wildly successful at effectively protecting the interests at stake. The earliest and most notorious example is the Icelandic *Biobanks Act 2000*, which was eventually declared unconstitutional (Gertz, 2004). Less controversial though barely more successful efforts to clarify rights and responsibilities in relation to biobanks include the Estonian *Human Genes Research Act 2000*, the Latvian *Human Genome Research Act 2003*, the Swedish *Biobanks in Medical Care Act 2003*, the Norwegian *Act Relating to Biobanks 2003*, the Portuguese *Personal Genetic Information Act 2005* (which contained provisions on genetic databases), and the Spanish *Biomedical Research Act 2007* (which had a section on biobanks). Concerns about these very diverse biobank-specific laws are manifold. One revolves around regulatory burden: care must be taken to ensure that regulation is proportionate, effective, and not overly burdensome. A second revolves around uniformity and interoperability: care must be taken to establish standards (and identify best practices) which both protect participants (no matter where their sample or data might go), and which also allow biobanks to work with networked researchers from around the world. It is a well-recognised fact that biobanks will not realise their potential unless there is cooperation and sharing on a global scale (P3G). Another concern revolves around changing practices and technologies associated with biobanking: care must be taken not to impose frameworks that rely unduly on current technologies or understandings. Yet another is that biobanking relies heavily on trust, which itself is constructed on the commonly-lauded idea that biobanks serve the public interest: care must be taken to construct governance frameworks which not only promote but also justify that trust.

This is a complicated (and ever-moving) target for a governance framework to hit and keep on hitting consistently and effectively over time. In the UK, this multifaceted and fluid objective has led to an overlapping morass of interactions and engagements, standards and rules, guidances and instruments that collectively comprise a 'governance framework'. Laurie (2011) has suggested that a good governance framework for biobanks will be one that has:

1. designed-in interoperability with other scientific and governance approaches;
2. designed-out approaches restrictive of sharing, cooperation, flexibility, and mutuality;
3. procedures to identify and protect adequately the interests of participants;

4. procedures to promote actively the use of the resource in keeping with its purposes;
5. longevity protection through good stewardship and carefully managed access policies;
6. governance policies and mechanisms that remain fit for purpose over time.

It should be obvious that, while the law might expound on guiding values that we would expect to remain, and desire to keep, solidly embedded over time, and while it might deliver on one or more of the specific elements, it cannot hope to deliver on all of these elements. This realisation – which might dismay some lawyers – requires a re-imagining or recasting of the law as one of several tools in the governance 'toolbox', or one component of the larger governance framework. This very suggestion highlights the issue of 'optimality'. While the law might rightfully be seen as one option, or one of several options that are all important, great effort should be taken to avoid regulatory fragmentation and complexity. Kaye et al. (2012) explore in detail the biobank governance situation in England and Wales and assert that practitioner awareness of the "multifarious sources of governance" is incomplete and inconsistent. Obviously, this is a situation that both researchers and the public would wish to avoid, and it implicates our remaining question.

4. The Need for Legal Foresighting?

If the law is best approached as one component of a larger governance matrix, it becomes incumbent on us to consider what methods can and should be used to determine what the law can and should be called upon to do, and when and what role might public engagement have in deciding this. As such, this final part offers a framework that facilitates effective and useful foresighting with respect to law and legal responses. The essential question *about* law is how it might be best deployed within systems that increase the chances of individuals and institutions approaching future challenges from the best possible starting point and taking into account the full scope of relevant considerations in a timely and appropriate manner. We have argued elsewhere for a robust method of legal foresighting which can be adapted to all manner of new technologies and which has at its heart robust public engagement (Laurie, Harmon and Arzuaga, 2012). We propose here that key elements of this model illustrate clearly not only our claims to recognise the limits of the law, but also how we might position law within the above-mentioned larger governance matrix.

This paper began with an acknowledgement of the relevance and prevalence of risk. In addition to all of the challenges identified above, it is self-evident that risk-based assessments are prone to hype. The hype that often colours the science communication and visions of risk also often colour futures-oriented ethical debates. We must commit to rejecting the contemplation of *possible* Frankenstein futures which are driven by media hype or 'speculative ethics' (Nordmann, 2007; Nordmann & Rip, 2009) because these distract from the core task at hand, which is to consider how best to respond to *probable* technological futures. The role of risk here, we suggest, must be seen relative to the twin objectives of both protecting and promoting core interests in any given novel scientific endeavour. That is, the objective is as much about *promoting* future interests as it is about *protecting* current (or future) interests. Precautionary approaches allow us to move forward cautiously and this is often entirely appropriate, but risks must be seen relative to these twin objectives; we must adopt a more

contextual and more rounded approach to risk. We must contemplate risk questions that are often ignored, such as:

- What are the risks of not advancing the science?
- What are the risks of not engaging publics?
- What are the risks of not recognising the limits of law?

These risk assessments must play their part. As suggested from these questions, risk is not only about *what* but also about *whom*. Risk can manifest to a wide range of actors and stakeholders in myriad ways from the tangible, economic, social, and cultural, to the intangible reputational and emotional. In this latter realm we encounter the ever-present and yet illusive role of trust. Quite simply, law cannot proscribe trust. This is a paradigmatic example of its own self-limiting nature. At best, it might construct architectures within which human practices take place and which, in time, will attract trust but even here it is severely restricted and there are no guarantees. But what is important are the practices themselves not the architectures within which they operate. And, like all human practices, interaction is key to their success.

Given this, we are concerned with the reflexivity encouraged in framework designers and participants by the foresighting exercise itself. In biobanking, the biobankers themselves are well placed to be 'first movers' and important 'carriers of agency' (Swierstra and Rip, 2007). The key interactions here will be with biobank participants and potential regulators. Regulators, in turn, can and ought to be rational initiators who not only enable development *through* regulation or governance, but are able to prompt positive regulatory or governance change through participative deliberation *about* regulation or governance (which in turn brings about scientific and social change). Once again, law cannot deliver on this, but robust public engagement is a viable mechanism to do so. It can help identify real, imagined, near and distant risks and also possible ways to address them. It should not be forgotten that public engagement exercises can provide vital (missing) evidence about the risks of proceeding when more traditional risk evidence (eg: scientific or medical) is lacking.

Two UK biobanking examples illustrate how interdisciplinary approaches can be used effectively to design responsive governance. The first example, which is UK Biobank, highlights the very important issue of governance mechanisms remaining effective and responsive over time. The second, Generation Scotland, highlights the importance of introducing a range of perspectives and practices to the governance endeavour. A third example, which is taken from our empirical research on stem cell research regulation in Argentina, highlights how foresighting and engagement can feed into the design of the legislative component when it is, in fact, deemed warranted.

UK Biobank is one of the world's largest biobanking projects, containing data and samples from over 500,000 adults collected when participants were between 40 and 69 years of age. The overarching objective of UK Biobank is to create a research resource that will be accessed from all over the world to promote the broad objective of 'health-related research'. The UK Biobank approach to governance relies on soft law options that are designed to reflect and respond to the particularities of the initiative. From both a foresighting and engagement perspective, two elements of the governance framework are worthy of note: (1) the Ethics and Governance Framework (EGF); and (2) the Ethics and Governance Council (EGC). The EGF is

a public instrument generated by UK Biobank that makes explicit the core undertakings of UK Biobank. It is, in essence, a communication to UK Biobank's participants, researchers, and wider society. It is a living document which is designed to adapt as science, society, and the project progress and face unforeseen challenges. The EGC is an independent oversight body charged with monitoring and advising UK Biobank throughout the life of the project, most particularly with respect to its conformance with the EGF and protection of the interests of participants. The EGC acts as a 'critical friend' to UK Biobank as it faces the uncertainties that arise from its longevity and wide-ranging objectives.

We have argued elsewhere that this experiment in governance is, in fact, an example of *reflexive* governance (Laurie, 2011), which is one possible outcome of a legal foresighting exercise. In this case, it is about the facilitation of mutual learning from experience over time and can be seen as "... a mode of steering that encourages actors to scrutinise and reconsider their underlying assumptions, institutional arrangements and practices" (Hendriks and Grin, 2007). We agree with Vincent-Jones and Mullen (2010) when they state, at 153, that "… [t]he legal framework by itself is incapable of facilitating the conditions necessary to promote a sufficiently receptive and deliberative orientation on the part of the relevant actors." Rather, "...fully reflexive governance is dependent on deliberation and openness to alternative possibilities in the framing of problems and the suggestion of solutions ..." (Vincent-Jones and Mullen, 2010, 175).

The UK Biobank model embodies in-parallel partnerships in governance in the face of future uncertainty (Wynne, 1992). Seen in the above light, the UK Biobank example is a possible model that can inform future foresighting exercises. It is neither a version of top-down regulation nor a system of up-front ethical approval of a scientific protocol or one-off consultation with publics, each of which might be too limiting and incapable of accommodating the uncertainties which biobanks generate. Reflexive governance provides a system of organic co-production of responses which, as we have suggested, are central to optimal legal and regulatory foresighting. Moreover, such an approach is both responsive to the demands of the particular initiative or technology and, at the same time, able to take in account a range of values and interests which can — and will — change over time.

The second example is Generation Scotland, Scotland's first biobank. The public consultation for Generation Scotland demonstrated to good effect how interdisciplinary approaches between law and social science can open up new horizons. Early focus group data demonstrated an ambivalence about pharmaceutical access to the biobank itself, and that this issue might affect participation. However, indications were that such access could be tolerated should a benefit-sharing scheme be adopted. Taking the public engagement exercise seriously, the idea of 'benefit-sharing' was turned into a pragmatic legal resolution. While a 'crude calculus' leading to a 'what the public wants, the public should get' approach must be avoided, the social science contribution here revealed an important policy pressure point. It uncovered the nature of the problem and a possible acceptable solution. The legal mechanisms that might be employed to achieve these ends were found in the Provincial Approval Model proposed by Pullman and Latus (2001). Under that model, which was designed for the historical-political-economic circumstances of Newfoundland and Labrador, Canada, anyone proposing to conduct research that includes a human genetic component must seek approval not only from an Ethics Committee, but also from a Standing Committee on Human Genetic Research (SCHGR). The

aim is to 'ensure a just allocation of the benefits that might accrue from human genetic research' (Pullman and Latus, 2002:1). In adopting a similar framework, important engagement-driven findings were put into practice.

The third example does not come from biobanking *per se*, but from stem cell research, which, it must be said, is closely allied and associated with biobanking. This demonstrates how engagement can serve as deliberations about the law, and can feed the development of law when it is felt that a hard law component is in fact necessary. Our empirical research in Argentina (GET: Social Values), admittedly relying on a very small sample from which to extrapolate, suggests that there are some rather sharp divergences between three key elements in the Argentine techno-legal setting:

1. the values the stakeholders expressed and what actions they felt those values demanded of them personally;

2. the extent to which existing regulatory frameworks reflected those values and supported actions taken in response thereto; and

3. the political possibilities of having the former two constituents come together in a socially beneficial manner.

The range of stakeholder meetings and interactions that we conducted suggests that dramatic legal realignment would be welcome, as was recently achieved in Brazil in the stem cell setting, and both the Advisory Commission on Regenerative Medicine and Cellular Therapies and the Ministry of Science, Technology and Innovative Production are aiming for such a shift via legislative reform.[1] In short, engagement and foresighting led to a determination that law had some characteristics which were felt to be important and useful to that technical field in that temporal period and cultural context. It demonstrates that law need not be abandoned but rather that its design and deployment must be thoughtful.

5. Conclusion

The modern biosciences require governance frameworks that are capable of simultaneously managing risk, coping with uncertainty, combatting ambivalence, and building trust, all the while encouraging the delivery of those instrumental outputs that we value/demand (better health, new technologies, commercial reward). This multi-dimensional task makes the design and delivery of good governance frameworks (eg: ones that are effective, efficient, responsive, and proportionate) extremely difficult. Efforts to date have, by and large, failed to deliver such frameworks, particularly where the law has been heavily relied on, or even implicated. Preoccupation with risk has tended to shape regulatory and governance systems, but the conception of risk relied on is deficient, and its use is often oriented to support precautionary approaches in the absence of 'evidence'.

Our collaborative efforts lead us to suggest that more robust mechanisms need to be deployed which reveal and promote interactions with the full gamut of risks, and that these must be seen as relative to the twin objective of both protecting and promoting the range of interests

involved in any given technology endeavour. Importantly, public engagement exercises have a crucial role to play here not only in providing important sources of evidence when more traditional sources are dry, but also in helping to shape governance and regulatory frameworks on an on-going basis.

As should be clear, we do not argue that the law should be ignored. It can be a valuable component of good governance in the biosciences setting. Rather, we argue for a reflexive mode of governance which is 'performed' in a manner reflective of the dynamic nature of science and which uses the law more effectively as a value- and institution-framing mechanism within a broader and more ground-up enterprise. In positing that the limits of the law must be recognised, however, and that the law must be better embedded in more interdisciplinary-designed governance regimes, we suggest that the framework designed by Laurie, Harmon and Arzuaga (2012) can usefully assist policy- and law-makers to anticipate which challenges might arise and to build systems that are sufficiently flexible and adaptive to respond timeously.

That framework was designed collaboratively and drawing on multiple disciplines. Both that experience and the authors' ongoing experience of working together (in an interdisciplinary fashion) leads us to conclude that a common foundational issue is that of the 'problem' of how to push public engagement results up into a policy framework paralleled with a need to make regulation more socially receptive and reflexive. In order to do so, however, there is a need to unambiguously define the realms of the debate and to ensure that concepts that have multiple meanings are clarified prior to utilisation. For example, 'trust' has a large and problematic history in the social sciences to which a legal scholar may well be oblivious. Our continuing efforts to collaborate despite the fact that we have very different "theories of the world in the head" we have a desire to work together.

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Footnotes

[1] These interactions include 22 qualitative stakeholder interviews as well as a series of 4 interactive stakeholder workshops held between 2007 and 2011 and involving as many as 40 key actors from a range of disciplines. For reports and recommendations emerging from these interactions, see Harmon, Laurie and Arzuaga (2007), Harmon and Laurie (2008), Harmon (2008), Harmon (2009), Harmon (2010a), Harmon (2010b).

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