Risk Compensation, Needle Exchanges and Bioethics

Life itself is risky business. Risk can be enticing because of the benefits to be gained, but also simply because of the tension that accompanies particular risks. Indeed it could be argued, "What is life without some risk?" Some are risk-takers and others avoid risk, but common to both is the desire to minimise, or at the very least safely manage the harmful consequences that can arise from the risks taken.

While we may not use the word "risk" all that often, our everyday lives are marked by decision-making that often carries an element of risk with it. Sometimes the risk is small and the possible consequences trivial. At other times the risk is more substantial and the consequences quite negative. As individuals we take risks that directly (but rarely) affect only ourselves, and at other times we take risks that may affect others in quite significant ways. Decisions made by individuals, groups, corporations, and governments about risk have the potential to affect large numbers of people. Thus have risk assessment, risk management and risk communication become important issues on the agenda of those involved in decision making for whole societies.

On a societal scale, risk assessment is the process of estimating the potential impact of a hazard on a specified human population or the environment under a specific set of conditions within an identifiable timeframe. It is the process of determining as accurately as possible both the actual likelihood and the consequences of the risks. With respect to genetically modified organisms (GMOs), one such framework has been described in the following way:

> Risk assessment is a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account.[1]

Risk management is the process of evaluating alternative actions, selecting options and implementing them in response to risk assessments.

Risk communication is the process of ensuring that an open and transparent process of identification of risks associated with a given technology has been rigorously followed, the community is adequately informed about what risks there are and how they are being managed, and public confidence in the regulatory system is maximised.[2]

For applications involving the intentional release of, for example, a GMO into the environment, the risk assessment and risk management plan should be made available to the public. Then a consultation process should seek input from government, non-government organisations and the community.

In the new biotech era a new urgency has emerged to make sense of risk, even though it would be fair to say that much of the philosophical groundwork has yet to be done.

Risk is one of those difficult words that can be hard to define. The Bioethics Encyclopaedia defines risk as,

> … an adverse future event that is not certain but only probable. Sometimes the term is used to name any uncertain future event, positive

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1 OGTR *Risk Analysis Framework* p.12

2 *Ibid*., p.13.

or negative, and frequently it is used to mean the likelihood of future harm being realised.[3]

On the basis of the first meaning, that is, " … an adverse future event that is not certain but only probable", risk involves the magnitude of negativity, or how bad the consequence is, and the probability of occurrence.

But this probabilistic interpretation of risk is only half the story, because on the second meaning risk is about "uncertainty" and refers to what cannot be clearly identified. This type of risk cannot be quantified in the way that the former can. When the extent or nature of the possible negativity cannot be known, and the probability of its occurrence cannot be given a number, we move onto very uncertain ground. Risk of this type is often called "epistemic" risk as it pertains to that branch of philosophy that has to do with the nature of knowledge. A further refinement of the way risk is conceptualised is to consider the probability and magnitude of hazards occurring *after* risk management strategies have been implemented.

One of the particular difficulties we now encounter with regard to biotechnology is the temptation to believe that all hazards or harms can not only be identified, but they can also be quantified. But such a pretence is not only illusory, it also has the potential to wreak havoc.

Another way of conceptualising risk has been adopted by Thompson and Dean[4], who identify two extremes, probabilists on the one hand and contextualists on the other. At the extreme probabilist end, the conception of risk is characterised by the probability of events and their consequences. One understands risk only if one understands probabilities and at the same time risk assessment is considered to be a value free process. This view has also been referred to as that of the 'naïve positivist'.[5]

At the opposite extreme is the contextualist conception. It sees all risk as characterised by subjective attributes that come into play depending upon the context in which the risk is being assessed. This view has also been referred to as 'social constructivist'[6] and 'relativist'[7]. Thompson and Dean argue that most conceptions of risk lie somewhere between these two extremes.

It is therefore not surprising that the concept of risk itself is not only contentious but determining risks and whether they are acceptable can be a daunting task, especially when risks are taken that affect others. People vary significantly in the risks they are prepared to take, and often perceive risks in very different ways. Furthermore, sometimes the perception of risk is quite different from one group to another. For example, the scientific community often interprets risks arising from new technologies in a more modest way compared to the wider community, and I will return to some of the reasons behind this disparity later.

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3 Schöne-Seifert, B *Risk*, in *The Encyclopedia of Bioethics*. Ed. By Warren T. Reich, MacMillan, New York, Vol. 4, PP. 2316-2321, 1995.

4 Paul B. Thompson and Wesley Dean, "Competing Conceptions of Risk", *Risk Health, Safety and Environment*, Vol. 7, (Fall, 1996).

5 K.S. Shrader-Frechette, Risk and Rationality: Philosophical Foundations for Populist Reforms, Berkeley, University of California Press, 1991.

6 Ortwin Renn, Concepts of Risk: A Classification, in Sheldon Krimsky and Dominic Golding, (eds.), *Social Theories or Risk*, Wesport Connecticut, Praeger, 1992, pp.53-79.

7 Schrader-Frechette, *op. cit.*

One of the few common features of people's calculation of risks versus benefits is inconsistency. As Teuber notes,

> Our attitudes toward risk vary according to what has happened to us, what we expect, what we feel, what we know, and what we care about. We ignore some risks, overestimate others. Our perceptions are selective and change as social life changes.[8]

He goes on to say,

> It is generally believed that consistency in judgements is a minimal condition of rationality. Since our judgements about risk are apparently inconsistent, it is hard not to draw the conclusion that our attitudes towards risk are irrational.[9]

This disturbing jibe at our own rationality about risk might be hard to swallow, and even though a brief look at some examples does appear to confirm it's truth, that apparent irrationality may have more to do with other factors taken into consideration when making a risky decision. And those other factors may be coupled up with specific values, to which I will return. The point is that even when presented with statistical information, people will still often go with what "feels" right. Such an approach, with all its inconsistencies, makes it difficult to rely upon peoples' consent when it comes to framing public policies. For that consent is not only from an inconsistent source, but at the community level it is also hard if not impossible to obtain.

How risks are perceived is informed by a complex interplay of factors, and some of the theories used to understand those factors include[10]:

1. *knowledge:* people perceive things to be dangerous because they know them to be dangerous.
2. *personality theory:* some love risk-taking, others are averse.
3. *economic theory:* (a) the rich are more willing to take risks because they benefit more and are shielded from the consequences, while the poor feel the opposite; (b) "post-materialist" – living standards have improved so the rich are more interested in social relations and better health.
4. *political theory:* struggles over interests, i.e. explanatory power in social and demographic characteristics.
5. *cultural theory:* individuals choose what to fear (and how much to fear it) in order to support their way of life. (Renn categorises people as hierarchists, individualists or egalitarians).

The importance of cultural theory is highlighted by Teuber's conclusion that:

> … we are not only end-oriented; we are also ideal-oriented. We do not care just about where we end up; we care about the kind of people we have to become in order to end up in one place or another"[11].

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8 Teuber A. "Justifying Risk" *Daedalus* 119 (1990) 235-253

9 Teuber A (1990) *op cit*

10 Wildavsky A and Dake K, "Theories of risk perception: who fears what and why?" *Daedalus* 119 (1990) pp 41-60

11 Teuber (1990) *op cit*

Slovic *et al*. have identified several subjective heuristics that people deploy when making judgements about risk:

- whether or not the risk is undertaken voluntarily,
- the immediacy of the effect if things go wrong,
- knowledge about the risk by persons exposed,
- to what extend the risks are known to science,
- the degree of control that can be exercised over the risk,
- whether the risk is new and novel or old and familiar,
- whether the effect is chronic acting gradually over time or catastrophic producing a large degree of harm in one instance,
- whether the risk is something we have learned to live with and can think about calmly, or dreaded, and
- the severity of the consequences.[12]

Clearly, the perception of risk relies upon many factors that cannot be easily pinned down or readily quantified.

If conceptualisation of risk leans heavily toward the probabilistic end of the risk concept spectrum, and indeed expressly eschews subjective factors, can the claim to be 'scientific' mean that the process is value-free?

A recent United States National Research Council report noted that:

> Ethical considerations are generally normative and cannot be resolved scientifically. Yet to ignore ethical concerns is to assume that science can and should be value-free, an obvious contradiction, since this is a normative assertion in itself (Thompson, 2001). Moreover, values can influence both the design of scientific inquiry and the interpretation of data and certainly motivate much of the pressure bought to bear on regulatory agencies and other government bodies to address impacts of biotechnology beyond those directly affecting health and the environment.[13]

According to the Australian Office of the Gene Technology Regulator when referring to the possible release of GMOs:

> The Risk Analysis Framework involves evaluating the impacts of potential risks and their significance before considering management plans. This analysis will lead to a science-based conclusion about the overall or composite level of risk, taking into account risk management measures (ie net risk). Either the risk will be too great to permit the

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12 P. Slovic, B. Fischhoff, and S. Lichtenstein, "Facts and Fears: Understanding Perceived Risk" in R. Schwing and W.A. Albers, (eds.), *Societal Risk Assessment: How Safe is Safe Enough?*, New York, Plenum Press; P. Slovic, "Perceptions of Risk: Reflections on the Psychometric Paradigm", in Sheldon Krimsky and Dominic Golding, (eds.), *Social Theories or Risk*, Wesport Connecticut, Praeger, 1992, 117-152.

13 Committee on Defining Science-Based Concerns Associated with Products of Animal Biotechnology; Committee on Agricultural Biotechnology,, Health, and the Environment; Board on Agricultural and Natural Resources, Board on Life Sciences, Division on Earth and Life Studies National Research Council, *Animal Biotechnology: Science-Based Concerns*, Washington D.C., National Academy Press, (prepublication 2002), p.121. Also available at http://www.nap.edu/catalog/10418.html?se_side. The reference to Thompson 2001 is to P.B. Thompson (2001) Food Animal Productivity and Welfare, paper presented to a National Academy of Sciences Workshop.

> dealing to proceed, or the risk will be manageable through imposed licence conditions, or there will be no risk that requires management. If there is a single (or more) significant risk (or risks) that cannot be managed, the overall risk will be regarded as unacceptable and the proposal will not be allowed to proceed.[14]

When we consider assessment of risk as 'scientific', consideration needs to be given as to what we think science can achieve. Science attempts to provide answers and explanations. Good science can provide answers that are close to correct. But the *questions* are of infinite importance since the questions reveal the values and priorities of the one who asks those questions. Who decides which questions must be asked, and why? What about the questions that are *not* asked? For example, which health effects should be measured in relation to GM products – cancers, anxiety, or maybe hiccups – and how are they measured? Furthermore, data interpretation is riddled with value judgments, for example making decisions about removing outliers, or setting confidence intervals and levels of significance.

Philip Regal puts it this way:

> Philosophers of science could do a great deal to improve the quality of risk assessment by helping regulators and the public to further identify and understand the differences between judgments based on credible scientific information and theory, and judgments based on world-views that include theory reductionism, essentialism, idealism, Greek cosmology, and utilitarianism masking as objective science … [S]ome environmentalists … also mistake Platonic or Aristotelian models of the balance and perfection of nature for hard science. They may strongly oppose any modifications of nature and may make the false claim that the science of ecology warns that any disturbance of nature is unsafe.[15]

'Scientific' risk assessment cannot be separated from values. A scientific risk analysis cannot replace the importance of values embedded in the process surrounding that analysis, even though the scientific analysis can inform that process.[16] And science itself cannot pretend to be 'objective'.[17] What is studied, how the research is designed, how it is interpreted and reported are all value-laden.[18] This leads to three corollaries. First, that disagreement about risk will not disappear in the face of 'scientific evidence'.[19] Second, that 'public education' is not the sole answer.[20] And third, that we don't only need improved risk assessment techniques; we also need greater participation in decision-making.[21]

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14 OGTR *Risk Analysis Framework* p. 17

15 Regal P J "Metaphysics in Genetic Engineering: Cryptic Philosophy and Ideology in the 'Science' of Risk Assessment", appears in Ad Van Dommelen (ed.) *Coping with Deliberate Release: The Limits of Risk Assessment*, International Center for Human and Public Affairs, Tilburg/Beunos Aires 1996: 15-32. Find also at www.psrast.org/pjrbiosafety.htm

16 Fischhoff B "Acceptable Risk: A Conceptual Proposal", *Risk: Health, Safety and the Environment* vol 5 (1): 1994

17 Thompson P B "Risk Objectivism and Risk Subjectivism: When are Risks Real?" *Risk: Health, Safety and the Environment* 1: 3 (1989) Also find at www.fplc.edu/risk/vol1/winter/thompson.htm

18 For example see Cranor C. "Scientific Conventions, Ethics and Legal Institutions", *Risk: Health, Safety and the Environment* 1 (1989):155. Presentation given at Symposium on Public Participation in Risk Management. www.fplc.edu/risk/vol1/spring/cranor.htm; the ethics of confidence and type I and II errors.

19 Slovic, Fischhoff and Lichtenstein (2000) *op cit*

20 Freudenberg W R and Rursch J A, "The risks of 'putting the numbers in context': a cautionary tale", in Löfstedt R and Frewer L, *The Earthscan Reader in Risk and Modern Society*, Earthscan London 1998, pp 77-90

21 Teuber (1990) *op cit*

When the community are informed about "what the risks are and how they are being managed" they are also being presented with a risk analysis outcome that has particular values embedded in it. If they are to accept statements such as "the risk is minimal" or "the risk is extremely low" they by implication are also being asked to accept the conceptualisation of risk adopted by the particular authority in question and the values that either frame or are inherently part of the process.

Thus, there has been a tendency for a 'Mexican stand-off' between companies involved in experiments with GMOs and large sections of the community that seem to distrust the safety and necessity for these developments.

Coming from the scientific and industry side, the developmental stages in risk management identified by Fischhoff seem to have been applied so far:

1. All we have to do is get the numbers right.
2. All we have to do is tell the public the numbers.
3. All we have to do is explain what we mean by the numbers.
4. All we have to do is show the public that they have accepted similar risks in the past.
5. All we have to do is show the public that it's a good deal for them.
6. All we have to do is treat the public nicely.
7. All we have to do is make partners of the public.
8. All of the above.[22]

Yet many sections of the community remain *sceptical* about the numbers because of their anxiety about a number of things. They are concerned that scientists cannot identify in advance all of the variables and then control for them, and that there may be catastrophic unforeseen consequences. Some argue that given there is no real necessity for these developments when the world already produces sufficient food for its populations (although we are nowhere near achieving equitable distribution), are these risks worth taking? Is it possible that the ones who are really running the agenda on risk assessment are those who stand to gain most financially and/or professionally from these developments? And if that is the case, is it possible that risks are, inadvertently or otherwise, being minimised? Moreover, many sections of the public simply do not trust "experts" where environmental issues are concerned.

That is, the attitudes one brings to a particular issue where risk assessment is concerned may well condition what one makes not only of the evidence that is available but who is interpreting the evidence.

There needs to be better communication and trust between agribusiness and science on the one hand, and the community on the other if a process is to be developed which will provide an agreed basis for risk assessment. At the moment public disquiet on the risks involved with GMOs is unlikely to be met by bland assurances of safety from business, government, and scientific authorities. That is, "just trust us" doesn't quite cut it.

22 Fischhoff, B (1998), *op. cit.*, 134

The Hastings Center (US) recently launched an international project, *Public Perceptions of Agricultural Biotechnology*, which is funded by the Rockefeller Foundation. At its first meeting in May 2000, participants from Europe and the US,

> generally agreed that perceptions of risk and benefit are multilayered and cannot be properly understood by scientific interpretations alone."[23]

The importance of trust cannot be overemphasised. Whether the issue is GMOs or embryonic stem cells, trust in those who make decisions that carry a risk for the community, even the global community, is fundamental.

The importance of trust was acutely highlighted recently in Australia in the stem cell debate. When one of the most outspoken advocates of embryonic stem cell research, also an authority on the subject and in receipt of large government grants to undertake stem cell research, was accused of misleading federal members of parliament, significant damage was done to the trust upon which relationships between scientists in biotechnology, the government and the community had been built. Government officials who relied upon expert opinion to form their views felt betrayed, as did the public and in particular, patient groups who were eager to follow researchers in search of promised cures.

Similarly, when it comes to GMOs, assurances of safety are greeted with scepticism when companies conduct their trials surrounded by secrecy and when GMO crops are introduced with specific barrier regions surrounding them.

In Slovic's analysis of trust[24], he makes the crucial and well known point that trust is fundamentally fragile, and when damaged, takes considerable time to repair. Two phenomena underlie this characteristic of trust. First, negative events that damage trust are more noticeable than positive events that build trust. Second,

I want to conclude with some comments on the risks that we may be taking in the use of human embryos in research as an example of the difficulty in identifying and quantifying risks, and yet how potentially damaging a particular course of action could be. The problem is, we just don't know.

What may be the effect of embryo experimentation on human communities and value systems?

On embryos – extinction.

Devaluing of life, loss of respect for human life

Prepared to accept that some can be sacrificed for the greater good – non-consensual. If others can likewise not consent, maybe they can also be used for the greater good.

Commodification of human life – the slide from subject to object.

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[23] *Hastings Center Report*, July-August 2000, 47

[24] Paul Slovic, Perceived Risk, Trust and Democracy. In: The Perception of Risk, Ed by Paul Slovic

Aware of slippery slopes, yet not caring – leads to a numbing of moral sensitivities. … a form of psychophysical numbing may result from our inability to appreciate losses of life as they become more catastrophic – a phenomenon that could impair our ability to make consistent, equitable and wise decisions.[25]

Redefines our understanding of what it means to be human – more committed to functionality as the criteria for defining human.

Changes our thinking - moral worth now conferred instead of inherent.

Protection of the weak and vulnerable is compromised – less tolerant.

Distributive Justice – committed to biotechnological solutions.

Already has fractured the community and raised an ugly sectarianism.

If treatments arise from embryonic stem cells some will suffer a crisis of conscience about whether to accept them.

Concluding remarks.

[25] Fetherstonhaugh *et al*., Insensitivity to the Value of Human Life: a Study of Psychophysical Numbing. *Journal of Risk and Uncertainty*, **14**, 283-300, 1997.