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Expanding Horizons: Scientific Frontiers, Legal Regulation and Globalization

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Expanding Horizons: Scientific Frontiers, Legal Regulation, and Globalization

BELINDA BENNETT*

ABSTRACT

In the six decades since the discovery of the double helix structure of DNA by Watson and Crick in 1953, developments in genetic science have transformed our understanding of human health and disease. These developments, along with those in other areas such as computer science, biotechnology, and nanotechnology, have opened exciting new possibilities for the future. In addition, the increasing trend for technologies to converge and build upon each other potentially increases the pace of change, constantly expanding the boundaries of the scientific frontier. At the same time, however, scientific advances are often accompanied by public unease over the potential for unforeseen, negative outcomes. For governments, these issues present significant challenges for effective regulation. This Article analyzes the challenges associated with crafting laws for rapidly changing science and technology. It considers whether we need to regulate, how best to regulate for converging technologies, and how best to ensure the continued relevance of laws in the face of change.

INTRODUCTION

Since our earliest days, people have explored unknown territory. Indeed, exploration is in many ways synonymous with human history. Whether we think of the earliest days of humanity and the movement of people within and beyond Africa," the great ocean journeys across the

* Professor of Health and Medical Law, Sydney Law School, University of Sydney, Australia. An earlier version of this paper was presented as the George P. Smith II lecture at Maurer School of Law, Bloomington, Indiana, on November 10, 2011. Parts of this paper were also presented at the Forum on Synthetic Biology: Challenges and Opportunities for Australia, in Sydney, Australia on March 13, 2012.


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Pacific by Polynesians, or the movement of people across land bridges in Asia during the last ice age, the new and the unknown have been constant companions. In time, the paths of some of these journeys came to be well-trodden trade routes with commodities such as spices, silks, and porcelain traveling vast distances before reaching their final destination—as was the case, for example, of the great Silk Road between China and Europe—and technology and innovation traveling alongside trade. It is necessary, however, to qualify this story of discovery of the unknown, for what was unknown territory to the discoverers was already familiar to the local populations who lived there, and at times the new arrivals brought with them death, disease, and the destruction of traditional ways of life. But this aspect of the story does not change the fact that for those who had never been there before, the territory was new and what one would find there on arrival was unknown. In this modern age of television, movies, and the Internet, it is difficult to imagine the completely unknowable nature of regions of our world in those past times. Perhaps our closest modern equivalent is outer space, although perhaps even space is not as unknowable as it once was.

The language of exploration and discovery is also used to describe modern science. We speak of scientific quests, of frontiers of knowledge, and of discoveries. There is the same sense of charting the unknown and the same sense of promise and risk sitting side by side. Just as the journeys and discoveries of old brought with them profound changes for all whose lives were touched, so too modern science brings with it the promise, and for some, the threat, of profound change.

I. THE CHALLENGE OF THE NEW

Concerns about the impact of modern science are usually focused on new technologies. This is not to suggest that there are no concerns about the impact of older technologies. Even well-established technologies may lead to concerns, such as contemporary debates about pollution and climate change. In contrast, the concerns about new technologies arise

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2. See generally id. at 53-66.
3. See generally id. at 41-44.
4. See id. at 239-64.
5. See id. at 210-14. As Diamond notes, "[t]he importance of lethal microbes in human history is well illustrated by Europeans' conquest and depopulation of the New World. Far more Native Americans died in bed from Eurasian germs than on the battlefield from European guns and swords." Id. at 210.
EXPANDING HORIZONS

when the technology is still new and emerging. However, debates about new technologies usually reveal particular anxieties about change and the pace of that change. During the twentieth century we witnessed a dramatic increase in scientific knowledge. The last 100 years have brought us the discovery of penicillin, television, computers and the Internet, the discovery of the double helix structure of DNA, the mapping of the human genome, and in vitro fertilization. There are, of course, many more examples. The rate of change in the realm of science is such that we constantly struggle to keep pace with it. Of course what is new today is not new tomorrow.

For the most part, technology rapidly becomes either obsolete or familiar. Some forms of technology, however, seem to present us with particular challenges, for they lead us to think about what it means to be human, what it means to manage risk, and whether law has a role in negotiating the technological future. These are the new or emerging technologies that are the subject of this Article.

In a recent consultation paper, the U.K. Nuffield Council on Bioethics described “emerging technologies” as those that

6. The emerging nature of new technologies presents challenges for the identification and management of risk. See Part II infra.

7. See The Nobel Prize in Physiology or Medicine 1945, NOBEL PRIZE, www.nobelprize.org/nobel_prizes/medicine/laureates/1945 (last visited Apr. 17, 2012) (“The Nobel Prize in Physiology or Medicine 1945 was awarded jointly to Sir Alexander Fleming, Ernst Boris Chain and Sir Howard Walter Florey ‘for the discovery of penicillin and its curative effect in various infectious diseases.’”).


11. The double helix structure of DNA was discovered by James Watson and Francis Crick in 1953. See generally JAMES WATSON, DNA: THE SECRET OF LIFE (2003).

12. See generally id. See also The Human Genome, 409 NATURE 745 (2001).


14. See Laurence Boisson de Chazournes, New Technologies, the Precautionary Principle, and Public Participation, in NEW TECHNOLOGIES AND HUMAN RIGHTS 161, 161 (Thérèse Murphy ed., 2009) (stating that “a ‘new technology’ of today will no longer be ‘new’ in the future, and that, more generally, all technologies are ‘new’ when they are first introduced into society”).
arise from new knowledge, or the innovative application of existing knowledge;

lead to the rapid development of new capabilities;

are projected to have significant systemic and long-lasting economic, social, and political impacts;

create new opportunities for and challenges to addressing global issues; and

have the potential to disrupt or create entire industries.  

As a consideration of assisted reproductive technologies, genetics, and nanotechnology reveals, emerging technologies bring scientific advances and social and regulatory challenges.

It is now more than thirty years since the birth of the world's first in vitro fertilization baby in England in 1978. In the subsequent period, assisted reproductive technologies (ART) have helped many infertile couples to conceive a child. So widespread is the use of ART that an estimated 3.1% of children born in Australia are conceived using ART.

The familiarity with the use of ART has eased many of the concerns that arose during the early days of the technology. Yet while we have moved past the early fears surrounding ART of "test-tube babies" and the scientific nature of the process, the increasing link between ART and genetics is, as Thérèse Murphy has pointed out, "taking us 'back to the future'... [in which] burgeoning references to designer babies and


18. As Don Chalmers noted, "The assisted reproductive technology (ART) debate has raised fundamental social, ethical and legal questions about the very essence of personhood and humanness. In the early days of ART, everything seemed possible and every ethical principle seemed vulnerable to these technologies." Don Chalmers, Professional Self-Regulation and Guidelines in Assisted Reproduction, 9 J. OF L. & MED. 414, 414 (2002).
parental eugenics could be said to resonate with the early labelling of ARTs as artificial reproduction technologies."^{19}

The discovery of the double helix structure of DNA in 1953 by Francis Crick and James Watson heralded the start of the modern genetic age.^{20} Since then, scientists have mapped the human genome, and a range of genetic mutations associated with disease have been identified, providing individuals with more information about their risk of disease.^{21} Yet, the genetic age has also brought with it heightened concerns over the potential for genetic discrimination in the context of employment and insurance,^{22} concerns over the potential for a new eugenics in the context of reproductive decision making,^{23} and concerns over the transformation of privacy rights as genetic information is increasingly configured as familial rather than individual.^{24} Genetics has also brought modification of crops, increasing production and yields while reducing loss due to pests and diseases. However, concern over the impact of genetically modified organisms on the environment has sparked public debate, and the genetic modification of foods has been controversial, particularly in England and elsewhere in Europe, where there has been widespread opposition to genetically modified (GM) foods.^{25}


20. For discussion, see generally WATSON, supra note 11.

21. For example, the BRCA1 and BRCA2 genetic mutations are associated with an increased risk of breast cancer. See BRCA1 and BRCA2: Cancer Risk and Genetic Testing, NAT'L CANCER INST., www.cancer.gov/cancertopics/factsheet/Risk/BRCA (last updated May 29, 2009).

22. For a comprehensive discussion of these issues, see AUSTL. LAW REFORM COMM'N & AUSTL. HEALTH ETHICS COMM., ESSENTIALLY YOURS: THE PROTECTION OF HUMAN GENETIC INFORMATION IN AUSTRALIA (2003).


24. See generally Dean Bell & Belinda Bennett, Genetic Secrets and the Family, 9 MED. L. REV. 130 (2001); see also Belinda Bennett, Genetics and the Transformation of the Personal, 35 MONASH U. L. REV. 296 (2009).

Like biotechnology and biomedicine, nanotechnology may allow for the development of new therapeutics. The Royal Society and the Royal Academy of Engineering define nanotechnologies as "the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometre scale."26 A nanometre is measured as one-billionth of a meter, or $10^{-9}$ m.27 Possible industrial applications from nanotechnology include the development of new cutting tools using nanocrystalline materials, the use of nanoparticles in paints to improve performance, and the use of longer-lasting nanomaterials in medical implants.28 Concerns have been expressed, however, about the potential for nano-sized particles to pose risks to human health and the environment. In their 2004 report on nanotechnology, the Royal Society and the Royal Academy of Engineering stated:

Free particles in the nanometre size range do raise health, environmental and safety concerns and their toxicology cannot be inferred from that of particles of the same chemical at larger size. The difference comes largely from two size-dependent factors: the larger surface area of small particles compared with larger particles, given equal mass, and the probable ability of nanoparticles to penetrate cells more easily and in a different manner than larger ones.29

One of the best-known concerns raised about the safety of nanotechnology is the "grey goo" scenario in which self-replicating nano-sized robots would eventually cover the planet.30 Yet in relation to grey goo, the Royal Society and the Royal Academy report concluded "[o]ur experience with chemistry and physics teaches us that we do not have any idea how to make an autonomous self-replicating mechanical machine at any scale, let alone nanoscale."31

Over recent decades, advances in reproductive technologies, genetics, and nanotechnologies have promised a dazzling array of scientific advances and benefits. At the same time, scientific and technological advances have been accompanied by concerns over the potential for unforeseen negative outcomes. Public debate around most

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27. Id.
28. Id. at 10-13.
29. Id. at 49.
30. See id. at 109.
31. Id.
new technologies share the common feature of being caught between the hope and promise of major advances on the one hand, and dystopian visions of a high-tech but bleak future on the other. The often-emotive landscape of public debate surrounding new technologies is further complicated by the pace of scientific change, which challenges all but experts to keep pace with the ever-expanding scientific frontier. For governments, the complexity of the science, the rapid pace of scientific change, the uncertain nature of risk for developing technologies, and the diversity of community views all present enormous challenges for effective regulation.

While each new technology brings a unique set of developments, possibilities, and challenges, increasingly too we are witnessing the convergence of technologies as developments in one field provide a platform for developments in another. The potential for new technologies to converge, to build upon, and leverage off each other in ways that support the development of a new round of technological advances, brings with it the potential for exciting new developments in science and technology. To date, the discussion of converging technologies has focused on “NBIC” technologies (i.e. nanotechnology, biotechnology, information technology, and cognitive science). This convergence represents the early stages of a new period in scientific advances. While biotechnology, nanotechnology, and information and communication technology have been described as being “among the last major technology initiatives of the 20th century,” their convergence has been described as “[t]he first major research initiative of the 21st century.” Alfred Nordmann describes this transformation as having wide-ranging ramifications, “[i]nf-, bio-, and nanotechnologies complement each other and have begun to join forces with cognitive science, social psychology and other social sciences. This convergence promises to transform every aspect of life.”

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35. Id.
II. RISK AND PRECAUTION

Risk is a key feature of journeys to the frontier. It is impossible to know in advance all that one might encounter on the journey, or the hazards that may be faced. As George Annas reminds us, the drawers of pre-Columbian maps often marked the boundaries of the known world with reminders that dragons inhabited the territory beyond as a symbol of the hazards of the unknown. Sometimes on our journeys of discovery the new territory brings with it a startling new insight—something that is unpredictable and unforeseen that changes our worldview. One only need to look at old maps to see this, for the discovery of a previously unknown land mass called for the redrawing of maps. Magellan's circumnavigation of the globe in the 1500s confirmed that the world was spherical rather than flat and that if you kept sailing in one direction, you would come back to your starting point rather than sail off the edge of the world.

Scientific discoveries have also transformed our outlook with the mapping of the human genome providing new insights into the nature of human health and disease. Meanwhile, nanotechnologies have altered our perceptions of scale and the properties of materials. Nikolas Rose has argued that genetic testing changes the way we think about genetic risk for, as he argues, “predictive genetic testing introduces a qualitative new dimension into genetic risk, creating new categories of individuals and according genetic risk a new calculability.” Yet, while new technologies may transform our understandings of our world in grand and sweeping ways, this challenging of one's knowledge can occur at a much more modest level and indeed may be as simple as the sighting of a bird.

Throughout European history, Europeans assumed that all swans were white. When Europeans arrived in Australia they discovered, however, that some swans were black. In fact, black swans are native to Australia, and the sighting of black swans suddenly challenged all previous assumptions about the inherent whiteness of swans. In his 2007 book, The Black Swan, Nassim Taleb uses the term “Black Swan”
to describe events that are highly improbable. As Taleb argues, the sighting of a black swan illustrates a severe limitation to our learning from observations or experience and the fragility of our knowledge. One single observation can invalidate a general statement derived from millennia of confirmatory sightings of millions of white swans.  

For Taleb, a Black Swan event has three characteristics. First, it is outside our expectations because we are unable to predict it on the basis of our past experience. Secondly, a Black Swan event has “an extreme impact.” Finally, although we were unable to predict it in advance, we will, after the event, find explanations for the event that will make it both “explainable and predictable.” These three characteristics, which Taleb summarizes as “rarity, extreme impact, and retrospective (though not prospective) predictability,” highlight the challenges we face when we attempt to plan or predict the future. According to Black Swan theory, “what you don’t know [is] far more relevant than what you do know.”

A Black Swan event is not necessarily a negative event. Taleb refers to the computer, the Internet, and the laser as three technological developments usually identified by people as having the most impact on our world. As Taleb points out, “[a]ll three were unplanned, unpredicted, and unappreciated upon their discovery, and remained unappreciated well after their initial use.” Each of these events is described as a Black Swan according to Taleb.

The Black Swan theory has some important lessons for our approach to new technologies and for our ability to predict and manage risk. Our response to risk is a key element in our response to new technologies. While the technologies outlined above offer enormous promise, they also potentially bring with them risks that we may not be able to foresee. As a recent report by the Presidential Commission for the Study of Bioethical Issues commented:

40. TALEB, supra note 38 at xvii.
41. Id.
42. Id.
43. Id. at xvii-xviii.
44. Id. at xviii.
45. Id. at xix.
46. Id. at 135.
47. Id.
Recent advances in biotechnology have transformed the life sciences, yielding a level of innovation rarely witnessed in human history. These achievements raise a host of complex and often controversial issues. Breakthroughs can help humankind in many ways, but they invariably carry some risks. Discoveries of new ways of improving or enhancing life raise public hopes and expectations, but they also raise public concerns and, often, fears.48

Our concern with risk in the context of new technologies is not surprising, for modern society has been characterized as one in which risk is a central concern. Indeed, Ulrich Beck describes contemporary society as “risk society.”49 While risk is a central concern, our approach to risk often separates risk assessment, which is a technical exercise by experts in the field, from risk management, which is essentially a political exercise.50 Although the importance of public engagement with new and emerging technologies has been recognized,51 it is important to realize that public opinion may vary across different applications of a technology.52 Furthermore, one challenging part of the public engagement process is “how to engage with the unengaged, rather than the already engaged.”53 Recognizing these challenges, Australia’s National Enabling Technologies Strategy has “engaging with the public” as one of its six themes.54

A. A Precautionary Approach to Risk?

The Precautionary Principle is one approach to managing risk in the face of uncertainty. It has been adopted widely in the context of

50. See Maria Lee, Beyond Safety? The Broadening Scope of Risk Regulation, 62 CURRENT LEGAL PROBS. 242, 244 (2009).
51. Id. at 245 (pointing out that we have moved beyond a view of public understanding of science as a deficit model where the public does not understand the science).
52. See generally Craig Cormick, Why Do We Need to Know What the Public Thinks About Nanotechnology?, 3 NANOETHICS 167 (2009).
environmental law and regulation. The Rio Declaration of the United Nations Conference on Environment and Development states the precautionary principle in the following terms in Principle 15: "[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." This cautious approach allows measures to be taken for environmental protection even where there is still scientific uncertainty over the threat. It has been suggested that this principle could also have useful application in the context of risk assessment and new technologies. In many ways, the use of the precautionary principle seems sensible. New technologies are characterized by scientific uncertainty over the nature and extent of associated risk, and an approach based on taking steps to prevent harm in the face of a threat, albeit an uncertain one, would seem to strike a workable balance.

Perhaps one of the main challenges with using the precautionary principle as a foundation for our management of new and emerging technologies is the absence of a shared definition of the principle. Although the Rio Declaration is one well-known definition of the precautionary principle, there are a number of other formulations of the principle, with versions ranging from weak to strong. Gary E. Marchant and Douglas J. Sylvester argue that although we refer to "the" precautionary principle, there is no standard or accepted version of the precautionary principle. At least nineteen different versions of the precautionary principle have been identified, differing in important respects in several different dimensions.

Both the weak and strong versions of the precautionary principle have been criticized.\(^{59}\)

In addition, the utility of the precautionary principle for managing risk has been hotly contested. Marchant and Sylvester argue, for example, that the precautionary principle is ambiguous on key issues of risk, such as the level of acceptable risk, the indicators necessary to trigger precaution, the data needed to demonstrate that it is safe to proceed with a technology, the manner whereby costs and benefits should be balanced, and the type of action needed in order to satisfy the precautionary principle.\(^{60}\)

Cass Sunstein has also critiqued the precautionary principle, arguing that it "threatens to be paralyzing, forbidding regulation, inaction, and every step in between."\(^{61}\) Sunstein does not object to the weaker versions of the precautionary principle, such as the Rio Declaration, which suggest that we should not defer regulating simply because of uncertainty.\(^{62}\) Rather, it is the stronger versions of the principle that Sunstein sees as problematic. Sunstein understands "the principle in a strong way, to suggest that regulation is required whenever there is a possible risk to health, safety, or the environment, even if the supporting evidence is speculative and even if the economic costs of regulation are high."\(^{63}\) For Sunstein, under the strong version of the principle, "the threshold burden is minimal, and once it is met, there is something like a presumption in favor of stringent regulatory controls."\(^{64}\) Rather than solving problems of risk, Sunstein argues that the precautionary principle "leads in no direction at all."\(^{65}\) As Sunstein concludes, "[t]he reason is that risks of one kind or another are on all sides of regulatory choices, and it is therefore impossible, in most real-world cases, to avoid running afoul of the principle."\(^{66}\)

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\(^{59}\) As Russell Powell observes, weak versions have been criticized as "impotent, vacuous, and trivial, and viewed as so narrow in scope and empty in prescriptive content that they add little to existing theories of policymaking and adjudication," while strong versions have been criticized as having "an irrational, parochial focus on risk-avoidance and environmental harm, which causes them to overlook the potential benefits of nonregulation and the importance of nonenvironmental factors." See Russell Powell, What's the Harm? An Evolutionary Theoretical Critique of the Precautionary Principle, 20 KENNEDY INST. ETHICS J. 181, 184 (2010).

\(^{60}\) Marchant & Sylvester, supra note 58, at 721.


\(^{62}\) See Sunstein, supra note 61, at 1012, 1016.

\(^{63}\) Id. at 1018. For discussion see Sachs, supra note 61, at 1312.

\(^{64}\) Id.

\(^{65}\) Id. at 1054.

\(^{66}\) Id.
While it is the stronger versions of the precautionary principle that have attracted the most criticism, John Applegate argues that as the principle has been adopted more widely, its elements have changed so as to become “less stringent or to narrow the scope of the principle.”\textsuperscript{67} The principle’s stronger versions have, according to Applegate, “been systematically tamed—reduced, as it were, from a tiger to a housecat.”\textsuperscript{68} Others argue that it is important that the principle not be confused “with the separate question of how precautionary regulatory policy should be, both in the breadth of regulatory targets and the stringency with which they are regulated.”\textsuperscript{69} Robert V. Percival contends that each country would need to decide, through democratic processes, “how precautionary regulatory policy should be”\textsuperscript{70} and urges us to “[f]ear not the precautionary principle.”\textsuperscript{71}

The precautionary principle does have a certain appeal as it “provides a useful framework for managing risk in the face of scientific uncertainty.”\textsuperscript{72} Perhaps most importantly, the precautionary principle allows us to take an incremental approach to regulatory decisions in the face of uncertain risks.\textsuperscript{73} Furthermore, the policy decisions involved in determining the strength of precautionary regulation will need to be made in the context of specific technologies, as the rationale for invoking the principle may vary in different contexts.\textsuperscript{74} Ultimately, the precautionary principle will be a reminder of the importance of risk and “to correct an imbalance between our perception of the costs of regulatory action and our understanding and consideration of the costs of regulatory inaction.”\textsuperscript{75} Yet, the critique of the principle highlights the need to develop sophisticated understandings of risk, while the debate over the utility of the principle as a guide for decision making serves as a clear reminder of the complexity of deciding which risks to regulate when we are dealing with new technologies and uncertain risks.

\begin{itemize}
  \item \textsuperscript{67} Applegate, \textit{supra} note 55, at 15-16.
  \item \textsuperscript{68} \textit{Id.} at 15.
  \item \textsuperscript{69} Robert V. Percival, \textit{Who’s Afraid of the Precautionary Principle?}, 23 PACE ENVTL. L. REV. 21, 22 (2006).
  \item \textsuperscript{70} \textit{Id.} at 81.
  \item \textsuperscript{71} \textit{Id}.
  \item \textsuperscript{72} Sachs, \textit{supra} note 61, at 1338.
  \item \textsuperscript{73} As Applegate argues, “[b]y providing a mechanism for regularly revisiting regulatory decisions, the precautionary principle permits early regulation in the absence of complete information because it can take another look later.” Applegate, \textit{supra} note 55, at 77.
  \item \textsuperscript{74} David Dana, \textit{The Contextual Rationality of the Precautionary Principle}, 35 QUEEN’S L.J. 67, 95 (2009).
  \item \textsuperscript{75} \textit{Id.} at 96.
\end{itemize}
B. Ethical Viewpoints and Precaution

Perceptions of risk are dependent on a range of factors, including one's ethical viewpoint. Roger Brownsword has argued that three dominant ethical viewpoints make up what he refers to as the "bioethical triangle": the utilitarian view that is concerned with human welfare; the human rights view that is focused on individual autonomy; and a third view, which Brownsword calls the "dignitarian alliance," that is concerned with threats to human dignity. As Brownsword notes:

The emergence of the new dignitarian view creates a genuinely triangular contest, the dignitarians disagreeing as much with the utilitarians as they do with the human rights constituency—with the former because they do not think that consequences, even entirely "beneficial" consequences (that is, "beneficial" relative to a utilitarian standard), are determinative; and with the latter because they do not think that informed consent cures the compromising of human dignity.

This three-way contest of ethical viewpoints has important implications for the legitimacy of regulatory responses to risk: for utilitarians, the precautionary approach will rest on a risk/benefit analysis; for human rights advocates, precaution may be articulated in terms of preventing harms to human rights; for the dignitarians, threats to human dignity are understood as a "red light" not to proceed. Indeed, as Brownsword notes, "[f]or dignitarians, the proposition that we should exercise precaution against the risk that biotechnology goes wrong misses the point; the point is that, if biotechnology goes right, human dignity is compromised." Of course, it is important to note that the concept of "dignity" is itself contested, and

76. BROWNSWORD, supra note 32, at 35; Roger Brownsword, Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies, in NEW TECHNOLOGIES AND HUMAN RIGHTS 19, 22 (Thérèse Murphy ed., 2009).
78. BROWNSWORD, supra note 32, at 39.
79. See id. at 108-10.
80. Id. at 110.
its meaning is subject to considerable scholarly debate. The important message here is that although a precautionary approach is one way of striking a balance between the benefits and risks of new technologies, a regulatory approach premised on precaution is unlikely to gain widespread legitimacy for those who believe that the technology itself is the harm. The challenge of diverse, and often deeply-held, community views about new technologies does require the development of processes for law reform and the development of regulatory frameworks that can take account of, and balance, these diverse viewpoints.

C. The Risk of Black Swans

The precautionary principle assumes that there may be scientific uncertainty over the extent and significance of risk in the context of new technologies, and that the uncertainty should not itself be a barrier to regulation. Yet the difficulty in evaluating new technologies is that the risks are, in many respects, unknowable. Furthermore, while the precautionary principle may help us to regulate in the face of potential, but as yet unquantified risks, the precautionary principle may be of limited value in helping us to anticipate a completely unexpected event that may arise—whether that is the unforeseen risk that in fact eventuates, or the entirely new technology or use of technology that comes along and completely changes the way we do things. In other words, the precautionary principle may not help us to predict Black Swan events. As Taleb notes, our tendency to predict the future based on our experience of the past, while natural for humans, does not help in anticipating Black Swan events—and it is the Black Swan events that may arise from new technologies that will be the most significant. To repeat the quote from Taleb from earlier in this Article “what you don’t know [is] far more relevant than what you do know,” Additionally, as Caroline Wraith and Niamh Stephenson have argued, we are moving from risk management focused on insurance, where risk is “calculable, probable and of relatively limited scope,” to approaches

82. See BROWNSWORD, supra note 32, at 130-31; see also ERIK PARENS, JOSEPHINE JOHNSTON & JACOB MOSES, ETHICAL ISSUES IN SYNTHETIC BIOLOGY: AN OVERVIEW OF THE DEBATES 23-25 (2009).
83. TALEB, supra note 38, at xix.
that focus on preparedness for "risks which are incalculable and potentially catastrophic." These are our Black Swan events.

The argument here should not be taken as suggesting that we throw out the precautionary principle. Indeed, far from it. The precautionary principle provides a useful framework for negotiating regulatory solutions to complex questions of risk in the face of uncertainty. Of course, if we are to avoid the potentially paralyzing effects of the precautionary principle identified by Sunstein, we will need to identify the risks, or perhaps more accurately the kinds of risks, upon which our precautionary approach is focused, and to prioritize these for our attention.

But while the precautionary principle is a valuable tool for negotiating risk, the precautionary principle alone is not sufficient. Although it works well once a technology has emerged or developed, it does not help us to develop the sort of flexible regulatory systems that we need in order to take account of the developments that we do not foresee—the Black Swan events that, according to Taleb, happen rarely, have an extreme impact and cannot be predicted in advance.

III. CUTTING EDGE LAWS FOR CUTTING EDGE SCIENCE

What factors are then relevant for the regulatory questions that arise in relation to new technologies? First, we should not underestimate the complexity and difficulty of regulating new technologies. The pace of scientific change, the uncertainty of risk, and the breadth and diversity of community opinion combine to make the already complex regulatory task even more complicated. John Applegate points out that in the context of genetically modified organisms, "two stories, of astonishing benefits and of fearsome dangers, dominate perceptions of genetically modified organisms (GMOs) and consequently dominate their regulation." Debates around risk and new technologies often range between those who express a positive view of science and technology and those who have a more cautious view. These views have been described as "pro-actionary" and "pre-cautionary." As

85. See TALEB, supra note 38, at xviii. As Boisson de Chazournes points out, "a precautionary measure must be anchored to a minimum level of knowledge, a basis of scientific data presenting a certain consistency." Boisson de Chazournes, supra note 14, at 175.
86. Applegate, supra note 57, at 208.
87. See PARENS, JOHNSTON & MOSES, supra note 82, at 18.
Brownsword notes, “under conditions of intense uncertainty, with risks of one kind or another associated with each of the options, and with divided opinion in the community, the regulatory challenge—the challenge of knowing when to regulate, and then knowing what to regulate and how—is daunting.” Part of this task involves assessing the adequacy of our existing forms of regulation and deciding the extent to which the issues raised by a new technology are truly new and whether new forms of regulation are required. Kahn has described this as the “Goldilocks question”—is the current oversight regime “too little, too much, or just right? Or do we need something different than the porridge we’ve been making for the last 30 years?” Of course, as Marchant and Sylvester point out, many new technologies are already regulated, to some degree, in existing regulatory frameworks, while other measures, such as funding decisions for research, support some areas of research and not others. The question is, do we need to regulate in this area, at this time?

Second, it is important to acknowledge the relevance of technologival convergence for law and to develop regulatory solutions that cut across traditional regulatory silos. As the authors of one recent report on synthetic biology have argued:

As emerging technologies converge, it becomes clearer that the ethical issues raised by these technologies are at core similar and familiar. It would be a waste of resources to take up the ethical questions in parallel; i.e., it is not profitable to invent a “new kind” of ethics for each new technology. Instead, we need to get better at productively engaging the familiar ethical questions that cut across those emerging—and converging—technologies. It is time to go from speaking about hyphenated ethical enterprises (gen-ethics, nano-ethics, neuro-ethics, synbio-ethics) to speaking about the ethics of emerging technologies.

88. BROWNSWORD, supra note 32, at 123; See also BENNETT, supra note 32, at 13-14.
89. See Diana M. Bowman, Governing Nanotechnologies: Weaving New Regulatory Webs or Patching Up the Old?, 2 NANOETHICS 179 (2008); Christopher J. Preston et al., The Novelty of Nano and the Regulatory Challenge of Newness, 4 NANOETHICS 13 (2010). See also, Bennett, supra note 33.
91. Marchant and Sylvester, supra note 58, at 714.
92. PARENS, JOHNSTON, & MOSES, supra note 82, at 4. See also Bennett, supra note 33, at 155-56.
A similar issue arises in relation to regulatory responses to convergence as “[i]ssues relating to the development of enabling technologies straddle jurisdictional and portfolio boundaries.”93 Diana Bowman and Graeme Hodge have identified the relevance of scientific convergence for regulation in the context of nanotechnology.94 They argue that in order to avoid “regulatory fissures” or gaps, governments must address the issues relating to nanotechnology across “six regulatory frontiers”: “product safety, privacy and civil liberties, occupational health and safety (OH&S), intellectual property (IP), international law and environmental law.”95 Addressing issues of technological convergence means that we need to look at the similarities and points of connection between technologies in order to assess the adequacy of our existing regulatory frameworks.

Third, we need to ensure that legislation is flexible and responsive to change. It is tempting to assume that a legal solution is a long-term and perhaps even permanent solution. Yet, in the context of new technologies, this may not be the case. Technologies change over time, they develop, they converge with other technologies, and they are put to uses that we could not have imagined in the early days of the technology. Fifteen years ago, how many of us could have foreseen the development of social networking and the way it would transform personal interaction? How many of us could have foreseen that personal computers and the Internet would also bring spam, phishing, and identity theft as new areas of concern? Because of the way that technologies change over time, it is important to accept that a legal solution may only be temporary. This means accepting that laws may need to be subject to regular review, and possibly regular change, in response to new needs and new knowledge.

In 1970, Justice Windeyer of the High Court of Australia commented on “[l]aw, marching with medicine but in the rear and limping a little,”96 and the challenges for law are as real now as they were then. If laws fail to keep pace with scientific change, they can quickly become irrelevant and fail to achieve the purpose for which they were introduced. Yet this challenge, of what Brownsword calls “regulatory connection,” brings its own challenges. As Brownsword notes: “[T]hese features geared for connection and flexibility tend to

93. DEPT OF INNOVATION, INDUS., SCI. & RES., supra note 54, at 3. See also Bennett, supra note 33, at 156-57.
95. Id. 12.
militate against predictability and consistency. Equally, if connection is maintained by regular review of legislation, the price to be paid is a period of regulatory uncertainty which, arguably, serves to chill investment and research initiatives. 97

Fourth, the contested nature of ethics in contemporary society—illustrated by Brownsword’s bioethical triangle—highlights the challenges associated with finding a common ethical language for ethically contentious issues. George P. Smith has argued that law can play an important role as “a third culture” between science and social commentary, thus endeavouring “to provide a framework for principled decision-making for complex biotechnological and medical issues in the 21st century.” 98 Recognizing that law has a role in this area is important, for as Smith has observed, “every complex moral issue is more often than not, transformed into a legal issue.” 99 In this context, Smith argues, law becomes the stabilizing force for human affairs. 100 Finding a stabilizing role for law is perhaps more important than ever before for, as Charles Taylor has pointed out, this is “a secular age.” 101

Finally, we must remember that because no country is an island, at least in terms of trade and technology, we need to continue to explore opportunities for international dialogue so that we can, as far as possible, develop harmonized approaches to the challenges posed by new technologies. Although law tends to be jurisdictionally based, national borders do not limit science, medicine, and business. The search for commonality is not an easy task, and the development of a global consensus has proven difficult, 102 although the international human rights reflected in the Universal Declaration of Human Rights 103 and, more recently, the Universal Declaration on Bioethics and Human Rights, 104 do represent efforts to articulate universal values. There is

98. George P. Smith, Setting Limits: Medical Technology and the Law, 23 SYDNEY L. REV. 283, 283 (2001). See also BENNETT, supra note 32, at 11-13; Bennett, supra note 33, at 159.
99. George P. Smith, Law, Religion and Medicine: Conjunctive or Disjunctive?, 2006 MACQUARIE L. SYMP. 9, 16. For discussion of Smith’s article see Belinda Bennett, Medical Science and the Law, 2006 MACQUARIE L. SYMP. 41.
100. See Smith, supra note 99, at 35.
value in continuing to search for common ground.\textsuperscript{105} The increasing recognition of the relevance of human rights to health and bioethics and to the development of the law\textsuperscript{106} demands that we look beyond our own borders and engage with the international community in meaningful ways about the best solutions to common problems facing humanity.

It may be that with all of these challenges, the regulatory task just seems too difficult. We could adopt a wait and see approach, holding back on regulation until we know for sure exactly what regulation is needed. However, "[i]n making our regulatory choices, we are making choices over the kind of society we want to have and the values that we hold dear."\textsuperscript{107} Ignoring the issues will not make them go away, and medical science and technology present challenges of global significance.\textsuperscript{108} Within this context, there is an important role for law. Francis Fukuyama argues that we need to move beyond polarized debates over biotechnology. As he says:

\begin{quote}
[w]hile everyone has been busy staking out ethical positions pro and con various technologies, almost no one has been looking concretely at what kinds of institutions would be needed to allow societies to control the pace and scope of technology development.\textsuperscript{109}
\end{quote}

The unknowable nature of Black Swan events means that we need to move beyond preparing for those events that may be uncertain but that are, at least to some degree, knowable, and move to models of regulation that anticipate not only foreseeable risks, but also the unknown and the unknowable. This means expressly adopting flexible and holistic approaches to regulation that will enable us to respond to new technologies and their challenges as they emerge. This is easier said than done. Even if we were to embrace the precautionary principle, in either a weak or strong version, we would need to develop approaches to law that embrace uncertainty and change. At a fundamental level, a


\textsuperscript{106} Smith, supra note 81; See \textit{Health Care and Global Justice}, supra note 104; \textit{Human Rights and Bioethics}, supra note 104.

\textsuperscript{107} BENNETT, supra note 32, at 115.


\textsuperscript{109} \textit{FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION} 183 (2002).
regulatory approach premised on precaution presents challenges to our traditional understanding of the role of law in the setting of clear limits and in providing clarity. As Jaye Ellis argues:

\[\text{[p]recaution seems destined to defeat these attempts with its fluidity and flexibility, the amorphous nature of the boundaries that are meant to identify and constrain the scope of its application, and with its injunction to keep changing the rules of the game as new knowledge and understandings are accumulated.}\]

Yet such is the nature of new technologies that recognition of the need for regulatory responses to be flexible and adaptive must be a key element in planning for the future.

A. A Role for Law Reform Commissions?

The factors outlined above represent formidable challenges for the development of regulatory responses to new technologies. The complexity of the science, the pace of change, the diversity of community viewpoints, the relevance of converging technologies, and the significance of global developments for regulation at a national level all give particular importance to the regulatory task. The model of Law Reform Commissions, used in many common law jurisdictions, provides a well-established framework for detailed consideration of law reform and would seem to be well suited to the task of considering "wide-ranging and controversial legal issues."\(^{110}\)

While law reform may arise from the recommendations of committees or inquiries,\(^{111}\) formal law reform commissions have been established in the U.K., Australia,

New Zealand and the Pacific Islands; Canada (federal and provincial); Hong Kong and South Asia (India, Pakistan, Sri Lanka and Bangladesh); the Caribbean (Jamaica, Trinidad and Tobago); and Eastern and


Southern Africa (South Africa, Namibia, Malawi, Lesotho, Kenya, Uganda, Tanzania, [Democratic Republic of the Congo], and Zimbabwe).\textsuperscript{113}

Modern law reform commissions have been described as permanent, authoritative, full-time, independent, generalist, interdisciplinary, consultative, and implementation-minded.\textsuperscript{114} Neither the courts nor the legislature are particularly well positioned to undertake law reform efforts: the courts, because they must necessarily focus on the issues related to the individual matter before them, and the legislature, because of the challenge of fitting law reform activities into busy legislative agenda.\textsuperscript{115} As Michael Tilbury has argued, a core function of law reform commissions is to provide advice to governments on legal policy:

Yet, the core function of law reform commissions in Australia can be identified both historically and from a present-day perspective: whether a commission is self-referencing or dependent on receiving its work from a government, its function in practice is to provide advice on legal policy. Indeed, the provision of such advice, which distinguishes law reform bodies from legislatures (which make law) and courts (which decide disputes), is implied in the articulated functions of all law reform commissions. Since commissions cannot themselves effect alterations in the law, they can only do so by providing advice, especially through formal recommendations, on how the law should be reformed.\textsuperscript{116}

In the field of science and technological change, law reform commissions can play a vital role in consideration of regulatory options and in community engagement with those options. Law reform commissions in Australia and New Zealand have reported on a wide


\textsuperscript{114} Weisbrot, \textit{supra} note 113, at 22-35.


\textsuperscript{116} \textit{See} Tilbury, \textit{supra} note 115, at 324.
range of issues relevant to new technologies in medical science including: human tissue transplants,\textsuperscript{117} genetic privacy,\textsuperscript{118} gene patents,\textsuperscript{119} reproductive technologies,\textsuperscript{120} surrogacy,\textsuperscript{121} and legal parentage of children conceived through assisted reproductive technologies or surrogacy.\textsuperscript{122} The principle of community consultation has been a defining feature of the work of law reform commissions in Australia. Indeed, as Michael Kirby, the first Chairman of the Australian Law Reform Commission (ALRC) has noted:

> [p]robably the most original “value added” of the ALRC—and its chief contribution to the law reform technique in the years after its establishment—was its emphasis on public consultation.\textsuperscript{123}

The independent nature of the commissions and their consultative approach to policy development allows for community engagement, consultation, and debate. For example, for their landmark 2003 report on genetic privacy,\textsuperscript{124} the ALRC and the Australian Health Ethics Committee (AHEC) undertook widespread consultation involving public hearings and submissions from community, commercial, and professional groups, as well as consultation with international agencies,\textsuperscript{125} ultimately producing “an independent, evidence-based and dispassionate set of recommendations to carry Australia forward.”\textsuperscript{126}

By engaging the community in discussions about the formulation of legal policy, law reform commissions “can play an important role in

\textsuperscript{117} See generally AUSTL. LAW REFORM COMM’N, HUMAN TISSUE TRANSPLANTS (1977).
\textsuperscript{118} See generally AUSTL. LAW REFORM COMM’N & AUSTL. HEALTH ETHICS COMM., supra note 22.
\textsuperscript{119} See generally AUSTL. LAW REFORM COMM’N, GENES AND INGENUITY: GENE PATENTING AND HUMAN HEALTH (2004).
\textsuperscript{120} See generally NEW SOUTH WALES LAW REFORM COMMISSION, ARTIFICIAL CONCEPTION: HUMAN ARTIFICIAL INSEMINATION (1986); NEW SOUTH WALES LAW REFORM COMMISSION, ARTIFICIAL CONCEPTION: IN VITRO FERTILISATION (1988); VICTORIAN LAW REFORM COMMISSION, ASSISTED REPRODUCTIVE TECHNOLOGY AND ADOPTION (2007).
\textsuperscript{121} See generally NEW SOUTH WALES LAW REFORM COMM’N, ARTIFICIAL CONCEPTION: SURROGATE MOTHERHOOD (1988).
\textsuperscript{122} See generally N.Z. LAW COMM’N, NEW ISSUES IN LEGAL PARENTAGE (2005).
\textsuperscript{123} Michael Kirby, Are We There Yet?, in THE PROMISE OF LAW REFORM 433, 435 (Brian Opeskin & David Weisbrot eds., 2005).
\textsuperscript{124} See generally AUSTL. LAW REFORM COMM’N & AUSTL. HEALTH ETHICS COMM., supra note 22.
\textsuperscript{126} Id. at 386.
building public trust." As Marcia Neave has argued, "public participation in the law reform process is a form of civic conversation, which can reinforce community trust in the rule of law and in legal institutions." Importantly, law reform commissions can also share information and expertise with other law reform commissions, a valuable feature in an increasingly globalized world.

In their 2003 report on genetic information, the ALRC and AHEC identified "seven attributes of the reform process" to ensure that legal reform would be relevant to future scientific developments. These attributes required that:

[G]overnments and other public institutions should:

- Promote widespread community participation in the formulation of relevant rules and principles;
- Find appropriate balances between competing interests;
- Adopt processes that facilitate contributions from all relevant disciplines;
- Consider the cross-border implications of the issues, whether they be federal or international in character;
- Consider forms of regulation that are flexible and quick to adapt to changing circumstances;
- Seek simple and effective regulation through greater harmonisation of the regulatory regimes in different jurisdictions; and
- Establish and maintain such institutions as are appropriate to address, on an on-going basis,

issues relating to the use and protection of human genetic information.\textsuperscript{130}

By reviewing our laws with these attributes in mind, we can ensure that our regulatory frameworks engage public trust and have the necessary flexibility to respond to new technologies.

CONCLUSION

We are all traveling together on a journey to the future. Since ours is a highly technological age, it is clear that our journey will, in many ways, be a technological one. Some of those technologies and uses of the technologies will be foreseeable, at least to some degree. But, as we travel along this journey, we may see some Black Swans along the way—completely new technologies may develop, or existing technologies may develop in surprising new ways. Law has an important role to play on the scientific frontier, and we must consider how best to craft our laws so they provide appropriate support for our journey to the future.

\textsuperscript{130} Austl. Law Reform Comm’n & Austl. Health Ethics Comm., supra note 22, at 155. See also Bennett, supra note 32, at 116-18.