

CANADIAN HEALTH LAW AND POLICY, 3RD ED.
CHAPTER 13

EMERGING HEALTH TECHNOLOGIES*

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I. THE ELIXIR OF THEUTH

It is not uncommon for a given society to perceive of itself as perched on the cusp of radical transformation in the fields of health and medicine. Steeped in mathematics and the natural sciences, the ancient Pythagoreans developed a careful and rigorous diet with the belief that, by understanding the four archetypal elements and keeping the body free of its base “Titanic” nature, they could achieve immortality.¹ Several centuries later, following numerous advances in the science of chemistry, Paracelsus radically transformed medicine² by advancing the theory that illness was not caused by an imbalance in the composition of natural elements or the four humours (as the ancients had believed), but that disease must be understood in terms of chemical causes that could be treated with chemical cures. He and other alchemists believed that the principles behind the transmutation of base metals into gold and silver might furnish a similar technique to create an “elixir of life”.

With increasing optimism in the wake of a new millennium, the medical community continues today in its quest for a universal panacea. Articulating its vision of the 21st Century, the *World Health Organization* has proclaimed that:

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1 BBC, “Pythagoras, c. 580 — c. 500 BC”, Historic Figures, online: <http://www.bbc.co.uk/history/historic_figures/pythagoras.shtml>.

2 Debates raged in Paris in the mid to late 16th century over the place of alchemy within the field of medicine. As Moran notes in Bruce T. Moran, *Distilling Knowledge: Alchemy, Chemistry, and the Scientific Revolution* (Cambridge: Harvard University Press, 2005) at 74-75

The real question being asked in the Parisian debate was this: Should alchemy be accepted as an independent discipline, which, because of its powers of understanding the operations of nature and the body, was not merely a part of medicine but *reigned over* medicine and provided medicine with a new, chemical, rationality?... The real problem was whether alchemy provided a better overall understanding of the workings of the body and better ways to maintain health than other, more ancient forms of medical wisdom.

Now, as we near the end of one century and enter the next, our past achievements and technological advances make us more optimistic about our future than perhaps at any stage in recent history.³

Canadian health agencies have expressed similar optimism. Consider the following remarks made by Dr. Alan Bernstein⁴ in an address to the Senate Standing Committee on Social Affairs, Science and Technology:

It would not be an understatement to state that the current revolution in health research will be one of the drivers, if not the single largest driver, of change in the health care system in the next 10 to 20 years. This scientific revolution is being fueled by our rapidly emerging understanding of the molecular basis of life, of human biology and human disease, and the recent and ongoing advances in genetics and genomics, together with an appreciation that our health and susceptibility to disease is really the summation of a complex interplay between environmental factors, genetics and social factors. That appreciate [sic] will transform our health care system in the next 10 to 20 years.⁵

In light of the optimism that is practically embedded into the design of emerging health technologies, it is perhaps instructive to commence this chapter with a brief retelling of an ancient myth about an inventor and the King of Egypt.

As the story goes,⁶ King Thamus was once visited by an inventor named Theuth. Seeking fame and fortune, Theuth hoped that the king would make his inventions widely available to the people of Egypt. In reference to one of his very best discoveries, Theuth promised the king that his new technology “will make the Egyptians wiser and will improve their memories; for it is an *elixir* of memory and wisdom that I have discovered.”⁷ Much to his chagrin, rather than praising him for the elixir, the king chided the inventor:

Theuth, my paragon of inventors, the discoverer of an art is not the best judge of the good or harm which will accrue to those who practice it. So it is in this; you ... have out of fondness for your offspring attributed to it quite the opposite of its real function. Those who acquire it will cease to exercise their memory and become forgetful; they will rely on [the elixir] to bring things to their remembrance by external signs instead of by their own internal resources. What you have discovered is a receipt for recollection, not for memory. And as for wisdom, your pupils will have the reputation for it without the reality: they will receive a quantity of

³ World Health Organization, *The World Health Report 1998 – Life in the 21st Century: A Vision For All* (Geneva: World Health Organization, 1998) at v.

⁴ President of the Canadian Institutes of Health Research.

⁵ Standing Senate Committee on Social Affairs, Science and Technology, *The State of the Health Care System in Canada*, 1st Sess., 37th Parl., Issue 9 (April 26, 2001).

⁶ The most famous retelling of the myth of Theuth is found in Plato’s *Phaedrus*.

⁷ Plato, *Phaedrus*, R. Hackforth, trans. (Cambridge: Cambridge University Press, 1972) at para. 274e.

information without proper instruction, and in consequence be thought very knowledgeable when they are for the most part quite ignorant. And because they are filled with the conceit of wisdom instead of real wisdom they will be a burden to society.⁸

So, what are we to learn from this exchange?

On one level, the myth of Theuth's elixir provides a succinct articulation of the two sides in the debate about memory enhancers. Although an ancient debate, it is one that recurs in modern times.⁹ The judgment of King Thamus also reminds us that we are often not well suited to evaluate emerging technologies because their future use may be subject to unintended consequences. A technology created for one purpose can be used for another: the stethoscope can be used to monitor a beating heart in crisis or to crack a safe.

But the story of Theuth's elixir is not just about opposing views on the social value of particular technological artifacts or their potential for misuse; it is not just about whether Theuth's memory elixir is good *or* bad for society. Carefully crafted by Plato,¹⁰ the moral of the story hinges on the indeterminacy of the word "elixir". Like the Greek word *pharmakon*, from which it derives, the notion of an "elixir" carries a duality of meaning. As Jacques Derrida points out in an essay titled "Plato's Pharmacy",¹¹ the word *pharmakon* refers to an undulating word-play in the practically invisible quantum between "poison" and "cure". In this sense, the story of Theuth's elixir challenges us to consider what happens when a technology is both good *and* bad; when it is at one and the same time the solution and the problem.

As the philosopher of technology, Langdon Winner, once warned:

[i]n our accustomed way of thinking technologies are seen as neutral tools that can be used well or poorly, for good, evil, or something in between. But we usually do not stop to inquire whether a given device might have been designed and built in such a way that it produces a set of consequences logically and temporally *prior to any of its professed uses*. ... technologies, however, encompass purposes far beyond their immediate use. If our moral and political language for evaluating tech-

⁸ Plato, *Phaedrus and Letters VII and VIII* (New York: Penguin Books, 1973) at 96.

⁹ One might just as easily replace Theuth's elixir with modern cognitive enhancers such as Prozac, Ritalin or other nootropic drugs and then imagine a reply by Francis Fukuyama not dissimilar to the judgment of King Thamus. See Francis Fukuyama, *Our Posthuman Future* (New York: Farrar, Straus and Giroux, 2002); and Ronald Bailey, "The Battle for Your Brain", Reasononline, February 2003, online: <<http://www.reason.com/0302/fe.rb.the.shtml>>.

¹⁰ Plato's presentation of the myth of Theuth's elixir is rich in irony. It is told through the voice of Socrates, the philosopher most famous for never having written anything. Plato used the character of Socrates in Plato's own writing as the vehicle for the delivery of Plato's own philosophy, written in prose so intriguing and influential that it has been said that "[t]he safest general characterization of the European philosophical tradition is that it consists of a series of footnotes to Plato". Alfred North Whitehead, *Process and Reality* (New York: Free Press, 1979) at 39.

¹¹ Jacques Derrida, "Plato's Pharmacy", in *Dissemination*, Barbara Johnson, trans. (Chicago: University of Chicago Press, 1981).

nology includes only categories having to do with tools and uses, if it does not include attention to the meaning of the designs and arrangements of our artifacts, then we will be blinded to much that is intellectually and practically crucial.¹²

In this chapter, we briefly survey four emerging technologies that are likely to have a significant impact on Canadian health law and policy in the coming years as both problems *and* solutions, as political artifacts that draw our attention to the meaning of their designs and arrangements. Our aim is not so much to prioritize or predict as it is to offer a new lens through which to consider various fundamental legal and ethical principles and their application to health law and policy in novel situations. Rather than providing comprehensive coverage of all known technologies or every issue that might possibly arise, we have chosen to sample a particular array of current and future technologies, presenting each alongside a core health law precept or principle.

We commence with a consideration of the Human Genome Project and how social policy might contend with the possibility of genetic discrimination. Then, we examine Radio Frequency Identification (RFID) technology as a means of linking an unconscious or disoriented patient to an electronic health record and the potential privacy implications of doing so. Next, we investigate stem cell research and the questions it raises about the challenges associated with making policy in a morally contested area. Finally, we contemplate issues not yet articulated in a field not yet defined: nanotechnology and how to regulate against potentially catastrophic harms that are not yet understood. After surveying these four emerging technologies and the issues they raise, we end the chapter with a brief consideration of issues associated with how science and technology are transferred from the laboratory to the community through the process of commercialization.

II. EMERGING TECHNOLOGIES

A. HUMAN GENETICS

The Human Genome Project (HGP), the international effort to map the entire human genome, was completed just a few years ago.¹³ This research initiative is one of the largest and most significant research efforts in human history. It has already generated a tremendous amount of new scientific knowledge¹⁴ and has laid the foundation for the development of new health care technologies and

¹² Langdon Winner, *The Whale and the Reactor: The Search for Limits in an Age of High Technology* (Chicago: University of Chicago Press, 1988) at 25.

¹³ The official website for the Human Genome Project declares: “The Human Genome Project was completed in 2003”. Despite this pronouncement, much of the detail work continues. See: Human Genome Project Information, Post-Human Genome Project Progress & Resources, online: <http://www.ornl.gov/sci/techresources/Human_Genome/project/progress.shtml>.

¹⁴ Francis Collins, “The Heritage of Humanity” (2006) S1, *Nature* 9.

therapies, including genetic tests to assist in the diagnosis and prevention of disease and drugs that are tailor-made to the genetic characteristics of individual patients, thus maximizing the benefits while, at the same time, minimizing the side effects.¹⁵ While we need to be careful not to succumb to the hype that has surrounded genetics (in fact, many of the promised breakthroughs have been slow to materialize),¹⁶ there is little doubt that this is an area of research that will, one day, have a significant impact on our health care system.

However, the advances in the area of human genetics have also generated a variety of concerns.¹⁷ Indeed, almost from the start of the HGP there has been concern that the scientific revolution in human genetics would result in new forms of genetic discrimination and the stigmatization of certain communities.¹⁸ In particular, there was concern that the information would be used in the context of employment decisions, health care and life insurance.¹⁹ Shortly after the start of the HGP, Professor O'Hara summarized the concerns as follows:

The use of genetic testing or test results has many adverse social and ethical problems leading to social stigmatization as well as a potential for creating an entire

¹⁵ For a useful overview of the uses of genetic testing technologies see Government of Canada BioPortal, "Genetic Testing", online: <<http://biobasics.gc.ca/english/View.asp?x=780>>.

¹⁶ Timothy Caulfield, "Popular Media, Biotechnology and the 'Cycle of Hype'" (2005) 5 J. Health L. & Pol'y 213. See also Collins, "The Heritage of Humanity" (2006) S1, Nature 9 at 12, where the author suggests that the research has been clouded by hype but: "Now, in 2006, when we consider the ultimate impact of the study of the genome on medicine and society, it is clear that, as long as we are patient, we are indeed in for some profound transformations".

¹⁷ There is a vast literature on the ethical, legal and social issues associated with human genetics, including work on the issues associated with the patenting process, concerns about potential eugenic applications, and its impact on health care systems. For example, see Tom Murray, Mark Rothstein & R. Murray, eds., *The Human Genome and the Future of Health Care* (Bloomington: Indiana University Press, 1997); Glenn McGee, *The Perfect Baby: A Pragmatic Approach to Genetics* (New York: Rowman and Littlefield, 1997); Therese Marteau & Marin Richards, eds., *The Troubled Helix* (Cambridge: Cambridge University Press, 1996); Phillip Kitcher, *The Lives to Come: The Genetic Revolution and Human Possibilities* (Toronto: Simon and Schuster, 1996); Lori B. Andrews et al., *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington D.C.: National Academic Press, 1994); R. Hubbard & E. Wald, *Exploding the Gene Myth* (Boston: Beacon Press, 1993); Tom Wilkie, *Perilous Knowledge: The Human Genome Project and Its Implications* (Boston: Faber and Faber, 1993); George Annas & Susan Elias, eds., *Gene Mapping: Using Law and Ethics* (Oxford: Oxford University Press, 1992); Richard C. Lewontin, *Biology as Ideology: The Doctrine of DNA* (New York: Harpers Perennial, 1992); Danial Kevles & L. Hood, *The Code of Codes* (Cambridge: Harvard University Press, 1992).

¹⁸ For example, see C. Lee, "Creating a Genetic Underclass: The Potential for Genetic Discrimination by the Health Insurance Industry" (1993) 13 Pace L. Rev. 227: "The single most effective way to prevent abuse is a ban on the use of genetic information in health insurance underwriting".

¹⁹ Trudo Lemmens, "Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?" (2000) 45 McGill L.J. 347-412.

population of uninsurable individuals. In addition, genetic testing by insurers can lead to serious psychological damage to those who test positive.²⁰

As a result of these issues, many jurisdictions throughout the world have legislated prohibitions against the use of genetic information for anything other than health reasons and research.²¹ In the U.S., for example, most states have enacted some form of “anti-genetic discrimination” law.²² The laws differ greatly in the types of discrimination that they protect against. Some, for example, prohibit discrimination against individuals with specific genetic traits or disorders while others “regulate both the use of genetic testing in employment decisions and the disclosure of genetic test results”²³ All, however, were enacted as a result of the concerns over genetic discrimination.

No province in Canada has enacted a specific anti-genetic discrimination law. Because of our publicly funded health care system, there is less concern about the impact of genetic testing on health care insurance and access to the health care system than in the U.S. Nevertheless, many policymaking entities have recommended some policy reforms,²⁴ including limiting the use of genetic information in the context of insurance and employment, strengthening privacy laws and mandating an entitlement to a minimum amount of life, disability and health insurance.²⁵

²⁰ S. O'Hara, “The Use of Genetic Testing in the Health Insurance Industry: The Creation of a ‘Biologic Underclass’” (1993) 22 Cambridge SW. U. L. Rev. 1227. See also P. Billings, *et al.*, “Discrimination as a Consequence of Genetic Testing” (1992) 50 Am. J. Hum. Genet. 476.

²¹ Bartha Knoppers & Yann Joly, “Physicians, Genetics and Life Insurance” (2004) 170 C.M.A.J. 1421; “In Europe, the Convention on Human Rights and Biomedicine ratified by 17 countries unambiguously states that genetic testing can be used only for health reasons and for research”. For an example of relevant legislation see also P. Kossiem, M. Letendre & B. Knoppers, “Protecting Genetic Information: A Comparison of Normative Approaches” (2000) 2 GenEdit, online: <www.humgen.umontreal.ca/en/GenEdit.cfm>.

²² Human Genome Project Information, “Genetics Privacy and Legislation”, online: <http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml#II>. See also National Conference of State Legislatures, “State Genetic Privacy Laws”, State Genetic Table on Privacy Law, online: <<http://www.ncsl.org/programs/health/genetics/prt.htm>>:

The majority of state legislatures have taken steps to safeguard genetic information beyond the protections provided for other types of health information. This approach to genetics policy is known as genetic exceptionalism, which calls for special legal protections for genetic information as a result of its predictive, personal and familial nature and other unique characteristics.

²³ Human Genome Project Information, “Genetics Privacy and Legislation”, online: <http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml#II>.

²⁴ Ontario Law Reform Commission, *Report on Genetic Testing* (Ontario, 1996); Privacy Commissioner of Canada, *Genetic Testing and Privacy* (Ottawa, 1992).

²⁵ For a review of possible policy options, see Bartha Knoppers *et al.*, “Genetics and Life Insurance in Canada: Points to Consider” (2002) 170 C.M.A.J. Online 2.

The concern of and regulatory responses to genetic discrimination raise some interesting policy questions. First, to what degree is genetic discrimination really a social problem worthy of a legislative action?²⁶ The public certainly seems worried about it, particularly in the U.S., where access to health insurance is a profound issue.²⁷ In fact, there is some evidence that the concerns about discrimination may deter participation in research and therapy and “influence access to care”²⁸ In one study it was found that 52.4 per cent of U.S. clinicians believed that mutation carriers have difficulty obtaining health insurance and “13% would not encourage genetic testing, despite a family history of cancer”.²⁹ Another study of almost 90,000 patients in the U.S. and Canada found that 40 per cent agreed with the statement: “genetic testing is not a good idea because you might have trouble getting or keeping your insurance”.³⁰

Despite these perceptions, some commentators have questioned the existence of the genetic discrimination problem — or, at least, its magnitude. Hank Greely, for example, has suggested that: “studies have shown that although there is widespread concern about genetic discrimination, there are few examples of it — and no evidence that it is common”.³¹ Others note that the current value of genetic information to insurers is likely fairly limited — largely because the meaning and predictive value of genetic data remains complex and unclear. As stated by Knoppers *et al.*: “Understanding the significance and impact of genetic testing results is difficult, and therefore, at the present time, genetic information

²⁶ See, for example, T. Lemmens, “Selective Justice, Genetic Discrimination, and Insurance: Should We Single Out Genes in Our Laws?” (2000) 45 McGill L.J. 347. The author provides an interesting critique of the anti-discrimination legislation, arguing that it does not address the underlying inequities associated with health disparities and access to health care.

²⁷ April Lynch, “Patients Fear Insurance Hikes and Hide Genetic Conditions”, Knight Ridder News (December 29, 2004), online: <<http://www.BillingsGazette.com>>: “Afraid that they will be denied care in an increasingly cutthroat health-care market if insurers know too much about them, patients are getting genetic tests without telling insurers, or even their doctors”.

²⁸ R. Nedelcu *et al.*, “Genetic Discrimination: The Clinician Perspective” (2004) 66 Clin. Gen. 311. See also Steve Mitchell, “Public Fears Genetic Discrimination”, American Assoc. of People with Disabilities (May 26, 2005), online: <<http://www.aapd-dc.org/News/disability/fearsgenetic.html>>.

²⁹ *Ibid.*

³⁰ Mark Hall *et al.*, “Concerns in a Primary Care Population about Genetic Discrimination by Insurers” (2005) 7 Genet Med 311; see also Peter Neuman, James Hammitt, Curt Mueller *et al.*, “Public Attitudes about Genetic Testing for Alzheimer’s Disease” (2001) 20 Health Affairs 252.

³¹ Hank Greely, “Banning Genetic Discrimination” (2005) 353 N.E.J.M. 865. However, see Peter Aldous, “Victims of Genetic Discrimination Speak Up”, NewScientist.com (November 5, 2005) online: <<http://www.newscientist.com/channel/life/genetics/mg18825244.300-victims-of-genetic-discrimination-speak-up.html>>: “Evidence is growing that employers and insurers are discriminating against people whose genes make them susceptible to serious diseases. In the most complete survey yet of possible discrimination, around 1 in 12 people who have taken a genetic test said they had been disadvantaged as a result — for example, by being denied appropriate life insurance”.

can rarely be effectively used in risk assessment”³² Unless this information has real actuarial value, it seems unlikely that it will be widely used, at least by insurers. And if others such as employers use it to draw scientifically inappropriate conclusions about individual risk, then education about the complex nature of genetic information, rather than prohibitions on its use, may be the more appropriate policy response.

Second, this controversy provides the opportunity to ask whether genetic information is truly special. In other words, should the law be treating genetic information as distinct from other forms of health information? Survey research has shown that Canadians do, rightly or not, think that genetic information is worthy of special protection.³³ Such views accord with a number of international policy documents, such as Article 4 of UNESCO’s 2003 *International Declaration on Human Genetic Data* that declares that human genetic information is special because it can be used to predict genetic predispositions, has relevance to biological relatives and may have cultural significance for persons or groups. As a result, the Declaration recommends that “[d]ue consideration should be given, and where appropriate special protection should be afforded to human genetic data and to the biological samples”³⁴

However, in many ways, even the genetic information that is relatively predictive has similarities to other forms of health information (information that is not afforded special legislative treatment). For example, a cholesterol test provides predictive information (that is, information about risks for cardiovascular disease) and has relevance to one’s biological relatives (cholesterol levels have a strong genetic component). Likewise, HIV status, a non-genetic condition, is also highly sensitive and predictive of future health concerns.

This line of reasoning has led some groups, such as the Nuffield Council on Bioethics, to conclude that genetic information is not significantly different from other forms of sensitive health information.³⁵ The Council goes on to recom-

³² Knoppers *et al.*, “Genetics and Life Insurance in Canada: Points to Consider” (2002) 170 C.M.A.J. Online 2. See also Trudo Lemmens *et al.*, “Genetics and Life Insurance: A Comparative Analysis” (2004) GenEdit 2: “Only a limited number of predictive tests are sufficiently reliable to be of real use to the insurers”; and Nick Raithatha and Richard Smith, “Disclosure of Genetic Tests for Health Insurance: Is It Ethical Not To?” (2004) 363 The Lancet 396: “[D]espite the introduction of innumerable screening, diagnostic, and therapeutic technologies over the past century, the percentage of people who have been able to obtain life insurance has in fact risen”. The authors go on to argue that the “biggest obstacle remains public perception of genetic testing”.

³³ Pollara & Earncliffe, “Public Opinion Research into Biotechnology Issues: Presented to the Biotechnology Assistant Deputy Minister Coordinating Committee (BACC), Government of Canada” (Ottawa: Earncliffe Research & Communications, December 2000).

³⁴ United Nations Educational, Scientific and Cultural Organization (UNESCO), “International Declaration on Human Genetic Data”, 32nd Session, Official Records (Paris: UNESCO, 2004).

³⁵ Nuffield Council on Bioethics, *Pharmacogenetics: Ethical Issues* (London: Nuffield Council on Bioethics, 2003) at 6. See also Caulfield, “Popular Media, Biotechnology and the ‘Cycle of Hype’” at 232.

mend that given the “similarities between genetic and other forms of personal information, it would be a mistake to assume that genetic information is qualitatively different in some way”.

The debate around genetic discrimination is far from over. With new applications on the horizon,³⁶ such as nutrigenomics and the profiling of athletes,³⁷ it seems likely that genetic testing technologies will continue to generate regulatory challenges. Genetic information can be used to individuate, providing natural identifiers that could become a basis for discrimination. Should we treat genetic information as special, and worthy of unique regulatory protection? Or, should we treat it as simply another form of sensitive health information? For the purposes of this chapter, the concerns raised about genetic discrimination stand as an example of how uncertainty and social angst about an emerging technology can trigger legal reform, such as the anti-discrimination laws in the U.S., before it is clear what the best long term regulatory response might be.

In the section that follows, we turn our investigation to another technology that has the ability to individuate, an identification technology that some hope will provide an access-control mechanism for the electronic health record.

B. RADIO FREQUENCY IDENTIFICATION (RFID)

Radio Frequency Identification (RFID) connotes a set of information technologies that enable the remote and automatic identification of physical entities by way of radio signals. Although best known for its ability to manage product inventory through a supply-chain,³⁸ RFID has many valuable applications in health care delivery. For example, RFID can be used to track the whereabouts of a mobile cardiac unit or other life-saving emergency care equipment in

³⁶ Carolyn Abraham, “Would you Gaze into a Genetic Crystal Ball?” *Globe & Mail* (December 31 2005) at A1.

³⁷ Regarding controversy over a genetic test for athletic ability, see Steven E. Humphries, “Genetic Testing for Cardiovascular Disease Risk: Fact or Fiction?” *BioNews.org.uk* (December 23, 2004) online: <<http://www.bionews.org.uk/commentary.lasso?storyid=2392>>: “An Australian company is offering a genetic test it claims can identify children who have the potential to excel at either sprinting and ‘power’ sports or endurance events”. Regarding nutrigenomics, an emerging field that involves the tailoring of nutrition to meet individual genetic characteristics, see Nola Ries & Timothy Caulfield, “First Pharmacogenomics, Next Nutrigenomics: Genohype or Genohealthy?” (2006) 46 *Jurimetrics* 281.

³⁸ AME Info, “How RFID Can Optimize Supply Chain Management” (August 21, 2005), online: <<http://www.ameinfo.com/66090.html>>.

real-time.³⁹ It can be used to help prevent child abduction in neonatal units.⁴⁰ And, as we shall see, it can be used to identify unconscious patients in emergency medicine.⁴¹

Unlike the larger and more costly anti-theft devices that we regularly encounter in clothing and department stores, the signals generated by an RFID tag not only announce their presence, they also announce themselves as uniquely individuated identities. Using radio waves that operate in the unlicensed part of the broadcast spectrum, RFID signals can pass through clothing, knapsacks, body parts and even buildings to communicate with reader devices some distance away. When associated with a database, RFID systems allow computers to recognize and distinguish between physical objects that have been tagged and to collect and integrate a myriad of information about those objects and the people using them.⁴²

³⁹ For example, three hospitals in Virginia have committed 3.9 million USD to the implementation of RFID technology into the management of medical equipment. See Jonathan Collins, "Hospitals Get Healthy Dose of RFID", *RFID J.* (April 27, 2004), online: <<http://www.rfidjournal.com/article/view/920>>. RFID systems that track equipment are said to improve the quality of health care, as locating equipment, especially in emergency situations, is made easier. In addition, such technology saves money, as less equipment is lost. See California Healthcare Foundation, "Brigham and Women's Hospital Uses RFID to Track Medical Equipment", *iHealthBeat* (January 20, 2006), online: <<http://www.ihealthbeat.org/index.cfm?Action=dspItem&itemID=118196>>; and Les Chappell, "RFID Can be a Matter of Life and Death in the Medical World", *Wisconsin Technology Network* (October 19, 2005), online: <<http://wistechnology.com/article.php?id=2383>>.

⁴⁰ The VeriChip Corporation has developed the Hugs and HALO systems for tracking infants in hospitals. See VeriChip, Solutions: Infant Protection, online: <http://www.verichipcorp.com/content/solutions/infant_protection>. RFID tags that are attached to the infants track their whereabouts and match them with their mothers. The technology was recently heralded worldwide as a bastion of security when the Hugs system foiled the abduction of an infant in a North Carolina hospital. See John Leyden, "Security Bracelet Foils Child Abduction". *The Register*, July 21, 2005, online: <http://www.theregister.co.uk/2005/07/21/child_abduction_foiled/>.

⁴¹ The VeriMed system from VeriChip Corporation is the first to implant RFID chips into human beings for this purpose. See VeriChip Corporation, online: <<http://www.verichipcorp.com/content/solutions/verimed>>.

⁴² There is a significant difference between objects that merely announce their presence and objects that can also identify themselves in the process. For example, consider the difference between knowing that: (1) there is "a tagged object" hidden in that knapsack, and (2) there is "a 1 kg bag of fertilizer EPC no. 016 37221 654321 2003004000, which was bought at the Home Depot Store on Merivale Road in Ottawa on February 26, 2006 at 09:06:17 by CIBC credit card holder no. 4408 0412 3456 XXXX and is hidden in the knapsack beside Ottawa Library book call no. 662.2014 B679 (titled: *Explosives*) signed out by library cardholder no. 11840003708286 on February 20, 2006 along with call no. 921 H6755 (*Mein Kampf*), call no. 320.533 H878 (*Les skinheads et l'extrême droite*), and call no. 296.6509 D288 (*Synagogue Architecture*).

An RFID system is comprised of two main components: (i) the tag, which emits a signal that carries a unique identifier through radio waves;⁴³ and (ii) the reader, which receives the signal and identifies the object. The tag component is itself comprised of an antenna and an integrated circuit. Tags are usually classified as either passive or active. Passive tags do not require a power source. They remain dormant until they come in proximity with an incoming signal from an RFID reader that powers the tag, enabling it to send a radio signal of its own. Passive tags typically have a relatively short radio range, can be made to be very small and are the least expensive to produce. Active tags, by contrast, usually include a battery to power the antenna.⁴⁴ Active tags are more reliable and can broadcast at a longer range, but are significantly larger, more expensive and have a shorter shelf life.⁴⁵ The “killer-app” of the future — item-level tagging⁴⁶ — is based on speculation that the price of tags will continue to diminish to a fraction of current costs.

Information on RFID tags is stored as strings of memory that can be either burned into the chip in advance (read-only) or assigned later as read/write memory using a reader.⁴⁷ Tags can be “promiscuous”,⁴⁸ that is, their signals will easily interact and be understood by *any* RFID scanner in its proximity. Secure tags,⁴⁹ on the other hand, send signals that incorporate authentication and encryption elements that prevent them from being read without a key.⁵⁰ Some tags also feature a kill switch, providing a means of deactivating the tag and preventing future communications.⁵¹

⁴³ Also known as a “transponder”.

⁴⁴ Klaus Finkenzeller, *RFID-Handbook*, 2nd ed., Rachel Waddington trans (Chichester: Wiley & Sons, Ltd., 2003), at 8.

⁴⁵ Simson Garfinkel & Henry Holtzman, “Understanding RFID Technology”, in *RFID: Applications, Security, and Privacy*, Simson Garfinkel & Beth Rosenberg, eds. (Upper Saddle River: Addison-Wesley, 2005), at 17.

⁴⁶ That is, tagging every single item in inventory (as opposed to merely tracking crates or cartons). Item-level tagging could have incredible implications, creating what some have called “the internet of things”. See Bruce Sterling, “The Internet of Things” (keynote address, O’Reilly Emerging Technology Conference, March 2006), online: <<http://www.oreillynet.com/pub/a/network/2006/03/20/distributing-the-future.html>>.

⁴⁷ Garfinkel & Holtzman, “Understanding RFID Technology” at 18.

⁴⁸ Sometimes referred to as “dumb”.

⁴⁹ Sometimes referred to as “smart”.

⁵⁰ Garfinkel & Holtzman, “Understanding RFID Technology” at 18.

⁵¹ From a privacy perspective, this is an important feature. It allows RFID to assist in the supply-chain without interfering with consumer rights after the point of sale.

RFID readers operate by constantly emitting radio waves until a tag is detected. When a tag comes within range, its antenna amplifies the signal and sends the information stored on the chip back to the reader. The reader usually links the information stored on the tag to a database, thus correlating potentially scads of information about the object identified by the tag. The read range depends on the power, efficiency, and data integrity requirements of both the tag and the reader.⁵² The radio frequency employed resides within the unlicensed portion of the broadcast spectrum and will be further determined by industry standards. For example, the FDA has assigned high-frequency bands for prescription drug identification while animal tagging uses the low-frequency range.⁵³

For present purposes, we will limit our attention to the VeriChip: a passive, proprietary promiscuous, short-range RFID that is embedded in a glass capsule and covered with a coating called biobond.⁵⁴ When an implanted individual comes in proximity with a VeriChip reader, the tag emits a unique subscriber number corresponding to its own proprietary patient registry database. This number can then be used by health care providers as a password to gain access to the online Verimed Patient Registry, linking patients and their electronic health record. Because the passive RFID inside the VeriChip is always on, it will “speak on the patient’s behalf” — even if the patient is unconscious or otherwise incapacitated — enabling access to vital health information in emergency situations.

To some, the idea of an implantable microchip wirelessly connecting our unconscious bodies to computer databases filled with the most intricate and intimate details of personal health information smacks of science fiction. And, yet, from an information technology perspective, VeriChip is in fact quite primitive. It is unencrypted, which means that the information transmitted from the chip can be easily intercepted, read and understood by any interoperable reader. Its signal can also be easily “cloned” with inexpensive, everyday equipment purchased at any electronics store.⁵⁵ This means that another person can cause a device to imitate the signal emitted by the chip, thus “spoofing” its identity and

52 Garfinkel & Holtzman, “Understanding RFID Technology” at 24.

53 *Ibid.*, at 21.

54 This polymer substance encourages tissue growth around the chip, preventing migration of the chip once it is implanted into the triceps. See Michael Kanellos, “RFID Tags May Be Implanted in Patients’ Arms”, ZDNetUK (July 28, 2004), online: <<http://news.zdnet.co.uk/communications/wireless/0,39020348,39161907,00.htm>>.

55 Jonathan Westhues recently cloned a VeriChip and posted his method on his website. See Jonathan Westhues, “Demo: Cloning a Verichip”, online: <<http://cq.cx/verichip.pl>>. See also Annalee Newitz, “RFID Hacking Underground” *Wired Magazine* 14 no. 5 (May 2006), online: <http://www.wired.com/wired/archive/14.05/rfid.html?pg=1&topic=rfid&topic_set=>>.

enabling unauthorized access to the patient's health care record.⁵⁶ Though it may seem odd, these are not bugs in the system but are in fact design features.⁵⁷

VeriChip raises a number of important issues for health law and policy. We will briefly canvass three: (i) regulating it as a medical device; (ii) informational privacy and security; and (iii) the broader implications of ICT-based medicine.⁵⁸

On October 12, 2004, the U.S. Food and Drug Administration (FDA) approved the VeriChip as a Class II medical device. Given that VeriChip has recently opened offices in Ottawa and Vancouver, our Therapeutic Products Directorate (TPD) will likely be asked to determine whether VeriChip can be sold as a "medical device" in Canada.⁵⁹ Like that of the FDA, the role of the TPD is to ensure that all medical devices offered for sale meet basic safety and efficacy requirements. It does so by ensuring that no apparatus that falls within the definition of a "medical device" under the *Food and Drugs Act* can be sold in Canada without prior approval and a corresponding licence based on the classification of the device.

However, prior to reaching the classification stage, VeriChip must first be able to demonstrate that its devices fall within the definition of a "medical device". For this determination, it is useful to turn to the description of the device in the original FDA application:

An implantable radiofrequency transponder system for patient identification and health information is a device intended to enable access to secure patient identification and corresponding health information. This system may include a passive implanted transponder, inserter, and scanner. The implanted transponder is used only to store a unique electronic identification code that is read by the scanner. The identification code is used to access patient identity and corresponding health information stored in a database.⁶⁰

Notice that VeriChip is not designed to serve a therapeutic purpose. Rather, it is a general purpose device that uses radio frequencies solely as a means of linking

⁵⁶ Or whatever privileges or permissions are assigned to the *no-longer-unique* subscriber identification number.

⁵⁷ From a design perspective, it is believed that VeriChip should be easy to clone so that an attacker then has less incentive to coerce victims or extract VeriChips from victims' bodies: John Hamka *et al.*, "The Security Implications of VeriChip Cloning", Privacy and Security in RFID Systems, (March 10, 2006), online: <<http://lasecwww.epfl.ch/~gavoine/rfid/>>.

⁵⁸ ICT is a well known acronym for "Information and Communication Technology", a term used to capture the convergence of information technology, telecommunications and data networking into a single technology.

⁵⁹ Pursuant to a licence under the *Medical Devices Regulation*, SOR/98-282 established pursuant to s. 30(a)(iii) of the *Food and Drugs Act*, R.S.C. 1985, c. F-27.

⁶⁰ U.S. Department of Health and Human Services, Food and Drug Administration, 21 CFR Part 880 (Docket No. 2004N-0477) "Medical Devices; Classification of Implantable Radiofrequency Transponder System for Patient Identification and Health Information" (December 10, 2004), online: <<http://www.fda.gov/ohrms/dockets/98fr/04-27077.htm>> (FDA Classification).

an entity to a unique identifier. Although one potential application of implantable RFID is to use it to link a patient to an electronic health record, it is unclear whether this makes the VeriChip a “medical device”.

It is instructive to look at the definition set out in section 2 of the *Food and Drug Act*:

“device” means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
- (c) the diagnosis of pregnancy in human beings or animals, or
- (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;⁶¹

It is clear that VeriChip falls within the first part of the definition of a “device”. However, it is less clear that it satisfies any of the second part of the definition’s four disjuncts. First, VeriChip is not an instrument of diagnosis or treatment, nor does it mitigate or prevent diseases and the like. Second, VeriChip plays no role in restoring, correcting or modifying body function or structure. Likewise, it has no diagnostic value in pregnancy and does not facilitate care during pregnancy or after. Given that it is devoid of therapeutic value or purpose, one would think that VeriChip is an unlikely candidate for TPD approval. And yet the FDA, governed by similar legislative provisions, has approved VeriChip as a medical device. Should the TPD do the same? Who should be allowed to perform implanta-

⁶¹ A similar approach has been adopted in 21 U.S.C. 201(h):

The term “device” ... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar related article, including any component, part, or accessory, which is —

- (1) recognized in the official National Formulary, or in the United States Pharmacopeia, or any supplement to them,
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

tion procedures?⁶² Is the current regulatory regime sufficient to accommodate the merger of ICT and medicine? As we shall see, such questions will gain increasing significance as future chip-enabled devices are developed that, unlike VeriChip, actually do achieve therapeutic ends.

Since the central purpose of the current VeriChip is limited to the non-therapeutic aim of automated identification, of central concern will be its privacy implications. Because the current proposals for its use are limited to those who consent to implantation, we will focus on informational privacy rather than the bodily privacy issues raised by the invasive implantation procedure. Informational privacy is concerned with “the claim of individuals ... to determine for themselves when, how, and to what extent information about them is communicated to others”.⁶³ While an implanted patient has voluntarily chosen to enable the chip to “communicate” information about them with emergency care workers, as described above, a passive, unencrypted chip that is easily read by inexpensive and commercially available scanners undermines the implanted individual’s ability to control the collection, use or disclosure of identifiable information. With the strategic placement of RFID readers in door portals and other locations, this could not only allow locational tracking of implanted individuals in real-time, but also the ability to collect associated information that would allow aggregated profiling and surveillance.⁶⁴

While it is tempting to think that obtaining an initial consent to implantation would suffice, the fair information practices⁶⁵ underlying federal and provincial privacy legislation generally require those who collect information about an identifiable individual to specify before or at the time of collection the purpose for doing so, and that the information collected cannot be disclosed to or otherwise used by others without fresh consent from the data subject.⁶⁶ Fair information practice principles also require that personal data be protected by reasonable security safeguards against unauthorized access or disclosure of data. VeriChip’s

⁶² For example, body piercers in Ontario have gained some notoriety for implanting chips similar to the VeriChip. See Anna Bahny, “High Tech Under the Skin”, *New York Times*, (February 2, 2006), online: <<http://www.nytimes.com/2006/02/02/fashion/thursdaystyles/02tags.html?ex=1296536400&en=de01f3be5ea7ce56&ei=5088&partner=rssnyt&emc=rss>>. However, it is questionable whether this practice would be considered legal, at least in Ontario. See *Regulated Health Professions Act, 1991*, S.O. 1991, c. 18, s. 27(2), which governs “controlled acts”, including “[p]erforming a procedure on tissue below the dermis” and “putting an instrument, hand or finger ... into an artificial opening into the body”. Exceptions to s. 27(2) have been made in the *Controlled Acts Regulation* (O. Reg. 107/96, s. 8), but only for piercing the body with jewellery.

⁶³ Alan F. Westin, *Privacy and Freedom* (New York: Atheneum, 1967), at 7.

⁶⁴ See generally, Katherine Albrecht & Liz McIntyre, *Spychips: How Major Corporations and Government Plan to Track your Every Move with RFID* (Nashville: Nelson Current, 2005).

⁶⁵ OECD, *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (1980); *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5, Sch. 1 (PIPEDA).

⁶⁶ PIPEDA, Principle 3.1.

current model for patient identification is not in accord with either of these core privacy principles.

The privacy discussion thus far has focused on the automated disclosure of the unique identifier, which is broadcast each time that a chip comes in proximity of a reader. Security concerns also arise when an unauthorized disclosure of that identifier leads to unauthorized access to an associated health record. Recall that the VeriChip subscriber number is the key that unlocks the patient's electronic health record, making VeriChip insecure by design. From an information security perspective, it is therefore not well suited as an "access control" device.⁶⁷ For some reason, this has not stopped more than 100 American hospitals and several hundred American physicians from implementing programs that use it for such purposes.⁶⁸

The use of implantable microchips in medicine is nascent but sure to result in therapeutic innovations that will repair and perhaps even enhance bodily function. For example, cochlear implants are gaining in popularity among those with hearing impairments, and it is not difficult to imagine that they will one day enhance rather than merely restore human hearing.⁶⁹ For example, while repairing hearing function, why not include within such devices the capability to stream voice transmissions wirelessly so that one does not have to carry or wear phones or portable music players? Living in a surveillance society that will soon require all telecommunications service providers to build a global intercept capability into all communications devices⁷⁰ (so that law enforcement can "listen in" under certain circumstances), the myriad of issues that arise transcend health law and policy. As we continue to experiment with totally implantable devices such as

67 Halamka *et al.*, "The Security Implications of VeriChip Cloning", online: <<http://lasecwww.epfl.ch/~gavoine/rfid/>>.

68 The latest data from VeriChip Corporation shows that 110 hospitals have committed to implement the VeriMed system, see VeriChip Corporation, "VeriChip Corporation Announces First Emergency Room Use of VeriMed Microchip," News Release (July 27, 2006). In addition, on its website, VeriChip Corporation states that 280 physicians have elected to offer the VeriMed chip to their patients. See VeriChip Corporation, online: <<http://www.verimedinfo.com/>>.

69 One of the better currently available products is in fact marketed as "HiResolution Bionic Ear System". See online: <<http://www.bionicear.com/>>.

70 Though it died on the Order Page with the fall of the Liberal government in 2005, Bill C-74, *An Act regulating telecommunications facilities to facilitate the lawful interception of information transmitted by means of those facilities and respecting the provision of telecommunications subscriber information*, 1st Sess., 38th Parl., 2005 (not passed) is sure to be resurrected in a substantially similar form, given the political pressure on Canada to ratify the *European Convention on Cybercrime* (Council of Europe, *European Convention on Cybercrime*, E.T.S., No. 185 (2001)).

artificial hearts,⁷¹ and as medicine becomes more and more dependent on wireless and network technologies to manage these devices, there will be an increasing need to understand the human-machine merger, the question of technological enhancement and all of the ethical and legal issues that are bound to ensue as a result of implantable radio frequency microchips.

In the section that follows, we turn our focus to a very different technology that also strikes at the core of what it means to be human, one that has stirred much controversy while, at the same time, generating tremendous potential for treating many serious illnesses.

C. EMBRYONIC STEM CELLS

Few areas of research have generated as much controversy as embryonic stem cell research. It is a topic that has received an incredible amount of media attention and policy analysis. It has been the subject of legislative debates throughout the world and it has divided the United Nations.⁷² But despite almost a decade of intense policy deliberations, there remains little international consensus about how this area should be regulated.⁷³

Why has stem cell research caused so much controversy? The focal issue is clearly the moral status of the embryo. While there are a variety of complex issues associated with this field of study — including concern about the consent processes used to obtain embryos for research⁷⁴ and the patenting of embryonic stem cell lines⁷⁵ — there seems to be little doubt that the issues related to the moral status of the embryo have been the dominant cause of controversy and the

71 For example, see the AbioCor, a fully implantable replacement heart manufactured by AbioMed, online: <http://www.abiomed.com/products/heart_replacement.cfm>.

72 CBS News, “UN gives up cloning ban”, (November 19, 2004), online: <<http://www.cbsnews.com/stories/2005/02/18/tech/main675124.shtml>>.

73 For two excellent reviews of the regulatory variation, see Lori P. Knowles, “A Regulatory Patchwork — Human ES Cell Research Oversight” (2004) 22 *Nature Biotech.* 157; and Rosario Isasi & Bartha Knoppers, “Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries” (2006) 13 *Euro. J. Health L.* 9-26. See also Shaun Pattinson & Timothy Caulfield, “Variations and Voids: The Regulation of Human Cloning Around the World” (2004) 5 *B.M.C. Medical Ethics* 9.

74 See Bernard Lo *et al.*, “Informed Consent in Human Oocyte, Embryo, and Embryonic Stem Cell Research” (2004) 82 *Fertility and Sterility* 559; Henry Greely, “Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions” (2006) *Public Library of Science Medicine* e143 and Margaret Munro, “Ethicist Repeats Call to Halt Embryo Donations”, *National Post* (June 28, 2006) at A7.

75 Timothy Caulfield, “Stem Cell Patents and Social Controversy: A Speculative View From Canada” (2006) 7 *Medical L. Int'l* 219-32.

primary source of the “regulatory patchwork” that now exists throughout the world.⁷⁶

Since 1998, when the first human embryonic stem cell lines (hESC) were created,⁷⁷ there has been a great deal of excitement about the scientific and therapeutic potential of stem cells. Embryonic stem cells, unlike stem cells derived from other sources (such as cord blood),⁷⁸ have the unique capacity to form almost any tissue in the body (and are, therefore, known as “pluripotent”). It is hoped that scientists will one day be able to coax them into becoming tissues that could be used to treat a wide variety of serious illnesses, including Parkinson’s, diabetes, and heart disease. The speculation about prospective benefits has, no doubt, been fueled by the large degree of hype that has surrounded the entire area.⁷⁹ Nevertheless, few would disagree with the suggestion that the therapeutic potential is real, albeit uncertain and, perhaps, a long way off.

However, for those who believe that a human embryo has full moral status, regardless of how early its stage of biological development,⁸⁰ no amount of therapeutic potential will justify its destruction — a necessary step in the derivation of a stem cell line.⁸¹ As such, they remain steadfastly opposed to embryonic stem cell research. To cite just one example, the Catholic Church has taken a consistent position against this work. Indeed, recently, a prominent Cardinal suggested: “Destroying an embryo is equivalent to abortion. ... Excommunica-

⁷⁶ Knowles, “A Regulatory Patchwork”, at 157.

⁷⁷ James Thomson *et al.*, “Embryonic Stem Cell Lines Derived from Human Blastocysts” (1998) 282 *Science* 1145; Abdallah S. Daar & Lorraine Sheremeta, “The Science of Stem Cells: Some Implications for Law and Policy” (2002) 11 *Health L. Rev.* 5.

⁷⁸ See Oonagh Corrigan *et al.*, *Ethical Legal and Social Issues in Stem Cell Research and Therapy* (briefing paper, Cambridge Genetics Knowledge Park, March 2006) at 1: “Stem cells are cells that have the potential both for self-renewal and to differentiate into specialized cell types. Stem cells found in the early mammalian embryo, at around 5-7 days after fertilisation, are able to give rise to all the different cell types of the organism. These embryonic stem (ES) cells are said to be ‘pluripotent’”.

⁷⁹ See, *e.g.*, N. Theise, “Stem Cell Research: Elephants in the Room” (2003) 78 *Mayo Clinic Proceedings* 1004-1009.

⁸⁰ Stem cells are generally removed from the embryo at a very early stage of development, when the embryo is at only a cluster of cells called a “blastocyst”.

⁸¹ However, scientists continue to strive to develop techniques that would allow the production of a stem cell line without the destruction of the embryos. See, *e.g.*, Nicholas Wade, “Stem Cell News Could Intensify Debate”, *New York Times* (August 24, 2006).

tion is valid for the women, the doctors and researchers who destroy embryos”⁸²

Despite the enduring presence of such sentiments, they seem to represent a minority position — at least in Canada. Most research has shown that the Canadian public supports embryonic stem cell research.⁸³ Recent studies have shown that Canadians tend to view stem cell research as one of a range of associated areas of biotechnology.⁸⁴ More significantly, a majority approve of stem cell research *under any circumstance*, as long as it is appropriately regulated.⁸⁵ Nevertheless, it seems likely that there will always remain a sector of society that will not endorse the use of human embryos for research purposes, thus making it impossible to craft policy that will be entirely satisfactory to all.

Indeed, it has been noted that individuals with extreme positions at either end of the continuum have done their best to try to portray the debate in terms that

82 News, “Prominent Cardinal Attacks Science Behind Stem Cell Research”, *New Scientist* (July 14, 2006) at 5. See also Elisabeth Rosenthal, “Excommunication is Sought for Stem Cell Researchers”, *New York Times* (July 1, 2006), online: <<http://www.nytimes.com/2006/07/01/world/europe/01vatican.html?ex=1309406400&en=0e0de4c51c312ccb&ei=5088&partner=rssnyt&emc=rss>>.

83 For a list of relevant surveys, see Health Law Institute, online: <<http://www.law.ualberta.ca/centres/hli/hlicando.html#>>.

84 This is in contrast to the situation in the United States, where media hype, politicization of the issue and public support by high-profile celebrities have contributed to making stem cell research “the ‘poster’ child of biotechnology”. Government of Canada BioPortal, “A Canada-US Public Opinion Research Study on Emerging Technologies — Report of Findings” (Ottawa: Decima Research Inc. for The Canadian Biotechnology Secretariat, Industry Canada (March 31, 2005)), online: <<http://www.biostrategy.gc.ca/english/view.asp?x=721&all=true#470>>. See also Norma Greenway, “Canadians Embrace Stem Cell Research”, *The Ottawa Citizen* (October 14, 2003).

85 Greenway, “Canadians Embrace Stem Cell Research”. See also Jeff Walker, “Report on a Study of Emerging Technologies in Canada and the U.S. “Prevailing Views, Awareness and Familiarity”, in *First Impressions: Understanding Public Views on Emerging Technologies* (Genome Prairie, September 2005) at 6-19. This finding is consistent with U.S. data. See e.g., Kathy L. Hudson, Joan Scott & Ruth Faden, *Values in Conflict: Public Attitudes on Embryonic Stem Cell Research* (Genetics and Public Policy Center, October 2005). The emphasis on tighter regulations is attributed to concerns over the efficacy of existing regulatory agencies and processes, and the potential influence of corporate interests. For an interesting comparison of Canadian and US views, see Edna Einsiedel, *First Impressions: Understanding Public Views on Emerging Technologies* (Genome Alberta, Prepared for the Canadian Biotechnology Secretariat, 2005) at 12:

Focus groups and survey research reveal that there are subtle but important differences of opinion on the morality of stem cell research. Twice as many Americans (12%) as Canadians (6%) find it flat-out morally unacceptable, more Canadians (38%) than Americans (31%) find it morally questionable — the mid-point on the five-point scale — while the same numbers (32%) in each country say it is acceptable and 17% and 18% say it is somewhat acceptable. US focus groups revealed that there is a larger core of individuals who adamantly oppose stem cell research on ethical grounds.

For a comprehensive review of European public opinion, see George Gaskell *et al.*, “Europeans and Biotechnology in 2005: Patterns and Trends” (May 2006) 64.3 Eurobarometer (A report to the European Commission’s Directorate-General for Research).

will help their cause.⁸⁶ For those who favour the work, this means emphasizing the potential scientific and health benefits. For those who oppose the work, the moral issues have remained the focus of debate. In the U.S., for example, some have speculated that a religious agenda has played a role in the tone of the national bioethics discourse, skewing it toward a neo-conservative ethos.⁸⁷ Though not as dominant as in the U.S., religion has also played a role in the direction of policy development in Canada and the United Kingdom.⁸⁸ We are left, then, with a seemingly irreconcilable polarity of positions.

This division has led to a diversity of regulatory approaches.⁸⁹ For example, some countries, such as Ireland, Italy, Germany and Austria, do not allow the use of human embryos for the purpose of stem cell research.⁹⁰ Other jurisdictions, such as the U.K., Sweden, California and Israel have a more permissive environment, allowing a wide range of research activities, including the creation of embryos for research purposes and “therapeutic cloning”.⁹¹

Where does Canada sit on the spectrum of regulatory responses? In 2004, the Canadian Parliament passed the *Assisted Human Reproduction Act*.⁹² This piece of legislation, which covers a broad range of activities associated with human reproductive material, sets the parameters under which embryonic stem cell research can occur in Canada. In some respects, Canada has taken a cautious mid-

⁸⁶ Matthew Nisbet, “The Competition for Worldviews: Values, Information, and Public Support for Stem Cell Research” (2005) 17 *Int’l J. Public Opinion Research* 92:

[A] scientifically literate public is assumed [to] be more appreciative of science and technology, and more supportive of science as an institution. In contrast, religious research opponents have sought to mobilize the public by attempting to define stem cell research in the media coverage as a moral issue, emphasizing certain considerations that are likely to promote public opposition to research.

⁸⁷ R.A. Charo, “Passing on the Right: Conservative Bioethics is Closer Than It Appears” (2004) 2 *J.L. Med. & Ethics* 307-14.

⁸⁸ A. Plomer, “Beyond the HFE Act 1990: The Regulation of Stem Cell Research in the U.K.” (2002) 10 *Med. L. Rev.* 132-63.

⁸⁹ “[T]he determination of the moral status of the human embryo influences possible responses to questions of the permissibility of, restrictions on, and prohibitions on embryonic research”. Isasi & Knoppers, “Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries” at 24.

⁹⁰ Many of these countries have a religious or historical precedent that, in part, informed the adoption of a more restrictive research environment — such as the role of the Catholic Church in Ireland and Italy. See, e.g., Pattinson & Caulfield, “Variations and Voids: The Regulation of Human Cloning Around the World” at 9.

⁹¹ For a detailed description of regulatory positions throughout the world see generally Isasi & Knoppers, “Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries” at 13; Knowles, “A Regulatory Patchwork” at 157; and Pattinson & Caulfield, “Variations and Voids: The Regulation of Human Cloning Around the World” at 9.

⁹² *Assisted Human Reproduction Act*, S.C. 2004, c. 2.

dle ground approach by allowing research on embryos that have already been created for the purposes of reproduction through *in vitro* fertilization (IVF).⁹³ So long as the regulatory requirements have been satisfied, which include approval by several research ethics boards and compliance with specific consent guidelines,⁹⁴ research on these human embryos can occur. However, the law also provides significant criminal sanctions against a number of related scientific activities that are permitted in some jurisdictions, including the creation of embryos specifically for research purposes and “therapeutic cloning”.⁹⁵

But even this middle ground approach is, for some, less than satisfactory. When immutable moral convictions are engaged, compromise is not always an option. The scientific advances that have occurred in the area of stem cell research force us to confront the question of what type of consensus is required as a prerequisite to the development of social policy.⁹⁶ To what degree should a particular view of the moral status of embryonic life dictate national policy on the use of stem cells?⁹⁷ When is it appropriate for the government to pass laws that may restrict academic research?⁹⁸

In the section that follows we will investigate the law and policy implications of scientific rather than moral uncertainty. What are the appropriate regulatory responses to the development of technologies so powerful that we are not currently in a position to predict or evaluate their potential danger?

D. NANOMEDICINE

What would happen if modern science were capable of healing the body at the molecular level, one atom at a time? When Nobel physicist Richard Feynman

⁹³ *Ibid.*, s. 40 [not yet in force].

⁹⁴ See *ibid.*, s. 40(3.1) [not yet in force]: “The Agency shall not issue a licence under subsection (1) for embryonic stem cell research unless it has received the written consent of the original gamete providers and the embryo provider in accordance with the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March, 2002, as specified in the regulations”.

⁹⁵ *Ibid.*, s. 5.

⁹⁶ See Isasi & Knoppers, “Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries” at 25: “Can we address such divisive issues while holding intact our democratic principles and socio-cultural values?”

⁹⁷ See, e.g., Norma Greenway, “Jewish, Islamic Faiths Support Controversial Stem Cell Research” (February 29, 2003) at A3.

⁹⁸ For an interesting debate about academic freedom in the context of “therapeutic cloning”, see Jocelyn Downie, Jennifer Llewellyn & Françoise Baylis, “A Constitutional Defence of the Federal Ban on Human Cloning for Research Purposes” (2005) 31 *Queen’s L.J.* 353; and Barbara Billingsley & Timothy Caulfield, “The Regulation of Science and the Charter of Rights: Would a Ban on Non-Reproductive Human Cloning Unjustifiably Violate Freedom of Expression?” (2004) 29 *Queen’s L.J.* 647-79.

first posed a generalized version of this question to the American Physical Society in a famous 1959 address,⁹⁹ he dreamed of “the great future” challenging his colleagues to think big by thinking small:

The principles of physics, as far as I can see, do not speak against the possibility of maneuvering things atom by atom. [I]t would be, in principle, possible (I think) for a physicist to synthesize any chemical substance that a chemist writes down. How? Put the atoms down where the chemist says, and so you make the substance.¹⁰⁰

Feynman’s vision inspired in the subsequent five decades theoretical, experimental, and applied scientists from various disciplines to conduct research collectively known today as *nanotechnology*.

Although Feynman’s bottom-up approach, subsequently elaborated by Drexler and others,¹⁰¹ focuses on developing an ability to program and manipulate matter with molecular precision, the term “nanotechnology” has broadened to include top-down¹⁰² technologies that operate on the nano-scale.¹⁰³ Debates concerning the feasibility of the bottom-up approach linger.¹⁰⁴ If achievable,

[f]ull fledged nanotechnology promises nothing less than complete control over the physical structure of matter — the same kind of control over the molecular and structural make-up of physical objects that a word processor provides over the content and form of a text. The implications of such capabilities are significant: to

⁹⁹ Richard Feynman, “There’s Plenty of Room at the Bottom: An Invitation to Enter a New Field of Physics” (lecture, American Physical Society, California Institute of Technology, December 29, 1959) (1960) *Engineering and Science* 22, online: <<http://www.zyvex.com/nanotech/feynman.html>>.

¹⁰⁰ *Ibid.*

¹⁰¹ See, e.g., K. Eric Drexler, *Engines of Creation: The Coming Era of Nanotechnology* (New York: Anchor Press/Doubleday, 1986); Eric Drexler, Chris Peterson & Gayle Pergamit, *Unbounding the Future: The Nanotechnology Revolution* (New York: William Morrow and Co. Inc., 1991).

¹⁰² A top-down approach builds things by taking existing matter and reducing or removing unwanted material, e.g., sawing a piece of wood or using a chemical reagent. A bottom-up approach would build matter atom by atom, or cell by cell. According to Drexler’s vision, nanomachines known as “assemblers” would be programmed to build larger, more complex materials similar to the manner in which a human being results from a single cell. See Drexler, *Engines of Creation: The Coming Era of Nanotechnology* (New York: Anchor Press/Doubleday, 1986) at 14.

¹⁰³ Which is an order of magnitude smaller than microtechnology. A nanometer (nm) is one-billionth of a meter, which is about 3 to 6 atoms in length; the thickness of a human hair is said to be 50,000 to 100,000 nm. See Center for Responsible Nanotechnology, “Nanotechnology Glossary”, online: <<http://www.crnano.org/crnglossary.htm>>.

¹⁰⁴ See, e.g., Ian Kerr & Goldie Bassi, “Not Much Room? Nanotechnology, Networks and the Politics of Dancing” (2004) 12 *Health L.J.* 103.

dramatize only slightly, they are comparable to producing a 747 or an ocean liner from the mechanical equivalent of a single fertilized egg.¹⁰⁵

However, most publicly funded nanotechnology research is a much less grandiose, much more traditional, top-down model of science (only done on the nanoscale). Even if the “assembler breakthrough” never occurs, many governments are investing heavily in nanotechnology,¹⁰⁶ expecting that it will address a broad range of environmental issues, drastically reduce energy consumption, increase food production, create new and better information technologies and consumer products, amplify the precision and efficacy of military devices and weapons, and dramatically advance medicine’s ability to cure and prevent diseases.¹⁰⁷ Already, there have been significant advancements in fields such as microscopy and materials science.¹⁰⁸ But the most prolific and high profile uses of nanotechnology to date are in the field of medicine.

Nanomedicine, as it is sometimes called,¹⁰⁹ aims to develop molecular tools that will diagnose, treat and prevent diseases or traumatic injuries. With significantly enhanced levels of control, it promises to eclipse the profit potential of modern pharmaceuticals. Imagine, for example, nano-sized sensors able to detect and diagnose cancer in the early stages when there are only a few thousand

¹⁰⁵ Glen Harlan Reynolds, “Forward to the Future: Nanotechnology and Regulatory Policy” (November 2002) Pacific Research 6, online: <http://www.pacificresearch.org/pub/sab/techno/forward_to_nanotech.pdf>.

¹⁰⁶ It is estimated that, as of 2005, there is approximately 9.6 billion USD in nanotechnology R&D funding worldwide. Governments are some of the heaviest investors, accounting for almost half of the money. See The Nanoethics Group, “The Nanotech Market”, online: <<http://www.nanoethics.org/investments.html>>. In 2005, the U.S. provided approximately \$1 billion in funding. See Robert F. Service, “Calls Rise for More Research on Toxicology of Nanomaterials” (2005) 310 Science 1609. The European Commission earmarked 1.3 billion euros for nanotechnology research between 2003 and 2006. See Robert A. Freitas Jr., “What is Nanomedicine” (2005) 51 Disease a Month 325. In Canada, the Federal government, in partnership with the government of Alberta, have guaranteed \$120 million of funding for the new National Institute of Nanotechnology (NINT) from 2001 until 2007, in addition to the \$100 million required to build the facility at the University of Alberta. See National Research Council of Canada, “Flagship Nanotechnology Institute’s New Home Features Canada’s Quietest Space”, online: <http://www.nrc-cnrc.gc.ca/newsroom/news/2006/nint06-nr_e.html>.

¹⁰⁷ See, e.g., Freitas Jr., “What is Nanomedicine?” (2005) 51 Disease a Month 325; The Nanoethics Group, “The Good”, online: <<http://www.nanoethics.org/good.html>>.

¹⁰⁸ See, e.g., Robert A. Wolkow, “The Ruse and Reality of Nanotechnology” (2004) 12 Health L. Rev. 14.

¹⁰⁹ For a comprehensive introduction to various applications in nanomedicine, see Freitas Jr. “What is Nanomedicine?” (2005) 51 Disease a Month 325.

cancerous cells in the body.¹¹⁰ Now imagine firing metal-coated nanoshells¹¹¹ with precision into the cracks of the tumour cells and no others, frying the cancer by using an external infrared light to heat the metal coating and thereby burn only tumour cells. In addition to the use of these sorts of nanomaterials and devices, research and development will also focus on other novel forms of therapy, new methods of drug delivery,¹¹² and techniques for improving imaging and other medical diagnostics.¹¹³

Like the elixir of Theuth, nanomedicine offers much promise but also potential peril. The unpredictability of nano-scale products and applications raise numerous health and safety issues. As we have seen with other emerging health technologies discussed in this chapter, this is not uncommon since, by definition, new technologies have not been subject to long term clinical trials. But there seems to be a crucial distinction between nano and other new technologies. Given their size, nanomaterials are governed not by the laws of gravity but the laws of quantum mechanics.¹¹⁴ Quantum mechanics in some cases requires a non-intuitive understanding of various scientific relationships:

Some of these dependencies are scientifically intuitive such as the relationship between properties of nanomaterials and their size, composition, impurities (both internally and superficially), the surface chemistry (including passivating agents) and degree of agglomeration. Other dependencies such as shape, change, zeta potential and phase seem less intuitive. And this is just the tip of the iceberg. To complicate matters further, many of the dependencies are intrinsically linked.¹¹⁵

One therefore cannot always extrapolate from existing knowledge about the behaviour of material properties on a macroscale. For example, some materials

¹¹⁰ James R. Heath, Michael E. Phelps & Leroy Hood, "NanoSystems Biology" (2003) 5 *Molecular Imaging & Biology* 312.

¹¹¹ A nanoshell is a 100 nm spherical shell containing a coat of metal around a core of silicon dioxide atoms. Preliminary experiments for the scenario presented above have already been published. See C. Loo *et al.*, "Nanoshell-enabled Photonics-based Imaging and Therapy of Cancer" (2004) 3 *Cancer Res. Treat* 33; Freitas Jr., "What is Nanomedicine?" (2005) 51 *Disease a Month* 325.

¹¹² Methods that have the ability to target selected cells or receptors within the body. U. Pison *et al.*, "Nanomedicine for Respiratory Diseases" (2006) 533 *Eur. J. Pharmacology* 343-44.

¹¹³ European Science Foundation (ESF), *Nanomedicine: An ESF European Medical Research Councils (EMRC) Forward Look Report* (ESF, 2005) at 7, online: <www.esf.org/publication/214/Nanomedicine.pdf>. For a discussion of nano-diagnostics in a respiratory context, see Pison, "Nanomedicine for Respiratory Diseases" (2006) 533 *Eur. J. Pharmacology* 342-43.

¹¹⁴ Mutaz B. Habal, "Nanosize, Mega-Impact, Potential for Medical Applications of Nanotechnology" (2006) 17 *J. Craniofacial Surgery* 3.

¹¹⁵ Amanda S. Barnard, "Nanohazards: Knowledge is our First Defence" (2006) 5 *Nature Materials* 245.

that are inert at the macroscale are reactive at the nanoscale.¹¹⁶ A similar difficulty exists when it comes to the relationship between size and phase.

Macroscopically the rutile phase is stable and the anatase phase is metastable, but when the particle size is under ~20nm this situation is reversed. ... This is of critical importance, because rutile and anatase react very differently when exposed to light. ... Both technologies are currently in use around the world without discernible risk, but a phase transition in either case would do more than reduce the efficiency of these respective products, it could also be damaging to the substrate — which in the case of rutile-based sunscreen, is us.¹¹⁷

Here, nanotechnology is *pharmakon* in the Derridean sense: the remedy becomes the poison. The inability to accurately predict what will transpire at the nanoscale can be further exacerbated by changes in temperature, pressure, humidity and the like.

Given its currently unpredictable nature, there is a budding debate about the need for a unique regulatory scheme for nanotechnology. In the U.S. context, some have argued that the Food and Drug Administration (FDA) is not particularly well-equipped to deal with many of the forthcoming challenges of nanotechnology. In addition to lacking the necessary complement of FDA scientists with sufficient expertise to evaluate new products, many nano-applications do not easily fit within existing FDA categories.¹¹⁸ Others, however, see no need for a new regulatory schema. They point out that, despite the recent buzz, research in nanomedicine is not new. Various such applications have obtained FDA approval for more than a decade.¹¹⁹

The same debate would, of course, apply to Canada. In fact, such debates are themselves not new. With practically each new round of so-called “disruptive” technologies,¹²⁰ law makers toil over whether regulation should be novel and unique or whether it should comport with the principle of technological neutrality. According to this principle, new laws or regulations should not depend upon a specific development or state of technology, but ought instead to be based on

¹¹⁶ *Ibid.*, at 246.

¹¹⁷ *Ibid.*

¹¹⁸ See, e.g., John Miller, “Beyond Biotechnology: FDA Regulation of Nanomedicine” (2003) 4 Columbia Sci. & Tech. L. Rev. 1.

¹¹⁹ See, e.g., Nuala Moran, “Nanomedicine Lacks Recognition in Europe” (2006) 24 Nature Biotech. 121, where she quotes Mike Eaton of UCB Celltech as stating, “I’m not sure you need new regulation. Nanomedicines are not new; they have been getting regulatory approval for ten years”.

¹²⁰ A technology is described as disruptive when it overthrows the existing dominant technology or product in a market. Typical examples include the steam engine (replacing human-power); the automobile (displacing horse and buggy); the integrated circuit (replacing the transistor). See generally, Clayton M. Christensen, *The Innovator’s Dilemma: When New Technologies Cause Great Firms to Fall* (Boston: Harvard Business School Press, 1997).

core principles that can be adapted to changing technologies.¹²¹ Since technological change is continuous, standards created in light of particular technologies are likely to become outdated with the rapid shift in technological paradigms.¹²²

It is perhaps too early to tell whether nanomedicine will be evolutionary or revolutionary. However, given its nascent state of development, its inherent unpredictability and the potential risks attendant in more general uses of nanotechnology,¹²³ it is difficult to imagine a completely unregulated program of research and development. Like genetically modified foods in the U.K., the likely impetus of such regulation will be the precautionary principle, an approach to managing threats of serious or irreversible harm in situations of scientific uncertainty.

Although referred to as though it were a singular, unified and coherent concept, the precautionary principle has in fact seen many different formulations ranging from Hippocrates' "First, do no harm"¹²⁴ to the 1992 Rio Declaration on Environment and Development statement that, "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a

¹²¹ One example of such an approach would be the fair information practice principles that form the basis of health privacy and other data protection regimes. See *e.g.*, Organisation for Economic Co-operation and Development (OECD), *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (OECD, 1980); *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5.

¹²² Michael Geist, "Is There a There There? Toward Greater Certainty for Internet Jurisdiction" (2002) 16 *Berkeley Tech. L.J.* 1345. For further discussion of the principle of technological neutrality, see Ian Kerr, Alanna Maurushat & Christian Tacit, "Technical Protection Measures: Part II, The Legal Protection of TPMs" (Study prepared for the Department of Canadian Heritage, April 2002) at 43, online: <http://www.patrimoinecanadien.gc.ca/progs/ac-ca/progs/pda-cpb/pubs/index_e.cfm>.

¹²³ To mention a few, these risks include: (i) catastrophic environmental damage due to unanticipated or uncontrollable consequences of its use; (ii) economic oppression by patent owners that would deny those in need of otherwise cheap lifesaving technologies; (iii) an unstable arms race as nanotechnology applications are developed for military or terrorist ends; (iv) ubiquitous surveillance of citizens by corporations and governments with the further miniaturization of devices. See generally David Williams, "The Risks of Nanotechnology" (2005) 16 *Med. Device Tech.* 6; The Nanoethics Group, "The Bad", online: <<http://www.nanoethics.org/bad.html>>; European Commission, *Nanotechnologies: A Preliminary Risk Analysis, on the Basis of a Workshop Organized in Brussels on 1-2 March 2004 by the Health and Consumer Protectorate General of the European Commission* (European Commission, March 2004), online: <http://www.ec.europa.eu/health/ph_risk/documents/ev_20040301_en.pdf>.

¹²⁴ While not part of the Hippocratic Oath itself, the maxim "First, do no harm" was reflected within Hippocrates' *Corpus* at *Epidemics*, Bk. I, Sect. V., where he states, "to help, or at least to do no harm".

reason for postponing cost-effective measures to prevent ... degradation".¹²⁵ Though there are divergent views, core elements of the precautionary approach are usually thought to entail that: (i) there exists a duty to take anticipatory action to prevent harm; (ii) the burden of proof of harmlessness for an unproven technology lies with its proponents, not the general public; (iii) prior to its adoption, there exists an obligation to examine a full range of alternatives (including the alternative of doing nothing); and (iv) applying the precautionary principle requires a process that is open, informed, democratic and inclusive of all affected parties.¹²⁶

In September 2001, the government of Canada announced its view that "the precautionary approach is a legitimate and distinctive decision-making tool within risk management".¹²⁷ In a series of documents aiming to develop "A Canadian Perspective on the Precautionary Approach/Principle", the government enumerated a set of guiding principles aimed at supporting "consistent, credible and predictable policy and regulatory decision making when applying the precautionary principle".¹²⁸

How ought the precautionary principle apply to nanomedicine?

There are divergent views on this. For example, the Action Group on Erosion, Technology and Concentration (ETC), has recommended that:

[g]iven the concerns raised over nanoparticle contamination in living organisms ... governments [must] declare an immediate moratorium on commercial production of new nanomaterials and launch a transparent global process for evaluating the socioeconomic, health and environmental implications of the technology.¹²⁹

¹²⁵ United Nations Environment Programme, *Rio Declaration on Environment and Development* (1992), Principle 15, online: <<http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163>>. This approach was subsequently particularized to include health concerns in the *Wingspread Statement on the Precautionary Principle*: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically". Global Development Research Center, *Wingspread Statement on the Precautionary Principle* (January 1998), online: <<http://www.gdrc.org/u-gov/precaution-3.html>>.

¹²⁶ See Joel Tickner, Carolyn Raffensperger & Nancy Myers, *The Precautionary Principle in Action: A Handbook* (AG BioTech InfoNet), online: <http://www.rachel.org/bulletin/index.cfm?issue_ID=532>.

¹²⁷ Environment Canada, *A Canadian Perspective on the Precautionary Approach/Principle* (Privy Council Office, September 2001), Principle 1, online: <www.pco-bcp.gc.ca/raoics-srdc/docs/Precaution/Discussion/discussion_e.pdf> at Executive Summary.

¹²⁸ *Ibid.*, Foreword.

¹²⁹ ETC Group, *The Big Down: Atomtech — Technologies Converging at the Nano-scale* (January 30, 2003) at 73, online: <www.etcgroup.org/documents/TheBigDown.pdf>. ETC Group's call for a moratorium on the use of nanotechnology was recently renewed. See ETC Group, "Nanotech Product Recall Underscores the Need for Nanotech Moratorium: Is the Magic Gone?" (April 1, 2006), online: <www.etcgroup.org/en/materials/publications.html?pub_id=14>.

Others, including the Center For Responsible Nanotechnology, offer a different perspective, drawing an important distinction between the “strict form” of precaution, which calls for inaction (usually by banning, prohibiting, or restricting scientific research and development), and an “active form” of precaution, which requires that we choose “less risky alternatives when they are available ... taking responsibility for potential risks”.¹³⁰ Concerned that a moratorium would simply result in inaction on the part of responsible and law-abiding people/institutions while the development and use of dangerous nanotechnologies would continue underground or offshore by less responsible people/institutions, their interpretation of the precautionary principle “does not automatically forbid risky activities; instead it calls for an appropriate effort to mitigate the risk — which may well involve finding and choosing a different activity”.¹³¹ On this approach, it is “imperative to find and implement the least risky plan that is realistically feasible”.¹³² These authors further suggest that the safest option is to create a single research and development program for nanotechnology with widespread, though regulated use of its outputs.¹³³

The government of Canada has not yet articulated how the precautionary principle might be applied to nanotechnology. Nor has it proposed any specific regulatory regimes for nanotechnology. The future abounds with question marks.

III. THE CHALLENGE OF COMMERCIALIZATION

When contemplating the appropriate regulatory responses to emerging health technologies, an important factor to remember is that the research environment is becoming ever more closely tied to private industry. Biomedical researchers are increasingly expected to obtain research funding from private sources and justify research goals in terms of economic development. Even the Canadian Institutes of Health Research (CIHR), the primary public funding agency for health research, has a mandate, explicitly stated in the CIHR enabling legislation, to “encourag[e] innovation, facilitat[e] the commercialization of health research in Canada and promot[e] economic development through health research in Canada”.¹³⁴ Other funding agencies, such as Genome Canada, are charged with similar commercial goals.¹³⁵

¹³⁰ Chris Phoenix & Mike Treder, “Applying the Precautionary Principle to Nanotechnology” (Center for Responsible Nanotechnology, January 2003; revised December 2003, January 2004), online: <<http://www.crnano.org/precautionary.htm>>.

¹³¹ *Ibid.*

¹³² *Ibid.*

¹³³ *Ibid.*

¹³⁴ *Canadian Institutes of Health Research Act*, S.C. 2000, c. 6.

¹³⁵ See Genome Canada, online: <<http://www.genomecanada.ca>>.

There are, of course, numerous benefits to working with industry, including increasing the funds available for research and providing an essential knowledge translation function. Arguably, many of the therapeutic benefits associated with emerging technologies could not be realized in our society without a partnership between academic researchers and industry. For example, new drug therapies or diagnostic technologies can cost hundreds of millions of dollars to produce and disseminate. The infrastructure and funding for this aspect of the research development process must come largely from industry, as universities and other public research institutions do not have the requisite public funding or support to do it on their own. As noted by DeAngelis:

The discovery of new medications, devices, and techniques is funded primarily by for-profit companies; testing new modalities of treatment is funded primarily by for-profit companies; and the manufacture and the profitable marketing aspects of these modalities appropriately falls in the purview of this industry.¹³⁶

That said, there are also profound concerns that flow from the commercialization of biomedical research. Indeed, some of the greatest challenges associated with the use and integration of emerging technologies can be traced to the influence and role of commercial forces.¹³⁷ Here, we will briefly consider the role of patents.¹³⁸

Patents provide the inventor with an exclusive, 20-year monopoly over new inventions. Patents are meant to encourage innovation by providing a clear incentive. The patenting of biomedical inventions, however, has long been a source of social concern — particularly when the “invention” involves human biological substances, such as genetic material and human embryonic stem cell lines.¹³⁹ For example, there are those who believe that such patents are unethical or contrary to notions of human dignity.¹⁴⁰ On a practical level, it has been suggested that the push toward patents skews the direction of research away from needed basic science toward research that focuses on commercializable prod-

¹³⁶ Catherine D. DeAngelis, “The Influence of Money on Medical Science” (2006) 296 J.A.M.A. 996.

¹³⁷ See, e.g., D. Chalmers & D. Nicol, “Commercialisation of Biotechnology: Public Trust in Research” (2004) 6 Int’l J. Biotech. 116-33.

¹³⁸ There are, of course, many other important social issues associated with commercialization and the involvement of industry not covered in this chapter. For example, see J. Thompson, P. Baird & J. Downie, *Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto and Apotex Inc.* (Toronto: James Lorimer & Co. Ltd., 2001).

¹³⁹ See, e.g., Gina Kolata, “Who Owns your Genes?”, *New York Times* (May 15, 2000) at A-1 and Timothy Caulfield, Richard Gold & Mildred Cho, “Patenting Human Genetic Material: Refocusing the Debate” (2000) 1 *Nature Rev. Genetics* 227-31. See also Mark Lemley, “Patenting Nanotechnology” (2005) 58 *Stanford L. Rev.* 601.

¹⁴⁰ For a critique of this view, see D.B. Resnik, “DNA Patents and Human Dignity” (2001) 29 *J.L. Med. & Ethics* 152.

ucts. There is also speculation that patenting pressure leads to a more secretive research environment, thus inhibiting collaborations and the free flow of valuable research data.¹⁴¹ Finally, and perhaps most importantly, there is concern that patents will drive up the cost of emerging technologies adding to the overall costs of our health care system.¹⁴²

This latter concern received considerable attention in the summer of 2001 when Myriad Genetics attempted to enforce its patents over the BRCA1/2 mutations (genetic mutations that, if present, increase the likelihood an individual will get breast or ovarian cancer).¹⁴³ Through cease and desist letters sent to most provincial health ministries, Myriad Genetics tried to force all testing to be done through the Myriad laboratory in Utah, at a cost of approximately \$3,800, considerably more than the cost of doing the test through available processes at existing provincial laboratories. Though no patent litigation has emerged from the Myriad controversy, it was a catalyst of considerable policy debate and was considered by some as a “harbinger” of things to come.¹⁴⁴

Despite such issues, the patenting of biomedical inventions, including human genes, has continued, relatively unfettered, for decades. In general, so long as an invention meets the basic statutory requirements for a patent — it must be new, useful and have a clear utility — it can be patented.¹⁴⁵ Indeed, it has been estimated that over 20 per cent of all human genes are associated with at least one patent.¹⁴⁶ That said, the concerns associated with biotechnology patents, particu-

¹⁴¹ P.A. David, “Can ‘Open Science’ be Protected from the Evolving Regime of IPR Protections?” (2004) 160 *Journal of Theoretical and Institutional Economics* 1-26; David Blumenthal, “Withholding Research Results in Academic Life Science: Evidence From a National Survey of Faculty” (1997) 277 *J.A.M.A.* 1224.

¹⁴² See Jon Merz *et al.*, “Diagnostic Testing Fails the Test” (2002) 415 *Nature* 577-79; and Timothy Caulfield, “Policy Conflicts: Gene Patents and Health Care in Canada” (2005) 8 *Community Gen.* 223-27.

¹⁴³ Bryn Williams-Jones, “History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing” (2002) 10 *Health L.J.* 123-46. For a discussion of the role of these mutations in the development of cancer see M.C. King, J. Marks & J. Mandell, “Breast and Ovarian Cancer Risk Due to Inherited Mutations in BRCA1 and BRCA2” (2003) 302 *Science* 643-46.

¹⁴⁴ Bryn Williams-Jones, “History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing” (2002) 10 *Health L.J.* 123-46; and Richard Gold, “From Theory to Practice: Health Care and the Patent System” (2003) *Health Law Journal Special Edition* 21-39.

¹⁴⁵ See, generally, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Since this landmark decision by the United States Supreme Court, there have been few legal obstacles to the patenting of biologically based “inventions”. It should be noted, however, that Canada is the only country with a high court decision that explicit rejects the patenting of “higher life forms” (*Harvard College v. Canada (Commissioner of Patents)*, [2002] S.C.C. No. 77, [2002] 4 S.C.R. 45, 219 D.L.R. (4th) 577 (S.C.C.)).

¹⁴⁶ K. Jensen and F. Murray, “Enhanced: Intellectual Property Landscape of the Human Genome” (2005) 310 *Science* 239-40.

larly those regarding the impact of patents on access, continue to stir debate and have led to a variety of policy recommendations from provincial governments,¹⁴⁷ bioethics and science policy entities,¹⁴⁸ and international organizations.¹⁴⁹ Recommendations have ranged from clarifying the research exemptions (so researchers can access patented inventions without fear of infringing a patent) to a consideration of compulsory licensing (so provincial health care systems can control the cost of patented inventions).¹⁵⁰

To date, there have been no major reforms to the Canadian patent system, and the degree to which the available empirical data supports or denies the existence of the noted concerns remains a subject of considerable debate.¹⁵¹ Nevertheless, there is some evidence that the public is becoming increasingly uncomfortable with biotechnology patents¹⁵² and that the patenting of controversial emerging technologies, including embryonic stem cell lines and nanotechnologies, might stir more interest in policy reform.¹⁵³ For example, because the source of embryonic stem cell lines remains controversial, there may be those who believe that the patenting of stem cell lines is morally inappropriate.

Another major concern associated with the commercialization process is that marketing pressure, inextricably tied with the involvement of industry, will lead

¹⁴⁷ Ontario Ministry of Health, *Genetics, Testing and Gene Patenting: Charting New Territory in Healthcare* (Toronto: Government of Ontario, 2002).

¹⁴⁸ See Danish Council of Ethics, *Patenting Human Genes and Stem Cells* (Copenhagen: Danish Council of Ethics, 2004); and The Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (London: Nuffield Council of Bioethics, 2002); and National Academy of Sciences, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (Washington, D.C.: National Academies Press, 2005).

¹⁴⁹ Organisation for Economic Cooperation and Development (OECD), "Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies" (2002), online: <<http://www.oecd.org/dataoecd/42/21/2491084.pdf>>.

¹⁵⁰ Ontario Ministry of Health, *Genetics, Testing and Gene Patenting* (Toronto: Government of Ontario, 2002).

¹⁵¹ Timothy Caulfield, Bob Cook-Deegan, Scott Kieff & John Walsh, "Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies" (2006) 24 *Nature Biotechnology* 1091-94.

¹⁵² E. Einsiedel & J. Smith, "Canadian Views on Patenting Biotechnology" (Canadian Biotechnology Advisory Committee, June 2005), online: <[http://www.cbac-ccb.ca/epic/internet/incbac-ccb.nsf/vwapj/FINAL_inseidel_e.pdf/\\$FILE/FINAL_inseidel_e.pdf](http://www.cbac-ccb.ca/epic/internet/incbac-ccb.nsf/vwapj/FINAL_inseidel_e.pdf/$FILE/FINAL_inseidel_e.pdf)>.

¹⁵³ See, for example, Timothy Caulfield, "Stem Cell Patents and Social Controversy: A Speculative View From Canada" at 219-32; and Mark Lemley, "Patenting Nanotechnology" (2005) 58 *Stanford L. Rev.* 601.

to an inappropriate increase in the utilization of a given technology.¹⁵⁴ There is evidence that this is already happening in a variety of domains, such as with imaging technologies,¹⁵⁵ genetic testing¹⁵⁶ and, of course, pharmaceuticals.¹⁵⁷ Industry has a natural and understandable desire to increase profits by increasing demand. But this inclination may result in marketing strategies that create inappropriate expectations, patient anxiety and more utilization than what might be considered ideal. In order to counter such pressures, regulatory strategies have been proposed, including independent technology assessment and controls on marketing approaches.¹⁵⁸

Finally, the impact of commercialization on that most valuable of assets, public trust, should be considered. Indeed, many scholars have noted that public trust is an essential element of the research infrastructure and, if lost, is tremendously difficult to regain.¹⁵⁹ There is at least some evidence that close ties with industry have the potential to compromise public trust. For example, university researchers funded by public sources are one of the most trusted voices in the area of biotechnology. However, those funded by industry are among the least trusted.¹⁶⁰ The source of funding, and its perceived impact on the impartiality of researchers, seems to be the critical element. And, given the evidence that industry funding impacts the nature and tone of research findings, the public's skepti-

¹⁵⁴ See, e.g., Patti Peppin, "The Power of Illusion and the Illusion of Power", in Colleen Flood, ed., *Just Medicare: What's In, What's Out, How We Decide* (Toronto: University of Toronto Press, 2005) at 355.

¹⁵⁵ Richard Smith, "The Screening Industry" (2003) 326 B.M.J.: "Simple minded enthusiasm for screening, combined with the industrial opportunity to make fat profits, may mean that soon none of us will be normal".

¹⁵⁶ Stacy Gray & Olufunmilayo I. Olopade, "Direct-to-Consumer Marketing of Genetic Tests for Cancer: Buyer Beware" (2003) 21 J. Clin. Oncology 3191-93.

¹⁵⁷ See Steven Woloshin & Lisa Schwartz, "Giving Legs to Restless Legs: A Case Study of How the Media Makes People Sick" (2006) 3 PLoS Med. 452; and Trudo Lemmens & Ron A. Bouchard, Chapter 8 in this volume.

¹⁵⁸ Barbara Mintzes, "Disease Mongering in Drug Promotion: Do Governments Have a Regulatory Role?" (2006) 3 PLoS Med. 461. An additional concern, not considered in this brief overview, is the impact that commercialization pressure will have on the direction of research — skewing it toward commercializable objectives and away from basic research and less profitable public health initiatives. Caulfield has explored this issue elsewhere. See, e.g., Timothy Caulfield, "Sustainability and the Balancing of the Health Care and Innovation Agendas: The Commercialization of Genetic Research" (2003) 66 Sask L. Rev. 629. See also Paul Nightingale & Paul Martin, "The Myth of the Biotech Revolution" (2004) 565 Trends in Biotech 566-67.

¹⁵⁹ Marcia Angel, "Is Academic Medicine for Sale?" (2000) 342, N.E.J.M. 1516-18.

¹⁶⁰ Government of Canada BioPortal, "A Canada-US Public Opinion Research Study on Emerging Technologies" at 55 (see slide no. 110).

cism is not without foundation.¹⁶¹ In areas like stem cell research, nanotechnology and human genetics, where the public may already have concerns about the use and implications of the technology,¹⁶² a loss of public trust could be particularly damaging.

If industry is going to continue to play an ever-increasing role in the funding of biomedical research, policies must be developed to ensure that the integrity of the research enterprise is maintained and that public trust is respected and engaged.¹⁶³

IV. CONCLUSION

In this chapter, we have examined four emerging health technologies. We have seen that each has significant potential health benefits to offer. Each also has various ethical and legal dimensions associated with its proposed use. In this chapter, we have limited our brief survey to a single health law and policy precept for each: genetics requires us to think about equality and equal treatment; radio frequency identification poses new challenges for informational privacy and security; embryonic stem cell techniques revive debates about the moral limits of human experimentation; nanotechnology raises questions about the practice of precaution. We also considered how scientific research is transformed into technological applications through the process of commercialization.

As we continue to think about these new elixirs, it is instructive to recall King Thamus and his admonition to the inventor: “Theuth, my paragon of inventors, the discoverer of an art is not the best judge of the good or harm which will accrue to those who practice it”.

When we consider the governance of science and the proper place of technology in our health care system, it is important to recognize that the technolo-

¹⁶¹ Council on Scientific Affairs, American Medical Association, *Influence of Funding Source on Outcome, Validity, and Reliability of Pharmaceutical Research* (C.S.A. Report 10, 2004 A.M.A. Annual Meeting, June 2004) where the authors summarize the research in the area:

Studies with positive findings are more likely to be published than studies with negative or null results and an association exists between pharmaceutical industry sponsorship of clinical research and publication of results favoring the sponsor’s products. Additionally, the publication of negative results may be delayed compared with the time to publication of studies with positive results.

¹⁶² In a 2005 study only 49 per cent of Canadians surveyed (compared with 57 per cent of Americans), thought that biotechnology was being developed with consideration to their interests, values and beliefs, Government of Canada BioPortal, “A Canada-US Public Opinion Research Study on Emerging Technologies”.

¹⁶³ See, e.g., Timothy Caulfield, Edna Einsiedel, Jon Merz & Dianne Nicol, “Trust, Patents and Public Perceptions: The Governance of Controversial Biotechnology Research” (2006) 24 *Nature Biotechnology* 1352-54, where the use of patent pools is recommended as a way of managing the commercialization.

gies that science enables are not neutral and that it is therefore not always appropriate to leave science to its own devices. As one team of scholars recently put it:

values; science alone cannot answer them. The public expect and want science and technology to solve problems, but they also want a say in deciding which problems are worth solving. This is not a matter of attracting public support for an agenda already established by science and scientists, but rather of seeing the public as participants in science policy with whom a shared vision of socially viable science and technological innovation can be achieved.¹⁶⁴

Likewise, bioethicists, lawyers, policy makers and other relevant experts all have a crucial role to play in determining the best way to harness emerging technologies that are both good *and* bad; at one and the same time the solution and the problem.

¹⁶⁴ George Gaskell *et al.*, "Social Values and the Governance of Science" (2005) 310 *Science* 1909.