Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution

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Rapid advances in the field of genetics in recent years have caused some commentators to suggest the emergence of a "genetic revolution". Such advances have been both praised as the "future of medicine" and condemned for encouraging the acceptance in society of laissez-faire eugenics. Yet the effect of technological advances flowing from the science of geneties appears somewhat overstated as few products of the genetic revolution, particularly in the areas of gene therapy and genetic testing, have managed to satisfy scientists' expectations to date. Furthermore, misdirected regulation of such advances can exacerbate the social, legal, and ethical problems associated with genetics, particularly in the context of health care, where issues of human cloning and the use of premature genetic testing technologies dominate current public debate.

In this article, the author criticizes the hyberbolic rhetoric surrounding the genetic revolution and calls for a more balanced and informed approach to the development of genetic policies and regulations. Such an approach should include substantial interdisciplinary debate and an active role on the part of government in the identification and communication of accurate information relating to the effects of recent technological advances in the field of genetics.

Les progrès rapides en génétique des dernières années out mené certains commentateurs à évoquer l'émergence d'une «révolution génétique». Ces progrès ont fait l'objet, à la fois, d'un enthousiasme faisant d'eux l'«avenir de la médecine» et de condamnations pour leur tendance à favoriser l'acceptation sociale du laisser-faire en matière d'eugénisme. Cependant, les effets concrets des percées technologiques issues des progrès en génétique apparaissent quelque peu exagérés. Jusqu'à maintenant, peu de produits issus de cette «révolution» ont rempli les attentes des scientifiques, en particulier dans les domaines du dépistage génétique et de la thérapie génique. De plus, une réglementation mal orientée de ces progrès est susceptible d'exacerber les problèmes sociaux, légaux et éthiques soulevés par la génétique, en particulier dans le contexte des soins de santé, où les questions relatives au clonage et à l'utilisation prématurée de technologies de dépistage génétique dominent le débat public actuel.

L'auteur critique l'inflation rhétorique entourant la révolution génétique et préconise une approche davantage équilibrée et informée pour le développement de politiques et de règlements relatifs à la génétique. Une telle approche devrait inclure un substantiel débat interdisciplinaire et la participation active du gouvernement dans l'identification et la dissémination d'informations précises concernant les effets et les conséquences des progrès rapides en génétique.

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Introduction

> *We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological interest.*
> Watson and Crick, 1953[1]

> *People today are now living through the most stunning information revolution, unlike anything before in the history of science.*
> Eric Lander, 1999[2]

The understated tone of the opening sentence to Watson and Crick's seminal paper, quoted above, describing the structure of DNA contrasts sharply with Eric Lander's recent characterization of the current genomic era. The contrast nicely highlights the distance the science of genetics has come in the past few decades. Not long ago a quiet bench science, genetics is currently the undisputed king of the biological disciplines. So rapid are the advances in this field, and so ubiquitous their impact, that it has been said that we are living in the midst of a "genetic revolution."

If we pick the commencement of the Human Genome Project ("HGP") as its birth, then the revolution has been with us for almost a decade.[3] During this time, the scientific and technological advances that have flowed from the science of genetics have been both widely praised as the "future of medicine"[4] and condemned as having the potential to usher in an era of genetic determinism and laissez-faire eugenics.[5] It has also been suggested that we are witnessing both the birth of the "biotech century" (a time when biotechnology, fuelled by molecular genetics, will become one of the

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[1] J. Watson & F. Crick, "A Structure for Deoxyribose Nucleic Acid" (1953) 171 Nature 737 at 737.

[2] E. Lander, "Genetics in the 21st Century" (1999) 10 Hum. Genome News 13 at 13.

[3] Of course, many dates have the potential to represent the beginning of the genetics era. The publication date of Watson and Crick's famous paper describing the structure of DNA, for example, was 1953 (*supra* note 1). However, most of the recent advances in genetics are closely tied to the massive international research initiative known as the Human Genome Project. The goal of the HGP is to clone and sequence all human genes, see R. Cook-Deegan, *The Gene Wars: Science, Politics and the Human Genome* (New York: Norton and Company, 1994). Recently, Francis Collins, director of the Human Genome Project at the National Institutes of Health in the U.S. called the HGP "the most important organized scientific effort that humankind has ever attempted. It dwarfs going to the moon" (J. Shreeve, "Secrets of the Gene" *National Geographic* 196:4 (October 1999) at 55).

[4] *Time Magazine: Special Issue: The Future of Medicine* 153:1 (11 January 1999) 42.

[5] For an early critique, see R. Hubbard & E. Wald, *Exploding the Gene Myth* (Boston: Beacon Press, 1993). As argued by D. King, "The Persistence of Eugenics" (February/March 1998) GenEthics News 6 at 8:

> [A] new eugenics will most likely be a *laissez faire* eugenics. The dominant concept now is consumer choice in reproduction, an idea unheard of in the 1930s. Although we are unlikely to see a new generation of eugenic activists publicly arguing for such polices, the outcome will be the same.

dominant economic engines)[6] and the emergence of a "genetic underclass". Such is the language of the genetic revolution. Grand claims, daily announcements of amazing discoveries, fearful predictions of the commodification of humanity—in this climate of hyperbole it is becoming increasingly difficult to distill fact from fancy and legitimate concern from polemic diatribe. But as the products of the revolution start to move from the laboratory into practical use, policy makers have a responsibility to cut through the headlines and the bombast to develop well-informed and thoughtful regulatory policy.

The scientific and health care advances which will accrue from the genetic revolution will undoubtedly be profound. And the belief in tremendous social benefit is justified and supportable, but so are the concerns—particularly given the dark social history of genetics.[7] Unfortunately, the overstated verbiage both praising and condemning the genetic revolution has the potential to undermine the realization of benefits and magnify the social and ethical issues. The hyperbolic rhetoric is bad for all concerned. It hurts the genetic scientists by undervaluing the real, basic, scientific advances which have already occurred and which are sure to continue. It hurts industry by creating unrealistic, short-term expectations and thus inevitably leading to disappointment and a fall in investment. It hurts public understanding and public participation in policy development. Finally, it hurts the debate around ethical issues and the development of regulatory policy by deflecting discourse and policy-making momentum toward the extreme and away from immediate, practical concerns.

This paper is a call for a balanced and informed approach to the development of genetic policies and regulations. The genetic revolution will not provide the antidote for all that ails the human species. Indeed, as we will see below, it has yet to produce even one broadly applicable therapeutic intervention. But nor is the genetic revolution an inherently corrupt phenomenon. The science of genetics is, however, moving at a breathtaking speed and many in our society seem eager to simplify and exploit the emerging genetic knowledge in order to forward agendas of dubious worth—be they political, commercial, sexist, or racist. As such, few would argue with the need for some degree of regulatory oversight. But policy-makers need to ensure that the discourse does not become tangled in false expectations or misguided and ill-informed denunciations.

The paper begins with a description of the genetic revolution. In order to develop sustainable and effective genetic policies, we must be sensitive to the scientific, economic, and cultural forces currently behind genetics. As such, understanding the tremendous scope and varied applications of genetics seems essential. The next section

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[6] N. Freundlich, "The Biotech Century" *Business Week* (10 March 1997) at 78.

[7] See *e.g.* T. Caulfield & G. Robertson, "Eugenic Policies in Alberta: From the Systematic to the Systemic?" (1996) 35 Alta. L. Rev. 59; M.H. Haller, *Eugenics: Hereditarian Attitudes in American Thought* (New Jersey: Rutgers University Press, 1963); and H. Friedlander, *The Origins of Nazi Genocide: From Euthanasia to the Final Solution* (Chapel Hill: University of North Carolina Press, 1995).

of the paper uses the examples of gene therapy and genetic testing to illustrate that, contrary to the tone of popular perception, few products of the revolution have yet to live up to the hype. This is followed by a discussion of a number of the social concerns associated with the genetic revolution. Specifically, I will examine the concerns of geneticization (as manifested in the cloning debate) and the premature entrance of genetic technologies (as exemplified in the marketing of genetic tests). While an admittedly narrow selection from a vast array of concerns identified in the literature, the issues of geneticization and the premature implementation of genetic technologies illustrate both the adverse effect of "genohype" and how misdirected genetic regulations can actually exacerbate the often noted social, legal and ethical problems.

Most of the paper concentrates on the impact of the genetic revolution in the context of health care. This is the area that has attracted much of the attention from the national and international legal and ethical communities. However, as discussed in the next section, the genetic revolution is a far broader scientific phenomenon and many of my comments about the adverse impact of genohype apply equally to other areas, such as agricultural biotechnology.[8]

I. What is the Genetic Revolution?: Science, Commerce, and Culture

What is the "genetic revolution?" First, it is important to note that it is not any one scientific advance or technological development. Xenotransplantation, genetically modified foods, the cloning of mammals, genetically derived drugs,[9] pharmacogenomics,[10] the prenatal diagnosis of genetic diseases, the alleged finding of behavioural genes, the prospect of gene therapy, the development of DNA vaccines[11]—these are all technologies or discoveries that have either benefitted from, or are a direct result of, the recent growth in our knowledge about genetics. Genetics is also touching an increasingly broad range of disciplines. For example, advances in molecular genetics have allowed anthropologists to gain a better understanding of the migration patterns of early human societies,[12] historians are now able to explore the biological relation-

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[8] The best non-health care example is undoubtedly the debate that has raged in relation to genetically modified foods. See *e.g.* A. Coghlan, "Caught in the Crossfire" *New Scientist* (18 September 1999) 22 and Editorial, "Friendly Fire" *New Scientist* (18 September 1999) 3.

[9] I. Wickelgren, "Mining the Genome for Drugs" (1999) 285 Science 998; and W.A. Haseltine, "Discovering Genes for New Medicines" *Scientific American* 276:3 (March 1997) 92.

[10] W. Evans and M. Relling, "Pharmacogenomics: Translating Functional Genomies into Rational Therapeutics" (1999) 286 Science 487.

[11] R. Seder & S. Gurunathan, "DNA Vaccines—Designer Vaccines for the 21st Century" (1999) 341 New England Journal of Medicine 277.

[12] K. Owens & M.C. King, "Genomic Views of Human History" (1999) 286 Science 451; and T. Powledge & M. Rose, "The Great DNA Hunt: Genetic Archaeology Zeroes in on the Origins of Modern Humans" (September/October 1996) Archacology 36.

ships of long dead individuals,[13] evolutionary scientists are gaining a greater understanding of the genetic heritage of species[14] and botanists can genetically engineer plants to perform specific functions.[15] In short, from the perspective of the biological sciences, genetics has become an omnipresent force—one that seems likely to remain dominant for decades to come.

Of course, genetics has already had an impact on the discipline of law—most notoriously as an evidentiary tool in criminal cases.[16] But genetic identification testing can be used in a variety of less dramatic settings such as determining relatedness for the purposes of inheritance and immigration[17] and even as a forensic tool to identify animals who have been unlawfully taken from the wild.[18] To date, however, the most common legal application of genetic identification technology is as a means of determining paternity for the purposes of family law (*e.g.* disputes over custody, access and maintenance payments).[19]

One of the most significant elements of the genetic revolution is its close ties with industry. Though science has always been associated with the private sector, the science of genetics is emerging at a time when universities and university researchers are building unprecedented ties with industry partners.[20] Moreover, an increasing amount

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[13] DNA analysis techniques were used, for example, to show that the then-deceased Anna Anderson was not, as many had believed, the Tsar's daughter Anastasia. See R. Massie, *The Romanovs: The Final Chapter* (New York: Random House, 1995) at 240-42.

[14] G. Poinar, "Ancient DNA" (1999) 87 American Scientist 446 at 456: "The molecular biology revolution of the last several decades has reached into every conceivable corner of biological investigation."

[15] See *e.g.* W. Stevens, "Redrawing the Tree of Life" *The Globe and Mail* (1 September 1999) A19 and K. Honey, "Plants Altered to Grow in Salty Soil: University of Toronto Scientist Clones Gene to Let Cells Trap Sodium, Accept Water" *The Globe and Mail* (20 August 1999) A2.

[16] See Canada, Department of Justice, *Obtaining and Banking DNA Forensic Evidence* (Ottawa: Supply and Services Canada, 1994).

[17] See J. Clay, "DNA and the Case of the Alleged Heir" (1993) 13 Estates & Trusts J. 145 and D. Singh, "DNA Profiling: Insurmountable Proof or Exaggeration?" (1995) 14 Med. L. 445.

[18] G. Shorrock, "The Success of DNA Profiling in Wildlife Law Enforcement" (1998) 1 Int'l J. Biosciences & L. 327. In this context, DNA technology is used to differentiate between animals that have been bread in captivity and those that have been illegally taken from the wild.

[19] J. Clay, "DNA Testing To Investigate The Ties That Bind—A Discussion of DNA Testing in Issues of Paternity" (1995) 12 C.F.L.Q. 301 at 305. It is interesting to note that some commentators fear a "genetization of the definition of family such that biological ties are emphasized at the expense of social ties." See *e.g.* R. A. Charo, "Biological Truths and Legal Fictions" (1998) 1 J. Health Care L. & Pol'y 301 at 301; R. Deech, "Family Law and Genetics" (1998) 61 Mod. L. Rev. 697; D. Nelkin & S. Lindee, *The DNA Mystique: The Gene As a Cultural Icon* (New York: W.H. Freeman & Co., 1995) at 59 and T. Caulfield, "Paternity Testing in the Genetic Era" (1996) 17 Health L. Can. 19.

[20] See R. Varma, "Professional Autonomy vs. Industrial Control?" (1999) 8 Science as Culture 23 at 37 who argues that from the perspective of government granting agencies, the needs of industry are considered paramount: "Basic science is valued only if it contributes to the creation of products or processes for the US industry. The government agencies are now supporting research which is geared to help industry."

of the most basic genetic research, such as the sequencing of the human genome, is occurring in the private sector.[21] The bottom line is that genetics is big business.

Another important element of the genetic revolution is how society, and the media in particular, reacts to these genetic technologies and scientific advances. Most individuals receive information about science and technology from the mass media[22] and, as such, it is the primary source of the hyperbolic message surrounding genetics. It is difficult to pick up a paper without finding at least one story relating to the science of genetics. Indeed, in addition to being a scientific and technical phenomenon, the genetic revolution is, to some degree, a cultural phenomenon. Examples of extreme headlines abound: "Cell Discovery a Major Step Toward Cloning of Humans",[23] "Warning Over 'Nazi' Genetic Screening",[24] "Scientists Isolate Group of 'Immortality' Genes",[25] "Scientists Raise Hopes of Cloning Woolly Mammoth",[26] "Scientist Claims He Found DNA from Blood of Christ",[27] and "Researcher Traces Gene for Obesity".[28] Many commentators have argued that the pervading nature of genetics in popular culture is, in fact, the most important aspect of the genetic revolution. "The gene of popular culture is not a biological entity", Dorothy Nelkin argues, "its symbolic meaning is independent of biological definition."[29]

In many respects, the overstatement is understandable. Researchers need to generate enthusiasm for their research ideas in order to secure government support.[30]

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[21] See generally E. Marshall, "A High-Stakes Gamble on Genome Sequencing" (1999) 284 Science 1906.

[22] T. Wilkie & E. Graham, "Power without Responsibility: Media Portrayals of Dolly and Science" (1998) 7 Cambridge Q. Healthcare Ethics 150 at 150. See also, J. Durant, A. Hansen & M. Bauer, "Public Understanding of the New Genetics" in T. Marteau & M. Richards, eds., *The Troubled Helix: Social and Psychological Implications of the New Human Genetics* (Cambridge: Cambridge University Press, 1996) 235.

[23] K. Foss, *Globe and Mail* (6 November 1998) A1.

[24] BBC News, Health (9 August 1999), online: <http://news2.th/s.bbc.co.uk/hi/english/health/news/d%5F415000/41536.stm> (date accessed: 27 November 1999).

[25] *Edmonton Journal* (4 July 1999) A5.

[26] *Edmonton Journal* (23 July 1999) A5.

[27] *Edmonton Journal* (15 November 1998) A4.

[28] M. Fox, *Globe and Mail* (5 March 1999) A9.

[29] Nelkin & Lindee, *supra* note 19; and quoted in Wilkie & Graham, *supra* note 22 at 150. See also D. Nelkin & S. Lindee, "The Revival of Eugenics in American Popular Culture" (1997) 53 J. Am. Med. Women's Assoc. 45 at 46:

> Eugenics in contemporary culture is less an ideology of the state than a set of ideals about a perfected and "healthy" human future. .... These beliefs—conveyed through many stories in popular culture—draw on the assumption that our social, political, and economic future will depend on controlling the genetic constitution of the species.

[30] In fact, some have argued that the Human Genome Project itself has been oversold. See *e.g.* L.B. Andrews, "Past as Prologue: Sobering Thoughts on Genetic Enthusiasm" (1997) 27 Seton Hall L. Rev. 893 at 898: "[The U.S.] Congress was convinced to fund [the HGP] on the promise that it would lead to diagnosis and cure of genetic disease. But, even if completed on time and as promised, mapping and sequencing will not provide information about diseases and their cures."

Biotechnology companies, through press releases, may over-emphasize the practical applications of a genetic discovery in the hope of attracting venture capital. These stories are then given a further spin by journalists who have a tendency to simplify complex information. As noted by Joan Stephenson, a reporter for the *Journal of the American Medical Association*: "[T]he influence of genes is usually complex, but science writers sometimes present new findings—'*the* breast cancer gene,' '*the* gay gene,' '*the* obesity gene' as if a single gene were directly responsible for the trait in question."[31] But these less than accurate claims and speculations have been translated into our genetic reality. As such, there is a danger that we will respond—that is, make laws, regulations, and policy decisions—not to the reality of genetic science but to the hyperbole of the genetic revolution.

In sum, the genetic revolution is an amalgamation of social forces. Genetics is transforming the bio-sciences, it is increasingly used as an evidentiary tool in legal cases, it is viewed by governments as an engine of economic growth, it is the target of private sector investment, and it has been largely embraced by popular culture.[32] The combination of these trends, and not any one acting alone, is what I mean when I speak of the genetic revolution. They all work together to add to the pervasive nature of genetics and help create the atmosphere of "genohype" which currently seems to exist. How society views and reacts to one genetically related phenomenon—human cloning or genetically modified foods, for example—will likely impact how we view and respond to another, not necessarily related, genetic development.[33] As such, it seems essential for policy-makers to remain sensitive to the tremendous breadth and inter-relatedness of various genetic developments.

And while some may wish to avoid the use of term "genetic revolution",[34] it is hard to deny that a broad social phenomenon is occurring. Whether the revolution was partly "created" by the hyperbolic rhetoric which has surrounded human genetics and whether, in the aggregate, it will be a constructive social force are irrelevant to the fact of its existence. As recently prophesized in *Time* magazine: "Ring farewell to the

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[31] J. Stephenson, "Genetics and Journalism: A View from the United States" in A. Thompson and R. Chadwick, eds., *Genetic Information: Acquisition, Access, and Control* (New York: Kluwer Academic, 1999) 201 at 204.

[32] Durant *et al.*, *supra* note 22 at 246, notes that:

> Today, DNA is not merely the name of the genetic material, it is also the name of a perfume. It is only be taking account of the shifts in meaning, in connotation and in significance that are involved in the transformation of molecular genetics into mass culture that we shall do justice to the public understanding of the new genetics.

[33] See *e.g.* Coghlan, *supra* note 8 at 22, where it is noted that there is a fear that "medical biotechnology will be damaged by controversy over engineered foods." For a discussion of patients' understanding, see J. Emery, S. Kumar & H. Smith, "Patient Understanding of Genetic Principles and Their Expectations of Genetic Services Within the NHS: A Qualitative Study" (1998) 1 Community Genet. 78.

[34] Abby Lippman, Panel discussion, *The Genetic Revolution and the Future for Health and Social Care*, University of Glamorgan, Wales, June 23-24, 1999.

century of physics, the one in which we split the atom and turned silicon into computing power. It's time to ring in the century of biotechnology."[35]

II. Products of the Revolution: Knowledge, Hope, and Hype

There is no doubt that the accomplishments of the science of genetics have been tremendous. Some have gone so far as to state that "[b]y all scientific measures the HGP has been a resounding success thus far."[36] In strict scientific terms, there is little reason to doubt such claims. For example, the rate of gene discovery has accelerated incredibly since the beginning of the HGP. The cystic fibrosis gene, identified in 1989, took ten years and fifty million dollars to find. In 1997, a gene responsible for some cases of Parkinson's disease was found in nine days.[37] In fact, it has become relatively easy to locate the genes associated with Mendelian (or monogenetic) diseases such as Huntington's. Eric Lander estimates that over 1000 rare Mendelian disorders have been mapped to a specific region on a chromosome and that approximately 140 have been specifically isolated.[38]

But in many other respects, the genetic revolution has not lived up to the hype. While the work of the HGP has undoubtedly shed light on our understanding of basic biology and human disease, very few health care-related, practical, and clearly useful products have been forthcoming. This is not to say that health care benefits have not been obtained, they have—particularly for specific "at risk" populations.[39] However, there is a danger that the hype surrounding genetic products will lead to both premature implementation of services and, ultimately, disappointment when expectations are not met. Health care policy should be informed by an understanding of the limits of the current technologies.

For example, gene therapy, arguably the most eagerly anticipated product of the genetic revolution, remains a dream. The primary goal of gene therapy is to "provide the patient with healthy copies of missing or flawed genes" and thus prevent or cure

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[35] W. Isaacson, "The Biotech Century" *Time* 153:1 (11 January 1999) 27 at 27. Many commentators have predicted that the coming century will be dominated by biotechnology. See *e.g.* J. Rifkin, *The Biotech Century* (New York: Putnam, 1998); "The Biotech Century" *Business Week* (10 March 1997); and Freundlich, *supra* note 6.

[36] M.K. Mansoura & F.S. Collins, "Medical Implications of the Genetic Revolution" (1998) 1 J. Health Care L. & Pol'y 329 at 330.

[37] *Ibid.* at 331; and R. Worton, "The Human Genome Project and Beyond" (Presentation, Genetics 2000: Gene Discovery and Beyond, University of Alberta, 9-10 April 1999).

[38] Lander, *supra* note 2 at 13.

[39] For example, research has shown that predictive testing for Huntington Disease with pre- and post-test counselling is safe and perhaps beneficial for most interested participants: see M. Huggins *et al.*, "Predictive testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk" (1992) 42 Am. J. Med. Genet. 508; and C. Benjamin *et al.*, "Proceed with Care: Direct Predictive Testing for Huntington Disease" (1994) 55 Am. J. Hum. Genet. 606.

diseases with a genetic basis.[40] To date, however, there have been no successful clinical trials and the scientific obstacles remain considerable.[41] In fact, recently, a patient enrolled in a controversial gene therapy experiment at the University of Pennsylvania died—allegedly as a result of his participation in the study.[42] So, while some significant scientific advances have occurred, "gene therapy has yet to produce any of the revolutionary treatments predicted back in 1990."[43]

Moreover, genetic testing technologies, one of the first and best known "products" of the genetic revolution, are still not as clinically useful as originally hoped—though, admittedly, many such technologies are still relatively new.[44] Genetic tests can be utilized in a variety of contexts (*e.g.* prenatal, carrier, or population testing) but generally serve to identify the presence of a genetic mutation that either causes a disorder (*e.g.* Tay-Sachs, cystic fibrosis, Huntington disease) or is responsible for increasing an individual's risk to develop, at some point during their lifetime, a given disease (*e.g.* breast cancer). Though this information may be of psychosocial value to many individuals,[45] the clinical value of individual genetic testing—particularly in the context of these latter, usually more common, diseases—remains ambiguous.[46] First,

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[40] J. Kinderlerer & D. Longley, "Human Genetics: The New Panacea?" (1998) 61 Mod. L. Rev. 603 at 614. The authors note that a recent NIH panel investigating gene therapy concluded that "clinical efficacy had not been definitively demonstrated at this time in any gene therapy protocol"—this despite the initiation of over one hundred gene therapy protocols in the U.S. alone.

[41] J. Wilson, "Human Gene Therapy: Present and Future" (1999) 10 Hum. Genome News 15. The main challenge appears to be finding a vector—that is, a mechanism to transfer the DNA into the desired human cell.

[42] See R. Weiss & D. Nelson, "Teen Dies Undergoing Experimental Gene Therapy" *The Washington Post* (29 September 1999) A01, online: Washington Post (Archives) <www.washingtonpost.com/wp-srv/WPlate/1999-09/29> where the authors note: "The death is the latest in a series of setbacks for a promising approach that has so far failed to deliver its first cure and that has been criticized as moving too quickly from the laboratory bench to the bedside." See also, D. Nelson & R. Weiss, "Family's Debate Mirrored Scientists' on Gene Therapy Risk" *The Washington Post* (30 September 1999) A07, online: Washington Post (Archives) <www.washingtonpost.com/wp-srv/WPlate/1999-09/30> and D. Nelson & R. Weiss, "NIH Not Told of Deaths in Gene Studies" *The Washington Post* (3 November 1999) A01.

[43] P. Nicholson, "Back to the Future" (1999) 2 Biotech. Focus 14 at 14. It should be noted, however, that not all are so pessimistic. One U.S. market report predicts the first commercial gene therapy product within two years and a $12 million market—particularly for cancer related products—by 2007 (*ibid.* at 14).

[44] For an interesting critique of existing genetic tests, see A. Motulsky, "If I Had a Gene Test, What Would I Have and Who Would I Tell?" (1999) 354 Lancet 35 [hereinafter "Gene Test"].

[45] See *e.g.* J. Hall, R. Viney & M. Haas, "Taking a Count: The Evaluation of Genetic Testing" (1998) 22 Austral. & N.Z. J. Pub. Health 754 and K. Macdonald *et al.*, "Genetic Vulnerability: The Unwanted Inheritance: Sociobehavioural Implications of Cancer Risk. Background Paper" (International Research and Policy Symposium (Toronto), Critical Choices: Ethical, Legal and Sociobehavioural Implications of Heritable Breast, Ovarian and Colon Caneer, 28-30 April 1995) [unpublished].

[46] G. Stix, "Is Genetic Testing Premature?" (1996) *Scientific American* 275:3 (September 1996) 107; H. Welch & W. Burke, "Uncertainties in Genetic Testing for Chronic Disease" (1998) 280 J.

there are very few cures, or even known preventative strategies, that can be utilized for those individuals who test positive for a given disease gene.[47] Second, the relationship between a disease mutation and the clinical manifestation "can be complex and unpredictable."[48] That is, scientists are still unsure of what the presence of a given mutation means for the expression of a given disease. Third, there are profound questions surrounding who should be offered genetic testing. In other words, who is the "at risk" population that would benefit the most from this information? Finally, there are also legal, ethical, and social consequences, discussed below, associated with genetic testing.

To illustrate these problems, let us look at one example. To date, there is still disagreement surrounding the use of the test for the BRCA1 and BRCA2 mutations.[49] This was one of the first genes to be identified with a common, multi-factorial disease. It has been estimated that these mutations are related to 5% to 10% of breast cancer and ovarian cases.[50] However, despite a significant amount of analysis and debate, the exact relationship between BRCA1/2 and cancer remains unclear.[51] Complicating matters further is the fact that it is also difficult to determine who should be offered the test.[52] If one tests positive, the only definitive procedures to prevent breast or ovarian cancer are the bilateral mastectomy and bilateral oophorectomy; and even

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Am. Med. Assoc. 1525; A. Motulsky, "Predictive Genetic Diagnosis" (1994) 55 Am. J. Hum. Genet. 603.

[47] There are a few exceptions to this general statement. For example, genetically based colon cancer can be successfully prevented.

[48] R. Hubbard & R.C. Lewontin, "Pitfalls of Genetic Testing" (1996) 334 New Engl. J. Med. 1192 at 1192.

[49] F. Collins, "*BRCA1*—Lots of Mutations, Lots of Dilemmas" (1996) 334 New Engl. J. Med. 186; B. Koenig *et al.* and the Beast Cancer Working Group of the Stanford Program in Genomics, Ethics and Society, "Genetic Testing for BRCA1 and BRCA2: Recommendations of the Stanford Program in Genomics, Ethics and Society" (1998) 7 J. Women's Health 531; B. Healy, "BRCA Genes—Bookmaking, Fortunetelling, and Medical Care" (1997) 336 New Engl. J. Med. 1448; and M. Singer & R. Cebul, "BRCA1: To Test or Not to Test, That is the Question" (1997) 7 Health Matrix 163.

[50] See generally W. Burke *et al.*, "Recommendations for Follow-Up Care of Individuals With and Inherited Predisposition to Cancer" (1997) 277 J. Am. Med. Assoc. 997; H. Noorani & L. McGahan, *Predictive Genetic Testing for Breast and Prostate Cancer* (Ottawa: Canadian Coordinating Office for Health Technology Assessment, 1999).

[51] See *e.g.* a study by J. Peto *et al.*, "Prevalence of BRCA1 and BRCA2 Gene Mutations in Patients With Early-Onset Breast Cancer" (1999) 91 Nat. Cancer Instit. Can. Rep. 943 at 948-49, where it is concluded that contrary to early views:

> [A] considerable proportion of the familial risk of breast cancer is not attributable to mutations in the BRCA1 and BRCA2 genes. .... Only a small proportion of patients with early-onset breast cancer carry a mutation in one or the other gene, and only a small proportion of the familial risk of breast cancer is attributable to these genes.

[52] See *e.g.* K. Malone *et al.*, "BRCA1 Mutations and Breast Cancer in the General Population" (1998) 279 J. Am. Med. Assoc. 922 at 922: "Women with BRCA1 germline mutations lacked a common family history profile"; and B. Newman *et al.*, "Frequency of Breast Cancer Attributable to BRCA1 in a Population-Based Series of American Women" (1998) 279 J. Am. Med. Assoc. 915.

these extreme strategies will not entirely remove the chance that cancer as "some tissue-at-risk" may remain.[53]

So, while the genetic revolution has provided us with indispensable scientific information, the clinical value of current health care products is, in the aggregate, still relatively small. Genetic testing, for instance, is certainly of use to a small percentage of the general population (for example, by providing information to assist in reproductive decisions or to confirm a clinical diagnosis of disorders such as Fragile X), and it is giving us a greater understanding of the disease process;[54] but without effective therapies, it could be argued that genetics may actually be sending medicine back to its "impotent past" when much became known about the causes of disease and so little was available to treat it effectively.[55]

III. Assessing Legal, Ethical, and Social Concerns

The genetic revolution has, of course, provided much fodder for legal, bioethic and policy commentators. With many countries wisely allocating specific percentages of their Human Genome Project budgets for the study of ethical, legal and social issues,[56] it is arguable that the genetic revolution is the most studied and critiqued scientific phenomenon in history. As a result, a tremendous amount of literature has emerged from the academic community,[57] government agencies,[58] and the popular

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[53] "Gene Test", *supra* note 44. See also, W. Burke *et al.*, "Recommendations for Follow-up Care of Individuals With an Inherited Predisposition to Cancer" (1997) 277 J. Am. Med. Assoc. 997.

[54] To cite but one example, see J. Martin, "Molecular Basis of the Neurodegenerative Disorders" (1999) 340 New Engl. J. Med. 1970.

[55] A. Jonsen, "The Impact of Mapping the Human Genome on the Patient-Physician Relationship" in T. Murray, M. Rothstein & R. Murray, Jr., eds., *The Human Genome Project and the Future of Health Care* (Bloomington: Indiana University Press, 1996) 12. See also K. Quinn, "Proceed with Caution: Genomic Information and the Future of American Health Care" (1998) 38 Jurimetrics 215. Some commentators have an even darker vision of the limits of genetic testing. See *e.g.* J. Fitzgerald, "Geneticizing Disability: The Human Genome Project and the Commodification of Self" (1998) 14 Issues in L. & Med. 147 at 149:

> At present, the options for the use of this information are quite limited: unable to cure, we can choose either to care for the person and their illness or impairment, or to eliminate the person (through selective abortion or denial of access to medical resources) or to discriminate against them (in areas such as employment and insuranee).

[56] Cook-Deegan, *supra* note 3.

[57] See *e.g.* T. Murray, M. Rothstein & R. Murray, Jr., eds., *supra* note 55; J. Rifkin, *The Biotech Century* (New York: Penguin Putman, 1998); G. McGee, *The Perfect Baby: A Pragmatic Approach to Genetics* (New York: Rowman & Littlefield, 1997); T. Marteau & M. Richards, eds., *supra* note 22; P. Kitcher, *The Lives to Come: The Genetic Revolution and Human Possibilities* (Toronto: Simon & Schuster, 1996); L.B. Andrews *et al.*, *Assessing Genetic Risks: Implications for Health and Social Policy* (Washington D.C.: National Academic Press, 1994); M. Frankel & A. Teich, eds., *The Genetic Frontier: Ethics, Law and Policy* (Washington D.C.: The American Association for the Advancement of Science, 1994); T. Wilkie, *Perilous Knowledge: The Human Genome Project and Its Implications* (London: Faber & Faber, 1993); G. Annas & S. Elias, eds., *Gene Mapping: Using Law and Ethics as*

press. Despite all this commentary, and a continual call for regulation, much of the formal responses to the concerns of the genetic revolution seem to be misplaced reactions to the hyperbole instead of thoughtful, and sustainable, regulatory strategies. In fact, it can be argued that ill-informed policy debates actually magnify many of the fundamental concerns associated with the genetic revolution.

A. Geneticization, the New Eugenics, and the Regulation of Cloning

Arguably the most often expressed and overarching of all concerns associated with the genetic revolution is that it will lead to the "geneticization" of society.[59] The idea is that genetics has the potential to fundamentally alter how we view ourselves and others. Noted by numerous commentators,[60] the concern is that we will (or have already begun to) inappropriately accentuate the essentialistic view that "I am my genes",[61] thus de-emphasizing the social, economic, and environmental factors relevant to the human condition and, concomitantly, awaking a new "eugenic ethos."

While the concern remains largely speculative, it is not without foundation. Indeed, many commentators fear that a trend toward finding a genetic explanation for all human experiences has already taken root "as many of the most influential scien-

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Guides (Oxford: Oxford University Press, 1992); R.C. Lewontin, *Biology as Ideology: The Doctrine of DNA* (Concord, Ont.: Anansi, 1991); D. Kevles and L. Hood, eds., *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (Cambridge: Harvard University Press, 1992).

[58] See *e.g.* OECD, *Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies* (Paris: OECD, 1996); Ontario Law Reform Commission, *Report on Genetic Testing* (Toronto: Ontario Law Reform Commission, 1996); U.K., H.C., Science and Technology Committee, *Third Report: Human Genetics: The Science and Its Consequences*; Danish Council of Ethics, *Patenting Human Genes: A Report* (Copenhagen: Danish Council of Ethics, 1994); Report of a Committee of the Health Council of the Netherlands, *Proper Use of Human Tissue* (The Hague: Health Council of the Netherlands, 1994).

[59] A. Lippman, "The Polities of Health: Geneticization Versus Health Promotion" in S. Sherwin *et al.*, *The Politics of Women's Health: Exploring Agency and Autonomy* (Philadelphia: Temple University Press, 1998) at 64: "*Geneticization* is a term coined to capture the ever-growing tendency to distinguish people one from another on the basis of genetics; to define most disorders, behaviours, and physiological variations as wholly or in part genetic in origin".

[60] See Fitzgerald, *supra* note 55; McGee, *supra* note 57; Kitcher, *supra* note 57; Hubbard & Wald, *supra* note 5; Lewontin, *supra* note 57; M. Crossley, "Choice, Conscience, and Context" (1996) 47 Hastings L.J. 1223; King, *supra* note 5; and D. Brock, "The Human Genome Project and Human Identity" (1992) 29 Houston L. Rev. 7.

[61] See *e.g.* D. Wertz, "Society and the Not-So-New Genetics: What Are We Afraid of? Some Future Predictions From a Social Scientist" (1997) 13 J. Contemp. Health L. & Pol'y 299 at 307: "[The] essentialistic view pervades popular culture. 'I am my genes' is a phrase constantly used by questioners at public forums, despite the efforts of panellists to try to explain that 'you' are not the same as 'your genes'"; and D. Morgan, "The Troubled Helix: Legal Aspects of the New Genetics" in T. Marteau & M. Richards, eds., *supra* note 22 at 187: "[A] genetic view of ourselves could change the way we think about ourselves...and importantly, of others; it may affect the way we come to view relatedness, otherness and difference..."

tists today are urging a genetically-determined view of humans."[62] Geneticist Richard Lewontin has argued that the mere existence of the Human Genome Project "has validated the determinism on which eugenics was based."[63] One study of 2901 genetics professionals in thirty-six countries came to the conclusion that "eugenic thought underlies perceptions of the goals of genetics ..."[64] And a number of studies have shown that the public also fear a geneticization or eugenic phenomenon. For example, a recent Finnish study found that 71% of those surveyed were worried that genetic testing may lead to "eugenics".[65]

The geneticization and eugenic concerns also seem creditable when one considers the commercial environment within which genetics is emerging. There is little doubt that modern health care is more business-oriented than at any other time in history, with patients increasingly cast as "consumers" entitled to unencumbered access to services.[66] At the same time, the science of genetics has become closely tied with industry.[67] A huge amount of money has been invested in the development of genetic technologies and products. As such, there is a fear that commercial pressure, coupled with our culture's consumer ethic, will facilitate the geneticization of our society by emphasizing a market-driven definition of normalcy, disease and disability.[68] Though there is as yet little empirical evidence to support the idea of a laissez-faire eugenics,

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[62] Andrews, *supra* note 30 at 914.

[63] R.C. Lewontin, *Biology as Ideology: The Doctrine of DNA* (New York: Harpers Perennial, 1992) at 72-73.

[64] D. Wertz, "Eugenics is Alive and Well: A Survey of Genetic Professionals around the World" (1998) 11 Science in Context 493 at 493. The author concludes:

> "Eugenic thought," if interpreted as a desired eugenic outcome based upon individual decisions, underlies genetic practice in much of the world today. Individual eugenics is achieved through presentation of purposely slanted information in counseling, sometimes accompanied by openly directive advice. The "non-directive" counseling found in English-speaking nations is an aberration from most approaches found elsewhere (*ibid.* at 507).

[65] P. Jallinoja *et al.*, "Attitudes Towards Genetic Testing: Analysis of Contradictions" (1998) 46 Soc. Sci. Med. 1367 at 1371.

[66] R. Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity* (New York: W.W. Norton, 1997) at 717-18.

[67] I have discussed the commercialization of genetic research elsewhere. See T. Caulfield, "The Commercialization of Human Genetics: A Discussion of Issues Relevant to Canadian Consumers" (1998) 21 J. Consumer Pol'y 483.

[68] As argued *e.g.* by J. Testart, "The New Eugenics and Medicalized Reproduction" (1995) 4 Cambridge Q. Healthcare Ethics 304 at 310: "For reasons associated with the economy and the market, normality of human beings will be more and more defined according to the needs of industry and insurance contracts." See also E. Kodish, "Commentary: Risks and Benefits, Testing and Screening, Cancer, Genes and Dollars" (1997) 25 J. L., Med. & Ethics 252; M. Renaud *et al.*, "Canadian Physicians and Prenatal Diagnosis: Prudence and Ambivalence" (1993) 13 Royal Commission on New Reproductive Technologies (Ottawa) at 298, Table 4.10, where it is noted that 51% of physicians surveyed thought that "PND makes disorders out of conditions hitherto considered normal" and 49% agreed that "PND increases intolerance toward anomalies."

as Philip Kitcher has termed it,[69] it is hard to deny that market forces can have a profound influence on social perceptions.[70] Obviously, the media hype which surrounds the genetic revolution is also closely related to the geneticization concern. The more we hear about the achievements of the science of genetics—be it about the discovery of a new disease gene, a genetically modified pig, or possible genetic therapy—the more likely we are to accept that essentialist message. Indeed, there seems to be particular media interest in the finding of genes which allegedly control complex behavioural characteristics like intelligence and sexuality.[71] Such stories add fuel to the concern that we are developing a "eugenic common sense"[72] as it invites people to think about genetics in the context of both desirable and unwanted characteristics. As argued by Dorothy Nelkin and Susan Lindee, eugenics in the age of the genetic revolution "can be productively understood as a constellation of beliefs about the importance of genetics in shaping human health and behaviour, the nature of worthwhile life, the interests of society, and, especially, the terms of reproductive responsibility."[73]

But the essentialist message is wrong. In fact, there are very few human conditions, whether behavioural or physical, that can be explained solely through genetics.[74] Contrary to the tenor of popular reports, one of the fundamental themes of modern genetic research is the incredible complexity of the interaction between genes and

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[69] Kitcher, *supra* note 57. See also A. Otchet, "The Dangers of Laissez Faire" *UNESCO Courier* (1999) where Kitcher is quoted thus: "We are putting the rat race into the womb. I used to be more optimistic. ... But now I see the root of the problem goes deep into capitalist society with the pressure to compete. Parents with the resources will feel pressured to make sure that their children have 'the right genetic stuff.'"

[70] The marketing of Protropin, a recombinant growth hormone, is often cited as an example of the impact of market forces as it arguably added to the perception that normal shortness should be considered a "disease" worthy of treatment. See M. Leopold, "The Commercialization of Biotechnology" (1993) 700 Ann. N.Y. Acad. Sci. 214; and N. Daniels, "The Human Genome Project and the Distribution of Scarce Medical Resources" in T. Murray, M. Rothstein & R. Murray Jr., eds., *supra* note 55, 173.

[71] See *e.g.* "The IQ Gene?" *Time* 154:11 (13 September 1999) 40; Reuters News Agency, "Scientists Question 'Gay-Gene' Study" *The Globe and Mail* (23 April 1999) A19; and Editorial, "The Genetic Illusion" *The Economist* 340:7983 (14 September 1996) 13.

[72] King, *supra* note 5; and Crossley, *supra* note 60 at 1234 who notes: "By encouraging us to conceptually break down persons into traits, prenatal genetic testing threatens to reinforce our existing and destructive reductivist tendencies."

[73] D. Nelkin & M.S. Lindee, "The Revival of Eugenics in American Popular Culture" (1997) 52 J. Am. Med. Women's Assoc. 45 at 46.

[74] "The Genetic Illusion", *supra* note 71. See also S. J. Gould, "Viewpoint: Message from a Mouse" *Time* 154:11 (13 September 1999) 48 at 48:

> No single gene determines even the most concrete aspect of my physical anatomy, say the length of my right thumb. The very notion of a gene "for" something as complex as intelligence lapses into absurdity. Intelligence is an array of largely independent and socially defined mental attributes, not a measure of a single something, secreted by one gene...

other genes[75] and genes and the environment. Even diseases that are passed on through basic mechanisms of inheritance have proven to be tremendously complex.[76] The limits of the current genetic testing technology, discussed above, highlight the fantastically intricate, and often unpredictable, way in which genetic mutations relate to human disease. So, while the genetic revolution will provide immeasurably valuable scientific knowledge, it will not provide "a gene" for all human characteristics. Our destiny is not in our genes.

The best way to address the concerns of geneticization and eugenics is to reveal the fallacy of the reductionist vision. We need to explain that the science of genetics *is* providing valuable scientific information, but that it is of a different character than that often offered by the media and the market. However, given the hype and the many systemic pressures—economic, professional and cultural—pushing to embrace genetics, it will be tough to meaningfully curb the essentialist tide.[77] Nevertheless, promoting a balanced and informed public debate should be one of the primary goals of the legal and ethical community.

Unfortunately, to date, much of the official commentary aimed at the concerns associated with the genetic revolution has been a reaction to exaggerated claims and speculation. For example, probably the most well known recent policy debate was that which surrounded the possibility of cloning humans. Central to the debate were concerns about eugenic selection and the loss of "genetic individuality."[78] Sparked by the announcement of Dolly, a cloned sheep, in 1997,[79] there was an almost immediate international reaction.[80] The U.S. National Bioethics Advisory Commission ("NBAC"), for instance, recommended a prohibition that resulted in a ban on federally-funded

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[75] It is also worth noting that the idea of "race" has been shown to have no foundation in science. As summarized by Owens and King, *supra* note 12 at 453: "The possibility that human history has been characterized by genetically relatively homogeneous groups ('races'), distinguished by major biological differences, is not consistent with genetic evidence."

[76] F. Collins, "*BRCA1*—Lots of Mutations, Lots of Dilemmas" (1996) 334 New Engl. J. Med. 186.

[77] T. Caulfield, "Regulating the Commercialization of Human Genetics: Can We Address the Big Concerns?" in A. Thompson & R. Chadwick, eds., *supra* note 31, 149 [hereinafter "Regulating Commercialization"].

[78] J. Savulescu, "Should We Clone Human Beings? Cloning as a Source of Tissue for Transplantation" (1999) 25 J. Med. Ethics 87. One author goes so far as to argue that cloning should be banned as it "crosses a significant boundary in removing the single most important feature of autonomy: the fact that each of us is genetically unique and individual" (R. Williamson, "Human Reproductive Cloning is Unethical Because it Undermines Autonomy" (1999) 25 J. Med. Ethics 96 at 96).

[79] I. Wilmut *et al.*, "Viable Offspring Derived From Fetal and Adult Mammalian Cells" (1997) 385 Nature 810.

[80] For a comprehensive review of the various national and international responses to the possibility of human cloning, see S. Lo Bris & M. Hirtle, "Ethical and Legal Aspects of Human Cloning: Comparative Approaches" in B.M. Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Montreal: Yvon Blais, 1998); and D. Beyleveld & S. Pattinson, "Legal Regulation of Assisted Procreation, Genetic Diagnosis, and Gene Therapy" in D. Beyleveld & H. Haker, eds., *Ethics of Genetics in Human Reproduction* (Aldershot, U.K.: Ashgate, 1999).

cloning research. In January 1998, seventeen European countries signed an agreement regulating human cloning.[81] And, in Canada, a ban on cloning was part of *The Genetic and Reproductive Technology Act,* Bill C-47. This Bill, which died as a result of the 1997 election, sought to make cloning a criminal offence.[82]

Intuitively, this strong, prohibitory approach may seem a logical course of action. But, as I have argued elsewhere,[83] there are problems with such a strategy. For instance, these regulations must, on some level, be embracing a view of genetic determinism.[84] If not, then why be concerned by a "genetic copy"? A human clone would, in fact, be a wholly unique individual. The fact that people share a significant portion of their DNA, as with all identical twins,[85] cannot, on its own, be an affront to "human dignity."[86] Indeed, such regulations arguably legitimize the hype surrounding the ge-

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[81] S. McEldowney and L.M. Warren, "The New Biology: A Challenge to Law" (1998) 1 Int'l J. Biosciences & L. 315 at 318.

[82] Bill C-47, *An Act respecting human reproduction technologies and commercial transactions relating to human reproduction,* 2d Sess., 35th Parl., 1996, s. 4(1): "No person shall knowingly (a) manipulate an ovum, zygote or embryo for the purpose of producing a zygote or embryo that contains the same genetic information as a living or deceased human being or a zygote, embryo or fœtus, or implant in a woman a zygote or embryo so produced."

The federal government seems likely to introduce another bill in the near future. Criticism of the prohibitory approach has already been forthcoming. See *e.g.* Editorial, "Science, Soviet-Style" *The Ottawa Citizen* (22 October 1999) A18, where it is argued that a ban on cloning would chill useful scientific inquiry: "It is possible to invent scary tales of clone soldiers, but such fairy tales, even if technically possible in future, are not a reasonable basis for deciding to crush emerging technologies now. ... No one can weigh the benefits of cloning, for example, against the alleged costs, because no one can know yet what those benefits will be."

[83] T. Caulfield, M. Hirtle & S. Le Bris, "Regulating NRGTs: Is Criminalization the Solution for Canada?" (1997) 18 Health L. Can. 3.

[84] Many of the reports in the popular press fueled the inaccurate perceptions of human cloning. Often accompanied by a picture of many indistinguishable sheep, these stories gave the impression, at least on first blush, that cloning would result in an identical individual. For a discussion of the media coverage of cloning see Wilkie & Graham, *supra* note 22.

[85] In fact, clones made through the "Dolly" technique would not share mitochondrial DNA and, as such, are less genetically similar than identical twins.

[86] Stating that cloning is an affront to human dignity is probably the most commonly used justification for prohibitions. See *e.g. Universal Declaration on the Human Genome and Human Rights,* UNESCO Gen. Conf., 29th Sess. (11 November 1997), Art. 11, online: UNESCO <http://unesdoc.unesco.org/images/0010/001096/109687cb.pdf> (date accessed: 22 February 2000): "Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted." See D. Beyleveld & R. Brownsword, "Human Dignity, Human Rights, and Human Genetics" (1998) 61 Mod. L. Rev. 661 at 678-79 for a critical discussion of the concept of "diguity" in relation to the regulation of human cloning. In general, the authors are sceptical of the legitimacy of invoking the notion of human dignity as a justification for prohibitions: "[F]rom any perspective that values rational debate about human genetics, it is an abuse of the concept of human dignity to operate it as a veto on any practice that is intuitively disliked" (*ibid.* at 680). See also D. McCarthy, "Persons and Their Copies" (1999) 25 J. Med. Ethics 98.

netic revolution and, thus, facilitate the geneticization trend.[87] They help to reify genetic material and build on the inaccurate message that an individual's personhood is closely tied to his or her genetic makeup. This is an ironic conclusion since cloning regulations explicitly seek to protect human dignity.

Let me be clear, I am not advocating human cloning, but rather an informed and scientifically accurate debate.[88] There are many solid arguments which support the regulation of human cloning (*e.g.* concern for the health of the clone, possibly adverse psychological implications on child clones, etc).[89] Nevertheless, if one scrutinizes the official recommendations for the banning of human cloning, it is difficult to find a satisfactory critique of the geneticization paradox.[90] The calls for regulation seem a direct result and, therefore, an affirmation of the hype.

The regulatory reaction to the possibility of human cloning is a good example of how we are fighting the battle in the frontiers when we should also be in the streets. That is, instead of stimulating an informed debate about the possibilities and limits of human genetics, we are jumping to pass simplistic prohibitions that, at some level, add to the atmosphere of overstatement. There are many justifiable reasons to be concerned about broad issues like geneticization and laissez-faire eugenics. And while I am sceptical that any form of regulation can meaningfully curb these trends,[91] these concerns need to be addressed rationally. Wasting always limited policy-making energy on science fiction-like concerns, such as the banning of cloning humans for warfare,[92] borders on the absurd.

B. Pressure to Use Genetic Tests

Another area where the hype seems likely to have a direct and adverse impact is in the implementation, acceptance and use of the emerging genetic-testing technolo-

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[87] Susan Wolf makes a similar argument in her criticism of genetic anti-discrimination laws: "This antidiscrimination approach is profoundly problematic as applied to genetics. It supports the fiction that there is such a thing as a 'normal' genotype, and that the goal is to change the treatment of people who deviate" (S.M. Wolf, "Beyond 'Genetic Discrimination': Toward the Broader Harm of Geneticism" (1995) 23 J. L., Med. & Ethics 345 at 348).

[88] See L.M. Silver, "Cloning, Ethics and Religion" (1998) 7 Cambridge Q. Healthcare Ethics 168 at 169: "The initial horror elicited by the announcement of Dolly's birth was due in large part to a misunderstanding by the lay public and the media of what biological cloning is and is not." See also G. Kolata, "Human Cloning: The Race is On" *Globe and Mail* (18 December 1998) A19.

[89] However, some commentators have gone so far as to argue that the concern for the safety and welfare of the cloned child is not enough to justify banning human cloning. See *e.g.* Silver, *ibid.*; and J. Burley & J. Harris, "Human Cloning and Child Welfare" (1999) 25 J. Med. Ethics 108.

[90] See *e.g.* Canada, Department of Health, *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Ottawa: Supply and Services Canada, 1996).

[91] "Regulating Commercialization", *supra* note 77.

[92] See J. Bronskill, "International Ban Proposed on Cloning Humans for Warfare" *Edmonton Journal* (19 August 1999) A3, where a report by the Canadian Department of Defence calls for an international ban on the use of cloning to "manufacture soldiers."

gies. As noted above, many questions remain regarding the utility of some of the current genetic tests. Nevertheless, many fear that a combination of commercial and professional zeal may lead to the premature and inappropriate implementation of these technologies.[93]

The possible premature push to use genetic testing is troubling for a number of reasons. First, there is concern that the tests will be offered to too broad a range of the population and that the uncertainties associated with testing will be de-emphasized.[94] That is, might media-generated interest and market pressure result in genetic tests being requested by, offered to and used by individuals who would otherwise not get testing?[95] This concern is well illustrated by the controversy around Myriad Genetics' (a company which markets genetic tests) definition of "at risk". Despite numerous national and international policy statements calling for caution in the use of BRCA1/2 test,[96] Myriad has advocated a broad definition of the "at risk population" (the broader the definition, the bigger the market) and will test anyone so long as the request comes through a physician.[97]

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[93] See H.G. Welch & W. Burke, "Uncertainties in Genetic Testing for Chronic Disease" (1998) 280 J. Am. Med. Assoc. 1525; and Kodish, *supra* note 68 at 254, who notes that capital investment, commercial pressure, and the "scientific and lay media's attention to genetics" are the forces "responsible for the rapid movement of genetic measures of cancer risk from the research environment to the clinic."

[94] This is a concern which is specifically associated with the marketing of testing services. See *e.g.* N.A. Holtzman, "Are Genetic Tests Adequately Regulated?" (1999) 286 Science 409 at 409: "When women at risk of breast cancer learned about the predictive uncertainties of testing from sources independent of the companies offering them, they were much less eager to have tests." See also Kodish, *supra* note 68 at 253: "In contrast to the many published statements by professional bodies which call for restraint, industry positions assume that genetic technology will provide clinical and potential public health benefits in cancer control."

[95] Andrews, *supra* note 30 at 917 reports that the information brochure given to patients by Oncor Med Inc. (a U.S. company offering commercial testing for predisposition to breast cancer) "overestimated the chance of women getting cancer, perhaps frightening people into testing." See also Holtzman, *ibid.* at 409: "Thc 'educational' materials prepared by companies for physicians and patients considering genetic tests can bo another form of genohype. Their claims for predictive tests for common complex disorders have frequently exaggerated clinical validity ... and utility." A British study of pamphlets on genetic tests for cystic fibrosis found that those provided by commercial companies differed from government pamphlets in that they tended to "minimize positive descriptions of CF" (L. Loeben, T. Marteau & B.S. Wilfond, "Mixed Messages: Presentation of Information in Cystic Fibrosis-Screening Pamphlets" (1998) 63 Am. J. Hum. Genet. 1181 at 1186).

[96] For example, the Stanford Program in Genomics, Ethics and Society suggests that "for most people, testing for BRCA1 and BRCA2 mutations is not appropriate" (Koenig *et al.*, *supra* note 49). Sce also Healy, *supra* note 49.

[97] K. Birmingham, "Myriad's Rationale for Wider Testing" (1997) 3 Nat. Med. 709; V. Brower, "Testing, testing .... testing?" (1997) 3 Nat. Med. 131; and O. Smith, "Breast Cancer Susceptibility Tests Still Valid, Companies Argue" (1997) 3 Nat. Med. 709. See also Myriad Genetics' Quarterly Report, *infra* note 114.

Second, there is worry that the enthusiasm created by the hype will also adversely impact the quality of care.[98] In one well-publicized American case, a women received an inaccurate test result which indicated the presence of the breast cancer gene. As a result of the false positive test result, she decided to take the drastic preventative step of undergoing a prophylactic double mastectomy and oophorectomy. It was later revealed that, in fact, she did not carry the predisposition gene.[99] While such tragic mistakes happen in all areas of medicine, some commentators worry that the push to introduce genetic tests in an unregulated, over-hyped environment will contribute to the frequency of these quality control errors.[100] Indeed, one study has found that many of the genetics laboratories currently operating in the U.S. had quality of assurance scores that suggest both personnel qualification and laboratory practice standards were "in need of improvement to ensure quality in clinical molecular genetics testing..."[101]

A third and related concern is that genetic testing services are being implemented prior to the satisfactory resolution of many legal and ethical issues. For instance, while the degree and nature of genetic discrimination continues to be debated,[102] survey research has consistently shown public anxiety about discrimination and a loss of

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[98] See Welch & Burke, *supra*, note 93 at 1526:

> As genetic tests become increasingly accessible, clinicians must be careful not to be inappropriately swayed by their eagerness to help high-risk persons. The messages about presumptive benefit of testing may be compelling. An insidious cycle may develop, beginning with an overestimation of disease risk associated with the mutation, followed by perception of elevated risks, which in turn prompts unproven surveillance strategies, which are then reinforced by the positive feedback of apparent benefit.

[99] See R. Weiss, "Genetic Testing's Human Toll" *Washington Post* (21 July 1999) A1.

[100] This case led Edward McCabe, Chair of the United States Advisory Committee on Genetic Testing, to note: "Many [genetic] tests are in the quasi-research category but everybody wants to charge for them" (*ibid.*). See also G.C. Cunningham, "A Public Health Perspective on the Control of Predictive Screening for Breast Cancer" (1997) 7 Health Matrix 31 at 41: "[U]nregulated screening of hereditary breast cancer could lead to faulty, or negligent DNA analysis"; and Holtzman, *supra* note 94 at 409: "[A]ll stakeholders, including test developers, will be better served if data on tests' clinical validity and utility begin to be collected before they are marketed." Of course, we can look to other areas of health care to find examples of the adverse impact of market pressure. For a recent example, see "IVF Competition Adds to Birth Risks" *BBC News* (5 November 1999), online: BBC <http://news.bbc.co.uk/hi/english/health> (date accessed: 29 February 2000).

[101] M.M. McGovern *et al.*, "Quality Assurance in Molecular Genetic Testing Laboratories" (1999) 281 J. Am. Med. Assoc. 835 at 835 (abstract). See also W. Grody & R. Pyeritz, "Report Card on Molecular Genetic Testing: Room for Improvement?" (1999) 281 J. Am. Med. Assoc. 845.

[102] See *e.g.* Wolf, *supra* note 87; T. Lemmens & P. Bahamin, "Genetics Is Life, Disability and Additional Health Insurance in Canada: A Comparative Legal and Ethical Analysis" in B. Knoppers, ed., *supra* note 80; O. O'Neill, "Insurance and Genetics: The Current State of Play" (1998) 61 Mod. L. Rev. 716; S. O'Hara, "The Use of Genetic Testing in the Health Insurance Industry: The Creation of a 'Biological Underclass'" (1993) 22 Sw. U. L. Rev. 1211.

confidentiality, particularly in relation to insurance.[103] In some countries this concern has led to the passage of anti-discrimination laws. Though no Canadian province has legislation to deal with the issue of genetic discrimination, many jurisdiction in the U.S. and Europe have laws which prohibit the use of genetic information for insurance or employment purposes.[104] Commentators such as Arthur Caplan believe that such laws are essential to the ethical implementation of genetic testing services and he has gone so far as to suggest a moratorium on testing in jurisdictions that fail to provide sufficient protection against genetic discrimination.[105] Regardless of such positions, testing seems likely to continue in a largely unabated fashion. As recently noted in an industry publication: "Ethical issues related to genetic testing are far from being resolved, although this factor does not seem to be deterring companies that provide this service."[106]

Finally, many fear that genetic testing services are being implemented without the appropriate consent and counselling processes. Despite numerous international and national policy statements stressing the need for comprehensive informed consent and pre- and post-test counselling,[107] recent studies have shown that tests are often provided without any counselling or formal consent.[108] For example, in a recent study of 245 American genetic laboratories, it was found that only 45% required informed consent prior to testing.[109] Even more disturbing results were reported in a study of commercially-provided genetic testing for familial adenomatous polyposis where it was found that only 18.6% of the patients received genetic counselling before genetic

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[103] M. Cho *et al.*, "Commercialization of BRCA1/2 Testing: Practitioner Awareness and Use of a New Genetic Test" (1999) 83 Am. J. Med. Genet. 157; H. Lynch, *et al.*, "A Descriptive Study of BRCA1 Testing and Reactions to Disclosure of Test Results" (1997) 79 Cancer 2219; and E. Lapham, C. Kozma, & J. Weiss, "Genetic Discrimination: Perspectives of Consumers" (1996) 274 Science 621.

[104] See *e.g.* M. Rothstein & C. Erwin, "Genetic Testing and Discrimination in Health Insurance" (May 1998), online: University of Houston Health Law & Policy Institute <http://www.law.uh.edu/healthlaw> (date accessed: 22 February 2000). There is also a U.S. federal proposal to genetic discrimination in health insurance; see *The Genetic Information Nondiscrimination in Health Insurance Act of 1997*, H.R. 306, 105th Cong. (1997). For a discussion of the European legislation see Lemmens & Bahamin, *supra* note 102. It is important to note that while Canada's health insurance scheme mitigates the dangers of genetic discrimination, this issue is still relevant in the context of employment and life and disability insurance (relevant to obtaining a mortgage).

[105] Andrews, *supra* note 30 at 904. See also Cunningham, *supra* note 100 at 42: "[U]nregulated screening for hereditary breast cancer poses the distinct possibility that positive individuals will be subjected to discrimination in employment and insurance."

[106] News: "Diagnostic Products Molecular Diagnostics and Gene Detection Products" (January 1997) Med. & Healthcare Marketplace Guide 7 at 7. See also Myriad Genetics' Quarterly Report, *infra* note 114.

[107] See *e.g. Universal Declaration on the Human Genome and Human Rights*, *supra* note 86, Art. 5(b): "In all cases, the prior, free and informed consent of the person concerned shall be obtained."

[108] For a useful review of the recent literature see L. B. Andrews, "Comprised Consent: Deficiencies in the Consent Process for Genetic Testing" (1997) 52 J. Am. Med. Women's Assoc. 39.

[109] McGovern *et al.*, *supra* note 101 at 835.

testing and only 16.9% were asked to provide written consent.[110] Though no similar research has been completed in Canada, given the large degree of misinformation and inaccurate perceptions associated with genetic testing,[111] these results remain worrisome. Indeed, effective patient and public education is likely to be one of the best mechanisms for addressing the dilemma of genetic hype.

Concerns about the provision of genetic services are magnified by the fact that research has shown that there is already a strong interest in the use of genetic tests. For example, one recent study found that 84% of women surveyed with a personal history of breast and/or ovarian cancer intended to have genetic testing for the BRAC1/2 mutation.[112] Studies of the general population have uncovered a similar level of enthusiasm. One study found 82% of the general population to be interested in hereditary cancer risk testing.[113] Such data reveal a potential for a large genetic testing market,[114] particularly if preventative or therapeutic strategies are developed. And while the exact source of this high level of interest is not known, it seems safe to conclude that the

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[110] F.M. Giardiello *et al.*, "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis" (1997) 336 New Engl. J. Med. 823.

[111] It has been noted, for instance, that in one study a high percentage of the high-risk women lacked basic knowledge about heritable breast cancer and greatly overestimated their risk. See L. Bluman *et al.*, "Attitudes, Knowledge, and Risk Perceptions of Women With Breast and/or Ovarian Cancer Considering Testing for *BRCA1* and *BRCA2*" (1999) 17 J. Clinical Oncology 1040. See also Emery, Kumar & Smith, *supra* note 33.

[112] See Bluman, *ibid.* and O. Bratt *et al.*, "Sons of Men with Prostate Cancer: Their Attitudes Regarding Possible Inheritance of Prostate Cancer, Screening, and Genetic Testing" (1997) 50 Urology 360, where it was found that about 90% of the sons of men surveyed with prostate cancer were positively inclined to undergo genetic testing. For a comprehensive review of the research relevant to the genetic testing market, see T. Caulfield & D. Wertz, "Give the People What They Want?: A Review of the Survey Data and Concerns Relevant to the Commercialization of Genetic Testing" (11 October 1999) [submitted for publication].

[113] M.A. Andrykowski *et al.*, "Hereditary Cancer Risk Notification and Testing: How Interested Is the General Population?" (1997) 15 J. Clinical Oncology 2139. See also E. Tamnor *et al.*, "Genetic Testing for Breast Cancer Susceptibility: Awareness and Interest Among Women in the General Population" (1997) 68 Am. J. Med. Genet. 43; and C. Ulrich *et al.*, "Genetic Testing for Cancer Risk: A Population Survey on Attitudes and Intention" (1999) 1 Community Genet. 213 where it was found that 83% of male and 76% of female respondents in the survey expressed the intention to be tested for breast or prostate cancer risk. It is important to recognize that a stated interest in genetic testing will not necessarily translate into the actual uptake of genetic services—as revealed by our experience with Huntington disease, cystic fibrosis and, more recently, BRCA1/2 testing. See *e.g.* C. Lerman, "Genetic Testing in Families with Hereditary Nonpolyposis Colon Cancer" (1999) 281 J. Am. Med. Assoc. 1618; and B.N. Peshkin & C. Lerman, "Genetic Counselling for Hereditary Breast Cancer" (1999) 353 Lancet 2176. However, from the perspective this paper, it is the interest in genetic testing which seems most crucial.

[114] Myriad Genetics' Quarterly Report states that: "Genetic testing revenues of $1,493,341 were recognized in the quarter ended March 31, 1999, an increase of 164% or $926,652 over the same quarter of the prior year. ... Sales and marketing efforts since that time have given rise to the increased revenues in the quarter ended March 31, 1999" (see Myriad Genetics Inc., 10-Q US SEC Quarterly Report Ending 31 March 1999 at 8, online: <http://www.sec.gov> (date accessed: 29 February 2000).

enthusiasm is associated with the hyperbole which surrounds the genetic revolution.[115] As argued by Freedman:

> The public's perceptions and expectations of the potential of genetic testing far outweigh the reality of what testing has yielded; and yet the media, reflecting public desire, have encouraged hope and faith in testing. But predictive the future is perhaps based more on wishful thinking and magical beliefs than on the concrete ability of testing to give workable answers.[116]

Despite the relatively well-documented issues associated with the provision of genetic tests, it remains a largely unregulated area.[117] Genohype has created an enthusiasm which cannot be supported by the current capacity of genetic tests, thus magnifying many of the potential problems. Meanwhile, as we struggle with cloning laws built on inaccurate notions of genetic essentialism, little is heard about practical solutions to real emerging issues. Do we have our regulatory priorities in order?

> [A] disproportionate amount of the law which has been enacted to date has related to genetic engineering rather than genetic screening although this cannot be an accurate reflection of where the current policy difficulties lie.[118]

Conclusion: The Regulatory Challenge

There are many reasons why regulating genetics, and biotechnology in general, will be challenging. Difficulty in writing scientifically meaningful legislation, the rapid pace of developments and a lack of consensus in the identification of concerns

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[115] See *e.g.* B.H. Lerner, "Great Expectations: Historical Perspectives on Genetic Breast Cancer Testing" (1999) 89 Am. J. Pub. Health 938. Of course, general practitioners are also an important source of information on genetic testing. Unfortunately, recent research has revealed that most physicians do not possess a strong knowledge base in the area of genetics. As such, general practitioners may not be able counter patient misinformation and, in fact, may be just as susceptible to "genohype." See Giardiello, *supra* note 110; and A. Hunter *et al.*, "Physician Knowledge and Attitudes Towards Molecular Genetic (DNA) Testing of Their Patients" (1998) 53 Clinical Genet. 447 where it was found that in a survey of 900 Canadian physicians there was only a 37% correct response rate to questions regarding the availability of DNA tests for a variety of conditions.

[116] T.G. Freedman, "Genetic Susceptibility Testing: A Therapeutic Illusion?" (1997) 79 Cancer 2063 at 2064.

[117] Holtzman, *supra* note 94 and M. Jackson *et al.*, "Regulatory Schemes Affecting Genetic Testing in Canada" Abstract, 11th Annual Canadian Bioethics Society Conference, Edmonton, Alberta (28-30 October 1999). See also M. Malinowski & R.J.R. Blatt, "Commercialization of Genetic Testing Services: The FDA, Market Forces and Biological Tarot Cards" (1997) 71 Tulane L. Rev. 1211 at 1218-19: "The danger is that, absent regulatory safeguards and quality controls, the forthcoming multitude of predictive genetic testing services will be overused ... and misinterpreted by patients, providers, insurance companies, and employers."

[118] This comment was made in relation to European genetic testing jurisprudence, however, its sentiment applies equally to Canada and the United States: see T. McGleenan, "Genetic Testing and Screening: The Developing European Jurisprudence" (1999) 5 Hum. Reprod. & Genet. 11 at 19.

worthy of a legislative response are but a few of the dilemmas facing regulators.[119] Nevertheless, dealing with the social, ethical and legal issues created by the genetic revolution seems essential. At a minimum, this should involve encouraging a well-informed interdisciplinary debate and taking an active role in the identification and communication of accurate information. Indeed, given the vast number of stakeholders involved in the genetic revolution, many of whom have a vested interest in adding to the hyperbolic noise which surrounds it, this should be one of the central goals of government in this context. If not government, then who?

Succumbing to the inaccurate, sloganistic messages that are permeating the discourse around genetics is to do a disservice to the true nature of both the social concerns and the scientific advances. We should not let "screaming headlines announcing designer babies in which fantasy parents choose the height, intelligence, looks and behaviour of their future offspring" set the Canadian regulatory agenda.[120] The maintenance of public trust[121] and the creation of a sustainable biotechnology policy demand that we cut through the hyperbole and seek a thoughtful, and well-informed, regulatory framework.

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[119] See T. Caulfield & M. Hirtle, "Regulating the Genetic Revolution" (1999) 5 Molecular Med. Today 198.

[120] H. Rose, "Screening Awakens Spectres of the Past" *UNESCO Courier* (September 1999) 22 at 23.

[121] "A recent article in the Houston Chronicle pointed out that the excessive claims about genetics have to be true, leading to a backlash against 'genetic hucksterism'" (Andrews, *supra* note 30 at 917).